Analysis of COVID-19 Vaccination in Pregnant Women

Pregnant women are particularly vulnerable to the effects of COVID-19, as shown in a comprehensive analysis by Smith et al. involving a total of 13,136 pregnant women from 12 studies across 12 countries and a multinational, observational study by Villar et al. conducted across 41 hospitals in 18 countries.[1,2] Pre-existing comorbidities such as diabetes, hypertension, and cardiovascular diseases further increase these risks. Large cohort studies demonstrated that pregnant women with COVID-19 had significantly higher risks of ICU admission, mechanical ventilation, and maternal morbidity compared to non-infected pregnant women. Preterm birth and stillbirth rates were notably higher in infected populations, particularly in those with underlying diabetes, hypertension and cardiovascular comorbidities.[3] Maternal COVID-19 has been linked to an increased risk of low birth weight, respiratory distress, prematurity, low 5-minute APGAR score, and neonatal death.[4] Exposure to SARS-CoV-2 *in utero* has been linked with the development of multisystem inflammatory syndrome in neonates (MIS-C), a rare but serious inflammatory syndrome that occurs in neonates either born to mothers with COVID-19 during late pregnancy who remain uninfected, and in neonates who acquire SARS-CoV-2 infection.[5,6] These findings emphasize the vulnerability of pregnant women and the need for preventative measures.

Available data show that effectiveness of mRNA COVID-19 vaccines is similar in pregnant and nonpregnant women of similar age for prevention of SARS-CoV-2 infection and hospitalizations. Maternal COVID-19 vaccination during pregnancy reduces the risk of SARS-CoV-2 infection and COVID-19–associated hospitalization in infants younger than 6 months of age. Additionally, COVID-19 vaccination has the potential to prevent stillbirths and preterm delivery. [7,8,9]

Available evidence suggests COVID-19 vaccination during pregnancy is both safe and well tolerated. Animal studies found no adverse effects on embryo-fetal development, birth, or postnatal growth. [10] Although pregnant women were excluded from initial clinical trials, a double-blind placebo-controlled study (C4501015) was initiated in 2021. However, enrollment in the study was stopped as the vaccine in pregnancy was recommended by the ACIP in September 2021 and providing study participants placebo once the recommendation was in place was not clinically appropriate. [11] In addition, subsequent post-marketing surveillance, including the C4591022 pregnancy registry, and other non-interventional studies have provided critical safety data. These studies reported vaccines to be well tolerated by both mothers and infants.

The C4591015 study evaluated the safety, tolerability, and immunogenicity of the COVID-19 vaccine in pregnant women, including women with HIV infection, vaccinated between 24-

and 34-weeks' gestation. The clinical study report was submitted to the FDA in July 2024, and around the same time, the topline safety findings were posted on ClinicalTrials.gov.[12, 13.] (See final Complete Study Report (CSR) for the C4591015 study at page 9).

In the study, most pregnancies were carried to term and most infants were born at term and had favorable newborn assessment outcomes. Infant outcome at birth was normal for 153 out of 167 (91.6 %) infants born to maternal participants in the vaccine group and 150 out of 168 (89.3%) of infants born to maternal participants in the placebo group.

The study demonstrated that adverse events were balanced between the 2 groups.

For maternal participants, in the vaccine group, serious adverse events (SAEs) reported in the SOC of pregnancy, puerperium and perinatal conditions (8.1%), were reported similarly in the placebo group (10.4%). In the vaccine group, numerically higher frequencies were observed for pre-eclampsia (2.5% vs 1.2%), fetal distress syndrome (1.9% vs 1.2%), and single cases of breech presentation, failed induction of labor, fetal growth restriction, hemorrhage in pregnancy, meconium stain, and retained placenta or membranes (all 0.6 vs none in placebo). Conversely, events occurring more frequently in placebo than the vaccine group included premature separation of placenta (1.8% vs none), postpartum hemorrhage (1.2% vs none), and single cases of arrested labor, meconium in amniotic fluid, omphalorrhexis, and placental insufficiency, preterm premature rupture of membrane and prolonged rupture of membrane (each 0.6% vs none).

For infant participants, from birth to 1 month of age, SAEs were reported with similar frequencies in two groups: 12.2% in the infant participants in the vaccine group and 13.8% in the placebo group; from birth to 6 months of age, SAEs were also reported with similar frequency (13.5% in the vaccine group and 15.1% in the placebo group. Congenital anomalies were reported in 9 out of 156 (5.8%) participants in the vaccine group and 5 out of 159 (3.1%) participants in the placebo group. When evaluating congenital anomalies as adverse events of special interest (AESIs), which included major congenital anomaly and developmental delay as defined per the study protocol and were reported at the discretion of investigators, the breakdown was 8 out of 156 (5.1%) participants in the vaccine group and 2 out of 159 (1.3%) participants in the placebo group. Although there is a numerical difference between the groups, the 95% confidence intervals of the point estimate of incidence proportion overlaps, and none of the events were assessed as related to treatment by the Principal Investigators. Apart from Atrial Septal Defect (4 cases; all grade 1), the others were single occurrences [DiGeorge's syndrome, Microcephaly, Trisomy 21 (all grade 3), Mucopolysaccharidosis (grade 2), Patent Ductus Arteriosus, Syndactyly, Ventricular septal defects (all grade 1)]. With the exception of Patent Ductus Arteriosus, which was observed in the placebo group, the observed congenital anomalies usually

either arise in the first or second trimester or are present at conception.[14-21] After reviewing these findings against background rates, i.e. what could be expected in a pregnant population, the data did not suggest an increased risk for congenital anomalies after vaccination in pregnancy. Consistently, the pregnancy registry and other studies evaluating safety after vaccine introduction have not identified any safety signals when the vaccine is given to pregnant women. As part of the routine surveillance, Pfizer closely monitors pregnancy outcomes with vaccination and reports data as appropriate to the FDA and other regulatory agencies. No safety signals have been identified to date.

No increase in adverse pregnancy outcomes was identified in other large studies. Marchand et al conducted a meta-analysis of 37 studies including 141,107 pregnant women (36.8% vaccinated), while Fernandez-Garcia et al analyzed 67 studies with over 1.8 million women.[22,23] Both found no higher risk of miscarriage, premature birth, postpartum hemorrhage, congenital anomalies, or hypertensive pregnancy disorders among vaccinated compared to unvaccinated groups. Likewise, another observational retrospective study by Citu IM et al including 124 cases of spontaneous abortions and 927 ongoing pregnancies, indicated that risk of spontaneous abortion after COVID-19 vaccine immunization during the first trimester of pregnancy was similar to the expected risk in unvaccinated pregnancies.[24] Sheth SS et al conducted a case–control study of clinically adjudicated spontaneous abortions (case group) occurring between January 19, 2021 and October 27, 2021, and live births (control group) at 8 Vaccine Safety Datalink sites. The matched analyses included 296 women in the spontaneous abortion case group and 592 in the live birth control group. There was no association between spontaneous abortion and COVID-19 vaccination, no association with vaccine dose number, and no association with vaccine manufacturer or vaccine exposure window of 6 weeks before spontaneous abortion or index date.[25] All these studies consistently show that there is no association between adverse pregnancy outcomes and COVID-19 vaccination. Furthermore, a statistically significant reduction in stillbirth with mRNA vaccines administered in the early stages of pregnancy, and in emergency caesarean deliveries with mRNA vaccines at any point in pregnancy, were observed in a systematic review and meta-analysis conducted by Ciapponi et al, including 177 studies with data from 638,791 pregnant women. [26] Overall, findings support the safety of COVID-19 vaccination in pregnancy.

Lastly, the data pooled from pharmacovigilance systems by the European Medicines Agency (EMA) reaffirmed these results, confirming that mRNA vaccination was well tolerated and not linked to an increase in adverse pregnancy outcomes. [27]

Ongoing surveillance continues through pharmacovigilance and active safety monitoring. Pfizer is sponsoring 10 post authorization safety studies (C4591009[28-32], C4591021[33-36], C4591010[37], C4591022[38], C4591062, C4591049, C4591038, C4591052, C4591070,

C4591008[39,40]) that robustly monitor safety of the vaccine during pregnancy. These studies cover millions of pregnant vaccinees, use varied and robust methodological approaches and are being conducted around the world. No safety concerns have been observed to date in these studies, many of which are ongoing. All data generated from these studies have been and will continue to be shared with regulators in a timely way.

In conclusion, SARS-CoV-2 infection poses significant risk to maternal and perinatal health. COVID-19 vaccination during pregnancy appears associated with reduced risk of severe maternal diseases without increasing adverse pregnancy outcomes. In totality, available data do not suggest an increased risk for serious adverse events after vaccination in pregnancy, and data support a favorable benefit risk profile in pregnant women. Pfizer continues to conduct surveillance through pharmacovigilance and active safety monitoring, as well as through Pfizer-sponsored global post authorization safety studies.

References

1. Smith ER, Oakley E, Grandner GW, Ferguson K, et al. Adverse maternal, fetal, and newborn outcomes among pregnant women with SARS-CoV-2 infection: an individual participant data meta-analysis. BMJ Glob Health. 2023 Jan;8(1):e009495. doi: 10.1136/bmjgh-2022-009495. PMID: 36646475; PMCID: PMC9895919 https://pubmed.ncbi.nlm.nih.gov/36646475/

2. Villar J, Soto Conti CP et al. INTERCOVID-2022 International Consortium. Pregnancy outcomes and vaccine effectiveness during the period of omicron as the variant of concern, INTERCOVID-2022: a multinational, observational study. Lancet. 2023 Feb 11;401(10375):447-457. doi: 10.1016/S0140-6736(22)02467-9. Epub 2023 Jan 17. PMID: 36669520; PMCID: PMC9910845. https://pubmed.ncbi.nlm.nih.gov/36669520/

3. Smith ER, Oakley E, Grandner GW, et al. Clinical risk factors of adverse outcomes among women with COVID-19 in the pregnancy and postpartum period: a sequential, prospective meta-analysis. Am J Obstet Gynecol. 2023 Feb;228(2):161-177. doi: 10.1016/j.ajog.2022.08.038. Epub 2022 Aug 24. PMID: 36027953; PMCID: PMC9398561. https://pubmed.ncbi.nlm.nih.gov/36027953/

4. El-Atawi K, Abdul Wahab MG, Elsayed Y, Saleh M. Perinatal outcomes of newborns of COVID-19-infected pregnant women: an updated systematic review and meta-analysis. Cureus. 2024;16(2):e54306. doi: 10.7759/ cureus.54306. https://pmc.ncbi.nlm.nih.gov/articles/PMC10944650/

5. Lakshminrusimha S, More K, Shah PS, Wynn JL, Sánchez PJ. Multisystem inflammatory syndrome in neonates (MIS-N) associated with perinatal SARS CoV-2 infection: does it

exist? Semin Fetal Neonatal Med. 2023;28 (2):101433. doi: 10.1016/j.siny.2023.101433 . https://pubmed.ncbi.nlm.nih.gov/37037695/

6. Aguilar, G., Tapia-Calle, G., Robinson, C., Baron, B., Lowson, D., Maximos, B., … Ruiz-Guiñazú, J. (2025). Safety, immunogenicity and pregnancy outcomes in mothers and infants after vaccination with an adenovirus-vector COVID-19 vaccine during pregnancy. *Human Vaccines & Immunotherapeutics*, *21*(1). https://doi.org/10.1080/21645515.2025.2538340

7. Prasad, S., Kalafat, E., Blakeway, H. et al. Systematic review and meta-analysis of the effectiveness and perinatal outcomes of COVID-19 vaccination in pregnancy. Nat Commun 13, 2414 (2022). https://pmc.ncbi.nlm.nih.gov/articles/PMC9090726/

8. Fleming-Dutra KE, Zauche LH, Roper LE, Ellington SR, Olson CK, Sharma AJ, Woodworth KR, Tepper N, Havers F, Oliver SE, Twentyman E, Jatlaoui TC. Safety and Effectiveness of Maternal COVID-19 Vaccines Among Pregnant People and Infants. Obstet Gynecol Clin North Am. 2023 Jun;50(2):279-297. https://pubmed.ncbi.nlm.nih.gov/37149310/

9. CDC web page COVID-19 Vaccination for Women Who Are Pregnant or Breastfeeding | COVID-19 | CDC

10. Bowman CJ, et al. Lack of effects on female fertility and prenatal and postnatal offspring development in rats with BNT162b2, a mRNA-based COVID-19 vaccine. Reprod Toxicol. 2021 Aug;103:28-35. doi: 10.1016/j.reprotox.2021.05.007. Epub 2021 May 28. PMID: 34058573; PMCID: PMC8163337.https://pmc.ncbi.nlm.nih.gov/articles/PMC8163337/

11. CDC Statement on Pregnancy Health Advisory https://archive.cdc.gov/www_cdc_gov/media/releases/2021/s0929-pregnancy-health-advisory.html

12. ClinicalTrial.gov web page: Study Results | NCT04754594 | To Evaluate the Safety, Tolerability, and Immunogenicity of BNT162b2 Against COVID-19 in Healthy Pregnant Women 18 Years of Age and Older | ClinicalTrials.gov

13. C4591015 Final Public Disclosure Synopsis https://cdn.pfizer.com/pfizercom/clinical%20trials/csr%20synopsis/C4591015%20Final%20Public%20Disclosure%20Synopsis.pdf?VersionId=eOzOBKJIDimi8wXmYFnCkZIw04R3qVVX

14. Mathew P, Bordoni B. Embryology, Heart. [Updated 2023 Aug 14]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan. https://www.ncbi.nlm.nih.gov/books/NBK537313/

15. Menillo AM, Alahmadi MH, Pearson-Shaver AL. Atrial Septal Defect. [Updated 2025 Jan 21]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan. https://www.ncbi.nlm.nih.gov/books/NBK535440/

16. Hinkley JR, Fallahi AKM. Syndactyly. [Updated 2022 Sep 18]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan. https://www.ncbi.nlm.nih.gov/books/NBK557704/

17. Antonarakis SE, Skotko BG, Rafii MS, Strydom A, Pape SE, Bianchi DW, Sherman SL, Reeves RH. Down syndrome. Nat Rev Dis Primers. 2020 Feb 6;6(1):9. https://doi.org/10.1038/s41572-019-0143-7

18. Neufeld, E.U. and Muenzer, J. (2001) The Mucopolysaccharidoses. In: Scriver, C.R., Ed., The Metabolic and Molecular Bases of Inherited Disease, McGraw-Hill, New York. https://ommbid.mhmedical.com/content.aspx?bookid=2709&sectionid=225544161

19. Woods CG, Parker A. Investigating microcephaly. Arch Dis Child. 2013 Sep;98(9):707-13. doi: 10.1136/archdischild-2012-302882. Epub 2013 Jun 28. PMID: 23814088. https://pubmed.ncbi.nlm.nih.gov/23814088/

20. Lackey AE, Muzio MR. DiGeorge Syndrome. [Updated 2023 Aug 8]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan. https://www.ncbi.nlm.nih.gov/books/NBK549798/

21. Conrad C, Newberry D. Understanding the Pathophysiology, Implications, and Treatment Options of Patent Ductus Arteriosus in the Neonatal Population. Adv Neonatal Care. 2019 Jun;19(3):179-187. doi: 10.1097/ANC.0000000000000590. PMID: 30720481. https://pubmed.ncbi.nlm.nih.gov/30720481/

22. Marchand et al. (2023): Maternal and neonatal outcomes of COVID-19 vaccination during pregnancy, a systematic review and meta-analysis. https://pmc.ncbi.nlm.nih.gov/articles/PMC10349851/

23. Fernandez-Garcia et al., 2024: Effectiveness and safety of Covid-19 vaccines on maternal and perinatal out outcomes: a systematic review and meta-analysis https://pmc.ncbi.nlm.nih.gov/articles/PMC11002410/

24. Citu IM, Citu C, Gorun F, et al. The Risk of Spontaneous Abortion Does Not Increase Following First Trimester mRNA COVID-19 Vaccination. J Clin Med. 2022; 11(6):1698. https://pmc.ncbi.nlm.nih.gov/articles/PMC8955378/

25. Sheth SS, Vazquez-Benitez G, DeSilva MB et al. Coronavirus Disease 2019 (COVID-19) Vaccination and Spontaneous Abortion. Obstet Gynecol 2025;146:129-37. https://pmc.ncbi.nlm.nih.gov/articles/PMC12169859/

26. Ciapponi A, Berrueta M, Argento FJ, et al. Safety and Effectiveness of COVID-19 Vaccines During Pregnancy: A Living Systematic Review and Meta-analysis. Drug Saf. 2024 Oct;47(10):991-1010. doi: 10.1007/s40264-024-01458-w. Epub 2024 Jul 15. PMID: 39009928; PMCID: PMC11399161. https://pmc.ncbi.nlm.nih.gov/articles/PMC11399161/

27. European Medicines Agency. COVID-19: Latest safety data provide reassurance about use of mRNA vaccines during pregnancy. Last updated 18 January 2022. Accessed October 2024.

28. Fuller et al., (2025, 08 22-26). Incidence Rates of Myocarditis/Pericarditis after Pfizer-BioNTech COVID-19 Vaccine in the United States: Interim Results from a Postapproval Safety Study, Primary Series Analysis [Covid-19 Vaccine Safety: Science, facts, and Public Health]. Washington, DC, United States of America https://www.rtihs.org/publications/incidence-rates-myocarditispericarditis-after-pfizer-biontech-covid-19-vaccine-united

29. Rao et al., (2025, 08 22-26). Baseline Characteristics of Patients Included in a Post-Approval Safety Study of Pfizer-BioNTech Monovalent COVID-19 Vaccine in the United States: Results From an Interim Analysis [Safety Outcomes/Other/Vaccines]. Washington, DC, United States of America. https://www.rtihs.org/publications/interim-utilization-results-post-approval-safety-study-pfizer-biontech-monovalent

30. Fuller et al., (2025, 08 22-26). Incidence rates of safety outcomes in a post-approval study of the Pfizer-BioNTech monovalent COVID-19 vaccine in the United States, booster dose analysis [Safety Outcomes/Other/Vaccines]. Washington, DC, United States of America.

31. Kawai et al., (2025, 08 22-26). Original Pfizer-BioNTech Monovalent COVID-19 Vaccine in the United States: Primary series analysis [Safety Outcomes/Other/Vaccines]. Washington, DC, United States of America.

32. Mayer et al., (2024, 08 24-28). Interim Utilization Results from a Post-Approval Safety Study of Pfizer-BioNTech monovalent COVID-19 Vaccine in the United. Berlin, Germany https://www.rtihs.org/publications/interim-utilization-results-post-approval-safety-study-pfizer-biontech-monovalent

33. Weibel et al (2025, 08 22-26). 2024 interim results from the VAC4EU post-authorisation safety study (PASS) for the Pfizer-BioNTech COVID-19 vaccine (Comirnaty®) in Europe,

[Safety Outcomes/Other/Vaccines]. Washington, DC, United States of America. 202408_icpe24_pfizer.pdf

34. Weibel et al., (2024, 08 24-28). Interim results from the VAC4EU Post-Authorization Safety Study (PASS) among recipients of the Pfizer-BioNTech COVID-19. Berlin, Germany. 202408_icpe24_pfizer.pdf

35. Weibel et al., (2023, 08 23-27). Utilisation patterns of the COVID-19 mRNA vaccine (Comirnaty®) from the VAC4EU active safety surveillance study in five European countries.). Halifax, Canada. 202308_ICPE23_Pfizer-PASS_Utilisation-patterns.pdf

36. Weibel et al., (2022, 08 24-28). Interim results from the VAC4EU Post-Authorization Safety Study (PASS) among recipients of the Pfizer-BioNTech COVID-19. Copenhagen, Denmark. 202408_icpe24_pfizer.pdf

37. Wong et al., (2023, 08 23-27). Preliminary findings from a Non-Interventional Post-Authorization Safety Study (PASS) for Active Safety Surveillance of Comirnaty Vaccine Recipients in the EU. Halifax, Canada.

38. Chambers et al., (2023, 08 23-27). Updated real-world safety of the Pfizer BioNTech COVID-19 vaccine in pregnancy: Data from the organization of teratology information specialists (OTIS)) pregnancy registry. Halifax, Canada. https://onlinelibrary.wiley.com/doi/epdf/10.1002/pds.5687

39. O'Brien et al., (2022, 08 24-28). Novel recruitment, data collection, and safety reporting methods in the era of COVID-19: Design of a post-Emergency Use Authorization COVID-19 vaccination safety-surveillance study. [Poster Session 2] Copenhagen, Denmark.

40. O'Brien et al., (2022, 08 24-28). Preliminary results from HERO-Together: A post-Emergency Use Authorization observational cohort study to evaluate the safety of the Pfizer-BioNTech COVID-19 vaccine in US healthcare workers, their families, and members of the community. [Novel Approaches to Pharmacovigilance] Copenhagen, Denmark.

CLINICAL STUDY REPORT SYNOPSIS

SYNOPSIS

Study Title: Final Report: A Phase 2/3, Placebo-Controlled, Randomized, Observer-Blind Study to Evaluate the Safety, Tolerability, and Immunogenicity of a SARS-CoV-2 RNA Vaccine Candidate (BNT162b2) Against COVID-19 in Healthy Pregnant Women 18 Years of Age and Older

Study Number: C4591015

Regulatory Agency or Public Disclosure Identifier Number:

European Union Drug Regulating Authorities Clinical Trials Database (EudraCT) Number: 2020-005444-35

ClinicalTrials.gov ID: NCT04754594

Study Phase: Phase 2/3

Name of Study Intervention: PF-07302048 (BNT162b2)

Trade Name: Comirnaty®

Name of Sponsor/Company: BioNTech SE

Clinical Study Report (CSR) Version and Report Date: Version 1.0 (22 May 2024)

Number of Study Center(s) and Investigator(s):

This study was conducted at 41 sites in Brazil (3), South Africa (5), Spain (6), the UK (6), and the US (21). A list of study centers and investigators involved in this study is provided in Appendix 16.1.4.1.

Publications:

Not Applicable.

Study Period:

Study Initiation Date (first participant first visit [FPFV]): 16 February 2021

Study Completion (last participant last visit [LPLV]) Date: 15 July 2022

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CLINICAL STUDY REPORT SYNOPSIS

Enrollment in this study was terminated on 25 October 2021 due to changes in the universal recommendations for coronavirus disease 2019 (COVID-19) vaccination of pregnant women with approximately 350 participants enrolled.

Rationale:

The purpose of the study was to describe the safety, tolerability, and immunogenicity of BNT162b2 ribonucleic acid (RNA)-based COVID-19 vaccine against COVID-19 in healthy pregnant women.

Pregnant women are at risk of acquiring SARS-CoV-2 infection, developing COVID-19 and COVID-19–associated complications. Given the global crisis of COVID-19 and fast expansion of the disease globally, the rapid development of an effective vaccine for use in this population is of utmost importance.

Objectives, Endpoints, and Statistical Methods:

Objectives, estimands, and endpoints for maternal participants and infants born to maternal participants are listed in Table S1 below:

Table S1. Objectives, Estimands, and Endpoints

Objectives[a]	Estimands	Endpoints
Primary Safety	**Primary Safety**	**Primary Safety**
To describe the safety and tolerability of prophylactic BNT162b2 when administered to maternal participants 18 years of age or older vaccinated at 24 to 34 weeks' gestation.	In maternal participants receiving at least 1 dose of study intervention from each vaccine group, the percentage of maternal participants reporting: • Local reactions for up to 7 days following each dose • Systemic events for up to 7 days following each dose adverse events (AEs) from Dose 1 through 1 month after Dose 2 • Serious adverse events (SAEs) from Dose 1 through 1 month after delivery	• Prompted local reactions (redness, swelling, and pain at the injection site) • Prompted systemic events (fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain) • AEs • SAEs

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CLINICAL STUDY REPORT SYNOPSIS

Table S1. Objectives, Estimands, and Endpoints

Objectives[a]	Estimands	Endpoints
Primary Immunogenicity	**Primary Immunogenicity**	**Primary Immunogenicity**
To describe the immune response to prophylactic BNT162b2 in maternal participants 18 years of age or older vaccinated at 24 to 34 weeks' gestation and reference to the immune response in nonpregnant women 18 years of age or older from the C4591001 study without evidence of past severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection.	In female participants complying with the key protocol criteria (evaluable participants) and no serological or virological evidence (up to 1 month after receipt of the second dose) of past SARS-CoV-2 infection: • Geometric mean ratio (GMR), estimated by the ratio of the geometric mean of SARS-CoV-2 neutralizing titers in pregnant women to those in nonpregnant women 1 month after Dose 2	• SARS-CoV-2 neutralizing titers
To describe the immune response to prophylactic BNT162b2 in maternal participants 18 years of age or older vaccinated at 24 to 34 weeks' gestation and reference to the immune response in nonpregnant women 18 years of age or older from the C4591001 study with and without evidence of prior SARS-CoV-2 infection.	In female participants complying with the key protocol criteria (evaluable participants): • GMR, estimated by the ratio of the geometric mean of SARS-CoV-2 neutralizing titers in pregnant women to those in nonpregnant female participants 1 month after Dose 2	• SARS-CoV-2 neutralizing titers
Secondary	**Secondary**	**Secondary**
To describe the efficacy of prophylactic BNT162b2 against confirmed COVID-19 occurring from 7 days after Dose 2 through 1 month after delivery in maternal participants 18 years of age or older vaccinated at 24 to 34 weeks' gestation without evidence of prior SARS-CoV-2 infection.	In maternal participants complying with the key protocol criteria (evaluable participants) and no serological or virological evidence (prior to 7 days after receipt of Dose 2) of past SARS-CoV-2 infection: • 100 × (1 – incidence rate ratio [IRR]) [ratio of active vaccine to placebo]	• COVID-19 incidence per 1000 person-years of blinded follow-up based on central laboratory or locally confirmed nucleic acid amplification test (NAAT)
To describe the efficacy of prophylactic BNT162b2 against confirmed COVID-19 occurring from 7 days after Dose 2 through 1 month after delivery in maternal	In maternal participants complying with the key protocol criteria (evaluable participants):	• COVID-19 incidence per 1000 person-years of blinded follow-up based on central

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CLINICAL STUDY REPORT SYNOPSIS

Table S1. Objectives, Estimands, and Endpoints

Objectives[a]	Estimands	Endpoints
participants 18 years of age or older vaccinated at 24 to 34 weeks' gestation with and without evidence of prior SARS-CoV-2 infection.	• 100 × (1 – IRR) [ratio of active vaccine to placebo]	laboratory or locally confirmed NAAT
To describe the efficacy of prophylactic BNT162b2 against asymptomatic SARS-CoV-2 infection through 1 month after delivery in maternal participants 18 years of age or older vaccinated at 24 to 34 weeks' gestation without evidence of prior SARS-CoV-2 infection.	In evaluable maternal participants without serological or virological evidence of prior SARS-CoV-2 infection: • 100 × (1 – IRR) [ratio of active vaccine to placebo]	• Incidence of asymptomatic infection of SARS-CoV-2 based on N-binding antibody seroconversion
To describe the immune response over time and persistence of prophylactic BNT162b2 when administered to maternal participants 18 years of age or older vaccinated at 24 to 34 weeks' gestation.	In maternal participants complying with the key protocol criteria (evaluable maternal participants) from each vaccine group: • Geometric mean concentrations (GMCs)/geometric mean titers (GMTs), at baseline (before Dose 1), 2 weeks after Dose 2, 1 month after Dose 2, at delivery, and 6 months after delivery • Geometric mean fold rises (GMFRs) from baseline through 2 weeks after Dose 2, 1 month after Dose 2, at delivery, and 6 months after delivery	• Full-length S-binding IgG levels • SARS-CoV-2 neutralizing titers
To assess the safety of maternal immunization in infants born to maternal participants 18 years of age or older who were vaccinated with BNT162b2 during pregnancy.	In infants born to maternal participants receiving at least 1 dose of study intervention from each vaccine group, the percentage of infants with: • Specific birth outcomes • AEs from birth through 1 month of age • SAEs and AESIs (major congenital anomalies, developmental delay) through 6 months of age	• Specific birth outcomes • AEs from birth through 1 month of age • SAEs and adverse events of special interest (AESIs) (major congenital anomalies, developmental delay) through 6 months of age

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CLINICAL STUDY REPORT SYNOPSIS

Table S1. Objectives, Estimands, and Endpoints

Objectives[a]	Estimands	Endpoints
To describe the immune response in infants born to maternal participants vaccinated with prophylactic BNT162b2 during pregnancy.	In infants born to evaluable maternal participants from each vaccine group: • GMCs and GMFRs, at birth and 6 months after delivery	• Full-length S-binding IgG levels

a. Human immunodeficiency virus (HIV)-infected participants will not be included in analyses of the objectives, but in separate exploratory analyses. Analyses among HIV-infected women and their infants will be summarized separately.

Methodology:

This was a global Phase 2/3, randomized, placebo-controlled, observer-blind study to evaluate the safety, tolerability, and immunogenicity of 30 µg of BNT162b2 or placebo administered in 2 doses, 21 days apart, in approximately 350 healthy pregnant women 18 years of age or older vaccinated at 24 to 34 weeks' gestation. Participants were randomized 1:1 to receive BNT162b2 or placebo (saline).

The Phase 2 portion of the study included approximately 200 pregnant women enrolled at 27 to 34 weeks' gestation. The IRC reviewed safety data through 7 days after the second dose for all Phase 2 participants.

The Phase 3 portion of this study assessed the safety, tolerability, and immunogenicity of BNT162b2 in approximately 150 pregnant women enrolled at 24 to 34 weeks' gestation. Phase 3 proceeded after the first 200 maternal participants had been enrolled in Phase 2.

Maternal participants who originally received placebo could receive BNT162b2 at the 1 month postdelivery visit.

Enrollment in this study was terminated on 25 October 2021 due to changes in the universal recommendations for COVID-19 vaccination of pregnant women with approximately 350 participants enrolled. Enrollment was terminated due to enrollment challenges into a placebo-controlled study as a result of universal recommendations for COVID-19 vaccination of pregnant women and the increased global availability of COVID-19 vaccines. Participant enrollment numbers were modified accordingly (~200 in Phase 2, and ~150 in Phase 3).

It was planned that each maternal participant would participate in the study for up to approximately 10 months, depending on the vaccine group to which she was randomized. Her infant would participate in the study for approximately 6 months. The planned study duration was approximately 14 months.

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CLINICAL STUDY REPORT SYNOPSIS

The BNT162b2 dose of 30 µg in this study is the same as that for Study C4591001 Phase 2/3 evaluation of safety, immunogenicity, and efficacy. A placebo was used as the control.

Number of Participants (planned and analyzed):

Maternal Participants

A total of 174 maternal participants were randomized to receive 2 doses of BNT162b2 30 µg and 174 were randomized to receive 2 doses of placebo. In total, 97.7% of maternal participants received both doses and 92.0% completed the 1-month postdelivery visit. Across groups, 5.5% of participants were withdrawn from the study; the most frequent reason was withdrawal by the participant.

Per protocol, participants originally randomized to placebo could receive BNT162b2 after being unblinded at the 1-month postdelivery visit. Among these participants, 152 (93.8%) received a first dose of BNT162b2 and 148 (91.4%) received a second dose of BNT162b2. Of these, 4 participants were withdrawn after the first dose of BNT162b2 and 1 after the second dose of BNT162b2.

Safety Population

The safety population for maternal participants included 173 participants in the BNT162b2 group and 173 participants in the placebo group; 2 maternal participants were excluded from the safety population because they did not receive the study intervention. Most maternal participants included in the safety population were breastfeeding, and 12 in the BNT162b2 group and 10 in the placebo group were HIV-positive.

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Immunogenicity Populations

The evaluable immunogenicity population for Study C4591015 maternal participants included 111 participants in the BNT162b2 group and 115 participants in the placebo group, and for Study C4591001 nonpregnant females included 114 participants in the BNT162b2 group and 124 participants in the placebo group. Exclusions from the evaluable immunogenicity population were balanced across BNT162b2 and placebo groups among C4591015 participants and among C4591001 participants; the most common reason for exclusion for C4591015 participants was due to a lack of at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.

The evaluable immunogenicity population without evidence of SARS-CoV-2 infection prior to 1 month after Dose 2 for Study C4591015 maternal participants included 59 participants (33.9%) in the BNT162b2 group and 58 participants (33.3%) in the placebo group; for Study C4591001 nonpregnant females included 107 participants (87.0%) in the BNT162b2 group and 113 participants (85.0%) in the placebo group. Of note, the proportions of participants without evidence of prior infection for the C4591015 and C4591001 study participants reflect varying conditions of the COVID-19 pandemic, as the studies were conducted in different times and countries.

Efficacy Populations

The proportions of maternal participants included in the efficacy populations were balanced between the BNT162b2 and placebo groups. The evaluable efficacy population included 161 participants in the BNT162b2 group and 163 participants in the placebo group. Exclusions from the evaluable efficacy population were similar across groups; the most common reason was due to other protocol deviation(s) as determined by the clinician.

The evaluable efficacy population without evidence of SARS-CoV-2 infection prior to 7 days after Dose 2 included 91 participants in the BNT162b2 group and 94 participants in the placebo group.

Infant Participants

A total of 167 infants were born to maternal participants in the BNT162b2 group and 168 were born to maternal participants in the placebo group. Most (86.9%) infant participants completed the 6-months-of-age follow-up visit. Withdrawal from the study was more frequently reported among infants whose mothers were randomized to placebo (17.3%) than those whose mothers were randomized to BNT162b2 (9.0%); the most frequent reasons for withdrawal during the study was withdrawal by parent/guardian and lost to follow-up. Two infant participants (1 in the BNT162b2 and 1 in the placebo group) died during the study due to SAEs that were assessed as unrelated to study vaccination, and were subsequently withdrawn from the study.

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Safety Population

The safety population for infant participants included 167 born to mothers in the BNT162b2 group and 168 born to mothers in the placebo group. Infants whose mothers were HIV-positive included 11 in the BNT162b2 group and 9 in the placebo group.

Immunogenicity Populations

The proportions of infant participants included in the immunogenicity populations were balanced between the BNT162b2 and placebo groups. The evaluable immunogenicity population for infant participants included 109 participants in the BNT162b2 group and 105 participants in the placebo group.

The proportion of participants excluded from the evaluable immunogenicity population was 34.7% and 37.5% for the BNT162b2 group and the placebo group, respectively. The most frequent reason for exclusion of infant participants from the evaluable immunogenicity populations was because the mother was not considered to be an evaluable immunogenicity maternal participant.

Efficacy Populations

The proportions of infant participants included in the efficacy populations were balanced between the BNT162b2 and placebo groups. The evaluable efficacy population included 167 participants in the BNT162b2 group and 168 participants in the placebo group.

For infants born to mothers in the BNT162b2 and placebo groups, most (88.0% and 90.5%, respectively) were breastfed and few (6.6% and 5.4%, respectively) were born to mothers who were HIV-positive.

Diagnosis and Main Criteria for Inclusion and Exclusion:

Enrolled in this study were participants who were healthy pregnant women ≥18 years of age and their infants, once born. Enrollment was monitored to help ensure distribution of vaccination across the gestational age ranges of 27 0/7 to 34 0/7 weeks for Phase 2 and ≥24 0/7 and ≤34 0/7 weeks for Phase 3.

Study Interventions, Dose, Mode of Administration, and Batch Number(s):

Details of the study interventions, administered intramuscularly, are provided below:

- BNT162b2 (BNT162 RNA-lipid nanoparticle [LNP] vaccine utilizing modified ribonucleic acid [modRNA] and encoding the SARS-CoV-2 full-length, P2 mutant, prefusion spike glycoprotein [P2 S]): 30 µg
- Normal saline (0.9% sodium chloride solution for injection)

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The manufacturing lot numbers for the study interventions dispensed in this study are provided in Table S2.

Table S2. Study Intervention Lot Numbers

Study Intervention	Manufacturer	Vendor Lot Number (Manufacturer)	Lot Number[a] (Pfizer)
BNT162b2	BioNTech	ER5832 EE3813	PA2094601/P222676-0003L NC2075485/P222676-0001L
Diluent (normal saline, 0.9% sodium chloride solution)	Pfizer	EE4253 DK2074 EX2624	PA2091593/P222676-0005L 20-002221 21-AE-00230
Placebo (normal saline, 0.9% sodium chloride solution)	Pfizer	EE4253 DK2074;20-002221	PA2091593/P222676-0004L PA2069407/P222676-0002L

a. Lot number assigned to the study intervention by Pfizer Global Clinical Supply.
Protocol C4591015 Study Intervention Lot Numbers Table –Final, Version 1.0, 08Mar2024.

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Duration of Study Intervention:

The Study C4591001 vaccine candidate selected for Phase 2/3 evaluation was BNT162b2 at a dose of 30 µg. Study C4591015 evaluated 2 doses of BNT162b2 30 µg or placebo administered 21 days apart (Visits 1 and 2). At 1 month after delivery, maternal participants who originally received placebo could receive 1 dose of BNT162b2 at Visits 101 and 102.

Summary of Results:

Demographic and Other Baseline Characteristics:

Maternal Participants

Safety Population

Demographic and baseline characteristics for the safety population of maternal participants were well balanced between the BNT162b2 and placebo groups. Overall, the majority of participants were White (67.9%), non-Hispanic/non-Latino (61.6%), and located in the United States (48.3%) or South Africa (23.7%). A total of 127 (36.7%) participants had a positive baseline SARS-CoV-2 status. The median age of participants at Dose 1 was 30.0 years, and the median gestational age at Dose 1 was 30.4 weeks. Both groups were similar with regards to HIV status and pre-pregnancy body mass index (BMI).

Medical history and obstetric history were generally similar for maternal participants in the BNT162b2 and placebo groups.

Baseline Charlson Comorbidities were reported for few maternal participants in the BNT162b2 and placebo groups (21 [12.1%] and 14 [8.1%], respectively). Across groups, the

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most common comorbidities reported were HIV-positive (6.4%) and chronic pulmonary disease (2.6%).

Immunogenicity Populations

Of note, a greater proportion of C4591015 participants identified as Black or African American (≥27.0% compared with ≥5.3% in C4591001) and a higher percentage were enrolled from South African sites (≥24.3% compared with ≥0.8% in C4591001). Additionally, the proportion of C4591015 maternal participants with positive baseline SARS-CoV-2 status (≥37.8%) was higher than what was observed among C4591001 participants (≥3.5%), which could have been due to the different timepoints at which participants were enrolled in each study relative to the progression of the COVID-19 pandemic. The majority of participants identified as non-Hispanic/non-Latino (63.7%). The median age of participants at Dose 1 was 30.0 years, and the median gestational age at Dose 1 for the BNT162b2 and placebo groups was 28.9 weeks and 29.1 weeks, respectively. Both groups were similar with regards to HIV status. Pre-pregnancy BMIs for C4591015 maternal participants were generally higher than those observed in C4591001 nonpregnant female participants.

Infant Participants

Safety Population

Demographics and baseline characteristics for the safety population of infant participants were balanced for the BNT162b2 and placebo groups. The majority of participants were White (65.4%), non-Hispanic/non-Latino (60.3%), and located in the United States (48.7%) or South Africa (23.9%). The majority of infants were born between ≥37 weeks to 41 weeks 6 days, and 89.3% of infant participants were breastfed. Both groups were similar with regards to HIV status.

Immunogenicity Populations

The demographics for the immunogenicity population of infant participants were generally similar to those of the safety population.

Exposure:

Most (≥97.7%) maternal participants were administered Dose 1 and Dose 2 as randomized. For participants who were originally randomized to placebo, 87.4% and 85.1% received a first dose and second dose of BNT162b2, respectively, following unblinding at the 1-month postdelivery visit.

In all randomized maternal participants, the majority (≥87.9%) in the BNT162b2 and placebo groups received Dose 2 in the protocol-defined window of 19 to 23 days after Dose 1. For the 152 (87.4%) maternal participants who were originally randomized to placebo and received a

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first dose of BNT162b2 after unblinding, the majority (127 [73.0%]) received a second dose of BNT162b2 in the protocol-defined window of 19 to 23 days after the first dose.

Vaccine administration timing was similar for Study C4591015 maternal participants and Study C4591001 nonpregnant female participants in the evaluable immunogenicity population across both vaccine groups.

Overall, important PDs were balanced among maternal participants in both the BNT162b2 and placebo groups. Important PDs in maternal participants were most frequently reported in the category of inclusion/exclusion criteria. One PD in the concomitant medications category was reported among infant participants in the placebo group. No PDs were reported among infants born to maternal participants in the BNT162b2 group.

Concomitant medications used after Dose 1 were reported similarly among maternal participants in the BNT162b2 and placebo groups (27.3% and 28.8%, respectively). The number of participants who received nonstudy vaccines after Dose 1 was also similar (16.1% and 20.9%, respectively). Concomitant medications received after birth were reported similarly among infants born to maternal participants in the BNT162b2 and placebo groups (13.5% and 14.5%, respectively).

In all randomized maternal participants, for each of the visits at which blood draws occurred the proportions were generally similar for the BNT162b2 and placebo groups through the delivery visit. For both groups, the majority (≥52.9%) of blood draws were within the protocol-defined window through the delivery visit. In infant participants, the majority had blood samples drawn at birth (≥89.9%) and in the protocol-defined window of 160 to 200 days (≥63.1%) for the 6-months of age follow-up visit.

For maternal participants, transmission of reactogenicity e-diary data for each day during the 7 days after Dose 1 of BNT162b2 ranged from 86.7% to 94.8%. After Dose 2 of BNT162b2, transmission of e-diary data ranged from 73.5% to 87.6% for Day 1 through Day 7.

Immunogenicity Results:

Primary Immunogenicity Analyses – Maternal Participants

GMR of Neutralizing Titers

Among participants without prior evidence of SARS-CoV-2 infection up to 1 month after Dose 2 (evaluable immunogenicity population), the ratio of the neutralizing GMT (GMR) in Study C4591015 maternal participants in the BNT162b2 (30 µg) group to that of Study C4591001 nonpregnant females who received BNT162b2 30 µg was 0.67 (95% confidence interval [CI]: 0.50, 0.90).

For participants with or without prior evidence of SARS-CoV-2 infection up to 1 month after Dose 2 (evaluable immunogenicity population), the model-adjusted ratio of the neutralizing GMT (adjusted GMR) in Study C4591015 maternal participants in the BNT162b2 (30 µg)

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group to that of Study C4591001 nonpregnant females who received BNT162b2 30 µg was 0.95 (95% CI: 0.69, 1.30). The adjusted GMT and GMR were calculated based on a regression model with vaccine group, age at Dose 1 and baseline neutralizing titers as the independent variables to minimize the confounding effect from imbalanced distribution of baseline SARS-CoV-2 infection.

Secondary Immunogenicity Analyses – Maternal Participants

Neutralizing GMTs and Full-length Spike Protein (S-binding) Immunoglobulin G (IgG) GMCs

For the evaluable immunogenicity population without evidence of infection, at 1 month after Dose 2 there was a substantial increase in SARS-CoV-2 50% neutralizing GMTs in maternal participants in the BNT162b2 group (1099.4 [95% CI: 820.6, 1473.0]) compared to the placebo group (43.5 [95% CI: 43.5, 43.5]), for which change from baseline was negligible; these results are consistent with those in nonpregnant females in Study C4591001. In maternal participants in the BNT162b2 group, GMTs were substantially increased, compared to the placebo group, peaked at 2 weeks after Dose 2 and remained elevated through the 6-month postdelivery visit. Results for participants in the evaluable immunogenicity population with or without evidence of infection followed a similar trend.

For the evaluable immunogenicity population without evidence of infection, at 2 weeks after Dose 2 there was a substantial increase in GMCs of full-length S-binding IgG in maternal participants in the BNT162b2 group (7639.0 [95% CI: 6403.0, 9113.6]) compared to the placebo group (1.7 [95% CI: 1.2, 2.6]), for which change from baseline was negligible. In the BNT162b2 group, GMCs were substantially increased, compared to the placebo group, peaked at 2 weeks after Dose 2 and remained elevated through the 6-month postdelivery visit. Results for participants in the evaluable immunogenicity population with or without evidence of infection followed a similar trend.

HIV-Positive Participants

Among HIV-positive maternal participants, SARS-CoV-2 50% neutralizing titers in maternal participants in the BNT162b2 group were generally higher compared to those in the placebo group at 1 month after Dose 2, and remained elevated at 6 months after Dose 2.

Overall, full-length S-binding IgG levels in HIV-positive maternal participants in the BNT162b2 group were substantially higher than those observed in the placebo group at 1 month after Dose 2, and remained elevated at 6 months after Dose 2. As this subgroup included a limited number of participants, these results should be interpreted with caution.

Subgroup Analyses

GMTs at prevaccination (Dose 1) and 1 month after Dose 2 were evaluated by race, ethnicity, and baseline SARS-CoV-2 status in Study C4591015 maternal participants and

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Study C4591001 nonpregnant females. Among participants with or without evidence of infection, higher baseline and post-vaccination titers were observed in Black/African American participants as compared to other race groups. Higher GMTs were also observed in participants with positive baseline SARS-CoV-2 status at both baseline and 1 month after Dose 2 timepoints compared to those observed in participants with negative baseline status. Overall, GMTs for the BNT162b2 groups for both studies were generally similar and did not identify any clinically meaningful differences for any other race subgroup or ethnicity. As several subgroups included a limited number of participants, these results should be interpreted with caution.

Neutralizing Titer and Full-length S-binding IgG GMFRs

In maternal participants in the evaluable immunogenicity population without evidence of infection, the SARS-CoV-2 NT GMFR at 1 month after Dose 2 was substantially higher in the BNT162b2 group (25.3 [95% CI: 18.9, 33.9]) compared to the placebo group (1.0 [95% CI: 1.0, 1.0]), for which change from baseline was negligible. In maternal participants in the BNT162b2 group, the GMFR peaked at 2 weeks after Dose 2 and remained elevated through the delivery visit and 6-month postdelivery timepoints. Results for participants in the overall evaluable immunogenicity population followed a similar trend.

In maternal participants in the evaluable immunogenicity population without evidence of infection, the full-length S-binding IgG GMFR at 1 month after Dose 2 was substantially higher in maternal participants in the BNT162b2 group (2276.4 [95% CI: 1545.5, 3352.9]) compared to the placebo group (0.9 [95% CI: 0.8, 1.1]), for which change from baseline was negligible. In maternal participants in the BNT162b2 group, the GMFR peaked at 2 weeks after Dose 2 and remained elevated compared to the placebo group through the delivery visit and 6-month postdelivery timepoints. Results for participants in the overall evaluable immunogenicity population followed a similar trend.

Secondary Immunogenicity Analyses – Infant Participants

Full-length S-binding IgG GMCs

Maternal vaccination with BNT162b2 30 µg yielded substantially higher GMCs of full-length S-binding IgG in infants compared to placebo. For the evaluable immunogenicity population, at birth and 6 months of age GMCs were 5576.4 (95% CI: 4246.2, 7323.2) and 311.1 (95% CI: 235.8, 410.5), respectively, for infants whose mothers received BNT162b2, compared to 19.4 (95% CI: 10.2, 37.0) and 22.0 (95% CI: 11.4, 42.7) for infants whose mothers received placebo.

Infants Born to HIV-Positive Maternal Participants

Among infants born to HIV-positive maternal participants, full-length S-binding IgG levels at birth and 6 months of age were higher among infants born to vaccinated participants (with ranges of 406.32-39970 at birth and 169.12-5029.4 at 6 months) than those born to

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participants in the placebo group (with ranges of 4.92-1561.33 at birth and 7.01-653.18 at 6 months). As this subgroup included a limited number of participants, these results should be interpreted with caution.

Exploratory Subgroup Analyses

GMCs of full-length S-binding IgG in infants in the evaluable immunogenicity population were evaluated by breastfeeding status. GMCs for breastfed infants were generally higher than those observed for infants who were not breastfed. GMCs for breastfed or not breastfed infants whose mothers received BNT162b2 were substantially higher at birth compared to infants whose mothers received placebo, and remained elevated at 6 months of age. As the not breasted subgroup included a limited number of participants, these results should be interpreted with caution.

GMFRs

In infants in the evaluable immunogenicity population whose mothers received BNT162b2, the GMFR of full-length S-binding IgG from birth to 6 months of age was 0.1 [95% CI: 0.0, 0.1], indicating a decline in antibody titers during this period.

Exploratory Subgroup Analyses

GMFRs of full-length S-binding IgG in infants in the evaluable immunogenicity population were evaluated by breastfeeding status. GMFRs by breastfeeding status were generally similar to those observed in the overall population. As the not breastfed subgroup included a limited number of participants, these results should be interpreted with caution.

Efficacy Results:

Secondary Efficacy Analyses – Maternal Participants

Vaccine Efficacy Against Confirmed COVID-19

Due to the very small sample size, and hence number of COVID-19 cases, vaccine efficacy (VE) results are uninterpretable; nevertheless, they are described below:

For confirmed COVID-19 based on the protocol definition, in maternal participants without evidence of SARS-CoV-2 infection prior to 7 days after Dose 2 in the evaluable efficacy population, the VE during the blinded follow-up period was observed as 3.8% (95% CI: -1227.8%, 93.0%) based on 2 cases in the BNT162b2 group and 2 cases in the placebo group confirmed from at least 7 days after Dose 2 through 1 month after delivery.

For confirmed COVID-19 based on the protocol definition, in maternal participants with or without evidence of SARS-CoV-2 infection prior to 7 days after Dose 2 in the evaluable efficacy population, the VE during the blinded follow-up period was observed as 35.1%

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(95% CI: -466.5%, 94.6%), with 2 cases reported in the BNT162b2 group and 3 cases in the placebo group confirmed from at least 7 days after Dose 2 through 1 month after delivery.

For confirmed COVID-19 based on the Centers for Disease Control and Prevention (CDC) definition, in maternal participants without evidence of SARS-CoV-2 infection prior to 7 days after Dose 2 in the evaluable efficacy population, the VE during the blinded follow-up period was observed as 36.2% (95% CI: -456.5%, 94.7%) based on 2 cases in the BNT162b2 group and 3 cases in the placebo group confirmed from at least 7 days after Dose 2 through 1 month after delivery.

For confirmed COVID-19, based on the CDC definition, in maternal participants with or without evidence of SARS-CoV-2 infection prior to 7 days after Dose 2 in the evaluable efficacy population, the observed VE during the blinded follow-up period was generally higher at 51.1% (95% CI: -241.0%, 95.6%), with 2 cases reported in the BNT162b2 group and 4 cases in the placebo group confirmed from at least 7 days after Dose 2 through 1 month after delivery.

Vaccine Efficacy Against Asymptomatic SARS-CoV-2 Infection Based on Seroconversion (Nucleoprotein Binding [N-Binding])

For asymptomatic infection, based on N-binding antibody seroconversion, in the evaluable efficacy population of maternal participants without evidence of SARS-CoV-2 infection prior to the first post-Dose 2 N-binding test, the VE during the blinded follow-up period was observed as 40.9% (95% CI: -104.9%, 86.5%) based on 4 cases in the BNT162b2 group and 10 cases in the placebo group confirmed from after Dose 2 through 1 month after delivery. As this subgroup included a limited number of participants, these results should be interpreted with caution.

Additional VE analyses for asymptomatic infection had similar results, with most cases occurring in the placebo group.

Safety Results:

Local Reactions – Maternal Participants

In maternal participants in the BNT162b2 group, pain at the injection site was the most frequently reported local reaction, and frequency was similar after Dose 1 and after Dose 2 (82.6% vs 75.0%). In the placebo group, pain at the injection site after each dose was less frequently reported compared to the BNT162b2 group and was reported more frequently after Dose 2 (16.4%) than Dose 1 (9.8%). Redness and swelling after either Dose 1 or Dose 2 were reported in ≤6.8% and ≤0.7% of participants in the BNT162b2 and placebo groups, respectively.

Most local reactions were mild or moderate in severity. A severe event of swelling was reported in 1 participant in the BNT162b2 group after Dose 1, and a severe event of pain at

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the injection site was reported in 1 participant in the same group after Dose 2. No Grade 4 local reactions were reported in either group.

Across both groups, median onset for all local reactions was between Day 1 and Day 2.5 after Dose 1 or Dose 2, and all events resolved with median durations between 1 to 2 days.

HIV-Positive Participants

Among HIV-positive participants, frequencies of local reactions within 7 days after Dose 1 and Dose 2 were generally reported at higher frequencies among participants in the BNT162b2 group compared to those in the placebo group. Of note, pain at the injection site was more frequently reported after each dose in the BNT162b2 group (≤50.0% after either Dose 1 or Dose 2) than in the placebo group (≤20.0% after Dose 1 and ≤22.2% after Dose 2). No severe or Grade 4 local reactions were reported in either group. As this subgroup included a limited number of participants, these results should be interpreted with caution.

Subgroup Analyses

Local reactions reported within 7 days after vaccination were evaluated by race, ethnicity, and baseline SARS-CoV-2 status. Overall, for these subgroups, local reactions were reported at higher frequencies among participants in the BNT162b2 group after both doses compared to those in the placebo group. Among vaccinated participants, no clinically meaningful differences were observed by race or ethnicity in either group. For participants with baseline negative SARS-CoV-2 status, higher frequencies of pain at the injection site were reported after each dose in both the BNT162b2 and placebo groups as compared to baseline positive participants. As several subgroups included a limited number of participants, these results should be interpreted with caution.

Systemic Events – Maternal Participants

In maternal participants, systemic events were generally similar frequencies in the placebo group compared to the BNT162b2 group after Dose 1; however, systemic events were observably higher after Dose 2 among participants in the BNT162b2 group. Fatigue and headache were most frequently reported after each dose in the BNT162b2 (≤50.0% reported fatigue and ≤41.2% reported headache) and placebo groups (≤42.9% reported fatigue and ≤35.6% reported headache). Fever was reported in few participants after each dose in both the BNT162b2 (≤2.7%) and placebo groups (≤1.8%).

Most systemic events were mild or moderate in severity. In both the BNT162b2 and placebo groups, the most frequently reported severe events after any dose were fatigue (2.0% and 0.6%, respectively) and headache (1.9% and 0.6%, respectively). No Grade 4 systemic events were reported in either group.

Across both groups, median onset for all systemic events was between Day 1 and Day 4 after Dose 1 or Dose 2, and all events resolved with median durations between 1 to 4.5 days.

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The reported frequencies of participants with baseline systemic events were similar for the BNT162b2 and placebo groups, with the baseline fatigue most frequently reported (29.7% and 33.8%, respectively).

HIV-Positive Participants

Among HIV-positive participants, systemic events were reported at numerically higher frequencies after Dose 1 in the placebo group compared to the BNT162b2 group; however, systemic events were reported at generally similar frequencies after Dose 2 in the two vaccine groups. In both the BNT162b2 and placebo groups, the most frequently reported systemic events after any dose were fatigue (≤66.7% and ≤60.0%, respectively) and headache (≤41.7% and ≤60.0%, respectively). No Grade 4 systemic events were reported in either group. As this subgroup included a limited number of participants, these results should be interpreted with caution.

Subgroup Analyses

Systemic events reported within 7 days after vaccination were evaluated by race, ethnicity, and baseline SARS-CoV-2 status. Among vaccinated participants, no clinically meaningful differences were observed by race, ethnicity, or SARS-CoV-2 status in either group. As several subgroups included a limited number of participants, these results should be interpreted with caution.

Adverse Events – Maternal Participants

From Dose 1 to 1 month after Dose 2 during the blinded follow-up period, the proportion of participants reporting any AE was similar in the BNT162b2 (23.6%) and placebo (22.7%) groups. Across both groups, any related, severe, or serious AEs were reported in ≤0.6%, ≤4.9%, and ≤5.6%, respectively. In the placebo group, life-threatening AEs were reported in 1.8% of participants.

No maternal participants had any AEs leading to withdrawal and none died from Dose 1 to 1 month after Dose 2 during the blinded follow-up period.

In maternal participants originally randomized to placebo who received BNT162b2 after unblinding at 1 month postdelivery, the frequency of AEs reported among participants who originally received placebo and then received BNT162b2 after unblinding (22.2%) was similar to that in the BNT162b2 group during the blinded follow-up period (23.6%), and overall the results did not suggest any meaningful differences in types of AEs reported.

From vaccination with BNT162b2 to 1 month after the second dose of BNT162b2 for original placebo participants who then received BNT162b2 after unblinding, there were no reported SAEs, life-threatening AEs, AEs leading to withdrawal, or deaths. Except for 1 participant, all AEs were mild or moderate in severity. Related AEs were reported in 12.5%

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of participants. The most frequently reported AEs in these participants unblinded at 1 month postdelivery were reactogenicity events.

HIV-Positive Participants

Among HIV-positive participants, AEs were reported in 16.7% of participants in the BNT162b2 group and 40.0% of participants in the placebo group. Most AEs were mild or moderate in severity (1 severe event was reported in the BNT162b2 group), and none were assessed as related. SAEs were reported in ≤10.0% between both groups. No life-threatening AEs were reported.

Subgroup Analyses

AEs reported in maternal participants from Dose 1 to 1 month after Dose 2 were evaluated by race, ethnicity, and SARS-CoV-2 status. Overall, results for both the BNT162b2 and placebo groups suggested no clinically meaningful differences across subgroups. As several subgroups included a limited number of participants, these results should be interpreted with caution.

Adverse Events – Infant Participants

The proportions of infant participants with any AEs reported from birth to 1 month of age were similar in the BNT162b2 (35.3%) and placebo (37.1%) groups. Most AEs were mild or moderate in severity (≤6.3% were severe between both groups), and none were assessed by the investigator as related. Between both groups, SAEs were reported in ≤13.8% and life-threatening AEs were reported in and ≤3.1% of infants.

One infant participant in the placebo group was withdrawn due to a fatal SAE of neonatal pneumonia that was assessed by the investigator as unrelated to study intervention. Additionally, 1 infant born to an HIV-positive maternal participant in the BNT162b2 group was withdrawn due to a fatal SAE of pneumonia that was also assessed as unrelated to study intervention by the investigator.

Conclusions:

In this study, the reactogenicity, safety, and tolerability profile of BNT162b2 at 30 µg was found to be satisfactory in maternal participants.

BNT162b2 (30 µg) elicited robust immunogenicity responses in healthy pregnant women 18 years of age and older, with SARS-CoV-2 neutralizing titers that were notably higher compared to placebo; however, among those without SARS-CoV-2 infection, numerically lower GMTs were observed in the maternal participants compared to the selected nonpregnant female participants from Study C4591001. A similar pattern was shown in those with or without SARS-CoV-2 infection after adjusting the baseline neutralizing titers.

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Infants born to vaccinated maternal participants had higher S-binding IgG concentrations at birth and at 6 months after delivery when compared to infants born to maternal participants from the placebo group. Breastfed infants had marginally higher antibody levels at 6 months after delivery than non-breastfed infants. No safety issues attributable to BNT162b2 exposure were identified in infants born to maternal participants who were vaccinated during pregnancy.

Overall, the data from this study support a favorable benefit risk profile in pregnant women and their infants.

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TITLE PAGE

FINAL FULL CLINICAL STUDY REPORT

Clinical Study Report Title:	Final Report: A Phase 2/3, Placebo-Controlled, Randomized, Observer-Blind Study to Evaluate the Safety, Tolerability, and Immunogenicity of a SARS-CoV-2 RNA Vaccine Candidate (BNT162b2) Against COVID-19 in Healthy Pregnant Women 18 Years of Age and Older
Study Number:	C4591015
Study Phase:	Phase 2/3
Compound:	PF-07302048 (BNT162b2)
Trade Name:	Comirnaty®
Study Sponsor:	BioNTech SE
Sponsor Agent:	Pfizer Inc.
Sponsor's Signatory:	[redacted] BioNTech SE
Sponsor Agent's Signatory:	[redacted] Pfizer Inc.
Name and Affiliation of Principal or Coordinating/Lead Investigator:	[redacted] United States
Study Initiation Date (FPFV):	16 February 2021
Study Completion (LPLV) Date:	15 July 2022
Serology Completion Date:	08 January 2024
Regulatory Agency or Public Disclosure Identifier Number:	**EudraCT Number:** 2020-005444-35 **ClinicalTrials.gov ID:** NCT04754594

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CSR Version and Report Date:	Document Version	Report Date
	Final CSR Version 1.0	22 May 2024

GOOD CLINICAL PRACTICE STATEMENT

This study was conducted in compliance with GCP guidelines and, where applicable, local country regulations relevant to the use of new therapeutic agents in the country/countries of conduct, including the archiving of essential documents.

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SYNOPSIS

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16. APPENDICES

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LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

Abbreviation	Definition
AE	adverse event
AESI	adverse event of special interest
BMI	body mass index
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CI	confidence interval
CIOMS	Council for International Organizations of Medical Sciences
COVID-19	coronavirus disease 2019
CRF	case report form
CRO	contract research organization
CSR	clinical study report
DCT	data collection tools
DMC	data monitoring committee
EUA	Emergency Use Authorization
EudraCT	European Union Drug Regulating Authorities Clinical Trials Database
FDA	Food and Drug Administration
FPFV	first participant first visit
GCP	Good Clinical Practice
GMC	geometric mean concentration
GMFR	geometric mean fold rise
GMR	geometric mean ratio
GMT	geometric mean titer
HIPAA	Health Insurance Portability and Accountability Act
HIV	human immunodeficiency virus
ICD	informed consent document
ICF	informed consent form
ICH	International Council of Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ID	identification
IEC	independent ethics committee
IgG	immunoglobulin G
IRB	institutional review board
IRC	institutional review committee
IRR	incidence rate ratio
IRT	interactive response technology
LLOQ	lower limit of quantification
LNP	lipid nanoparticle
LPLV	last participant last visit
MedDRA	Medical Dictionary for Regulatory Activities
MIS-C	multisystem inflammatory syndrome in children
mITT	modified intent-to-treat

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modRNA	modified ribonucleic acid
N	number of participants in the specified group, or the total sample
n	number of participants with the specified characteristic
N/A	not applicable
NAAT	nucleic acid amplification test
N-binding	nucleoprotein-binding
NT50	50% neutralizing titer
P2 S	SARS-CoV-2 full-length, P2 mutant, prefusion spike glycoprotein
PACL	protocol amendment change letter
PD	protocol deviation
PT	preferred term
QTL	quality tolerance limit
RCDC	reverse cumulative distribution curve
RNA	ribonucleic acid
RT-PCR	reverse transcription polymerase chain reaction
S	spike protein
SAE	serious adverse event
SAP	statistical analysis plan
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
SD	standard deviation
SOC	system organ class
TME	targeted medical event
UK	United Kingdom
US	United States
VE	vaccine efficacy
WHO	World Health Organization

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ETHICS

Independent Ethics Committee and/or Institutional Review Board

The protocol, protocol amendments, ICF, Investigator Brochure, and other relevant documents (eg, advertisements) were submitted to an IRB/IEC by the investigator and reviewed and approved by the IRB/IEC before the study was initiated. The IRBs/IECs are listed in Appendix 16.1.3.1.

Any amendments to the protocol required IRB/IEC approval before implementation of changes made to the study design, except for changes necessary to eliminate an immediate hazard to study participants.

Ethical Conduct of the Study

This study was conducted in accordance with the protocol and consensus ethical principles derived from international guidelines including the Declaration of Helsinki Council and CIOMS International Ethical Guidelines, applicable ICH GCP Guidelines, and other applicable laws and regulations, including privacy laws.

Participant Information and Consent

In this clinical study report, the terms “participant” and “subject” are used interchangeably.

The investigator or his/her representative explained the nature of the study to the participant or his/her legally authorized representative and answered all questions regarding the study.

Participants or their legally authorized representative were informed that their participation was voluntary. Participants or their legally authorized representative signed a statement of informed consent that met the requirements of 21 CFR 50, local regulations, ICH guidelines, HIPAA requirements, where applicable, and the IRB/IEC or study center.

Investigative sites were instructed to obtain written informed consent before the participant was enrolled in the study and document the date the written consent was obtained. The authorized person obtaining the informed consent was also instructed to sign the ICF. Participants were reconsented to the most current version of the ICF(s) during their participation in the study.

A copy of the ICF(s) was provided to the participant or the participant’s legally authorized representative.

1. INTRODUCTION

The global spread of the outbreak of COVID-19, caused by the SARS-CoV-2 virus, originating in Wuhan, China was characterized by the WHO as a pandemic in March 2020 [1]. Pfizer and BioNTech have developed an RNA-based SARS-CoV-2 vaccine, BNT162b2, that was investigated for the prevention of COVID-19 in individuals ≥6 months of age. A 2-dose series of BNT162b2 (given 21 days apart) has been granted a conditional marketing authorization, EUA, or temporary authorization in a total of more than 100

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countries,[2],[3],[4] and has been fully licensed for use in individuals 12 years of age and above in the US.

Pregnant women are at risk for acquiring SARS-CoV-2 infection and COVID-19 [5],[6],[7]. Pregnancy may confer increased risk of severe COVID-19 because of physiological changes during pregnancy that can increase susceptibility to respiratory infections and subsequent rapid progression to respiratory failure [8]. Additionally, pregnant women with COVID-19 have been reported to have higher rates of preterm birth, cesarean delivery, foetal distress, and infants requiring neonatal intensive care [8],[9],[10],[11]. Prevention of SARS-CoV-2 infection and COVID-19 is critically important in pregnant women.

The Phase 2/3 Study C4591015 was designed to assess the safety of BNT162b2 in pregnant women and their infants, and also the immunogenicity of BNT162b2 in pregnant women, the transfer of antibody to their infants, and the kinetics of antibody transfer in the infant. The analyses included in this report are for the ~350 maternal participants and their infants enrolled before early study termination (25 October 2021) due to enrollment challenges (see Section 3.1.1).

2. STUDY OBJECTIVES, ESTIMANDS, AND ENDPOINTS

Objectives, estimands, and endpoints for maternal participants and infants born to maternal participants are listed in Table 1 below:

Table 1. Objectives, Estimands, and Endpoints

Objectives[a]	Estimands	Endpoints
Primary Safety	**Primary Safety**	**Primary Safety**
To describe the safety and tolerability of prophylactic BNT162b2 when administered to maternal participants 18 years of age or older vaccinated at 24 to 34 weeks' gestation.	In maternal participants receiving at least 1 dose of study intervention from each vaccine group, the percentage of maternal participants reporting: • Local reactions for up to 7 days following each dose • Systemic events for up to 7 days following each dose • AEs from Dose 1 through 1 month after Dose 2 • SAEs from Dose 1 through 1 month after delivery	• Prompted local reactions (redness, swelling, and pain at the injection site) • Prompted systemic events (fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain) • AEs • SAEs

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Table 1. Objectives, Estimands, and Endpoints

Objectives[a]	Estimands	Endpoints
Primary Immunogenicity	**Primary Immunogenicity**	**Primary Immunogenicity**
To describe the immune response to prophylactic BNT162b2 in maternal participants 18 years of age or older vaccinated at 24 to 34 weeks' gestation and reference to the immune response in nonpregnant women 18 years of age or older from the C4591001 study without evidence of past SARS-CoV-2 infection.	In female participants complying with the key protocol criteria (evaluable participants) and no serological or virological evidence (up to 1 month after receipt of the second dose) of past SARS-CoV-2 infection: • GMR, estimated by the ratio of the geometric mean of SARS-CoV-2 neutralizing titers in pregnant women to those in nonpregnant women 1 month after Dose 2	• SARS-CoV-2 neutralizing titers
To describe the immune response to prophylactic BNT162b2 in maternal participants 18 years of age or older vaccinated at 24 to 34 weeks' gestation and reference to the immune response in nonpregnant women 18 years of age or older from the C4591001 study with and without evidence of prior SARS-CoV-2 infection.	In female participants complying with the key protocol criteria (evaluable participants): • GMR, estimated by the ratio of the geometric mean of SARS-CoV-2 neutralizing titers in pregnant women to those in nonpregnant female participants 1 month after Dose 2	• SARS-CoV-2 neutralizing titers
Secondary	**Secondary**	**Secondary**
To describe the efficacy of prophylactic BNT162b2 against confirmed COVID-19 occurring from 7 days after Dose 2 through 1 month after delivery in maternal participants 18 years of age or older vaccinated at 24 to 34 weeks' gestation without evidence of prior SARS-CoV-2 infection.	In maternal participants complying with the key protocol criteria (evaluable participants) and no serological or virological evidence (prior to 7 days after receipt of Dose 2) of past SARS-CoV-2 infection: • 100 × (1 – IRR) [ratio of active vaccine to placebo]	• COVID-19 incidence per 1000 person-years of blinded follow-up based on central laboratory or locally confirmed NAAT
To describe the efficacy of prophylactic BNT162b2 against confirmed COVID-19 occurring from 7 days after Dose 2 through 1 month after delivery in maternal participants 18 years of age or older vaccinated at 24 to 34 weeks' gestation with and without evidence of prior SARS-CoV-2 infection.	In maternal participants complying with the key protocol criteria (evaluable participants): • 100 × (1 – IRR) [ratio of active vaccine to placebo]	• COVID-19 incidence per 1000 person-years of blinded follow-up based on central laboratory or locally confirmed NAAT

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Table 1. Objectives, Estimands, and Endpoints

Objectives[a]	Estimands	Endpoints
To describe the efficacy of prophylactic BNT162b2 against asymptomatic SARS-CoV-2 infection through 1 month after delivery in maternal participants 18 years of age or older vaccinated at 24 to 34 weeks' gestation without evidence of prior SARS-CoV-2 infection.	In evaluable maternal participants without serological or virological evidence of prior SARS-CoV-2 infection: • 100 × (1 – IRR) [ratio of active vaccine to placebo]	• Incidence of asymptomatic infection of SARS-CoV-2 based on N-binding antibody seroconversion
To describe the immune response over time and persistence of prophylactic BNT162b2 when administered to maternal participants 18 years of age or older vaccinated at 24 to 34 weeks' gestation.	In maternal participants complying with the key protocol criteria (evaluable maternal participants) from each vaccine group: • GMCs/GMTs, at baseline (before Dose 1), 2 weeks after Dose 2, 1 month after Dose 2, at delivery, and 6 months after delivery • GMFRs from baseline through 2 weeks after Dose 2, 1 month after Dose 2, at delivery, and 6 months after delivery	• Full-length S-binding IgG levels • SARS-CoV-2 neutralizing titers
To assess the safety of maternal immunization in infants born to maternal participants 18 years of age or older who were vaccinated with BNT162b2 during pregnancy.	In infants born to maternal participants receiving at least 1 dose of study intervention from each vaccine group, the percentage of infants with: • Specific birth outcomes • AEs from birth through 1 month of age • SAEs and AESIs (major congenital anomalies, developmental delay) through 6 months of age	• Specific birth outcomes • AEs from birth through 1 month of age • SAEs and AESIs (major congenital anomalies, developmental delay) through 6 months of age
To describe the immune response in infants born to maternal participants vaccinated with prophylactic BNT162b2 during pregnancy.	In infants born to evaluable maternal participants from each vaccine group: • GMCs and GMFRs, at birth and 6 months after delivery	• Full-length S-binding IgG levels

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Table 1. Objectives, Estimands, and Endpoints

Objectives[a]	Estimands	Endpoints
Exploratory	**Exploratory**	**Exploratory**
To describe the incidence of confirmed COVID-19 among maternal participants who were vaccinated with BNT162b2.	In maternal participants who received BNT162b2 at initial randomization: • Incidence per 1000 person-years of follow-up	COVID-19 incidence per 1000 person-years of follow-up based on central laboratory or locally confirmed NAAT
To describe the incidence of asymptomatic SARS-CoV-2 infection through 6 months after delivery in maternal participants 18 years of age or older vaccinated at 24 to 34 weeks' gestation with BNT162b2 at initial randomization and without evidence of prior SARS-CoV-2 infection.	In maternal participants who received BNT162b2 at initial randomization and without evidence of prior SARS-CoV-2 infection: • Incidence per 1000 person-years of follow-up	Incidence of asymptomatic SARS-CoV-2 infection per 1000 person-years of follow-up based on N-binding antibody seroconversion
To describe the serological responses among maternal participants to the BNT162b2 vaccine candidate in cases of: • Confirmed COVID-19 • Confirmed severe COVID-19 • SARS-CoV-2 infection without confirmed COVID-19	In each subset of evaluable maternal participants from each vaccine group with: • Confirmed COVID-19 • Confirmed severe COVID-19 • SARS-CoV-2 infection but no confirmed COVID-19 • GMCs/GMTs and GMFRs at baseline, 1 month after Dose 2, at delivery, and 6 months after delivery	• Full-length S-binding IgG levels • SARS-CoV-2 neutralizing titers
To describe the immune response to prophylactic BNT162b2 between Dose 1 and Dose 2 when administered to maternal participants 18 years of age or older vaccinated at 27 to 34 weeks' gestation in the Phase 2 portion of the study.	In evaluable maternal participants: • GMCs/GMTs at baseline and before Dose 2 • GMFRs from baseline to before Dose 2	• Full-length S-binding IgG levels • SARS-CoV-2 neutralizing titers
To describe the immune response in infants born to breastfeeding maternal participants vaccinated with prophylactic BNT162b2 during pregnancy.	In infants born to maternal participants from each vaccine group, based on the breastfeeding status: • GMCs and GMFRs, at birth and 6 months after delivery	• Full-length S-binding IgG levels

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Table 1. Objectives, Estimands, and Endpoints

Objectives[a]	Estimands	Endpoints
To describe the safety of maternal immunization in infants born to breastfeeding maternal participants vaccinated with prophylactic BNT162b2 during pregnancy.	In infants born to maternal participants receiving at least 1 dose of study intervention from each vaccine group, based on the breastfeeding status, the percentage of infants with: • AEs from birth through 1 month of age • SAEs and AESIs (major congenital anomalies, developmental delay) through 6 months of age	• AEs from birth through 1 month of age • SAEs and AESIs (major congenital anomalies, developmental delay) through 6 months of age
To describe the incidence of confirmed COVID-19 in infants born to maternal participants who were vaccinated with BNT162b2 during pregnancy.	In infants born to maternal participants from each vaccine group: • Incidence rate of infant participants with confirmed COVID-19	• COVID-19 incidence per 1000 person-years of follow-up based on central laboratory or locally confirmed NAAT
To describe MIS-C cases in infants born to maternal participants who were vaccinated with BNT162b2 during pregnancy.	In infants born to maternal participants from each vaccine group: • Incidence rate of MIS-C	• MIS-C incidence per 1000 person-years of follow-up

Source: Appendix 16.1.1, Protocol Section 3

a. HIV-infected participants will not be included in analyses of the objectives, but in separate exploratory analyses. Analyses among HIV-infected women and their infants will be summarized separately.

For additional information on estimands, refer to Appendix 16.1.1, Protocol Section 9.1.1, and Appendix 16.1.9, SAP Section 6.

3. INVESTIGATIONAL PLAN

3.1. Overview of Study Design

This was a global Phase 2/3, randomized, placebo-controlled, observer-blind study to evaluate the safety, tolerability, and immunogenicity of 30 µg of BNT162b2 or placebo administered in 2 doses, 21 days apart, in approximately 350 healthy pregnant women 18 years of age or older vaccinated at 24 to 34 weeks' gestation. Participants were randomized 1:1 to receive BNT162b2 or placebo (saline).

The Phase 2 portion of the study included approximately 200 pregnant women enrolled at 27 to 34 weeks' gestation. The IRC reviewed safety data through 7 days after the second dose for all Phase 2 participants.

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The Phase 3 portion of this study included approximately 150 pregnant women enrolled at 24 to 34 weeks' gestation. Phase 3 proceeded after the first 200 maternal participants had been enrolled in Phase 2.

Maternal participants who originally received placebo could receive BNT162b2 at the 1-month post delivery visit.

3.1.1. Discussion of Study Design

Enrollment in this study was terminated on 25 October 2021 with approximately 350 participants enrolled, due to enrollment challenges into a placebo-controlled study as a result of universal recommendations for COVID-19 vaccination of pregnant women and the increased global availability of COVID-19 vaccines. Participant enrollment numbers were modified accordingly (~200 in Phase 2, and ~150 in Phase 3).

It was planned that each maternal participant would participate in the study for up to approximately 10 months, depending on the vaccine group to which she was randomized. Her infant would participate in the study for approximately 6 months. The planned study duration was approximately 14 months.

This study used stopping rules. An IRC and an external DMC monitored safety in this study (see Appendix 16.1.1, Protocol Section 8.2.3).

The BNT162b2 dose of 30 µg in this study is the same as that for Study C4591001 Phase 2/3 evaluation of safety, immunogenicity, and efficacy. A placebo was used as the control.

Additional details regarding features of the study design, including chosen control group(s), dose(s), and endpoint(s), are discussed in the Scientific Rationale for Study Design section of the protocol (Appendix 16.1.1, Protocol Section 4.2).

3.1.2. Changes in Study Conduct

All changes in the conduct of the study were implemented by protocol amendments, and are described in Appendix 16.1.1, Protocol Amendment Summary of Changes Table. All PACLs issued were incorporated into the subsequent protocol amendment.

3.2. Investigators and Study Administrative Structure

The study was managed by Pfizer Inc. (the sponsor agent) and BioNTech (the sponsor) and conducted by investigators contracted by and under the direction of Pfizer. The investigators were responsible for adhering to the study procedures described in the protocol, for keeping records of study intervention, and for accurately completing and signing the CRFs/DCTs supplied by the sponsor agent. A list of investigators and sites (including participants by country), and service providers involved in this study is available in Appendix 16.1.4.

No sites were terminated from the study.

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3.3. Selection of Study Population

3.3.1. Inclusion/Exclusion Criteria

Enrolled in this study were participants who were healthy pregnant women ≥18 years of age and their infants, once born. Enrollment was monitored to help ensure distribution of vaccination across the gestational age ranges of 27 0/7 to 34 0/7 weeks for Phase 2 and ≥24 0/7 and ≤34 0/7 weeks for Phase 3. Detailed inclusion and exclusion criteria are provided in Appendix 16.1.1, Protocol Section 5.

3.3.2. Removal of Participants From Intervention or Study

The specific criteria and procedures for early discontinuation from study intervention(s) or withdrawal from the study are described in Appendix 16.1.1, Protocol Section 7.

3.4. Study Intervention

3.4.1. Study Interventions Administered

Study C4591015 evaluated 2 doses of BNT162b2 30 µg or placebo administered 21 days apart (Visits 1 and 2). At 1 month after delivery, maternal participants who originally received placebo could receive 1 dose of BNT162b2 at Visits 101 and 102. Details of the study interventions, administered intramuscularly, are provided below:

- BNT162b2 (BNT162 RNA-LNP vaccine utilizing modRNA and encoding the P2 S): 30 µg
- Normal saline (0.9% sodium chloride solution for injection)

The manufacturing lot numbers for the study interventions dispensed in this study are provided in Table 2. Appendix 16.1.6 provides a listing of participants receiving study interventions from specific batches, where more than one batch was used. The justification for the dose(s) selected is described in Appendix 16.1.1, Protocol Section 4.3.

Table 2. Study Intervention Lot Numbers

Study Intervention	Manufacturer	Vendor Lot Number (Manufacturer)	Lot Number[a] (Pfizer)
BNT162b2	BioNTech	ER5832 EE3813	PA2094601/P222676-0003L NC2075485/P222676-0001L
Diluent (normal saline, 0.9% sodium chloride solution)	Pfizer	EE4253 DK2074 EX2624	PA2091593/P222676-0005L 20-002221 21-AE-00230
Placebo (normal saline, 0.9% sodium chloride solution)	Pfizer	EE4253 DK2074;20-002221	PA2091593/P222676-0004L PA2069407/P222676-0002L

a. Lot number assigned to the study intervention by Pfizer Global Clinical Supply.
Protocol C4591015 Study Intervention Lot Numbers Table –Final, Version 1.0, 08Mar2024.

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3.4.2. Measures to Minimize Bias

Allocation

All participants were centrally assigned to randomized study intervention using an IRT system. The method used to assign/allocate participants is further described in Appendix 16.1.1, Protocol Section 6.3.1.

Blinding

The study was observer-blinded, as the physical appearance of the investigational vaccine and the placebo may differ. The participant, investigator, study coordinator, and other site staff were blinded through the 1-month postdelivery visit for each maternal participant, at which point maternal participants who originally received placebo could receive BNT162b2 (Section 3.1). At the study site, only the dispenser(s)/administrator(s) were unblinded.

Further detail is provided in Appendix 16.1.1, Protocol Sections 6.3.2 to 6.3.5.

3.4.3. Study Intervention Compliance

Participants vaccinated at the site received study intervention directly from the investigator or designee, under medical supervision.

Refer to Appendix 16.1.1, Protocol Section 6.4 for details of compliance with study intervention.

3.4.4. Prior, Concomitant, and Post-Intervention Therapy

Refer to Appendix 16.1.1, Protocol Section 6.5 for details on prohibited and permitted concomitant vaccines and medications.

3.5. Study Assessments and Procedures

3.5.1. Planned Measurements and Timing of Assessments

The specific immunogenicity, efficacy, and safety assessments and the schedule and measurement/collection methods are provided in the protocol Schedule of Activities (Appendix 16.1.1, Protocol Section 1.3) and described in the protocol (Appendix 16.1.1, Protocol Sections 8.1 and 8.2).

Immunogenicity

The below assays were performed for immunogenicity analyses, which were all based on samples analyzed at the central laboratory.

- SARS-CoV-2 neutralization assay;
- Full-length S-binding IgG levels;
- N-binding antibody assay.

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Efficacy

Efficacy was assessed throughout a maternal and infant participant's involvement in the study through surveillance for potential cases of COVID-19. If, at any time, a maternal or infant participant developed acute respiratory illness, for the purposes of the study he or she was considered to potentially have COVID-19 illness. The assessments included a nasal (midturbinate) swab, which was tested at a central laboratory using an approved and validated RT-PCR test, or other equivalent nucleic acid amplification–based test (ie, NAAT) to detect SARS-CoV-2. In addition, clinical information and results from local standard-of-care tests were assessed. The central laboratory NAAT result was used for the case definition, unless no result was available from the central laboratory, in which case a local NAAT result could be used. Refer to Appendix 16.1.1, Protocol Section 8.1 for further details, including definitions (per FDA and CDC) for SARS-CoV-2-related cases, SARS-CoV-2-related severe cases, and MIS-C, and which assays must be used for results from local laboratories.

Safety

The collection and assessment of safety information during the study (evaluation, definitions, recording, and reporting of AEs, SAEs, AESIs and other reportable safety events) is detailed in Appendix 16.1.1, Protocol Sections 8.2 and 8.3.

Potential COVID-19/MIS-C illnesses and their sequelae that were consistent with the clinical endpoint definition were **not** recorded as AEs. These data were captured as efficacy assessment data only on the relevant pages of the CRF, as these were expected endpoints (Appendix 16.1.1, Protocol Section 8.3.7).

The following events were protocol-specified AESIs (Appendix 16.1.1, Protocol Section 8.3.8):

- A confirmed diagnosis of myocarditis or pericarditis.
- Major congenital anomaly (for infant participants)
- Developmental delay (for infant participants)

Additionally, the study utilized a list of targeted MedDRA terms (known as targeted medical events) that are highlighted during routine review of clinical safety data. The list is dynamic and the terms are chosen based on vaccine pharmacology, toxicology, possible class effects, information from published literature, and potential signals arising from safety data assessments. Terms may also be included due to their known association with COVID 19 infection.

3.5.2. Appropriateness of Measures

The estimands and endpoints used in this study (eg, immunogenicity, efficacy, and safety) were consistent with those for prior BNT162b2 studies (C4591001, C4591007, and

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C4591031), considered to be reliable, and relevant to the objectives set forth in the protocol (Appendix 16.1.1, Protocol Section 3).

3.6. Data Quality Assurance

The sections below summarize the steps taken to ensure quality of the data included in this CSR with an LPLV of 15 July 2022.

3.6.1. Study Monitoring

Study centers were monitored by [redacted] Centers were visited at regular intervals and a visit log was maintained. Monitors were responsible for reviewing adherence to the protocol; compliance with GCP; and the completeness, accuracy, and consistency of the data. Direct access to participant medical and laboratory records was permitted to verify entries on the study-specific CRFs.

3.6.2. Investigator Meetings and Staff Training

Investigator staff training was provided by Pfizer and [redacted] during the investigator meeting, site initiation visit, and routine monitoring visits. Pfizer organized investigator and clinical research associate meetings before study start and during the study to provide information on the study intervention, the study rationale and design, responsibilities under ICH/FDA/GCP, and training on the detailed study requirements.

3.6.3. Laboratory Procedures

A central laboratory was used to analyze the samples (eg, nasal swab to test for COVID-19, serum sample for immunogenicity testing) (Appendix 16.1.10). Local laboratories could be used only if testing was performed using the assays specified in Appendix 16.1.1, Protocol Section 8.1. All immunogenicity analyses were based upon samples analyzed at the central laboratory. A list of laboratories that performed the assays included in the analyses is included in Appendix 16.1.10.

3.6.4. Investigator Responsibilities

The investigators were responsible for all data entered in the CRFs and documented their review and approval of the data, verifying the validity and completeness of the data. The investigator was responsible for appropriate retention of essential study documents.

3.6.5. Clinical Data Management

Case report form data were captured via data entry by study center personnel in a sponsor agent database system. Data quality checks were applied using manual and electronic verification methods. An audit trail was maintained to support data query resolution and any modification to the data.

3.6.6. Clinical Quality Assurance Audits

Audits of this study were included as part of the independent sponsor agent quality assessment performed by Pfizer's own independent quality assurance group or by a CRO

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and/or individual contract personnel under the group's direction. The audit certificates for this study are provided in Appendix 16.1.8.

3.6.7. Quality Tolerance Limits

The quality management approach used in this study identified risks significant to human participant protection or reliability of trial results. The quality risk management plan used in this study documents risks and controls that are in place throughout the life of the study. In this study, QTLs were defined during the quality risk management planning.

During the trial, the QTLs were routinely assessed, and no important deviations were observed.

3.7. Statistical Analysis

3.7.1. Statistical Analysis Plan

The planned analyses, analysis populations, and determination of sample size are described in the protocol (Appendix 16.1.1, Protocol Section 9) and SAP (Appendix 16.1.9).

General Considerations

The safety analyses were based on the safety populations. Participants were summarized by vaccine group according to the study intervention they (or their mothers) actually received.

All of the immunogenicity analyses were based on the evaluable immunogenicity populations. An additional analysis was performed based on the all-available immunogenicity populations as there was over 10% difference in sample size between the all-available immunogenicity populations and the evaluable immunogenicity populations. Participants were summarized according to the vaccine group to which they (or their mothers) were randomized.

The efficacy analyses were based on the evaluable efficacy populations. In addition, VE was also analyzed by the all-available efficacy (mITT) populations.

Refer to Appendix 16.1.9, SAP Section 4 for the descriptions for each analysis population.

Due to early enrollment termination and reduced sample size, all endpoints were analyzed descriptively without formal hypothesis tests. Refer to Appendix 16.1.9, SAP Section 5.2 for analyses of binary and continuous data.

Subgroup analyses based on race and ethnicity were performed on all primary safety and immunogenicity endpoints (as supplemental analyses).

Analyses among HIV-positive women and their infants were provided separately, as these were considered special populations for this study.

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Immunogenicity

For the primary immunogenicity objective, the GMR at 1 month after Dose 2 was calculated as the difference in means of logarithmically transformed assay results (SARS-CoV-2 neutralizing titers in pregnant women minus those in nonpregnant women) and exponentiating the difference. Two-sided CIs were obtained by calculating CIs using Student t distribution for the difference of the means of the logarithmically transformed assay results and exponentiating the confidence limits. The primary immunogenicity analysis included participants without evidence of prior SARS-CoV-2 infection and with and without evidence of prior SARS-CoV-2 infection. The nonpregnant participants were randomly selected from Study C4591001 female participants based on 1:1 age matching to the maternal participants within each vaccine group.

Analyses for additional immunogenicity endpoints (geometric means, GMFRs, RCDCs) are defined in Appendix 16.1.9, SAP Section 5.2.2.

Efficacy

VE calculations for secondary efficacy endpoints are provided in Appendix 16.1.9, SAP Section 6.2.1.

Safety

Descriptive statistics were provided for each reactogenicity endpoint by vaccine group, including counts and percentages of participants with the indicated endpoint and the associated Clopper-Pearson 95% CIs.

A 3-tier approach was used to summarize AEs (Appendix 16.1.9, SAP Section 5). AEs with a reported frequency ≥1% in at least 1 vaccine group were classified as Tier 2. For Tier 2 events, the 95% CI for the between-group difference in proportions were calculated based on the Miettinen and Nurminen method. Tier 1 events are prespecified events of clinical importance and are identified in a list in the product's safety review plan. No Tier 1 events have been identified to date for BNT162b2. Tier 3 events were defined as events that were neither Tier 1 nor Tier 2.

3.7.2. Changes in Planned Analyses Prior to Unblinding or Database Lock

All changes in the planned analyses for the study were implemented by SAP or protocol amendments, as described in Appendix 16.1.9 and Appendix 16.1.1, respectively.

3.7.3. Changes Following Study Unblinding/Database Lock and Post Hoc Analyses

After unblinding, it was observed that the baseline SARS-COV-2 infection rate was much higher in maternal participants as compared to nonpregnant female participants randomly selected from Study C4591001, leading to a confounding effect on the comparison of immune response to the study vaccine between these two cohorts. To address this, a post hoc analysis was conducted after database lock to calculate the adjusted GMR for SARS-CoV-2 neutralizing titers in maternal participants (Study C4591015) to those in nonpregnant female

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participants (Study C4591001) with or without evidence of prior infection based on a linear regression model that adjusted for age and baseline neutralizing titer levels.

An analysis comparing proportions of AESIs reported in infants (born to C4591015 maternal participants) between the two maternal vaccine groups (BNT162b2 vs. placebo) from birth to 6 months of age was also conducted post hoc.

Exploratory analyses of the serological response at baseline, 1 month after Dose 2, delivery, and 6 months after delivery were planned for maternal participants with confirmed COVID-19, confirmed severe COVID-19, or SARS-CoV-2 infection, based on both protocol and CDC definitions (provided in Appendix 16.1.1, Protocol Section 8.1.1); however, since there were no maternal participants who reported severe COVID-19 and a limited number of confirmed COVID-19 cases, these analyses were not conducted as the sample sizes would have been too small for any meaningful interpretation. A listing of immunogenicity assay data for participants with confirmed COVID-19 or SARS-CoV-2 infection has been provided in Appendix 16.2.6.1.1.

4. STUDY PARTICIPANTS

This study was conducted at 41 sites in Brazil (3), South Africa (5), Spain (6), the UK (6), and the US (21) (Appendix 16.1.4.1).

4.1. Disposition of Participants

4.1.1. Maternal Participants

A total of 174 maternal participants were randomized to receive 2 doses of BNT162b2 30 µg and 174 were randomized to receive 2 doses of placebo (Table 3). In total, 97.7% of maternal participants received both doses and 92.0% completed the 1-month postdelivery visit. Across groups, 5.5% of participants were withdrawn from the study; the most frequent reason was withdrawal by the participant.

Per protocol, participants originally randomized to placebo could receive BNT162b2 after being unblinded at the 1-month postdelivery visit (Section 3.1; Section 3.4.2). Among these participants, 152 (93.8%) received a first dose of BNT162b2 and 148 (91.4%) received a second dose of BNT162b2. Of these, 4 participants were withdrawn after the first dose of BNT162b2 and 1 after the second dose of BNT162b2.

Table 3. Disposition of All Randomized Participants – Maternal – Prior to Unblinding

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=174) n[b] (%)	Placebo (N[a]=174) n[b] (%)	Total (N[a]=348) n[b] (%)

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Table 3. Disposition of All Randomized Participants – Maternal – Prior to Unblinding

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=174) n[b] (%)	Placebo (N[a]=174) n[b] (%)	Total (N[a]=348) n[b] (%)
Randomized	174 (100.0)	174 (100.0)	348 (100.0)
Not vaccinated	1 (0.6)	1 (0.6)	2 (0.6)
Vaccinated			
Dose 1	173 (99.4)	173 (99.4)	346 (99.4)
Dose 2	170 (97.7)	170 (97.7)	340 (97.7)
Completed 1-month postdelivery visit	161 (92.5)	159 (91.4)	320 (92.0)
Withdrawn from the study	7 (4.0)	12 (6.9)	19 (5.5)
Withdrawn before Dose 1	1 (0.6)	1 (0.6)	2 (0.6)
Withdrawn after Dose 1 and before Dose 2	2 (1.1)	2 (1.1)	4 (1.1)
Withdrawn after Dose 2	4 (2.3)	9 (5.2)	13 (3.7)
Reason for withdrawal			
Withdrawal by subject	4 (2.3)	9 (5.2)	13 (3.7)
Protocol deviation	2 (1.1)	2 (1.1)	4 (1.1)
Lost to follow-up	1 (0.6)	1 (0.6)	2 (0.6)

Note: Human immunodeficiency virus (HIV)-positive participants are included in this summary but analyzed and reported separately.
a. N = number of randomized participants in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (09:53) Source Data: adds Table Generation: 12MAY2023 (12:05) Output File: ./nda3/C4591015_BR/adds_s002_all_p3_rand

Additional data for maternal participants are presented in the following:

Disposition of All Randomized Participants – Maternal – After Unblinding	Supplemental Table 14.1
Listing of Participants Discontinued From Vaccination and/or From the Study (Maternal)	Appendix 16.2.1.1

4.1.2. Infant Participants

A total of 167 infants were born to maternal participants in the BNT162b2 group and 168 were born to maternal participants in the placebo group. Most (86.9%) infant participants completed the 6-months-of-age follow-up visit (Table 4). Withdrawal from the study was more frequently reported among infants whose mothers were randomized to placebo (17.3%) than those whose mothers were randomized to BNT162b2 (9.0%); the most frequent reasons for withdrawal during the study was withdrawal by parent/guardian and lost to follow-up. Two infant participants (1 in the BNT162b2 and 1 in the placebo group) died during the

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study due to SAEs that were assessed as unrelated to study vaccination (Section 5.3.3.2.2), and were subsequently withdrawn from the study; narrative summaries of these events are provided in Section 14.

Table 4. Disposition of All Randomized Participants – Infant

	Maternal Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=167) n[b] (%)	Placebo (N[a]=168) n[b] (%)	Total (N[a]=335) n[b] (%)
Randomized[c]	167 (100.0)	168 (100.0)	335 (100.0)
Completed 6-months-of-age follow-up visit	152 (91.0)	139 (82.7)	291 (86.9)
Withdrawn from the study	15 (9.0)	29 (17.3)	44 (13.1)
Withdrawn before 1-week-of-age visit	3 (1.8)	4 (2.4)	7 (2.1)
Withdrawn after 1-week-of-age visit and before 6-months-of-age follow-up visit	12 (7.2)	25 (14.9)	37 (11.0)
Reason for withdrawal			
Withdrawal by parent/guardian	9 (5.4)	17 (10.1)	26 (7.8)
Lost to follow-up	4 (2.4)	10 (6.0)	14 (4.2)
Death	1 (0.6)	1 (0.6)	2 (0.6)
Other	1 (0.6)	1 (0.6)	2 (0.6)

a. N = number of randomized participants in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic.
c. Infants were not randomized and vaccinated but are summarized according to their mother's randomization group.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (09:53) Source Data: adds Table Generation: 12MAY2023 (12:16) Output File: ./nda3/C4591015_BR/adds_s002_all_p3_rand_inf

Additional data for infant participants are presented in the following:

Listing of Participants Discontinued From From the Study (Infant) Appendix 16.2.1.2

4.2. Important Protocol Deviations

Important PDs are those that may significantly impact the completeness, accuracy, and/or reliability of the study data or that may significantly affect a participant's rights, safety, or well-being.

4.2.1. Maternal Participants

Overall, important PDs were balanced among maternal participants in both the BNT162b2 and placebo groups. Important PDs in maternal participants were most frequently reported in

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the category of inclusion/exclusion criteria, with 7 participants in the BNT162b2 group and 4 participants in the placebo group (Appendix 16.2.2.1).

4.2.2. Infant Participants

One PD in the concomitant medications category was reported among infant participants in the placebo group, where the participant was reported to have received blood/plasma products or immunoglobulins within 60 days before enrollment through conclusion of the study. No PDs were reported among infants born to maternal participants in the BNT162b2 group (Appendix 16.2.2.2).

4.3. Populations Analyzed

4.3.1. Maternal Participants

4.3.1.1. Safety Population

The safety population for maternal participants included 173 participants in the BNT162b2 group and 173 participants in the placebo group; 2 maternal participants were excluded from the safety population because they did not receive the study intervention. Most maternal participants included in the safety population were breastfeeding, and 12 in the BNT162b2 group and 10 in the placebo group were HIV-positive (Table 5 and Appendix 16.2.3.2.1).

Table 5. Safety Population (Maternal)

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) n[a]	Placebo n[a]	Total n[a] (%)
Randomized[b]			348 (100.0)
Vaccinated	173	173	346 (99.4)
Safety population	173	173	346 (99.4)
Breastfeeding	147	152	299 (85.9)
HIV-positive	12	10	22 (6.3)
Participants excluded from safety population			2 (0.6)
Reason for exclusion			
Did not receive study intervention			2 (0.6)

Note: Human immunodeficiency virus (HIV)-positive participants are included in this summary but not included in the analyses of the overall study objectives.
a. n = Number of participants with the specified characteristic, or the total sample.
b. This value is the denominator for the percentage calculations.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (09:47) Source Data: adsl Table Generation: 03MAY2023 (10:30) Output File: ./nda3/C4591015_BR/adsl_s003_saf_pop_p2

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4.3.1.2. Immunogenicity Populations

Table 6 presents the immunogenicity populations for C4591015 maternal participants and C4591001 nonpregnant female participants included in the immunogenicity analyses (Section 3.7.1).

The evaluable immunogenicity population for Study C4591015 maternal participants included 111 participants in the BNT162b2 group and 115 participants in the placebo group, and for Study C4591001 nonpregnant females included 114 participants in the BNT162b2 group and 124 participants in the placebo group. Exclusions from the evaluable immunogenicity population were balanced across BNT162b2 and placebo groups among C4591015 participants and among C4591001 participants; the most common reason for exclusion for C4591015 participants was due to a lack of at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.

The evaluable immunogenicity population without evidence of SARS-CoV-2 infection prior to 1 month after Dose 2 for Study C4591015 maternal participants included 59 participants (33.9%) in the BNT162b2 group and 58 participants (33.3%) in the placebo group (Table 6); for Study C4591001 nonpregnant females included 107 participants (87.0%) in the BNT162b2 group and 113 participants (85.0%) in the placebo group. Of note, the proportions of participants without evidence of prior infection for the C4591015 and C4591001 study participants reflect varying conditions of the COVID-19 pandemic, as the studies were conducted in different times and countries.

Table 6. Immunogenicity Populations – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001) – All Randomized Participants

	Vaccine Group (as Randomized)			
	BNT162b2 (30 µg)		Placebo	
	C4591015 (Maternal)	C4591001 (Nonpregnant Women)	C4591015 (Maternal)	C4591001 (Nonpregnant Women)
	n[a] (%)	n[a] (%)	n[a] (%)	n[a] (%)
Randomized[b]	174 (100.0)	123 (100.0)	174 (100.0)	133 (100.0)
All-available immunogenicity population	171 (98.3)	120 (97.6)	170 (97.7)	129 (97.0)
HIV-positive	12 (6.9)	0	9 (5.2)	0
Participants excluded from all-available immunogenicity population	3 (1.7)	3 (2.4)	4 (2.3)	4 (3.0)
Reason for exclusion				
Did not receive at least 1 dose of the study intervention	1 (0.6)	0	1 (0.6)	0
Did not have at least 1 valid and determinate immunogenicity result after vaccination	2 (1.1)	N/A	3 (1.7)	N/A

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Table 6. Immunogenicity Populations – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001) – All Randomized Participants

	Vaccine Group (as Randomized)			
	BNT162b2 (30 µg)		Placebo	
	C4591015 (Maternal)	C4591001 (Nonpregnant Women)	C4591015 (Maternal)	C4591001 (Nonpregnant Women)
	n[a] (%)	n[a] (%)	n[a] (%)	n[a] (%)
Did not have at least 1 valid and determinate immunogenicity result after Dose 2	N/A	3 (2.4)	N/A	4 (3.0)
Evaluable immunogenicity population	111 (63.8)	114 (92.7)	115 (66.1)	124 (93.2)
HIV-positive	10 (5.7)	0	9 (5.2)	0
Without evidence of infection up to 1 month after Dose 2[c]	59 (33.9)	107 (87.0)	58 (33.3)	113 (85.0)
Participants excluded from evaluable immunogenicity population	63 (36.2)	9 (7.3)	59 (33.9)	9 (6.8)
Reason for exclusion[d]				
Not eligible for the study at randomization	7 (4.0)	0	4 (2.3)	0
Did not receive 2 doses of the vaccine to which they were randomized	4 (2.3)	1 (0.8)	4 (2.3)	4 (3.0)
Did not receive Dose 2 within 19-42 days after Dose 1	3 (1.7)	3 (2.4)	3 (1.7)	1 (0.8)
Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2	59 (33.9)	6 (4.9)	57 (32.8)	8 (6.0)
Had other protocol deviation(s) as determined by the clinician	8 (4.6)	0	5 (2.9)	0

Abbreviation: N/A = not applicable.
Note: Participants from C4591001 are a selected subset of age matched nonpregnant female Phase 3 participants.
Note: Blood samples for immunogenicity assessment drawn at the delivery visit but within 1 month after Dose 2 visit window were also included in this analysis.
a. n = Number of participants with the specified characteristic.
b. These values are the denominators for the percentage calculations.
c. Participants who had no serological or virological evidence (prior to the 1 month after Dose 2 blood sample collection) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Dose 1 and 1 month after Dose 2 and no positive result between visits, negative NAAT [nasal swab] at Dose 1, Dose 2, and any unscheduled visit prior to the 1 month after Dose 2 blood sample collection) were included in the analysis.
d. Participants may have been excluded for more than 1 reason.
PFIZER CONFIDENTIAL Source Data: adsl Table Generation: 01MAR2024 (02:39)
(Data cutoff date : C4591001 [31Aug2021]) Output File: ./nda3/C4591015_Bridging/adva_s008_imm_pop_brdg

Additional data for maternal participants are presented in the following:

Immunogenicity Populations (Maternal) Supplemental Table 14.2

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Listing of Participants Excluded From Immunogenicity Populations - Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001) Appendix 16.2.3.1.3

Listing of Participants Excluded From Immunogenicity Populations (Maternal) Appendix 16.2.3.1.1

4.3.1.3. Efficacy Populations

The proportions of maternal participants included in the efficacy populations were balanced between the BNT162b2 and placebo groups (Table 7). The evaluable efficacy population included 161 participants in the BNT162b2 group and 163 participants in the placebo group. Exclusions from the evaluable efficacy population were similar across groups; the most common reason was due to other protocol deviation(s) as determined by the clinician.

The evaluable efficacy population without evidence of SARS-CoV-2 infection prior to 7 days after Dose 2 included 91 participants in the BNT162b2 group and 94 participants in the placebo group.

Table 7. Efficacy Populations (Maternal)

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) n[a] (%)	Placebo n[a] (%)	Total n[a] (%)
Randomized[b]	174 (100.0)	174 (100.0)	348 (100.0)
Dose 1 all-available efficacy population	173 (99.4)	173 (99.4)	346 (99.4)
HIV-positive	12 (6.9)	10 (5.7)	22 (6.3)
Participants excluded from Dose 1 all-available efficacy population	1 (0.6)	1 (0.6)	2 (0.6)
Reason for exclusion			
Did not receive at least 1 dose of the study intervention	1 (0.6)	1 (0.6)	2 (0.6)
Dose 2 all-available efficacy population	170 (97.7)	170 (97.7)	340 (97.7)
HIV-positive	12 (6.9)	10 (5.7)	22 (6.3)
Participants without evidence of infection prior to 7 days after Dose 2	95 (54.6)	99 (56.9)	194 (55.7)
Participants excluded from Dose 2 all-available efficacy population	4 (2.3)	4 (2.3)	8 (2.3)
Reason for exclusion			
Did not receive 2 doses of the vaccine	4 (2.3)	4 (2.3)	8 (2.3)
Evaluable efficacy population	161 (92.5)	163 (93.7)	324 (93.1)
HIV-positive	12 (6.9)	10 (5.7)	22 (6.3)
Participants without evidence of infection prior to 7 days after Dose 2	91 (52.3)	94 (54.0)	185 (53.2)
Participants excluded from evaluable efficacy population	13 (7.5)	11 (6.3)	24 (6.9)
Reason for exclusion[c]			
Not eligible for the study at randomization	7 (4.0)	4 (2.3)	11 (3.2)

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Table 7. Efficacy Populations (Maternal)

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) n[a] (%)	Placebo n[a] (%)	Total n[a] (%)
Did not receive 2 doses of the vaccine to which they were randomized	4 (2.3)	4 (2.3)	8 (2.3)
Did not receive Dose 2 within 19-42 days after Dose 1	3 (1.7)	3 (1.7)	6 (1.7)
Had other protocol deviation(s) as determined by the clinician	8 (4.6)	5 (2.9)	13 (3.7)

a. n = Number of participants with the specified characteristic, or the total sample.
b. These values are the denominators for the percentage calculations.
c. Participants may have been excluded for more than 1 reason.
PFIZER CONFIDENTIAL SDTM Creation: 03MAY2023 (09:05) Source Data: adsl Table Generation: 10JAN2024 (17:30) Output File: ./nda3/C4591015_EFF/adsl_eff_pop

Additional data for maternal participants are presented in the following:

Listing of Participants Excluded From the Efficacy Populations (Maternal) — Appendix 16.2.3.3.1

4.3.2. Infant Participants

4.3.2.1. Safety Population

The safety population for infant participants included 167 born to mothers in the BNT162b2 group and 168 born to mothers in the placebo group (Table 8). Infants whose mothers were HIV-positive included 11 in the BNT162b2 group and 9 in the placebo group.

Table 8. Safety Population (Infant)

	Maternal Vaccine Group (as Administered)		
	BNT162b2 (30 µg) n[a]	Placebo n[a]	Total n[a] (%)
Maternal participants vaccinated	167	168	335 (100.0)
Safety population	167	168	335 (100.0)
Breastfeeding	147	152	299 (89.3)
HIV-positive maternal participants	11	9	20 (6.0)

Note: Human immunodeficiency virus (HIV)-positive participants are included in this summary but not included in the analyses of the overall study objectives.
a. n = Number of participants with the specified characteristic, or the total sample.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (09:47) Source Data: adsl Table Generation: 03MAY2023 (10:30) Output File: ./nda3/C4591015_BR/adsl_s003_saf_pop_inf_p2

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4.3.2.2. Immunogenicity Populations

The proportions of infant participants included in the immunogenicity populations were balanced between the BNT162b2 and placebo groups. The evaluable immunogenicity population for infant participants included 109 participants in the BNT162b2 group and 105 participants in the placebo group (Table 9).

The proportion of participants excluded from the evaluable immunogenicity population was 34.7% and 37.5% for the BNT162b2 group and the placebo group, respectively. The most frequent reason for exclusion of infant participants from the evaluable immunogenicity populations was because the mother was not considered to be an evaluable immunogenicity maternal participant (see Section 4.3.1.2).

Table 9. Immunogenicity Populations (Infant)

	Maternal Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) n[a] (%)	Placebo n[a] (%)	Total n[a] (%)
Randomized[b]	167 (100.0)	168 (100.0)	335 (100.0)
All-available immunogenicity population (infant)	163 (97.6)	156 (92.9)	319 (95.2)
HIV-positive maternal	11 (6.6)	9 (5.4)	20 (6.0)
Participants excluded from all-available immunogenicity population (infant)	4 (2.4)	12 (7.1)	16 (4.8)
Reason for exclusion[c]			
Were born to maternal participants who were not all-available immunogenicity maternal participants	0	1 (0.6)	1 (0.3)
Did not have at least 1 valid and determinate immunogenicity result	4 (2.4)	12 (7.1)	16 (4.8)
Evaluable immunogenicity population (infant)	109 (65.3)	105 (62.5)	214 (63.9)
HIV-positive maternal	10 (6.0)	9 (5.4)	19 (5.7)
Participants excluded from evaluable immunogenicity population (infant)	58 (34.7)	63 (37.5)	121 (36.1)
Reason for exclusion[c]			
Were born to maternal participants who were not evaluable immunogenicity maternal participants	58 (34.7)	54 (32.1)	112 (33.4)
Did not have at least 1 valid and determinate immunogenicity result	4 (2.4)	12 (7.1)	16 (4.8)
Had other protocol deviation(s) as determined by the clinician	0	1 (0.6)	1 (0.3)

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Table 9. Immunogenicity Populations (Infant)

	Maternal Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) n[a] (%)	Placebo n[a] (%)	Total n[a] (%)

a. n = Number of participants with the specified characteristic, or the total sample.
b. Infants were not randomized and vaccinated but are summarized according to the vaccine group to which their mothers were randomized. These values are the denominators for the percentage calculations .
c. Participants may have been excluded for more than 1 reason.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (08:47) Source Data: adsl Table Generation: 19FEB2024 (04:02)
(Database snapshot date: Safety [29Mar2023], Immunogenicity [09Jan2024]) Output File: ./nda3/C4591015_CSR/adva_s008_imm_pop_inf

Additional data for infant participants are presented in the following:

Listing of Participants Excluded From Immunogenicity Populations (Infant) — Appendix 16.2.3.1.2

4.3.2.3. Efficacy Populations

The proportions of infant participants included in the efficacy populations were balanced between the BNT162b2 and placebo groups. The evaluable efficacy population included 167 participants in the BNT162b2 group and 168 participants in the placebo group.

For infants born to mothers in the BNT162b2 and placebo groups, most (88.0% and 90.5%, respectively) were breastfed and few (6.6% and 5.4%, respectively) were born to mothers who were HIV-positive.

Additional data for infant participants are presented in the following:

Efficacy Populations (Infant) — Supplemental Table 14.3

4.4. Demographic and Other Baseline Characteristics

4.4.1. Maternal Participants

4.4.1.1. Safety Population

Demographic and baseline characteristics for the safety population of maternal participants were well balanced between the BNT162b2 and placebo groups (Table 10). Overall, the majority of participants were White (67.9%), non-Hispanic/non-Latino (61.6%), and located in the US (48.3%) or South Africa (23.7%). A total of 127 (36.7%) participants had a positive baseline SARS-CoV-2 status. The median age of participants at Dose 1 was

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30.0 years, and the median gestational age at Dose 1 was 30.4 weeks. Both groups were similar with regards to HIV status and pre-pregnancy BMI.

Medical history and obstetric history were generally similar for maternal participants in the BNT162b2 and placebo groups.

Baseline Charlson Comorbidities were reported for few maternal participants in the BNT162b2 and placebo groups (21 [12.1%] and 14 [8.1%], respectively). Across groups, the most common comorbidities reported were HIV-positive (6.4%) and chronic pulmonary disease (2.6%).

Table 10. Demographic Characteristics – Safety Population (Maternal)

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=173) n[b] (%)	Placebo (N[a]=173) n[b] (%)	Total (N[a]=346) n[b] (%)
Race			
White	117 (67.6)	118 (68.2)	235 (67.9)
Black or African American	47 (27.2)	43 (24.9)	90 (26.0)
American Indian or Alaska Native	1 (0.6)	1 (0.6)	2 (0.6)
Asian	5 (2.9)	9 (5.2)	14 (4.0)
Native Hawaiian or other Pacific Islander	0	1 (0.6)	1 (0.3)
Multiracial	1 (0.6)	0	1 (0.3)
Not reported	2 (1.2)	1 (0.6)	3 (0.9)
Ethnicity			
Hispanic/Latino	70 (40.5)	63 (36.4)	133 (38.4)
Non-Hispanic/Non-Latino	103 (59.5)	110 (63.6)	213 (61.6)
Country			
Brazil	24 (13.9)	19 (11.0)	43 (12.4)
South Africa	40 (23.1)	42 (24.3)	82 (23.7)
Spain	21 (12.1)	18 (10.4)	39 (11.3)
United Kingdom	7 (4.0)	8 (4.6)	15 (4.3)
United States	81 (46.8)	86 (49.7)	167 (48.3)
HIV-positive			
Yes	12 (6.9)	10 (5.8)	22 (6.4)
No	161 (93.1)	163 (94.2)	324 (93.6)
Age at Dose 1 (years)			
Mean (SD)	29.6 (6.27)	29.6 (5.79)	29.6 (6.03)
Median	30.0	30.0	30.0
Min, max	(18, 44)	(18, 44)	(18, 44)
Gestational age at Dose 1 (weeks)			
n	173	173	346
Mean (SD)	30.0 (2.74)	30.2 (2.64)	30.1 (2.69)

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Table 10. Demographic Characteristics – Safety Population (Maternal)

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=173) n[b] (%)	Placebo (N[a]=173) n[b] (%)	Total (N[a]=346) n[b] (%)
Median	30.1	30.4	30.4
Min, max	(24.0, 34.9)	(24.1, 36.1)	(24.0, 36.1)
Gestational age at Dose 2 (weeks)			
n	170	170	340
Mean (SD)	33.1 (2.68)	33.4 (2.72)	33.2 (2.70)
Median	33.3	33.4	33.4
Min, max	(27.0, 37.7)	(27.0, 39.6)	(27.0, 39.6)
Baseline SARS-CoV-2 status confirmed			
Positive	63 (36.4)	64 (37.0)	127 (36.7)
Negative	102 (59.0)	105 (60.7)	207 (59.8)
Missing	8 (4.6)	4 (2.3)	12 (3.5)
Body mass index (BMI)			
Underweight (<18.5 kg/m^2)	0	1 (0.6)	1 (0.3)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	43 (24.9)	39 (22.5)	82 (23.7)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	65 (37.6)	62 (35.8)	127 (36.7)
Obese (≥30.0 kg/m^2)	65 (37.6)	70 (40.5)	135 (39.0)
Missing	0	1 (0.6)	1 (0.3)

Abbreviations: HIV = human immunodeficiency virus; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Gestational age at Dose 2 (weeks) = gestational age at Dose 1 (weeks) + (date of Dose 2 – date of Dose 1)/7.
a. N = number of participants in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (09:47) Source Data: adsl Table Generation: 10MAY2023 (10:21) Output File: ./nda3/C4591015_BR/adsl_s005_demo_p3_saf

Additional data for maternal participants are presented in the following:

Medical History – Safety Population (Maternal)	Supplemental Table 14.4
Obstetric History – Safety Population (Maternal)	Supplemental Table 14.5
Baseline Charlson Comorbidities – Safety Population (Maternal)	Supplemental Table 14.6
Listing of Demogrpahic Characteristics (Maternal)	Appendix 16.2.4.1
Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)	Appendix 16.2.4.3
Listing of Medical History (Maternal)	Appendix 16.2.5.1

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4.4.1.2. Immunogenicity Populations

The demographics of the evaluable immunogenicity population for maternal participants in Study C4591015 and nonpregnant female participants in Study C4591001 are presented in Table 11 (Section 3.7.1). Of note, a greater proportion of C4591015 participants identified as Black or African American (≥27.0% compared with ≥5.3% in C4591001) and a higher percentage were enrolled from South African sites (≥24.3% compared with ≥0.8% in C4591001). Additionally, the proportion of C4591015 maternal participants with positive baseline SARS-CoV-2 status (≥37.8%) was higher than what was observed among C4591001 participants (≥3.5%), which could have been due to the different timepoints at which participants were enrolled in each study relative to the progression of the COVID-19 pandemic. The majority of participants identified as non-Hispanic/non-Latino (≥62.2%). The median age of participants at Dose 1 was 30.0 years, and the median gestational age at Dose 1 for the BNT162b2 and placebo groups was 28.9 weeks and 29.1 weeks, respectively. Both groups were similar with regards to HIV status. Pre-pregnancy BMIs for C4591015 maternal participants were generally higher than those observed in C4591001 nonpregnant female participants.

Table 11. Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001) – Evaluable Immunogenicity Population

	Vaccine Group (as Randomized)			
	BNT162b2 (30 µg)		Placebo	
	C4591015 (Maternal) (N[a]=111) n[b] (%)	C4591001 (Nonpregnant Women) (N[a]=114) n[b] (%)	C4591015 (Maternal) (N[a]=115) n[b] (%)	C4591001 (Nonpregnant Women) (N[a]=124) n[b] (%)
Race				
White	77 (69.4)	94 (82.5)	77 (67.0)	94 (75.8)
Black or African American	30 (27.0)	6 (5.3)	32 (27.8)	14 (11.3)
American Indian or Alaska Native	0	2 (1.8)	0	2 (1.6)
Asian	2 (1.8)	7 (6.1)	6 (5.2)	8 (6.5)
Multiracial	0	5 (4.4)	0	6 (4.8)
Not reported	2 (1.8)	0	0	0
Ethnicity				
Hispanic/Latino	42 (37.8)	39 (34.2)	40 (34.8)	45 (36.3)
Non-Hispanic/non-Latino	69 (62.2)	75 (65.8)	75 (65.2)	79 (63.7)
Country				
Argentina	0	24 (21.1)	0	27 (21.8)
Brazil	11 (9.9)	16 (14.0)	10 (8.7)	11 (8.9)
Germany	0	5 (4.4)	0	5 (4.0)
South Africa	27 (24.3)	2 (1.8)	31 (27.0)	1 (0.8)
Spain	16 (14.4)	0	11 (9.6)	0

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Table 11. Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001) – Evaluable Immunogenicity Population

	Vaccine Group (as Randomized)			
	BNT162b2 (30 µg)		Placebo	
	C4591015 (Maternal) (N[a]=111) n[b] (%)	C4591001 (Nonpregnant Women) (N[a]=114) n[b] (%)	C4591015 (Maternal) (N[a]=115) n[b] (%)	C4591001 (Nonpregnant Women) (N[a]=124) n[b] (%)
Turkey	0	2 (1.8)	0	1 (0.8)
United Kingdom	5 (4.5)	0	4 (3.5)	0
United States	52 (46.8)	65 (57.0)	59 (51.3)	79 (63.7)
HIV-Positive				
No	101 (91.0)	114 (100.0)	106 (92.2)	124 (100.0)
Yes	10 (9.0)	0	9 (7.8)	0
Age at Dose 1 (years)				
Mean (SD)	30.0 (6.04)	30.1 (6.24)	30.0 (5.93)	29.8 (5.88)
Median	30.0	30.0	30.0	30.0
Min, max	(18, 44)	(18, 44)	(18, 44)	(18, 44)
Gestational age at Dose 1 (weeks)				
n	111	N/A	115	N/A
Mean (SD)	29.2 (2.49)	N/A	29.3 (2.34)	N/A
Median	28.9	N/A	29.1	N/A
Min, max	(24.0, 34.9)	N/A	(24.1, 35.6)	N/A
Gestational age at Dose 2 (weeks)				
n	111	N/A	115	N/A
Mean (SD)	32.2 (2.46)	N/A	32.4 (2.36)	N/A
Median	32.0	N/A	32.3	N/A
Min, max	(27.0, 37.7)	N/A	(27.0, 38.6)	N/A
Baseline SARS-CoV-2 status				
Positive	42 (37.8)	4 (3.5)	49 (42.6)	6 (4.8)
Negative	67 (60.4)	109 (95.6)	63 (54.8)	118 (95.2)
Missing	2 (1.8)	1 (0.9)	3 (2.6)	0
Body mass index (BMI)				
Underweight (<18.5 kg/m^2)	0	2 (1.8)	0	5 (4.0)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	27 (24.3)	51 (44.7)	27 (23.5)	49 (39.5)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	41 (36.9)	30 (26.3)	42 (36.5)	32 (25.8)
Obese (≥30.0 kg/m^2)	43 (38.7)	31 (27.2)	46 (40.0)	38 (30.6)

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Table 11. Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001) – Evaluable Immunogenicity Population

	Vaccine Group (as Randomized)			
	BNT162b2 (30 µg)		Placebo	
	C4591015 (Maternal) (N[a]=111) n[b] (%)	C4591001 (Nonpregnant Women) (N[a]=114) n[b] (%)	C4591015 (Maternal) (N[a]=115) n[b] (%)	C4591001 (Nonpregnant Women) (N[a]=124) n[b] (%)

Abbreviations: N/A = not applicable; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Gestational age at Dose 2 (weeks) = gestational age at Dose 1 (weeks) + (date of Dose 2 - date of Dose 1)/7.
Note: Participants from C4591001 are a selected subset of age matched nonpregnant female Phase 3 participants.
Note: As per inclusion criteria 10 for weight in C4591015 protocol, the BMI included is pre-pregnancy and if unavailable, the BMI recorded from the first obstetric visit was used. The weight categories included in the table were created as per these records.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic.
PFIZER CONFIDENTIAL Source Data: adsl Table Generation: 01MAR2024 (02:39)
(Data cutoff date : C4591001 [31Aug2021]) Output File: ./nda3/C4591015_Bridging/adsl_s005_demo_p3_saf17

Additional data are presented in the following:

Demographics Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001) – All-Available Immunogenicity Population	Supplemental Table 14.7
Demographics Characteristics – Participants Without Evidence of SARS-CoV-2 Infection up to 1 Month After Dose 2 – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001) – Evaluable Immunogenicity Population	Supplemental Table 14.8
Demographics Characteristics – Phase 2 – Dose 1 Evaluable Immunogenicity Population (Maternal)	Supplemental Table 14.9

4.4.2. Infant Participants

4.4.2.1. Safety Population

Demographics and baseline characteristics for the safety population of infant participants were balanced for the BNT162b2 and placebo groups (Table 12). The majority of participants were White (65.4%), non-Hispanic/non-Latino (60.3%), and located in the US (48.7%) or South Africa (23.9%). The majority of infants were born ≥37 weeks to 41 weeks 6 days, and 89.3% of infant participants were breastfed. Both groups were similar with regards to HIV status.

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Table 12. Demographic Characteristics – Safety Population (Infant)

	Maternal Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=167) n[b] (%)	Placebo (N[a]=168) n[b] (%)	Total (N[a]=335) n[b] (%)
Sex			
Male	82 (49.1)	95 (56.5)	177 (52.8)
Female	85 (50.9)	73 (43.5)	158 (47.2)
Race			
White	115 (68.9)	104 (61.9)	219 (65.4)
Black or African American	40 (24.0)	40 (23.8)	80 (23.9)
American Indian or Alaska Native	1 (0.6)	2 (1.2)	3 (0.9)
Asian	3 (1.8)	7 (4.2)	10 (3.0)
Multiracial	0	6 (3.6)	6 (1.8)
Not reported	8 (4.8)	9 (5.4)	17 (5.1)
Ethnicity			
Hispanic/Latino	65 (38.9)	60 (35.7)	125 (37.3)
Non-Hispanic/Non-Latino	98 (58.7)	104 (61.9)	202 (60.3)
Not reported	4 (2.4)	4 (2.4)	8 (2.4)
Country			
Brazil	24 (14.4)	19 (11.3)	43 (12.8)
South Africa	39 (23.4)	41 (24.4)	80 (23.9)
Spain	20 (12.0)	16 (9.5)	36 (10.7)
United Kingdom	6 (3.6)	7 (4.2)	13 (3.9)
United States	78 (46.7)	85 (50.6)	163 (48.7)
Mother HIV-positive			
Yes	11 (6.6)	9 (5.4)	20 (6.0)
No	156 (93.4)	159 (94.6)	315 (94.0)
Breast feeding status			
Yes	147 (88.0)	152 (90.5)	299 (89.3)
No	17 (10.2)	11 (6.5)	28 (8.4)
Missing	3 (1.8)	5 (3.0)	8 (2.4)
Gestational age at birth (weeks)			
<37 weeks 0 days	2 (1.2)	8 (4.8)	10 (3.0)
≥37 weeks - 41 weeks 6 days	162 (97.0)	157 (93.5)	319 (95.2)
≥42 weeks	2 (1.2)	2 (1.2)	4 (1.2)
Missing	1 (0.6)	1 (0.6)	2 (0.6)

Abbreviations: HIV = human immunodeficiency virus; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
a. N = number of participants in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (09:47) Source Data: adsl Table Generation: 03MAY2023 (12:29) Output File: ./nda3/C4591015_BR/adsl_s005_demo_p3_inf

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Additional data for infant participants are presented in the following:

Listing of Demographic Characteristics (Infant)	Appendix 16.2.4.2

4.4.2.2. Immunogenicity Populations

The demographics for the immunogenicity population of infant participants (Table 13) were generally similar to those of the safety population (Section 4.4.2.1).

Table 13. Demographic Characteristics – Evaluable Immunogenicity Population (Infant)

	Maternal Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=109) n[b] (%)	Placebo (N[a]=105) n[b] (%)	Total (N[a]=214) n[b] (%)
Sex			
Male	50 (45.9)	57 (54.3)	107 (50.0)
Female	59 (54.1)	48 (45.7)	107 (50.0)
Race			
White	76 (69.7)	67 (63.8)	143 (66.8)
Black or African American	29 (26.6)	29 (27.6)	58 (27.1)
Asian	1 (0.9)	5 (4.8)	6 (2.8)
Multiracial	0	1 (1.0)	1 (0.5)
Not reported	3 (2.8)	3 (2.9)	6 (2.8)
Ethnicity			
Hispanic/Latino	40 (36.7)	35 (33.3)	75 (35.0)
Non-Hispanic/non-Latino	67 (61.5)	69 (65.7)	136 (63.6)
Not reported	2 (1.8)	1 (1.0)	3 (1.4)
Country			
Brazil	11 (10.1)	8 (7.6)	19 (8.9)
South Africa	27 (24.8)	31 (29.5)	58 (27.1)
Spain	16 (14.7)	10 (9.5)	26 (12.1)
United Kingdom	5 (4.6)	4 (3.8)	9 (4.2)
United States	50 (45.9)	52 (49.5)	102 (47.7)
Mother HIV-Positive			
Yes	10 (9.2)	9 (8.6)	19 (8.9)
No	99 (90.8)	96 (91.4)	195 (91.1)
Breast Feeding Status			
Yes	96 (88.1)	94 (89.5)	190 (88.8)
No	13 (11.9)	8 (7.6)	21 (9.8)
Missing	0	3 (2.9)	3 (1.4)
Gestational age at birth (weeks)			

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Table 13. Demographic Characteristics – Evaluable Immunogenicity Population (Infant)

	Maternal Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=109) n[b] (%)	Placebo (N[a]=105) n[b] (%)	Total (N[a]=214) n[b] (%)
<37 weeks 0 days	1 (0.9)	4 (3.8)	5 (2.3)
≥37 weeks - 41 weeks 6 days	107 (98.2)	99 (94.3)	206 (96.3)
≥42 weeks	1 (0.9)	2 (1.9)	3 (1.4)

a. N = number of participants in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (08:47) Source Data: adsl Table Generation: 19FEB2024 (03:17)
(Database snapshot date: Safety [29Mar2023], Immunogenicity [09Jan2024]) Output File: ./nda3/C4591015_CSR/adsl_s005_evalim_inf

Additional data for infant participants are presented in the following:

Demographics Characteristics – All-Available Immunogenicity Population (Infant)	Supplemental Table 14.10

4.5. Prior, Concomitant, and Post-Intervention Therapy

4.5.1. Maternal Participants

Concomitant medications used after Dose 1 were reported similarly among maternal participants in the BNT162b2 and placebo groups (27.3% and 28.8%, respectively). The number of participants who received nonstudy vaccines after Dose 1 was also similar (16.1% and 20.9%, respectively). The most common nonstudy vaccine received was diphtheria vaccine toxoid; pertussis vaccine acellular; tetanus vaccine toxoid (6.8% and 9.2%, respectively).

Additional data for maternal participants are presented in the following:

Concomitant Medications Used After Dose 1 – Safety Population (Maternal)	Supplemental Table 14.11
Nonstudy Vaccines Received After Dose 1 – Safety Population (Maternal)	Supplemental Table 14.12
Listing of Nonstudy Vaccines Received (Maternal)	Appendix 16.2.5.2
Listing of Concomitant Medications Used After Dose 1 (Maternal)	Appendix 16.2.5.3.1

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4.5.2. Infant Participants

Concomitant medications received after birth were reported similarly among infants born to maternal participants in the BNT162b2 and placebo groups (13.5% and 14.5%, respectively).

Additional data for infant participants are presented in the following:

Concomitant Medications Received After Birth – Safety Population (Infant)	Supplemental Table 14.13
Listing of Concomitant Medications Received After Birth (Infant)	Appendix 16.2.5.3.2

4.6. Study Intervention Compliance

4.6.1. Vaccine Administration and Timing – Maternal Participants

Most (≥97.7%) maternal participants were administered Dose 1 and Dose 2 as randomized. For participants who were originally randomized to placebo, 87.4% and 85.1% received a first dose and second dose of BNT162b2, respectively, following unblinding at the 1-month postdelivery visit.

In all randomized maternal participants, the majority (≥87.9%) in the BNT162b2 and placebo groups received Dose 2 in the protocol-defined window of 19 to 23 days after Dose 1. For the 152 (87.4%) maternal participants who were originally randomized to placebo and received a first dose of BNT162b2 after unblinding, the majority (127 [73.0%]) received a second dose of BNT162b2 in the protocol-defined window of 19 to 23 days after the first dose.

Vaccine administration timing was similar for Study C4591015 maternal participants and Study C4591001 nonpregnant female participants in the evaluable immunogenicity population across both vaccine groups.

Additional data are presented in the following:

Vaccine as Administered, by Vaccine Group – All Randomized Participants (Maternal)	Supplemental Table 14.14
Vaccine Administration Timing – All Randomized Participants (Maternal)	Supplemental Table 14.15
Vaccine Administration Timing – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001) – Evaluable Immunogenicity Population	Supplemental Table 14.16

4.6.2. Immunogenicity Blood Samples

4.6.2.1. Maternal Participants

In all randomized maternal participants, for each of the visits at which blood draws occurred the proportions were generally similar for the BNT162b2 and placebo groups through the delivery visit. For both groups, the majority (≥52.9%) of blood draws were within the protocol-defined window through the delivery visit. Per protocol, blood samples were also drawn at the 6-month postdelivery visit for participants originally randomized to BNT162b2

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(the placebo group was unblinded at the 1-month postdelivery visit in order to receive BNT162b2).

For Study C4591015 maternal participants and selected nonpregnant female participants from Study C4591001, ≥98.3% of participants in the BNT162b2 and placebo groups in both studies had samples drawn before Dose 1. At 1 month after Dose 2, ≥62.6% of C4591015 participants and ≥93.2% of C4591001 participants had blood samples drawn within the protocol-defined window of 28 to 35 days. Note: In Appendix 16.2.6.1.1, 2 participants mistakenly had serology samples drawn at Visit 2, which were then used for immunogenicity testing instead of being destroyed; this is documented in a CSR Errata.

Additional data are presented in the following:

Immunogenicity Blood Samples Drawn – All Randomized Participants (Maternal)	Supplemental Table 14.17
Immunogenicity Blood Samples Drawn Through 1 Month After Dose 2 – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001) – All Randomized Participants	Supplemental Table 14.18

4.6.2.2. Infant Participants

In infant participants, the majority had blood samples drawn at birth (≥89.9%) and in the protocol-defined window of 160 to 200 days (≥63.1%) for the 6-months of age follow-up visit (Supplemental Table 14.19).

4.6.3. Reactogenicity E-Diary – Maternal Participants

For maternal participants, transmission of reactogenicity e-diary data for each day during the 7 days after Dose 1 of BNT162b2 ranged from 86.7% to 94.8%. After Dose 2 of BNT162b2, transmission of e-diary data ranged from 73.5% to 87.6% for Day 1 through Day 7. Results were similar for the placebo group (Supplemental Table 14.20).

5. EVALUATION OF RESPONSE TO STUDY INTERVENTION

5.1. Immunogenicity

5.1.1. Primary Immunogenicity Analyses - Maternal Participants

5.1.1.1. GMR of Neutralizing Titers

Among participants without prior evidence of SARS-CoV-2 infection up to 1 month after Dose 2 (evaluable immunogenicity population), the ratio of the neutralizing GMT (GMR) in Study C4591015 maternal participants in the BNT162b2 (30 µg) group to that of Study C4591001 nonpregnant females who received BNT162b2 30 µg was 0.67 (95% CI: 0.50, 0.90) (Table 14).

For participants with or without prior evidence of SARS-CoV-2 infection up to 1 month after Dose 2 (evaluable immunogenicity population), the model-adjusted ratio of the neutralizing GMT (adjusted GMR) in Study C4591015 maternal participants in the BNT162b2 (30 µg) group to that of Study C4591001 nonpregnant females who received BNT162b2 30 µg was

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0.95 (95% CI: 0.69, 1.30) (Table 15). The adjusted GMT and GMR were calculated based on a regression model with vaccine group, age at Dose 1 and baseline neutralizing titers as the independent variables to minimize the confounding effect from imbalanced distribution of baseline SARS-CoV-2 infection (Section 3.7.3).

Table 14. Geometric Mean Ratios – Participants Without Evidence of Infection up to 1 Month After Dose 2 – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001) – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)				
		BNT162b2 (30 µg)				
		C4591015 (Maternal)		C4591001 (Nonpregnant Women)		Pregnant/Nonpregnant
Assay	Dose/Sampling Time Point[a]	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])	GMR[d] (95% CI[d])
SARS-CoV-2 neutralization assay - NT50 (titer)	2/1 Month	58	1109.2 (849.2, 1448.9)	107	1663.7 (1411.5, 1960.8)	0.67 (0.50, 0.90)

Abbreviations: GMR = geometric mean ratio; GMT = geometric mean titer; LLOQ = lower limit of quantitation; N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Blood samples for immunogenicity assessment drawn at the delivery visit but within 1 month after Dose 2 visit window were also included in this analysis.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: Participants from C4591001 are a selected subset of age matched nonpregnant female Phase 3 participants.
Note: Participants who had no serological or virological evidence (prior to the 1 month after Dose 2 blood sample collection) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Dose 1 and 1 month after Dose 2 and no positive result between visits, negative NAAT [nasal swab] at Dose 1, Dose 2, and any unscheduled visit prior to the 1 month after Dose 2 blood sample collection) were included in the analysis.
a. Protocol-specified timing for blood sample collection.
b. n = Number of participants with valid and determinate assay results for the specified assay at the given dose/sampling time point.
c. GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
d. GMRs and 2-sided 95% CIs were calculated by exponentiating the mean difference of the logarithms of the assay and the corresponding CIs (based on the Student t distribution).
PFIZER CONFIDENTIAL Source Data: adva Table Generation: 01MAR2024 (02:39)
(Data cutoff date : C4591001 [31Aug2021]) Output File: ./nda3/C4591015_Bridging/adva_s009_gmr_noninf_eval

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Table 15. Model Adjusted Geometric Mean Ratios – Participants With or Without Evidence of Infection – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001) – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)				
		BNT162b2 (30 µg)				
		C4591015 (Maternal)		C4591001 (Nonpregnant Women)		Pregnant/Nonpregnant
Assay	Dose/Sampling Time Point[a]	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])	GMR[d] (95% CI[d])
SARS-CoV-2 neutralization assay - NT50 (titer)	2/1 Month	99	1900.0 (1518.2, 2377.7)	113	2005.7 (1627.0, 2472.6)	0.95 (0.69, 1.30)

Abbreviations: GMR = geometric mean ratio; GMT = geometric mean titer; LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Blood samples for immunogenicity assessment drawn at the delivery visit but within 1 month after Dose 2 visit window were also included in this analysis.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: Participants from C4591001 are a selected subset of age matched nonpregnant female Phase 3 participants.
a. Protocol-specified timing for blood sample collection.
b. n = Number of participants with valid and determinate assay results for the specified assay at both baseline and the given dose/sampling time point.
c. GMTs and 2-sided CIs were calculated by exponentiating the LS means and the corresponding CIs based on analysis of log-transformed NT50 titers using a regression model with group, age at Dose 1 in years (continuous), and baseline log transformed NT50 titers.
d. GMRs (ratio of GMTs of pregnant women to nonpregnant women) and 2-sided CIs were calculated by exponentiating the difference of LS means and the corresponding CIs based on the same regression model as above.
PFIZER CONFIDENTIAL Source Data: adva Table Generation: 01MAR2024 (02:39)
(Data cutoff date : C4591001 [31Aug2021]) Output File: ./nda3/C4591015_Bridging/adva_s009_gmr_eval_adj

Additional data are presented in the following:

Geometric Mean Ratios – Participants With or Without Evidence of Infection – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001) (Evaluable Immunogenicity Population, All-Available Immunogenicity Population)	Supplemental Tables 14.21-14.22
Model-adjusted Geometric Mean Ratios – Participants With or Without Evidence of Infection – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001) – All-Available Immunogenicity Population	Supplemental Table 14.23
Geometric Mean Titers – Participants Without Evidence of Infection up to 1 Month After Dose 2 – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001) (Evaluable Immunogenicity Population)	Supplemental Table 14.24
Geometric Mean Titers – Participants With or Without Evidence of Infection – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001) (Evaluable Immunogenicity Population, All-Available Immunogenicity Population)	Supplemental Tables 14.25-14.26

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Geometric Mean Fold Rise – Participants Without Evidence of Infection up to 1 Month After Dose 2 – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001) - Evaluable Immunogenicity Population	Supplemental Table 14.27
Geometric Mean Fold Rise, by Baseline SARS-CoV-2 Status – Participants With or Without Evidence of Infection – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001) – Evaluable Immunogenicity Population	Supplemental Table 14.28

5.1.2. Secondary Immunogenicity Analyses

5.1.2.1. Maternal Participants

5.1.2.1.1. Neutralizing GMTs and Full-length S-binding IgG GMCs

For the evaluable immunogenicity population without evidence of infection, at 1 month after Dose 2 there was a substantial increase in SARS-CoV-2 50% neutralizing GMTs in maternal participants in the BNT162b2 group (1099.4 [95% CI: 820.6, 1473.0]) compared to the placebo group (43.5 [95% CI: 43.5, 43.5]), for which change from baseline was negligible (Table 16); as seen in Supplemental Table 14.24, these results are consistent with those in nonpregnant females in Study C4591001. In maternal participants in the BNT162b2 group, GMTs were substantially increased, compared to the placebo group, peaked at 2 weeks after Dose 2 and remained elevated through the 6-month postdelivery visit. Results for participants in the evaluable immunogenicity population with or without evidence of infection followed a similar trend.

For the evaluable immunogenicity population without evidence of infection, at 2 weeks after Dose 2 there was a substantial increase in GMCs of full-length S-binding IgG in maternal participants in the BNT162b2 group (7639.0 [95% CI: 6403.0, 9113.6]) compared to the placebo group (1.7 [95% CI: 1.2, 2.6]), for which change from baseline was negligible (Table 16). In the BNT162b2 group, GMCs were substantially increased, compared to the placebo group, peaked at 2 weeks after Dose 2 and remained elevated through the 6-month postdelivery visit. Results for participants in the evaluable immunogenicity population with or without evidence of infection followed a similar trend.

Table 16. Geometric Mean Titers and Concentrations of Participants Without Evidence of Infection – Evaluable Immunogenicity Population (Maternal)

		Vaccine Group (as Randomized)			
		BNT162b2 (30 µg)		Placebo	
Assay	Dose/Sampling Time Point[a]	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Prevax	65	43.5 (43.5, 43.5)	59	44.8 (42.3, 47.5)

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Table 16. Geometric Mean Titers and Concentrations of Participants Without Evidence of Infection – Evaluable Immunogenicity Population (Maternal)

		Vaccine Group (as Randomized)			
		BNT162b2 (30 µg)		Placebo	
Assay	Dose/Sampling Time Point[a]	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])
	2/2 Weeks	58	1901.8 (1472.9, 2455.5)	54	44.5 (42.5, 46.5)
	2/1 Month	50	1099.4 (820.6, 1473.0)	49	43.5 (43.5, 43.5)
	Delivery	55	678.3 (526.4, 874.0)	47	43.5 (43.5, 43.5)
	6-Month postdelivery	26	492.8 (219.6, 1105.7)	N/A	
Full-length S-binding IgG level assay (U/mL)	1/Prevax	65	2.1 (1.5, 2.8)	59	2.0 (1.3, 3.0)
	2/2 Weeks	58	7639.0 (6403.0, 9113.6)	54	1.7 (1.2, 2.6)
	2/1 Month	50	4336.9 (3456.0, 5442.4)	49	1.6 (1.1, 2.3)
	Delivery	55	2894.2 (2370.8, 3533.1)	47	1.5 (1.0, 2.2)
	6-Month postdelivery	26	1603.3 (887.8, 2895.5)	N/A	

Abbreviations: GMC = geometric mean concentration; GMT = geometric mean titer; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; N/A = not applicable; NT50 = 50% neutralizing titer; S = spike protein; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: Participants who had no serological or virological evidence (up to the reporting timepoints) of past SARS-CoV-2 infection (ie, a negative N-binding antibody [serum] result at all planned visits up to the reporting timepoints, a negative NAAT [nasal swab] result at the study vaccination visit and at any unscheduled visit up to the reporting timepoints) and were included in the analysis.
a. Protocol-specified timing for blood sample collection.
b. n = Number of participants with valid and determinate assay results for the specified assay at the given dose/sampling time point.
c. GMTs, GMCs, and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers or concentrations and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 12JAN2024 (03:07) Source Data: adva Table Generation: 22FEB2024 (01:04)
(Database snapshot date: Safety [29Mar2023], Immunogenicity [09Jan2024]) Output File: ./nda3/C4591015_CSR/adva_s001_eval_wo

Additional data are presented in the following:

Geometric Mean Titers and Concentrations (Evaluable Immunogenicity Population, All-Available Immunogenicity Population [Maternal])	Supplemental Tables 14.29-14.30
Reverse Cumulative Distribution Curves, SARS-CoV-2 Neutralization Assay – NT50 – Evaluable Immunogenicity Population (Maternal)	Supplemental Figure 14.1

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Reverse Cumulative Distribution Curves, Full-Length S-Binding IgG Level Assay – Evaluable Immunogenicity Population (Maternal)	Supplemental Figure 14.2
Geometric Mean Titers and Concentrations of Participants Without Evidence of Infection – Phase 2 – Dose 1 Evaluable Immunogenicity Population (Maternal)	Supplemental Table 14.31

5.1.2.1.2. HIV-Positive Participants

Among HIV-positive maternal participants, SARS-CoV-2 50% neutralizing titers in maternal participants in the BNT162b2 group were generally higher compared to those in the placebo group at 1 month after Dose 2, and remained elevated at 6 months after Dose 2.

Overall, full-length S-binding IgG levels in HIV-positive maternal participants in the BNT162b2 group were substantially higher than those observed in the placebo group at 1 month after Dose 2, and remained elevated at 6 months after Dose 2. As this subgroup included a limited number of participants, these results should be interpreted with caution.

Additional data are presented in the following:

Listing of Assay Data – Phase 2/3 HIV-Positive Subjects (Infant)	Appendix 16.2.6.1.2

5.1.2.1.3. Subgroup Analyses

GMTs at prevaccination (Dose 1) and 1 month after Dose 2 were evaluated by race, ethnicity, and baseline SARS-CoV-2 status in Study C4591015 maternal participants and Study C4591001 nonpregnant females. Among participants with or without evidence of infection, higher baseline and post-vaccination titers were observed in Black/African American participants as compared to other race groups. Higher GMTs were also observed in participants with positive baseline SARS-CoV-2 status at both baseline and 1 month after Dose 2 timepoints compared to those observed in participants with negative baseline status. Overall, GMTs for the BNT162b2 groups for both studies were generally similar and did not identify any clinically meaningful differences for any other race subgroup or ethnicity. As several subgroups included a limited number of participants, these results should be interpreted with caution.

Additional data are presented in the following:

Geometric Mean Titers, by Subgroup– Participants Without Evidence of Infection up to 1 Month After Dose 2 – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001) (Evaluable Immunogenicity Population)	Supplemental Table 14.32
Geometric Mean Titers, by Subgroup – Participants With or Without Evidence of Infection up to 1 Month After Dose 2 – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001) (Evaluable Immunogenicity Population)	Supplemental Table 14.33

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Listing of Assay Data - Nonpregnant Female Participants (Study C4591001)	Appendix 16.2.6.3

5.1.2.1.4. Neutralizing Titer and Full-length S-binding IgG GMFRs

In maternal participants in the evaluable immunogenicity population without evidence of infection, the SARS-CoV-2 NT GMFR at 1 month after Dose 2 was substantially higher in the BNT162b2 group (25.3 [95% CI: 18.9, 33.9]) compared to the placebo group (1.0 [95% CI: 1.0, 1.0]), for which change from baseline was negligible. In maternal participants in the BNT162b2 group, the GMFR peaked at 2 weeks after Dose 2 and remained elevated through the delivery visit and 6-month postdelivery timepoints. Results for participants in the overall evaluable immunogenicity population followed a similar trend.

In maternal participants in the evaluable immunogenicity population without evidence of infection, the full-length S-binding IgG GMFR at 1 month after Dose 2 was substantially higher in maternal participants in the BNT162b2 group (2276.4 [95% CI: 1545.5, 3352.9]) compared to the placebo group (0.9 [95% CI: 0.8, 1.1]), for which change from baseline was negligible. In maternal participants in the BNT162b2 group, the GMFR peaked at 2 weeks after Dose 2 and remained elevated compared to the placebo group through the delivery visit and 6-month postdelivery timepoints. Results for participants in the overall evaluable immunogenicity population followed a similar trend.

Additional data are presented in the following:

Geometric Mean Fold Rise From Before Vaccination to Each Subsequent Time Point (Evaluable Immunogenicity Population, All-Available Immunogenicity Population [Maternal])	Supplemental Table 14.34-14.35
Geometric Mean Fold Rise For Participants Without Evidence of Infection From Before Vaccination to Each Subsequent Time Point – Evaluable Immunogenicity Population (Maternal)	Supplemental Table 14.36
Geometric Mean Fold Rise of Participants Without Evidence of Infection – From Before Vaccination to Subsequent Timepoints – Phase 2 – Dose 1 Evaluable Immunogenicity Population (Maternal)	Supplemental Table 14.37

5.1.2.2. Infant Participants

5.1.2.2.1. Full-length S-binding IgG GMCs

Maternal vaccination with BNT162b2 30 µg yielded substantially higher GMCs of full-length S-binding IgG in infants compared to placebo. For the evaluable immunogenicity population, at birth and 6 months of age GMCs were 5576.4 (95% CI: 4246.2, 7323.2) and 311.1 (95% CI: 235.8, 410.5), respectively, for infants whose mothers received BNT162b2, compared to 19.4 (95% CI: 10.2, 37.0) and 22.0 (95% CI: 11.4, 42.7) for infants whose mothers received placebo (Table 17).

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Table 17. Geometric Mean Concentrations – Evaluable Immunogenicity Population (Infant)

Assay	Sampling Time Point[a]	Maternal Vaccine Group (as Randomized)			
		BNT162b2 (30 µg)		Placebo	
		n[b]	GMC[c] (95% CI[c])	n[b]	GMC[c] (95% CI[c])
Full-length S-binding IgG level assay (U/mL)	Birth	91	5576.4 (4246.2, 7323.2)	92	19.4 (10.2, 37.0)
	6 Months of age	83	311.1 (235.8, 410.5)	69	22.0 (11.4, 42.7)

Abbreviations: GMC = geometric mean concentration; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; S = spike protein.
Note: Infants born to human immunodeficiency virus (HIV)-positive participants are not included in this summary.
a. Protocol-specified timing for blood sample collection.
b. n = Number of participants with valid and determinate assay results for the specified assay at the given sampling time point.
c. GMCs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the concentrations and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 12JAN2024 (03:07) Source Data: adva Table Generation: 22FEB2024 (01:04)
(Database snapshot date: Safety [29Mar2023], Immunogenicity [09Jan2024]) Output File: ./nda3/C4591015_CSR/adva_s001_eval_infant

Additional data for infant participants are presented in the following:

Geometric Mean Concentrations – All-Available Immunogenicity Population (Infant)	Supplemental Table 14.38
Reverse Cumulative Distribution Curves, Full-Length S-Binding IgG Level Assay – Evaluable Immunogenicity Population (Infant)	Supplemental Figure 14.3
Listing of Assay Data (Infant)	Appendix 16.2.6.2.1

5.1.2.2.2. Infants Born to HIV-Positive Maternal Participants

Among infants born to HIV-positive maternal participants, full-length S-binding IgG levels at birth and 6 months of age were higher among infants born to vaccinated participants (with ranges of 406.32-39970 at birth and 169.12-5029.4 at 6 months) than those born to participants in the placebo group (with ranges of 4.92-1561.33 at birth and 7.01-653.18 at 6 months). As this subgroup included a limited number of participants, these results should be interpreted with caution.

Additional data for infant participants are presented in the following:

Listing of Assay Data – Born to HIV-Positive Maternal Participants	Appendix 16.2.6.2.2

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5.1.2.2.3. Exploratory Subgroup Analyses

GMCs of full-length S-binding IgG in infants in the evaluable immunogenicity population were evaluated by breastfeeding status. GMCs for breastfed infants were generally higher than those observed for infants who were not breastfed. GMCs for breastfed or not breastfed infants whose mothers received BNT162b2 were substantially higher at birth compared to infants whose mothers received placebo, and remained elevated at 6 months of age. As the not breasted subgroup included a limited number of participants, these results should be interpreted with caution.

Additional data for infant participants are presented in the following:

Geometric Mean Concentrations, by Breastfeeding Status – Evaluable Immunogenicity Population (Infant)	Supplemental Table 14.39

5.1.2.2.4. GMFRs

In infants in the evaluable immunogenicity population whose mothers received BNT162b2, the GMFR of full-length S-binding IgG from birth to 6 months of age was 0.1 [95% CI: 0.0, 0.1], indicating a decline in antibody titers during this period (Section 5.1.2.2.1).

5.1.2.2.5. Exploratory Subgroup Analyses

GMFRs of full-length S-binding IgG in infants in the evaluable immunogenicity population were evaluated by breastfeeding status. GMFRs by breastfeeding status were generally similar to those observed in the overall population. As the not breastfed subgroup included a limited number of participants, these results should be interpreted with caution.

Additional data for infant participants are presented in the following:

Geometric Mean Fold Rise From Birth to 6 Months of Age, by Breastfeeding Status (Evaluable Immunogenicity Population [Infant])	Supplemental Tables 14.40

5.1.3. Exploratory Immunogenicity Analyses – Maternal Participants

Immunogenicity Between Dose 1 and Dose 2 in Phase 2 Participants

In Phase 2 maternal participants in the Dose 1 evaluable immunogenicity population, for the BNT162b2 group there was an increase in SARS-CoV-2 50% neutralizing GMTs and GMCs of full-length S-binding IgG from the Dose 1 prevaccination to the Dose 2 prevaccination time points; however, this increase was not as substantial as the increase observed after Dose 2.

Additional data for Phase 2 maternal participants are presented in the following:

Geometric Mean Titers and Concentrations – Phase 2 – Dose 1 Evaluable Immunogenicity Population (Maternal)	Supplemental Table 14.41

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Geometric Mean Fold Rise From Before Vaccination to Subsequent Timepoints – Phase 2 – Dose 1 Evaluable Immunogenicity Population (Maternal)	Supplemental Table 14.42
Reverse Cumulative Distribution Curves, SARS-CoV-2 Neutralization Assay – NT50 – Phase 2 – Dose 1 Evaluable Immunogenicity Population (Maternal)	Supplemental Figure 14.4
Reverse Cumulative Distribution Curves, Full-Length S-Binding IgG Level Assay – Phase 2 – Dose 1 Evaluable Immunogenicity Population (Maternal)	Supplemental Figure 14.5

5.2. Efficacy

5.2.1. Secondary Efficacy Analyses – Maternal Participants

5.2.1.1. Vaccine Efficacy Against Confirmed COVID-19

Due to the very small sample size resulted from early termination of enrollment, and hence number of COVID-19 cases, VE results are uninterpretable; nevertheless, they are described below:

For confirmed COVID-19 based on the protocol definition, in maternal participants without evidence of SARS-CoV-2 infection prior to 7 days after Dose 2 in the evaluable efficacy population, the VE during the blinded follow-up period was observed as 3.8% (95% CI: -1227.8%, 93.0%) based on 2 cases in the BNT162b2 group and 2 cases in the placebo group confirmed from at least 7 days after Dose 2 through 1 month after delivery (Table 18).

For confirmed COVID-19 based on the protocol definition, in maternal participants with or without evidence of SARS-CoV-2 infection prior to 7 days after Dose 2 in the evaluable efficacy population, the VE during the blinded follow-up period was observed as 35.1% (95% CI: -466.5%, 94.6%), with 2 cases reported in the BNT162b2 group and 3 cases in the placebo group confirmed from at least 7 days after Dose 2 through 1 month after delivery.

For confirmed COVID-19 based on the CDC definition, in maternal participants without evidence of SARS-CoV-2 infection prior to 7 days after Dose 2 in the evaluable efficacy population, the VE during the blinded follow-up period was observed as 36.2% (95% CI: -456.5%, 94.7%) based on 2 cases in the BNT162b2 group and 3 cases in the placebo group confirmed from at least 7 days after Dose 2 through 1 month after delivery.

For confirmed COVID-19, based on the CDC definition, in maternal participants with or without evidence of SARS-CoV-2 infection prior to 7 days after Dose 2 in the evaluable efficacy population, the observed VE during the blinded follow-up period was generally higher at 51.1% (95% CI: -241.0%, 95.6%), with 2 cases reported in the BNT162b2 group and 4 cases in the placebo group confirmed from at least 7 days after Dose 2 through 1 month after delivery.

Additional details regarding both the protocol and CDC definitions are provided in Appendix 16.1.1, Protocol Section 8.1.1.

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Table 18. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Follow-Up Period – Participants Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy Population (Maternal)

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=88)		Placebo (N[a]=90)			
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence from 7 days after Dose 2	2	0.155 (86)	2	0.149 (89)	3.8	(-1227.8, 93.0)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Participants who had no serological or virological evidence (prior to 7 days after receipt of Dose 2) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1, not positive at Visit 2, NAAT [nasal swab] negative at Visits 1, 2, and any unscheduled visit prior to 7 days after Dose 2) were included in the analysis.
a. N = number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 100 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
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Additional data (for maternal participants) are presented in the following:

Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Follow-up Period – Participants With or Without Evidence of Infection Prior to 7 Days After Dose 2 (Evaluable Efficacy Population, Dose 2 All-Available Efficacy Population [Maternal])	Supplemental Tables 14.43-14.44
Cumulative Incidence Curves for the First COVID-19 Occurrence After Dose 1 – Blinded Follow-up Period – All-Available Efficacy Population (Maternal)	Supplemental Figure 14.6
Cumulative Incidence Curves for the First COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Follow-up Period – Participants Without Evidence of Infection Prior to 7 Days After Dose 2 - Evaluable Efficacy Population (Maternal)	Supplemental Figure 14.7
Cumulative Incidence Curves for the First COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Follow-up Period – Participants With or Without Evidence of Infection Prior to 7 Days After Dose 2 (Evaluable Efficacy Population [Maternal])	Supplemental Figure 14.8
Vaccine Efficacy – First COVID-19 Occurrence After Dose 1 – Blinded Follow-up Period - Dose 1 All-Available Efficacy Population (Maternal)	Supplemental Table 14.45

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Vaccine Efficacy – First COVID-19 Occurrence Based on CDC Definition After Dose 1 – Blinded Follow-up Period – Dose 1 All-Available Efficacy Population (Maternal)	Supplemental Table 14.46
Vaccine Efficacy – First COVID-19 Occurrence Based on CDC Definition From 7 Days After Dose 2 – Blinded Follow-up Period – Participants Without Evidence of Infection Prior to 7 Days After Dose 2 - Evaluable Efficacy Population (Maternal)	Supplemental Table 14.47
Vaccine Efficacy – First COVID-19 Occurrence Based on CDC Definition From 7 Days After Dose 2 – Blinded Follow-up Period – Participants With or Without Evidence of Infection Prior to 7 Days After Dose 2 (Evaluable Efficacy Population, Dose 2 All-Available Efficacy Population [Maternal])	Supplemental Tables 14.48-14.49

5.2.1.2. Vaccine Efficacy Against Asymptomatic SARS-CoV-2 Infection Based on Seroconversion (N-Binding)

For asymptomatic infection, based on N-binding antibody seroconversion, in the evaluable efficacy population of maternal participants without evidence of SARS-CoV-2 infection prior to the first post-Dose 2 N-binding test, the VE during the blinded follow-up period was observed as 40.9% (95% CI: -104.9%, 86.5%) based on 4 cases in the BNT162b2 group and 10 cases in the placebo group confirmed from after Dose 2 through 1 month after delivery (Table 19). As this subgroup included a limited number of participants, these results should be interpreted with caution.

Additional VE analyses for asymptomatic infection had similar results, with most cases occurring in the placebo group.

Table 19. Vaccine Efficacy – Asymptomatic Infection Based on N-Binding Antibody Seroconversion – Blinded Follow-up Period – Participants Without Evidence of Infection Prior to the First Post–Dose 2 N-Binding Test – Evaluable Efficacy Population (Maternal)

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=84)		Placebo (N[a]=89)			
Efficacy Endpoint	n[b]	Surveillance Time[c]	n[b]	Surveillance Time[c]	VE (%)	(95% CI[d])
Asymptomatic infection based on N-binding antibody seroconversion after Dose 2	4	0.099	10	0.147	40.9	(-104.9, 86.5)

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Table 19. Vaccine Efficacy – Asymptomatic Infection Based on N-Binding Antibody Seroconversion – Blinded Follow-up Period – Participants Without Evidence of Infection Prior to the First Post–Dose 2 N-Binding Test – Evaluable Efficacy Population (Maternal)

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=84)		Placebo (N[a]=89)			
Efficacy Endpoint	n[b]	Surveillance Time[c]	n[b]	Surveillance Time[c]	VE (%)	(95% CI[d])

Abbreviations: NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein–binding; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Participants who had no serological or virological evidence (before Dose 2) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Dose 1 and no positive before Dose 2, negative NAAT [nasal swab] at Dose 1, Dose 2, and at any unscheduled visit before Dose 2) and had at least one post-dose 2 N-binding Test in the blinded follow up period were included in the analysis.
a. N = number of participants in the specified group.
b. n = Number of participants meeting the endpoint definition.
c. Total surveillance time in 100 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for case accrual is from Dose 2 to the end of the surveillance period.
d. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (09:10) Source Data: adc19asm Table Generation: 12DEC2023 (23:18) Output File: ./nda3/C4591015_EFF/adc19ef_ve_cov_d2_wo_evlm

Additional data (for maternal participants) are presented in the following:

Vaccine Efficacy – Asymptomatic Infection Based on N-Binding Antibody Seroconversion – Blinded Follow-up Period – Participants Without Evidence of Infection Prior to the First Post–Dose 2 N-Binding Test (Dose 2 All-Available Efficacy Population [Maternal])	Supplemental Table 14.50
Vaccine Efficacy – Asymptomatic Infection Based on N-Binding Antibody Seroconversion – Blinded Follow-up Period – Participants Without Evidence of Infection Prior to the First Post–Dose 1 N-Binding Test (Dose 1 All-Available Efficacy Population [Maternal])	Supplemental Table 14.51

5.2.2. Exploratory Efficacy Analyses

5.2.2.1. Maternal Participants

Incidence of Confirmed COVID-19

Among the evaluable efficacy populations of maternal participants who originally received BNT162b2, the incidence (per 100 person-years) of COVID-19 occurrence from 7 days after Dose 2 was 20.3 (95% CI: 11.6, 33.0) based on the protocol definition and 20.5 (95% CI: 11.7, 33.3) based on the CDC definition.

Additional data (for maternal participants) are presented in the following:

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COVID-19 Occurrence From 7 Days After Dose 2 – Participants Who Originally Received BNT162b2 (Evaluable Efficacy Population, Dose 2 All-Available Efficacy Population [Maternal])	Supplemental Tables 14.52-14.53
COVID-19 Occurrence Based on CDC Definition From 7 Days After Dose 2 – Participants Who Originally Received BNT162b2 (Evaluable Efficacy Population, Dose 2 All-Available Efficacy Population [Maternal])	Supplemental Tables 14.54-14.55

Incidence of Asymptomatic SARS-CoV-2 Infection Based on Seroconversion (N-Binding)

In maternal participants who originally received BNT162b2, the incidence (per 100 person-years) of asymptomatic infection based on N-binding antibody seroconversion after Dose 2 was 45.5 (95% CI: 26.5, 72.9).

Additional data (for maternal participants) are presented in the following:

Asymptomatic Infection Based on N-Binding Antibody Seroconversion Through 6 Months After Delivery – Participants Who Originally Received BNT162b2 - Without Evidence of Infection Prior to the First Post–Dose 2 N-Binding Test (Evaluable Efficacy Population, All-Available Efficacy Population [Maternal])	Supplemental Tables 14.56-14.57

5.2.2.2. Infant Participants

Incidence of Confirmed COVID-19

The incidence of COVID-19, based on both protocol and CDC definitions (provided in Appendix 16.1.1, Protocol Section 8.1.2), was analyzed from birth for infants in the all-available efficacy population.

In infants born to mothers in the BNT162b2 and placebo groups, the incidence (per 100 person-years) of COVID-19 was 11.3 (95% CI: 4.9, 22.3) and 11.7 (95% CI: 5.1, 23.1), respectively.

Similarly, in infants born to mothers in the BNT162b2 and placebo groups, the incidence (per 100 person-years) of COVID-19 based on the CDC definition was 11.4 (95% CI: 4.9, 22.4) and 13.3 (95% CI: 6.1, 25.3), respectively.

Narratives are provided in Section 14 for the infant participants with confirmed severe COVID-19 or multiple cases of COVID-19 illness.

Additional data (for infant participants) are presented in the following:

COVID-19 Occurrence After Birth - All-Available Efficacy Population (Infant)	Supplemental Table 14.58

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COVID-19 Occurrence Based on CDC Definition After Birth - All-Available Efficacy Population (Infant)	Supplemental Table 14.59

Incidence of MIS-C

There were no cases of MIS-C in infant participants in the study (Appendix 16.2.8.3).

5.3. Safety

5.3.1. Local Reactions – Maternal Participants

In maternal participants in the BNT162b2 group, pain at the injection site was the most frequently reported local reaction, and frequency was similar after Dose 1 and after Dose 2 (82.6% vs 75.0%; Figure 1). In the placebo group, pain at the injection site after each dose was less frequently reported compared to the BNT162b2 group and was reported more frequently after Dose 2 (16.4%) than Dose 1 (9.8%). Redness and swelling after either Dose 1 or Dose 2 were reported in ≤6.8% and ≤0.7% of participants in the BNT162b2 and placebo groups, respectively.

Most local reactions were mild or moderate in severity. A severe event of swelling was reported in 1 participant in the BNT162b2 group after Dose 1, and a severe event of pain at the injection site was reported in 1 participant in the same group after Dose 2. No Grade 4 local reactions were reported in either group.

Across both groups, median onset for all local reactions was between Day 1 and Day 2.5 after Dose 1 or Dose 2, and all events resolved with median durations between 1 to 2 days.

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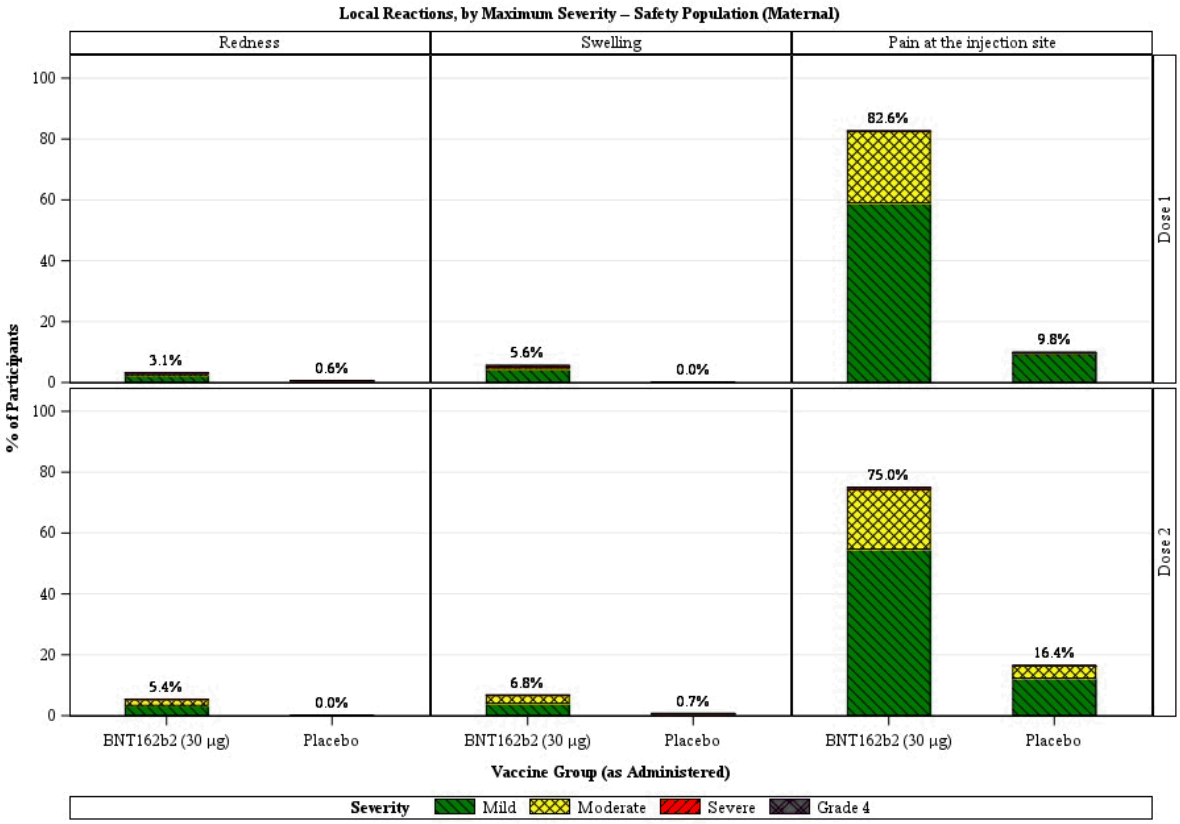
Figure 1. Local Reactions, by Maximum Severity - Safety Population (Maternal)



Note: Human immunodeficiency virus (HIV)-positive participants are not included in this figure. Analyses for HIV-positive participants and their infants will be listed separately.
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Additional data (for maternal participants) are presented in the following:

Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Safety Population (Maternal)	Supplemental Table 14.60
Duration (Days) From First to Last Day of Local Reactions After Each Dose – Safety Population (Maternal)	Supplemental Table 14.61
Onset Day (Days) for Local Reactions After Each Dose – Safety Population (Maternal)	Supplemental Table 14.62

5.3.1.1. HIV-Positive Participants

Among HIV-positive participants, frequencies of local reactions within 7 days after Dose 1 and Dose 2 were generally reported at higher frequencies among participants in the BNT162b2 group compared to those in the placebo group. Of note, pain at the injection site was more frequently reported after each dose in the BNT162b2 group (≤50.0% after either Dose 1 or Dose 2) than in the placebo group (≤20.0% after Dose 1 and ≤22.2% after Dose 2). No severe or Grade 4 local reactions were reported in either group. As this subgroup included a limited number of participants, these results should be interpreted with caution.

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Additional data (for HIV-positive maternal participants) are presented in the following:

Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – HIV-Positive Participants - Safety Population (Maternal)	Supplemental Table 14.63

5.3.1.2. Subgroup Analyses

Local reactions reported within 7 days after vaccination were evaluated by race, ethnicity, and baseline SARS-CoV-2 status. Overall, for these subgroups, local reactions were reported at higher frequencies among participants in the BNT162b2 group after both doses compared to those in the placebo group. Among vaccinated participants, no clinically meaningful differences were observed by race or ethnicity in either group. For participants with baseline negative SARS-CoV-2 status, higher frequencies of pain at the injection site were reported after each dose in both the BNT162b2 and placebo groups as compared to baseline positive participants. As several subgroups included a limited number of participants, these results should be interpreted with caution.

Additional data (for maternal participants) are presented in the following:

Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Race – Safety Population (Maternal) (Race: White, Black or African American, All Others)	Supplemental Tables 14.64-14.66
Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Ethnicity – Safety Population (Maternal) (Ethnicity: Hispanic/Latino, Non-Hispanic/Non-Latino)	Supplemental Tables 14.67-14.68
Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Safety Population (Maternal) (Baseline SARS-CoV-2 Status: Positive, Negative, Missing)	Supplemental Tables 14.69-14.71
Listing of All Local Reactions	Appendix 16.2.7.2
Listing of Severe and Grade 4 Local Reactions	Appendix 16.2.7.3

5.3.2. Systemic Events – Maternal Participants

In maternal participants, systemic events were reported at generally similar frequencies in the placebo group and the BNT162b2 group after Dose 1; however, systemic events were observably higher after Dose 2 among participants in the BNT162b2 group (Figure 2). Fatigue and headache were most frequently reported after each dose in the BNT162b2 (≤50.0% reported fatigue and ≤41.2% reported headache) and placebo groups (≤42.9% reported fatigue and ≤35.6% reported headache). Fever was reported in few participants after each dose in both the BNT162b2 (≤2.7%) and placebo groups (≤1.8%).

Most systemic events were mild or moderate in severity. In both the BNT162b2 and placebo groups, the most frequently reported severe events after any dose were fatigue (2.0% and 0.6%, respectively) and headache (1.9% and 0.6%, respectively). No Grade 4 systemic events were reported in either group.

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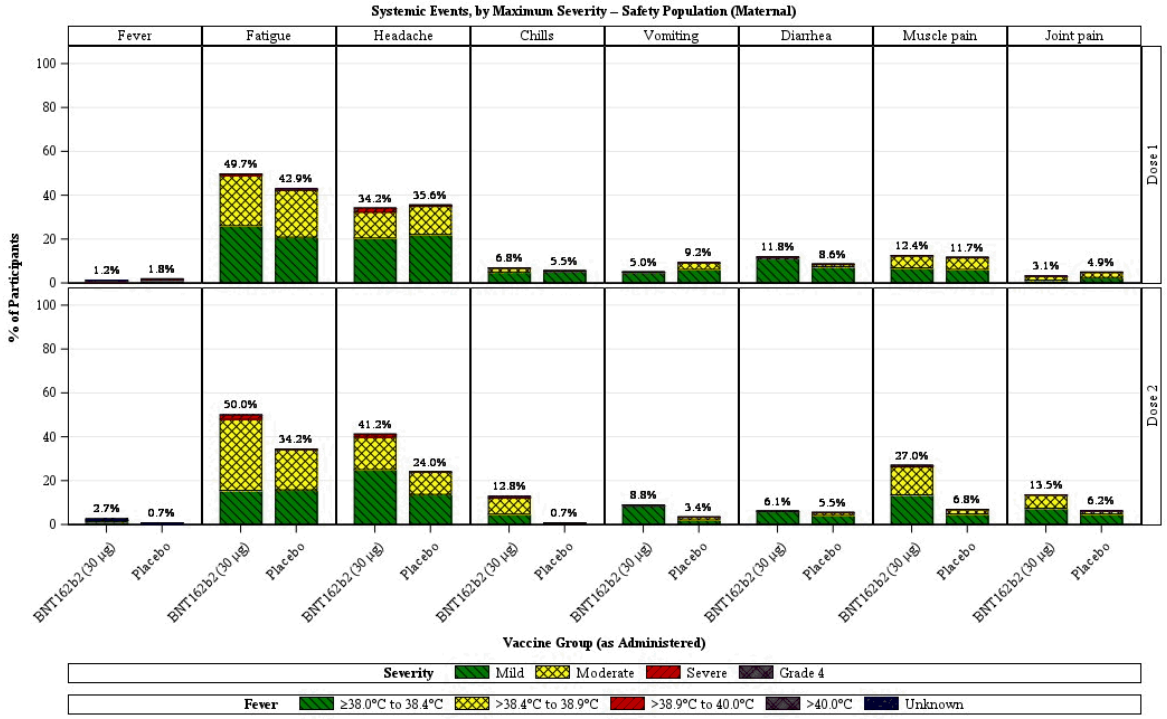
Across both groups, median onset for all systemic events was between Day 1 and Day 4 after Dose 1 or Dose 2, and all events resolved with median durations between 1 to 4.5 days.

The reported frequencies of participants with baseline systemic events were similar for the BNT162b2 and placebo groups, with the baseline fatigue most frequently reported (29.7% and 33.8%, respectively).

Figure 2. Systemic Events, by Maximum Severity - Safety Population (Maternal)



Note: Human immunodeficiency virus (HIV)-positive participants are not included in this figure. Analyses for HIV-positive participants and their infants will be listed separately.
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Additional data (for maternal participants) are presented in the following:

Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Safety Population (Maternal)	Supplemental Table 14.72
Duration (Days) From First to Last Day of Systemic Events After Each Dose – Safety Population (Maternal)	Supplemental Table 14.73
Onset Days (Days) for Systemic Events After Each Dose – Safety Population (Maternal)	Supplemental Table 14.74
Participants Reporting Baseline Systemic Events, by Severity – Safety Population (Maternal)	Supplemental Table 14.75, Supplemental Figure 14.9

5.3.2.1. HIV-Positive Participants

Among HIV-positive participants, systemic events were reported at numerically higher frequencies after Dose 1 in the placebo group compared to the BNT162b2 group; however, systemic events were reported at generally similar frequencies after Dose 2 in the two

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vaccine groups. In both the BNT162b2 and placebo groups, the most frequently reported systemic events after any dose were fatigue (≤66.7% and ≤60.0%, respectively) and headache (≤41.7% and ≤60.0%, respectively). No Grade 4 systemic events were reported in either group. As this subgroup included a limited number of participants, these results should be interpreted with caution.

Additional data (for HIV-positive maternal participants) are presented in the following:

Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – HIV-Positive Participants - Safety Population (Maternal)	Supplemental Table 14.76

5.3.2.2. Subgroup Analyses

Systemic events reported within 7 days after vaccination were evaluated by race, ethnicity, and baseline SARS-CoV-2 status. Among vaccinated participants, no clinically meaningful differences were observed by race, ethnicity, or SARS-CoV-2 status in either group. As several subgroups included a limited number of participants, these results should be interpreted with caution.

Additional data (for maternal participants) are presented in the following:

Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Race – Safety Population (Maternal) (Race: White, Black or African American, All Others)	Supplemental Tables 14.77-14.79
Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Ethnicity – Safety Population (Maternal) (Ethnicity: Hispanic/Latino, Non-Hispanic/Non-Latino)	Supplemental Tables 14.80-14.81
Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Safety Population (Maternal) (Baseline SARS-CoV-2 Status: Positive, Negative, Missing)	Supplemental Tables 14.82-14.84
Listing of All Systemic Events (Maternal)	Appendix 16.2.7.4
Listing of Severe and Grade 4 Systemic Events (Maternal)	Appendix 16.2.7.5

5.3.3. Adverse Events

5.3.3.1. Summary of Adverse Events

5.3.3.1.1. Overview of Adverse Events by Category

5.3.3.1.1.1. Maternal Participants

From Dose 1 to 1 month after Dose 2 during the blinded follow-up period, the proportion of participants reporting any AE was similar in the BNT162b2 (23.6%) and placebo (22.7%) groups. Across both groups, any related, severe, or serious AEs were reported in ≤0.6%, ≤4.9%, and ≤5.6%, respectively. In the placebo group, life-threatening AEs were reported in 1.8% of participants (Table 20). Refer to the narratives in Section 14 for further details.

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No maternal participants had any AEs leading to withdrawal and none died from Dose 1 to 1 month after Dose 2 during the blinded follow-up period.

Table 20. Number (%) of Participants Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2 – Blinded Follow-Up Period – Safety Population (Maternal)

	Vaccine Group (as Administered)	
Adverse Event	BNT162b2 (30 µg) (N[a]=161) n[b] (%)	Placebo (N[a]=163) n[b] (%)
Any adverse event	38 (23.6)	37 (22.7)
Related[c]	1 (0.6)	1 (0.6)
Severe	7 (4.3)	8 (4.9)
Life-threatening	0	3 (1.8)
Any serious adverse event	9 (5.6)	9 (5.5)
Related[c]	0	0
Severe	5 (3.1)	4 (2.5)
Life-threatening	0	3 (1.8)
Any nonserious adverse event	33 (20.5)	33 (20.2)
Related[c]	1 (0.6)	1 (0.6)
Severe	2 (1.2)	4 (2.5)
Life-threatening	0	0
Any adverse event leading to withdrawal	0	0
Related[c]	0	0
Severe	0	0
Life-threatening	0	0
Death	0	0

Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary. Analyses for HIV-positive participants and their infants will be summarized separately.
Note: Nonserious adverse events related to study intervention with onset within 7 days (excluding immediate adverse event and adverse events leading to withdrawal) after vaccination and identified as reactogenicity events were excluded from the analysis of adverse events. These events were included in the analysis of reactogenicity events.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event category. For "any adverse event," n = the number of participants reporting at least 1 occurrence of any adverse event.
c. Assessed by the investigator as related to investigational product.
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5.3.3.1.1.1.1. Participants Randomized to Placebo and Who Received BNT162b2 After Unblinding

In maternal participants originally randomized to placebo who received BNT162b2 after unblinding at 1 month postdelivery (Section 4.1.1), an overview of AEs reported from the first dose of BNT162b2 to 1 month after the second dose of BNT162b2 is provided in Table 21. Note that these participants did not use an e-diary to record local reactions or systemic events occurring within 7 days of vaccination after receipt of BNT162b2 after unblinding at 1 month postdelivery, and all such events were reported as AEs.

The frequency of AEs reported among participants who originally received placebo and then received BNT162b2 after unblinding (22.2%) was similar to that in the BNT162b2 group during the blinded follow-up period (23.6%; Table 20), and overall the results did not suggest any meaningful differences in types of AEs reported.

From vaccination with BNT162b2 to 1 month after the second dose of BNT162b2 for original placebo participants who then received BNT162b2 after unblinding, there were no reported SAEs, life-threatening AEs, AEs leading to withdrawal, or deaths. Except for 1 participant, all AEs were mild or moderate in severity. Related AEs were reported in 12.5% of participants. As discussed in Section 5.3.3.1.2.1.1, the most frequently reported AEs in these participants unblinded at 1 month postdelivery were reactogenicity events.

Table 21. Number (%) of Participants Reporting at Least 1 Adverse Event From the First Dose of BNT162b2 to 1 Month After the Second Dose of BNT162b2 – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population (Maternal)

	Vaccine Group (as Administered)
Adverse Event	BNT162b2 (30 µg) (N[a]=144) n[b] (%)
Any adverse event	32 (22.2)
Related[c]	18 (12.5)
Severe	1 (0.7)
Life-threatening	0
Any serious adverse event	0
Related[c]	0
Severe	0
Life-threatening	0
Any nonserious adverse event	32 (22.2)
Related[c]	18 (12.5)
Severe	1 (0.7)
Life-threatening	0
Any adverse event leading to withdrawal	0
Related[c]	0

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Table 21. Number (%) of Participants Reporting at Least 1 Adverse Event From the First Dose of BNT162b2 to 1 Month After the Second Dose of BNT162b2 – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population (Maternal)

	Vaccine Group (as Administered)
	BNT162b2 (30 µg) (N[a]=144)
Adverse Event	n[b] (%)
Severe	0
Life-threatening	0
Death	0

Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary. Analyses for HIV-positive participants and their infants will be listed separately.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event category. For "any adverse event," n = the number of participants reporting at least 1 occurrence of any adverse event.
c. Assessed by the investigator as related to investigational product.
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5.3.3.1.1.2. HIV-Positive Participants

Among HIV-positive participants, AEs were reported in 16.7% of participants in the BNT162b2 group and 40.0% of participants in the placebo group. Most AEs were mild or moderate in severity (1 severe event was reported in the BNT162b2 group), and none were assessed as related. SAEs were reported in ≤10.0% between both groups. No life-threatening AEs were reported.

Additional data (for HIV-positive maternal participants) are presented in the following:

Number (%) of Participants Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2 – HIV-Positive Participants – Blinded Follow-Up Period - Safety Population (Maternal)	Supplemental Table 14.85

5.3.3.1.1.3. Subgroup Analyses

AEs reported in maternal participants from Dose 1 to 1 month after Dose 2 were evaluated by race, ethnicity, and SARS-CoV-2 status. Overall, results for both the BNT162b2 and placebo groups suggested no clinically meaningful differences across subgroups. As several subgroups included a limited number of participants, these results should be interpreted with caution.

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Additional data (for maternal participants) are presented in the following:

Number (%) of Participants Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by Race – Blinded Follow-Up Period – Safety Population (Maternal) (Race: White, Black or African American, All Others)	Supplemental Tables 14.86-14.88
Number (%) of Participants Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by Ethnicity – Blinded Follow-Up Period – Safety Population (Maternal) (Ethnicity: Hispanic/Latino, Non-Hispanic/Non-Latino)	Supplemental Tables 14.89-14.90
Number (%) of Participants Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2 , by Baseline SARS-CoV-2 Status – Blinded Follow-Up Period - Safety Population (Maternal) (Baseline SARS-CoV-2 Status: Positive, Negative, Missing)	Supplemental Tables 14.91-14.93

5.3.3.1.1.4. Infant Participants

The proportions of infant participants with any AEs reported from birth to 1 month of age were similar in the BNT162b2 (35.3%) and placebo (37.1%) groups (Table 22). Most AEs were mild or moderate in severity (≤6.3% were severe between both groups), and none were assessed by the investigator as related. Between both groups, SAEs were reported in ≤13.8% and life-threatening AEs were reported in and ≤3.1% of infants.

One infant participant in the placebo group was withdrawn due to a fatal SAE of neonatal pneumonia that was assessed by the investigator as unrelated to study intervention. Additionally, 1 infant born to an HIV-positive maternal participant in the BNT162b2 group was withdrawn due to a fatal SAE of pneumonia that was also assessed as unrelated to study intervention by the investigator (Appendix 16.2.7.10.2). These events are discussed in Section 5.3.3.2.2 and the narratives in Section 14.

Table 22. Number (%) of Participants Reporting at Least 1 Adverse Event From Birth to 1 Month of Age – Safety Population (Infant)

	Maternal Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=156)	Placebo (N[a]=159)
Adverse Event	n[b] (%)	n[b] (%)
Any adverse event	55 (35.3)	59 (37.1)
Related[c]	0	0
Severe	5 (3.2)	10 (6.3)
Life-threatening	1 (0.6)	5 (3.1)
Any serious adverse event	19 (12.2)	22 (13.8)
Related[c]	0	0
Severe	5 (3.2)	8 (5.0)

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Table 22. Number (%) of Participants Reporting at Least 1 Adverse Event From Birth to 1 Month of Age – Safety Population (Infant)

	Maternal Vaccine Group (as Administered)	
Adverse Event	BNT162b2 (30 µg) (N[a]=156) n[b] (%)	Placebo (N[a]=159) n[b] (%)
Life-threatening	1 (0.6)	5 (3.1)
Any nonserious adverse event	42 (26.9)	44 (27.7)
Related[c]	0	0
Severe	0	2 (1.3)
Life-threatening	0	0
Any adverse event leading to withdrawal	0	1 (0.6)
Related[c]	0	0
Severe	0	0
Life-threatening	0	1 (0.6)
Death	0	1 (0.6)

Note: Infants born to human immunodeficiency virus (HIV)-positive participants are not included in this summary. Analyses for HIV-positive participants and their infants will be listed separately.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event category. For "any adverse event," n = the number of participants reporting at least 1 occurrence of any adverse event.
c. Assessed by the investigator as related to investigational product.
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5.3.3.1.2. Adverse Events by System Organ Class and Preferred Term

5.3.3.1.2.1. Maternal Participants

AEs in maternal participants from Dose 1 to 1 month after Dose 2 that were most frequently reported for the BNT162b2 group were in the SOCs of pregnancy, puerperium and perinatal conditions (9.3%), infections and infestations (5.0%), and gastrointestinal disorders (4.3%); in the placebo group, AEs were reported in these SOCs for pregnancy, puerperium and perinatal conditions (9.2%), gastrointestinal disorders (6.1%), infections and infestations (2.5%), and blood and lymphatic system disorders (2.5%), respectively. The frequency of AEs reported by PT was generally similar between the BNT162b2 and placebo groups.

Few Tier 2 AEs[1] were reported in maternal participants from Dose 1 to 1 month after Dose 2. In the BNT162b2 group, most Tier 2 AEs were reported in 2 participants each.

[1] A MedDRA PT is defined as a Tier 2 event if there are at least 1% of participants in at least 1 vaccine group reporting the event.

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Additional data (for maternal participants) are presented in the following:

Number (%) of Participants Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population (Maternal)	Supplemental Table 14.94
Tier 2 Adverse Events Reported From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population (Maternal)	Supplemental Table 14.95

5.3.3.1.2.1.1. Participants Randomized to Placebo and Who Received BNT162b2 After Unblinding

In maternal participants originally randomized to placebo, who received BNT162b2 after unblinding at 1 month postdelivery, AEs reported from the first dose of BNT162b2 to 1 month after the second dose of BNT162b2 were most frequently in the SOCs of general disorders and administration site conditions (13.2%), infections and infestations (6.9%), and nervous system disorders (5.6%). The few AEs reported in >1 participant were primarily reactogenicity events; the most frequently reported were injection site pain (9.0%) and headache (4.9%).

Additional data (for maternal participants) are presented in the following:

Number (%) of Participants Reporting at Least 1 Adverse Event From First Dose of BNT162b2 to 1 Month After the Second Dose of BNT162b2, by System Organ Class and Preferred Term – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population (Maternal)	Supplemental Table 14.96

5.3.3.1.2.1.2. HIV-Positive Participants

There were few HIV-positive maternal participants with AEs reported during the study; most were in the placebo group. None of the AEs was assessed as related.

Additional data (for HIV-positive maternal participants) are presented in the following:

Number (%) of Participants Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2 – by System Organ Class and Preferred Term - HIV-Positive Participants – Blinded Follow-Up Period - Safety Population (Maternal)	Supplemental Table 14.97
Listing of Adverse Events (Maternal)	Appendix 16.2.7.7.1

5.3.3.1.2.1.3. Subgroup Analyses

AEs, by SOC and PT, reported in maternal participants from Dose 1 to 1 month after Dose 2 were evaluated by race, ethnicity, and baseline SAR-CoV-2 status. Overall, results for both the BNT162b2 and placebo groups suggested no clinically meaningful differences across

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subgroups. As several subgroups included a limited number of participants, these results should be interpreted with caution.

Additional data (for maternal participants) are presented in the following:

Number (%) of Participants Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – Blinded Follow-Up Period – Safety Population (Maternal) (Race: White, Black or African American, All Others)	Supplemental Tables 14.98-14.100
Number (%) of Participants Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – Blinded Follow-Up Period – Safety Population (Maternal) (Ethnicity: Hispanic/Latino, Non-Hispanic/Non-Latino)	Supplemental Tables 14.101-14.102
Number (%) of Participants Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Blinded Follow-Up Period – Safety Population (Maternal) (Baseline SARS-CoV-2 Status: Positive, Negative, Missing)	Supplemental Tables 14.103-14.105

5.3.3.1.2.2. Infant Participants

AEs in infant participants from birth to 1 month of age that were most frequently reported for the BNT162b2 group were in the SOCs of pregnancy, puerperium and perinatal conditions (16.7%) and congenital, familial and genetic disorders (10.3%); in the placebo group, AEs were reported in these SOCs for 19.5% and 5.0%, respectively. In the BNT162b2 group, most AEs were reported in 1 participant each. The most frequently reported AE in the BNT162b2 group was jaundice neonatal (12.2%), which was reported similarly in the placebo group (10.7%).

Tier 2 AEs[2] were reported at similar frequencies between the BNT162b2 and placebo groups (53 and 61 participants, respectively). In the BNT162b2 group, most Tier 2 AEs were reported in 1 to 3 participants each.

Additional data (for infant participants) are presented in the following:

Number (%) of Participants Reporting at Least 1 Adverse Event From Birth to 1 Month of Age, by System Organ Class and Preferred Term – Safety Population (Infant)	Supplemental Table 14.106
Tier 2 Adverse Events Reported From Birth to 1 Month of Age, by System Organ Class and Preferred Term – Safety Population (Infant)	Supplemental Table 14.107

[2] A MedDRA PT is defined as a Tier 2 event if there are at least 1% of participants in at least 1 vaccine group reporting the event.

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5.3.3.1.2.2.1. Infants Born to HIV-Positive Participants

There were few infants born to HIV-positive maternal participants with AEs reported during the study; most were born to mothers in the placebo group. None of the AEs were assessed as related. One infant born to an HIV-positive participant maternal participant in the BNT162b2 group had a fatal SAE of pneumonia that was assessed by the investigator as not related. Refer to Section 5.3.3.2.2 and the narratives in Section 14 for further details.

Additional data for infants born to HIV-positive participants are presented in the following:

Number (%) of Participants Reporting at Least 1 Adverse Event From Birth to 1 Month of Age, by System Organ Class and Preferred Term – Born to HIV-Positive Maternal Participants – Safety Population (Infant)	Supplemental Table 14.108
Listing of Adverse Events (Infant)	Appendix 16.2.7.7.2

5.3.3.1.2.2.2. Subgroup Analyses

AEs reported in infant participants from birth to 1 month of age were evaluated by breastfeeding status. The majority of AEs were reported in infants who were breastfed, which comprised the majority of the safety population (Section 4.3.2). The frequency of AE reported in the BNT162b2 (37.3%) and placebo (36.3%) groups were similar to those in the main analyses (35.3% and 37.1%, respectively; Table 22). Overall, the results did not suggest clinically meaningful differences in AEs by breastfeeding status; however, these results should be interpreted with caution due to a limited number of infant participants who were not breastfed.

Additional data (for infant participants) are presented in the following:

Number (%) of Participants Reporting at Least 1 Adverse Event From Birth to 1 Month of Age, by System Organ Class and Preferred Term, by Breastfeeding Status – Safety Population (Infant) (Breastfeeding Status: Yes, No, Missing)	Supplemental Tables 14.109-14.111

5.3.3.1.3. Related Adverse Events

5.3.3.1.3.1. Maternal Participants

Two maternal participants reported AEs from Dose 1 to 1 month after Dose 2 that were assessed by the investigator as related to study intervention: 1 (0.6%) event of tachypnoea in the BNT162b2 group and 1 (0.6%) event of injection site pain in the placebo group (Table 23). Neither of the two related AEs were SAEs or AEs which led to withdrawal (Table 20).

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Table 23. Number (%) of Participants Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population (Maternal)

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=161)		Placebo (N[a]=163)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	1 (0.6)	(0.0, 3.4)	1 (0.6)	(0.0, 3.4)
General disorders and administration site conditions	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Injection site pain	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Respiratory, thoracic and mediastinal disorders	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Tachypnoea	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)

Note: MedDRA (v25.1) coding dictionary applied.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary. Analyses of HIV-positive participants and their infants will be listed separately.
Note: Nonserious adverse events related to study intervention with onset within 7 days (excluding immediate adverse event and adverse events leading to withdrawal) after vaccination and identified as reactogenicity events were excluded from the analysis of adverse events. These events were included in the analysis of reactogenicity events.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event. For "Any event," n = number of participants reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
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5.3.3.1.3.2. Infant Participants

In infant participants, none of the AEs reported from birth to 1 month of age were assessed as related to study intervention by the investigator.

5.3.3.1.4. Immediate Adverse Events – Maternal Participants

In maternal participants, there were no immediate AEs reported within 30 minutes after receiving Dose 1. After Dose 2, 1 participant in the placebo group reported an immediate AE of injection site pain.

5.3.3.1.4.1. Participants Randomized to Placebo and Who Received BNT162b2 After Unblinding

In maternal participants who were originally randomized to placebo and then received BNT162b2 after unblinding at 1 month postdelivery, there were no immediate AEs reported after the first or second dose of BNT162b2.

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Additional data (for maternal participants) are presented in the following:

Number (%) of Participants Reporting at Least 1 Immediate Adverse Event After Dose 2, by System Organ Class and Preferred Term – Safety Population (Maternal)	Supplemental Table 14.112

5.3.3.1.5. Severe and Life-Threatening Adverse Events

5.3.3.1.5.1. Maternal Participants

In maternal participants, the frequencies of severe or life-threatening events reported from Dose 1 to 1 month after Dose 2 were low (≤4.9%) across the BNT162b2 and placebo groups (Table 20).

Severe AEs were reported by 7 participants (4.3%) in the BNT162b2 group and 8 participants (4.9%) in the placebo group from Dose 1 to 1 month after Dose 2. In the BNT162b2 group, severe AEs were mostly reported by 1 participant each and were most frequently reported (≤2 participants) in the SOCs of pregnancy, puerperium and perinatal conditions and infections and infestations. The few severe AEs that were SAEs were similar in frequency between groups (5 [3.1%] participants in the BNT162b2 group, 4 [2.5%] participants in the placebo group), and none were assessed by the investigator as related (Section 5.3.3.3.1 and Table 20).

Life-threatening AEs were reported by no participants in the BNT162b2 group and 3 participants (1.8%) in the placebo group from Dose 1 to 1 month after Dose 2. In the placebo group, life-threatening AEs were reported in 1 participant each and were most frequently reported in the SOC of pregnancy, puerperium and perinatal conditions. The few life-threatening AEs that were reported were all SAEs (3 [1.8%] participants in the placebo group), and none were assessed by the investigator as related (Table 20).

Additional data (for maternal participants) are presented in the following:

Number (%) of Participants Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population (Maternal)	Supplemental Table 14.113
Number (%) of Participants Reporting at Least 1 Life-Threatening Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population (Maternal)	Supplemental Table 14.114
Listing of Serious Adverse Events (Maternal)	Appendix 16.2.7.9.1

5.3.3.1.5.2. Infant Participants

In infants participants, the frequencies of severe or life-threatening events reported from birth to 1 month of age were low (≤6.3%) across the BNT162b2 and placebo groups (Table 22).

Severe AEs were reported by 5 participants (3.2%) in the BNT162b2 group and 10 participants (6.3%) in the placebo group from birth to 1 month of age. In the BNT162b2

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group, severe AEs were reported in 1 participant each and were most frequently reported (≤3 participants) in the SOCs of congenital, familial and genetic disorders and pregnancy, puerperium and perinatal conditions. The few severe AEs that were SAEs were similar in frequency between groups (5 [3.2%] participants in the BNT162b2 group, 8 [5.0%] participants in the placebo group), and none were assessed by the investigator as related (Section 5.3.3.3.2 and Table 22).

Life-threatening AEs that were SAEs were reported by 1 participant (0.6%) in the BNT162b2 group and 5 participants (3.1%) in the placebo group from birth to 1 month of age. In the BNT162b2 group, a life-threatening AE of pyelonephritis acute was reported in 1 participant in the SOC of infections and infestations. None of the events were assessed by the investigator as related (Table 22).

Additional data (for infant participants) are presented in the following:

Number (%) of Participants Reporting at Least 1 Severe Adverse Event From Birth to 1 Month of Age, by System Organ Class and Preferred Term – Safety Population (Infant)	Supplemental Table 14.115
Number (%) of Participants Reporting at Least 1 Life-Threatening Adverse Event From Birth to 1 Month of Age, by System Organ Class and Preferred Term – Safety Population (Infant)	Supplemental Table 14.116
Listing of Serious Adverse Events (Infant)	Appendix 16.2.7.9.2

5.3.3.2. Deaths

5.3.3.2.1. Maternal Participants

There were no deaths in maternal participants (Table 20; Appendix 16.2.7.8.1).

5.3.3.2.2. Infant Participants

One infant born at 32 weeks and 3 days gestational age, to a maternal participant in the placebo group, died at 7 days of age due to an SAE of neonatal pneumonia; the event duration was 7 days, and was assessed as not related by the investigator.

Additionally, one infant born at 40 weeks gestational age, to an HIV-positive maternal participant in the BNT162b2 group, died at 124 days of age due to an SAE of pneumonia; the event duration was 6 days, and was investigator-assessed as not related.

Refer to the narratives in Section 14 for further details.

Additional data (for infants) are presented in the following:

Listing of Deaths (Infant)	Appendix 16.2.7.8.2
Listing of Adverse Events (Infant)	Appendix 16.2.7.7.2

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5.3.3.3. Serious Adverse Events

5.3.3.3.1. Maternal Participants

For SAEs reported in maternal participants from Dose 1 to 1 month after Dose 2, the proportions were similar in the BNT162b2 (5.6%) and placebo (5.5%) groups; none were assessed by the investigator as related (Table 20).

For SAEs reported in maternal participants from Dose 1 through 1 month after delivery, the proportions were similar in the BNT162b2 (13.0%) and placebo (14.1%) groups (Table 24); none were assessed by the investigator as related. In the BNT162b2 group, SAEs were most frequently reported in the SOC of pregnancy, puerperium and perinatal conditions (8.1%), which were reported similarly in the placebo group (10.4%). By PT, all SAEs in the BNT162b2 group were reported in ≤4 participants respectively.

In maternal participants originally randomized to BNT162b2, there were no additional participants with SAEs reported from 1 month after delivery up to 6 months postdelivery.

Table 24. Number (%) of Participants Reporting at Least 1 Serious Adverse Event From Dose 1 Through 1 Month After Delivery, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population (Maternal)

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=161)		Placebo (N[a]=163)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	21 (13.0)	(8.3, 19.2)	23 (14.1)	(9.2, 20.4)
Cardiac disorders	1 (0.6)	(0.0, 3.4)	2 (1.2)	(0.1, 4.4)
Nonreassuring foetal heart rate pattern	0	(0.0, 2.3)	2 (1.2)	(0.1, 4.4)
Bradycardia foetal	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Gastrointestinal disorders	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Abdominal wall haematoma	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Hepatobiliary disorders	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Cholelithiasis	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Infections and infestations	3 (1.9)	(0.4, 5.3)	2 (1.2)	(0.1, 4.4)
Endometritis	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Lower respiratory tract infection	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Pneumonia	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Pyelonephritis	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Urinary tract infection	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Injury, poisoning and procedural complications	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Urinary tract procedural complication	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Investigations	0	(0.0, 2.3)	2 (1.2)	(0.1, 4.4)

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Table 24. Number (%) of Participants Reporting at Least 1 Serious Adverse Event From Dose 1 Through 1 Month After Delivery, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population (Maternal)

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=161)		Placebo (N[a]=163)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Foetal heart rate abnormal	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Ultrasound foetal abnormal	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Musculoskeletal and connective tissue disorders	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Osteoarthritis	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Pregnancy, puerperium and perinatal conditions	13 (8.1)	(4.4, 13.4)	17 (10.4)	(6.2, 16.2)
Pre-eclampsia	4 (2.5)	(0.7, 6.2)	2 (1.2)	(0.1, 4.4)
Foetal distress syndrome	3 (1.9)	(0.4, 5.3)	2 (1.2)	(0.1, 4.4)
Cephalo-pelvic disproportion	1 (0.6)	(0.0, 3.4)	3 (1.8)	(0.4, 5.3)
Premature separation of placenta	0	(0.0, 2.3)	3 (1.8)	(0.4, 5.3)
Foetal hypokinesia	1 (0.6)	(0.0, 3.4)	1 (0.6)	(0.0, 3.4)
Gestational hypertension	1 (0.6)	(0.0, 3.4)	1 (0.6)	(0.0, 3.4)
Postpartum haemorrhage	0	(0.0, 2.3)	2 (1.2)	(0.1, 4.4)
Arrested labour	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Breech presentation	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Failed induction of labour	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Foetal growth restriction	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Haemorrhage in pregnancy	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Meconium in amniotic fluid	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Meconium stain	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Omphalorrhexis	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Placental insufficiency	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Preterm premature rupture of membranes	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Prolonged rupture of membranes	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Retained placenta or membranes	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Reproductive system and breast disorders	2 (1.2)	(0.2, 4.4)	0	(0.0, 2.2)
Uterine disorder	2 (1.2)	(0.2, 4.4)	0	(0.0, 2.2)
Skin and subcutaneous tissue disorders	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Pruritus	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Vascular disorders	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Deep vein thrombosis	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)

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Table 24. Number (%) of Participants Reporting at Least 1 Serious Adverse Event From Dose 1 Through 1 Month After Delivery, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population (Maternal)

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=161)		Placebo (N[a]=163)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])

Note: MedDRA (v25.1) coding dictionary applied.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary. Analyses of HIV-positive participants and their infants will be summarized separately.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event. For "any event," n = number of participants reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 03MAY2023 (10:43) Output File: ./nda3/C4591015_BR/adae_s130_immd_vax1_all_p3_saf

Additional data (for maternal participants) are presented in the following:

Number (%) of Participants Reporting at Least 1 Severe Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population (Maternal)	Supplemental Table 14.117
Number (%) of Participants Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months Postdelivery, by System Organ Class and Preferred Term – Participants Originally Received BNT162b2 – Blinded and Open-Label Follow-Up Period – Safety Population (Maternal)	Supplemental Table 14.118

5.3.3.3.1.1. Participants Randomized to Placebo and Who Received BNT162b2 After Unblinding

In maternal participants originally randomized to placebo, who received BNT162b2 after unblinding at 1 month postdelivery, from the first dose of BNT162b2 to 1 month after the second dose of BNT162b2 there were no SAEs reported (Appendix 16.2.7.9.1).

5.3.3.3.1.2. HIV-Positive Participants

There were few HIV-positive maternal participants with SAEs reported from Dose 1 through 1 month after delivery; most were in the placebo group. None of the SAEs were assessed as related. As this subgroup included a limited number of participants, these results should be interpreted with caution.

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Additional data (for HIV-positive maternal participants) are presented in the following:

Number (%) of Participants Reporting at Least 1 Serious Adverse Event From Dose 1 Through 1 Month After Delivery, by System Organ Class and Preferred Term – HIV-Positive Participants – Blinded Follow-Up Period – Safety Population (Maternal)	Supplemental Table 14.119
Listing of Serious Adverse Events (Maternal)	Appendix 16.2.7.9.1

5.3.3.3.1.3. Subgroup Analyses

SAEs reported in maternal participants from Dose 1 through 1 month after delivery were evaluated by race, ethnicity, and SARS-CoV-2 status. Overall, results for both the BNT162b2 and placebo groups suggested no clinically meaningful differences across subgroups. As several subgroups included a limited number of participants, these results should be interpreted with caution.

Additional data (for maternal participants) are presented in the following:

Number (%) of Participants Reporting at Least 1 Serious Adverse Event From Dose 1 Through 1 Month After Delivery, by System Organ Class and Preferred Term, by Race - Blinded Follow-Up Period – Safety Population (Maternal) (Race: White, Black or African American, All Others)	Supplemental Tables 14.120-14.122
Number (%) of Participants Reporting at Least 1 Serious Adverse Event From Dose 1 Through 1 Month After Delivery, by System Organ Class and Preferred Term, by Ethnicity - Blinded Follow-Up Period – Safety Population (Maternal) (Ethnicity: Hispanic/Latino, Non-Hispanic/Non-Latino)	Supplemental Tables 14.123-14.124
Number (%) of Participants Reporting at Least 1 Serious Adverse Event From Dose 1 Through 1 Month After Delivery, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status - Blinded Follow-Up Period – Safety Population (Maternal) (Baseline SARS-CoV-2 Status: Positive, Negative, Missing)	Supplemental Tables 14.125-14.127
Listing of Serious Adverse Events (Maternal)	Appendix 16.2.7.9.1

5.3.3.3.2. Infant Participants

From birth to 1 month of age, SAEs were reported in 12.2% and 13.8% of infant participants in the BNT162b2 and placebo groups, respectively; none were assessed by the investigator as related (Table 22).

From birth to 6 months of age, SAEs were reported in 13.5% and 15.1% of infant participants in the BNT162b2 and placebo groups, respectively (Table 25); none was assessed by the investigator as related. In the BNT162b2 group, SAEs were most frequently reported in the SOCs of pregnancy, puerperium and perinatal conditions (5.8%) and congenital, familial and genetic disorders (5.8%), which were reported at similar frequencies

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in the placebo group (3.1% and 3.1%, respectively). By PT, all SAEs in the BNT162b2 group were reported in ≤3 participants each, except for jaundice neonatal (7 participants).

In the placebo group, an SAE of neonatal pneumonia, assessed by the investigator as not related, was fatal (Appendix 16.2.7.9.2). Refer to Section 5.3.3.2.2 and the narratives in Section 14 for further details.

Table 25. Number (%) of Participants Reporting at Least 1 Serious Adverse Event From Birth to 6 Months of Age, by System Organ Class and Preferred Term – Safety Population (Infant)

	Maternal Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=156)		Placebo (N[a]=159)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	21 (13.5)	(8.5, 19.8)	24 (15.1)	(9.9, 21.6)
Blood and lymphatic system disorders	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Coagulopathy	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Thrombocytopenia	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Congenital, familial and genetic disorders	9 (5.8)	(2.7, 10.7)	5 (3.1)	(1.0, 7.2)
Atrial septal defect	3 (1.9)	(0.4, 5.5)	1 (0.6)	(0.0, 3.5)
Ankyloglossia congenital	0	(0.0, 2.3)	2 (1.3)	(0.2, 4.5)
Congenital rubella syndrome	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Congenital skin dimples	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
DiGeorge's syndrome	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Microcephaly	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Mucopolysaccharidosis	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Patent ductus arteriosus	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Polydactyly	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Syndactyly	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Trisomy 21	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Ventricular septal defect	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Gastrointestinal disorders	1 (0.6)	(0.0, 3.5)	3 (1.9)	(0.4, 5.4)
Allergic colitis	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Allergic gastroenteritis	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Dysphagia	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Intestinal perforation	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Meconium plug syndrome	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Pneumoperitoneum	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Hepatobiliary disorders	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Hyperbilirubinaemia neonatal	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Infections and infestations	4 (2.6)	(0.7, 6.4)	6 (3.8)	(1.4, 8.0)
Bronchiolitis	2 (1.3)	(0.2, 4.6)	1 (0.6)	(0.0, 3.5)

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Table 25. Number (%) of Participants Reporting at Least 1 Serious Adverse Event From Birth to 6 Months of Age, by System Organ Class and Preferred Term – Safety Population (Infant)

	Maternal Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=156)		Placebo (N[a]=159)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Neonatal pneumonia	1 (0.6)	(0.0, 3.5)	1 (0.6)	(0.0, 3.5)
Sepsis neonatal	0	(0.0, 2.3)	2 (1.3)	(0.2, 4.5)
Pneumonia respiratory syncytial viral	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Pyelonephritis	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Pyelonephritis acute	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Sepsis	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Injury, poisoning and procedural complications	0	(0.0, 2.3)	2 (1.3)	(0.2, 4.5)
Injury to brachial plexus due to birth trauma	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Traumatic intracranial haemorrhage	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Investigations	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Cardiac murmur	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Metabolism and nutrition disorders	0	(0.0, 2.3)	2 (1.3)	(0.2, 4.5)
Hypoglycaemia neonatal	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Metabolic acidosis	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Nervous system disorders	1 (0.6)	(0.0, 3.5)	2 (1.3)	(0.2, 4.5)
Coma	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Encephalopathy neonatal	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Hypoxic-ischaemic encephalopathy	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Nervous system disorder	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Seizure	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Pregnancy, puerperium and perinatal conditions	9 (5.8)	(2.7, 10.7)	5 (3.1)	(1.0, 7.2)
Jaundice neonatal	7 (4.5)	(1.8, 9.0)	4 (2.5)	(0.7, 6.3)
Caput succedaneum	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Low birth weight baby	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Premature baby	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Small for dates baby	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Weight decrease neonatal	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Renal and urinary disorders	1 (0.6)	(0.0, 3.5)	1 (0.6)	(0.0, 3.5)
Renal tubular necrosis	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Vesicoureteric reflux	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Respiratory, thoracic and mediastinal disorders	2 (1.3)	(0.2, 4.6)	8 (5.0)	(2.2, 9.7)
Meconium aspiration syndrome	2 (1.3)	(0.2, 4.6)	0	(0.0, 2.3)
Neonatal respiratory distress	0	(0.0, 2.3)	2 (1.3)	(0.2, 4.5)
Hypoxia	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Neonatal pneumothorax	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Neonatal respiratory distress syndrome	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Neonatal respiratory failure	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)

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Table 25. Number (%) of Participants Reporting at Least 1 Serious Adverse Event From Birth to 6 Months of Age, by System Organ Class and Preferred Term – Safety Population (Infant)

System Organ Class Preferred Term	Maternal Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=156)		Placebo (N[a]=159)	
	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Pulmonary hypertension	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Respiratory distress	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Respiratory failure	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Tachypnoea	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Vascular disorders	0	(0.0, 2.3)	2 (1.3)	(0.2, 4.5)
Hypoperfusion	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Hypotension	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Shock	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Subgaleal haemorrhage	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)

Note: MedDRA (v25.1) coding dictionary applied.
Note: Infants born to human immunodeficiency virus (HIV)-positive participants are not included in this summary. Analyses for HIV-positive participants and their infants will be summarized separately.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event. For "any event," n = number of participants reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
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Additional data (for infant participants) are presented in the following:

Number (%) of Participants Reporting at Least 1 Serious Adverse Event From Birth to 6 Months of Age, by System Organ Class and Preferred Term, by Breast Feeding Status – Safety Population (Infant) (Breastfeeding Status: Yes, No, Missing)	Supplemental Tables 14.128-14.130
Listing of Serious Adverse Events (Infant)	Appendix 16.2.7.9.2

5.3.3.3.2.1. Infants Born to HIV-Positive Participants

From birth to 6 months of age, SAEs were reported in 9.1% and 22.2% of infants born to HIV-positive participants in the BNT162b2 and placebo groups, respectively (Supplemental Table 14.131); none were assessed by the investigator as related. One infant born to an HIV-positive participant in the BNT162b2 group had a fatal SAE of pneumonia that was assessed by the investigator as not related to study vaccine (Appendix 16.2.7.9.2). Refer to Section 5.3.3.2.2 and the narratives in Section 14 for further details.

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5.3.3.4. Discontinuations from Study Due to Adverse Events

5.3.3.4.1. Maternal Participants

There were no maternal participants who were withdrawn due to AEs (Appendix 16.2.7.10.1).

5.3.3.4.2. Infant Participants

In the placebo group, 1 infant was withdrawn due to a fatal SAE of neonatal pneumonia that was assessed by the investigator as not related. Additionally, 1 infant born to an HIV-positive participant maternal participant in the BNT162b2 group was withdrawn due to a fatal SAE of pneumonia that was assessed by the investigator as not related (Appendix 16.2.7.10.2). Refer to Section 5.3.3.2.2 and the narratives in Section 14 for further details.

5.3.3.5. Adverse Events of Special Interest

Protocol-defined AESIs for maternal and infant participants (Appendix 16.1.1, Protocol Section 8.3.8) are summarized below.

5.3.3.5.1. Maternal Participants

No protocol-defined AESIs were reported in maternal participants during the study (before or after unblinding).

5.3.3.5.2. Infant Participants

In infant participants, there were no reports of myocarditis or pericarditis (Appendix 16.2.7.9.2).

Overall, there were few other protocol-defined AESIs reported in infants from birth to 6 months of age. Numerical differences between infant participants with reported congenital anomalies were observed between groups, with anomalies reported in 8 participants in the BNT162b2 group and 2 in the placebo group (Table 26). None of the events were assessed by the investigator as related. All participants with reported AESIs were breastfed.

Table 26. Number (%) and Comparison of Participants Reporting at Least 1 Adverse Events of Special Interest From Birth to 6 Months of Age, by System Organ Class and Preferred Term – Safety Population (Infant)

	Maternal Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]= 156)		Placebo (N[a]= 159)		Difference	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	%[d]	(95% CI[e])
Congenital, familial and genetic disorders	8 (5.1)	(2.2, 9.9)	2 (1.3)	(0.2, 4.5)	3.9	(-0.0, 8.7)
Atrial septal defect	3 (1.9)	(0.4, 5.5)	1 (0.6)	(0.0, 3.5)	1.3	(-1.7, 5.0)
DiGeorge's syndrome	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)	0.6	(-1.7, 3.5)

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Table 26. Number (%) and Comparison of Participants Reporting at Least 1 Adverse Events of Special Interest From Birth to 6 Months of Age, by System Organ Class and Preferred Term – Safety Population (Infant)

System Organ Class Preferred Term	Maternal Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]= 156) n[b] (%)	 (95% CI[c])	 Placebo (N[a]= 159) n[b] (%)	 (95% CI[c])	Difference %[d]	 (95% CI[e])
Microcephaly	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)	0.6	(-1.7, 3.5)
Mucopolysaccharidosis	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)	0.6	(-1.7, 3.5)
Patent ductus arteriosus	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)	-0.6	(-3.5, 1.8)
Syndactyly	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)	0.6	(-1.7, 3.5)
Trisomy 21	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)	0.6	(-1.7, 3.5)
Ventricular septal defect	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)	-0.6	(-3.5, 1.8)
Renal and urinary disorders	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)	0.6	(-1.7, 3.5)
Vesicoureteric reflux	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)	0.6	(-1.7, 3.5)

Note: MedDRA (v25.1) coding dictionary applied.
Note: Adverse event of special interest terms are from the COVID-19 program targeted medical event (TME) list dated 16Nov2022.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary. Analyses of HIV-positive participants and their infants will be listed separately.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event. For "Any event," n = number of participants reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
d. Difference in proportions, expressed as a percentage (BNT162b2 [30 µg] - placebo).
e. 2-Sided CI, based on the Miettinen and Nurminen method for the difference in proportions, expressed as a percentage.
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(Database snapshot date: Safety [29Mar2023], Immunogenicity [09Jan2024]) Output File: ./nda3/C4591015_CSR/adae_s130_specint_inf_dif

Additional data (for infant participants) are presented in the following:

Number (%) of Participants Reporting at Least 1 Adverse Event of Special Interest From Birth to 6 Months of Age, by System Organ Class and Preferred Term, by Breast Feeding Status – Safety Population (Infant) (Breastfeeding Status: Yes, No, Missing)	Supplemental Tables 14.132-14.134
Number (%) of Participants Reporting at Least 1 Adverse Event of Special Interest From Birth to 6 Months of Age, by System Organ Class and Preferred Term – Safety Population (Infant)	Supplemental Table 14.135

5.3.3.6. Other Significant Adverse Events – Maternal Participants

Analysis of specific events requested by the FDA are summarized below for maternal participants (Appendix 16.2.7.7.1):

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- **Anaphylaxis/hypersensitivity:** In the BNT162b2 group, there was 1 participant with hypersensitivity (allergy) of moderate severity that was reported 12 days after Dose 2, which was assessed by the investigator as not related to study intervention, and resolved within 3 days.

- **Bell's palsy:** There were no reported AEs of Bell's palsy in either vaccine group.

- **Appendicitis:** There were no reported AEs of appendicitis in either vaccine group.

- **Lymphadenopathy:** In the placebo group, there was 1 participant with lymphadenopathy (left axillary) of mild severity that was reported 2 days after Dose 1, which was assessed by the investigator as related, and resolved within 2 days. There were no reported AEs of axillary pain, lymph node pain, or lymphadenitis.

5.3.4. Other Safety Evaluations

5.3.4.1. Pregnancy Outcomes – Maternal Participants

Most maternal participants delivered via the vaginal route (69.0% in BNT162b2 and 66.1% in placebo), and fewer had an emergency Cesarean delivery (7.7% in BNT162b2 and 10.7% in placebo; Supplemental Table 14.136). For 1 HIV-positive participant in the BNT162b2 group, the outcome was a stillbirth (Appendix 16.2.7.7.1).

5.3.4.2. Birth Outcomes – Infant Participants

Most infants were born at term and had favorable newborn assessment outcomes. (Supplemental Table 14.137). Infant outcome was normal for 91.6% and 89.3% of infants born to maternal participants in the BNT162b2 and placebo groups, respectively. Infant participants born with a congenital malformation/anomaly were reported in 6.0% (95% CI: 2.9%, 10.7%) of participants in the BNT162b2 group and 3.6% (95% CI: 1.3%, 7.6%) of participants in the placebo group. Other neonatal problems were reported in 1.8% (95% CI: 0.4%, 5.2%) of participants in the BNT162b2 group and 6.5% (95% CI: 3.3%, 11.4%) of participants in the placebo group.

As this study included a limited number of infant participants, these results should be interpreted with caution.

5.4. Summary of Evaluation of Response to Study Intervention

5.4.1. Immunogenicity

Immunogenicity analysis of samples from both maternal participants and their infants was done for protocol-specified timepoints. SARS-CoV-2 neutralizing titers from the maternal participants were compared with age-matched nonpregnant participants from the C4591001 study at 1 month after Dose 2 of BNT162b2. Analyses were carried out separately for participants without evidence of prior infection from the baseline to 1 month after Dose 2, and for participants with and without evidence of prior infection. Model-adjusted GMRs were included in the analyses on participants with and without evidence of prior infection to minimize the confounding effect caused by imbalanced baseline SARS-CoV-2 status between the 2 studies.

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The immunogenicity outcomes for evaluable maternal participants in this study are as follows:

- The observed SARS-CoV-2 50% neutralizing GMT 1 month after Dose 2 was lower in the maternal participants without evidence of prior SARS-CoV-2 infection, when compared to similar nonpregnant female participants from Study C4591001, which is consistent with what has been observed in other maternal COVID vaccine studies across the wider literature [12-14].

- In the group inclusive of participants with prior evidence of SARS-CoV-2 infection, maternal participants had higher antibody levels than nonpregnant participants from Study C4591001. This observation is due to the higher prior SARS-CoV-2 infection rate in the maternal participants. After accounting for the baseline neutralizing titers, the model-adjusted SARS-CoV-2 50% neutralizing GMT in maternal participants was numerically lower than nonpregnant comparators.

- The SARS-CoV-2 50% neutralizing GMTs and full-length S-binding IgG GMCs for both participants without prior infection and those with or without prior infection were substantially higher in groups vaccinated with BNT162b2 versus the placebo group for all post-vaccination timepoints.

- The SARS-CoV-2 50% neutralizing GMT and full-length S-binding IgG GMC responses for both participants without prior infection and those with or without prior infection were highest 2 weeks after Dose 2 and dropped at the 6 month after Dose 2 timepoint. Antibody levels remained elevated in participants vaccinated with BNT162b2 at the 6 month timepoint compared to those observed in the placebo group at any previous timepoint.

- There was an increase in SARS-CoV-2 50% neutralizing GMTs and GMCs of full-length S-binding IgG from the Dose 1 prevaccination to the Dose 2 prevaccination time points; however, this increase was not as substantial as the increase observed after post-Dose 2.

The immunogenicity outcomes for evaluable infant participants in this study are as follows:

- Full-length S-binding IgG GMC levels at birth were higher in the infants born to vaccinated maternal participants than those born to participants in the placebo group. These concentrations dropped over the following 6 months but remained higher in infants born to vaccinated participants compared to those born to participants in the placebo group, even at the 6 month post-birth timepoint.

- Breastfed infants had marginally higher full-length S-binding IgG GMCs than non-breastfed infants at birth as well as 6-month post-birth timepoints.

Comparing the maternal and infant full-length S-binding IgG GMCs [4336.9 (95% CI: 3456.0, 5442.4) 1 month post-dose 2 and 5576.4 (95% CI: 4246.2, 7323.2) at birth respectively] indicates effective transplacental transfer of antibody.

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5.4.2. Efficacy

Secondary efficacy objectives included vaccine efficacy against the confirmed COVID-19 cases and against asymptomatic SARS-CoV-2 infection through 1 month after delivery. Due to the very small sample size resulted from early termination of enrollment, and hence number of COVID-19 cases, VE results are uninterpretable.

5.4.3. Safety

- BNT162b2 was safe and well-tolerated in maternal and infant participants.

- Among maternal participants who received BNT162b2, local reactions and systemic events following vaccination were predominantly mild to moderate in severity and short-lived (median duration 1.0 to 3.0 days). Reactogenicity after each dose was generally higher among participants in the BNT162b2 group compared to what was observed in the placebo group.

- The frequency of maternal participants with any AE reported from Dose 1 to 1 month after Dose 2 of BNT162b2 was similar to what was observed in the placebo group (23.6% and 22.7%, respectively). The frequency of participants reporting any SAE was low and comparable to what was reported in the placebo group (5.6% and 5.5%, respectively).

- The frequency of infant participants with any AE reported from birth to 1 month of age was comparable between those born to participants in the BNT162b2 and placebo groups (35.3% and 37%, respectively). From birth to 6 months, the frequency of infant participants for whom SAEs were reported was also similar (13.5% and 15.1%, respectively). None of the events was assessed as related by the investigator.

- No maternal participants had any AEs leading to withdrawal and none died. One infant born to an HIV-positive participant maternal participant in the BNT162b2 group was withdrawn due to a fatal SAE of pneumonia that was assessed by the investigator as not related to study intervention.

- Overall, there were few AESIs reported in infants from birth to 6 months of age. Numerical differences between infant participants with reported congenital anomalies were observed between groups, with anomalies reported in 8 participants in the BNT162b2 group and 2 in the placebo group. For each anomaly observed, the frequency difference between the BNT162b2 and placebo groups was low with 95% confidence intervals that encompassed zero. Apart from atrial septal defect, all anomalies were single occurrences. The clinical data were reviewed in the context of the available data on background rates of the observed congenital anomalies [15-23]. Taking this and the low number of events reported in this study into consideration, the findings were not determined to be indicative of a safety risk for infants.

- There were no reports of myocarditis or pericarditis in maternal or infant participants during the study.

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6. CONCLUSIONS

In this study, the reactogenicity, safety, and tolerability profile of BNT162b2 at 30 µg was found to be satisfactory in maternal participants.

BNT162b2 (30 µg) elicited robust immunogenicity responses in healthy pregnant women 18 years of age and older, with SARS-CoV-2 neutralizing titers that were notably higher compared to placebo; however, among those without SARS-CoV-2 infection, numerically lower GMTs were observed in the maternal participants compared to the selected nonpregnant female participants from Study C4591001. A similar pattern was shown in those with or without SARS-CoV-2 infection after adjusting the baseline neutralizing titers.

Infants born to vaccinated maternal participants had higher S-binding IgG concentrations at birth and at 6 months after delivery when compared to infants born to maternal participants from the placebo group. Breastfed infants had marginally higher antibody levels at 6 months after delivery than non-breastfed infants. No safety issues attributable to BNT162b2 exposure were identified in infants born to maternal participants who were vaccinated during pregnancy.

Overall, the data from this study support a favorable benefit risk profile in pregnant women and their infants.

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7. REFERENCES

1. World Health Organization. WHO Director-General's opening remarks at the media briefing on COVID-19. [Internet]. Available from: https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020. Published: 11 March 2020. Accessed: 01 April 2020.
2. Food and Drug Administration. Comirnaty and Pfizer-BioNTech COVID-19 vaccine. [Internet]. Available from: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine. Accessed: 28 Mar 2021.
3. Pfizer. Real-world evidence confirms high effectiveness of Pfizer-BioNTech COVID-19 vaccine and profound public health impact of vaccination one year after pandemic declared [press release]. [Internet]. Available from: https://www.pfizer.com/news/press-release/press-release-detail/real-world-evidence-confirms-high-effectiveness-pfizer. Accessed: 28 Mar 2021.
4. McGill COVID19 Vaccine Tracker Team. COVID19 vaccine tracker: Pfizer/BioNTech: BNT162b2. [Internet]. Available from: https://covid19.trackvaccines.org/vaccines/6/. Accessed: 28 Mar 2021.
5. Sutton D, Fuchs K, D'Alton M, et al. Universal Screening for SARS-CoV-2 in Women Admitted for Delivery. N Engl J Med. 2020;382(22):2163-64.
6. Ellington S, Strid P, Tong VT, et al. Characteristics of Women of Reproductive Age with Laboratory-Confirmed SARS-CoV-2 Infection by Pregnancy Status - United States, January 22-June 7, 2020. MMWR Morb Mortal Wkly Rep. 2020;69(25):769-75.
7. Yu N, Li W, Kang Q, et al. Clinical features and obstetric and neonatal outcomes of pregnant patients with COVID-19 in Wuhan, China: a retrospective, single-centre, descriptive study. Lancet Infect Dis. 2020;20(5):559-64.
8. Smith V, Seo D, Warty R, et al. Maternal and neonatal outcomes associated with COVID-19 infection: A systematic review. PLoS One. 2020;15(6):e0234187.
9. Di Mascio D, Khalil A, Saccone G, et al. Outcome of coronavirus spectrum infections (SARS, MERS, COVID-19) during pregnancy: a systematic review and meta-analysis. Am J Obstet Gynecol MFM. 2020;2(2):100107.
10. Khalil A, Kalafat E, Benlioglu C, et al. SARS-CoV-2 infection in pregnancy: A systematic review and meta-analysis of clinical features and pregnancy outcomes. EClinicalMedicine. 2020;25:100446.
11. Khalil A, von Dadelszen P, Draycott T, et al. Change in the Incidence of Stillbirth and Preterm Delivery During the COVID-19 Pandemic. JAMA. 2020;10.1001/jama.2020.12746.
12. Atyeo C, DeRiso EA, Davis C, et al. COVID-19 mRNA vaccines drive differential antibody Fc-functional profiles in pregnant, lactating, and nonpregnant women. Sci Transl Med. 2021;13(617):eabi8631.
13. Blakeway H, Amin-Chowdhury Z, Prasad S, et al. Evaluation of immunogenicity and reactogenicity of COVID-19 vaccines in pregnant women. Ultrasound Obstet Gynecol. 2022;60(5):673-80.

090177e1a0c1d3a9\Approved\Approved On: 23-May-2024 05:18 (GMT)

14. Prabhu M, Yang YJ, Johnston CD, et al. Longitudinal antibody response kinetics following SARS-CoV-2 messenger RNA vaccination in pregnant and nonpregnant persons. Am J Obstet Gynecol MFM. 2023;5(2):100796.
15. Prevention CfDCa. About Atrial Septal Defect (ASD). Available from: https://www.cdc.gov/heart-defects/about/atrial-septal-defect.html?CDC_AAref_Val=https://www.cdc.gov/ncbddd/heartdefects/atrialseptaldefect.html. Accessed on: 20 May 2024.
16. Fortescue E, Lock J, Galvin T, et al. To Close or Not to Close: The Very Small Patent Ductus Arteriosus. Congenit Heart Dis. 2010;5(4):354-65.
17. Prevention CfDCa. About Ventricular Septal Defect. Available from: https://www.cdc.gov/heart-defects/about/ventricular-septal-defect.html?CDC_AAref_Val=https://www.cdc.gov/ncbddd/heartdefects/ventricularseptaldefect.html. Accessed on: 20 May 2024.
18. Prevention CfDCa. About Microcephaly. Available from: https://www.cdc.gov/birth-defects/about/microcephaly.html?CDC_AAref_Val=https://www.cdc.gov/ncbddd/birthdefects/microcephaly.html. Accessed on: 20 May 2024.
19. Malik S. Syndactyly: phenotypes, genetics and current classification. Eur J Hum Genet. 2012;20(8):817-24.
20. Celik B, Tomatsu SC, Tomatsu S, et al. Epidemiology of Mucopolysaccharidoses Update. Diagnostics (Basel). 2021;11(2).
21. Prevention CfDCa. About Down Syndrome. Available from: https://www.cdc.gov/birth-defects/about/down-syndrome.html. Accessed on: 20 May 2024.
22. Medicine NLo. 22q11.2 deletion syndrome. Available from: https://medlineplus.gov/genetics/condition/22q112-deletion-syndrome/#frequency. Accessed on: 20 May 2024.
23. Sargent M. What is the normal prevalence of vesicoureteral reflux? Pediatr Radiol. 2000;30(9):587-93.

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14. TABLES AND FIGURES REFERRED TO BUT NOT INCLUDED IN THE TEXT

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SUPPLEMENTAL TABLES

Conduct of Study

14.1. Disposition of All Randomized Participants – Maternal – After Unblinding

	Vaccine Group (as Randomized)	
	BNT162b2 (30 µg) (N[a]=167) n[b] (%)	Placebo (N[a]=162) n[b] (%)
Originally received BNT162b2	167 (100.0)	
Unblinded before 1-month postdelivery visit	6 (3.6)	
Completed 1-month postdelivery visit	2 (1.2)	
Unblinded after 1-month postdelivery visit	161 (96.4)	
Completed the study	151 (90.4)	
Withdrawn from the study	16 (9.6)	
Withdrawn after Dose 1 and before Dose 2	1 (0.6)	
Withdrawn after Dose 2	15 (9.0)	
Reason for withdrawal		
Withdrawal by subject	6 (3.6)	
Lost to follow-up	5 (3.0)	
Protocol deviation	2 (1.2)	
Other	3 (1.8)	
Originally received placebo		162 (100.0)
Vaccinated		152 (93.8)
First dose of BNT162b2 30 µg		152 (93.8)
Second dose of BNT162b2 30 µg		148 (91.4)
Unblinded before 1-month postdelivery visit		3 (1.9)
Completed 1-month postdelivery visit		0
Unblinded after 1-month postdelivery visit		159 (98.1)
Completed the study		147 (90.7)
Withdrawn from the study		15 (9.3)
Withdrawn after Dose 1 and before Dose 2		1 (0.6)
Withdrawn after Dose 2 and before first dose of BNT162b2 30 µg		9 (5.6)
Withdrawn after first dose of BNT162b2 30 µg and before second dose of BNT162b2 30 µg		4 (2.5)
Withdrawn after second dose of BNT162b2 30 µg		1 (0.6)
Reason for withdrawal		
Withdrawal by subject		8 (4.9)
Lost to follow-up		3 (1.9)
Protocol deviation		4 (2.5)

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14.1. Disposition of All Randomized Participants – Maternal – After Unblinding

	Vaccine Group (as Randomized)	
	BNT162b2 (30 µg) (N[a]=167) n[b] (%)	Placebo (N[a]=162) n[b] (%)

a. N = number of randomized participants in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic.
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14.2. Immunogenicity Populations (Maternal)

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) n[a] (%)	Placebo n[a] (%)	Total n[a] (%)
Randomized[b]	174 (100.0)	174 (100.0)	348 (100.0)
All-available immunogenicity population(maternal)	171 (98.3)	170 (97.7)	341 (98.0)
HIV-positive	12 (6.9)	9 (5.2)	21 (6.0)
Participants excluded from all-available immunogenicity population(maternal)	3 (1.7)	4 (2.3)	7 (2.0)
Reason for exclusion			
Did not receive at least 1 dose of the study intervention	1 (0.6)	1 (0.6)	2 (0.6)
Did not have at least 1 valid and determinate immunogenicity result after vaccination	2 (1.1)	3 (1.7)	5 (1.4)
Dose 1 evaluable immunogenicity population(maternal)	92 (52.9)	91 (52.3)	183 (52.6)
HIV-positive	0	0	0
Without evidence of infection up to Visit 2[c]	62 (35.6)	59 (33.9)	121 (34.8)
Participants excluded from Dose 1 evaluable immunogenicity population(maternal)	82 (47.1)	83 (47.7)	165 (47.4)
Reason for exclusion[d]			
Not applicable for Phase 3 participants	69 (39.7)	70 (40.2)	139 (39.9)
Not eligible for the study at randomization	4 (2.3)	1 (0.6)	5 (1.4)
Did not receive Dose 1 of the vaccine to which they were randomized	0	1 (0.6)	1 (0.3)
Did not have at least 1 valid and determinate immunogenicity result within 19-23 days after Dose 1	9 (5.2)	13 (7.5)	22 (6.3)
Had other protocol deviation(s) as determined by the clinician	4 (2.3)	1 (0.6)	5 (1.4)
Evaluable immunogenicity population(maternal)	111 (63.8)	115 (66.1)	226 (64.9)
HIV-positive	10 (5.7)	9 (5.2)	19 (5.5)
Without evidence of infection up to 1 month after Dose 2[e]	59 (33.9)	58 (33.3)	117 (33.6)

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14.2. Immunogenicity Populations (Maternal)

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) n[a] (%)	Placebo n[a] (%)	Total n[a] (%)
Participants excluded from evaluable immunogenicity population(maternal)	63 (36.2)	59 (33.9)	122 (35.1)
Reason for exclusion[d]			
Not eligible for the study at randomization	7 (4.0)	4 (2.3)	11 (3.2)
Did not receive 2 doses of the vaccine to which they were randomized	4 (2.3)	4 (2.3)	8 (2.3)
Did not receive Dose 2 within 19-42 days after Dose 1	3 (1.7)	3 (1.7)	6 (1.7)
Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2	59 (33.9)	57 (32.8)	116 (33.3)
Had other protocol deviation(s) as determined by the clinician	8 (4.6)	5 (2.9)	13 (3.7)

a. n = Number of participants with the specified characteristic, or the total sample.
b. These values are the denominators for the percentage calculations.
c. Phase 2 Participants who had no serological or virological evidence (prior to Visit 2 blood sample collection) of past SARS-CoV-2 infection
(ie, N-binding antibody [serum] negative at Dose 1 and Dose 2 and no positive result between visits, negative NAAT [nasal swab] at Dose 1, Dose 2, and any unscheduled visit prior to the Dose 2 blood sample collection) were included in the analysis.
d. Participants may have been excluded for more than 1 reason.
e. Participants who had no serological or virological evidence (prior to the 1 month after Dose 2 blood sample collection) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Dose 1 and 1 month after Dose 2 and no positive result between visits, negative NAAT [nasal swab] at Dose 1, Dose 2, and any unscheduled visit prior to the 1 month after Dose 2 blood sample collection) were included in the analysis.
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14.3. Efficacy Populations (Infant)

	Maternal Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) n[a] (%)	Placebo n[a] (%)	Total n[a] (%)
Randomized[b]	167 (100.0)	168 (100.0)	335 (100.0)
All-available efficacy population	167 (100.0)	168 (100.0)	335 (100.0)
HIV-positive maternal participants	11 (6.6)	9 (5.4)	20 (6.0)
Breastfeeding Status			
Breastfed	147 (88.0)	152 (90.5)	299 (89.3)
Not breastfed	17 (10.2)	11 (6.5)	28 (8.4)
Missing	3 (1.8)	5 (3.0)	8 (2.4)

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14.3. Efficacy Populations (Infant)

	Maternal Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) n[a] (%)	Placebo n[a] (%)	Total n[a] (%)

Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. n = Number of participants with the specified characteristic, or the total sample.
b. Infants were not randomized and vaccinated but are summarized according to the vaccine group their mothers were randomized to. These values are the denominators for the percentage calculations.
PFIZER CONFIDENTIAL SDTM Creation: 03MAY2023 (09:05) Source Data: adsl Table Generation: 19JAN2024 (14:37) Output File: ./nda3/C4591015_EFF/adsl_eff_pop_inf

14.4. Medical History – Safety Population (Maternal)

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=173) n[b] (%)	 Placebo (N[a]=173) n[b] (%)
Any medical history	92 (53.2)	87 (50.3)
Blood and lymphatic system disorders	6 (3.5)	8 (4.6)
Anaemia	5 (2.9)	4 (2.3)
Anaemia of pregnancy	1 (0.6)	1 (0.6)
Iron deficiency anaemia	0	2 (1.2)
Thrombocytopenia	0	2 (1.2)
Cardiac disorders	5 (2.9)	1 (0.6)
Cardiac disorder	1 (0.6)	0
Pulmonary valve stenosis	1 (0.6)	0
Sinus tachycardia	1 (0.6)	0
Supraventricular tachycardia	0	1 (0.6)
Ventricular extrasystoles	2 (1.2)	0
Congenital, familial and genetic disorders	3 (1.7)	2 (1.2)
Accessory kidney	0	1 (0.6)
Congenital pulmonary artery anomaly	1 (0.6)	0
Heart disease congenital	0	1 (0.6)
Kidney duplex	1 (0.6)	0
Thalassaemia	1 (0.6)	0
Ear and labyrinth disorders	0	1 (0.6)
Ear congestion	0	1 (0.6)
Endocrine disorders	6 (3.5)	11 (6.4)
Hyperthyroidism	1 (0.6)	0

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14.4. Medical History – Safety Population (Maternal)

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=173) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=173) n[b] (%)
Hypothyroidism	2 (1.2)	10 (5.8)
Thyroid dysfunction in pregnancy	2 (1.2)	0
Thyroid mass	1 (0.6)	0
Thyroiditis	0	1 (0.6)
Toxic nodular goitre	1 (0.6)	0
Eye disorders	1 (0.6)	2 (1.2)
Glaucoma	0	1 (0.6)
Myopia	1 (0.6)	0
Visual impairment	0	1 (0.6)
Gastrointestinal disorders	10 (5.8)	9 (5.2)
Abdominal pain	1 (0.6)	0
Abdominal pain lower	0	1 (0.6)
Bowel movement irregularity	1 (0.6)	0
Diarrhoea	0	1 (0.6)
Dyspepsia	0	2 (1.2)
Eosinophilic oesophagitis	1 (0.6)	0
Gastric disorder	0	1 (0.6)
Gastrooesophageal reflux disease	6 (3.5)	2 (1.2)
Hiatus hernia	1 (0.6)	0
Irritable bowel syndrome	1 (0.6)	2 (1.2)
Nausea	3 (1.7)	3 (1.7)
Umbilical hernia	0	1 (0.6)
Vomiting	1 (0.6)	0
General disorders and administration site conditions	3 (1.7)	4 (2.3)
Chest pain	1 (0.6)	0
Drug intolerance	0	1 (0.6)
Fatigue	2 (1.2)	3 (1.7)
Hepatobiliary disorders	2 (1.2)	5 (2.9)
Cholecystitis	1 (0.6)	1 (0.6)
Cholelithiasis	0	4 (2.3)
Primary biliary cholangitis	1 (0.6)	0
Immune system disorders	11 (6.4)	13 (7.5)
Allergy to animal	0	1 (0.6)
Allergy to arthropod sting	0	2 (1.2)
Anaphylactic reaction	1 (0.6)	0
Drug hypersensitivity	3 (1.7)	4 (2.3)
Food allergy	3 (1.7)	1 (0.6)
Rubber sensitivity	1 (0.6)	1 (0.6)
Seasonal allergy	5 (2.9)	8 (4.6)
Infections and infestations	18 (10.4)	20 (11.6)
Appendicitis	4 (2.3)	4 (2.3)

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14.4. Medical History – Safety Population (Maternal)

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=173) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=173) n[b] (%)
Asymptomatic bacteriuria	0	1 (0.6)
Bacterial vulvovaginitis	0	1 (0.6)
Bronchitis	0	1 (0.6)
Candida infection	1 (0.6)	0
Chlamydial infection	2 (1.2)	0
Chronic tonsillitis	0	1 (0.6)
Ear infection	1 (0.6)	0
Echinococciasis	1 (0.6)	0
Endometritis	0	1 (0.6)
Folliculitis	0	1 (0.6)
Fungal infection	0	1 (0.6)
Gastrointestinal infection	0	1 (0.6)
Genital herpes simplex	0	1 (0.6)
HIV infection	1 (0.6)	2 (1.2)
Herpes simplex	1 (0.6)	2 (1.2)
Herpes virus infection	0	1 (0.6)
Influenza	1 (0.6)	0
Meningitis viral	0	1 (0.6)
Oral herpes	0	1 (0.6)
Papilloma viral infection	1 (0.6)	0
Pelvic inflammatory disease	0	1 (0.6)
Pharyngitis	0	1 (0.6)
Pulmonary tuberculosis	1 (0.6)	0
Sinusitis	0	1 (0.6)
Tinea cruris	0	1 (0.6)
Tonsillitis	4 (2.3)	3 (1.7)
Trichomoniasis	0	1 (0.6)
Tuberculosis	1 (0.6)	0
Urinary tract infection	2 (1.2)	2 (1.2)
Vaginal infection	0	2 (1.2)
Varicella	3 (1.7)	1 (0.6)
Vulvovaginal candidiasis	1 (0.6)	0
Injury, poisoning and procedural complications	4 (2.3)	7 (4.0)
Cartilage injury	1 (0.6)	0
Facial bones fracture	0	2 (1.2)
Femur fracture	1 (0.6)	0
Fibula fracture	1 (0.6)	0
Joint injury	0	1 (0.6)
Ligament sprain	0	1 (0.6)
Lip injury	0	1 (0.6)
Lower limb fracture	0	1 (0.6)
Road traffic accident	1 (0.6)	1 (0.6)

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14.4. Medical History – Safety Population (Maternal)

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=173) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=173) n[b] (%)
Upper limb fracture	0	1 (0.6)
Investigations	15 (8.7)	17 (9.8)
Arthroscopy	1 (0.6)	0
Biopsy	0	1 (0.6)
Biopsy breast normal	0	1 (0.6)
Biopsy cervix	1 (0.6)	0
Biopsy thyroid gland	1 (0.6)	0
Cardiac murmur	0	1 (0.6)
Chlamydia test positive	1 (0.6)	1 (0.6)
Cystoscopy	0	1 (0.6)
Endoscopy	0	1 (0.6)
HIV test positive	11 (6.4)	8 (4.6)
Human papilloma virus test positive	2 (1.2)	2 (1.2)
Oesophagogastroduodenoscopy	0	1 (0.6)
Rhesus antigen negative	0	1 (0.6)
Smear cervix abnormal	0	1 (0.6)
Metabolism and nutrition disorders	6 (3.5)	6 (3.5)
Diabetes mellitus	1 (0.6)	0
Insulin resistance	0	1 (0.6)
Lactose intolerance	0	1 (0.6)
Obesity	1 (0.6)	1 (0.6)
Type 1 diabetes mellitus	1 (0.6)	0
Vitamin B12 deficiency	0	1 (0.6)
Vitamin D deficiency	3 (1.7)	2 (1.2)
Musculoskeletal and connective tissue disorders	4 (2.3)	5 (2.9)
Back pain	1 (0.6)	1 (0.6)
Fibromyalgia	0	1 (0.6)
Intervertebral disc degeneration	0	1 (0.6)
Intervertebral disc protrusion	1 (0.6)	1 (0.6)
Muscle spasms	1 (0.6)	0
Osteoarthritis	1 (0.6)	0
Pain in extremity	1 (0.6)	0
Rheumatic fever	1 (0.6)	0
Scoliosis	0	1 (0.6)
Symphysiolysis	1 (0.6)	0
Trigger finger	0	1 (0.6)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3 (1.7)	3 (1.7)
Lipoma	1 (0.6)	0
Ovarian germ cell teratoma benign	1 (0.6)	0
Pituitary tumour benign	0	1 (0.6)
Thyroid cancer	1 (0.6)	0

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14.4. Medical History – Safety Population (Maternal)

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=173) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=173) n[b] (%)
Uterine leiomyoma	0	2 (1.2)
Nervous system disorders	10 (5.8)	8 (4.6)
Disturbance in attention	0	1 (0.6)
Headache	2 (1.2)	2 (1.2)
Migraine	7 (4.0)	4 (2.3)
Migraine with aura	0	1 (0.6)
Relapsing-remitting multiple sclerosis	1 (0.6)	0
Sinus headache	1 (0.6)	0
Pregnancy, puerperium and perinatal conditions	4 (2.3)	7 (4.0)
Ectopic pregnancy	0	1 (0.6)
Gestational diabetes	1 (0.6)	2 (1.2)
Gestational hypertension	2 (1.2)	0
Morning sickness	1 (0.6)	3 (1.7)
Placenta praevia haemorrhage	0	1 (0.6)
Psychiatric disorders	22 (12.7)	12 (6.9)
Anxiety	15 (8.7)	7 (4.0)
Anxiety disorder	1 (0.6)	0
Attention deficit hyperactivity disorder	0	3 (1.7)
Bipolar I disorder	1 (0.6)	0
Bipolar disorder	2 (1.2)	1 (0.6)
Depression	10 (5.8)	7 (4.0)
Insomnia	1 (0.6)	1 (0.6)
Mixed anxiety and depressive disorder	1 (0.6)	0
Obsessive-compulsive disorder	1 (0.6)	0
Panic disorder	1 (0.6)	0
Perinatal depression	1 (0.6)	0
Post-traumatic stress disorder	0	1 (0.6)
Renal and urinary disorders	1 (0.6)	1 (0.6)
Leukocyturia	0	1 (0.6)
Nephrolithiasis	1 (0.6)	0
Reproductive system and breast disorders	10 (5.8)	8 (4.6)
Abnormal uterine bleeding	1 (0.6)	0
Adnexa uteri pain	1 (0.6)	0
Breast tenderness	0	1 (0.6)
Cervical dysplasia	3 (1.7)	2 (1.2)
Dysmenorrhoea	1 (0.6)	0
Endometriosis	1 (0.6)	0
Intermenstrual bleeding	0	1 (0.6)
Ovarian cyst	0	1 (0.6)
Pelvic pain	1 (0.6)	0
Polycystic ovaries	2 (1.2)	2 (1.2)

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14.4. Medical History – Safety Population (Maternal)

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=173) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=173) n[b] (%)
Uterine polyp	0	1 (0.6)
Uterine spasm	0	1 (0.6)
Vaginal discharge	1 (0.6)	0
Vaginal haemorrhage	0	1 (0.6)
Respiratory, thoracic and mediastinal disorders	12 (6.9)	4 (2.3)
Asthma	5 (2.9)	4 (2.3)
Dyspnoea	1 (0.6)	0
Nasal polyps	1 (0.6)	0
Rhinitis allergic	5 (2.9)	0
Skin and subcutaneous tissue disorders	2 (1.2)	4 (2.3)
Acne	0	1 (0.6)
Dermatitis allergic	1 (0.6)	0
Dermatitis contact	0	2 (1.2)
Night sweats	0	1 (0.6)
Sensitive skin	1 (0.6)	0
Surgical and medical procedures	29 (16.8)	24 (13.9)
Abdominoplasty	2 (1.2)	1 (0.6)
Abortion induced	1 (0.6)	0
Adenoidectomy	0	2 (1.2)
Adenotonsillectomy	1 (0.6)	1 (0.6)
Appendicectomy	3 (1.7)	3 (1.7)
Bone operation	0	1 (0.6)
Bunion operation	1 (0.6)	0
Cervical conisation	1 (0.6)	0
Cholecystectomy	1 (0.6)	5 (2.9)
Cyst removal	0	1 (0.6)
Debridement	1 (0.6)	0
Fracture treatment	1 (0.6)	2 (1.2)
Gastrectomy	0	1 (0.6)
Gastric banding	1 (0.6)	0
Gastric stapling	1 (0.6)	0
Internal fixation of fracture	1 (0.6)	0
Intestinal operation	0	1 (0.6)
Joint arthroplasty	1 (0.6)	0
Keratomileusis	0	1 (0.6)
Knee operation	1 (0.6)	0
Laparotomy	0	1 (0.6)
Ligament operation	2 (1.2)	0
Lip operation	0	1 (0.6)
Lipoma excision	1 (0.6)	0
Liposuction	1 (0.6)	1 (0.6)

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14.4. Medical History – Safety Population (Maternal)

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=173) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=173) n[b] (%)
Liver operation	1 (0.6)	0
Loop electrosurgical excision procedure	1 (0.6)	1 (0.6)
Mammoplasty	1 (0.6)	1 (0.6)
Myomectomy	0	1 (0.6)
Myopia correction	1 (0.6)	0
Nasal septal operation	1 (0.6)	0
Oesophagogastric fundoplasty	1 (0.6)	0
Oophorectomy	1 (0.6)	0
Pyloroplasty	0	1 (0.6)
Rhinoplasty	3 (1.7)	1 (0.6)
Sinuplasty	1 (0.6)	0
Sinus operation	0	1 (0.6)
Temporomandibular joint surgery	1 (0.6)	0
Tendon sheath incision	0	1 (0.6)
Thyroidectomy	2 (1.2)	0
Tonsillectomy	3 (1.7)	2 (1.2)
Uterine dilation and curettage	2 (1.2)	1 (0.6)
Valvuloplasty cardiac	1 (0.6)	0
Varicose vein operation	1 (0.6)	0
Wisdom teeth removal	2 (1.2)	5 (2.9)
Vascular disorders	1 (0.6)	0
Varicose vein	1 (0.6)	0

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic. Participants with multiple occurrences of the same preferred term are counted only once.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:02) Source Data: admh Table Generation: 03MAY2023 (10:29) Output File: ./nda3/C4591015_BR/admh_s002_all_p3_saf

14.5. Obstetric History – Safety Population (Maternal)

	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=173) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=173) n[b] (%)	Total (N[a]=346) n[b] (%)
Number of previous pregnancies			

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14.5. Obstetric History – Safety Population (Maternal)

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=173) n[b] (%)	Placebo (N[a]=173) n[b] (%)	Total (N[a]=346) n[b] (%)
0	67 (38.7)	51 (29.5)	118 (34.1)
1	51 (29.5)	51 (29.5)	102 (29.5)
2	31 (17.9)	48 (27.7)	79 (22.8)
≥3	24 (13.9)	23 (13.3)	47 (13.6)
Number of live births[c]			
0	77 (44.5)	65 (37.6)	142 (41.0)
1	59 (34.1)	58 (33.5)	117 (33.8)
2	23 (13.3)	38 (22.0)	61 (17.6)
≥3	14 (8.1)	12 (6.9)	26 (7.5)
Number of stillbirths[c]			
0	172 (99.4)	173 (100.0)	345 (99.7)
1	1 (0.6)	0	1 (0.3)
Number of vaginal deliveries[c]			
0	95 (54.9)	91 (52.6)	186 (53.8)
1	49 (28.3)	49 (28.3)	98 (28.3)
2	17 (9.8)	23 (13.3)	40 (11.6)
≥3	12 (6.9)	10 (5.8)	22 (6.4)
Cesarean deliveries[c]			
0	151 (87.3)	137 (79.2)	288 (83.2)
1	17 (9.8)	27 (15.6)	44 (12.7)
2	4 (2.3)	8 (4.6)	12 (3.5)
≥3	1 (0.6)	1 (0.6)	2 (0.6)
Number of spontaneous abortions[c]			
0	133 (76.9)	130 (75.1)	263 (76.0)
1	33 (19.1)	37 (21.4)	70 (20.2)
2	7 (4.0)	6 (3.5)	13 (3.8)

a. N = number of participants in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic.
c. Zero (0) includes those participants who never had a prior pregnancy.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:02) Source Data: adrp Table Generation: 10MAY2023 (12:18) Output File: ./nda3/C4591015_BR/adrpgy_s001

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14.6. Baseline Charlson Comorbidities – Safety Population (Maternal)

Charlson Comorbidity Index Category	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=173) n[b] (%)	Placebo (N[a]=173) n[b] (%)	Total (N[a]=346) n[b] (%)
Participants with any Charlson comorbidity[c]	21 (12.1)	14 (8.1)	35 (10.1)
Any malignancy	1 (0.6)	0	1 (0.3)
Chronic pulmonary disease	5 (2.9)	4 (2.3)	9 (2.6)
Diabetes without chronic complication	2 (1.2)	0	2 (0.6)
HIV positive	12 (6.9)	10 (5.8)	22 (6.4)
Mild liver disease	1 (0.6)	0	1 (0.3)

Abbreviation: HIV = human immunodeficiency virus.
Note: MedDRA (v25.1) coding dictionary applied.
Note: Human immunodeficiency virus (HIV)-positive participants are included in this summary.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic. Participants with multiple occurrences within each category are counted only once.
c. Participants reporting at least 1 occurrence of any Charlson comorbidity.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:02) Source Data: admh Table Generation: 03MAY2023 (10:29) Output File: ./nda3/C4591015_BR/admh_s002_risk_all_p3_saf

14.7. Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001) – All-Available Immunogenicity Population

	Vaccine Group (as Randomized)			
	BNT162b2 (30 µg)		Placebo	
	C4591015 (Maternal) (N[a]=171) n[b] (%)	C4591001 (Nonpregnant Women) (N[a]=120) n[b] (%)	C4591015 (Maternal) (N[a]=170) n[b] (%)	C4591001 (Nonpregnant Women) (N[a]=129) n[b] (%)
Race				
White	116 (67.8)	98 (81.7)	117 (68.8)	99 (76.7)
Black or African American	47 (27.5)	8 (6.7)	42 (24.7)	14 (10.9)
American Indian or Alaska Native	1 (0.6)	2 (1.7)	1 (0.6)	2 (1.6)
Asian	4 (2.3)	7 (5.8)	9 (5.3)	8 (6.2)
Native Hawaiian or other Pacific Islander	0	0	1 (0.6)	0
Multiracial	1 (0.6)	5 (4.2)	0	6 (4.7)
Not reported	2 (1.2)	0	0	0

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14.7. Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001) – All-Available Immunogenicity Population

	Vaccine Group (as Randomized)			
	BNT162b2 (30 µg)		Placebo	
	C4591015 (Maternal) (N[a]=171) n[b] (%)	C4591001 (Nonpregnant Women) (N[a]=120) n[b] (%)	C4591015 (Maternal) (N[a]=170) n[b] (%)	C4591001 (Nonpregnant Women) (N[a]=129) n[b] (%)
Ethnicity				
Hispanic/Latino	69 (40.4)	42 (35.0)	61 (35.9)	46 (35.7)
Non-Hispanic/non-Latino	102 (59.6)	78 (65.0)	109 (64.1)	83 (64.3)
Country				
Argentina	0	27 (22.5)	0	28 (21.7)
Brazil	24 (14.0)	16 (13.3)	18 (10.6)	11 (8.5)
Germany	0	5 (4.2)	0	5 (3.9)
South Africa	40 (23.4)	3 (2.5)	41 (24.1)	1 (0.8)
Spain	21 (12.3)	0	18 (10.6)	0
Turkey	0	2 (1.7)	0	1 (0.8)
United Kingdom	6 (3.5)	0	8 (4.7)	0
United States	80 (46.8)	67 (55.8)	85 (50.0)	83 (64.3)
HIV-Positive				
No	159 (93.0)	120 (100.0)	161 (94.7)	129 (100.0)
Yes	12 (7.0)	0	9 (5.3)	0
Age at Dose 1 (years)				
Mean (SD)	29.6 (6.26)	29.9 (6.21)	29.5 (5.82)	29.9 (5.80)
Median	30.0	30.0	30.0	30.0
Min, max	(18, 44)	(18, 44)	(18, 44)	(18, 44)
Gestational age at Dose 1 (weeks)				
n	171	N/A	170	N/A
Mean (SD)	30.0 (2.71)	N/A	30.3 (2.62)	N/A
Median	30.3	N/A	30.4	N/A
Min, max	(24.0, 34.9)	N/A	(24.1, 36.1)	N/A
Gestational age at Dose 2 (weeks)				
n	170	N/A	169	N/A
Mean (SD)	33.1 (2.68)	N/A	33.4 (2.69)	N/A
Median	33.3	N/A	33.4	N/A
Min, max	(27.0, 37.7)	N/A	(27.0, 39.6)	N/A
Baseline SARS-CoV-2 status				
Positive	62 (36.3)	4 (3.3)	63 (37.1)	6 (4.7)
Negative	101 (59.1)	115 (95.8)	103 (60.6)	123 (95.3)
Missing	8 (4.7)	1 (0.8)	4 (2.4)	0
Body mass index (BMI)				
Underweight (<18.5 kg/m^2)	0	2 (1.7)	1 (0.6)	5 (3.9)

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14.7. Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001) – All-Available Immunogenicity Population

	Vaccine Group (as Randomized)			
	BNT162b2 (30 µg)		Placebo	
	C4591015 (Maternal) (N[a]=171) n[b] (%)	C4591001 (Nonpregnant Women) (N[a]=120) n[b] (%)	C4591015 (Maternal) (N[a]=170) n[b] (%)	C4591001 (Nonpregnant Women) (N[a]=129) n[b] (%)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	42 (24.6)	53 (44.2)	38 (22.4)	51 (39.5)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	64 (37.4)	32 (26.7)	62 (36.5)	32 (24.8)
Obese (≥30.0 kg/m^2)	65 (38.0)	33 (27.5)	68 (40.0)	41 (31.8)
Missing	0	0	1 (0.6)	0

Abbreviations: N/A = not applicable; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Gestational age at Dose 2 (weeks) = gestational age at Dose 1 (weeks) + (date of Dose 2 - date of Dose 1)/7.
Note: Participants from C4591001 are a selected subset of age matched nonpregnant female Phase 3 participants.
Note: As per inclusion criteria 10 for weight in C4591015 protocol, the BMI included is pre-pregnancy and if unavailable, the BMI recorded from the first obstetric visit was used. The weight categories included in the table were created as per these records.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic.
PFIZER CONFIDENTIAL Source Data: adsl Table Generation: 01MAR2024 (02:39)
(Data cutoff date : C4591001 [31Aug2021]) Output File: ./nda3/C4591015_Bridging/adsl_s005_demo_p3_aleval

14.8. Demographic Characteristics – Participants Without Evidence of SARS-CoV-2 Infection up to 1 Month After Dose 2 – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001) – Evaluable Immunogenicity Population

	Vaccine Group (as Randomized)			
	BNT162b2 (30 µg)		Placebo	
	C4591015 (Maternal) (N[a]=59) n[b] (%)	C4591001 (Nonpregnant Women) (N[a]=107) n[b] (%)	C4591015 (Maternal) (N[a]=58) n[b] (%)	C4591001 (Nonpregnant Women) (N[a]=113) n[b] (%)
Race				
White	53 (89.8)	92 (86.0)	46 (79.3)	88 (77.9)
Black or African American	3 (5.1)	3 (2.8)	9 (15.5)	11 (9.7)
American Indian or Alaska Native	0	2 (1.9)	0	1 (0.9)
Asian	2 (3.4)	7 (6.5)	3 (5.2)	8 (7.1)

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14.8. Demographic Characteristics – Participants Without Evidence of SARS-CoV-2 Infection up to 1 Month After Dose 2 – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001) – Evaluable Immunogenicity Population

	Vaccine Group (as Randomized)			
	BNT162b2 (30 µg)		Placebo	
	C4591015 (Maternal) (N[a]=59) n[b] (%)	C4591001 (Nonpregnant Women) (N[a]=107) n[b] (%)	C4591015 (Maternal) (N[a]=58) n[b] (%)	C4591001 (Nonpregnant Women) (N[a]=113) n[b] (%)
Multiracial	0	3 (2.8)	0	5 (4.4)
Not reported	1 (1.7)	0	0	0
Ethnicity				
Hispanic/Latino	22 (37.3)	38 (35.5)	22 (37.9)	42 (37.2)
Non-Hispanic/non-Latino	37 (62.7)	69 (64.5)	36 (62.1)	71 (62.8)
Country				
Argentina	0	23 (21.5)	0	24 (21.2)
Brazil	2 (3.4)	13 (12.1)	4 (6.9)	9 (8.0)
Germany	0	5 (4.7)	0	5 (4.4)
South Africa	3 (5.1)	1 (0.9)	8 (13.8)	1 (0.9)
Spain	15 (25.4)	0	10 (17.2)	0
Turkey	0	2 (1.9)	0	1 (0.9)
United Kingdom	5 (8.5)	0	3 (5.2)	0
United States	34 (57.6)	63 (58.9)	33 (56.9)	73 (64.6)
HIV-Positive				
No	58 (98.3)	107 (100.0)	54 (93.1)	113 (100.0)
Yes	1 (1.7)	0	4 (6.9)	0
Age at Dose 1 (years)				
Mean (SD)	31.3 (5.68)	30.2 (6.26)	30.9 (5.52)	30.0 (5.86)
Median	31.0	30.0	31.0	30.0
Min, max	(19, 44)	(18, 44)	(21, 41)	(18, 44)
Gestational age at Dose 1 (weeks)				
n	59	N/A	58	N/A
Mean (SD)	29.2 (2.53)	N/A	29.4 (2.15)	N/A
Median	28.4	N/A	29.1	N/A
Min, max	(24.0, 33.7)	N/A	(24.1, 35.6)	N/A
Gestational age at Dose 2 (weeks)				
n	59	N/A	58	N/A
Mean (SD)	32.2 (2.54)	N/A	32.5 (2.14)	N/A
Median	31.6	N/A	32.4	N/A
Min, max	(27.0, 36.7)	N/A	(27.0, 38.6)	N/A
Baseline SARS-CoV-2 status				
Negative	59 (100.0)	107 (100.0)	58 (100.0)	113 (100.0)
Body mass index (BMI)				

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14.8. Demographic Characteristics – Participants Without Evidence of SARS-CoV-2 Infection up to 1 Month After Dose 2 – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001) – Evaluable Immunogenicity Population

	Vaccine Group (as Randomized)			
	BNT162b2 (30 µg)		Placebo	
	C4591015 (Maternal) (N[a]=59) n[b] (%)	C4591001 (Nonpregnant Women) (N[a]=107) n[b] (%)	C4591015 (Maternal) (N[a]=58) n[b] (%)	C4591001 (Nonpregnant Women) (N[a]=113) n[b] (%)
Underweight (<18.5 kg/m^2)	0	2 (1.9)	0	4 (3.5)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	20 (33.9)	49 (45.8)	16 (27.6)	45 (39.8)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	22 (37.3)	27 (25.2)	23 (39.7)	28 (24.8)
Obese (≥30.0 kg/m^2)	17 (28.8)	29 (27.1)	19 (32.8)	36 (31.9)

Abbreviations: N/A = not applicable; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Gestational age at Dose 2 (weeks) = gestational age at Dose 1 (weeks) + (date of Dose 2 - date of Dose 1)/7.
Note: Participants from C4591001 are a selected subset of age matched nonpregnant female Phase 3 participants.
Note: As per inclusion criteria 10 for weight in C4591015 protocol, the BMI included is pre-pregnancy and if unavailable, the BMI recorded from the first obstetric visit was used. The weight categories included in the table were created as per these records.
Note: Participants who had no serological or virological evidence (prior to the 1 month after Dose 2 blood sample collection) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Dose 1 and 1 month after Dose 2 and no positive result between visits, negative NAAT [nasal swab] at Dose 1, Dose 2, and any unscheduled visit prior to the 1 month after Dose 2 blood sample collection) were included in the analysis.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic.
PFIZER CONFIDENTIAL Source Data: adsl Table Generation: 01MAR2024 (02:39)
(Data cutoff date : C4591001 [31Aug2021]) Output File: ./nda3/C4591015_Bridging/adsl_s005_demo_p3_saf172

14.9. Demographic Characteristics – Phase 2 – Dose 1 Evaluable Immunogenicity Population (Maternal)

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=92) n[b] (%)	Placebo (N[a]=91) n[b] (%)	Total (N[a]=183) n[b] (%)
Race			
White	77 (83.7)	80 (87.9)	157 (85.8)
Black or African American	10 (10.9)	5 (5.5)	15 (8.2)
American Indian or Alaska Native	1 (1.1)	1 (1.1)	2 (1.1)
Asian	2 (2.2)	4 (4.4)	6 (3.3)

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14.9. Demographic Characteristics – Phase 2 – Dose 1 Evaluable Immunogenicity Population (Maternal)

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=92) n[b] (%)	Placebo (N[a]=91) n[b] (%)	Total (N[a]=183) n[b] (%)
Native Hawaiian or other Pacific Islander	0	1 (1.1)	1 (0.5)
Multiracial	1 (1.1)	0	1 (0.5)
Not reported	1 (1.1)	0	1 (0.5)
Ethnicity			
Hispanic/Latino	43 (46.7)	39 (42.9)	82 (44.8)
Non-Hispanic/non-Latino	49 (53.3)	52 (57.1)	101 (55.2)
Country			
Brazil	19 (20.7)	16 (17.6)	35 (19.1)
South Africa	2 (2.2)	2 (2.2)	4 (2.2)
Spain	12 (13.0)	10 (11.0)	22 (12.0)
United Kingdom	1 (1.1)	2 (2.2)	3 (1.6)
United States	58 (63.0)	61 (67.0)	119 (65.0)
HIV-Positive			
No	92 (100.0)	91 (100.0)	183 (100.0)
Age at Dose 1 (years)			
Mean (SD)	30.3 (6.47)	29.4 (5.55)	29.8 (6.03)
Median	30.5	30.0	30.0
Min, max	(18, 44)	(18, 41)	(18, 44)
Gestational age at Dose 1 (weeks)			
n	92	91	183
Mean (SD)	30.3 (2.44)	30.9 (2.18)	30.6 (2.32)
Median	30.3	30.9	30.6
Min, max	(27.0, 34.0)	(27.0, 35.6)	(27.0, 35.6)
Gestational age at Dose 2 (weeks)			
n	91	91	182
Mean (SD)	33.3 (2.40)	33.8 (2.19)	33.6 (2.30)
Median	33.3	33.9	33.6
Min, max	(30.0, 36.9)	(30.0, 38.6)	(30.0, 38.6)
Baseline SARS-CoV-2 status			
Positive	20 (21.7)	28 (30.8)	48 (26.2)
Negative	65 (70.7)	59 (64.8)	124 (67.8)
Missing	7 (7.6)	4 (4.4)	11 (6.0)
Body mass index (BMI)			
Underweight (<18.5 kg/m^2)	0	1 (1.1)	1 (0.5)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	21 (22.8)	19 (20.9)	40 (21.9)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	29 (31.5)	34 (37.4)	63 (34.4)
Obese (≥30.0 kg/m^2)	42 (45.7)	37 (40.7)	79 (43.2)

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14.9. Demographic Characteristics – Phase 2 – Dose 1 Evaluable Immunogenicity Population (Maternal)

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=92) n[b] (%)	Placebo (N[a]=91) n[b] (%)	Total (N[a]=183) n[b] (%)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Gestational age at Dose 2 (weeks) = gestational age at Dose 1 (weeks) + (date of Dose 2 - date of Dose 1)/7.
Note: As per inclusion criteria 10 for weight in C4591015 protocol, the BMI included is pre-pregnancy and if unavailable, the BMI recorded from the first obstetric visit was used. The weight categories included in the table were created as per these records.
a. N = number of participants in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (08:47) Source Data: adsl Table Generation: 28FEB2024 (09:56)
(Database snapshot date: Safety [29Mar2023], Immunogenicity [09Jan2024]) Output File: ./nda3/C4591015_CSR/adsl_s005_demo_d1eval_immuno

14.10. Demographic Characteristics – All-Available Immunogenicity Population (Infant)

	Maternal Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=163) n[b] (%)	Placebo (N[a]=156) n[b] (%)	Total (N[a]=319) n[b] (%)
Sex			
Male	80 (49.1)	90 (57.7)	170 (53.3)
Female	83 (50.9)	66 (42.3)	149 (46.7)
Race			
White	115 (70.6)	99 (63.5)	214 (67.1)
Black or African American	39 (23.9)	37 (23.7)	76 (23.8)
American Indian or Alaska Native	1 (0.6)	2 (1.3)	3 (0.9)
Asian	3 (1.8)	6 (3.8)	9 (2.8)
Multiracial	0	6 (3.8)	6 (1.9)
Not reported	5 (3.1)	6 (3.8)	11 (3.4)
Ethnicity			
Hispanic/Latino	63 (38.7)	52 (33.3)	115 (36.1)
Non-Hispanic/non-Latino	97 (59.5)	101 (64.7)	198 (62.1)
Not reported	3 (1.8)	3 (1.9)	6 (1.9)
Country			
Brazil	22 (13.5)	15 (9.6)	37 (11.6)

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14.10. Demographic Characteristics – All-Available Immunogenicity Population (Infant)

	Maternal Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=163) n[b] (%)	Placebo (N[a]=156) n[b] (%)	Total (N[a]=319) n[b] (%)
South Africa	39 (23.9)	40 (25.6)	79 (24.8)
Spain	20 (12.3)	16 (10.3)	36 (11.3)
United Kingdom	6 (3.7)	7 (4.5)	13 (4.1)
United States	76 (46.6)	78 (50.0)	154 (48.3)
Mother HIV-Positive			
Yes	11 (6.7)	9 (5.8)	20 (6.3)
No	152 (93.3)	147 (94.2)	299 (93.7)
Breast Feeding Status			
Yes	145 (89.0)	141 (90.4)	286 (89.7)
No	17 (10.4)	11 (7.1)	28 (8.8)
Missing	1 (0.6)	4 (2.6)	5 (1.6)
Gestational age at birth (weeks)			
<37 weeks 0 days	2 (1.2)	8 (5.1)	10 (3.1)
≥37 weeks - 41 weeks 6 days	159 (97.5)	146 (93.6)	305 (95.6)
≥42 weeks	2 (1.2)	2 (1.3)	4 (1.3)

a. N = number of participants in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (08:47) Source Data: adsl Table Generation: 19FEB2024 (03:17)
(Database snapshot date: Safety [29Mar2023], Immunogenicity [09Jan2024]) Output File: ./nda3/C4591015_CSR/adsl_s005_availimm_infant

14.11. Concomitant Medications Used After Dose 1 – Safety Population (Maternal)

Medication[b]	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=161) n[c] (%)	Placebo (N[a]=163) n[c] (%)
Any concomitant medication	44 (27.3)	47 (28.8)
AMOXICILLIN	2 (1.2)	4 (2.5)
AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM	0	1 (0.6)
AMOXICILLIN;CLAVULANIC ACID	2 (1.2)	1 (0.6)

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14.11. Concomitant Medications Used After Dose 1 – Safety Population (Maternal)

Medication[b]	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=161) n[c] (%)	Placebo (N[a]=163) n[c] (%)
AMPICILLIN	1 (0.6)	1 (0.6)
AMYLMETACRESOL;DICHLOROBENZYL ALCOHOL	1 (0.6)	0
ANTHOXANTHUM ODORATUM;DACTYLIS GLOMERATA;LOLIUM PERENNE;PHLEUM PRATENSE;POA PRATENSIS	1 (0.6)	0
ANTI-D IMMUNOGLOBULIN	3 (1.9)	1 (0.6)
ANTIBIOTICS	0	1 (0.6)
ASCORBIC ACID	1 (0.6)	3 (1.8)
ASCORBIC ACID;CYANOCOBALAMIN;FOLIC ACID;IRON	1 (0.6)	0
AZITHROMYCIN	2 (1.2)	2 (1.2)
BENZYLPENICILLIN POTASSIUM	0	2 (1.2)
BETAMETHASONE	0	1 (0.6)
BETAMETHASONE ACETATE;BETAMETHASONE SODIUM PHOSPHATE	1 (0.6)	0
BETAMETHASONE DIPROPIONATE	1 (0.6)	0
BROMHEXINE HYDROCHLORIDE;ORCIPRENALINE SULFATE	1 (0.6)	1 (0.6)
BUDESONIDE	1 (0.6)	0
CAFFEINE;CHLORPHENAMINE MALEATE;EPHEDRINE HYDROCHLORIDE;PARACETAMOL	0	1 (0.6)
CAFFEINE;PARACETAMOL	1 (0.6)	1 (0.6)
CALCIUM CARBONATE	1 (0.6)	0
CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE	2 (1.2)	1 (0.6)
CAPTOPRIL	0	1 (0.6)
CEFADROXIL	0	1 (0.6)
CEFALEXIN	3 (1.9)	0
CEFAZOLIN	0	1 (0.6)
CEFAZOLIN SODIUM	3 (1.9)	4 (2.5)
CEFDINIR	0	1 (0.6)
CEFPROZIL	0	1 (0.6)
CEFTRIAXONE	1 (0.6)	0
CEFUROXIME	1 (0.6)	0
CINCHOCAINE HYDROCHLORIDE;PREDNISOLONE CAPROATE	1 (0.6)	0
CINITAPRIDE	1 (0.6)	0
CLAVULANIC ACID	1 (0.6)	0
CLINDAMYCIN	2 (1.2)	1 (0.6)
CLOTRIMAZOLE	0	1 (0.6)
CODEINE	1 (0.6)	0
COLECALCIFEROL	1 (0.6)	0
COUGH AND COLD PREPARATIONS	1 (0.6)	0
DEXAMETHASONE	0	1 (0.6)
DEXKETOPROFEN	2 (1.2)	0
DEXKETOPROFEN TROMETAMOL	1 (0.6)	0
DIAZEPAM	1 (0.6)	0

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14.11. Concomitant Medications Used After Dose 1 – Safety Population (Maternal)

Medication[b]	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=161) n[c] (%)	Placebo (N[a]=163) n[c] (%)
DIHYDROCODEINE	1 (0.6)	0
DINOPROSTONE	0	1 (0.6)
DIPHENHYDRAMINE HYDROCHLORIDE	2 (1.2)	0
DOCUSATE SODIUM	0	2 (1.2)
ENOXAPARIN SODIUM	2 (1.2)	2 (1.2)
ERGOMETRINE;OXYTOCIN	0	1 (0.6)
ERYTHROMYCIN	0	2 (1.2)
FAMOTIDINE	2 (1.2)	2 (1.2)
FERRIC CARBOXYMALTOSE	1 (0.6)	1 (0.6)
FERROUS SULFATE	0	2 (1.2)
FEXOFENADINE	0	1 (0.6)
FLUCONAZOLE	0	1 (0.6)
FOSFOMYCIN	0	2 (1.2)
FOSFOMYCIN TROMETAMOL	1 (0.6)	0
FUROSEMIDE	1 (0.6)	0
GENTAMICIN	2 (1.2)	1 (0.6)
GLUCOSE	1 (0.6)	0
HALOPERIDOL	1 (0.6)	0
HYDRALAZINE HYDROCHLORIDE	1 (0.6)	0
HYDROCODONE BITARTRATE;PARACETAMOL	2 (1.2)	1 (0.6)
HYDROCORTISONE	0	1 (0.6)
HYDROCORTISONE ACETATE	0	1 (0.6)
HYDROXYZINE HYDROCHLORIDE	1 (0.6)	0
HYOSCINE BUTYLBROMIDE	1 (0.6)	0
IBUPROFEN	5 (3.1)	2 (1.2)
IRON	1 (0.6)	2 (1.2)
LABETALOL	2 (1.2)	0
LIDOCAINE HYDROCHLORIDE;PENTOSAN POLYSULFATE SODIUM;TRIAMCINOLONE ACETONIDE	0	1 (0.6)
LORATADINE	2 (1.2)	0
MAGNESIUM OXIDE	0	1 (0.6)
MAGNESIUM SULFATE	2 (1.2)	1 (0.6)
METAMIZOLE MAGNESIUM	2 (1.2)	0
METAMIZOLE SODIUM	1 (0.6)	1 (0.6)
METHYLDOPA	0	2 (1.2)
METHYLERGOMETRINE	1 (0.6)	0
METHYLERGOMETRINE MALEATE	1 (0.6)	0
METOCLOPRAMIDE	3 (1.9)	3 (1.8)
METOCLOPRAMIDE HYDROCHLORIDE	1 (0.6)	2 (1.2)
METRONIDAZOLE	1 (0.6)	3 (1.8)
MISOPROSTOL	0	1 (0.6)

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14.11. Concomitant Medications Used After Dose 1 – Safety Population (Maternal)

Medication[b]	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=161) n[c] (%)	Placebo (N[a]=163) n[c] (%)
NATALIZUMAB	1 (0.6)	0
NIFEDIPINE	1 (0.6)	3 (1.8)
NITROFURANTOIN	2 (1.2)	3 (1.8)
OMEPRAZOLE	1 (0.6)	1 (0.6)
ONDANSETRON	1 (0.6)	0
OXYTOCIN	2 (1.2)	1 (0.6)
PANCREATIN	1 (0.6)	0
PARACETAMOL	21 (13.0)	16 (9.8)
PETHIDINE	1 (0.6)	2 (1.2)
PETHIDINE HYDROCHLORIDE	1 (0.6)	0
PHYTOMENADIONE	0	1 (0.6)
POTASSIUM CHLORIDE	2 (1.2)	0
PREDNISONE	1 (0.6)	0
PROMETHAZINE	1 (0.6)	2 (1.2)
PSEUDOEPHEDRINE	0	1 (0.6)
SERTRALINE HYDROCHLORIDE	1 (0.6)	0
SIMETICONE	1 (0.6)	0
SODIUM CHLORIDE	0	1 (0.6)
SODIUM PHOSPHATE;SODIUM PHOSPHATE MONOBASIC (ANHYDROUS)	0	1 (0.6)
SULFAMETHOXAZOLE	0	1 (0.6)
TERBUTALINE	0	1 (0.6)
TRAMADOL	1 (0.6)	0
TRANEXAMIC ACID	2 (1.2)	1 (0.6)
URSODEOXYCHOLIC ACID	1 (0.6)	0
VITAMIN D NOS	0	1 (0.6)
WARFARIN	1 (0.6)	0
ZINC	0	2 (1.2)

Note: WHODDG B3 v202203 coding dictionary applied.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary. Data for HIV-positive participants and their infants will be included in the listings.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. Participants are counted only once for each preferred term.
c. n = Number of participants with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adcm Table Generation: 03MAY2023 (13:22) Output File: ./nda3/C4591015_BR/adcm_s001_d1

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14.12. Nonstudy Vaccines Received After Dose 1 – Safety Population (Maternal)

Vaccine[b]	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=161) n[c] (%)	Placebo (N[a]=163) n[c] (%)
Any nonstudy vaccine	26 (16.1)	34 (20.9)
COVID-19 VACCINE INACT (VERO) CZ02	1 (0.6)	0
DIPHTHERIA VACCINE TOXOID	0	1 (0.6)
DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR 3-COMPONENT;POLIO VACCINE INACT 3V (VERO);TETANUS VACCINE TOXOID	1 (0.6)	0
DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR 3-COMPONENT;TETANUS VACCINE TOXOID	4 (2.5)	4 (2.5)
DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID	11 (6.8)	15 (9.2)
ELASOMERAN	2 (1.2)	0
HEPATITIS A VACCINE;HEPATITIS B VACCINE	1 (0.6)	0
HEPATITIS B VACCINE	2 (1.2)	1 (0.6)
INFLUENZA VACCINE	9 (5.6)	5 (3.1)
INFLUENZA VACCINE INACT SPLIT 4V	0	1 (0.6)
MEASLES VACCINE LIVE (ENDERS-EDMONSTON);MUMPS VACCINE LIVE (JERYL LYNN);RUBELLA VACCINE LIVE (WISTAR RA 27/3)	1 (0.6)	2 (1.2)
MEASLES VACCINE;MUMPS VACCINE;RUBELLA VACCINE	1 (0.6)	2 (1.2)
MENINGOCOCCAL VACCINE	1 (0.6)	0
PENTETIC ACID	0	1 (0.6)
PERTUSSIS VACCINE	2 (1.2)	2 (1.2)
TETANUS VACCINE	0	1 (0.6)
TETANUS VACCINE TOXOID	0	4 (2.5)
TOZINAMERAN	0	3 (1.8)

Note: WHODDG B3 v202203 coding dictionary applied.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary. Analyses for HIV-positive participants and their infants will be listed separately.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. Participants are counted only once for each preferred term.
c. n = Number of participants with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adcm Table Generation: 03MAY2023 (10:29) Output File: ./nda3/C4591015_BR/adcm_s001_p3_cm

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14.13. Concomitant Medications Received After Birth – Safety Population (Infant)

Medication[b]	Maternal Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=156) n[c] (%)	Placebo (N[a]=159) n[c] (%)
Any concomitant medication	21 (13.5)	23 (14.5)
ACICLOVIR	1 (0.6)	1 (0.6)
AMIKACIN	2 (1.3)	1 (0.6)
AMINO ACIDS NOS;FATS NOS;MALTODEXTRIN;MINERALS NOS;VITAMINS NOS	1 (0.6)	0
AMOXICILLIN	0	1 (0.6)
AMOXICILLIN;CLAVULANIC ACID	1 (0.6)	0
AMPICILLIN	5 (3.2)	6 (3.8)
AMPICILLIN SODIUM	0	1 (0.6)
ASCORBIC ACID;PSEUDOEPHEDRINE HYDROCHLORIDE;TRIPROLIDINE HYDROCHLORIDE	0	1 (0.6)
BENZYLPENICILLIN	0	1 (0.6)
BROMHEXINE HYDROCHLORIDE;ORCIPRENALINE SULFATE	2 (1.3)	0
CALCIUM GLUCONATE	0	1 (0.6)
CEFEPIME	0	1 (0.6)
CEFOTAXIME	1 (0.6)	0
CEFTRIAXONE SODIUM	0	1 (0.6)
CEFUROXIME	1 (0.6)	0
CERATONIA SILIQUA EXTRACT	1 (0.6)	0
CHLORAMPHENICOL SODIUM SUCCINATE	0	1 (0.6)
CLOBAZAM	1 (0.6)	0
COUGH AND COLD PREPARATIONS	1 (0.6)	0
DEXAMETHASONE	0	1 (0.6)
DEXAMETHASONE SODIUM PHOSPHATE;GENTAMICIN SULFATE;TETRYZOLINE HYDROCHLORIDE	1 (0.6)	0
DEXMEDETOMIDINE	0	1 (0.6)
DEXTROMETHORPHAN HYDROBROMIDE;PSEUDOEPHEDRINE HYDROCHLORIDE;TRIPROLIDINE HYDROCHLORIDE MONOHYDRATE	1 (0.6)	0
DRIMIA MARITIMA;MYROXYLON BALSAMUM;PSYCHOTRIA IPECACUANHA	1 (0.6)	1 (0.6)
EPINEPHRINE	0	1 (0.6)
FENTANYL	0	1 (0.6)
GENTAMICIN	3 (1.9)	6 (3.8)
GLUCOSE	0	2 (1.3)
GLUCOSE;SODIUM CHLORIDE	0	1 (0.6)
GUAIFENESIN;PSEUDOEPHEDRINE HYDROCHLORIDE	0	1 (0.6)
HEDERA HELIX LEAF	1 (0.6)	0
HYDRALAZINE	0	1 (0.6)
HYDROCORTISONE	0	1 (0.6)
LEVETIRACETAM	1 (0.6)	1 (0.6)
LIPIDS NOS	0	1 (0.6)
MELATONIN	1 (0.6)	0

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14.13. Concomitant Medications Received After Birth – Safety Population (Infant)

Medication[b]	Maternal Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=156) n[c] (%)	Placebo (N[a]=159) n[c] (%)
MICONAZOLE	1 (0.6)	0
NEVIRAPINE	0	1 (0.6)
NYSTATIN	1 (0.6)	2 (1.3)
OFLOXACIN	1 (0.6)	0
OMEPRAZOLE	1 (0.6)	0
OXYGEN	2 (1.3)	4 (2.5)
OXYMETAZOLINE	3 (1.9)	1 (0.6)
OXYMETAZOLINE HYDROCHLORIDE	0	1 (0.6)
PARACETAMOL	8 (5.1)	7 (4.4)
PHENOBARBITAL	0	1 (0.6)
PHYTOMENADIONE	1 (0.6)	0
PREDNISOLONE	1 (0.6)	1 (0.6)
PROPRANOLOL	0	1 (0.6)
PSEUDOEPHEDRINE HYDROCHLORIDE;TRIPROLIDINE HYDROCHLORIDE	1 (0.6)	1 (0.6)
PSEUDOEPHEDRINE;TRIPROLIDINE	0	1 (0.6)
RED BLOOD CELLS, CONCENTRATED	0	1 (0.6)
SALBUTAMOL	1 (0.6)	1 (0.6)
SILVER NITRATE	1 (0.6)	0
SIMETICONE	0	1 (0.6)
SODIUM ACETATE	0	1 (0.6)
SODIUM BICARBONATE	0	1 (0.6)
SODIUM CHLORIDE	3 (1.9)	3 (1.9)
SUCROSE	0	1 (0.6)
SULFAMETHOXAZOLE;TRIMETHOPRIM	1 (0.6)	0
TOTAL PARENTERAL NUTRITION	0	1 (0.6)
VALGANCICLOVIR	1 (0.6)	0
ZIDOVUDINE	0	1 (0.6)
ZINC	2 (1.3)	3 (1.9)

Note: WHODDG B3 v202203 coding dictionary applied.
Note: Infants born to human immunodeficiency virus (HIV)-positive participants are not included in this summary. Data for HIV-positive participants and their infants will be included in the listings.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. Participants are counted only once for each preferred term.
c. n = Number of participants with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adcm Table Generation: 03MAY2023 (13:24) Output File: ./nda3/C4591015_BR/adcm_s001_d2

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14.14. Vaccine as Administered, by Vaccine Group – All Randomized Participants (Maternal)

Vaccine (as Administered)	Vaccine Group (as Randomized)	
	BNT162b2 (30 µg) (N[a]=174) n[b] (%)	Placebo (N[a]=174) n[b] (%)
Vaccinated	173 (99.4)	173 (99.4)
Not vaccinated	1 (0.6)	1 (0.6)
Original placebo-controlled period		
Dose 1		
BNT162b2 (30 µg)	173 (99.4)	0
Placebo	0	173 (99.4)
Dose 2		
BNT162b2 (30 µg)	170 (97.7)	0
Placebo	0	170 (97.7)
Open-label BNT162b2 vaccination for original placebo recipients		
First crossover dose		
BNT162b2 (30 µg)		152 (87.4)
Second crossover dose		
BNT162b2 (30 µg)		148 (85.1)

Note: Human immunodeficiency virus (HIV)-positive participants are included in this summary.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (09:47) Source Data: adsl Table Generation: 03MAY2023 (10:28) Output File: ./nda3/C4591015_BR/advx_s002_adm_p3_rand

14.15. Vaccine Administration Timing – All Randomized Participants (Maternal)

	Vaccine Group (as Randomized)	
	BNT162b2 (30 µg) (N[a]=174) n[b] (%)	Placebo (N[a]=174) n[b] (%)
Randomized	174 (100.0)	174 (100.0)
Not vaccinated	1 (0.6)	1 (0.6)
Original placebo-controlled period		
Dose 1	173 (99.4)	173 (99.4)
Dose 2[c]	170 (97.7)	170 (97.7)
<19 Days	1 (0.6)	1 (0.6)
19-23 Days	157 (90.2)	153 (87.9)
>23 Days	12 (6.9)	16 (9.2)

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14.15. Vaccine Administration Timing – All Randomized Participants (Maternal)

	Vaccine Group (as Randomized)	
	BNT162b2 (30 µg) (N[a]=174) n[b] (%)	Placebo (N[a]=174) n[b] (%)
Open-label BNT162b2 vaccination for original placebo recipients		
First dose of BNT162b2 (30 µg)		152 (87.4)
Second dose of BNT162b2 (30 µg)[d]		148 (85.1)
<19 Days		1 (0.6)
19-23 Days		127 (73.0)
>23 Days		20 (11.5)

Note: Human immunodeficiency virus (HIV)-positive participants are included in this summary.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic.
c. Days calculated since Dose 1.
d. Days calculated since second dose of BNT162b2 for original placebo recipients.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (09:47) Source Data: adsl Table Generation: 03MAY2023 (10:29) Output File: ./nda3/C4591015_BR/advx_s002_time_p3_rand

14.16. Vaccine Administration Timing – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001) – Evaluable Immunogenicity Population

	Vaccine Group (as Randomized)			
	BNT162b2 (30 µg)		Placebo	
	C4591015 (Maternal) (N[a]=111) n[b] (%)	C4591001 (Nonpregnant Women) (N[a]=114) n[b] (%)	C4591015 (Maternal) (N[a]=115) n[b] (%)	C4591001 (Nonpregnant Women) (N[a]=124) n[b] (%)
Randomized	111 (100.0)	114 (100.0)	115 (100.0)	124 (100.0)
Not vaccinated	0	0	0	0
Dose 1	111 (100.0)	114 (100.0)	115 (100.0)	124 (100.0)
Dose 2[c]	111 (100.0)	114 (100.0)	115 (100.0)	124 (100.0)
<19 Days	0	0	0	0
19-23 Days[d]	107 (96.4)	113 (99.1)	104 (90.4)	119 (96.0)
>23 Days	4 (3.6)	1 (0.9)	11 (9.6)	5 (4.0)

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14.16. Vaccine Administration Timing – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001) – Evaluable Immunogenicity Population

	Vaccine Group (as Randomized)			
	BNT162b2 (30 µg)		Placebo	
	C4591015 (Maternal) (N^a=111) n^b (%)	C4591001 (Nonpregnant Women) (N^a=114) n^b (%)	C4591015 (Maternal) (N^a=115) n^b (%)	C4591001 (Nonpregnant Women) (N^a=124) n^b (%)

Note: Participants from C4591001 are a selected subset of age matched nonpregnant female Phase 3 participants.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic.
c. Days calculated since Dose 1.
d. Protocol-specified time frame.
PFIZER CONFIDENTIAL Source Data: adsl Table Generation: 01MAR2024 (02:39)
(Data cutoff date : C4591001 [31Aug2021]) Output File: ./nda3/C4591015_Bridging/advx_s002_time_p3_eval

14.17. Immunogenicity Blood Samples Drawn – All Randomized Participants (Maternal)

	Vaccine Group (as Randomized)	
	BNT162b2 (30 µg) (N^a=174) n^b (%)	Placebo (N^a=174) n^b (%)
Randomized	174 (100.0)	174 (100.0)
Not vaccinated	1 (0.6)	1 (0.6)
Dose 1	173 (99.4)	173 (99.4)
Blood sample drawn before Dose 1	171 (98.3)	173 (99.4)
Not obtained	1 (0.6)	0
Blood sample drawn 3 weeks after Dose 1*		
<19 Days	1 (0.6)	0
19-23 Days[c]	97 (55.7)	92 (52.9)
>23 Days	7 (4.0)	10 (5.7)
Not obtained	68 (39.1)	71 (40.8)
Dose 2	170 (97.7)	170 (97.7)
Blood sample drawn 2 weeks after Dose 2		
<11 Days	1 (0.6)	2 (1.1)
11-17 Days[c]	150 (86.2)	149 (85.6)
>17 Days	10 (5.7)	4 (2.3)
Not obtained	9 (5.2)	15 (8.6)
Blood sample drawn 1 month after Dose 2		

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14.17. Immunogenicity Blood Samples Drawn – All Randomized Participants (Maternal)

	Vaccine Group (as Randomized)	
	BNT162b2 (30 µg) (N[a]=174) n[b] (%)	Placebo (N[a]=174) n[b] (%)
<28 Days	3 (1.7)	4 (2.3)
28-35 Days[c]	97 (55.7)	103 (59.2)
>35 Days	9 (5.2)	8 (4.6)
Not obtained	61 (35.1)	55 (31.6)
Delivery	168 (96.6)	168 (96.6)
Blood sample drawn for delivery visit	154 (88.5)	149 (85.6)
Not obtained	14 (8.0)	19 (10.9)
Blood sample drawn 6 months after delivery		
<160 Days	1 (0.6)	0
160-200 Days[c]	136 (78.2)	0
>200 Days	9 (5.2)	0
Not obtained	22 (12.6)	168 (96.6)

Note: A prevaccination blood draw at Visit 2 was not required for Phase 3 participants per protocol.
Note: One participant had vaccine 1 blood draw on day 2 (after Dose 1).
Note: * = Blood draw is before Dose 2 and is only required for Phase 2 participants.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic.
c. Protocol-specified time frame.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (08:47) Source Data: adsl Table Generation: 19FEB2024 (04:02)
(Database snapshot date: Safety [29Mar2023], Immunogenicity [09Jan2024]) Output File: ./nda3/C4591015_CSR/adva_s011

14.18. Immunogenicity Blood Samples Drawn Through 1 Month After Dose 2 – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001) – All Randomized Participants

	Vaccine Group (as Randomized)			
	BNT162b2 (30 µg)		Placebo	
	C4591015 (Maternal) (N[a]=174) n[b] (%)	C4591001 (Nonpregnant Women) (N[a]=123) n[b] (%)	C4591015 (Maternal) (N[a]=174) n[b] (%)	C4591001 (Nonpregnant Women) (N[a]=133) n[b] (%)
Randomized	174 (100.0)	123 (100.0)	174 (100.0)	133 (100.0)
Not vaccinated	1 (0.6)	0	1 (0.6)	0
Vaccinated	173 (99.4)	123 (100.0)	173 (99.4)	133 (100.0)

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14.18. Immunogenicity Blood Samples Drawn Through 1 Month After Dose 2 – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001) – All Randomized Participants

	Vaccine Group (as Randomized)			
	BNT162b2 (30 µg)		Placebo	
	C4591015 (Maternal) (N[a]=174) n[b] (%)	C4591001 (Nonpregnant Women) (N[a]=123) n[b] (%)	C4591015 (Maternal) (N[a]=174) n[b] (%)	C4591001 (Nonpregnant Women) (N[a]=133) n[b] (%)
Dose 1	173 (99.4)	123 (100.0)	173 (99.4)	133 (100.0)
Blood sample drawn before Dose 1[c]	171 (98.3)	122 (99.2)	173 (99.4)	133 (100.0)
Not obtained	1 (0.6)	1 (0.8)	0	0
Dose 2	170 (97.7)	122 (99.2)	170 (97.7)	129 (97.0)
Blood sample drawn 1 month after Dose 2				
<28 Days	3 (1.7)	3 (2.4)	4 (2.3)	1 (0.8)
28-35 Days[c]	109 (62.6)	115 (93.5)	110 (63.2)	124 (93.2)
>35 Days	11 (6.3)	4 (3.3)	10 (5.7)	4 (3.0)
Not obtained	47 (27.0)	0	46 (26.4)	0

Note: Blood samples for immunogenicity assessment drawn at the delivery visit but within 1 month after Dose 2 visit window were also included in this analysis.
Note: Participants from C4591001 are a selected subset of age matched nonpregnant female Phase 3 participants.
Note: One participant had vaccine 1 blood draw on day 2 (after Dose 1).
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic.
c. Protocol-specified time frame.
PFIZER CONFIDENTIAL Source Data: adsl Table Generation: 01MAR2024 (02:39)
(Data cutoff date : C4591001 [31Aug2021]) Output File: ./nda3/C4591015_Bridging/adva_s011_brdg

14.19. Immunogenicity Blood Samples Drawn – All Randomized Participants (Infant)

	Maternal Vaccine Group (as Randomized)	
	BNT162b2 (30 µg) (N[a]=167) n[b] (%)	Placebo (N[a]=168) n[b] (%)
Randomized[c]	167 (100.0)	168 (100.0)
Blood sample drawn at birth[d]	153 (91.6)	151 (89.9)
Not obtained	14 (8.4)	17 (10.1)
Blood sample drawn at 6-months-of-age follow-up visit[d]		
<160 Days	1 (0.6)	1 (0.6)

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14.19. Immunogenicity Blood Samples Drawn – All Randomized Participants (Infant)

	Maternal Vaccine Group (as Randomized)	
	BNT162b2 (30 µg) (N[a]=167) n[b] (%)	Placebo (N[a]=168) n[b] (%)
160-200 Days	126 (75.4)	106 (63.1)
>200 Days	6 (3.6)	3 (1.8)
Not obtained	34 (20.4)	58 (34.5)

a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic.
c. Infants were not randomized and vaccinated but are summarized according to the vaccine group to which their mothers were randomized.
d. Protocol-specified time frame.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (08:47) Source Data: adsl Table Generation: 19FEB2024 (04:03)
(Database snapshot date: Safety [29Mar2023], Immunogenicity [09Jan2024]) Output File: ./nda3/C4591015_CSR/adva_s011_inf

14.20. E-Diary Transmission – Safety Population (Maternal)

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) n[a] (%)	Placebo n[a] (%)
Vaccinated at Dose 1[b]	173	173
E-diary		
Not transmitted[c]	0	0
Transmitted[d]		
Day 1	162 (93.6)	161 (93.1)
Day 2	164 (94.8)	166 (96.0)
Day 3	158 (91.3)	162 (93.6)
Day 4	164 (94.8)	161 (93.1)
Day 5	156 (90.2)	160 (92.5)
Day 6	150 (86.7)	159 (91.9)
Day 7	161 (93.1)	155 (89.6)
All 7 days[e]	112 (64.7)	122 (70.5)
Vaccinated at Dose 2[b]	170	170
E-diary		
Not transmitted[c]	10 (5.9)	15 (8.8)
Transmitted[d]		
Day 1	125 (73.5)	123 (72.4)
Day 2	145 (85.3)	133 (78.2)
Day 3	145 (85.3)	132 (77.6)

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14.20. E-Diary Transmission – Safety Population (Maternal)

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg)	Placebo
	n[a] (%)	n[a] (%)
Day 4	144 (84.7)	132 (77.6)
Day 5	146 (85.9)	137 (80.6)
Day 6	149 (87.6)	141 (82.9)
Day 7	148 (87.1)	141 (82.9)
All 7 days[e]	91 (53.5)	76 (44.7)

Note: Human immunodeficiency virus (HIV)-positive participants are included in this summary.
a. n = Number of participants with the specified characteristic.
b. These values are the denominators for the percentage calculations.
c. If no data for temperature, local reactions, fever/pain medication, or systemic events are reported for the entire electronic diary (e-diary) collection period (Day 1 through Day 7), the e-diary is considered not transmitted.
d. If any data for temperature, local reactions, fever/pain medication, or systemic events are reported for the specified day or set of days (ie, "all 7 days"), the e-diary is considered transmitted.
e. "All 7 days" includes Day 1 through Day 7 after vaccination. Day 1 is the day of vaccination.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adfacevd Table Generation: 03MAY2023 (10:31) Output File: ./nda3/C4591015_BR/adce_s200

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Immunogenicity

14.21. Geometric Mean Ratios – Participants With or Without Evidence of Infection – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001) – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)				
		BNT162b2 (30 µg)				
		C4591015 (Maternal)		C4591001 (Nonpregnant Women)		Pregnant/Nonpregnant
Assay	Dose/Sampling Time Point[a]	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])	GMR[d] (95% CI[d])
SARS-CoV-2 neutralization assay - NT50 (titer)	2/1 Month	100	2198.7 (1618.5, 2987.0)	114	1732.0 (1469.4, 2041.5)	1.27 (0.91, 1.77)

Abbreviations: GMR = geometric mean ratio; GMT = geometric mean titer; LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Blood samples for immunogenicity assessment drawn at the delivery visit but within 1 month after Dose 2 visit window were also included in this analysis.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: Participants from C4591001 are a selected subset of age matched nonpregnant female Phase 3 participants.
a. Protocol-specified timing for blood sample collection.
b. n = Number of participants with valid and determinate assay results for the specified assay at the given dose/sampling time point.
c. GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
d. GMRs and 2-sided 95% CIs were calculated by exponentiating the mean difference of the logarithms of the assay and the corresponding CIs (based on the Student t distribution).
PFIZER CONFIDENTIAL Source Data: adva Table Generation: 01MAR2024 (02:39)
(Data cutoff date : C4591001 [31Aug2021]) Output File: ./nda3/C4591015_Bridging/adva_s009_gmr_eval

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14.22. Geometric Mean Ratios – Participants With or Without Evidence of Infection – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001) – All-Available Immunogenicity Population

		Vaccine Group (as Randomized)				
		BNT162b2 (30 µg)				
		C4591015 (Maternal)		C4591001 (Nonpregnant Women)		Pregnant/Nonpregnant
Assay	Dose/Sampling Time Point[a]	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])	GMR[d] (95% CI[d])
SARS-CoV-2 neutralization assay - NT50 (titer)	2/1 Month	111	2349.5 (1748.5, 3157.2)	120	1706.7 (1456.6, 1999.7)	1.38 (0.99, 1.91)

Abbreviations: GMR = geometric mean ratio; GMT = geometric mean titer; LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Blood samples for immunogenicity assessment drawn at the delivery visit but within 1 month after Dose 2 visit window were also included in this analysis.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: Participants from C4591001 are a selected subset of age matched nonpregnant female Phase 3 participants.
a. Protocol-specified timing for blood sample collection.
b. n = Number of participants with valid and determinate assay results for the specified assay at the given dose/sampling time point.
c. GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
d. GMRs and 2-sided 95% CIs were calculated by exponentiating the mean difference of the logarithms of the assay and the corresponding CIs (based on the Student t distribution).
PFIZER CONFIDENTIAL Source Data: adva Table Generation: 01MAR2024 (02:39)
(Data cutoff date : C4591001 [31Aug2021]) Output File: ./nda3/C4591015_Bridging/adva_s009_gmr_aai

14.23. Model Adjusted Geometric Mean Ratios – Participants With or Without Evidence of Infection – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001) – All-Available Immunogenicity Population

		Vaccine Group (as Randomized)				
		BNT162b2 (30 µg)				
		C4591015 (Maternal)		C4591001 (Nonpregnant Women)		Pregnant/Nonpregnant
Assay	Dose/Sampling Time Point[a]	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])	GMR[d] (95% CI[d])
SARS-CoV-2 neutralization assay - NT50 (titer)	2/1 Month	110	2017.6 (1628.6, 2499.4)	119	2001.0 (1629.2, 2457.5)	1.01 (0.74, 1.37)

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14.23. Model Adjusted Geometric Mean Ratios – Participants With or Without Evidence of Infection – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001) – All-Available Immunogenicity Population

		Vaccine Group (as Randomized)				
		BNT162b2 (30 µg)				
		C4591015 (Maternal)		C4591001 (Nonpregnant Women)		Pregnant/Nonpregnant
Assay	Dose/Sampling Time Point[a]	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])	GMR[d] (95% CI[d])

Abbreviations: GMR = geometric mean ratio; GMT = geometric mean titer; LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Blood samples for immunogenicity assessment drawn at the delivery visit but within 1 month after Dose 2 visit window were also included in this analysis.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: Participants from C4591001 are a selected subset of age matched nonpregnant female Phase 3 participants.
a. Protocol-specified timing for blood sample collection.
b. n = Number of participants with valid and determinate assay results for the specified assay at both baseline and the given dose/sampling time point.
c. GMTs and 2-sided CIs were calculated by exponentiating the LS means and the corresponding CIs based on analysis of log-transformed NT50 titers using a regression model with group, age at Dose 1 in years (continuous), and baseline log transformed NT50 titers.
d. GMRs (ratio of GMTs of pregnant women to nonpregnant women) and 2-sided CIs were calculated by exponentiating the difference of LS means and the corresponding CIs based on the same regression model as above.
PFIZER CONFIDENTIAL Source Data: adva Table Generation: 01MAR2024 (02:38)
(Data cutoff date : C4591001 [31Aug2021]) Output File: ./nda3/C4591015_Bridging/adva_s009_gmr_aai_adj

14.24. Geometric Mean Titers – Participants Without Evidence of Infection up to 1 Month After Dose 2 – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001) – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		BNT162b2 (30 µg)				Placebo			
		C4591015 (Maternal)		C4591001 (Nonpregnant Women)		C4591015 (Maternal)		C4591001 (Nonpregnant Women)	
Assay	Dose/Sampling Time Point[a]	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Prevax	58	43.5 (43.5, 43.5)	107	43.5 (43.5, 43.5)	54	43.5 (43.5, 43.5)	113	43.5 (43.5, 43.5)
	2/1 Month	58	1109.2 (849.2, 1448.9)	107	1663.7 (1411.5, 1960.8)	54	43.5 (43.5, 43.5)	113	43.5 (43.5, 43.5)

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14.24. Geometric Mean Titers – Participants Without Evidence of Infection up to 1 Month After Dose 2 – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001) – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		BNT162b2 (30 µg)				Placebo			
		C4591015 (Maternal)		C4591001 (Nonpregnant Women)		C4591015 (Maternal)		C4591001 (Nonpregnant Women)	
Assay	Dose/Sampling Time Point[a]	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])

Abbreviations: GMT = geometric mean titer; LLOQ = lower limit of quantitation; N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Blood samples for immunogenicity assessment drawn at the delivery visit but within 1 month after Dose 2 visit window were also included in this analysis.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: Participants from C4591001 are a selected subset of age matched nonpregnant female Phase 3 participants.
Note: Participants who had no serological or virological evidence (prior to the 1 month after Dose 2 blood sample collection) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Dose 1 and 1 month after Dose 2 and no positive result between visits, negative NAAT [nasal swab] at Dose 1, Dose 2, and any unscheduled visit prior to the 1 month after Dose 2 blood sample collection) were included in the analysis.
a. Protocol-specified timing for blood sample collection.
b. n = Number of participants with valid and determinate assay results for the specified assay at the given dose/sampling time point.
c. GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL Source Data: adva Table Generation: 01MAR2024 (02:34)
(Data cutoff date : C4591001 [31Aug2021]) Output File: ./nda3/C4591015_Bridging/adva_s001_gmtc_noninf_eval

14.25. Geometric Mean Titers – Participants With or Without Evidence of Infection – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001) – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		BNT162b2 (30 µg)				Placebo			
		C4591015 (Maternal)		C4591001 (Nonpregnant Women)		C4591015 (Maternal)		C4591001 (Nonpregnant Women)	
Assay	Dose/Sampling Time Point[a]	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Prevax	100	70.4 (57.7, 85.9)	113	45.4 (43.2, 47.6)	106	72.9 (59.7, 89.0)	124	46.4 (43.4, 49.6)

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14.25. Geometric Mean Titers – Participants With or Without Evidence of Infection – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001) – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		BNT162b2 (30 µg)				Placebo			
		C4591015 (Maternal)		C4591001 (Nonpregnant Women)		C4591015 (Maternal)		C4591001 (Nonpregnant Women)	
Assay	Dose/Sampling Time Point[a]	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])
	2/1 Month	100	2198.7 (1618.5, 2987.0)	114	1732.0 (1469.4, 2041.5)	106	98.4 (74.3, 130.4)	124	44.7 (43.0, 46.5)

Abbreviations: GMT = geometric mean titer; LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Blood samples for immunogenicity assessment drawn at the delivery visit but within 1 month after Dose 2 visit window were also included in this analysis.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: Participants from C4591001 are a selected subset of age matched nonpregnant female Phase 3 participants.
a. Protocol-specified timing for blood sample collection.
b. n = Number of participants with valid and determinate assay results for the specified assay at the given dose/sampling time point.
c. GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL Source Data: adva Table Generation: 01MAR2024 (02:34)
(Data cutoff date : C4591001 [31Aug2021]) Output File: ./nda3/C4591015_Bridging/adva_s001_gmtc_eval

14.26. Geometric Mean Titers – Participants With or Without Evidence of Infection – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001) – All-Available Immunogenicity Population

		Vaccine Group (as Randomized)							
		BNT162b2 (30 µg)				Placebo			
		C4591015 (Maternal)		C4591001 (Nonpregnant Women)		C4591015 (Maternal)		C4591001 (Nonpregnant Women)	
Assay	Dose/Sampling Time Point[a]	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Prevax	157	73.5 (62.5, 86.5)	119	45.3 (43.2, 47.4)	161	68.8 (58.8, 80.4)	129	46.3 (43.4, 49.4)

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14.26. Geometric Mean Titers – Participants With or Without Evidence of Infection – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001) – All-Available Immunogenicity Population

		Vaccine Group (as Randomized)							
		BNT162b2 (30 µg)				Placebo			
		C4591015 (Maternal)		C4591001 (Nonpregnant Women)		C4591015 (Maternal)		C4591001 (Nonpregnant Women)	
Assay	Dose/Sampling Time Point[a]	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])
	2/1 Month	111	2349.5 (1748.5, 3157.2)	120	1706.7 (1456.6, 1999.7)	115	95.2 (73.0, 124.3)	129	45.0 (43.3, 46.9)

Abbreviations: GMT = geometric mean titer; LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Blood samples for immunogenicity assessment drawn at the delivery visit but within 1 month after Dose 2 visit window were also included in this analysis.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: Participants from C4591001 are a selected subset of age matched nonpregnant female Phase 3 participants.
a. Protocol-specified timing for blood sample collection.
b. n = Number of participants with valid and determinate assay results for the specified assay at the given dose/sampling time point.
c. GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL Source Data: adva Table Generation: 01MAR2024 (02:34)
(Data cutoff date : C4591001 [31Aug2021]) Output File: ./nda3/C4591015_Bridging/adva_s001_gmtc_aai

14.27. Geometric Mean Fold Rise – Participants Without Evidence of Infection up to 1 Month After Dose 2 – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001) – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		BNT162b2 (30 µg)				Placebo			
		C4591015 (Maternal)		C4591001 (Nonpregnant Women)		C4591015 (Maternal)		C4591001 (Nonpregnant Women)	
Assay	Dose/Sampling Time Point[a]	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	2/1 Month	58	25.5 (19.5, 33.3)	107	38.2 (32.4, 45.1)	54	1.0 (1.0, 1.0)	113	1.0 (1.0, 1.0)

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14.27. Geometric Mean Fold Rise – Participants Without Evidence of Infection up to 1 Month After Dose 2 – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001) – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		BNT162b2 (30 µg)				Placebo			
		C4591015 (Maternal)		C4591001 (Nonpregnant Women)		C4591015 (Maternal)		C4591001 (Nonpregnant Women)	
Assay	Dose/Sampling Time Point[a]	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])

Abbreviations: GMFR = geometric mean fold rise; LLOQ = lower limit of quantitation; N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Blood samples for immunogenicity assessment drawn at the delivery visit but within 1 month after Dose 2 visit window were also included in this analysis.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: Participants from C4591001 are a selected subset of age matched nonpregnant female Phase 3 participants.
Note: Participants who had no serological or virological evidence (prior to the 1 month after Dose 2 blood sample collection) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Dose 1 and 1 month after Dose 2 and no positive result between visits, negative NAAT [nasal swab] at Dose 1, Dose 2, and any unscheduled visit prior to the 1 month after Dose 2 blood sample collection) were included in the analysis.
a. Protocol-specified timing for blood sample collection.
b. n = Number of participants with valid and determinate assay results for the specified assay both before vaccination and at the given dose/sampling time point.
c. GMFRs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL Source Data: adva Table Generation: 01MAR2024 (02:34)
(Data cutoff date : C4591001 [31Aug2021]) Output File: ./nda3/C4591015_Bridging/adva_s002_gmfr_wo_evl

14.28. Geometric Mean Fold Rise, by Baseline SARS-CoV-2 Status – Participants With or Without Evidence of Infection – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001) – Evaluable Immunogenicity Population

			Vaccine Group (as Randomized)								
			BNT162b2 (30 µg)				Placebo				
			C4591015 (Maternal)		C4591001 (Nonpregnant Women)		C4591015 (Maternal)		C4591001 (Nonpregnant Women)		
Assay	Dose/Sampling Time Point[a]	Baseline SARS-CoV-2 Status	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	

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14.28. Geometric Mean Fold Rise, by Baseline SARS-CoV-2 Status – Participants With or Without Evidence of Infection – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001) – Evaluable Immunogenicity Population

			Vaccine Group (as Randomized)							
			BNT162b2 (30 µg)				Placebo			
			C4591015 (Maternal)		C4591001 (Nonpregnant Women)		C4591015 (Maternal)		C4591001 (Nonpregnant Women)	
Assay	Dose/Sampling Time Point[a]	Baseline SARS-CoV-2 Status	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	2/1 Month		99	31.4 (23.5, 41.8)	113	38.6 (33.0, 45.1)	106	1.3 (1.1, 1.7)	124	1.0 (0.9, 1.0)
		Positive	34	48.7 (25.3, 93.6)	4	50.0 (33.6, 74.3)	44	1.7 (1.1, 2.8)	6	0.5 (0.1, 2.3)
		Negative	64	25.9 (19.8, 33.8)	109	38.2 (32.5, 44.9)	59	1.1 (1.0, 1.3)	118	1.0 (1.0, 1.0)

Abbreviations: GMFR = geometric mean fold rise; LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Blood samples for immunogenicity assessment drawn at the delivery visit but within 1 month after Dose 2 visit window were also included in this analysis.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: Participants from C4591001 are a selected subset of age matched nonpregnant female Phase 3 participants.
a. Protocol-specified timing for blood sample collection.
b. n = Number of participants with valid and determinate assay results for the specified assay both before vaccination and at the given dose/sampling time point.
c. GMFRs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL Source Data: adva Table Generation: 01MAR2024 (02:14)
(Data cutoff date : C4591001 [31Aug2021]) Output File: ./nda3/C4591015_Bridging/adva_s002_gmfr_evl_brdg

14.29. Geometric Mean Titers and Concentrations – Evaluable Immunogenicity Population (Maternal)

		Vaccine Group (as Randomized)			
		BNT162b2 (30 µg)		Placebo	
Assay	Dose/Sampling Time Point[a]	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Prevax	100	70.4 (57.7, 85.9)	106	72.9 (59.7, 89.0)

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14.29. Geometric Mean Titers and Concentrations – Evaluable Immunogenicity Population (Maternal)

Assay	Dose/Sampling Time Point[a]	Vaccine Group (as Randomized)			
		BNT162b2 (30 µg)		Placebo	
		n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])
	2/2 Weeks	101	3240.6 (2371.5, 4428.2)	106	76.7 (62.4, 94.4)
	2/1 Month	87	2504.0 (1813.9, 3456.6)	97	104.5 (77.1, 141.5)
	Delivery	93	1281.0 (920.9, 1782.0)	90	91.4 (69.1, 120.9)
	6-Month postdelivery	86	2202.7 (1439.7, 3370.2)	N/A	
Full-length S-binding IgG level assay (U/mL)	1/Prevax	100	11.3 (6.6, 19.2)	106	16.9 (9.6, 29.8)
	2/2 Weeks	101	8684.6 (6200.1, 12164.8)	106	19.5 (10.8, 35.4)
	2/1 Month	88	6400.0 (5063.1, 8089.9)	97	25.5 (13.2, 49.1)
	Delivery	93	4304.3 (3434.1, 5395.0)	91	17.6 (9.0, 34.3)
	6-Month postdelivery	86	3615.8 (2592.6, 5042.7)	N/A	

Abbreviations: GMC = geometric mean concentration; GMT = geometric mean titer; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; N/A = not applicable; NT50 = 50% neutralizing titer; S = spike protein; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
a. Protocol-specified timing for blood sample collection.
b. n = Number of participants with valid and determinate assay results for the specified assay at the given dose/sampling time point.
c. GMTs, GMCs, and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers or concentrations and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 12JAN2024 (03:07) Source Data: adva Table Generation: 22FEB2024 (01:04)
(Database snapshot date: Safety [29Mar2023], Immunogenicity [09Jan2024]) Output File: ./nda3/C4591015_CSR/adva_s001_eval

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14.30. Geometric Mean Titers and Concentrations – All-Available Immunogenicity Population (Maternal)

Assay	Dose/Sampling Time Point[a]	Vaccine Group (as Randomized)			
		BNT162b2 (30 µg)		Placebo	
		n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Prevax	157	73.5 (62.5, 86.5)	161	68.8 (58.8, 80.4)
	2/2 Weeks	149	3325.0 (2567.3, 4306.3)	146	70.7 (59.2, 84.4)
	2/1 Month	97	2751.5 (2028.4, 3732.5)	106	100.3 (75.4, 133.5)
	Delivery	141	1441.0 (1087.3, 1909.7)	138	80.3 (64.5, 99.8)
	6-Month postdelivery	134	2005.9 (1436.4, 2801.2)	N/A	
Full-length S-binding IgG level assay (U/mL)	1/Prevax	157	12.9 (8.4, 20.0)	161	13.2 (8.4, 20.6)
	2/2 Weeks	149	9188.1 (6968.4, 12115.1)	146	13.9 (8.5, 22.8)
	2/1 Month	98	6798.3 (5438.4, 8498.3)	106	23.0 (12.4, 42.6)
	Delivery	141	4478.6 (3440.8, 5829.4)	140	13.6 (8.1, 22.9)
	6-Month postdelivery	134	3154.0 (2421.7, 4107.6)	N/A	

Abbreviations: GMC = geometric mean concentration; GMT = geometric mean titer; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; N/A = not applicable; NT50 = 50% neutralizing titer; S = spike protein; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
a. Protocol-specified timing for blood sample collection.
b. n = Number of participants with valid and determinate assay results for the specified assay at the given dose/sampling time point.
c. GMTs, GMCs, and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers or concentrations and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 12JAN2024 (03:07) Source Data: adva Table Generation: 22FEB2024 (01:04)
(Database snapshot date: Safety [29Mar2023], Immunogenicity [09Jan2024]) Output File: ./nda3/C4591015_CSR/adva_s001_aai

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14.31. Geometric Mean Titers and Concentrations of Participants Without Evidence of Infection – Phase 2 – Dose 1 Evaluable Immunogenicity Population (Maternal)

Assay	Dose/Sampling Time Point[a]	Vaccine Group (as Randomized)			
		BNT162b2 (30 µg)		Placebo	
		n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Prevax	65	47.6 (41.6, 54.4)	59	43.5 (43.5, 43.5)
	2/Prevax	61	129.3 (93.4, 179.1)	59	45.5 (41.6, 49.9)
	2/2 Weeks	41	1991.8 (1456.3, 2724.1)	35	45.0 (42.0, 48.3)
	2/1 Month	36	1212.6 (855.2, 1719.4)	31	43.5 (43.5, 43.5)
	Delivery	39	695.7 (500.6, 966.8)	29	43.5 (43.5, 43.5)
	6-Month postdelivery	20	465.4 (168.6, 1284.5)	N/A	
Full-length S-binding IgG level assay (U/mL)	1/Prevax	65	2.4 (1.6, 3.7)	59	2.0 (1.4, 2.8)
	2/Prevax	62	1529.0 (1092.1, 2140.7)	59	2.1 (1.3, 3.4)
	2/2 Weeks	41	7802.0 (6273.3, 9703.2)	35	1.8 (1.1, 3.1)
	2/1 Month	36	4281.0 (3234.7, 5665.7)	31	1.8 (1.1, 2.9)
	Delivery	39	2747.6 (2144.7, 3520.0)	29	1.7 (1.0, 3.0)
	6-Month postdelivery	20	1639.4 (780.1, 3445.4)	N/A	

Abbreviations: GMC = geometric mean concentration; GMT = geometric mean titer; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; N/A = not applicable; NT50 = 50% neutralizing titer; S = spike protein; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: Participants who had no serological or virological evidence (up to the reporting timepoints) of past SARS-CoV-2 infection (ie, a negative N-binding antibody [serum] result at all planned visits up to the reporting timepoints, a negative NAAT [nasal swab] result at the study vaccination visit and at any unscheduled visit up to the reporting timepoints) and were included in the analysis.
a. Protocol-specified timing for blood sample collection.
b. n = Number of participants with valid and determinate assay results for the specified assay at the given dose/sampling time point.
c. GMTs, GMCs, and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers or concentrations and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 12JAN2024 (03:07) Source Data: adva Table Generation: 22FEB2024 (01:04)
(Database snapshot date: Safety [29Mar2023], Immunogenicity [09Jan2024]) Output File: ./nda3/C4591015_CSR/adva_s001_dos1eval_wo_inf

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14.32. Geometric Mean Titers, by Subgroup – Participants Without Evidence of Infection up to 1 Month After Dose 2 – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001) – Evaluable Immunogenicity Population

			Vaccine Group (as Randomized)							
			BNT162b2 (30 µg)				Placebo			
			C4591015 (Maternal)		C4591001 (Nonpregnant Women)		C4591015 (Maternal)		C4591001 (Nonpregnant Women)	
Assay	Dose/Sampling Time Point[a]	Subgroup	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Prevax	All	58	43.5 (43.5, 43.5)	107	43.5 (43.5, 43.5)	54	43.5 (43.5, 43.5)	113	43.5 (43.5, 43.5)
		Race								
		White	53	43.5 (43.5, 43.5)	92	43.5 (43.5, 43.5)	46	43.5 (43.5, 43.5)	88	43.5 (43.5, 43.5)
		Black or African American	2	43.5 (43.5, 43.5)	3	43.5 (43.5, 43.5)	5	43.5 (43.5, 43.5)	11	43.5 (43.5, 43.5)
		All others	3	43.5 (43.5, 43.5)	12	43.5 (43.5, 43.5)	3	43.5 (43.5, 43.5)	14	43.5 (43.5, 43.5)
		Ethnicity								
		Hispanic/Latino	22	43.5 (43.5, 43.5)	38	43.5 (43.5, 43.5)	22	43.5 (43.5, 43.5)	42	43.5 (43.5, 43.5)
		Non-Hispanic/non-Latino	36	43.5 (43.5, 43.5)	69	43.5 (43.5, 43.5)	32	43.5 (43.5, 43.5)	71	43.5 (43.5, 43.5)
	2/1 Month	All	58	1109.2 (849.2, 1448.9)	107	1663.7 (1411.5, 1960.8)	54	43.5 (43.5, 43.5)	113	43.5 (43.5, 43.5)
		Race								
		White	53	1216.5 (925.2, 1599.4)	92	1615.3 (1348.8, 1934.3)	46	43.5 (43.5, 43.5)	88	43.5 (43.5, 43.5)
		Black or African American	2	443.0 (13.2, 14845.3)	3	1887.5 (473.1, 7530.2)	5	43.5 (43.5, 43.5)	11	43.5 (43.5, 43.5)
		All others	3	400.4 (30.1, 5336.3)	12	2021.3 (1184.0, 3450.8)	3	43.5 (43.5, 43.5)	14	43.5 (43.5, 43.5)
		Ethnicity								
		Hispanic/Latino	22	865.8 (558.6, 1342.0)	38	1850.0 (1414.3, 2419.8)	22	43.5 (43.5, 43.5)	42	43.5 (43.5, 43.5)

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14.32. Geometric Mean Titers, by Subgroup – Participants Without Evidence of Infection up to 1 Month After Dose 2 – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001) – Evaluable Immunogenicity Population

			Vaccine Group (as Randomized)							
			BNT162b2 (30 µg)				Placebo			
			C4591015 (Maternal)		C4591001 (Nonpregnant Women)		C4591015 (Maternal)		C4591001 (Nonpregnant Women)	
Assay	Dose/Sampling Time Point[a]	Subgroup	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])
		Non-Hispanic/non-Latino	36	1290.5 (915.0, 1820.2)	69	1569.2 (1270.4, 1938.3)	32	43.5 (43.5, 43.5)	71	43.5 (43.5, 43.5)

Abbreviations: GMT = geometric mean titer; LLOQ = lower limit of quantitation; N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: All others = American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
Note: Blood samples for immunogenicity assessment drawn at the delivery visit but within 1 month after Dose 2 visit window were also included in this analysis.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: Participants from C4591001 are a selected subset of age matched nonpregnant female Phase 3 participants.
Note: Participants who had no serological or virological evidence (prior to the 1 month after Dose 2 blood sample collection) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Dose 1 and 1 month after Dose 2 and no positive result between visits, negative NAAT [nasal swab] at Dose 1, Dose 2, and any unscheduled visit prior to the 1 month after Dose 2 blood sample collection) were included in the analysis.
a. Protocol-specified timing for blood sample collection.
b. n = Number of participants with valid and determinate assay results for the specified assay at the given dose/sampling time point.
c. GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL Source Data: adva Table Generation: 01MAR2024 (02:34)
(Data cutoff date : C4591001 [31Aug2021]) Output File: ./nda3/C4591015_Bridging/adva_s001_gmtc_ni_sub_eval

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14.33. Geometric Mean Titers, by Subgroup – Participants With or Without Evidence of Infection – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001) – Evaluable Immunogenicity Population

			Vaccine Group (as Randomized)							
			BNT162b2 (30 µg)				Placebo			
			C4591015 (Maternal)		C4591001 (Nonpregnant Women)		C4591015 (Maternal)		C4591001 (Nonpregnant Women)	
Assay	Dose/Sampling Time Point[a]	Subgroup	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Prevax	All	100	70.4 (57.7, 85.9)	113	45.4 (43.2, 47.6)	106	72.9 (59.7, 89.0)	124	46.4 (43.4, 49.6)
		Race								
		White	76	59.3 (49.1, 71.7)	94	43.5 (43.5, 43.5)	77	63.6 (52.8, 76.6)	94	46.4 (42.9, 50.3)
		Black or African American	20	148.5 (79.7, 276.7)	5	82.9 (26.7, 257.3)	23	122.5 (63.5, 236.3)	14	43.5 (43.5, 43.5)
		All others	4	43.5 (43.5, 43.5)	14	48.4 (38.5, 60.8)	6	57.9 (27.8, 120.8)	16	48.9 (38.1, 62.6)
		Ethnicity								
		Hispanic/Latino	41	65.0 (50.2, 84.1)	39	43.5 (43.5, 43.5)	40	77.2 (56.3, 105.8)	45	49.9 (42.2, 58.9)
		Non-Hispanic/non-Latino	59	74.4 (55.6, 99.6)	74	46.4 (43.1, 49.9)	66	70.5 (54.2, 91.7)	79	44.5 (42.5, 46.7)
		Baseline SARS-CoV-2 status								
		Positive	34	179.2 (114.4, 280.8)	4	141.3 (37.8, 528.6)	44	145.3 (97.5, 216.3)	6	165.7 (47.6, 577.2)
		Negative	65	43.5 (43.5, 43.5)	109	43.5 (43.5, 43.5)	59	44.8 (42.3, 47.5)	118	43.5 (43.5, 43.5)
	2/1 Month	All	100	2198.7 (1618.5, 2987.0)	114	1732.0 (1469.4, 2041.5)	106	98.4 (74.3, 130.4)	124	44.7 (43.0, 46.5)
		Race								
		White	76	1685.1 (1214.9, 2337.3)	94	1615.8 (1354.5, 1927.5)	77	65.5 (53.4, 80.4)	94	44.3 (42.7, 46.0)
		Black or African American	20	8016.9 (4356.2, 14753.8)	6	2688.4 (750.2, 9634.0)	23	336.6 (140.3, 808.1)	14	48.9 (38.0, 62.9)

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14.33. Geometric Mean Titers, by Subgroup – Participants With or Without Evidence of Infection – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001) – Evaluable Immunogenicity Population

			Vaccine Group (as Randomized)							
			BNT162b2 (30 µg)				Placebo			
			C4591015 (Maternal)		C4591001 (Nonpregnant Women)		C4591015 (Maternal)		C4591001 (Nonpregnant Women)	
Assay	Dose/Sampling Time Point[a]	Subgroup	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])
		All others	4	535.0 (103.9, 2754.0)	14	2286.5 (1390.8, 3759.2)	6	162.6 (16.7, 1587.1)	16	43.5 (43.5, 43.5)
		Ethnicity								
		Hispanic/Latino	40	1940.1 (1140.7, 3299.8)	39	1850.8 (1425.2, 2403.5)	40	76.6 (54.4, 107.8)	45	45.3 (41.8, 49.0)
		Non-Hispanic/non-Latino	60	2390.0 (1635.0, 3493.8)	75	1673.3 (1351.5, 2071.6)	66	114.5 (76.4, 171.6)	79	44.4 (42.6, 46.3)
		Baseline SARS-CoV-2 status								
		Positive	34	8728.0 (5441.3, 14000.0)	4	7062.2 (2589.4, 19261.0)	44	253.5 (151.2, 425.2)	6	76.8 (30.4, 193.8)
		Negative	64	1124.8 (861.3, 1469.0)	109	1663.2 (1415.4, 1954.4)	59	50.6 (41.7, 61.6)	118	43.5 (43.5, 43.5)

Abbreviations: GMT = geometric mean titer; LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: All others = American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
Note: Blood samples for immunogenicity assessment drawn at the delivery visit but within 1 month after Dose 2 visit window were also included in this analysis.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: Participants from C4591001 are a selected subset of age matched nonpregnant female Phase 3 participants.
a. Protocol-specified timing for blood sample collection.
b. n = Number of participants with valid and determinate assay results for the specified assay at the given dose/sampling time point.
c. GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL Source Data: adva Table Generation: 01MAR2024 (02:12)
(Data cutoff date : C4591001 [31Aug2021]) Output File: ./nda3/C4591015_Bridging/adva_s001_gmtc_sub_eval

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14.34. Geometric Mean Fold Rise From Before Vaccination to Each Subsequent Time Point – Evaluable Immunogenicity Population (Maternal)

Assay	Dose/Sampling Time Point[a]	Vaccine Group (as Randomized)			
		BNT162b2 (30 µg)		Placebo	
		n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	2/2 Weeks	100	46.8 (34.8, 62.9)	106	1.1 (0.9, 1.2)
	2/1 Month	87	34.7 (26.0, 46.1)	97	1.4 (1.1, 1.7)
	Delivery	92	17.8 (12.9, 24.7)	90	1.2 (1.0, 1.5)
	6-Month postdelivery	85	28.8 (18.2, 45.6)	N/A	
Full-length S-binding IgG level assay (U/mL)	2/2 Weeks	100	770.0 (445.2, 1331.8)	106	1.2 (0.9, 1.5)
	2/1 Month	88	562.2 (349.5, 904.5)	97	1.3 (1.0, 1.6)
	Delivery	92	382.2 (229.0, 637.9)	91	1.0 (0.8, 1.4)
	6-Month postdelivery	85	252.2 (127.0, 500.7)	N/A	

Abbreviations: GMFR = geometric mean fold rise; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; N/A = not applicable; NT50 = 50% neutralizing titer; S = spike protein; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
a. Protocol-specified timing for blood sample collection.
b. n = Number of participants with valid and determinate assay results for the specified assay both before vaccination and at the given dose/sampling time point.
c. GMFRs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 12JAN2024 (03:07) Source Data: adva Table Generation: 22FEB2024 (01:04)
(Database snapshot date: Safety [29Mar2023], Immunogenicity [09Jan2024]) Output File: ./nda3/C4591015_CSR/adva_s002_gmfr_evl

14.35. Geometric Mean Fold Rise From Before Vaccination to Each Subsequent Time Point – All-Available Immunogenicity Population (Maternal)

Assay	Dose/Sampling Time Point[a]	Vaccine Group (as Randomized)			
		BNT162b2 (30 µg)		Placebo	
		n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])

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14.35. Geometric Mean Fold Rise From Before Vaccination to Each Subsequent Time Point – All-Available Immunogenicity Population (Maternal)

Assay	Dose/Sampling Time Point[a]	Vaccine Group (as Randomized)			
		BNT162b2 (30 µg)		Placebo	
		n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	2/2 Weeks	148	45.2 (35.5, 57.7)	146	1.1 (0.9, 1.2)
	2/1 Month	97	37.4 (28.5, 49.0)	106	1.3 (1.1, 1.6)
	Delivery	140	18.8 (14.1, 25.0)	138	1.2 (1.0, 1.4)
	6-Month postdelivery	133	25.8 (18.0, 37.2)	N/A	
Full-length S-binding IgG level assay (U/mL)	2/2 Weeks	148	667.4 (428.6, 1039.0)	146	1.1 (0.9, 1.4)
	2/1 Month	98	516.3 (323.6, 823.8)	106	1.2 (1.0, 1.5)
	Delivery	140	324.6 (201.1, 523.9)	140	1.1 (0.9, 1.4)
	6-Month postdelivery	133	200.5 (116.7, 344.3)	N/A	

Abbreviations: GMFR = geometric mean fold rise; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; N/A = not applicable; NT50 = 50% neutralizing titer; S = spike protein; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
a. Protocol-specified timing for blood sample collection.
b. n = Number of participants with valid and determinate assay results for the specified assay both before vaccination and at the given dose/sampling time point.
c. GMFRs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 12JAN2024 (03:07) Source Data: adva Table Generation: 22FEB2024 (01:04)
(Database snapshot date: Safety [29Mar2023], Immunogenicity [09Jan2024]) Output File: ./nda3/C4591015_CSR/adva_s002_gmfr_aai

14.36. Geometric Mean Fold Rise For Participants Without Evidence of Infection – From Before Vaccination to Each Subsequent Time Point – Evaluable Immunogenicity Population (Maternal)

Assay	Dose/Sampling Time Point[a]	Vaccine Group (as Randomized)			
		BNT162b2 (30 µg)		Placebo	
		n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])

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14.36. Geometric Mean Fold Rise For Participants Without Evidence of Infection – From Before Vaccination to Each Subsequent Time Point – Evaluable Immunogenicity Population (Maternal)

		Vaccine Group (as Randomized)			
		BNT162b2 (30 µg)		Placebo	
Assay	Dose/Sampling Time Point[a]	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	2/2 Weeks	58	43.7 (33.9, 56.4)	54	1.0 (1.0, 1.1)
	2/1 Month	50	25.3 (18.9, 33.9)	49	1.0 (1.0, 1.0)
	Delivery	55	15.6 (12.1, 20.1)	47	1.0 (1.0, 1.0)
	6-Month postdelivery	26	11.3 (5.0, 25.4)	N/A	
Full-length S-binding IgG level assay (U/mL)	2/2 Weeks	58	3618.7 (2489.1, 5260.7)	54	0.9 (0.8, 1.1)
	2/1 Month	50	2276.4 (1545.5, 3352.9)	49	0.9 (0.8, 1.1)
	Delivery	55	1377.6 (948.6, 2000.5)	47	0.8 (0.6, 1.0)
	6-Month postdelivery	26	650.3 (279.3, 1514.3)	N/A	

Abbreviations: GMFR = geometric mean fold rise; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; N/A = not applicable; NT50 = 50% neutralizing titer; S = spike protein; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: Participants who had no serological or virological evidence (up to the reporting timepoints) of past SARS-CoV-2 infection (ie, a negative N-binding antibody [serum] result at all planned visits up to the reporting timepoints, a negative NAAT [nasal swab] result at the study vaccination visit and at any unscheduled visit up to the reporting timepoints) and were included in the analysis.
a. Protocol-specified timing for blood sample collection.
b. n = Number of participants with valid and determinate assay results for the specified assay both before vaccination and at the given dose/sampling time point.
c. GMFRs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 12JAN2024 (03:07) Source Data: adva Table Generation: 22FEB2024 (01:04)
(Database snapshot date: Safety [29Mar2023], Immunogenicity [09Jan2024]) Output File: ./nda3/C4591015_CSR/adva_s002_gmfr_evl_wo_inf

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14.37. Geometric Mean Fold Rise of Participants Without Evidence of Infection – From Before Vaccination to Subsequent Timepoints – Phase 2 – Dose 1 Evaluable Immunogenicity Population (Maternal)

		Vaccine Group (as Randomized)			
		BNT162b2 (30 µg)		Placebo	
Assay	Dose/Sampling Time Point[a]	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	2/Prevax	61	2.9 (2.1, 3.9)	59	1.0 (1.0, 1.1)
	2/2 Weeks	41	45.8 (33.5, 62.6)	35	1.0 (1.0, 1.1)
	2/1 Month	36	27.9 (19.7, 39.5)	31	1.0 (1.0, 1.0)
	Delivery	39	16.0 (11.5, 22.2)	29	1.0 (1.0, 1.0)
	6-Month postdelivery	20	10.7 (3.9, 29.5)	N/A	
Full-length S-binding IgG level assay (U/mL)	2/Prevax	62	710.0 (477.2, 1056.4)	59	1.1 (0.8, 1.5)
	2/2 Weeks	41	3814.5 (2529.4, 5752.6)	35	0.9 (0.7, 1.2)
	2/1 Month	36	2413.7 (1571.5, 3707.2)	31	0.9 (0.7, 1.1)
	Delivery	39	1284.6 (817.5, 2018.6)	29	0.7 (0.5, 1.0)
	6-Month postdelivery	20	664.0 (244.6, 1802.7)	N/A	

Abbreviations: GMFR = geometric mean fold rise; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; N/A = not applicable; NT50 = 50% neutralizing titer; S = spike protein; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: Participants who had no serological or virological evidence (up to the reporting timepoints) of past SARS-CoV-2 infection (ie, a negative N-binding antibody [serum] result at all planned visits up to the reporting timepoints, a negative NAAT [nasal swab] result at the study vaccination visit and at any unscheduled visit up to the reporting timepoints) and were included in the analysis.
a. Protocol-specified timing for blood sample collection.
b. n = Number of participants with valid and determinate assay results for the specified assay both before vaccination and at the given dose/sampling time point.
c. GMFRs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 12JAN2024 (03:07) Source Data: adva Table Generation: 22FEB2024 (01:04)
(Database snapshot date: Safety [29Mar2023], Immunogenicity [09Jan2024]) Output File: ./nda3/C4591015_CSR/adva_s002_gmfr_evl01_wo_inf

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14.38. Geometric Mean Concentrations – All-Available Immunogenicity Population (Infant)

Assay	Sampling Time Point[a]	Maternal Vaccine Group (as Randomized)			
		BNT162b2 (30 µg)		Placebo	
		n[b]	GMC[c] (95% CI[c])	n[b]	GMC[c] (95% CI[c])
Full-length S-binding IgG level assay (U/mL)	Birth	141	5014.7 (3696.9, 6802.1)	142	13.4 (8.1, 22.2)
	6 Months of age	122	272.2 (213.0, 347.7)	103	16.2 (9.5, 27.6)

Abbreviations: GMC = geometric mean concentration; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; S = spike protein.
Note: Infants born to human immunodeficiency virus (HIV)-positive participants are not included in this summary.
a. Protocol-specified timing for blood sample collection.
b. n = Number of participants with valid and determinate assay results for the specified assay at the given sampling time point.
c. GMCs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the concentrations and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 12JAN2024 (03:07) Source Data: adva Table Generation: 22FEB2024 (01:04)
(Database snapshot date: Safety [29Mar2023], Immunogenicity [09Jan2024]) Output File: ./nda3/C4591015_CSR/adva_s001_aai_inf

14.39. Geometric Mean Concentrations, by Breastfeeding Status – Evaluable Immunogenicity Population (Infant)

Assay	Sampling Time Point[a]	Breastfeeding Status	Maternal Vaccine Group (as Randomized)			
			BNT162b2 (30 µg)		Placebo	
			n[b]	GMC[c] (95% CI[c])	n[b]	GMC[c] (95% CI[c])
Full-length S-binding IgG level assay (U/mL)	Birth	Overall[d]	91	5576.4 (4246.2, 7323.2)	92	19.4 (10.2, 37.0)
		Breastfed	81	5810.9 (4305.5, 7842.8)	84	20.6 (10.4, 40.8)
		Not breastfed	7	4858.4 (2218.3, 10640.4)	6	10.3 (0.5, 201.8)
	6 Months of age	Overall[d]	83	311.1 (235.8, 410.5)	69	22.0 (11.4, 42.7)
		Breastfed	62	358.5 (254.0, 505.8)	48	26.6 (11.9, 59.5)

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14.39. Geometric Mean Concentrations, by Breastfeeding Status – Evaluable Immunogenicity Population (Infant)

Assay	Sampling Time Point[a]	Breastfeeding Status	Maternal Vaccine Group (as Randomized)			
			BNT162b2 (30 µg)		Placebo	
			n[b]	GMC[c] (95% CI[c])	n[b]	GMC[c] (95% CI[c])
		Not breastfed	21	204.8 (138.0, 303.9)	20	9.9 (3.6, 27.4)

Abbreviations: GMC = geometric mean concentration; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; S = spike protein.
Note: Infants born to human immunodeficiency virus (HIV)-positive participants are not included in this summary.
a. Protocol-specified timing for blood sample collection.
b. n = Number of participants with valid and determinate assay results for the specified assay at the given sampling time point.
c. GMCs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the concentrations and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
d. Participants with unknown breastfeeding status are included in the 'Overall' category as well.
PFIZER CONFIDENTIAL SDTM Creation: 12JAN2024 (03:07) Source Data: adva Table Generation: 22FEB2024 (01:01)
(Database snapshot date: Safety [29Mar2023], Immunogenicity [09Jan2024]) Output File: ./nda3/C4591015_CSR/adva_s001_eval_brstfd_inf

14.40. Geometric Mean Fold Rise From Birth to 6 Months of Age, by Breastfeeding Status – Evaluable Immunogenicity Population (Infant)

Assay	Sampling Time Point[a]	Breastfeeding Status	Maternal Vaccine Group (as Randomized)			
			BNT162b2 (30 µg)		Placebo	
			n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])
Full-length S-binding IgG level assay (U/mL)	6 Months of age	Overall[d]	75	0.1 (0.0, 0.1)	65	0.6 (0.3, 1.3)
		Breastfed	54	0.1 (0.0, 0.1)	44	0.5 (0.2, 1.3)
		Not breastfed	21	0.0 (0.0, 0.1)	20	0.5 (0.2, 1.6)

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14.40. Geometric Mean Fold Rise From Birth to 6 Months of Age, by Breastfeeding Status – Evaluable Immunogenicity Population (Infant)

Assay	Sampling Time Point[a]	Breastfeeding Status	Maternal Vaccine Group (as Randomized)			
			BNT162b2 (30 µg)		Placebo	
			n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])

Abbreviations: GMFR = geometric mean fold rise; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; S = spike protein.
Note: Infants born to human immunodeficiency virus (HIV)-positive participants are not included in this summary.
a. Protocol-specified timing for blood sample collection.
b. n = Number of participants with valid and determinate assay results at both birth and 6 months of age.
c. GMFRs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
d. Participants with unknown breastfeeding status are included in the 'Overall' category as well.
PFIZER CONFIDENTIAL SDTM Creation: 12JAN2024 (03:07) Source Data: adva Table Generation: 22FEB2024 (01:04)
(Database snapshot date: Safety [29Mar2023], Immunogenicity [09Jan2024]) Output File: ./nda3/C4591015_CSR/adva_s002_gmfr_inf_brf_evl

14.41. Geometric Mean Titers and Concentrations – Phase 2 – Dose 1 Evaluable Immunogenicity Population (Maternal)

Assay	Dose/Sampling Time Point[a]	Vaccine Group (as Randomized)			
		BNT162b2 (30 µg)		Placebo	
		n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Prevax	90	63.9 (52.8, 77.4)	91	64.9 (53.7, 78.5)
	2/Prevax	91	317.3 (199.5, 504.6)	91	64.9 (54.2, 77.8)
	2/2 Weeks	61	2600.3 (1762.1, 3837.1)	60	61.6 (50.4, 75.2)
	2/1 Month	51	2134.5 (1450.9, 3140.0)	53	73.1 (56.4, 94.6)
	Delivery	56	913.9 (624.9, 1336.4)	49	62.1 (49.9, 77.3)
	6-Month postdelivery	53	1719.0 (943.8, 3130.8)	N/A	
Full-length S-binding IgG level assay (U/mL)	1/Prevax	90	6.7 (4.0, 11.3)	91	9.7 (5.5, 17.3)

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14.41. Geometric Mean Titers and Concentrations – Phase 2 – Dose 1 Evaluable Immunogenicity Population (Maternal)

Assay	Dose/Sampling Time Point[a]	Vaccine Group (as Randomized)			
		BNT162b2 (30 µg)		Placebo	
		n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])
	2/Prevax	92	2462.4 (1729.6, 3505.7)	91	11.1 (6.0, 20.6)
	2/2 Weeks	61	7354.1 (4683.5, 11547.4)	60	11.9 (5.7, 24.9)
	2/1 Month	52	5250.7 (3941.0, 6995.6)	53	13.4 (6.1, 29.6)
	Delivery	56	3270.7 (2510.7, 4260.8)	49	8.5 (3.9, 18.7)
	6-Month postdelivery	53	3420.9 (2174.9, 5380.7)	N/A	

Abbreviations: GMC = geometric mean concentration; GMT = geometric mean titer; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; N/A = not applicable; NT50 = 50% neutralizing titer; S = spike protein; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
a. Protocol-specified timing for blood sample collection.
b. n = Number of participants with valid and determinate assay results for the specified assay at the given dose/sampling time point.
c. GMTs, GMCs, and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers or concentrations and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 12JAN2024 (03:07) Source Data: adva Table Generation: 22FEB2024 (01:04)
(Database snapshot date: Safety [29Mar2023], Immunogenicity [09Jan2024]) Output File: ./nda3/C4591015_CSR/adva_s001_dos1eval

14.42. Geometric Mean Fold Rise From Before Vaccination to Subsequent Timepoints – Phase 2 – Dose 1 Evaluable Immunogenicity Population (Maternal)

Assay	Dose/Sampling Time Point[a]	Vaccine Group (as Randomized)			
		BNT162b2 (30 µg)		Placebo	
		n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	2/Prevax	89	4.8 (3.3, 7.1)	91	1.0 (0.9, 1.2)
	2/2 Weeks	60	42.7 (28.5, 63.9)	60	1.0 (0.9, 1.1)
	2/1 Month	51	33.3 (23.3, 47.5)	53	1.1 (0.9, 1.4)

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14.42. Geometric Mean Fold Rise From Before Vaccination to Subsequent Timepoints – Phase 2 – Dose 1 Evaluable Immunogenicity Population (Maternal)

Assay	Dose/Sampling Time Point[a]	Vaccine Group (as Randomized)			
		BNT162b2 (30 µg)		Placebo	
		n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])
Full-length S-binding IgG level assay (U/mL)	Delivery	55	14.4 (9.8, 21.3)	49	1.0 (0.9, 1.2)
	6-Month postdelivery	52	25.5 (13.1, 49.6)	N/A	
	2/Prevax	90	359.8 (236.1, 548.3)	91	1.1 (0.9, 1.4)
	2/2 Weeks	60	1139.0 (563.8, 2301.0)	60	1.1 (0.8, 1.4)
	2/1 Month	52	880.9 (493.3, 1572.9)	53	1.0 (0.8, 1.2)
	Delivery	55	514.6 (283.6, 933.7)	49	0.8 (0.6, 1.0)
	6-Month postdelivery	52	420.8 (179.8, 984.7)	N/A	

Abbreviations: GMFR = geometric mean fold rise; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; N/A = not applicable; NT50 = 50% neutralizing titer; S = spike protein; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
a. Protocol-specified timing for blood sample collection.
b. n = Number of participants with valid and determinate assay results for the specified assay both before vaccination and at the given dose/sampling time point.
c. GMFRs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 12JAN2024 (03:07) Source Data: adva Table Generation: 22FEB2024 (01:04)
(Database snapshot date: Safety [29Mar2023], Immunogenicity [09Jan2024]) Output File: ./nda3/C4591015_CSR/adva_s002_gmfr_evl01

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Efficacy

14.43. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Follow-up Period – Participants With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy Population (Maternal)

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=149)		Placebo (N[a]=153)			
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence from 7 days after Dose 2	2	0.270 (145)	3	0.263 (149)	35.1	(-466.5, 94.6)

Abbreviation: VE = vaccine efficacy.
a. N = number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 100 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (09:10) Source Data: adc19ef Table Generation: 12DEC2023 (23:13) Output File: ./nda3/C4591015_EFF/adc19ef_ve_cov_7pd2_evlm

14.44. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Follow-up Period – Participants With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Dose 2 All-Available Efficacy Population (Maternal)

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=158)		Placebo (N[a]=160)			
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence from 7 days after Dose 2	2	0.281 (152)	3	0.271 (156)	35.8	(-460.4, 94.6)

Abbreviation: VE = vaccine efficacy.
a. N = number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 100 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (09:10) Source Data: adc19ef Table Generation: 12DEC2023 (23:13) Output File: ./nda3/C4591015_EFF/adc19ef_ve_cov_7pd2_aai2m

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14.45. Vaccine Efficacy – First COVID-19 Occurrence After Dose 1 – Blinded Follow-up Period – Dose 1 All-Available Efficacy Population (Maternal)

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=161)		Placebo (N[a]=163)			
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence after Dose 1	2	0.403 (156)	5	0.393 (159)	61.0	(-138.3, 96.3)

Abbreviation: VE = vaccine efficacy.
a. N = number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 100 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from Dose 1 to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (09:10) Source Data: adc19ef Table Generation: 12DEC2023 (23:18) Output File: ./nda3/C4591015_EFF/adc19ef_ve_cov_d1_aai1m

14.46. Vaccine Efficacy – First COVID-19 Occurrence Based on CDC Definition After Dose 1 – Blinded Follow-up Period – Dose 1 All-Available Efficacy Population (Maternal)

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=161)		Placebo (N[a]=163)			
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence based on CDC definition after Dose 1	2	0.400 (155)	6	0.392 (159)	67.3	(-82.7, 96.8)

Abbreviation: VE = vaccine efficacy.
a. N = number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 100 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from Dose 1 to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (09:10) Source Data: adc19ef Table Generation: 12DEC2023 (23:18) Output File: ./nda3/C4591015_EFF/adc19ef_ve_cov_cdc_d1_aai1m

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14.47. Vaccine Efficacy – First COVID-19 Occurrence Based on CDC Definition From 7 Days After Dose 2 – Blinded Follow-up Period – Participants Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy Population (Maternal)

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=88)		Placebo (N[a]=90)			
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence based on CDC definition from 7 days after Dose 2	2	0.155 (86)	3	0.148 (89)	36.2	(-456.5, 94.7)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Participants who had no serological or virological evidence (prior to 7 days after receipt of Dose 2) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Dose 1 and no positive before 7 days after Dose 2, SARS-CoV-2 not detected by NAAT [nasal swab] at Dose 1 and Dose 2, and negative NAAT [nasal swab] at any unscheduled visit before 7 days after Dose 2) were included in the analysis.
a. N = number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 100 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (09:10) Source Data: adc19ef Table Generation: 12DEC2023 (23:13) Output File: ./nda3/C4591015_EFF/adc19ef_ve_cov_cdc_7pd2_wo_evlm

14.48. Vaccine Efficacy – First COVID-19 Occurrence Based on CDC Definition From 7 Days After Dose 2 – Blinded Follow-up Period – Participants With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy Population (Maternal)

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=149)		Placebo (N[a]=153)			
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence based on CDC definition from 7 days after Dose 2	2	0.268 (144)	4	0.262 (149)	51.1	(-241.0, 95.6)

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14.48. Vaccine Efficacy – First COVID-19 Occurrence Based on CDC Definition From 7 Days After Dose 2 – Blinded Follow-up Period – Participants With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy Population (Maternal)

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=149)		Placebo (N[a]=153)			
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])

Abbreviation: VE = vaccine efficacy.
a. N = number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 100 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (09:10) Source Data: adc19ef Table Generation: 12DEC2023 (23:13) Output File: ./nda3/C4591015_EFF/adc19ef_ve_cov_cdc_7pd2_evlm

14.49. Vaccine Efficacy – First COVID-19 Occurrence Based on CDC Definition From 7 Days After Dose 2 – Blinded Follow-up Period – Participants With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Dose 2 All-Available Efficacy Population (Maternal)

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=158)		Placebo (N[a]=160)			
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence based on CDC definition from 7 days after Dose 2	2	0.279 (151)	4	0.270 (156)	51.7	(-237.3, 95.6)

Abbreviation: VE = vaccine efficacy.
a. N = number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 100 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (09:10) Source Data: adc19ef Table Generation: 12DEC2023 (23:18) Output File: ./nda3/C4591015_EFF/adc19ef_ve_cov_cdc_7pd2_aai2m

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14.50. Vaccine Efficacy – Asymptomatic Infection Based on N-Binding Antibody Seroconversion – Blinded Follow-up Period – Participants Without Evidence of Infection Prior to the First Post –Dose 2 N-Binding Test–Dose 2 All-Available Efficacy Population (Maternal)

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=88)		Placebo (N[a]=94)			
Efficacy Endpoint	n[b]	Surveillance Time[c]	n[b]	Surveillance Time[c]	VE (%)	(95% CI[d])
Asymptomatic infection based on N-binding antibody seroconversion after Dose 2	4	0.102	10	0.153	40.2	(-107.4, 86.3)

Abbreviations: NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein–binding; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Participants who had no serological or virological evidence (before Dose 2) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Dose 1 and no positive before Dose 2, negative NAAT [nasal swab] at Dose 1, Dose 2, and at any unscheduled visit before Dose 2) and had at least one post-dose 2 N-binding Test in the blinded follow up period were included in the analysis.
a. N = number of participants in the specified group.
b. n = Number of participants meeting the endpoint definition.
c. Total surveillance time in 100 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for case accrual is from Dose 2 to the end of the surveillance period.
d. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (09:10) Source Data: adc19asm Table Generation: 12DEC2023 (23:18) Output File: ./nda3/C4591015_EFF/adc19ef_ve_cov_d2_wo_aai

14.51. Vaccine Efficacy – Asymptomatic Infection Based on N-Binding Antibody Seroconversion – Blinded Follow-up Period – Participants Without Evidence of Infection Prior to the First Post–Dose 1 N-Binding Test – Dose 1 All-Available Efficacy Population (Maternal)

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=98)		Placebo (N[a]=97)			
Efficacy Endpoint	n[b]	Surveillance Time[c]	n[b]	Surveillance Time[c]	VE (%)	(95% CI[d])
Asymptomatic infection based on N-binding antibody seroconversion after Dose 2	6	0.165	11	0.215	29.1	(-109.0, 78.5)

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14.51. Vaccine Efficacy – Asymptomatic Infection Based on N-Binding Antibody Seroconversion – Blinded Follow-up Period – Participants Without Evidence of Infection Prior to the First Post–Dose 1 N-Binding Test – Dose 1 All-Available Efficacy Population (Maternal)

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=98)		Placebo (N[a]=97)			
Efficacy Endpoint	n[b]	Surveillance Time[c]	n[b]	Surveillance Time[c]	VE (%)	(95% CI[d])

Abbreviations: NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein–binding; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Participants who had no serological or virological evidence (before Dose 1) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Dose 1, negative NAAT [nasal swab] at Dose 1) and had at least one post-dose 1 N-binding Test in the blinded follow up period were included in the analysis.
a. N = number of participants in the specified group.
b. n = Number of participants meeting the endpoint definition.
c. Total surveillance time in 100 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for case accrual is from Dose 1 to the end of the surveillance period.
d. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (09:10) Source Data: adc19asm Table Generation: 12DEC2023 (23:18) Output File: ./nda3/C4591015_EFF/adc19ef_ve_cov_d1_wo_aai

14.52. COVID-19 Occurrence From 7 Days After Dose 2 – Participants Who Originally Received BNT162b2 – Evaluable Efficacy Population (Maternal)

	Vaccine Group (as Randomized)			
	BNT162b2 (30 µg) (N[a]=149)			
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	Incidence (per 100 Person-Years)	(95% CI[e])
COVID-19 occurrence from 7 days after Dose 2	16	0.787 (140)	20.3	(11.6, 33.0)

a. N = number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 100 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.
e. Confidence interval (CI) for incidence is derived based on the Poisson distribution method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (09:10) Source Data: adc19ef Table Generation: 12DEC2023 (23:18) Output File: ./nda3/C4591015_EFF/adc19ef_oc_cov_7pd2_evlm

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14.53. COVID-19 Occurrence From 7 Days After Dose 2 – Participants Who Originally Received BNT162b2 – Dose 2 All-Available Efficacy Population (Maternal)

	Vaccine Group (as Randomized)			
		BNT162b2 (30 µg) (N[a]=158)		
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	Incidence (per 100 Person-Years)	(95% CI[e])
COVID-19 occurrence from 7 days after Dose 2	16	0.831 (147)	19.3	(11.0, 31.3)

a. N = number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 100 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.
e. Confidence interval (CI) for incidence is derived based on the Poisson distribution method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (09:10) Source Data: adc19ef Table Generation: 12DEC2023 (23:18) Output File: ./nda3/C4591015_EFF/adc19ef_oc_cov_7pd2_aai2m

14.54. COVID-19 Occurrence Based on CDC Definition From 7 Days After Dose 2 – Participants Who Originally Received BNT162b2 – Evaluable Efficacy Population (Maternal)

	Vaccine Group (as Randomized)			
		BNT162b2 (30 µg) (N[a]=149)		
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	Incidence (per 100 Person-Years)	(95% CI[e])
COVID-19 occurrence based on CDC definition from 7 days after Dose 2	16	0.780 (139)	20.5	(11.7, 33.3)

a. N = number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 100 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.
e. Confidence interval (CI) for incidence is derived based on the Poisson distribution method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (09:10) Source Data: adc19ef Table Generation: 12DEC2023 (23:19) Output File: ./nda3/C4591015_EFF/adc19ef_oc_cov_cdc_7pd2_evlm

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14.55. COVID-19 Occurrence Based on CDC Definition From 7 Days After Dose 2 – Participants Who Originally Received BNT162b2 – Dose 2 All-Available Efficacy Population (Maternal)

	Vaccine Group (as Randomized)			
		BNT162b2 (30 µg) (N[a]=158)		
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	Incidence (per 100 Person-Years)	(95% CI[e])
COVID-19 occurrence based on CDC definition from 7 days after Dose 2	16	0.824 (146)	19.4	(11.1, 31.5)

a. N = number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 100 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.
e. Confidence interval (CI) for incidence is derived based on the Poisson distribution method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (09:10) Source Data: adc19ef Table Generation: 12DEC2023 (23:19) Output File: ./nda3/C4591015_EFF/adc19ef_oc_cov_cdc_7pd2_aai2m

14.56. Asymptomatic Infection Based on N-Binding Antibody Seroconversion Through 6 Months After Delivery – Participants Who Originally Received BNT162b2 – Without Evidence of Infection Prior to the First Post–Dose 2 N-Binding Test – Evaluable Efficacy Population (Maternal)

	Vaccine Group (as Randomized)			
		BNT162b2 (30 µg) (N[a]=85)		
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	Incidence (per 100 Person-Years)	(95% CI[e])
Asymptomatic infection based on N-binding antibody seroconversion after Dose 2	17	0.373 (85)	45.5	(26.5, 72.9)

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14.56. Asymptomatic Infection Based on N-Binding Antibody Seroconversion Through 6 Months After Delivery – Participants Who Originally Received BNT162b2 – Without Evidence of Infection Prior to the First Post–Dose 2 N-Binding Test – Evaluable Efficacy Population (Maternal)

	Vaccine Group (as Randomized)			
		BNT162b2 (30 µg) (N[a]=85)		
Efficacy Endpoint	**n1[b]**	**Surveillance Time[c] (n2[d])**	**Incidence (per 100 Person-Years)**	**(95% CI[e])**

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Participants who had no serological or virological evidence (prior to the first Post–Dose 2 N-binding test) of past SARS-CoV-2 infection
(ie, negative N-binding antibody [serum] result at Visit 1, SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2, and negative NAAT
[nasal swab] result at any unscheduled visit prior to the first Post–Dose 2 N-binding test) were included in the analysis.
a. N = number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 100 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for case accrual is from Dose 2 to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.
e. Confidence interval (CI) for incidence is derived based on the Poisson distribution method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (09:10) Source Data: adc19ef Table Generation: 12DEC2023 (23:19) Output File: ./nda3/C4591015_EFF/adc19asm_oc_cov_d2_evlm

14.57. Asymptomatic Infection Based on N-Binding Antibody Seroconversion Through 6 Months After Delivery – Participants Who Originally Received BNT162b2 – Without Evidence of Infection Prior to the First Post–Dose 2 N-Binding Test – All Available Efficacy Population (Maternal)

	Vaccine Group (as Randomized)			
		BNT162b2 (30 µg) (N[a]=89)		
Efficacy Endpoint	**n1[b]**	**Surveillance Time[c] (n2[d])**	**Incidence (per 100 Person-Years)**	**(95% CI[e])**
Asymptomatic infection based on N-binding antibody seroconversion after Dose 2	18	0.392 (89)	46.0	(27.2, 72.7)

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14.57. Asymptomatic Infection Based on N-Binding Antibody Seroconversion Through 6 Months After Delivery – Participants Who Originally Received BNT162b2 – Without Evidence of Infection Prior to the First Post–Dose 2 N-Binding Test – All Available Efficacy Population (Maternal)

	Vaccine Group (as Randomized)			
		BNT162b2 (30 µg) (N[a]=89)		
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	Incidence (per 100 Person-Years)	(95% CI[e])

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Participants who had no serological or virological evidence (prior to the first Post–Dose 2 N-binding test) of past SARS-CoV-2 infection
(ie, negative N-binding antibody [serum] result at Visit 1, SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2, and negative NAAT
[nasal swab] result at any unscheduled visit prior to the first Post–Dose 2 N-binding test) were included in the analysis.
a. N = number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 100 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for case accrual is from Dose 2 to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.
e. Confidence interval (CI) for incidence is derived based on the Poisson distribution method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (09:10) Source Data: adc19ef Table Generation: 12DEC2023 (23:19) Output File: ./nda3/C4591015_EFF/adc19asm_oc_cov_d2_aai

14.58. COVID-19 Occurrence After Birth – All-Available Efficacy Population (Infant)

	Maternal Vaccine Group (as Randomized)							
	BNT162b2 (30 µg) (N[a]=156)				Placebo (N[a]=159)			
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	Incidence (per 100 Person-Years)	(95% CI[e])	n1[b]	Surveillance Time[c] (n2[d])	Incidence (per 100 Person-Years)	(95% CI[e])
COVID-19 occurrence after birth	8	0.708 (148)	11.3	(4.9, 22.3)	8	0.684 (152)	11.7	(5.1, 23.1)

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14.58. COVID-19 Occurrence After Birth – All-Available Efficacy Population (Infant)

	Maternal Vaccine Group (as Randomized)							
	BNT162b2 (30 µg) (N[a]=156)				Placebo (N[a]=159)			
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	Incidence (per 100 Person-Years)	(95% CI[e])	n1[b]	Surveillance Time[c] (n2[d])	Incidence (per 100 Person-Years)	(95% CI[e])

a. N = number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 100 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is after birth to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.
e. Confidence interval (CI) for incidence is derived based on the Poisson distribution method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (09:10) Source Data: adc19ef Table Generation: 10JAN2024 (10:01) Output File: ./nda3/C4591015_EFF/adc19ef_oc_cov_brth_aaii

14.59. COVID-19 Occurrence Based on CDC Definition After Birth – All-Available Efficacy Population (Infant)

	Maternal Vaccine Group (as Randomized)							
	BNT162b2 (30 µg) (N[a]=156)				Placebo (N[a]=159)			
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	Incidence (per 100 Person-Years)	(95% CI[e])	n1[b]	Surveillance Time[c] (n2[d])	Incidence (per 100 Person-Years)	(95% CI[e])
COVID-19 occurrence based on CDC definition after birth	8	0.703 (147)	11.4	(4.9, 22.4)	9	0.675 (151)	13.3	(6.1, 25.3)

a. N = number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 100 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is after birth to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.
e. Confidence interval (CI) for incidence is derived based on the Poisson distribution method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (09:10) Source Data: adc19ef Table Generation: 10JAN2024 (16:15) Output File: ./nda3/C4591015_EFF/adc19ef_oc_cov_cdc_brth_aaii

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Safety

Local Reactions

14.60. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Safety Population (Maternal)

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Redness[d]						
	Any	161	5 (3.1)	(1.0, 7.1)	163	1 (0.6)	(0.0, 3.4)
	Mild	161	4 (2.5)	(0.7, 6.2)	163	1 (0.6)	(0.0, 3.4)
	Moderate	161	1 (0.6)	(0.0, 3.4)	163	0	(0.0, 2.2)
	Severe	161	0	(0.0, 2.3)	163	0	(0.0, 2.2)
	Grade 4	161	0	(0.0, 2.3)	163	0	(0.0, 2.2)
	Swelling[d]						
	Any	161	9 (5.6)	(2.6, 10.3)	163	0	(0.0, 2.2)
	Mild	161	7 (4.3)	(1.8, 8.8)	163	0	(0.0, 2.2)
	Moderate	161	1 (0.6)	(0.0, 3.4)	163	0	(0.0, 2.2)
	Severe	161	1 (0.6)	(0.0, 3.4)	163	0	(0.0, 2.2)
	Grade 4	161	0	(0.0, 2.3)	163	0	(0.0, 2.2)
	Pain at the injection site[e]						
	Any	161	133 (82.6)	(75.9, 88.1)	163	16 (9.8)	(5.7, 15.5)
	Mild	161	95 (59.0)	(51.0, 66.7)	163	16 (9.8)	(5.7, 15.5)
	Moderate	161	38 (23.6)	(17.3, 30.9)	163	0	(0.0, 2.2)
	Severe	161	0	(0.0, 2.3)	163	0	(0.0, 2.2)
	Grade 4	161	0	(0.0, 2.3)	163	0	(0.0, 2.2)
	Any local reaction[f]	161	133 (82.6)	(75.9, 88.1)	163	16 (9.8)	(5.7, 15.5)
2	Redness[d]						
	Any	148	8 (5.4)	(2.4, 10.4)	146	0	(0.0, 2.5)
	Mild	148	5 (3.4)	(1.1, 7.7)	146	0	(0.0, 2.5)
	Moderate	148	3 (2.0)	(0.4, 5.8)	146	0	(0.0, 2.5)
	Severe	148	0	(0.0, 2.5)	146	0	(0.0, 2.5)
	Grade 4	148	0	(0.0, 2.5)	146	0	(0.0, 2.5)
	Swelling[d]						
	Any	148	10 (6.8)	(3.3, 12.1)	146	1 (0.7)	(0.0, 3.8)
	Mild	148	6 (4.1)	(1.5, 8.6)	146	1 (0.7)	(0.0, 3.8)
	Moderate	148	4 (2.7)	(0.7, 6.8)	146	0	(0.0, 2.5)
	Severe	148	0	(0.0, 2.5)	146	0	(0.0, 2.5)
	Grade 4	148	0	(0.0, 2.5)	146	0	(0.0, 2.5)
	Pain at the injection site[e]						
	Any	148	111 (75.0)	(67.2, 81.7)	146	24 (16.4)	(10.8, 23.5)
	Mild	148	81 (54.7)	(46.3, 62.9)	146	18 (12.3)	(7.5, 18.8)
	Moderate	148	29 (19.6)	(13.5, 26.9)	146	6 (4.1)	(1.5, 8.7)

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14.60. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Safety Population (Maternal)

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Severe	148	1 (0.7)	(0.0, 3.7)	146	0	(0.0, 2.5)
	Grade 4	148	0	(0.0, 2.5)	146	0	(0.0, 2.5)
	Any local reaction[f]	148	111 (75.0)	(67.2, 81.7)	146	24 (16.4)	(10.8, 23.5)
Any dose	Redness[d]						
	Any	161	11 (6.8)	(3.5, 11.9)	163	1 (0.6)	(0.0, 3.4)
	Mild	161	7 (4.3)	(1.8, 8.8)	163	1 (0.6)	(0.0, 3.4)
	Moderate	161	4 (2.5)	(0.7, 6.2)	163	0	(0.0, 2.2)
	Severe	161	0	(0.0, 2.3)	163	0	(0.0, 2.2)
	Grade 4	161	0	(0.0, 2.3)	163	0	(0.0, 2.2)
	Swelling[d]						
	Any	161	17 (10.6)	(6.3, 16.4)	163	1 (0.6)	(0.0, 3.4)
	Mild	161	11 (6.8)	(3.5, 11.9)	163	1 (0.6)	(0.0, 3.4)
	Moderate	161	5 (3.1)	(1.0, 7.1)	163	0	(0.0, 2.2)
	Severe	161	1 (0.6)	(0.0, 3.4)	163	0	(0.0, 2.2)
	Grade 4	161	0	(0.0, 2.3)	163	0	(0.0, 2.2)
	Pain at the injection site[e]						
	Any	161	138 (85.7)	(79.3, 90.7)	163	31 (19.0)	(13.3, 25.9)
	Mild	161	85 (52.8)	(44.8, 60.7)	163	25 (15.3)	(10.2, 21.8)
	Moderate	161	52 (32.3)	(25.2, 40.1)	163	6 (3.7)	(1.4, 7.8)
	Severe	161	1 (0.6)	(0.0, 3.4)	163	0	(0.0, 2.2)
	Grade 4	161	0	(0.0, 2.3)	163	0	(0.0, 2.2)
	Any local reaction[f]	161	138 (85.7)	(79.3, 90.7)	163	31 (19.0)	(13.3, 25.9)

Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary. Analyses for HIV-positive participants and their infants will be summarized separately.
Note: Reactions were collected in the e-diary and any unscheduled clinical assessments from Day 1 through Day 7 after each dose. Grade 4 reactions were classified by the investigator or medically qualified person. Reactions reported as adverse events in the case report form within 7 days after the study vaccination were also included in the analysis; the severity of these events is based on the grading scale in the adverse event section of the case report form.
a. N = number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose. These values are the denominators for the percentage calculations.
b. n = Number of participants with the specified characteristic.
c. Exact 2-sided confidence interval (CI), based on the Clopper and Pearson method.
d. Mild: >2.0 to 5.0 cm; moderate: >5.0 to 10.0 cm; severe: >10.0 cm; Grade 4: necrosis (redness and swelling categories) or exfoliative dermatitis (redness category only).
e. Mild: does not interfere with activity; moderate: interferes with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe pain at the injection site.
f. Any local reaction: any redness >2.0 cm, any swelling >2.0 cm, or any pain at the injection site.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adfacevd Table Generation: 03MAY2023 (10:31) Output File: ./nda3/C4591015_BR/adce_s010

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14.61. Duration (Days) From First to Last Day of Local Reactions After Each Dose – Safety Population (Maternal)

		Vaccine Group (as Administered)	
Dose	**Local Reaction**	**BNT162b2 (30 µg)**	**Placebo**
1	Redness		
	n[a]	5	1
	Mean (SD)	1.8 (0.45)	1.0 (NE)
	Median	2.0	1.0
	Min, max	(1, 2)	(1, 1)
	Swelling		
	n[a]	9	0
	Mean (SD)	1.3 (0.46)	NE (NE)
	Median	1.0	NE
	Min, max	(1, 2)	(NE, NE)
	Unknown[b]	1	0
	Pain at the injection site		
	n[a]	133	16
	Mean (SD)	2.1 (1.06)	1.3 (0.58)
	Median	2.0	1.0
	Min, max	(1, 7)	(1, 3)
	Unknown[b]	1	0
2	Redness		
	n[a]	8	0
	Mean (SD)	2.1 (1.13)	NE (NE)
	Median	2.0	NE
	Min, max	(1, 4)	(NE, NE)
	Swelling		
	n[a]	10	1
	Mean (SD)	1.5 (0.71)	1.0 (NE)
	Median	1.0	1.0
	Min, max	(1, 3)	(1, 1)
	Pain at the injection site		
	n[a]	111	24
	Mean (SD)	2.3 (1.21)	1.5 (1.44)
	Median	2.0	1.0
	Min, max	(1, 8)	(1, 8)

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14.61. Duration (Days) From First to Last Day of Local Reactions After Each Dose – Safety Population (Maternal)

		Vaccine Group (as Administered)	
Dose	**Local Reaction**	**BNT162b2 (30 µg)**	**Placebo**

Abbreviation: NE = not estimable.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary. Analyses for HIV-positive participants and their infants will be listed separately.
Note: Duration was calculated in days as the difference from the start of the first reported reaction to the resolution of the last reported reaction, inclusive. For symptoms that are ongoing at the time of the next dose, stop date is computed as the next dose date.
Note: Reactions were collected in the electronic diary (e-diary) and from any unscheduled clinical assessments from Day 1 through Day 7 after each dose. Reactions reported as adverse events in the case report form within 7 days after the study vaccination were also included in the analysis. The resolution date for reactions lasting longer than 7 days was recorded on the participant's case report form.
a. n = Number of participants reporting the specified reaction on any of the 7 days, including participants with reactions of unknown duration.
b. Includes those reactions where the resolution date is partial or missing.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adcevd Table Generation: 03MAY2023 (17:46) Output File: ./nda3/C4591015_BR/adce_s030

14.62. Onset Day (Days) for Local Reactions After Each Dose – Safety Population (Maternal)

		Vaccine Group (as Administered)	
Dose	**Local Reaction**	**BNT162b2 (30 µg)**	**Placebo**
1	Redness		
	n[a]	5	1
	Mean (SD)	2.4 (0.55)	1.0 (NE)
	Median	2.0	1.0
	(Min, max)	(2, 3)	(1, 1)
	Swelling		
	n[a]	9	0
	Mean (SD)	2.0 (0.87)	NE (NE)
	Median	2.0	NE
	(Min, max)	(1, 3)	(NE, NE)
	Pain at the injection site		
	n[a]	133	16
	Mean (SD)	1.3 (0.46)	1.4 (0.81)
	Median	1.0	1.0
	(Min, max)	(1, 2)	(1, 4)
	Any local reaction[b]		

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14.62. Onset Day (Days) for Local Reactions After Each Dose – Safety Population (Maternal)

Dose	Local Reaction	Vaccine Group (as Administered) BNT162b2 (30 µg)	Placebo
	n[a]	133	16
	Mean (SD)	1.3 (0.46)	1.4 (0.81)
	Median	1.0	1.0
	(Min, max)	(1, 2)	(1, 4)
2	Redness		
	n[a]	8	0
	Mean (SD)	2.5 (0.93)	NE (NE)
	Median	2.5	NE
	(Min, max)	(1, 4)	(NE, NE)
	Swelling		
	n[a]	10	1
	Mean (SD)	1.9 (0.88)	2.0 (NE)
	Median	2.0	2.0
	(Min, max)	(1, 4)	(2, 2)
	Pain at the injection site		
	n[a]	111	24
	Mean (SD)	1.4 (0.54)	1.4 (0.71)
	Median	1.0	1.0
	(Min, max)	(1, 3)	(1, 3)
	Any local reaction[b]		
	n[a]	111	24
	Mean (SD)	1.4 (0.54)	1.3 (0.64)
	Median	1.0	1.0
	(Min, max)	(1, 3)	(1, 3)

Abbreviation: NE = not estimable.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary. Analyses for HIV-positive participants and their infants will be listed separately.
Note: Day of onset is the first day the specified reaction was reported.
Note: Reactions reported as adverse events in the case report form within 7 days after the study vaccination were also included in the analysis.
a. n = Number of participants reporting the specified reaction, with each participant counted only once per reaction.
b. Any local reaction: any redness >2.0 cm, any swelling >2.0 cm, or any pain at the injection site.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adfacevd Table Generation: 03MAY2023 (17:47) Output File: ./nda3/C4591015_BR/adce_s050

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14.63. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – HIV-Positive Participants – Safety Population (Maternal)

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Redness[d]						
	Any	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	Mild	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	Moderate	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	Severe	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	Grade 4	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	Swelling[d]						
	Any	12	1 (8.3)	(0.2, 38.5)	10	0	(0.0, 30.8)
	Mild	12	1 (8.3)	(0.2, 38.5)	10	0	(0.0, 30.8)
	Moderate	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	Severe	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	Grade 4	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	Pain at the injection site[e]						
	Any	12	10 (83.3)	(51.6, 97.9)	10	3 (30.0)	(6.7, 65.2)
	Mild	12	6 (50.0)	(21.1, 78.9)	10	1 (10.0)	(0.3, 44.5)
	Moderate	12	4 (33.3)	(9.9, 65.1)	10	2 (20.0)	(2.5, 55.6)
	Severe	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	Grade 4	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	Any local reaction[f]	12	10 (83.3)	(51.6, 97.9)	10	3 (30.0)	(6.7, 65.2)
2	Redness[d]						
	Any	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Mild	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Swelling[d]						
	Any	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Mild	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Moderate	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Pain at the injection site[e]						
	Any	12	11 (91.7)	(61.5, 99.8)	9	3 (33.3)	(7.5, 70.1)
	Mild	12	6 (50.0)	(21.1, 78.9)	9	2 (22.2)	(2.8, 60.0)
	Moderate	12	5 (41.7)	(15.2, 72.3)	9	1 (11.1)	(0.3, 48.2)
	Severe	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Any local reaction[f]	12	11 (91.7)	(61.5, 99.8)	9	3 (33.3)	(7.5, 70.1)
Any dose	Redness[d]						
	Any	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)

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14.63. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – HIV-Positive Participants – Safety Population (Maternal)

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Mild	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	Moderate	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	Severe	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	Grade 4	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	Swelling[d]						
	Any	12	1 (8.3)	(0.2, 38.5)	10	0	(0.0, 30.8)
	Mild	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	Moderate	12	1 (8.3)	(0.2, 38.5)	10	0	(0.0, 30.8)
	Severe	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	Grade 4	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	Pain at the injection site[e]						
	Any	12	12 (100.0)	(73.5, 100.0)	10	4 (40.0)	(12.2, 73.8)
	Mild	12	6 (50.0)	(21.1, 78.9)	10	1 (10.0)	(0.3, 44.5)
	Moderate	12	6 (50.0)	(21.1, 78.9)	10	3 (30.0)	(6.7, 65.2)
	Severe	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	Grade 4	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	Any local reaction[f]	12	12 (100.0)	(73.5, 100.0)	10	4 (40.0)	(12.2, 73.8)

Note: Reactions were collected in the e-diary and any unscheduled clinical assessments from Day 1 through Day 7 after each dose. Grade 4 reactions were classified by the investigator or medically qualified person. Reactions reported as adverse events in the case report form within 7 days after the study vaccination were also included in the analysis; the severity of these events is based on the grading scale in the adverse event section of the case report form.
a. N = number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose. These values are the denominators for the percentage calculations.
b. n = Number of participants with the specified characteristic.
c. Exact 2-sided confidence interval (CI), based on the Clopper and Pearson method.
d. Mild: >2.0 to 5.0 cm; moderate: >5.0 to 10.0 cm; severe: >10.0 cm; Grade 4: necrosis (redness and swelling categories) or exfoliative dermatitis (redness category only).
e. Mild: does not interfere with activity; moderate: interferes with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe pain at the injection site.
f. Any local reaction: any redness >2.0 cm, any swelling >2.0 cm, or any pain at the injection site.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adfacevd Table Generation: 10MAY2023 (14:26) Output File: ./nda3/C4591015_BR/adce_s010_HIV

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14.64. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Race – Safety Population (Maternal) Race: White

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Redness[d]						
	Any	117	4 (3.4)	(0.9, 8.5)	118	1 (0.8)	(0.0, 4.6)
	Mild	117	3 (2.6)	(0.5, 7.3)	118	1 (0.8)	(0.0, 4.6)
	Moderate	117	1 (0.9)	(0.0, 4.7)	118	0	(0.0, 3.1)
	Severe	117	0	(0.0, 3.1)	118	0	(0.0, 3.1)
	Grade 4	117	0	(0.0, 3.1)	118	0	(0.0, 3.1)
	Swelling[d]						
	Any	117	6 (5.1)	(1.9, 10.8)	118	0	(0.0, 3.1)
	Mild	117	4 (3.4)	(0.9, 8.5)	118	0	(0.0, 3.1)
	Moderate	117	1 (0.9)	(0.0, 4.7)	118	0	(0.0, 3.1)
	Severe	117	1 (0.9)	(0.0, 4.7)	118	0	(0.0, 3.1)
	Grade 4	117	0	(0.0, 3.1)	118	0	(0.0, 3.1)
	Pain at the injection site[e]						
	Any	117	98 (83.8)	(75.8, 89.9)	118	12 (10.2)	(5.4, 17.1)
	Mild	117	64 (54.7)	(45.2, 63.9)	118	12 (10.2)	(5.4, 17.1)
	Moderate	117	34 (29.1)	(21.0, 38.2)	118	0	(0.0, 3.1)
	Severe	117	0	(0.0, 3.1)	118	0	(0.0, 3.1)
	Grade 4	117	0	(0.0, 3.1)	118	0	(0.0, 3.1)
	Any local reaction[f]	117	98 (83.8)	(75.8, 89.9)	118	12 (10.2)	(5.4, 17.1)
2	Redness[d]						
	Any	110	6 (5.5)	(2.0, 11.5)	105	0	(0.0, 3.5)
	Mild	110	4 (3.6)	(1.0, 9.0)	105	0	(0.0, 3.5)
	Moderate	110	2 (1.8)	(0.2, 6.4)	105	0	(0.0, 3.5)
	Severe	110	0	(0.0, 3.3)	105	0	(0.0, 3.5)
	Grade 4	110	0	(0.0, 3.3)	105	0	(0.0, 3.5)
	Swelling[d]						
	Any	110	6 (5.5)	(2.0, 11.5)	105	0	(0.0, 3.5)
	Mild	110	5 (4.5)	(1.5, 10.3)	105	0	(0.0, 3.5)
	Moderate	110	1 (0.9)	(0.0, 5.0)	105	0	(0.0, 3.5)
	Severe	110	0	(0.0, 3.3)	105	0	(0.0, 3.5)
	Grade 4	110	0	(0.0, 3.3)	105	0	(0.0, 3.5)
	Pain at the injection site[e]						
	Any	110	82 (74.5)	(65.4, 82.4)	105	15 (14.3)	(8.2, 22.5)
	Mild	110	56 (50.9)	(41.2, 60.6)	105	14 (13.3)	(7.5, 21.4)
	Moderate	110	25 (22.7)	(15.3, 31.7)	105	1 (1.0)	(0.0, 5.2)
	Severe	110	1 (0.9)	(0.0, 5.0)	105	0	(0.0, 3.5)
	Grade 4	110	0	(0.0, 3.3)	105	0	(0.0, 3.5)
	Any local reaction[f]	110	82 (74.5)	(65.4, 82.4)	105	15 (14.3)	(8.2, 22.5)
Any dose	Redness[d]						
	Any	117	9 (7.7)	(3.6, 14.1)	118	1 (0.8)	(0.0, 4.6)

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14.64. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Race – Safety Population (Maternal) Race: White

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Mild	117	6 (5.1)	(1.9, 10.8)	118	1 (0.8)	(0.0, 4.6)
	Moderate	117	3 (2.6)	(0.5, 7.3)	118	0	(0.0, 3.1)
	Severe	117	0	(0.0, 3.1)	118	0	(0.0, 3.1)
	Grade 4	117	0	(0.0, 3.1)	118	0	(0.0, 3.1)
	Swelling[d]						
	Any	117	10 (8.5)	(4.2, 15.2)	118	0	(0.0, 3.1)
	Mild	117	7 (6.0)	(2.4, 11.9)	118	0	(0.0, 3.1)
	Moderate	117	2 (1.7)	(0.2, 6.0)	118	0	(0.0, 3.1)
	Severe	117	1 (0.9)	(0.0, 4.7)	118	0	(0.0, 3.1)
	Grade 4	117	0	(0.0, 3.1)	118	0	(0.0, 3.1)
	Pain at the injection site[e]						
	Any	117	100 (85.5)	(77.8, 91.3)	118	21 (17.8)	(11.4, 25.9)
	Mild	117	54 (46.2)	(36.9, 55.6)	118	20 (16.9)	(10.7, 25.0)
	Moderate	117	45 (38.5)	(29.6, 47.9)	118	1 (0.8)	(0.0, 4.6)
	Severe	117	1 (0.9)	(0.0, 4.7)	118	0	(0.0, 3.1)
	Grade 4	117	0	(0.0, 3.1)	118	0	(0.0, 3.1)
	Any local reaction[f]	117	100 (85.5)	(77.8, 91.3)	118	21 (17.8)	(11.4, 25.9)

Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: Reactions were collected in the e-diary and any unscheduled clinical assessments from Day 1 through Day 7 after each dose. Grade 4 reactions were classified by the investigator or medically qualified person. Reactions reported as adverse events in the case report form within 7 days after the study vaccination were also included in the analysis; the severity of these events is based on the grading scale in the adverse event section of the case report form.
Note: All others = American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose. These values are the denominators for the percentage calculations.
b. n = Number of participants with the specified characteristic.
c. Exact 2-sided confidence interval (CI), based on the Clopper and Pearson method.
d. Mild: >2.0 to 5.0 cm; moderate: >5.0 to 10.0 cm; severe: >10.0 cm; Grade 4: necrosis (redness and swelling categories) or exfoliative dermatitis (redness category only).
e. Mild: does not interfere with activity; moderate: interferes with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe pain at the injection site.
f. Any local reaction: any redness >2.0 cm, any swelling >2.0 cm, or any pain at the injection site.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adfacevd Table Generation: 03MAY2023 (10:31) Output File: ./nda3/C4591015_BR/adce_s010_race

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14.65. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Race – Safety Population (Maternal) Race: Black or African American

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Redness[d]						
	Any	35	1 (2.9)	(0.1, 14.9)	33	0	(0.0, 10.6)
	Mild	35	1 (2.9)	(0.1, 14.9)	33	0	(0.0, 10.6)
	Moderate	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	Severe	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	Grade 4	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	Swelling[d]						
	Any	35	2 (5.7)	(0.7, 19.2)	33	0	(0.0, 10.6)
	Mild	35	2 (5.7)	(0.7, 19.2)	33	0	(0.0, 10.6)
	Moderate	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	Severe	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	Grade 4	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	Pain at the injection site[e]						
	Any	35	27 (77.1)	(59.9, 89.6)	33	4 (12.1)	(3.4, 28.2)
	Mild	35	24 (68.6)	(50.7, 83.1)	33	4 (12.1)	(3.4, 28.2)
	Moderate	35	3 (8.6)	(1.8, 23.1)	33	0	(0.0, 10.6)
	Severe	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	Grade 4	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	Any local reaction[f]	35	27 (77.1)	(59.9, 89.6)	33	4 (12.1)	(3.4, 28.2)
2	Redness[d]						
	Any	30	2 (6.7)	(0.8, 22.1)	30	0	(0.0, 11.6)
	Mild	30	1 (3.3)	(0.1, 17.2)	30	0	(0.0, 11.6)
	Moderate	30	1 (3.3)	(0.1, 17.2)	30	0	(0.0, 11.6)
	Severe	30	0	(0.0, 11.6)	30	0	(0.0, 11.6)
	Grade 4	30	0	(0.0, 11.6)	30	0	(0.0, 11.6)
	Swelling[d]						
	Any	30	3 (10.0)	(2.1, 26.5)	30	0	(0.0, 11.6)
	Mild	30	1 (3.3)	(0.1, 17.2)	30	0	(0.0, 11.6)
	Moderate	30	2 (6.7)	(0.8, 22.1)	30	0	(0.0, 11.6)
	Severe	30	0	(0.0, 11.6)	30	0	(0.0, 11.6)
	Grade 4	30	0	(0.0, 11.6)	30	0	(0.0, 11.6)
	Pain at the injection site[e]						
	Any	30	23 (76.7)	(57.7, 90.1)	30	7 (23.3)	(9.9, 42.3)
	Mild	30	20 (66.7)	(47.2, 82.7)	30	3 (10.0)	(2.1, 26.5)
	Moderate	30	3 (10.0)	(2.1, 26.5)	30	4 (13.3)	(3.8, 30.7)
	Severe	30	0	(0.0, 11.6)	30	0	(0.0, 11.6)
	Grade 4	30	0	(0.0, 11.6)	30	0	(0.0, 11.6)
	Any local reaction[f]	30	23 (76.7)	(57.7, 90.1)	30	7 (23.3)	(9.9, 42.3)
Any dose	Redness[d]						

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14.65. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Race – Safety Population (Maternal) Race: Black or African American

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Any	35	2 (5.7)	(0.7, 19.2)	33	0	(0.0, 10.6)
	Mild	35	1 (2.9)	(0.1, 14.9)	33	0	(0.0, 10.6)
	Moderate	35	1 (2.9)	(0.1, 14.9)	33	0	(0.0, 10.6)
	Severe	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	Grade 4	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	Swelling[d]						
	Any	35	5 (14.3)	(4.8, 30.3)	33	0	(0.0, 10.6)
	Mild	35	3 (8.6)	(1.8, 23.1)	33	0	(0.0, 10.6)
	Moderate	35	2 (5.7)	(0.7, 19.2)	33	0	(0.0, 10.6)
	Severe	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	Grade 4	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	Pain at the injection site[e]						
	Any	35	30 (85.7)	(69.7, 95.2)	33	8 (24.2)	(11.1, 42.3)
	Mild	35	25 (71.4)	(53.7, 85.4)	33	4 (12.1)	(3.4, 28.2)
	Moderate	35	5 (14.3)	(4.8, 30.3)	33	4 (12.1)	(3.4, 28.2)
	Severe	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	Grade 4	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	Any local reaction[f]	35	30 (85.7)	(69.7, 95.2)	33	8 (24.2)	(11.1, 42.3)

Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: Reactions were collected in the e-diary and any unscheduled clinical assessments from Day 1 through Day 7 after each dose. Grade 4 reactions were classified by the investigator or medically qualified person. Reactions reported as adverse events in the case report form within 7 days after the study vaccination were also included in the analysis; the severity of these events is based on the grading scale in the adverse event section of the case report form.
Note: All others = American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose. These values are the denominators for the percentage calculations.
b. n = Number of participants with the specified characteristic.
c. Exact 2-sided confidence interval (CI), based on the Clopper and Pearson method.
d. Mild: >2.0 to 5.0 cm; moderate: >5.0 to 10.0 cm; severe: >10.0 cm; Grade 4: necrosis (redness and swelling categories) or exfoliative dermatitis (redness category only).
e. Mild: does not interfere with activity; moderate: interferes with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe pain at the injection site.
f. Any local reaction: any redness >2.0 cm, any swelling >2.0 cm, or any pain at the injection site.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adfacevd Table Generation: 03MAY2023 (10:31) Output File: ./nda3/C4591015_BR/adce_s010_race

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14.66. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Race – Safety Population (Maternal) Race: All Others

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Redness[d]						
	Any	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Mild	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Moderate	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Severe	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Grade 4	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Swelling[d]						
	Any	9	1 (11.1)	(0.3, 48.2)	12	0	(0.0, 26.5)
	Mild	9	1 (11.1)	(0.3, 48.2)	12	0	(0.0, 26.5)
	Moderate	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Severe	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Grade 4	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Pain at the injection site[e]						
	Any	9	8 (88.9)	(51.8, 99.7)	12	0	(0.0, 26.5)
	Mild	9	7 (77.8)	(40.0, 97.2)	12	0	(0.0, 26.5)
	Moderate	9	1 (11.1)	(0.3, 48.2)	12	0	(0.0, 26.5)
	Severe	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Grade 4	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Any local reaction[f]	9	8 (88.9)	(51.8, 99.7)	12	0	(0.0, 26.5)
2	Redness[d]						
	Any	8	0	(0.0, 36.9)	11	0	(0.0, 28.5)
	Mild	8	0	(0.0, 36.9)	11	0	(0.0, 28.5)
	Moderate	8	0	(0.0, 36.9)	11	0	(0.0, 28.5)
	Severe	8	0	(0.0, 36.9)	11	0	(0.0, 28.5)
	Grade 4	8	0	(0.0, 36.9)	11	0	(0.0, 28.5)
	Swelling[d]						
	Any	8	1 (12.5)	(0.3, 52.7)	11	1 (9.1)	(0.2, 41.3)
	Mild	8	0	(0.0, 36.9)	11	1 (9.1)	(0.2, 41.3)
	Moderate	8	1 (12.5)	(0.3, 52.7)	11	0	(0.0, 28.5)
	Severe	8	0	(0.0, 36.9)	11	0	(0.0, 28.5)
	Grade 4	8	0	(0.0, 36.9)	11	0	(0.0, 28.5)
	Pain at the injection site[e]						
	Any	8	6 (75.0)	(34.9, 96.8)	11	2 (18.2)	(2.3, 51.8)
	Mild	8	5 (62.5)	(24.5, 91.5)	11	1 (9.1)	(0.2, 41.3)
	Moderate	8	1 (12.5)	(0.3, 52.7)	11	1 (9.1)	(0.2, 41.3)
	Severe	8	0	(0.0, 36.9)	11	0	(0.0, 28.5)
	Grade 4	8	0	(0.0, 36.9)	11	0	(0.0, 28.5)
	Any local reaction[f]	8	6 (75.0)	(34.9, 96.8)	11	2 (18.2)	(2.3, 51.8)
Any dose	Redness[d]						

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14.66. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Race – Safety Population (Maternal) Race: All Others

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Any	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Mild	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Moderate	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Severe	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Grade 4	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Swelling[d]						
	Any	9	2 (22.2)	(2.8, 60.0)	12	1 (8.3)	(0.2, 38.5)
	Mild	9	1 (11.1)	(0.3, 48.2)	12	1 (8.3)	(0.2, 38.5)
	Moderate	9	1 (11.1)	(0.3, 48.2)	12	0	(0.0, 26.5)
	Severe	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Grade 4	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Pain at the injection site[e]						
	Any	9	8 (88.9)	(51.8, 99.7)	12	2 (16.7)	(2.1, 48.4)
	Mild	9	6 (66.7)	(29.9, 92.5)	12	1 (8.3)	(0.2, 38.5)
	Moderate	9	2 (22.2)	(2.8, 60.0)	12	1 (8.3)	(0.2, 38.5)
	Severe	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Grade 4	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Any local reaction[f]	9	8 (88.9)	(51.8, 99.7)	12	2 (16.7)	(2.1, 48.4)

Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: Reactions were collected in the e-diary and any unscheduled clinical assessments from Day 1 through Day 7 after each dose. Grade 4 reactions were classified by the investigator or medically qualified person. Reactions reported as adverse events in the case report form within 7 days after the study vaccination were also included in the analysis; the severity of these events is based on the grading scale in the adverse event section of the case report form.
Note: All others = American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose. These values are the denominators for the percentage calculations.
b. n = Number of participants with the specified characteristic.
c. Exact 2-sided confidence interval (CI), based on the Clopper and Pearson method.
d. Mild: >2.0 to 5.0 cm; moderate: >5.0 to 10.0 cm; severe: >10.0 cm; Grade 4: necrosis (redness and swelling categories) or exfoliative dermatitis (redness category only).
e. Mild: does not interfere with activity; moderate: interferes with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe pain at the injection site.
f. Any local reaction: any redness >2.0 cm, any swelling >2.0 cm, or any pain at the injection site.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adfacevd Table Generation: 03MAY2023 (10:31) Output File: ./nda3/C4591015_BR/adce_s010_race

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14.67. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Ethnicity – Safety Population (Maternal) Ethnicity: Hispanic/Latino

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Redness[d]						
	Any	69	1 (1.4)	(0.0, 7.8)	63	1 (1.6)	(0.0, 8.5)
	Mild	69	1 (1.4)	(0.0, 7.8)	63	1 (1.6)	(0.0, 8.5)
	Moderate	69	0	(0.0, 5.2)	63	0	(0.0, 5.7)
	Severe	69	0	(0.0, 5.2)	63	0	(0.0, 5.7)
	Grade 4	69	0	(0.0, 5.2)	63	0	(0.0, 5.7)
	Swelling[d]						
	Any	69	2 (2.9)	(0.4, 10.1)	63	0	(0.0, 5.7)
	Mild	69	1 (1.4)	(0.0, 7.8)	63	0	(0.0, 5.7)
	Moderate	69	0	(0.0, 5.2)	63	0	(0.0, 5.7)
	Severe	69	1 (1.4)	(0.0, 7.8)	63	0	(0.0, 5.7)
	Grade 4	69	0	(0.0, 5.2)	63	0	(0.0, 5.7)
	Pain at the injection site[e]						
	Any	69	53 (76.8)	(65.1, 86.1)	63	7 (11.1)	(4.6, 21.6)
	Mild	69	34 (49.3)	(37.0, 61.6)	63	7 (11.1)	(4.6, 21.6)
	Moderate	69	19 (27.5)	(17.5, 39.6)	63	0	(0.0, 5.7)
	Severe	69	0	(0.0, 5.2)	63	0	(0.0, 5.7)
	Grade 4	69	0	(0.0, 5.2)	63	0	(0.0, 5.7)
	Any local reaction[f]	69	53 (76.8)	(65.1, 86.1)	63	7 (11.1)	(4.6, 21.6)
2	Redness[d]						
	Any	64	1 (1.6)	(0.0, 8.4)	54	0	(0.0, 6.6)
	Mild	64	0	(0.0, 5.6)	54	0	(0.0, 6.6)
	Moderate	64	1 (1.6)	(0.0, 8.4)	54	0	(0.0, 6.6)
	Severe	64	0	(0.0, 5.6)	54	0	(0.0, 6.6)
	Grade 4	64	0	(0.0, 5.6)	54	0	(0.0, 6.6)
	Swelling[d]						
	Any	64	4 (6.3)	(1.7, 15.2)	54	0	(0.0, 6.6)
	Mild	64	2 (3.1)	(0.4, 10.8)	54	0	(0.0, 6.6)
	Moderate	64	2 (3.1)	(0.4, 10.8)	54	0	(0.0, 6.6)
	Severe	64	0	(0.0, 5.6)	54	0	(0.0, 6.6)
	Grade 4	64	0	(0.0, 5.6)	54	0	(0.0, 6.6)
	Pain at the injection site[e]						
	Any	64	41 (64.1)	(51.1, 75.7)	54	9 (16.7)	(7.9, 29.3)
	Mild	64	29 (45.3)	(32.8, 58.3)	54	7 (13.0)	(5.4, 24.9)
	Moderate	64	12 (18.8)	(10.1, 30.5)	54	2 (3.7)	(0.5, 12.7)
	Severe	64	0	(0.0, 5.6)	54	0	(0.0, 6.6)
	Grade 4	64	0	(0.0, 5.6)	54	0	(0.0, 6.6)
	Any local reaction[f]	64	41 (64.1)	(51.1, 75.7)	54	9 (16.7)	(7.9, 29.3)
Any dose	Redness[d]						
	Any	69	2 (2.9)	(0.4, 10.1)	63	1 (1.6)	(0.0, 8.5)

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14.67. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Ethnicity – Safety Population (Maternal) Ethnicity: Hispanic/Latino

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Mild	69	1 (1.4)	(0.0, 7.8)	63	1 (1.6)	(0.0, 8.5)
	Moderate	69	1 (1.4)	(0.0, 7.8)	63	0	(0.0, 5.7)
	Severe	69	0	(0.0, 5.2)	63	0	(0.0, 5.7)
	Grade 4	69	0	(0.0, 5.2)	63	0	(0.0, 5.7)
	Swelling[d]						
	Any	69	5 (7.2)	(2.4, 16.1)	63	0	(0.0, 5.7)
	Mild	69	2 (2.9)	(0.4, 10.1)	63	0	(0.0, 5.7)
	Moderate	69	2 (2.9)	(0.4, 10.1)	63	0	(0.0, 5.7)
	Severe	69	1 (1.4)	(0.0, 7.8)	63	0	(0.0, 5.7)
	Grade 4	69	0	(0.0, 5.2)	63	0	(0.0, 5.7)
	Pain at the injection site[e]						
	Any	69	54 (78.3)	(66.7, 87.3)	63	12 (19.0)	(10.2, 30.9)
	Mild	69	30 (43.5)	(31.6, 56.0)	63	10 (15.9)	(7.9, 27.3)
	Moderate	69	24 (34.8)	(23.7, 47.2)	63	2 (3.2)	(0.4, 11.0)
	Severe	69	0	(0.0, 5.2)	63	0	(0.0, 5.7)
	Grade 4	69	0	(0.0, 5.2)	63	0	(0.0, 5.7)
	Any local reaction[f]	69	54 (78.3)	(66.7, 87.3)	63	12 (19.0)	(10.2, 30.9)

Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: Reactions were collected in the e-diary and any unscheduled clinical assessments from Day 1 through Day 7 after each dose. Grade 4 reactions were classified by the investigator or medically qualified person. Reactions reported as adverse events in the case report form within 7 days after the study vaccination were also included in the analysis; the severity of these events is based on the grading scale in the adverse event section of the case report form.
a. N = number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose. These values are the denominators for the percentage calculations.
b. n = Number of participants with the specified characteristic.
c. Exact 2-sided confidence interval (CI), based on the Clopper and Pearson method.
d. Mild: >2.0 to 5.0 cm; moderate: >5.0 to 10.0 cm; severe: >10.0 cm; Grade 4: necrosis (redness and swelling categories) or exfoliative dermatitis (redness category only).
e. Mild: does not interfere with activity; moderate: interferes with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe pain at the injection site.
f. Any local reaction: any redness >2.0 cm, any swelling >2.0 cm, or any pain at the injection site.
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14.68. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Ethnicity – Safety Population (Maternal) Ethnicity: Non-Hispanic/Non-Latino

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Redness[d]						
	Any	92	4 (4.3)	(1.2, 10.8)	100	0	(0.0, 3.6)
	Mild	92	3 (3.3)	(0.7, 9.2)	100	0	(0.0, 3.6)
	Moderate	92	1 (1.1)	(0.0, 5.9)	100	0	(0.0, 3.6)
	Severe	92	0	(0.0, 3.9)	100	0	(0.0, 3.6)
	Grade 4	92	0	(0.0, 3.9)	100	0	(0.0, 3.6)
	Swelling[d]						
	Any	92	7 (7.6)	(3.1, 15.1)	100	0	(0.0, 3.6)
	Mild	92	6 (6.5)	(2.4, 13.7)	100	0	(0.0, 3.6)
	Moderate	92	1 (1.1)	(0.0, 5.9)	100	0	(0.0, 3.6)
	Severe	92	0	(0.0, 3.9)	100	0	(0.0, 3.6)
	Grade 4	92	0	(0.0, 3.9)	100	0	(0.0, 3.6)
	Pain at the injection site[e]						
	Any	92	80 (87.0)	(78.3, 93.1)	100	9 (9.0)	(4.2, 16.4)
	Mild	92	61 (66.3)	(55.7, 75.8)	100	9 (9.0)	(4.2, 16.4)
	Moderate	92	19 (20.7)	(12.9, 30.4)	100	0	(0.0, 3.6)
	Severe	92	0	(0.0, 3.9)	100	0	(0.0, 3.6)
	Grade 4	92	0	(0.0, 3.9)	100	0	(0.0, 3.6)
	Any local reaction[f]	92	80 (87.0)	(78.3, 93.1)	100	9 (9.0)	(4.2, 16.4)
2	Redness[d]						
	Any	84	7 (8.3)	(3.4, 16.4)	92	0	(0.0, 3.9)
	Mild	84	5 (6.0)	(2.0, 13.3)	92	0	(0.0, 3.9)
	Moderate	84	2 (2.4)	(0.3, 8.3)	92	0	(0.0, 3.9)
	Severe	84	0	(0.0, 4.3)	92	0	(0.0, 3.9)
	Grade 4	84	0	(0.0, 4.3)	92	0	(0.0, 3.9)
	Swelling[d]						
	Any	84	6 (7.1)	(2.7, 14.9)	92	1 (1.1)	(0.0, 5.9)
	Mild	84	4 (4.8)	(1.3, 11.7)	92	1 (1.1)	(0.0, 5.9)
	Moderate	84	2 (2.4)	(0.3, 8.3)	92	0	(0.0, 3.9)
	Severe	84	0	(0.0, 4.3)	92	0	(0.0, 3.9)
	Grade 4	84	0	(0.0, 4.3)	92	0	(0.0, 3.9)
	Pain at the injection site[e]						
	Any	84	70 (83.3)	(73.6, 90.6)	92	15 (16.3)	(9.4, 25.5)
	Mild	84	52 (61.9)	(50.7, 72.3)	92	11 (12.0)	(6.1, 20.4)
	Moderate	84	17 (20.2)	(12.3, 30.4)	92	4 (4.3)	(1.2, 10.8)
	Severe	84	1 (1.2)	(0.0, 6.5)	92	0	(0.0, 3.9)
	Grade 4	84	0	(0.0, 4.3)	92	0	(0.0, 3.9)
	Any local reaction[f]	84	70 (83.3)	(73.6, 90.6)	92	15 (16.3)	(9.4, 25.5)
Any dose	Redness[d]						

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14.68. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Ethnicity – Safety Population (Maternal) Ethnicity: Non-Hispanic/Non-Latino

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Any	92	9 (9.8)	(4.6, 17.8)	100	0	(0.0, 3.6)
	Mild	92	6 (6.5)	(2.4, 13.7)	100	0	(0.0, 3.6)
	Moderate	92	3 (3.3)	(0.7, 9.2)	100	0	(0.0, 3.6)
	Severe	92	0	(0.0, 3.9)	100	0	(0.0, 3.6)
	Grade 4	92	0	(0.0, 3.9)	100	0	(0.0, 3.6)
	Swelling[d]						
	Any	92	12 (13.0)	(6.9, 21.7)	100	1 (1.0)	(0.0, 5.4)
	Mild	92	9 (9.8)	(4.6, 17.8)	100	1 (1.0)	(0.0, 5.4)
	Moderate	92	3 (3.3)	(0.7, 9.2)	100	0	(0.0, 3.6)
	Severe	92	0	(0.0, 3.9)	100	0	(0.0, 3.6)
	Grade 4	92	0	(0.0, 3.9)	100	0	(0.0, 3.6)
	Pain at the injection site[e]						
	Any	92	84 (91.3)	(83.6, 96.2)	100	19 (19.0)	(11.8, 28.1)
	Mild	92	55 (59.8)	(49.0, 69.9)	100	15 (15.0)	(8.6, 23.5)
	Moderate	92	28 (30.4)	(21.3, 40.9)	100	4 (4.0)	(1.1, 9.9)
	Severe	92	1 (1.1)	(0.0, 5.9)	100	0	(0.0, 3.6)
	Grade 4	92	0	(0.0, 3.9)	100	0	(0.0, 3.6)
	Any local reaction[f]	92	84 (91.3)	(83.6, 96.2)	100	19 (19.0)	(11.8, 28.1)

Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: Reactions were collected in the e-diary and any unscheduled clinical assessments from Day 1 through Day 7 after each dose. Grade 4 reactions were classified by the investigator or medically qualified person. Reactions reported as adverse events in the case report form within 7 days after the study vaccination were also included in the analysis; the severity of these events is based on the grading scale in the adverse event section of the case report form.
a. N = number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose. These values are the denominators for the percentage calculations.
b. n = Number of participants with the specified characteristic.
c. Exact 2-sided confidence interval (CI), based on the Clopper and Pearson method.
d. Mild: >2.0 to 5.0 cm; moderate: >5.0 to 10.0 cm; severe: >10.0 cm; Grade 4: necrosis (redness and swelling categories) or exfoliative dermatitis (redness category only).
e. Mild: does not interfere with activity; moderate: interferes with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe pain at the injection site.
f. Any local reaction: any redness >2.0 cm, any swelling >2.0 cm, or any pain at the injection site.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adfacevd Table Generation: 03MAY2023 (10:31) Output File: ./nda3/C4591015_BR/adce_s010_eth

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14.69. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Safety Population (Maternal) Baseline SARS-CoV-2 Status: Positive

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Redness[d]						
	Any	54	1 (1.9)	(0.0, 9.9)	58	0	(0.0, 6.2)
	Mild	54	1 (1.9)	(0.0, 9.9)	58	0	(0.0, 6.2)
	Moderate	54	0	(0.0, 6.6)	58	0	(0.0, 6.2)
	Severe	54	0	(0.0, 6.6)	58	0	(0.0, 6.2)
	Grade 4	54	0	(0.0, 6.6)	58	0	(0.0, 6.2)
	Swelling[d]						
	Any	54	2 (3.7)	(0.5, 12.7)	58	0	(0.0, 6.2)
	Mild	54	2 (3.7)	(0.5, 12.7)	58	0	(0.0, 6.2)
	Moderate	54	0	(0.0, 6.6)	58	0	(0.0, 6.2)
	Severe	54	0	(0.0, 6.6)	58	0	(0.0, 6.2)
	Grade 4	54	0	(0.0, 6.6)	58	0	(0.0, 6.2)
	Pain at the injection site[e]						
	Any	54	41 (75.9)	(62.4, 86.5)	58	6 (10.3)	(3.9, 21.2)
	Mild	54	32 (59.3)	(45.0, 72.4)	58	6 (10.3)	(3.9, 21.2)
	Moderate	54	9 (16.7)	(7.9, 29.3)	58	0	(0.0, 6.2)
	Severe	54	0	(0.0, 6.6)	58	0	(0.0, 6.2)
	Grade 4	54	0	(0.0, 6.6)	58	0	(0.0, 6.2)
	Any local reaction[f]	54	41 (75.9)	(62.4, 86.5)	58	6 (10.3)	(3.9, 21.2)
2	Redness[d]						
	Any	49	2 (4.1)	(0.5, 14.0)	51	0	(0.0, 7.0)
	Mild	49	1 (2.0)	(0.1, 10.9)	51	0	(0.0, 7.0)
	Moderate	49	1 (2.0)	(0.1, 10.9)	51	0	(0.0, 7.0)
	Severe	49	0	(0.0, 7.3)	51	0	(0.0, 7.0)
	Grade 4	49	0	(0.0, 7.3)	51	0	(0.0, 7.0)
	Swelling[d]						
	Any	49	4 (8.2)	(2.3, 19.6)	51	0	(0.0, 7.0)
	Mild	49	2 (4.1)	(0.5, 14.0)	51	0	(0.0, 7.0)
	Moderate	49	2 (4.1)	(0.5, 14.0)	51	0	(0.0, 7.0)
	Severe	49	0	(0.0, 7.3)	51	0	(0.0, 7.0)
	Grade 4	49	0	(0.0, 7.3)	51	0	(0.0, 7.0)
	Pain at the injection site[e]						
	Any	49	35 (71.4)	(56.7, 83.4)	51	7 (13.7)	(5.7, 26.3)
	Mild	49	27 (55.1)	(40.2, 69.3)	51	6 (11.8)	(4.4, 23.9)
	Moderate	49	8 (16.3)	(7.3, 29.7)	51	1 (2.0)	(0.0, 10.4)
	Severe	49	0	(0.0, 7.3)	51	0	(0.0, 7.0)
	Grade 4	49	0	(0.0, 7.3)	51	0	(0.0, 7.0)
	Any local reaction[f]	49	35 (71.4)	(56.7, 83.4)	51	7 (13.7)	(5.7, 26.3)
Any dose	Redness[d]						

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14.69. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Safety Population (Maternal) Baseline SARS-CoV-2 Status: Positive

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Any	54	2 (3.7)	(0.5, 12.7)	58	0	(0.0, 6.2)
	Mild	54	1 (1.9)	(0.0, 9.9)	58	0	(0.0, 6.2)
	Moderate	54	1 (1.9)	(0.0, 9.9)	58	0	(0.0, 6.2)
	Severe	54	0	(0.0, 6.6)	58	0	(0.0, 6.2)
	Grade 4	54	0	(0.0, 6.6)	58	0	(0.0, 6.2)
	Swelling[d]						
	Any	54	6 (11.1)	(4.2, 22.6)	58	0	(0.0, 6.2)
	Mild	54	4 (7.4)	(2.1, 17.9)	58	0	(0.0, 6.2)
	Moderate	54	2 (3.7)	(0.5, 12.7)	58	0	(0.0, 6.2)
	Severe	54	0	(0.0, 6.6)	58	0	(0.0, 6.2)
	Grade 4	54	0	(0.0, 6.6)	58	0	(0.0, 6.2)
	Pain at the injection site[e]						
	Any	54	44 (81.5)	(68.6, 90.7)	58	10 (17.2)	(8.6, 29.4)
	Mild	54	32 (59.3)	(45.0, 72.4)	58	9 (15.5)	(7.3, 27.4)
	Moderate	54	12 (22.2)	(12.0, 35.6)	58	1 (1.7)	(0.0, 9.2)
	Severe	54	0	(0.0, 6.6)	58	0	(0.0, 6.2)
	Grade 4	54	0	(0.0, 6.6)	58	0	(0.0, 6.2)
	Any local reaction[f]	54	44 (81.5)	(68.6, 90.7)	58	10 (17.2)	(8.6, 29.4)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: Reactions were collected in the e-diary and any unscheduled clinical assessments from Day 1 through Day 7 after each dose. Grade 4 reactions were classified by the investigator or medically qualified person. Reactions reported as adverse events in the case report form within 7 days after the study vaccination were also included in the analysis; the severity of these events is based on the grading scale in the adverse event section of the case report form.
a. N = number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose. These values are the denominators for the percentage calculations.
b. n = Number of participants with the specified characteristic.
c. Exact 2-sided confidence interval (CI), based on the Clopper and Pearson method.
d. Mild: >2.0 to 5.0 cm; moderate: >5.0 to 10.0 cm; severe: >10.0 cm; Grade 4: necrosis (redness and swelling categories) or exfoliative dermatitis (redness category only).
e. Mild: does not interfere with activity; moderate: interferes with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe pain at the injection site.
f. Any local reaction: any redness >2.0 cm, any swelling >2.0 cm, or any pain at the injection site.
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14.70. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Safety Population (Maternal) Baseline SARS-CoV-2 Status: Negative

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Redness[d]						
	Any	99	4 (4.0)	(1.1, 10.0)	101	1 (1.0)	(0.0, 5.4)
	Mild	99	3 (3.0)	(0.6, 8.6)	101	1 (1.0)	(0.0, 5.4)
	Moderate	99	1 (1.0)	(0.0, 5.5)	101	0	(0.0, 3.6)
	Severe	99	0	(0.0, 3.7)	101	0	(0.0, 3.6)
	Grade 4	99	0	(0.0, 3.7)	101	0	(0.0, 3.6)
	Swelling[d]						
	Any	99	7 (7.1)	(2.9, 14.0)	101	0	(0.0, 3.6)
	Mild	99	5 (5.1)	(1.7, 11.4)	101	0	(0.0, 3.6)
	Moderate	99	1 (1.0)	(0.0, 5.5)	101	0	(0.0, 3.6)
	Severe	99	1 (1.0)	(0.0, 5.5)	101	0	(0.0, 3.6)
	Grade 4	99	0	(0.0, 3.7)	101	0	(0.0, 3.6)
	Pain at the injection site[e]						
	Any	99	85 (85.9)	(77.4, 92.0)	101	8 (7.9)	(3.5, 15.0)
	Mild	99	60 (60.6)	(50.3, 70.3)	101	8 (7.9)	(3.5, 15.0)
	Moderate	99	25 (25.3)	(17.1, 35.0)	101	0	(0.0, 3.6)
	Severe	99	0	(0.0, 3.7)	101	0	(0.0, 3.6)
	Grade 4	99	0	(0.0, 3.7)	101	0	(0.0, 3.6)
	Any local reaction[f]	99	85 (85.9)	(77.4, 92.0)	101	8 (7.9)	(3.5, 15.0)
2	Redness[d]						
	Any	93	6 (6.5)	(2.4, 13.5)	92	0	(0.0, 3.9)
	Mild	93	4 (4.3)	(1.2, 10.6)	92	0	(0.0, 3.9)
	Moderate	93	2 (2.2)	(0.3, 7.6)	92	0	(0.0, 3.9)
	Severe	93	0	(0.0, 3.9)	92	0	(0.0, 3.9)
	Grade 4	93	0	(0.0, 3.9)	92	0	(0.0, 3.9)
	Swelling[d]						
	Any	93	6 (6.5)	(2.4, 13.5)	92	1 (1.1)	(0.0, 5.9)
	Mild	93	4 (4.3)	(1.2, 10.6)	92	1 (1.1)	(0.0, 5.9)
	Moderate	93	2 (2.2)	(0.3, 7.6)	92	0	(0.0, 3.9)
	Severe	93	0	(0.0, 3.9)	92	0	(0.0, 3.9)
	Grade 4	93	0	(0.0, 3.9)	92	0	(0.0, 3.9)
	Pain at the injection site[e]						
	Any	93	71 (76.3)	(66.4, 84.5)	92	16 (17.4)	(10.3, 26.7)
	Mild	93	52 (55.9)	(45.2, 66.2)	92	11 (12.0)	(6.1, 20.4)
	Moderate	93	18 (19.4)	(11.9, 28.9)	92	5 (5.4)	(1.8, 12.2)
	Severe	93	1 (1.1)	(0.0, 5.8)	92	0	(0.0, 3.9)
	Grade 4	93	0	(0.0, 3.9)	92	0	(0.0, 3.9)
	Any local reaction[f]	93	71 (76.3)	(66.4, 84.5)	92	16 (17.4)	(10.3, 26.7)

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14.70. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Safety Population (Maternal) Baseline SARS-CoV-2 Status: Negative

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
Any dose	Redness[d]						
	Any	99	9 (9.1)	(4.2, 16.6)	101	1 (1.0)	(0.0, 5.4)
	Mild	99	6 (6.1)	(2.3, 12.7)	101	1 (1.0)	(0.0, 5.4)
	Moderate	99	3 (3.0)	(0.6, 8.6)	101	0	(0.0, 3.6)
	Severe	99	0	(0.0, 3.7)	101	0	(0.0, 3.6)
	Grade 4	99	0	(0.0, 3.7)	101	0	(0.0, 3.6)
	Swelling[d]						
	Any	99	11 (11.1)	(5.7, 19.0)	101	1 (1.0)	(0.0, 5.4)
	Mild	99	7 (7.1)	(2.9, 14.0)	101	1 (1.0)	(0.0, 5.4)
	Moderate	99	3 (3.0)	(0.6, 8.6)	101	0	(0.0, 3.6)
	Severe	99	1 (1.0)	(0.0, 5.5)	101	0	(0.0, 3.6)
	Grade 4	99	0	(0.0, 3.7)	101	0	(0.0, 3.6)
	Pain at the injection site[e]						
	Any	99	87 (87.9)	(79.8, 93.6)	101	19 (18.8)	(11.7, 27.8)
	Mild	99	52 (52.5)	(42.2, 62.7)	101	14 (13.9)	(7.8, 22.2)
	Moderate	99	34 (34.3)	(25.1, 44.6)	101	5 (5.0)	(1.6, 11.2)
	Severe	99	1 (1.0)	(0.0, 5.5)	101	0	(0.0, 3.6)
	Grade 4	99	0	(0.0, 3.7)	101	0	(0.0, 3.6)
	Any local reaction[f]	99	87 (87.9)	(79.8, 93.6)	101	19 (18.8)	(11.7, 27.8)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: Reactions were collected in the e-diary and any unscheduled clinical assessments from Day 1 through Day 7 after each dose. Grade 4 reactions were classified by the investigator or medically qualified person. Reactions reported as adverse events in the case report form within 7 days after the study vaccination were also included in the analysis; the severity of these events is based on the grading scale in the adverse event section of the case report form.
a. N = number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose. These values are the denominators for the percentage calculations.
b. n = Number of participants with the specified characteristic.
c. Exact 2-sided confidence interval (CI), based on the Clopper and Pearson method.
d. Mild: >2.0 to 5.0 cm; moderate: >5.0 to 10.0 cm; severe: >10.0 cm; Grade 4: necrosis (redness and swelling categories) or exfoliative dermatitis (redness category only).
e. Mild: does not interfere with activity; moderate: interferes with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe pain at the injection site.
f. Any local reaction: any redness >2.0 cm, any swelling >2.0 cm, or any pain at the injection site.
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14.71. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Safety Population (Maternal) Baseline SARS-CoV-2 Status: Missing

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Redness[d]						
	Any	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Mild	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Moderate	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Severe	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Grade 4	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Swelling[d]						
	Any	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Mild	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Moderate	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Severe	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Grade 4	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Pain at the injection site[e]						
	Any	8	7 (87.5)	(47.3, 99.7)	4	2 (50.0)	(6.8, 93.2)
	Mild	8	3 (37.5)	(8.5, 75.5)	4	2 (50.0)	(6.8, 93.2)
	Moderate	8	4 (50.0)	(15.7, 84.3)	4	0	(0.0, 60.2)
	Severe	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Grade 4	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Any local reaction[f]	8	7 (87.5)	(47.3, 99.7)	4	2 (50.0)	(6.8, 93.2)
2	Redness[d]						
	Any	6	0	(0.0, 45.9)	3	0	(0.0, 70.8)
	Mild	6	0	(0.0, 45.9)	3	0	(0.0, 70.8)
	Moderate	6	0	(0.0, 45.9)	3	0	(0.0, 70.8)
	Severe	6	0	(0.0, 45.9)	3	0	(0.0, 70.8)
	Grade 4	6	0	(0.0, 45.9)	3	0	(0.0, 70.8)
	Swelling[d]						
	Any	6	0	(0.0, 45.9)	3	0	(0.0, 70.8)
	Mild	6	0	(0.0, 45.9)	3	0	(0.0, 70.8)
	Moderate	6	0	(0.0, 45.9)	3	0	(0.0, 70.8)
	Severe	6	0	(0.0, 45.9)	3	0	(0.0, 70.8)
	Grade 4	6	0	(0.0, 45.9)	3	0	(0.0, 70.8)
	Pain at the injection site[e]						
	Any	6	5 (83.3)	(35.9, 99.6)	3	1 (33.3)	(0.8, 90.6)
	Mild	6	2 (33.3)	(4.3, 77.7)	3	1 (33.3)	(0.8, 90.6)
	Moderate	6	3 (50.0)	(11.8, 88.2)	3	0	(0.0, 70.8)
	Severe	6	0	(0.0, 45.9)	3	0	(0.0, 70.8)
	Grade 4	6	0	(0.0, 45.9)	3	0	(0.0, 70.8)
	Any local reaction[f]	6	5 (83.3)	(35.9, 99.6)	3	1 (33.3)	(0.8, 90.6)

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14.71. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Safety Population (Maternal) Baseline SARS-CoV-2 Status: Missing

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
Any dose	Redness[d]						
	Any	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Mild	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Moderate	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Severe	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Grade 4	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Swelling[d]						
	Any	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Mild	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Moderate	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Severe	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Grade 4	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Pain at the injection site[e]						
	Any	8	7 (87.5)	(47.3, 99.7)	4	2 (50.0)	(6.8, 93.2)
	Mild	8	1 (12.5)	(0.3, 52.7)	4	2 (50.0)	(6.8, 93.2)
	Moderate	8	6 (75.0)	(34.9, 96.8)	4	0	(0.0, 60.2)
	Severe	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Grade 4	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Any local reaction[f]	8	7 (87.5)	(47.3, 99.7)	4	2 (50.0)	(6.8, 93.2)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: Reactions were collected in the e-diary and any unscheduled clinical assessments from Day 1 through Day 7 after each dose. Grade 4 reactions were classified by the investigator or medically qualified person. Reactions reported as adverse events in the case report form within 7 days after the study vaccination were also included in the analysis; the severity of these events is based on the grading scale in the adverse event section of the case report form.
a. N = number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose. These values are the denominators for the percentage calculations.
b. n = Number of participants with the specified characteristic.
c. Exact 2-sided confidence interval (CI), based on the Clopper and Pearson method.
d. Mild: >2.0 to 5.0 cm; moderate: >5.0 to 10.0 cm; severe: >10.0 cm; Grade 4: necrosis (redness and swelling categories) or exfoliative dermatitis (redness category only).
e. Mild: does not interfere with activity; moderate: interferes with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe pain at the injection site.
f. Any local reaction: any redness >2.0 cm, any swelling >2.0 cm, or any pain at the injection site.
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Systemic Events

14.72. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Safety Population (Maternal)

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Fever						
	Any	161	2 (1.2)	(0.2, 4.4)	163	3 (1.8)	(0.4, 5.3)
	≥38.0°C to 38.4°C	161	1 (0.6)	(0.0, 3.4)	163	2 (1.2)	(0.1, 4.4)
	>38.4°C to 38.9°C	161	0	(0.0, 2.3)	163	0	(0.0, 2.2)
	>38.9°C to 40.0°C	161	1 (0.6)	(0.0, 3.4)	163	1 (0.6)	(0.0, 3.4)
	>40.0°C	161	0	(0.0, 2.3)	163	0	(0.0, 2.2)
	Unknown[d]	161	0	(0.0, 2.3)	163	0	(0.0, 2.2)
	Fatigue/tiredness[e]						
	Any	161	80 (49.7)	(41.7, 57.7)	163	70 (42.9)	(35.2, 50.9)
	Mild	161	42 (26.1)	(19.5, 33.6)	163	34 (20.9)	(14.9, 27.9)
	Moderate	161	37 (23.0)	(16.7, 30.3)	163	35 (21.5)	(15.4, 28.6)
	Severe	161	1 (0.6)	(0.0, 3.4)	163	1 (0.6)	(0.0, 3.4)
	Grade 4	161	0	(0.0, 2.3)	163	0	(0.0, 2.2)
	Headache[e]						
	Any	161	55 (34.2)	(26.9, 42.0)	163	58 (35.6)	(28.3, 43.4)
	Mild	161	33 (20.5)	(14.5, 27.6)	163	36 (22.1)	(16.0, 29.2)
	Moderate	161	19 (11.8)	(7.3, 17.8)	163	21 (12.9)	(8.2, 19.0)
	Severe	161	3 (1.9)	(0.4, 5.3)	163	1 (0.6)	(0.0, 3.4)
	Grade 4	161	0	(0.0, 2.3)	163	0	(0.0, 2.2)
	Chills[e]						
	Any	161	11 (6.8)	(3.5, 11.9)	163	9 (5.5)	(2.6, 10.2)
	Mild	161	8 (5.0)	(2.2, 9.6)	163	9 (5.5)	(2.6, 10.2)
	Moderate	161	3 (1.9)	(0.4, 5.3)	163	0	(0.0, 2.2)
	Severe	161	0	(0.0, 2.3)	163	0	(0.0, 2.2)
	Grade 4	161	0	(0.0, 2.3)	163	0	(0.0, 2.2)
	Vomiting[f]						
	Any	161	8 (5.0)	(2.2, 9.6)	163	15 (9.2)	(5.2, 14.7)
	Mild	161	8 (5.0)	(2.2, 9.6)	163	10 (6.1)	(3.0, 11.0)
	Moderate	161	0	(0.0, 2.3)	163	5 (3.1)	(1.0, 7.0)
	Severe	161	0	(0.0, 2.3)	163	0	(0.0, 2.2)
	Grade 4	161	0	(0.0, 2.3)	163	0	(0.0, 2.2)
	Diarrhea[g]						
	Any	161	19 (11.8)	(7.3, 17.8)	163	14 (8.6)	(4.8, 14.0)
	Mild	161	18 (11.2)	(6.8, 17.1)	163	12 (7.4)	(3.9, 12.5)
	Moderate	161	1 (0.6)	(0.0, 3.4)	163	2 (1.2)	(0.1, 4.4)
	Severe	161	0	(0.0, 2.3)	163	0	(0.0, 2.2)
	Grade 4	161	0	(0.0, 2.3)	163	0	(0.0, 2.2)

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14.72. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Safety Population (Maternal)

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	New or worsened muscle pain[e]						
	Any	161	20 (12.4)	(7.8, 18.5)	163	19 (11.7)	(7.2, 17.6)
	Mild	161	11 (6.8)	(3.5, 11.9)	163	10 (6.1)	(3.0, 11.0)
	Moderate	161	9 (5.6)	(2.6, 10.3)	163	9 (5.5)	(2.6, 10.2)
	Severe	161	0	(0.0, 2.3)	163	0	(0.0, 2.2)
	Grade 4	161	0	(0.0, 2.3)	163	0	(0.0, 2.2)
	New or worsened joint pain[e]						
	Any	161	5 (3.1)	(1.0, 7.1)	163	8 (4.9)	(2.1, 9.4)
	Mild	161	2 (1.2)	(0.2, 4.4)	163	4 (2.5)	(0.7, 6.2)
	Moderate	161	3 (1.9)	(0.4, 5.3)	163	4 (2.5)	(0.7, 6.2)
	Severe	161	0	(0.0, 2.3)	163	0	(0.0, 2.2)
	Grade 4	161	0	(0.0, 2.3)	163	0	(0.0, 2.2)
	Any systemic event[h]	161	98 (60.9)	(52.9, 68.5)	163	100 (61.3)	(53.4, 68.9)
	Use of antipyretic or pain medication[i]	161	22 (13.7)	(8.8, 20.0)	163	22 (13.5)	(8.7, 19.7)
2	Fever						
	Any	148	4 (2.7)	(0.7, 6.8)	146	1 (0.7)	(0.0, 3.8)
	≥38.0°C to 38.4°C	148	2 (1.4)	(0.2, 4.8)	146	1 (0.7)	(0.0, 3.8)
	>38.4°C to 38.9°C	148	1 (0.7)	(0.0, 3.7)	146	0	(0.0, 2.5)
	>38.9°C to 40.0°C	148	0	(0.0, 2.5)	146	0	(0.0, 2.5)
	>40.0°C	148	0	(0.0, 2.5)	146	0	(0.0, 2.5)
	Unknown[d]	148	1 (0.7)	(0.0, 3.7)	146	0	(0.0, 2.5)
	Fatigue/tiredness[e]						
	Any	148	74 (50.0)	(41.7, 58.3)	146	50 (34.2)	(26.6, 42.5)
	Mild	148	23 (15.5)	(10.1, 22.4)	146	23 (15.8)	(10.3, 22.7)
	Moderate	148	48 (32.4)	(25.0, 40.6)	146	27 (18.5)	(12.6, 25.8)
	Severe	148	3 (2.0)	(0.4, 5.8)	146	0	(0.0, 2.5)
	Grade 4	148	0	(0.0, 2.5)	146	0	(0.0, 2.5)
	Headache[e]						
	Any	148	61 (41.2)	(33.2, 49.6)	146	35 (24.0)	(17.3, 31.7)
	Mild	148	37 (25.0)	(18.3, 32.8)	146	20 (13.7)	(8.6, 20.4)
	Moderate	148	22 (14.9)	(9.6, 21.6)	146	15 (10.3)	(5.9, 16.4)
	Severe	148	2 (1.4)	(0.2, 4.8)	146	0	(0.0, 2.5)
	Grade 4	148	0	(0.0, 2.5)	146	0	(0.0, 2.5)
	Chills[e]						
	Any	148	19 (12.8)	(7.9, 19.3)	146	1 (0.7)	(0.0, 3.8)
	Mild	148	7 (4.7)	(1.9, 9.5)	146	1 (0.7)	(0.0, 3.8)
	Moderate	148	11 (7.4)	(3.8, 12.9)	146	0	(0.0, 2.5)
	Severe	148	1 (0.7)	(0.0, 3.7)	146	0	(0.0, 2.5)
	Grade 4	148	0	(0.0, 2.5)	146	0	(0.0, 2.5)

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14.72. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Safety Population (Maternal)

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Vomiting[f]						
	Any	148	13 (8.8)	(4.8, 14.6)	146	5 (3.4)	(1.1, 7.8)
	Mild	148	13 (8.8)	(4.8, 14.6)	146	3 (2.1)	(0.4, 5.9)
	Moderate	148	0	(0.0, 2.5)	146	2 (1.4)	(0.2, 4.9)
	Severe	148	0	(0.0, 2.5)	146	0	(0.0, 2.5)
	Grade 4	148	0	(0.0, 2.5)	146	0	(0.0, 2.5)
	Diarrhea[g]						
	Any	148	9 (6.1)	(2.8, 11.2)	146	8 (5.5)	(2.4, 10.5)
	Mild	148	9 (6.1)	(2.8, 11.2)	146	6 (4.1)	(1.5, 8.7)
	Moderate	148	0	(0.0, 2.5)	146	2 (1.4)	(0.2, 4.9)
	Severe	148	0	(0.0, 2.5)	146	0	(0.0, 2.5)
	Grade 4	148	0	(0.0, 2.5)	146	0	(0.0, 2.5)
	New or worsened muscle pain[e]						
	Any	148	40 (27.0)	(20.1, 34.9)	146	10 (6.8)	(3.3, 12.2)
	Mild	148	20 (13.5)	(8.5, 20.1)	146	7 (4.8)	(1.9, 9.6)
	Moderate	148	19 (12.8)	(7.9, 19.3)	146	3 (2.1)	(0.4, 5.9)
	Severe	148	1 (0.7)	(0.0, 3.7)	146	0	(0.0, 2.5)
	Grade 4	148	0	(0.0, 2.5)	146	0	(0.0, 2.5)
	New or worsened joint pain[e]						
	Any	148	20 (13.5)	(8.5, 20.1)	146	9 (6.2)	(2.9, 11.4)
	Mild	148	11 (7.4)	(3.8, 12.9)	146	7 (4.8)	(1.9, 9.6)
	Moderate	148	9 (6.1)	(2.8, 11.2)	146	2 (1.4)	(0.2, 4.9)
	Severe	148	0	(0.0, 2.5)	146	0	(0.0, 2.5)
	Grade 4	148	0	(0.0, 2.5)	146	0	(0.0, 2.5)
	Any systemic event[h]	148	89 (60.1)	(51.8, 68.1)	146	67 (45.9)	(37.6, 54.3)
	Use of antipyretic or pain medication[i]	148	29 (19.6)	(13.5, 26.9)	146	10 (6.8)	(3.3, 12.2)
Any dose	Fever						
	Any	161	6 (3.7)	(1.4, 7.9)	163	4 (2.5)	(0.7, 6.2)
	≥38.0°C to 38.4°C	161	3 (1.9)	(0.4, 5.3)	163	3 (1.8)	(0.4, 5.3)
	>38.4°C to 38.9°C	161	1 (0.6)	(0.0, 3.4)	163	0	(0.0, 2.2)
	>38.9°C to 40.0°C	161	1 (0.6)	(0.0, 3.4)	163	1 (0.6)	(0.0, 3.4)
	>40.0°C	161	0	(0.0, 2.3)	163	0	(0.0, 2.2)
	Unknown[d]	161	1 (0.6)	(0.0, 3.4)	163	0	(0.0, 2.2)
	Fatigue/tiredness[e]						
	Any	161	101 (62.7)	(54.8, 70.2)	163	82 (50.3)	(42.4, 58.2)
	Mild	161	36 (22.4)	(16.2, 29.6)	163	33 (20.2)	(14.4, 27.2)
	Moderate	161	62 (38.5)	(31.0, 46.5)	163	48 (29.4)	(22.6, 37.1)
	Severe	161	3 (1.9)	(0.4, 5.3)	163	1 (0.6)	(0.0, 3.4)

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14.72. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Safety Population (Maternal)

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Grade 4	161	0	(0.0, 2.3)	163	0	(0.0, 2.2)
	Headache[e]						
	Any	161	85 (52.8)	(44.8, 60.7)	163	72 (44.2)	(36.4, 52.1)
	Mild	161	45 (28.0)	(21.2, 35.6)	163	42 (25.8)	(19.2, 33.2)
	Moderate	161	36 (22.4)	(16.2, 29.6)	163	29 (17.8)	(12.3, 24.5)
	Severe	161	4 (2.5)	(0.7, 6.2)	163	1 (0.6)	(0.0, 3.4)
	Grade 4	161	0	(0.0, 2.3)	163	0	(0.0, 2.2)
	Chills[e]						
	Any	161	28 (17.4)	(11.9, 24.1)	163	10 (6.1)	(3.0, 11.0)
	Mild	161	13 (8.1)	(4.4, 13.4)	163	10 (6.1)	(3.0, 11.0)
	Moderate	161	14 (8.7)	(4.8, 14.2)	163	0	(0.0, 2.2)
	Severe	161	1 (0.6)	(0.0, 3.4)	163	0	(0.0, 2.2)
	Grade 4	161	0	(0.0, 2.3)	163	0	(0.0, 2.2)
	Vomiting[f]						
	Any	161	18 (11.2)	(6.8, 17.1)	163	16 (9.8)	(5.7, 15.5)
	Mild	161	18 (11.2)	(6.8, 17.1)	163	10 (6.1)	(3.0, 11.0)
	Moderate	161	0	(0.0, 2.3)	163	6 (3.7)	(1.4, 7.8)
	Severe	161	0	(0.0, 2.3)	163	0	(0.0, 2.2)
	Grade 4	161	0	(0.0, 2.3)	163	0	(0.0, 2.2)
	Diarrhea[g]						
	Any	161	24 (14.9)	(9.8, 21.4)	163	21 (12.9)	(8.2, 19.0)
	Mild	161	23 (14.3)	(9.3, 20.7)	163	17 (10.4)	(6.2, 16.2)
	Moderate	161	1 (0.6)	(0.0, 3.4)	163	4 (2.5)	(0.7, 6.2)
	Severe	161	0	(0.0, 2.3)	163	0	(0.0, 2.2)
	Grade 4	161	0	(0.0, 2.3)	163	0	(0.0, 2.2)
	New or worsened muscle pain[e]						
	Any	161	53 (32.9)	(25.7, 40.8)	163	26 (16.0)	(10.7, 22.5)
	Mild	161	25 (15.5)	(10.3, 22.1)	163	16 (9.8)	(5.7, 15.5)
	Moderate	161	27 (16.8)	(11.4, 23.5)	163	10 (6.1)	(3.0, 11.0)
	Severe	161	1 (0.6)	(0.0, 3.4)	163	0	(0.0, 2.2)
	Grade 4	161	0	(0.0, 2.3)	163	0	(0.0, 2.2)
	New or worsened joint pain[e]						
	Any	161	22 (13.7)	(8.8, 20.0)	163	13 (8.0)	(4.3, 13.3)
	Mild	161	11 (6.8)	(3.5, 11.9)	163	8 (4.9)	(2.1, 9.4)
	Moderate	161	11 (6.8)	(3.5, 11.9)	163	5 (3.1)	(1.0, 7.0)
	Severe	161	0	(0.0, 2.3)	163	0	(0.0, 2.2)
	Grade 4	161	0	(0.0, 2.3)	163	0	(0.0, 2.2)
	Any systemic event[h]	161	119 (73.9)	(66.4, 80.5)	163	109 (66.9)	(59.1, 74.0)
	Use of antipyretic or pain medication[i]	161	41 (25.5)	(18.9, 32.9)	163	26 (16.0)	(10.7, 22.5)

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14.72. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Safety Population (Maternal)

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])

Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary. Analyses for HIV-positive participants and their infants will be summarized separately.
Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) and from any unscheduled clinical assessments from Day 1 through Day 7 after each dose. Grade 4 events were classified by the investigator or medically qualified person. Events reported as adverse events in the case report form within 7 days after the study vaccination were also included in the analysis; the severity of these events is based on the grading scale in the adverse event section of the case report form.
a. N = number of participants reporting at least 1 yes or no response for the specified event after the specified dose. These values are the denominators for the percentage calculations.
b. n = Number of participants with the specified characteristic.
c. Exact 2-sided confidence interval (CI), based on the Clopper and Pearson method.
d. This row includes counts of participants with "pyrexia" and "body temperature increased" MedDRA preferred terms with a nonmissing AE toxicity grade recorded on the AE case report form and who are also missing e-diary fever measurements.
e. Mild: does not interfere with activity; moderate: some interference with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe fatigue/tiredness, severe headache, severe chills, severe muscle pain, or severe joint pain.
f. Mild: 1 to 2 times in 24 hours; moderate: >2 times in 24 hours; severe: requires intravenous hydration; Grade 4: emergency room visit or hospitalization for severe vomiting.
g. Mild: 2 to 3 loose stools in 24 hours; moderate: 4 to 5 loose stools in 24 hours; severe: 6 or more loose stools in 24 hours; Grade 4: emergency room visit or hospitalization for severe diarrhea.
h. Any systemic event: any fever, any fatigue/tiredness, any vomiting, any chills, any diarrhea, any headache, any new or worsened muscle pain, or any new or worsened joint pain.
i. The use of antipyretic medication was included and summarized in the tables but was not considered as a systemic event. Severity was not applicable.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adfacevd Table Generation: 03MAY2023 (10:31) Output File: ./nda3/C4591015_BR/adce_s020

14.73. Duration (Days) From First to Last Day of Systemic Events After Each Dose – Safety Population (Maternal)

		Vaccine Group (as Administered)	
Dose	Systemic Event	BNT162b2 (30 µg)	Placebo
1	Fever		
	n[a]	2	3
	Mean (SD)	1.0 (0.00)	2.7 (2.89)
	Median	1.0	1.0
	Min, max	(1, 1)	(1, 6)

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14.73. Duration (Days) From First to Last Day of Systemic Events After Each Dose – Safety Population (Maternal)

Dose	Systemic Event	Vaccine Group (as Administered) BNT162b2 (30 µg)	Placebo
	Fatigue/tiredness		
	n[a]	80	70
	Mean (SD)	4.5 (4.58)	6.5 (7.20)
	Median	3.0	4.0
	Min, max	(1, 23)	(1, 24)
	Headache		
	n[a]	55	58
	Mean (SD)	2.4 (2.87)	2.7 (2.64)
	Median	1.0	2.0
	Min, max	(1, 19)	(1, 14)
	Chills		
	n[a]	11	9
	Mean (SD)	1.5 (1.29)	1.6 (1.01)
	Median	1.0	1.0
	Min, max	(1, 5)	(1, 4)
	Vomiting		
	n[a]	8	15
	Mean (SD)	1.9 (2.10)	3.3 (5.12)
	Median	1.0	1.0
	Min, max	(1, 7)	(1, 21)
	Diarrhea		
	n[a]	19	14
	Mean (SD)	2.3 (2.63)	2.3 (2.10)
	Median	1.0	1.0
	Min, max	(1, 12)	(1, 6)
	Unknown[b]	0	1
	New or worsened muscle pain		
	n[a]	20	19
	Mean (SD)	1.9 (1.52)	2.9 (4.90)
	Median	1.0	1.0
	Min, max	(1, 7)	(1, 19)
	New or worsened joint pain		
	n[a]	5	8
	Mean (SD)	2.6 (2.51)	3.6 (6.63)
	Median	2.0	1.0
	Min, max	(1, 7)	(1, 20)
	Use of antipyretic or pain medication		
	n[a]	22	22
	Mean (SD)	1.7 (1.39)	2.8 (3.29)
	Median	1.0	1.0
	Min, max	(1, 5)	(1, 14)

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14.73. Duration (Days) From First to Last Day of Systemic Events After Each Dose – Safety Population (Maternal)

Dose	Systemic Event	Vaccine Group (as Administered)	
		BNT162b2 (30 µg)	Placebo
2	Fever		
	n[a]	4	1
	Mean (SD)	1.0 (0.00)	1.0 (NE)
	Median	1.0	1.0
	Min, max	(1, 1)	(1, 1)
	Fatigue/tiredness		
	n[a]	74	50
	Mean (SD)	3.8 (5.14)	7.5 (9.77)
	Median	2.0	4.5
	Min, max	(1, 40)	(1, 44)
	Headache		
	n[a]	61	35
	Mean (SD)	2.8 (3.97)	2.7 (2.29)
	Median	2.0	2.0
	Min, max	(1, 30)	(1, 9)
	Chills		
	n[a]	19	1
	Mean (SD)	1.3 (0.56)	1.0 (NE)
	Median	1.0	1.0
	Min, max	(1, 3)	(1, 1)
	Vomiting		
	n[a]	13	5
	Mean (SD)	1.3 (1.11)	2.6 (2.30)
	Median	1.0	1.0
	Min, max	(1, 5)	(1, 6)
	Diarrhea		
	n[a]	9	8
	Mean (SD)	2.2 (2.22)	2.4 (1.77)
	Median	1.0	2.0
	Min, max	(1, 7)	(1, 6)
	New or worsened muscle pain		
	n[a]	40	10
	Mean (SD)	1.4 (0.67)	1.4 (0.52)
	Median	1.0	1.0
	Min, max	(1, 3)	(1, 2)
	New or worsened joint pain		
	n[a]	20	9
	Mean (SD)	1.2 (0.49)	3.9 (6.62)
	Median	1.0	1.0
	Min, max	(1, 3)	(1, 21)
	Use of antipyretic or pain medication		

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14.73. Duration (Days) From First to Last Day of Systemic Events After Each Dose – Safety Population (Maternal)

Dose	Systemic Event	Vaccine Group (as Administered)	
		BNT162b2 (30 µg)	Placebo
	n[a]	29	10
	Mean (SD)	1.9 (1.27)	1.1 (0.32)
	Median	1.0	1.0
	Min, max	(1, 5)	(1, 2)

Abbreviation: NE = not estimable.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary. Analyses for HIV-positive participants and their infants will be listed separately.
Note: Duration was calculated in days as the difference from the start of the first reported event to the resolution of the last reported event, inclusive. For symptoms that are ongoing at the time of the next dose, stop date is computed as the next dose date.
Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) and from any unscheduled clinical assessments from Day 1 through Day 7 after each dose. The resolution date for events lasting longer than 7 days was recorded on the participant's case report form. Events reported as adverse events in the case report form within 7 days after the study vaccination were also included in the analysis.
a. n = Number of participants reporting the specified event on any of the 7 days, including participants with events of unknown duration.
b. Includes those events where the resolution date is partial or missing.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adfacevd Table Generation: 03MAY2023 (17:53) Output File: ./nda3/C4591015_BR/adce_s040

14.74. Onset Day (Days) for Systemic Events After Each Dose – Safety Population (Maternal)

Dose	Systemic Event	Vaccine Group (as Administered)	
		BNT162b2 (30 µg)	Placebo
1	Fever		
	n[a]	2	3
	Mean (SD)	1.5 (0.71)	2.7 (2.08)
	Median	1.5	2.0
	(Min, max)	(1, 2)	(1, 5)
	Fatigue/tiredness		
	n[a]	80	70
	Mean (SD)	2.1 (1.40)	2.1 (1.23)
	Median	2.0	2.0
	(Min, max)	(1, 7)	(1, 6)
	Headache		
	n[a]	55	58

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14.74. Onset Day (Days) for Systemic Events After Each Dose – Safety Population (Maternal)

Dose	Systemic Event	Vaccine Group (as Administered) BNT162b2 (30 µg)	Placebo
	Mean (SD)	2.9 (1.88)	2.9 (1.98)
	Median	2.0	2.0
	(Min, max)	(1, 7)	(1, 7)
	Chills		
	n[a]	11	9
	Mean (SD)	1.7 (0.90)	3.8 (1.79)
	Median	2.0	4.0
	(Min, max)	(1, 4)	(1, 6)
	Vomiting		
	n[a]	8	15
	Mean (SD)	3.3 (1.83)	3.7 (1.72)
	Median	2.5	4.0
	(Min, max)	(2, 7)	(1, 6)
	Diarrhea		
	n[a]	19	14
	Mean (SD)	3.7 (1.88)	3.1 (1.64)
	Median	3.0	2.5
	(Min, max)	(1, 7)	(1, 6)
	New or worsened muscle pain		
	n[a]	20	19
	Mean (SD)	2.8 (1.71)	3.3 (1.77)
	Median	2.0	3.0
	(Min, max)	(1, 7)	(1, 7)
	New or worsened joint pain		
	n[a]	5	8
	Mean (SD)	2.8 (2.17)	4.4 (1.85)
	Median	2.0	4.0
	(Min, max)	(1, 6)	(2, 7)
	Any systemic event[b]		
	n[a]	98	100
	Mean (SD)	1.9 (1.42)	2.1 (1.33)
	Median	1.0	2.0
	(Min, max)	(1, 7)	(1, 7)
	Use of antipyretic or pain medication		
	n[a]	22	22
	Mean (SD)	3.3 (1.59)	3.8 (1.82)
	Median	3.0	3.5
	(Min, max)	(1, 6)	(1, 7)
2	Fever		
	n[a]	4	1
	Mean (SD)	2.0 (0.00)	3.0 (NE)

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14.74. Onset Day (Days) for Systemic Events After Each Dose – Safety Population (Maternal)

Dose	Systemic Event	Vaccine Group (as Administered) BNT162b2 (30 µg)	Placebo
	Median	2.0	3.0
	(Min, max)	(2, 2)	(3, 3)
	Fatigue/tiredness		
	n[a]	74	50
	Mean (SD)	1.9 (0.93)	1.7 (1.23)
	Median	2.0	1.0
	(Min, max)	(1, 6)	(1, 7)
	Headache		
	n[a]	61	35
	Mean (SD)	2.1 (0.91)	3.0 (1.98)
	Median	2.0	2.0
	(Min, max)	(1, 6)	(1, 7)
	Chills		
	n[a]	19	1
	Mean (SD)	1.9 (0.46)	3.0 (NE)
	Median	2.0	3.0
	(Min, max)	(1, 3)	(3, 3)
	Vomiting		
	n[a]	13	5
	Mean (SD)	3.2 (1.54)	2.0 (0.71)
	Median	3.0	2.0
	(Min, max)	(2, 6)	(1, 3)
	Diarrhea		
	n[a]	9	8
	Mean (SD)	2.8 (1.30)	3.1 (1.55)
	Median	2.0	3.0
	(Min, max)	(1, 5)	(1, 6)
	New or worsened muscle pain		
	n[a]	40	10
	Mean (SD)	2.4 (1.13)	3.2 (1.75)
	Median	2.0	3.0
	(Min, max)	(1, 7)	(1, 6)
	New or worsened joint pain		
	n[a]	20	9
	Mean (SD)	1.9 (0.31)	3.2 (1.56)
	Median	2.0	3.0
	(Min, max)	(1, 2)	(1, 6)
	Any systemic event[b]		
	n[a]	89	67
	Mean (SD)	1.9 (0.95)	2.0 (1.36)
	Median	2.0	1.0

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14.74. Onset Day (Days) for Systemic Events After Each Dose – Safety Population (Maternal)

Dose	Systemic Event	Vaccine Group (as Administered) BNT162b2 (30 µg)	Placebo
	(Min, max)	(1, 6)	(1, 7)
	Use of antipyretic or pain medication		
	n[a]	29	10
	Mean (SD)	2.2 (0.99)	4.0 (1.94)
	Median	2.0	3.5
	(Min, max)	(1, 6)	(1, 7)

Abbreviation: NE = not estimable.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary. Analyses for HIV-positive participants and their infants will be listed separately.
Note: Day of onset is the first day the specified event was reported.
Note: Events reported as adverse events in the case report form within 7 days after the study vaccination were also included in the analysis.
a. n = Number of participants reporting the specified event, with each participant counted only once per event.
b. Any systemic event: any fever, any fatigue/tiredness, any vomiting, any chills, any diarrhea, any headache, any new or worsened muscle pain, or any new or worsened joint pain.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adfacevd Table Generation: 03MAY2023 (17:54) Output File: ./nda3/C4591015_BR/adce_s060

14.75. Participants Reporting Baseline Systemic Events, by Severity – Safety Population (Maternal)

Systemic Event	Vaccine Group (as Administered) BNT162b2 (30 µg) N[a]	n[b] (%)	(95% CI[c])	Placebo N[a]	n[b] (%)	(95% CI[c])
Fatigue/tiredness[d]						
Any	138	41 (29.7)	(22.2, 38.1)	145	49 (33.8)	(26.2, 42.1)
Mild	138	23 (16.7)	(10.9, 24.0)	145	31 (21.4)	(15.0, 29.0)
Moderate	138	17 (12.3)	(7.3, 19.0)	145	18 (12.4)	(7.5, 18.9)
Severe	138	1 (0.7)	(0.0, 4.0)	145	0	(0.0, 2.5)
Grade 4	138	0	(0.0, 2.6)	145	0	(0.0, 2.5)
Headache[d]						
Any	138	16 (11.6)	(6.8, 18.1)	145	23 (15.9)	(10.3, 22.8)
Mild	138	16 (11.6)	(6.8, 18.1)	145	18 (12.4)	(7.5, 18.9)
Moderate	138	0	(0.0, 2.6)	145	4 (2.8)	(0.8, 6.9)
Severe	138	0	(0.0, 2.6)	145	1 (0.7)	(0.0, 3.8)
Grade 4	138	0	(0.0, 2.6)	145	0	(0.0, 2.5)

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14.75. Participants Reporting Baseline Systemic Events, by Severity – Safety Population (Maternal)

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg)			Placebo		
Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
Nausea[d]						
Any	138	20 (14.5)	(9.1, 21.5)	145	13 (9.0)	(4.9, 14.8)
Mild	138	19 (13.8)	(8.5, 20.7)	145	8 (5.5)	(2.4, 10.6)
Moderate	138	1 (0.7)	(0.0, 4.0)	145	5 (3.4)	(1.1, 7.9)
Severe	138	0	(0.0, 2.6)	145	0	(0.0, 2.5)
Grade 4	138	0	(0.0, 2.6)	145	0	(0.0, 2.5)
Vomiting[e]						
Any	138	9 (6.5)	(3.0, 12.0)	145	11 (7.6)	(3.8, 13.2)
Mild	138	9 (6.5)	(3.0, 12.0)	145	11 (7.6)	(3.8, 13.2)
Moderate	138	0	(0.0, 2.6)	145	0	(0.0, 2.5)
Severe	138	0	(0.0, 2.6)	145	0	(0.0, 2.5)
Grade 4	138	0	(0.0, 2.6)	145	0	(0.0, 2.5)
Diarrhea[f]						
Any	138	5 (3.6)	(1.2, 8.3)	145	4 (2.8)	(0.8, 6.9)
Mild	138	5 (3.6)	(1.2, 8.3)	145	3 (2.1)	(0.4, 5.9)
Moderate	138	0	(0.0, 2.6)	145	1 (0.7)	(0.0, 3.8)
Severe	138	0	(0.0, 2.6)	145	0	(0.0, 2.5)
Grade 4	138	0	(0.0, 2.6)	145	0	(0.0, 2.5)
Muscle pain[d]						
Any	138	14 (10.1)	(5.7, 16.4)	145	18 (12.4)	(7.5, 18.9)
Mild	138	11 (8.0)	(4.0, 13.8)	145	9 (6.2)	(2.9, 11.5)
Moderate	138	3 (2.2)	(0.5, 6.2)	145	9 (6.2)	(2.9, 11.5)
Severe	138	0	(0.0, 2.6)	145	0	(0.0, 2.5)
Grade 4	138	0	(0.0, 2.6)	145	0	(0.0, 2.5)
Joint pain[d]						
Any	138	14 (10.1)	(5.7, 16.4)	145	13 (9.0)	(4.9, 14.8)
Mild	138	10 (7.2)	(3.5, 12.9)	145	8 (5.5)	(2.4, 10.6)
Moderate	138	4 (2.9)	(0.8, 7.3)	145	5 (3.4)	(1.1, 7.9)
Severe	138	0	(0.0, 2.6)	145	0	(0.0, 2.5)
Grade 4	138	0	(0.0, 2.6)	145	0	(0.0, 2.5)
Any systemic event[g]	138	60 (43.5)	(35.1, 52.2)	145	66 (45.5)	(37.2, 54.0)

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14.75. Participants Reporting Baseline Systemic Events, by Severity – Safety Population (Maternal)

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg)			Placebo		
Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])

Note: Prior to vaccination on Day 1, a baseline assessment of fatigue, headache, vomiting, nausea, diarrhea, muscle pain, and joint pain were recorded in the e-diary.
Note: Grade 4 events were classified by the investigator or medically qualified person.
a. N = number of participants reporting at least 1 yes or no response for the specified event at baseline. These values are the denominators for the percentage calculations.
b. n = Number of participants with the specified characteristic.
c. Exact 2-sided confidence interval (CI), based on the Clopper and Pearson method.
d. Mild: does not interfere with activity; moderate: some interference with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe fatigue/tiredness, severe headache, severe muscle pain, or severe joint pain.
e. Mild: 1 to 2 times in 24 hours; moderate: >2 times in 24 hours; severe: requires intravenous hydration; Grade 4: emergency room visit or hospitalization for severe vomiting.
f. Mild: 2 to 3 loose stools in 24 hours; moderate: 4 to 5 loose stools in 24 hours; severe: 6 or more loose stools in 24 hours; Grade 4: emergency room visit or hospitalization for severe diarrhea.
g. Any systemic event: any fatigue/tiredness, any vomiting, any nausea, any diarrhea, any headache, any muscle pain, or any joint pain.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adfacevd Table Generation: 03MAY2023 (10:31) Output File: ./nda3/C4591015_BR/adce_s020_1

14.76. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – HIV-Positive Participants – Safety Population (Maternal)

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Fever						
	Any	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	≥38.0°C to 38.4°C	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	>38.4°C to 38.9°C	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	>38.9°C to 40.0°C	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	>40.0°C	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	Unknown[d]	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	Fatigue/tiredness[e]						
	Any	12	7 (58.3)	(27.7, 84.8)	10	6 (60.0)	(26.2, 87.8)
	Mild	12	4 (33.3)	(9.9, 65.1)	10	3 (30.0)	(6.7, 65.2)
	Moderate	12	3 (25.0)	(5.5, 57.2)	10	2 (20.0)	(2.5, 55.6)
	Severe	12	0	(0.0, 26.5)	10	1 (10.0)	(0.3, 44.5)

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14.76. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – HIV-Positive Participants – Safety Population (Maternal)

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Grade 4	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	Headache[e]						
	Any	12	5 (41.7)	(15.2, 72.3)	10	6 (60.0)	(26.2, 87.8)
	Mild	12	3 (25.0)	(5.5, 57.2)	10	3 (30.0)	(6.7, 65.2)
	Moderate	12	1 (8.3)	(0.2, 38.5)	10	3 (30.0)	(6.7, 65.2)
	Severe	12	1 (8.3)	(0.2, 38.5)	10	0	(0.0, 30.8)
	Grade 4	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	Chills[e]						
	Any	12	0	(0.0, 26.5)	10	1 (10.0)	(0.3, 44.5)
	Mild	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	Moderate	12	0	(0.0, 26.5)	10	1 (10.0)	(0.3, 44.5)
	Severe	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	Grade 4	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	Vomiting[f]						
	Any	12	1 (8.3)	(0.2, 38.5)	10	1 (10.0)	(0.3, 44.5)
	Mild	12	1 (8.3)	(0.2, 38.5)	10	1 (10.0)	(0.3, 44.5)
	Moderate	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	Severe	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	Grade 4	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	Diarrhea[g]						
	Any	12	1 (8.3)	(0.2, 38.5)	10	2 (20.0)	(2.5, 55.6)
	Mild	12	1 (8.3)	(0.2, 38.5)	10	2 (20.0)	(2.5, 55.6)
	Moderate	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	Severe	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	Grade 4	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	New or worsened muscle pain[e]						
	Any	12	3 (25.0)	(5.5, 57.2)	10	3 (30.0)	(6.7, 65.2)
	Mild	12	2 (16.7)	(2.1, 48.4)	10	2 (20.0)	(2.5, 55.6)
	Moderate	12	1 (8.3)	(0.2, 38.5)	10	1 (10.0)	(0.3, 44.5)
	Severe	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	Grade 4	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	New or worsened joint pain[e]						
	Any	12	1 (8.3)	(0.2, 38.5)	10	4 (40.0)	(12.2, 73.8)
	Mild	12	1 (8.3)	(0.2, 38.5)	10	3 (30.0)	(6.7, 65.2)
	Moderate	12	0	(0.0, 26.5)	10	1 (10.0)	(0.3, 44.5)
	Severe	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	Grade 4	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	Any systemic event[h]	12	9 (75.0)	(42.8, 94.5)	10	9 (90.0)	(55.5, 99.7)
	Use of antipyretic or pain medication[i]	12	1 (8.3)	(0.2, 38.5)	10	1 (10.0)	(0.3, 44.5)
2	Fever						

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14.76. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – HIV-Positive Participants – Safety Population (Maternal)

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Any	12	0	(0.0, 26.5)	9	1 (11.1)	(0.3, 48.2)
	≥38.0°C to 38.4°C	12	0	(0.0, 26.5)	9	1 (11.1)	(0.3, 48.2)
	>38.4°C to 38.9°C	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	>38.9°C to 40.0°C	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	>40.0°C	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Unknown[d]	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Fatigue/tiredness[e]						
	Any	12	8 (66.7)	(34.9, 90.1)	9	5 (55.6)	(21.2, 86.3)
	Mild	12	3 (25.0)	(5.5, 57.2)	9	2 (22.2)	(2.8, 60.0)
	Moderate	12	4 (33.3)	(9.9, 65.1)	9	2 (22.2)	(2.8, 60.0)
	Severe	12	1 (8.3)	(0.2, 38.5)	9	1 (11.1)	(0.3, 48.2)
	Grade 4	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Headache[e]						
	Any	12	5 (41.7)	(15.2, 72.3)	9	4 (44.4)	(13.7, 78.8)
	Mild	12	2 (16.7)	(2.1, 48.4)	9	2 (22.2)	(2.8, 60.0)
	Moderate	12	3 (25.0)	(5.5, 57.2)	9	2 (22.2)	(2.8, 60.0)
	Severe	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Chills[e]						
	Any	12	1 (8.3)	(0.2, 38.5)	9	1 (11.1)	(0.3, 48.2)
	Mild	12	0	(0.0, 26.5)	9	1 (11.1)	(0.3, 48.2)
	Moderate	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Vomiting[f]						
	Any	12	3 (25.0)	(5.5, 57.2)	9	1 (11.1)	(0.3, 48.2)
	Mild	12	2 (16.7)	(2.1, 48.4)	9	1 (11.1)	(0.3, 48.2)
	Moderate	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Grade 4	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Diarrhea[g]						
	Any	12	2 (16.7)	(2.1, 48.4)	9	2 (22.2)	(2.8, 60.0)
	Mild	12	2 (16.7)	(2.1, 48.4)	9	1 (11.1)	(0.3, 48.2)
	Moderate	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Severe	12	0	(0.0, 26.5)	9	1 (11.1)	(0.3, 48.2)
	Grade 4	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	New or worsened muscle pain[e]						
	Any	12	5 (41.7)	(15.2, 72.3)	9	2 (22.2)	(2.8, 60.0)
	Mild	12	1 (8.3)	(0.2, 38.5)	9	0	(0.0, 33.6)
	Moderate	12	4 (33.3)	(9.9, 65.1)	9	1 (11.1)	(0.3, 48.2)

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14.76. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – HIV-Positive Participants – Safety Population (Maternal)

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Severe	12	0	(0.0, 26.5)	9	1 (11.1)	(0.3, 48.2)
	Grade 4	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	New or worsened joint pain[e]						
	Any	12	1 (8.3)	(0.2, 38.5)	9	1 (11.1)	(0.3, 48.2)
	Mild	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Moderate	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Severe	12	1 (8.3)	(0.2, 38.5)	9	1 (11.1)	(0.3, 48.2)
	Grade 4	12	0	(0.0, 26.5)	9	0	(0.0, 33.6)
	Any systemic event[h]	12	10 (83.3)	(51.6, 97.9)	9	7 (77.8)	(40.0, 97.2)
	Use of antipyretic or pain medication[i]	12	2 (16.7)	(2.1, 48.4)	9	2 (22.2)	(2.8, 60.0)
Any dose	Fever						
	Any	12	0	(0.0, 26.5)	10	1 (10.0)	(0.3, 44.5)
	≥38.0°C to 38.4°C	12	0	(0.0, 26.5)	10	1 (10.0)	(0.3, 44.5)
	>38.4°C to 38.9°C	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	>38.9°C to 40.0°C	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	>40.0°C	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	Unknown[d]	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	Fatigue/tiredness[e]						
	Any	12	8 (66.7)	(34.9, 90.1)	10	8 (80.0)	(44.4, 97.5)
	Mild	12	3 (25.0)	(5.5, 57.2)	10	3 (30.0)	(6.7, 65.2)
	Moderate	12	4 (33.3)	(9.9, 65.1)	10	4 (40.0)	(12.2, 73.8)
	Severe	12	1 (8.3)	(0.2, 38.5)	10	1 (10.0)	(0.3, 44.5)
	Grade 4	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	Headache[e]						
	Any	12	7 (58.3)	(27.7, 84.8)	10	7 (70.0)	(34.8, 93.3)
	Mild	12	3 (25.0)	(5.5, 57.2)	10	4 (40.0)	(12.2, 73.8)
	Moderate	12	3 (25.0)	(5.5, 57.2)	10	3 (30.0)	(6.7, 65.2)
	Severe	12	1 (8.3)	(0.2, 38.5)	10	0	(0.0, 30.8)
	Grade 4	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	Chills[e]						
	Any	12	1 (8.3)	(0.2, 38.5)	10	1 (10.0)	(0.3, 44.5)
	Mild	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	Moderate	12	1 (8.3)	(0.2, 38.5)	10	1 (10.0)	(0.3, 44.5)
	Severe	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	Grade 4	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	Vomiting[f]						
	Any	12	3 (25.0)	(5.5, 57.2)	10	1 (10.0)	(0.3, 44.5)
	Mild	12	2 (16.7)	(2.1, 48.4)	10	1 (10.0)	(0.3, 44.5)
	Moderate	12	1 (8.3)	(0.2, 38.5)	10	0	(0.0, 30.8)
	Severe	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)

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14.76. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – HIV-Positive Participants – Safety Population (Maternal)

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Grade 4	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	Diarrhea[g]						
	Any	12	3 (25.0)	(5.5, 57.2)	10	3 (30.0)	(6.7, 65.2)
	Mild	12	3 (25.0)	(5.5, 57.2)	10	2 (20.0)	(2.5, 55.6)
	Moderate	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	Severe	12	0	(0.0, 26.5)	10	1 (10.0)	(0.3, 44.5)
	Grade 4	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	New or worsened muscle pain[e]						
	Any	12	5 (41.7)	(15.2, 72.3)	10	3 (30.0)	(6.7, 65.2)
	Mild	12	1 (8.3)	(0.2, 38.5)	10	1 (10.0)	(0.3, 44.5)
	Moderate	12	4 (33.3)	(9.9, 65.1)	10	1 (10.0)	(0.3, 44.5)
	Severe	12	0	(0.0, 26.5)	10	1 (10.0)	(0.3, 44.5)
	Grade 4	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	New or worsened joint pain[e]						
	Any	12	1 (8.3)	(0.2, 38.5)	10	5 (50.0)	(18.7, 81.3)
	Mild	12	0	(0.0, 26.5)	10	3 (30.0)	(6.7, 65.2)
	Moderate	12	0	(0.0, 26.5)	10	1 (10.0)	(0.3, 44.5)
	Severe	12	1 (8.3)	(0.2, 38.5)	10	1 (10.0)	(0.3, 44.5)
	Grade 4	12	0	(0.0, 26.5)	10	0	(0.0, 30.8)
	Any systemic event[h]	12	11 (91.7)	(61.5, 99.8)	10	9 (90.0)	(55.5, 99.7)
	Use of antipyretic or pain medication[i]	12	2 (16.7)	(2.1, 48.4)	10	2 (20.0)	(2.5, 55.6)

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14.76. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – HIV-Positive Participants – Safety Population (Maternal)

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])

Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) and from any unscheduled clinical assessments from Day 1 through Day 7 after each dose. Grade 4 events were classified by the investigator or medically qualified person. Events reported as adverse events in the case report form within 7 days after the study vaccination were also included in the analysis; the severity of these events is based on the grading scale in the adverse event section of the case report form.
a. N = number of participants reporting at least 1 yes or no response for the specified event after the specified dose. These values are the denominators for the percentage calculations.
b. n = Number of participants with the specified characteristic.
c. Exact 2-sided confidence interval (CI), based on the Clopper and Pearson method.
d. This row includes counts of participants with "pyrexia" and "body temperature increased" MedDRA preferred terms with a nonmissing AE toxicity grade recorded on the AE case report form and who are also missing e-diary fever measurements.
e. Mild: does not interfere with activity; moderate: some interference with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe fatigue/tiredness, severe headache, severe chills, severe muscle pain, or severe joint pain.
f. Mild: 1 to 2 times in 24 hours; moderate: >2 times in 24 hours; severe: requires intravenous hydration; Grade 4: emergency room visit or hospitalization for severe vomiting.
g. Mild: 2 to 3 loose stools in 24 hours; moderate: 4 to 5 loose stools in 24 hours; severe: 6 or more loose stools in 24 hours; Grade 4: emergency room visit or hospitalization for severe diarrhea.
h. Any systemic event: any fever, any fatigue/tiredness, any vomiting, any chills, any diarrhea, any headache, any new or worsened muscle pain, or any new or worsened joint pain.
i. The use of antipyretic medication was included and summarized in the tables but was not considered as a systemic event. Severity was not applicable.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adfacevd Table Generation: 10MAY2023 (14:27) Output File: ./nda3/C4591015_BR/adce_s020_HIV

14.77. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Race – Safety Population (Maternal) Race: White

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Fever						
	Any	117	1 (0.9)	(0.0, 4.7)	118	1 (0.8)	(0.0, 4.6)
	≥38.0°C to 38.4°C	117	1 (0.9)	(0.0, 4.7)	118	1 (0.8)	(0.0, 4.6)
	>38.4°C to 38.9°C	117	0	(0.0, 3.1)	118	0	(0.0, 3.1)
	>38.9°C to 40.0°C	117	0	(0.0, 3.1)	118	0	(0.0, 3.1)
	>40.0°C	117	0	(0.0, 3.1)	118	0	(0.0, 3.1)
	Unknown[d]	117	0	(0.0, 3.1)	118	0	(0.0, 3.1)

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14.77. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Race – Safety Population (Maternal) Race: White

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Fatigue/tiredness[e]						
	Any	117	65 (55.6)	(46.1, 64.7)	118	51 (43.2)	(34.1, 52.7)
	Mild	117	31 (26.5)	(18.8, 35.5)	118	23 (19.5)	(12.8, 27.8)
	Moderate	117	33 (28.2)	(20.3, 37.3)	118	27 (22.9)	(15.7, 31.5)
	Severe	117	1 (0.9)	(0.0, 4.7)	118	1 (0.8)	(0.0, 4.6)
	Grade 4	117	0	(0.0, 3.1)	118	0	(0.0, 3.1)
	Headache[e]						
	Any	117	44 (37.6)	(28.8, 47.0)	118	46 (39.0)	(30.1, 48.4)
	Mild	117	26 (22.2)	(15.1, 30.8)	118	29 (24.6)	(17.1, 33.4)
	Moderate	117	16 (13.7)	(8.0, 21.3)	118	17 (14.4)	(8.6, 22.1)
	Severe	117	2 (1.7)	(0.2, 6.0)	118	0	(0.0, 3.1)
	Grade 4	117	0	(0.0, 3.1)	118	0	(0.0, 3.1)
	Chills[e]						
	Any	117	11 (9.4)	(4.8, 16.2)	118	9 (7.6)	(3.5, 14.0)
	Mild	117	8 (6.8)	(3.0, 13.0)	118	9 (7.6)	(3.5, 14.0)
	Moderate	117	3 (2.6)	(0.5, 7.3)	118	0	(0.0, 3.1)
	Severe	117	0	(0.0, 3.1)	118	0	(0.0, 3.1)
	Grade 4	117	0	(0.0, 3.1)	118	0	(0.0, 3.1)
	Vomiting[f]						
	Any	117	4 (3.4)	(0.9, 8.5)	118	11 (9.3)	(4.7, 16.1)
	Mild	117	4 (3.4)	(0.9, 8.5)	118	7 (5.9)	(2.4, 11.8)
	Moderate	117	0	(0.0, 3.1)	118	4 (3.4)	(0.9, 8.5)
	Severe	117	0	(0.0, 3.1)	118	0	(0.0, 3.1)
	Grade 4	117	0	(0.0, 3.1)	118	0	(0.0, 3.1)
	Diarrhea[g]						
	Any	117	13 (11.1)	(6.1, 18.3)	118	8 (6.8)	(3.0, 12.9)
	Mild	117	13 (11.1)	(6.1, 18.3)	118	6 (5.1)	(1.9, 10.7)
	Moderate	117	0	(0.0, 3.1)	118	2 (1.7)	(0.2, 6.0)
	Severe	117	0	(0.0, 3.1)	118	0	(0.0, 3.1)
	Grade 4	117	0	(0.0, 3.1)	118	0	(0.0, 3.1)
	New or worsened muscle pain[e]						
	Any	117	14 (12.0)	(6.7, 19.3)	118	13 (11.0)	(6.0, 18.1)
	Mild	117	6 (5.1)	(1.9, 10.8)	118	6 (5.1)	(1.9, 10.7)
	Moderate	117	8 (6.8)	(3.0, 13.0)	118	7 (5.9)	(2.4, 11.8)
	Severe	117	0	(0.0, 3.1)	118	0	(0.0, 3.1)
	Grade 4	117	0	(0.0, 3.1)	118	0	(0.0, 3.1)
	New or worsened joint pain[e]						
	Any	117	5 (4.3)	(1.4, 9.7)	118	6 (5.1)	(1.9, 10.7)
	Mild	117	2 (1.7)	(0.2, 6.0)	118	2 (1.7)	(0.2, 6.0)
	Moderate	117	3 (2.6)	(0.5, 7.3)	118	4 (3.4)	(0.9, 8.5)

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14.77. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Race – Safety Population (Maternal) Race: White

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Severe	117	0	(0.0, 3.1)	118	0	(0.0, 3.1)
	Grade 4	117	0	(0.0, 3.1)	118	0	(0.0, 3.1)
	Any systemic event[h]	117	75 (64.1)	(54.7, 72.8)	118	74 (62.7)	(53.3, 71.4)
	Use of antipyretic or pain medication[i]	117	19 (16.2)	(10.1, 24.2)	118	20 (16.9)	(10.7, 25.0)
2	Fever						
	Any	110	4 (3.6)	(1.0, 9.0)	105	1 (1.0)	(0.0, 5.2)
	≥38.0°C to 38.4°C	110	2 (1.8)	(0.2, 6.4)	105	1 (1.0)	(0.0, 5.2)
	>38.4°C to 38.9°C	110	1 (0.9)	(0.0, 5.0)	105	0	(0.0, 3.5)
	>38.9°C to 40.0°C	110	0	(0.0, 3.3)	105	0	(0.0, 3.5)
	>40.0°C	110	0	(0.0, 3.3)	105	0	(0.0, 3.5)
	Unknown[d]	110	1 (0.9)	(0.0, 5.0)	105	0	(0.0, 3.5)
	Fatigue/tiredness[e]						
	Any	110	62 (56.4)	(46.6, 65.8)	105	38 (36.2)	(27.0, 46.1)
	Mild	110	15 (13.6)	(7.8, 21.5)	105	15 (14.3)	(8.2, 22.5)
	Moderate	110	45 (40.9)	(31.6, 50.7)	105	23 (21.9)	(14.4, 31.0)
	Severe	110	2 (1.8)	(0.2, 6.4)	105	0	(0.0, 3.5)
	Grade 4	110	0	(0.0, 3.3)	105	0	(0.0, 3.5)
	Headache[e]						
	Any	110	53 (48.2)	(38.6, 57.9)	105	27 (25.7)	(17.7, 35.2)
	Mild	110	31 (28.2)	(20.0, 37.6)	105	14 (13.3)	(7.5, 21.4)
	Moderate	110	20 (18.2)	(11.5, 26.7)	105	13 (12.4)	(6.8, 20.2)
	Severe	110	2 (1.8)	(0.2, 6.4)	105	0	(0.0, 3.5)
	Grade 4	110	0	(0.0, 3.3)	105	0	(0.0, 3.5)
	Chills[e]						
	Any	110	17 (15.5)	(9.3, 23.6)	105	1 (1.0)	(0.0, 5.2)
	Mild	110	7 (6.4)	(2.6, 12.7)	105	1 (1.0)	(0.0, 5.2)
	Moderate	110	10 (9.1)	(4.4, 16.1)	105	0	(0.0, 3.5)
	Severe	110	0	(0.0, 3.3)	105	0	(0.0, 3.5)
	Grade 4	110	0	(0.0, 3.3)	105	0	(0.0, 3.5)
	Vomiting[f]						
	Any	110	10 (9.1)	(4.4, 16.1)	105	3 (2.9)	(0.6, 8.1)
	Mild	110	10 (9.1)	(4.4, 16.1)	105	2 (1.9)	(0.2, 6.7)
	Moderate	110	0	(0.0, 3.3)	105	1 (1.0)	(0.0, 5.2)
	Severe	110	0	(0.0, 3.3)	105	0	(0.0, 3.5)
	Grade 4	110	0	(0.0, 3.3)	105	0	(0.0, 3.5)
	Diarrhea[g]						
	Any	110	4 (3.6)	(1.0, 9.0)	105	6 (5.7)	(2.1, 12.0)
	Mild	110	4 (3.6)	(1.0, 9.0)	105	4 (3.8)	(1.0, 9.5)
	Moderate	110	0	(0.0, 3.3)	105	2 (1.9)	(0.2, 6.7)

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14.77. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Race – Safety Population (Maternal) Race: White

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Severe	110	0	(0.0, 3.3)	105	0	(0.0, 3.5)
	Grade 4	110	0	(0.0, 3.3)	105	0	(0.0, 3.5)
	New or worsened muscle pain[e]						
	Any	110	36 (32.7)	(24.1, 42.3)	105	7 (6.7)	(2.7, 13.3)
	Mild	110	18 (16.4)	(10.0, 24.6)	105	5 (4.8)	(1.6, 10.8)
	Moderate	110	18 (16.4)	(10.0, 24.6)	105	2 (1.9)	(0.2, 6.7)
	Severe	110	0	(0.0, 3.3)	105	0	(0.0, 3.5)
	Grade 4	110	0	(0.0, 3.3)	105	0	(0.0, 3.5)
	New or worsened joint pain[e]						
	Any	110	19 (17.3)	(10.7, 25.7)	105	5 (4.8)	(1.6, 10.8)
	Mild	110	11 (10.0)	(5.1, 17.2)	105	3 (2.9)	(0.6, 8.1)
	Moderate	110	8 (7.3)	(3.2, 13.8)	105	2 (1.9)	(0.2, 6.7)
	Severe	110	0	(0.0, 3.3)	105	0	(0.0, 3.5)
	Grade 4	110	0	(0.0, 3.3)	105	0	(0.0, 3.5)
	Any systemic event[h]	110	73 (66.4)	(56.7, 75.1)	105	51 (48.6)	(38.7, 58.5)
	Use of antipyretic or pain medication[i]	110	27 (24.5)	(16.8, 33.7)	105	8 (7.6)	(3.3, 14.5)
Any dose	Fever						
	Any	117	5 (4.3)	(1.4, 9.7)	118	2 (1.7)	(0.2, 6.0)
	≥38.0°C to 38.4°C	117	3 (2.6)	(0.5, 7.3)	118	2 (1.7)	(0.2, 6.0)
	>38.4°C to 38.9°C	117	1 (0.9)	(0.0, 4.7)	118	0	(0.0, 3.1)
	>38.9°C to 40.0°C	117	0	(0.0, 3.1)	118	0	(0.0, 3.1)
	>40.0°C	117	0	(0.0, 3.1)	118	0	(0.0, 3.1)
	Unknown[d]	117	1 (0.9)	(0.0, 4.7)	118	0	(0.0, 3.1)
	Fatigue/tiredness[e]						
	Any	117	81 (69.2)	(60.0, 77.4)	118	61 (51.7)	(42.3, 61.0)
	Mild	117	23 (19.7)	(12.9, 28.0)	118	22 (18.6)	(12.1, 26.9)
	Moderate	117	56 (47.9)	(38.5, 57.3)	118	38 (32.2)	(23.9, 41.4)
	Severe	117	2 (1.7)	(0.2, 6.0)	118	1 (0.8)	(0.0, 4.6)
	Grade 4	117	0	(0.0, 3.1)	118	0	(0.0, 3.1)
	Headache[e]						
	Any	117	70 (59.8)	(50.4, 68.8)	118	57 (48.3)	(39.0, 57.7)
	Mild	117	35 (29.9)	(21.8, 39.1)	118	33 (28.0)	(20.1, 37.0)
	Moderate	117	32 (27.4)	(19.5, 36.4)	118	24 (20.3)	(13.5, 28.7)
	Severe	117	3 (2.6)	(0.5, 7.3)	118	0	(0.0, 3.1)
	Grade 4	117	0	(0.0, 3.1)	118	0	(0.0, 3.1)
	Chills[e]						
	Any	117	26 (22.2)	(15.1, 30.8)	118	10 (8.5)	(4.1, 15.0)
	Mild	117	13 (11.1)	(6.1, 18.3)	118	10 (8.5)	(4.1, 15.0)
	Moderate	117	13 (11.1)	(6.1, 18.3)	118	0	(0.0, 3.1)

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14.77. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Race – Safety Population (Maternal) Race: White

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Severe	117	0	(0.0, 3.1)	118	0	(0.0, 3.1)
	Grade 4	117	0	(0.0, 3.1)	118	0	(0.0, 3.1)
	Vomiting[f]						
	Any	117	13 (11.1)	(6.1, 18.3)	118	12 (10.2)	(5.4, 17.1)
	Mild	117	13 (11.1)	(6.1, 18.3)	118	8 (6.8)	(3.0, 12.9)
	Moderate	117	0	(0.0, 3.1)	118	4 (3.4)	(0.9, 8.5)
	Severe	117	0	(0.0, 3.1)	118	0	(0.0, 3.1)
	Grade 4	117	0	(0.0, 3.1)	118	0	(0.0, 3.1)
	Diarrhea[g]						
	Any	117	15 (12.8)	(7.4, 20.3)	118	14 (11.9)	(6.6, 19.1)
	Mild	117	15 (12.8)	(7.4, 20.3)	118	10 (8.5)	(4.1, 15.0)
	Moderate	117	0	(0.0, 3.1)	118	4 (3.4)	(0.9, 8.5)
	Severe	117	0	(0.0, 3.1)	118	0	(0.0, 3.1)
	Grade 4	117	0	(0.0, 3.1)	118	0	(0.0, 3.1)
	New or worsened muscle pain[e]						
	Any	117	44 (37.6)	(28.8, 47.0)	118	19 (16.1)	(10.0, 24.0)
	Mild	117	19 (16.2)	(10.1, 24.2)	118	11 (9.3)	(4.7, 16.1)
	Moderate	117	25 (21.4)	(14.3, 29.9)	118	8 (6.8)	(3.0, 12.9)
	Severe	117	0	(0.0, 3.1)	118	0	(0.0, 3.1)
	Grade 4	117	0	(0.0, 3.1)	118	0	(0.0, 3.1)
	New or worsened joint pain[e]						
	Any	117	21 (17.9)	(11.5, 26.1)	118	9 (7.6)	(3.5, 14.0)
	Mild	117	11 (9.4)	(4.8, 16.2)	118	4 (3.4)	(0.9, 8.5)
	Moderate	117	10 (8.5)	(4.2, 15.2)	118	5 (4.2)	(1.4, 9.6)
	Severe	117	0	(0.0, 3.1)	118	0	(0.0, 3.1)
	Grade 4	117	0	(0.0, 3.1)	118	0	(0.0, 3.1)
	Any systemic event[h]	117	92 (78.6)	(70.1, 85.7)	118	81 (68.6)	(59.5, 76.9)
	Use of antipyretic or pain medication[i]	117	37 (31.6)	(23.3, 40.9)	118	23 (19.5)	(12.8, 27.8)

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14.77. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Race – Safety Population (Maternal) Race: White

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])

Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) and from any unscheduled clinical assessments from Day 1 through Day 7 after each dose. Grade 4 events were classified by the investigator or medically qualified person. Events reported as adverse events in the case report form within 7 days after the study vaccination were also included in the analysis; the severity of these events is based on the grading scale in the adverse event section of the case report form.
Note: All others = American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of participants reporting at least 1 yes or no response for the specified event after the specified dose. These values are the denominators for the percentage calculations.
b. n = Number of participants with the specified characteristic.
c. Exact 2-sided confidence interval (CI), based on the Clopper and Pearson method.
d. This row includes counts of participants with "pyrexia" and "body temperature increased" MedDRA preferred terms with a nonmissing AE toxicity grade recorded on the AE case report form and who are also missing e-diary fever measurements.
e. Mild: does not interfere with activity; moderate: some interference with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe fatigue/tiredness, severe headache, severe chills, severe muscle pain, or severe joint pain.
f. Mild: 1 to 2 times in 24 hours; moderate: >2 times in 24 hours; severe: requires intravenous hydration; Grade 4: emergency room visit or hospitalization for severe vomiting.
g. Mild: 2 to 3 loose stools in 24 hours; moderate: 4 to 5 loose stools in 24 hours; severe: 6 or more loose stools in 24 hours; Grade 4: emergency room visit or hospitalization for severe diarrhea.
h. Any systemic event: any fever, any fatigue/tiredness, any vomiting, any chills, any diarrhea, any headache, any new or worsened muscle pain, or any new or worsened joint pain.
i. The use of antipyretic medication was included and summarized in the tables but was not considered as a systemic event. Severity was not applicable.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adfacevd Table Generation: 03MAY2023 (10:31) Output File: ./nda3/C4591015_BR/adce_s020_race

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14.78. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Race – Safety Population (Maternal) Race: Black or African American

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Fever						
	Any	35	1 (2.9)	(0.1, 14.9)	33	2 (6.1)	(0.7, 20.2)
	≥38.0°C to 38.4°C	35	0	(0.0, 10.0)	33	1 (3.0)	(0.1, 15.8)
	>38.4°C to 38.9°C	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	>38.9°C to 40.0°C	35	1 (2.9)	(0.1, 14.9)	33	1 (3.0)	(0.1, 15.8)
	>40.0°C	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	Unknown[d]	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	Fatigue/tiredness[e]						
	Any	35	11 (31.4)	(16.9, 49.3)	33	14 (42.4)	(25.5, 60.8)
	Mild	35	9 (25.7)	(12.5, 43.3)	33	8 (24.2)	(11.1, 42.3)
	Moderate	35	2 (5.7)	(0.7, 19.2)	33	6 (18.2)	(7.0, 35.5)
	Severe	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	Grade 4	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	Headache[e]						
	Any	35	8 (22.9)	(10.4, 40.1)	33	9 (27.3)	(13.3, 45.5)
	Mild	35	5 (14.3)	(4.8, 30.3)	33	4 (12.1)	(3.4, 28.2)
	Moderate	35	2 (5.7)	(0.7, 19.2)	33	4 (12.1)	(3.4, 28.2)
	Severe	35	1 (2.9)	(0.1, 14.9)	33	1 (3.0)	(0.1, 15.8)
	Grade 4	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	Chills[e]						
	Any	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	Mild	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	Moderate	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	Severe	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	Grade 4	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	Vomiting[f]						
	Any	35	3 (8.6)	(1.8, 23.1)	33	4 (12.1)	(3.4, 28.2)
	Mild	35	3 (8.6)	(1.8, 23.1)	33	3 (9.1)	(1.9, 24.3)
	Moderate	35	0	(0.0, 10.0)	33	1 (3.0)	(0.1, 15.8)
	Severe	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	Grade 4	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	Diarrhea[g]						
	Any	35	5 (14.3)	(4.8, 30.3)	33	5 (15.2)	(5.1, 31.9)
	Mild	35	5 (14.3)	(4.8, 30.3)	33	5 (15.2)	(5.1, 31.9)
	Moderate	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	Severe	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	Grade 4	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	New or worsened muscle pain[e]						
	Any	35	5 (14.3)	(4.8, 30.3)	33	4 (12.1)	(3.4, 28.2)

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14.78. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Race – Safety Population (Maternal) Race: Black or African American

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Mild	35	4 (11.4)	(3.2, 26.7)	33	3 (9.1)	(1.9, 24.3)
	Moderate	35	1 (2.9)	(0.1, 14.9)	33	1 (3.0)	(0.1, 15.8)
	Severe	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	Grade 4	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	New or worsened joint pain[e]						
	Any	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	Mild	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	Moderate	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	Severe	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	Grade 4	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	Any systemic event[h]	35	19 (54.3)	(36.6, 71.2)	33	20 (60.6)	(42.1, 77.1)
	Use of antipyretic or pain medication[i]	35	3 (8.6)	(1.8, 23.1)	33	2 (6.1)	(0.7, 20.2)
2	Fever						
	Any	30	0	(0.0, 11.6)	30	0	(0.0, 11.6)
	≥38.0°C to 38.4°C	30	0	(0.0, 11.6)	30	0	(0.0, 11.6)
	>38.4°C to 38.9°C	30	0	(0.0, 11.6)	30	0	(0.0, 11.6)
	>38.9°C to 40.0°C	30	0	(0.0, 11.6)	30	0	(0.0, 11.6)
	>40.0°C	30	0	(0.0, 11.6)	30	0	(0.0, 11.6)
	Unknown[d]	30	0	(0.0, 11.6)	30	0	(0.0, 11.6)
	Fatigue/tiredness[e]						
	Any	30	9 (30.0)	(14.7, 49.4)	30	8 (26.7)	(12.3, 45.9)
	Mild	30	6 (20.0)	(7.7, 38.6)	30	5 (16.7)	(5.6, 34.7)
	Moderate	30	2 (6.7)	(0.8, 22.1)	30	3 (10.0)	(2.1, 26.5)
	Severe	30	1 (3.3)	(0.1, 17.2)	30	0	(0.0, 11.6)
	Grade 4	30	0	(0.0, 11.6)	30	0	(0.0, 11.6)
	Headache[e]						
	Any	30	6 (20.0)	(7.7, 38.6)	30	6 (20.0)	(7.7, 38.6)
	Mild	30	4 (13.3)	(3.8, 30.7)	30	4 (13.3)	(3.8, 30.7)
	Moderate	30	2 (6.7)	(0.8, 22.1)	30	2 (6.7)	(0.8, 22.1)
	Severe	30	0	(0.0, 11.6)	30	0	(0.0, 11.6)
	Grade 4	30	0	(0.0, 11.6)	30	0	(0.0, 11.6)
	Chills[e]						
	Any	30	2 (6.7)	(0.8, 22.1)	30	0	(0.0, 11.6)
	Mild	30	0	(0.0, 11.6)	30	0	(0.0, 11.6)
	Moderate	30	1 (3.3)	(0.1, 17.2)	30	0	(0.0, 11.6)
	Severe	30	1 (3.3)	(0.1, 17.2)	30	0	(0.0, 11.6)
	Grade 4	30	0	(0.0, 11.6)	30	0	(0.0, 11.6)
	Vomiting[f]						
	Any	30	3 (10.0)	(2.1, 26.5)	30	2 (6.7)	(0.8, 22.1)
	Mild	30	3 (10.0)	(2.1, 26.5)	30	1 (3.3)	(0.1, 17.2)

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14.78. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Race – Safety Population (Maternal) Race: Black or African American

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Moderate	30	0	(0.0, 11.6)	30	1 (3.3)	(0.1, 17.2)
	Severe	30	0	(0.0, 11.6)	30	0	(0.0, 11.6)
	Grade 4	30	0	(0.0, 11.6)	30	0	(0.0, 11.6)
	Diarrhea[g]						
	Any	30	4 (13.3)	(3.8, 30.7)	30	2 (6.7)	(0.8, 22.1)
	Mild	30	4 (13.3)	(3.8, 30.7)	30	2 (6.7)	(0.8, 22.1)
	Moderate	30	0	(0.0, 11.6)	30	0	(0.0, 11.6)
	Severe	30	0	(0.0, 11.6)	30	0	(0.0, 11.6)
	Grade 4	30	0	(0.0, 11.6)	30	0	(0.0, 11.6)
	New or worsened muscle pain[e]						
	Any	30	4 (13.3)	(3.8, 30.7)	30	2 (6.7)	(0.8, 22.1)
	Mild	30	2 (6.7)	(0.8, 22.1)	30	1 (3.3)	(0.1, 17.2)
	Moderate	30	1 (3.3)	(0.1, 17.2)	30	1 (3.3)	(0.1, 17.2)
	Severe	30	1 (3.3)	(0.1, 17.2)	30	0	(0.0, 11.6)
	Grade 4	30	0	(0.0, 11.6)	30	0	(0.0, 11.6)
	New or worsened joint pain[e]						
	Any	30	1 (3.3)	(0.1, 17.2)	30	2 (6.7)	(0.8, 22.1)
	Mild	30	0	(0.0, 11.6)	30	2 (6.7)	(0.8, 22.1)
	Moderate	30	1 (3.3)	(0.1, 17.2)	30	0	(0.0, 11.6)
	Severe	30	0	(0.0, 11.6)	30	0	(0.0, 11.6)
	Grade 4	30	0	(0.0, 11.6)	30	0	(0.0, 11.6)
	Any systemic event[h]	30	12 (40.0)	(22.7, 59.4)	30	12 (40.0)	(22.7, 59.4)
	Use of antipyretic or pain medication[i]	30	2 (6.7)	(0.8, 22.1)	30	2 (6.7)	(0.8, 22.1)
Any dose	Fever						
	Any	35	1 (2.9)	(0.1, 14.9)	33	2 (6.1)	(0.7, 20.2)
	≥38.0°C to 38.4°C	35	0	(0.0, 10.0)	33	1 (3.0)	(0.1, 15.8)
	>38.4°C to 38.9°C	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	>38.9°C to 40.0°C	35	1 (2.9)	(0.1, 14.9)	33	1 (3.0)	(0.1, 15.8)
	>40.0°C	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	Unknown[d]	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	Fatigue/tiredness[e]						
	Any	35	16 (45.7)	(28.8, 63.4)	33	16 (48.5)	(30.8, 66.5)
	Mild	35	11 (31.4)	(16.9, 49.3)	33	8 (24.2)	(11.1, 42.3)
	Moderate	35	4 (11.4)	(3.2, 26.7)	33	8 (24.2)	(11.1, 42.3)
	Severe	35	1 (2.9)	(0.1, 14.9)	33	0	(0.0, 10.6)
	Grade 4	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	Headache[e]						
	Any	35	11 (31.4)	(16.9, 49.3)	33	12 (36.4)	(20.4, 54.9)
	Mild	35	7 (20.0)	(8.4, 36.9)	33	6 (18.2)	(7.0, 35.5)
	Moderate	35	3 (8.6)	(1.8, 23.1)	33	5 (15.2)	(5.1, 31.9)

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14.78. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Race – Safety Population (Maternal) Race: Black or African American

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Severe	35	1 (2.9)	(0.1, 14.9)	33	1 (3.0)	(0.1, 15.8)
	Grade 4	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	Chills[e]						
	Any	35	2 (5.7)	(0.7, 19.2)	33	0	(0.0, 10.6)
	Mild	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	Moderate	35	1 (2.9)	(0.1, 14.9)	33	0	(0.0, 10.6)
	Severe	35	1 (2.9)	(0.1, 14.9)	33	0	(0.0, 10.6)
	Grade 4	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	Vomiting[f]						
	Any	35	4 (11.4)	(3.2, 26.7)	33	4 (12.1)	(3.4, 28.2)
	Mild	35	4 (11.4)	(3.2, 26.7)	33	2 (6.1)	(0.7, 20.2)
	Moderate	35	0	(0.0, 10.0)	33	2 (6.1)	(0.7, 20.2)
	Severe	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	Grade 4	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	Diarrhea[g]						
	Any	35	7 (20.0)	(8.4, 36.9)	33	6 (18.2)	(7.0, 35.5)
	Mild	35	7 (20.0)	(8.4, 36.9)	33	6 (18.2)	(7.0, 35.5)
	Moderate	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	Severe	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	Grade 4	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	New or worsened muscle pain[e]						
	Any	35	8 (22.9)	(10.4, 40.1)	33	5 (15.2)	(5.1, 31.9)
	Mild	35	5 (14.3)	(4.8, 30.3)	33	4 (12.1)	(3.4, 28.2)
	Moderate	35	2 (5.7)	(0.7, 19.2)	33	1 (3.0)	(0.1, 15.8)
	Severe	35	1 (2.9)	(0.1, 14.9)	33	0	(0.0, 10.6)
	Grade 4	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	New or worsened joint pain[e]						
	Any	35	1 (2.9)	(0.1, 14.9)	33	2 (6.1)	(0.7, 20.2)
	Mild	35	0	(0.0, 10.0)	33	2 (6.1)	(0.7, 20.2)
	Moderate	35	1 (2.9)	(0.1, 14.9)	33	0	(0.0, 10.6)
	Severe	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	Grade 4	35	0	(0.0, 10.0)	33	0	(0.0, 10.6)
	Any systemic event[h]	35	22 (62.9)	(44.9, 78.5)	33	22 (66.7)	(48.2, 82.0)
	Use of antipyretic or pain medication[i]	35	4 (11.4)	(3.2, 26.7)	33	3 (9.1)	(1.9, 24.3)

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14.78. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Race – Safety Population (Maternal) Race: Black or African American

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])

Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) and from any unscheduled clinical assessments from Day 1 through Day 7 after each dose. Grade 4 events were classified by the investigator or medically qualified person. Events reported as adverse events in the case report form within 7 days after the study vaccination were also included in the analysis; the severity of these events is based on the grading scale in the adverse event section of the case report form.
Note: All others = American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of participants reporting at least 1 yes or no response for the specified event after the specified dose. These values are the denominators for the percentage calculations.
b. n = Number of participants with the specified characteristic.
c. Exact 2-sided confidence interval (CI), based on the Clopper and Pearson method.
d. This row includes counts of participants with "pyrexia" and "body temperature increased" MedDRA preferred terms with a nonmissing AE toxicity grade recorded on the AE case report form and who are also missing e-diary fever measurements.
e. Mild: does not interfere with activity; moderate: some interference with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe fatigue/tiredness, severe headache, severe chills, severe muscle pain, or severe joint pain.
f. Mild: 1 to 2 times in 24 hours; moderate: >2 times in 24 hours; severe: requires intravenous hydration; Grade 4: emergency room visit or hospitalization for severe vomiting.
g. Mild: 2 to 3 loose stools in 24 hours; moderate: 4 to 5 loose stools in 24 hours; severe: 6 or more loose stools in 24 hours; Grade 4: emergency room visit or hospitalization for severe diarrhea.
h. Any systemic event: any fever, any fatigue/tiredness, any vomiting, any chills, any diarrhea, any headache, any new or worsened muscle pain, or any new or worsened joint pain.
i. The use of antipyretic medication was included and summarized in the tables but was not considered as a systemic event. Severity was not applicable.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adfacevd Table Generation: 03MAY2023 (10:31) Output File: ./nda3/C4591015_BR/adce_s020_race

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14.79. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Race – Safety Population (Maternal) Race: All Others

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Fever						
	Any	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	≥38.0°C to 38.4°C	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	>38.4°C to 38.9°C	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	>38.9°C to 40.0°C	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	>40.0°C	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Unknown[d]	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Fatigue/tiredness[e]						
	Any	9	4 (44.4)	(13.7, 78.8)	12	5 (41.7)	(15.2, 72.3)
	Mild	9	2 (22.2)	(2.8, 60.0)	12	3 (25.0)	(5.5, 57.2)
	Moderate	9	2 (22.2)	(2.8, 60.0)	12	2 (16.7)	(2.1, 48.4)
	Severe	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Grade 4	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Headache[e]						
	Any	9	3 (33.3)	(7.5, 70.1)	12	3 (25.0)	(5.5, 57.2)
	Mild	9	2 (22.2)	(2.8, 60.0)	12	3 (25.0)	(5.5, 57.2)
	Moderate	9	1 (11.1)	(0.3, 48.2)	12	0	(0.0, 26.5)
	Severe	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Grade 4	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Chills[e]						
	Any	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Mild	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Moderate	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Severe	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Grade 4	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Vomiting[f]						
	Any	9	1 (11.1)	(0.3, 48.2)	12	0	(0.0, 26.5)
	Mild	9	1 (11.1)	(0.3, 48.2)	12	0	(0.0, 26.5)
	Moderate	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Severe	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Grade 4	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Diarrhea[g]						
	Any	9	1 (11.1)	(0.3, 48.2)	12	1 (8.3)	(0.2, 38.5)
	Mild	9	0	(0.0, 33.6)	12	1 (8.3)	(0.2, 38.5)
	Moderate	9	1 (11.1)	(0.3, 48.2)	12	0	(0.0, 26.5)
	Severe	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Grade 4	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	New or worsened muscle pain[e]						
	Any	9	1 (11.1)	(0.3, 48.2)	12	2 (16.7)	(2.1, 48.4)

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14.79. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Race – Safety Population (Maternal) Race: All Others

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Mild	9	1 (11.1)	(0.3, 48.2)	12	1 (8.3)	(0.2, 38.5)
	Moderate	9	0	(0.0, 33.6)	12	1 (8.3)	(0.2, 38.5)
	Severe	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Grade 4	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	New or worsened joint pain[e]						
	Any	9	0	(0.0, 33.6)	12	2 (16.7)	(2.1, 48.4)
	Mild	9	0	(0.0, 33.6)	12	2 (16.7)	(2.1, 48.4)
	Moderate	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Severe	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Grade 4	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Any systemic event[h]	9	4 (44.4)	(13.7, 78.8)	12	6 (50.0)	(21.1, 78.9)
	Use of antipyretic or pain medication[i]	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
2	Fever						
	Any	8	0	(0.0, 36.9)	11	0	(0.0, 28.5)
	≥38.0°C to 38.4°C	8	0	(0.0, 36.9)	11	0	(0.0, 28.5)
	>38.4°C to 38.9°C	8	0	(0.0, 36.9)	11	0	(0.0, 28.5)
	>38.9°C to 40.0°C	8	0	(0.0, 36.9)	11	0	(0.0, 28.5)
	>40.0°C	8	0	(0.0, 36.9)	11	0	(0.0, 28.5)
	Unknown[d]	8	0	(0.0, 36.9)	11	0	(0.0, 28.5)
	Fatigue/tiredness[e]						
	Any	8	3 (37.5)	(8.5, 75.5)	11	4 (36.4)	(10.9, 69.2)
	Mild	8	2 (25.0)	(3.2, 65.1)	11	3 (27.3)	(6.0, 61.0)
	Moderate	8	1 (12.5)	(0.3, 52.7)	11	1 (9.1)	(0.2, 41.3)
	Severe	8	0	(0.0, 36.9)	11	0	(0.0, 28.5)
	Grade 4	8	0	(0.0, 36.9)	11	0	(0.0, 28.5)
	Headache[e]						
	Any	8	2 (25.0)	(3.2, 65.1)	11	2 (18.2)	(2.3, 51.8)
	Mild	8	2 (25.0)	(3.2, 65.1)	11	2 (18.2)	(2.3, 51.8)
	Moderate	8	0	(0.0, 36.9)	11	0	(0.0, 28.5)
	Severe	8	0	(0.0, 36.9)	11	0	(0.0, 28.5)
	Grade 4	8	0	(0.0, 36.9)	11	0	(0.0, 28.5)
	Chills[e]						
	Any	8	0	(0.0, 36.9)	11	0	(0.0, 28.5)
	Mild	8	0	(0.0, 36.9)	11	0	(0.0, 28.5)
	Moderate	8	0	(0.0, 36.9)	11	0	(0.0, 28.5)
	Severe	8	0	(0.0, 36.9)	11	0	(0.0, 28.5)
	Grade 4	8	0	(0.0, 36.9)	11	0	(0.0, 28.5)
	Vomiting[f]						
	Any	8	0	(0.0, 36.9)	11	0	(0.0, 28.5)
	Mild	8	0	(0.0, 36.9)	11	0	(0.0, 28.5)

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14.79. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Race – Safety Population (Maternal) Race: All Others

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Moderate	8	0	(0.0, 36.9)	11	0	(0.0, 28.5)
	Severe	8	0	(0.0, 36.9)	11	0	(0.0, 28.5)
	Grade 4	8	0	(0.0, 36.9)	11	0	(0.0, 28.5)
	Diarrhea[g]						
	Any	8	1 (12.5)	(0.3, 52.7)	11	0	(0.0, 28.5)
	Mild	8	1 (12.5)	(0.3, 52.7)	11	0	(0.0, 28.5)
	Moderate	8	0	(0.0, 36.9)	11	0	(0.0, 28.5)
	Severe	8	0	(0.0, 36.9)	11	0	(0.0, 28.5)
	Grade 4	8	0	(0.0, 36.9)	11	0	(0.0, 28.5)
	New or worsened muscle pain[e]						
	Any	8	0	(0.0, 36.9)	11	1 (9.1)	(0.2, 41.3)
	Mild	8	0	(0.0, 36.9)	11	1 (9.1)	(0.2, 41.3)
	Moderate	8	0	(0.0, 36.9)	11	0	(0.0, 28.5)
	Severe	8	0	(0.0, 36.9)	11	0	(0.0, 28.5)
	Grade 4	8	0	(0.0, 36.9)	11	0	(0.0, 28.5)
	New or worsened joint pain[e]						
	Any	8	0	(0.0, 36.9)	11	2 (18.2)	(2.3, 51.8)
	Mild	8	0	(0.0, 36.9)	11	2 (18.2)	(2.3, 51.8)
	Moderate	8	0	(0.0, 36.9)	11	0	(0.0, 28.5)
	Severe	8	0	(0.0, 36.9)	11	0	(0.0, 28.5)
	Grade 4	8	0	(0.0, 36.9)	11	0	(0.0, 28.5)
	Any systemic event[h]	8	4 (50.0)	(15.7, 84.3)	11	4 (36.4)	(10.9, 69.2)
	Use of antipyretic or pain medication[i]	8	0	(0.0, 36.9)	11	0	(0.0, 28.5)
Any dose	Fever						
	Any	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	≥38.0°C to 38.4°C	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	>38.4°C to 38.9°C	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	>38.9°C to 40.0°C	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	>40.0°C	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Unknown[d]	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Fatigue/tiredness[e]						
	Any	9	4 (44.4)	(13.7, 78.8)	12	5 (41.7)	(15.2, 72.3)
	Mild	9	2 (22.2)	(2.8, 60.0)	12	3 (25.0)	(5.5, 57.2)
	Moderate	9	2 (22.2)	(2.8, 60.0)	12	2 (16.7)	(2.1, 48.4)
	Severe	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Grade 4	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Headache[e]						
	Any	9	4 (44.4)	(13.7, 78.8)	12	3 (25.0)	(5.5, 57.2)
	Mild	9	3 (33.3)	(7.5, 70.1)	12	3 (25.0)	(5.5, 57.2)
	Moderate	9	1 (11.1)	(0.3, 48.2)	12	0	(0.0, 26.5)

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14.79. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Race – Safety Population (Maternal) Race: All Others

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Severe	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Grade 4	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Chills[e]						
	Any	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Mild	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Moderate	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Severe	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Grade 4	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Vomiting[f]						
	Any	9	1 (11.1)	(0.3, 48.2)	12	0	(0.0, 26.5)
	Mild	9	1 (11.1)	(0.3, 48.2)	12	0	(0.0, 26.5)
	Moderate	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Severe	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Grade 4	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Diarrhea[g]						
	Any	9	2 (22.2)	(2.8, 60.0)	12	1 (8.3)	(0.2, 38.5)
	Mild	9	1 (11.1)	(0.3, 48.2)	12	1 (8.3)	(0.2, 38.5)
	Moderate	9	1 (11.1)	(0.3, 48.2)	12	0	(0.0, 26.5)
	Severe	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Grade 4	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	New or worsened muscle pain[e]						
	Any	9	1 (11.1)	(0.3, 48.2)	12	2 (16.7)	(2.1, 48.4)
	Mild	9	1 (11.1)	(0.3, 48.2)	12	1 (8.3)	(0.2, 38.5)
	Moderate	9	0	(0.0, 33.6)	12	1 (8.3)	(0.2, 38.5)
	Severe	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Grade 4	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	New or worsened joint pain[e]						
	Any	9	0	(0.0, 33.6)	12	2 (16.7)	(2.1, 48.4)
	Mild	9	0	(0.0, 33.6)	12	2 (16.7)	(2.1, 48.4)
	Moderate	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Severe	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Grade 4	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)
	Any systemic event[h]	9	5 (55.6)	(21.2, 86.3)	12	6 (50.0)	(21.1, 78.9)
	Use of antipyretic or pain medication[i]	9	0	(0.0, 33.6)	12	0	(0.0, 26.5)

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14.79. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Race – Safety Population (Maternal) Race: All Others

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])

Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) and from any unscheduled clinical assessments from Day 1 through Day 7 after each dose. Grade 4 events were classified by the investigator or medically qualified person. Events reported as adverse events in the case report form within 7 days after the study vaccination were also included in the analysis; the severity of these events is based on the grading scale in the adverse event section of the case report form.
Note: All others = American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of participants reporting at least 1 yes or no response for the specified event after the specified dose. These values are the denominators for the percentage calculations.
b. n = Number of participants with the specified characteristic.
c. Exact 2-sided confidence interval (CI), based on the Clopper and Pearson method.
d. This row includes counts of participants with "pyrexia" and "body temperature increased" MedDRA preferred terms with a nonmissing AE toxicity grade recorded on the AE case report form and who are also missing e-diary fever measurements.
e. Mild: does not interfere with activity; moderate: some interference with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe fatigue/tiredness, severe headache, severe chills, severe muscle pain, or severe joint pain.
f. Mild: 1 to 2 times in 24 hours; moderate: >2 times in 24 hours; severe: requires intravenous hydration; Grade 4: emergency room visit or hospitalization for severe vomiting.
g. Mild: 2 to 3 loose stools in 24 hours; moderate: 4 to 5 loose stools in 24 hours; severe: 6 or more loose stools in 24 hours; Grade 4: emergency room visit or hospitalization for severe diarrhea.
h. Any systemic event: any fever, any fatigue/tiredness, any vomiting, any chills, any diarrhea, any headache, any new or worsened muscle pain, or any new or worsened joint pain.
i. The use of antipyretic medication was included and summarized in the tables but was not considered as a systemic event. Severity was not applicable.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adfacevd Table Generation: 03MAY2023 (10:31) Output File: ./nda3/C4591015_BR/adce_s020_race

14.80. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Ethnicity – Safety Population (Maternal) Ethnicity: Hispanic/Latino

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Fever						
	Any	69	1 (1.4)	(0.0, 7.8)	63	1 (1.6)	(0.0, 8.5)
	≥38.0°C to 38.4°C	69	1 (1.4)	(0.0, 7.8)	63	1 (1.6)	(0.0, 8.5)
	>38.4°C to 38.9°C	69	0	(0.0, 5.2)	63	0	(0.0, 5.7)
	>38.9°C to 40.0°C	69	0	(0.0, 5.2)	63	0	(0.0, 5.7)

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14.80. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Ethnicity – Safety Population (Maternal) Ethnicity: Hispanic/Latino

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	>40.0°C	69	0	(0.0, 5.2)	63	0	(0.0, 5.7)
	Unknown[d]	69	0	(0.0, 5.2)	63	0	(0.0, 5.7)
	Fatigue/tiredness[e]						
	Any	69	33 (47.8)	(35.6, 60.2)	63	25 (39.7)	(27.6, 52.8)
	Mild	69	17 (24.6)	(15.1, 36.5)	63	14 (22.2)	(12.7, 34.5)
	Moderate	69	15 (21.7)	(12.7, 33.3)	63	11 (17.5)	(9.1, 29.1)
	Severe	69	1 (1.4)	(0.0, 7.8)	63	0	(0.0, 5.7)
	Grade 4	69	0	(0.0, 5.2)	63	0	(0.0, 5.7)
	Headache[e]						
	Any	69	24 (34.8)	(23.7, 47.2)	63	22 (34.9)	(23.3, 48.0)
	Mild	69	10 (14.5)	(7.2, 25.0)	63	14 (22.2)	(12.7, 34.5)
	Moderate	69	11 (15.9)	(8.2, 26.7)	63	8 (12.7)	(5.6, 23.5)
	Severe	69	3 (4.3)	(0.9, 12.2)	63	0	(0.0, 5.7)
	Grade 4	69	0	(0.0, 5.2)	63	0	(0.0, 5.7)
	Chills[e]						
	Any	69	6 (8.7)	(3.3, 18.0)	63	5 (7.9)	(2.6, 17.6)
	Mild	69	4 (5.8)	(1.6, 14.2)	63	5 (7.9)	(2.6, 17.6)
	Moderate	69	2 (2.9)	(0.4, 10.1)	63	0	(0.0, 5.7)
	Severe	69	0	(0.0, 5.2)	63	0	(0.0, 5.7)
	Grade 4	69	0	(0.0, 5.2)	63	0	(0.0, 5.7)
	Vomiting[f]						
	Any	69	4 (5.8)	(1.6, 14.2)	63	9 (14.3)	(6.7, 25.4)
	Mild	69	4 (5.8)	(1.6, 14.2)	63	8 (12.7)	(5.6, 23.5)
	Moderate	69	0	(0.0, 5.2)	63	1 (1.6)	(0.0, 8.5)
	Severe	69	0	(0.0, 5.2)	63	0	(0.0, 5.7)
	Grade 4	69	0	(0.0, 5.2)	63	0	(0.0, 5.7)
	Diarrhea[g]						
	Any	69	6 (8.7)	(3.3, 18.0)	63	5 (7.9)	(2.6, 17.6)
	Mild	69	6 (8.7)	(3.3, 18.0)	63	4 (6.3)	(1.8, 15.5)
	Moderate	69	0	(0.0, 5.2)	63	1 (1.6)	(0.0, 8.5)
	Severe	69	0	(0.0, 5.2)	63	0	(0.0, 5.7)
	Grade 4	69	0	(0.0, 5.2)	63	0	(0.0, 5.7)
	New or worsened muscle pain[e]						
	Any	69	9 (13.0)	(6.1, 23.3)	63	8 (12.7)	(5.6, 23.5)
	Mild	69	5 (7.2)	(2.4, 16.1)	63	4 (6.3)	(1.8, 15.5)
	Moderate	69	4 (5.8)	(1.6, 14.2)	63	4 (6.3)	(1.8, 15.5)
	Severe	69	0	(0.0, 5.2)	63	0	(0.0, 5.7)
	Grade 4	69	0	(0.0, 5.2)	63	0	(0.0, 5.7)
	New or worsened joint pain[e]						
	Any	69	2 (2.9)	(0.4, 10.1)	63	2 (3.2)	(0.4, 11.0)

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14.80. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Ethnicity – Safety Population (Maternal) Ethnicity: Hispanic/Latino

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Mild	69	2 (2.9)	(0.4, 10.1)	63	1 (1.6)	(0.0, 8.5)
	Moderate	69	0	(0.0, 5.2)	63	1 (1.6)	(0.0, 8.5)
	Severe	69	0	(0.0, 5.2)	63	0	(0.0, 5.7)
	Grade 4	69	0	(0.0, 5.2)	63	0	(0.0, 5.7)
	Any systemic event[h]	69	39 (56.5)	(44.0, 68.4)	63	37 (58.7)	(45.6, 71.0)
	Use of antipyretic or pain medication[i]	69	9 (13.0)	(6.1, 23.3)	63	10 (15.9)	(7.9, 27.3)
2	Fever						
	Any	64	1 (1.6)	(0.0, 8.4)	54	1 (1.9)	(0.0, 9.9)
	≥38.0°C to 38.4°C	64	1 (1.6)	(0.0, 8.4)	54	1 (1.9)	(0.0, 9.9)
	>38.4°C to 38.9°C	64	0	(0.0, 5.6)	54	0	(0.0, 6.6)
	>38.9°C to 40.0°C	64	0	(0.0, 5.6)	54	0	(0.0, 6.6)
	>40.0°C	64	0	(0.0, 5.6)	54	0	(0.0, 6.6)
	Unknown[d]	64	0	(0.0, 5.6)	54	0	(0.0, 6.6)
	Fatigue/tiredness[e]						
	Any	64	27 (42.2)	(29.9, 55.2)	54	18 (33.3)	(21.1, 47.5)
	Mild	64	10 (15.6)	(7.8, 26.9)	54	11 (20.4)	(10.6, 33.5)
	Moderate	64	16 (25.0)	(15.0, 37.4)	54	7 (13.0)	(5.4, 24.9)
	Severe	64	1 (1.6)	(0.0, 8.4)	54	0	(0.0, 6.6)
	Grade 4	64	0	(0.0, 5.6)	54	0	(0.0, 6.6)
	Headache[e]						
	Any	64	24 (37.5)	(25.7, 50.5)	54	14 (25.9)	(15.0, 39.7)
	Mild	64	18 (28.1)	(17.6, 40.8)	54	8 (14.8)	(6.6, 27.1)
	Moderate	64	5 (7.8)	(2.6, 17.3)	54	6 (11.1)	(4.2, 22.6)
	Severe	64	1 (1.6)	(0.0, 8.4)	54	0	(0.0, 6.6)
	Grade 4	64	0	(0.0, 5.6)	54	0	(0.0, 6.6)
	Chills[e]						
	Any	64	8 (12.5)	(5.6, 23.2)	54	1 (1.9)	(0.0, 9.9)
	Mild	64	1 (1.6)	(0.0, 8.4)	54	1 (1.9)	(0.0, 9.9)
	Moderate	64	7 (10.9)	(4.5, 21.2)	54	0	(0.0, 6.6)
	Severe	64	0	(0.0, 5.6)	54	0	(0.0, 6.6)
	Grade 4	64	0	(0.0, 5.6)	54	0	(0.0, 6.6)
	Vomiting[f]						
	Any	64	6 (9.4)	(3.5, 19.3)	54	5 (9.3)	(3.1, 20.3)
	Mild	64	6 (9.4)	(3.5, 19.3)	54	3 (5.6)	(1.2, 15.4)
	Moderate	64	0	(0.0, 5.6)	54	2 (3.7)	(0.5, 12.7)
	Severe	64	0	(0.0, 5.6)	54	0	(0.0, 6.6)
	Grade 4	64	0	(0.0, 5.6)	54	0	(0.0, 6.6)
	Diarrhea[g]						
	Any	64	1 (1.6)	(0.0, 8.4)	54	1 (1.9)	(0.0, 9.9)
	Mild	64	1 (1.6)	(0.0, 8.4)	54	1 (1.9)	(0.0, 9.9)

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14.80. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Ethnicity – Safety Population (Maternal) Ethnicity: Hispanic/Latino

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Moderate	64	0	(0.0, 5.6)	54	0	(0.0, 6.6)
	Severe	64	0	(0.0, 5.6)	54	0	(0.0, 6.6)
	Grade 4	64	0	(0.0, 5.6)	54	0	(0.0, 6.6)
	New or worsened muscle pain[e]						
	Any	64	13 (20.3)	(11.3, 32.2)	54	3 (5.6)	(1.2, 15.4)
	Mild	64	9 (14.1)	(6.6, 25.0)	54	2 (3.7)	(0.5, 12.7)
	Moderate	64	4 (6.3)	(1.7, 15.2)	54	1 (1.9)	(0.0, 9.9)
	Severe	64	0	(0.0, 5.6)	54	0	(0.0, 6.6)
	Grade 4	64	0	(0.0, 5.6)	54	0	(0.0, 6.6)
	New or worsened joint pain[e]						
	Any	64	7 (10.9)	(4.5, 21.2)	54	1 (1.9)	(0.0, 9.9)
	Mild	64	5 (7.8)	(2.6, 17.3)	54	1 (1.9)	(0.0, 9.9)
	Moderate	64	2 (3.1)	(0.4, 10.8)	54	0	(0.0, 6.6)
	Severe	64	0	(0.0, 5.6)	54	0	(0.0, 6.6)
	Grade 4	64	0	(0.0, 5.6)	54	0	(0.0, 6.6)
	Any systemic event[h]	64	33 (51.6)	(38.7, 64.2)	54	28 (51.9)	(37.8, 65.7)
	Use of antipyretic or pain medication[i]	64	11 (17.2)	(8.9, 28.7)	54	4 (7.4)	(2.1, 17.9)
Any dose	Fever						
	Any	69	2 (2.9)	(0.4, 10.1)	63	2 (3.2)	(0.4, 11.0)
	≥38.0°C to 38.4°C	69	2 (2.9)	(0.4, 10.1)	63	2 (3.2)	(0.4, 11.0)
	>38.4°C to 38.9°C	69	0	(0.0, 5.2)	63	0	(0.0, 5.7)
	>38.9°C to 40.0°C	69	0	(0.0, 5.2)	63	0	(0.0, 5.7)
	>40.0°C	69	0	(0.0, 5.2)	63	0	(0.0, 5.7)
	Unknown[d]	69	0	(0.0, 5.2)	63	0	(0.0, 5.7)
	Fatigue/tiredness[e]						
	Any	69	40 (58.0)	(45.5, 69.8)	63	31 (49.2)	(36.4, 62.1)
	Mild	69	15 (21.7)	(12.7, 33.3)	63	14 (22.2)	(12.7, 34.5)
	Moderate	69	24 (34.8)	(23.7, 47.2)	63	17 (27.0)	(16.6, 39.7)
	Severe	69	1 (1.4)	(0.0, 7.8)	63	0	(0.0, 5.7)
	Grade 4	69	0	(0.0, 5.2)	63	0	(0.0, 5.7)
	Headache[e]						
	Any	69	35 (50.7)	(38.4, 63.0)	63	28 (44.4)	(31.9, 57.5)
	Mild	69	18 (26.1)	(16.3, 38.1)	63	16 (25.4)	(15.3, 37.9)
	Moderate	69	14 (20.3)	(11.6, 31.7)	63	12 (19.0)	(10.2, 30.9)
	Severe	69	3 (4.3)	(0.9, 12.2)	63	0	(0.0, 5.7)
	Grade 4	69	0	(0.0, 5.2)	63	0	(0.0, 5.7)
	Chills[e]						
	Any	69	14 (20.3)	(11.6, 31.7)	63	6 (9.5)	(3.6, 19.6)
	Mild	69	5 (7.2)	(2.4, 16.1)	63	6 (9.5)	(3.6, 19.6)
	Moderate	69	9 (13.0)	(6.1, 23.3)	63	0	(0.0, 5.7)

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14.80. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Ethnicity – Safety Population (Maternal) Ethnicity: Hispanic/Latino

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Severe	69	0	(0.0, 5.2)	63	0	(0.0, 5.7)
	Grade 4	69	0	(0.0, 5.2)	63	0	(0.0, 5.7)
	Vomiting[f]						
	Any	69	8 (11.6)	(5.1, 21.6)	63	10 (15.9)	(7.9, 27.3)
	Mild	69	8 (11.6)	(5.1, 21.6)	63	8 (12.7)	(5.6, 23.5)
	Moderate	69	0	(0.0, 5.2)	63	2 (3.2)	(0.4, 11.0)
	Severe	69	0	(0.0, 5.2)	63	0	(0.0, 5.7)
	Grade 4	69	0	(0.0, 5.2)	63	0	(0.0, 5.7)
	Diarrhea[g]						
	Any	69	6 (8.7)	(3.3, 18.0)	63	6 (9.5)	(3.6, 19.6)
	Mild	69	6 (8.7)	(3.3, 18.0)	63	5 (7.9)	(2.6, 17.6)
	Moderate	69	0	(0.0, 5.2)	63	1 (1.6)	(0.0, 8.5)
	Severe	69	0	(0.0, 5.2)	63	0	(0.0, 5.7)
	Grade 4	69	0	(0.0, 5.2)	63	0	(0.0, 5.7)
	New or worsened muscle pain[e]						
	Any	69	18 (26.1)	(16.3, 38.1)	63	10 (15.9)	(7.9, 27.3)
	Mild	69	10 (14.5)	(7.2, 25.0)	63	6 (9.5)	(3.6, 19.6)
	Moderate	69	8 (11.6)	(5.1, 21.6)	63	4 (6.3)	(1.8, 15.5)
	Severe	69	0	(0.0, 5.2)	63	0	(0.0, 5.7)
	Grade 4	69	0	(0.0, 5.2)	63	0	(0.0, 5.7)
	New or worsened joint pain[e]						
	Any	69	8 (11.6)	(5.1, 21.6)	63	3 (4.8)	(1.0, 13.3)
	Mild	69	6 (8.7)	(3.3, 18.0)	63	2 (3.2)	(0.4, 11.0)
	Moderate	69	2 (2.9)	(0.4, 10.1)	63	1 (1.6)	(0.0, 8.5)
	Severe	69	0	(0.0, 5.2)	63	0	(0.0, 5.7)
	Grade 4	69	0	(0.0, 5.2)	63	0	(0.0, 5.7)
	Any systemic event[h]	69	47 (68.1)	(55.8, 78.8)	63	41 (65.1)	(52.0, 76.7)
	Use of antipyretic or pain medication[i]	69	15 (21.7)	(12.7, 33.3)	63	13 (20.6)	(11.5, 32.7)

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14.80. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Ethnicity – Safety Population (Maternal) Ethnicity: Hispanic/Latino

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])

Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) and from any unscheduled clinical assessments from Day 1 through Day 7 after each dose. Grade 4 events were classified by the investigator or medically qualified person. Events reported as adverse events in the case report form within 7 days after the study vaccination were also included in the analysis; the severity of these events is based on the grading scale in the adverse event section of the case report form.
a. N = number of participants reporting at least 1 yes or no response for the specified event after the specified dose. These values are the denominators for the percentage calculations.
b. n = Number of participants with the specified characteristic.
c. Exact 2-sided confidence interval (CI), based on the Clopper and Pearson method.
d. This row includes counts of participants with "pyrexia" and "body temperature increased" MedDRA preferred terms with a nonmissing AE toxicity grade recorded on the AE case report form and who are also missing e-diary fever measurements.
e. Mild: does not interfere with activity; moderate: some interference with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe fatigue/tiredness, severe headache, severe chills, severe muscle pain, or severe joint pain.
f. Mild: 1 to 2 times in 24 hours; moderate: >2 times in 24 hours; severe: requires intravenous hydration; Grade 4: emergency room visit or hospitalization for severe vomiting.
g. Mild: 2 to 3 loose stools in 24 hours; moderate: 4 to 5 loose stools in 24 hours; severe: 6 or more loose stools in 24 hours; Grade 4: emergency room visit or hospitalization for severe diarrhea.
h. Any systemic event: any fever, any fatigue/tiredness, any vomiting, any chills, any diarrhea, any headache, any new or worsened muscle pain, or any new or worsened joint pain.
i. The use of antipyretic medication was included and summarized in the tables but was not considered as a systemic event. Severity was not applicable.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adfacevd Table Generation: 03MAY2023 (10:31) Output File: ./nda3/C4591015_BR/adce_s020_eth

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14.81. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Ethnicity – Safety Population (Maternal) Ethnicity: Non-Hispanic/Non-Latino

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Fever						
	Any	92	1 (1.1)	(0.0, 5.9)	100	2 (2.0)	(0.2, 7.0)
	≥38.0°C to 38.4°C	92	0	(0.0, 3.9)	100	1 (1.0)	(0.0, 5.4)
	>38.4°C to 38.9°C	92	0	(0.0, 3.9)	100	0	(0.0, 3.6)
	>38.9°C to 40.0°C	92	1 (1.1)	(0.0, 5.9)	100	1 (1.0)	(0.0, 5.4)
	>40.0°C	92	0	(0.0, 3.9)	100	0	(0.0, 3.6)
	Unknown[d]	92	0	(0.0, 3.9)	100	0	(0.0, 3.6)
	Fatigue/tiredness[e]						
	Any	92	47 (51.1)	(40.4, 61.7)	100	45 (45.0)	(35.0, 55.3)
	Mild	92	25 (27.2)	(18.4, 37.4)	100	20 (20.0)	(12.7, 29.2)
	Moderate	92	22 (23.9)	(15.6, 33.9)	100	24 (24.0)	(16.0, 33.6)
	Severe	92	0	(0.0, 3.9)	100	1 (1.0)	(0.0, 5.4)
	Grade 4	92	0	(0.0, 3.9)	100	0	(0.0, 3.6)
	Headache[e]						
	Any	92	31 (33.7)	(24.2, 44.3)	100	36 (36.0)	(26.6, 46.2)
	Mild	92	23 (25.0)	(16.6, 35.1)	100	22 (22.0)	(14.3, 31.4)
	Moderate	92	8 (8.7)	(3.8, 16.4)	100	13 (13.0)	(7.1, 21.2)
	Severe	92	0	(0.0, 3.9)	100	1 (1.0)	(0.0, 5.4)
	Grade 4	92	0	(0.0, 3.9)	100	0	(0.0, 3.6)
	Chills[e]						
	Any	92	5 (5.4)	(1.8, 12.2)	100	4 (4.0)	(1.1, 9.9)
	Mild	92	4 (4.3)	(1.2, 10.8)	100	4 (4.0)	(1.1, 9.9)
	Moderate	92	1 (1.1)	(0.0, 5.9)	100	0	(0.0, 3.6)
	Severe	92	0	(0.0, 3.9)	100	0	(0.0, 3.6)
	Grade 4	92	0	(0.0, 3.9)	100	0	(0.0, 3.6)
	Vomiting[f]						
	Any	92	4 (4.3)	(1.2, 10.8)	100	6 (6.0)	(2.2, 12.6)
	Mild	92	4 (4.3)	(1.2, 10.8)	100	2 (2.0)	(0.2, 7.0)
	Moderate	92	0	(0.0, 3.9)	100	4 (4.0)	(1.1, 9.9)
	Severe	92	0	(0.0, 3.9)	100	0	(0.0, 3.6)
	Grade 4	92	0	(0.0, 3.9)	100	0	(0.0, 3.6)
	Diarrhea[g]						
	Any	92	13 (14.1)	(7.7, 23.0)	100	9 (9.0)	(4.2, 16.4)
	Mild	92	12 (13.0)	(6.9, 21.7)	100	8 (8.0)	(3.5, 15.2)
	Moderate	92	1 (1.1)	(0.0, 5.9)	100	1 (1.0)	(0.0, 5.4)
	Severe	92	0	(0.0, 3.9)	100	0	(0.0, 3.6)
	Grade 4	92	0	(0.0, 3.9)	100	0	(0.0, 3.6)
	New or worsened muscle pain[e]						
	Any	92	11 (12.0)	(6.1, 20.4)	100	11 (11.0)	(5.6, 18.8)

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14.81. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Ethnicity – Safety Population (Maternal) Ethnicity: Non-Hispanic/Non-Latino

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Mild	92	6 (6.5)	(2.4, 13.7)	100	6 (6.0)	(2.2, 12.6)
	Moderate	92	5 (5.4)	(1.8, 12.2)	100	5 (5.0)	(1.6, 11.3)
	Severe	92	0	(0.0, 3.9)	100	0	(0.0, 3.6)
	Grade 4	92	0	(0.0, 3.9)	100	0	(0.0, 3.6)
	New or worsened joint pain[e]						
	Any	92	3 (3.3)	(0.7, 9.2)	100	6 (6.0)	(2.2, 12.6)
	Mild	92	0	(0.0, 3.9)	100	3 (3.0)	(0.6, 8.5)
	Moderate	92	3 (3.3)	(0.7, 9.2)	100	3 (3.0)	(0.6, 8.5)
	Severe	92	0	(0.0, 3.9)	100	0	(0.0, 3.6)
	Grade 4	92	0	(0.0, 3.9)	100	0	(0.0, 3.6)
	Any systemic event[h]	92	59 (64.1)	(53.5, 73.9)	100	63 (63.0)	(52.8, 72.4)
	Use of antipyretic or pain medication[i]	92	13 (14.1)	(7.7, 23.0)	100	12 (12.0)	(6.4, 20.0)
2	Fever						
	Any	84	3 (3.6)	(0.7, 10.1)	92	0	(0.0, 3.9)
	≥38.0°C to 38.4°C	84	1 (1.2)	(0.0, 6.5)	92	0	(0.0, 3.9)
	>38.4°C to 38.9°C	84	1 (1.2)	(0.0, 6.5)	92	0	(0.0, 3.9)
	>38.9°C to 40.0°C	84	0	(0.0, 4.3)	92	0	(0.0, 3.9)
	>40.0°C	84	0	(0.0, 4.3)	92	0	(0.0, 3.9)
	Unknown[d]	84	1 (1.2)	(0.0, 6.5)	92	0	(0.0, 3.9)
	Fatigue/tiredness[e]						
	Any	84	47 (56.0)	(44.7, 66.8)	92	32 (34.8)	(25.1, 45.4)
	Mild	84	13 (15.5)	(8.5, 25.0)	92	12 (13.0)	(6.9, 21.7)
	Moderate	84	32 (38.1)	(27.7, 49.3)	92	20 (21.7)	(13.8, 31.6)
	Severe	84	2 (2.4)	(0.3, 8.3)	92	0	(0.0, 3.9)
	Grade 4	84	0	(0.0, 4.3)	92	0	(0.0, 3.9)
	Headache[e]						
	Any	84	37 (44.0)	(33.2, 55.3)	92	21 (22.8)	(14.7, 32.8)
	Mild	84	19 (22.6)	(14.2, 33.0)	92	12 (13.0)	(6.9, 21.7)
	Moderate	84	17 (20.2)	(12.3, 30.4)	92	9 (9.8)	(4.6, 17.8)
	Severe	84	1 (1.2)	(0.0, 6.5)	92	0	(0.0, 3.9)
	Grade 4	84	0	(0.0, 4.3)	92	0	(0.0, 3.9)
	Chills[e]						
	Any	84	11 (13.1)	(6.7, 22.2)	92	0	(0.0, 3.9)
	Mild	84	6 (7.1)	(2.7, 14.9)	92	0	(0.0, 3.9)
	Moderate	84	4 (4.8)	(1.3, 11.7)	92	0	(0.0, 3.9)
	Severe	84	1 (1.2)	(0.0, 6.5)	92	0	(0.0, 3.9)
	Grade 4	84	0	(0.0, 4.3)	92	0	(0.0, 3.9)
	Vomiting[f]						
	Any	84	7 (8.3)	(3.4, 16.4)	92	0	(0.0, 3.9)

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14.81. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Ethnicity – Safety Population (Maternal) Ethnicity: Non-Hispanic/Non-Latino

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Mild	84	7 (8.3)	(3.4, 16.4)	92	0	(0.0, 3.9)
	Moderate	84	0	(0.0, 4.3)	92	0	(0.0, 3.9)
	Severe	84	0	(0.0, 4.3)	92	0	(0.0, 3.9)
	Grade 4	84	0	(0.0, 4.3)	92	0	(0.0, 3.9)
	Diarrhea[g]						
	Any	84	8 (9.5)	(4.2, 17.9)	92	7 (7.6)	(3.1, 15.1)
	Mild	84	8 (9.5)	(4.2, 17.9)	92	5 (5.4)	(1.8, 12.2)
	Moderate	84	0	(0.0, 4.3)	92	2 (2.2)	(0.3, 7.6)
	Severe	84	0	(0.0, 4.3)	92	0	(0.0, 3.9)
	Grade 4	84	0	(0.0, 4.3)	92	0	(0.0, 3.9)
	New or worsened muscle pain[e]						
	Any	84	27 (32.1)	(22.4, 43.2)	92	7 (7.6)	(3.1, 15.1)
	Mild	84	11 (13.1)	(6.7, 22.2)	92	5 (5.4)	(1.8, 12.2)
	Moderate	84	15 (17.9)	(10.4, 27.7)	92	2 (2.2)	(0.3, 7.6)
	Severe	84	1 (1.2)	(0.0, 6.5)	92	0	(0.0, 3.9)
	Grade 4	84	0	(0.0, 4.3)	92	0	(0.0, 3.9)
	New or worsened joint pain[e]						
	Any	84	13 (15.5)	(8.5, 25.0)	92	8 (8.7)	(3.8, 16.4)
	Mild	84	6 (7.1)	(2.7, 14.9)	92	6 (6.5)	(2.4, 13.7)
	Moderate	84	7 (8.3)	(3.4, 16.4)	92	2 (2.2)	(0.3, 7.6)
	Severe	84	0	(0.0, 4.3)	92	0	(0.0, 3.9)
	Grade 4	84	0	(0.0, 4.3)	92	0	(0.0, 3.9)
	Any systemic event[h]	84	56 (66.7)	(55.5, 76.6)	92	39 (42.4)	(32.1, 53.1)
	Use of antipyretic or pain medication[i]	84	18 (21.4)	(13.2, 31.7)	92	6 (6.5)	(2.4, 13.7)
Any dose	Fever						
	Any	92	4 (4.3)	(1.2, 10.8)	100	2 (2.0)	(0.2, 7.0)
	≥38.0°C to 38.4°C	92	1 (1.1)	(0.0, 5.9)	100	1 (1.0)	(0.0, 5.4)
	>38.4°C to 38.9°C	92	1 (1.1)	(0.0, 5.9)	100	0	(0.0, 3.6)
	>38.9°C to 40.0°C	92	1 (1.1)	(0.0, 5.9)	100	1 (1.0)	(0.0, 5.4)
	>40.0°C	92	0	(0.0, 3.9)	100	0	(0.0, 3.6)
	Unknown[d]	92	1 (1.1)	(0.0, 5.9)	100	0	(0.0, 3.6)
	Fatigue/tiredness[e]						
	Any	92	61 (66.3)	(55.7, 75.8)	100	51 (51.0)	(40.8, 61.1)
	Mild	92	21 (22.8)	(14.7, 32.8)	100	19 (19.0)	(11.8, 28.1)
	Moderate	92	38 (41.3)	(31.1, 52.1)	100	31 (31.0)	(22.1, 41.0)
	Severe	92	2 (2.2)	(0.3, 7.6)	100	1 (1.0)	(0.0, 5.4)
	Grade 4	92	0	(0.0, 3.9)	100	0	(0.0, 3.6)
	Headache[e]						
	Any	92	50 (54.3)	(43.6, 64.8)	100	44 (44.0)	(34.1, 54.3)

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14.81. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Ethnicity – Safety Population (Maternal) Ethnicity: Non-Hispanic/Non-Latino

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Mild	92	27 (29.3)	(20.3, 39.8)	100	26 (26.0)	(17.7, 35.7)
	Moderate	92	22 (23.9)	(15.6, 33.9)	100	17 (17.0)	(10.2, 25.8)
	Severe	92	1 (1.1)	(0.0, 5.9)	100	1 (1.0)	(0.0, 5.4)
	Grade 4	92	0	(0.0, 3.9)	100	0	(0.0, 3.6)
	Chills[e]						
	Any	92	14 (15.2)	(8.6, 24.2)	100	4 (4.0)	(1.1, 9.9)
	Mild	92	8 (8.7)	(3.8, 16.4)	100	4 (4.0)	(1.1, 9.9)
	Moderate	92	5 (5.4)	(1.8, 12.2)	100	0	(0.0, 3.6)
	Severe	92	1 (1.1)	(0.0, 5.9)	100	0	(0.0, 3.6)
	Grade 4	92	0	(0.0, 3.9)	100	0	(0.0, 3.6)
	Vomiting[f]						
	Any	92	10 (10.9)	(5.3, 19.1)	100	6 (6.0)	(2.2, 12.6)
	Mild	92	10 (10.9)	(5.3, 19.1)	100	2 (2.0)	(0.2, 7.0)
	Moderate	92	0	(0.0, 3.9)	100	4 (4.0)	(1.1, 9.9)
	Severe	92	0	(0.0, 3.9)	100	0	(0.0, 3.6)
	Grade 4	92	0	(0.0, 3.9)	100	0	(0.0, 3.6)
	Diarrhea[g]						
	Any	92	18 (19.6)	(12.0, 29.1)	100	15 (15.0)	(8.6, 23.5)
	Mild	92	17 (18.5)	(11.1, 27.9)	100	12 (12.0)	(6.4, 20.0)
	Moderate	92	1 (1.1)	(0.0, 5.9)	100	3 (3.0)	(0.6, 8.5)
	Severe	92	0	(0.0, 3.9)	100	0	(0.0, 3.6)
	Grade 4	92	0	(0.0, 3.9)	100	0	(0.0, 3.6)
	New or worsened muscle pain[e]						
	Any	92	35 (38.0)	(28.1, 48.8)	100	16 (16.0)	(9.4, 24.7)
	Mild	92	15 (16.3)	(9.4, 25.5)	100	10 (10.0)	(4.9, 17.6)
	Moderate	92	19 (20.7)	(12.9, 30.4)	100	6 (6.0)	(2.2, 12.6)
	Severe	92	1 (1.1)	(0.0, 5.9)	100	0	(0.0, 3.6)
	Grade 4	92	0	(0.0, 3.9)	100	0	(0.0, 3.6)
	New or worsened joint pain[e]						
	Any	92	14 (15.2)	(8.6, 24.2)	100	10 (10.0)	(4.9, 17.6)
	Mild	92	5 (5.4)	(1.8, 12.2)	100	6 (6.0)	(2.2, 12.6)
	Moderate	92	9 (9.8)	(4.6, 17.8)	100	4 (4.0)	(1.1, 9.9)
	Severe	92	0	(0.0, 3.9)	100	0	(0.0, 3.6)
	Grade 4	92	0	(0.0, 3.9)	100	0	(0.0, 3.6)
	Any systemic event[h]	92	72 (78.3)	(68.4, 86.2)	100	68 (68.0)	(57.9, 77.0)
	Use of antipyretic or pain medication[i]	92	26 (28.3)	(19.4, 38.6)	100	13 (13.0)	(7.1, 21.2)

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14.81. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Ethnicity – Safety Population (Maternal) Ethnicity: Non-Hispanic/Non-Latino

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])

Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) and from any unscheduled clinical assessments from Day 1 through Day 7 after each dose. Grade 4 events were classified by the investigator or medically qualified person. Events reported as adverse events in the case report form within 7 days after the study vaccination were also included in the analysis; the severity of these events is based on the grading scale in the adverse event section of the case report form.
a. N = number of participants reporting at least 1 yes or no response for the specified event after the specified dose. These values are the denominators for the percentage calculations.
b. n = Number of participants with the specified characteristic.
c. Exact 2-sided confidence interval (CI), based on the Clopper and Pearson method.
d. This row includes counts of participants with "pyrexia" and "body temperature increased" MedDRA preferred terms with a nonmissing AE toxicity grade recorded on the AE case report form and who are also missing e-diary fever measurements.
e. Mild: does not interfere with activity; moderate: some interference with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe fatigue/tiredness, severe headache, severe chills, severe muscle pain, or severe joint pain.
f. Mild: 1 to 2 times in 24 hours; moderate: >2 times in 24 hours; severe: requires intravenous hydration; Grade 4: emergency room visit or hospitalization for severe vomiting.
g. Mild: 2 to 3 loose stools in 24 hours; moderate: 4 to 5 loose stools in 24 hours; severe: 6 or more loose stools in 24 hours; Grade 4: emergency room visit or hospitalization for severe diarrhea.
h. Any systemic event: any fever, any fatigue/tiredness, any vomiting, any chills, any diarrhea, any headache, any new or worsened muscle pain, or any new or worsened joint pain.
i. The use of antipyretic medication was included and summarized in the tables but was not considered as a systemic event. Severity was not applicable.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adfacevd Table Generation: 03MAY2023 (10:31) Output File: ./nda3/C4591015_BR/adce_s020_eth

14.82. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Safety Population (Maternal) Baseline SARS-CoV-2 Status: Positive

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Fever						
	Any	54	2 (3.7)	(0.5, 12.7)	58	2 (3.4)	(0.4, 11.9)
	≥38.0°C to 38.4°C	54	1 (1.9)	(0.0, 9.9)	58	1 (1.7)	(0.0, 9.2)
	>38.4°C to 38.9°C	54	0	(0.0, 6.6)	58	0	(0.0, 6.2)
	>38.9°C to 40.0°C	54	1 (1.9)	(0.0, 9.9)	58	1 (1.7)	(0.0, 9.2)

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14.82. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Safety Population (Maternal) Baseline SARS-CoV-2 Status: Positive

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	>40.0°C	54	0	(0.0, 6.6)	58	0	(0.0, 6.2)
	Unknown[d]	54	0	(0.0, 6.6)	58	0	(0.0, 6.2)
	Fatigue/tiredness[e]						
	Any	54	23 (42.6)	(29.2, 56.8)	58	19 (32.8)	(21.0, 46.3)
	Mild	54	16 (29.6)	(18.0, 43.6)	58	9 (15.5)	(7.3, 27.4)
	Moderate	54	7 (13.0)	(5.4, 24.9)	58	9 (15.5)	(7.3, 27.4)
	Severe	54	0	(0.0, 6.6)	58	1 (1.7)	(0.0, 9.2)
	Grade 4	54	0	(0.0, 6.6)	58	0	(0.0, 6.2)
	Headache[e]						
	Any	54	15 (27.8)	(16.5, 41.6)	58	20 (34.5)	(22.5, 48.1)
	Mild	54	8 (14.8)	(6.6, 27.1)	58	10 (17.2)	(8.6, 29.4)
	Moderate	54	6 (11.1)	(4.2, 22.6)	58	9 (15.5)	(7.3, 27.4)
	Severe	54	1 (1.9)	(0.0, 9.9)	58	1 (1.7)	(0.0, 9.2)
	Grade 4	54	0	(0.0, 6.6)	58	0	(0.0, 6.2)
	Chills[e]						
	Any	54	4 (7.4)	(2.1, 17.9)	58	1 (1.7)	(0.0, 9.2)
	Mild	54	2 (3.7)	(0.5, 12.7)	58	1 (1.7)	(0.0, 9.2)
	Moderate	54	2 (3.7)	(0.5, 12.7)	58	0	(0.0, 6.2)
	Severe	54	0	(0.0, 6.6)	58	0	(0.0, 6.2)
	Grade 4	54	0	(0.0, 6.6)	58	0	(0.0, 6.2)
	Vomiting[f]						
	Any	54	7 (13.0)	(5.4, 24.9)	58	6 (10.3)	(3.9, 21.2)
	Mild	54	7 (13.0)	(5.4, 24.9)	58	3 (5.2)	(1.1, 14.4)
	Moderate	54	0	(0.0, 6.6)	58	3 (5.2)	(1.1, 14.4)
	Severe	54	0	(0.0, 6.6)	58	0	(0.0, 6.2)
	Grade 4	54	0	(0.0, 6.6)	58	0	(0.0, 6.2)
	Diarrhea[g]						
	Any	54	5 (9.3)	(3.1, 20.3)	58	6 (10.3)	(3.9, 21.2)
	Mild	54	5 (9.3)	(3.1, 20.3)	58	5 (8.6)	(2.9, 19.0)
	Moderate	54	0	(0.0, 6.6)	58	1 (1.7)	(0.0, 9.2)
	Severe	54	0	(0.0, 6.6)	58	0	(0.0, 6.2)
	Grade 4	54	0	(0.0, 6.6)	58	0	(0.0, 6.2)
	New or worsened muscle pain[e]						
	Any	54	11 (20.4)	(10.6, 33.5)	58	7 (12.1)	(5.0, 23.3)
	Mild	54	6 (11.1)	(4.2, 22.6)	58	5 (8.6)	(2.9, 19.0)
	Moderate	54	5 (9.3)	(3.1, 20.3)	58	2 (3.4)	(0.4, 11.9)
	Severe	54	0	(0.0, 6.6)	58	0	(0.0, 6.2)
	Grade 4	54	0	(0.0, 6.6)	58	0	(0.0, 6.2)
	New or worsened joint pain[e]						

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14.82. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Safety Population (Maternal) Baseline SARS-CoV-2 Status: Positive

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Any	54	1 (1.9)	(0.0, 9.9)	58	2 (3.4)	(0.4, 11.9)
	Mild	54	0	(0.0, 6.6)	58	2 (3.4)	(0.4, 11.9)
	Moderate	54	1 (1.9)	(0.0, 9.9)	58	0	(0.0, 6.2)
	Severe	54	0	(0.0, 6.6)	58	0	(0.0, 6.2)
	Grade 4	54	0	(0.0, 6.6)	58	0	(0.0, 6.2)
	Any systemic event[h]	54	31 (57.4)	(43.2, 70.8)	58	33 (56.9)	(43.2, 69.8)
	Use of antipyretic or pain medication[i]	54	7 (13.0)	(5.4, 24.9)	58	10 (17.2)	(8.6, 29.4)
2	Fever						
	Any	49	1 (2.0)	(0.1, 10.9)	51	0	(0.0, 7.0)
	≥38.0°C to 38.4°C	49	1 (2.0)	(0.1, 10.9)	51	0	(0.0, 7.0)
	>38.4°C to 38.9°C	49	0	(0.0, 7.3)	51	0	(0.0, 7.0)
	>38.9°C to 40.0°C	49	0	(0.0, 7.3)	51	0	(0.0, 7.0)
	>40.0°C	49	0	(0.0, 7.3)	51	0	(0.0, 7.0)
	Unknown[d]	49	0	(0.0, 7.3)	51	0	(0.0, 7.0)
	Fatigue/tiredness[e]						
	Any	49	20 (40.8)	(27.0, 55.8)	51	10 (19.6)	(9.8, 33.1)
	Mild	49	9 (18.4)	(8.8, 32.0)	51	9 (17.6)	(8.4, 30.9)
	Moderate	49	11 (22.4)	(11.8, 36.6)	51	1 (2.0)	(0.0, 10.4)
	Severe	49	0	(0.0, 7.3)	51	0	(0.0, 7.0)
	Grade 4	49	0	(0.0, 7.3)	51	0	(0.0, 7.0)
	Headache[e]						
	Any	49	14 (28.6)	(16.6, 43.3)	51	12 (23.5)	(12.8, 37.5)
	Mild	49	9 (18.4)	(8.8, 32.0)	51	7 (13.7)	(5.7, 26.3)
	Moderate	49	5 (10.2)	(3.4, 22.2)	51	5 (9.8)	(3.3, 21.4)
	Severe	49	0	(0.0, 7.3)	51	0	(0.0, 7.0)
	Grade 4	49	0	(0.0, 7.3)	51	0	(0.0, 7.0)
	Chills[e]						
	Any	49	4 (8.2)	(2.3, 19.6)	51	1 (2.0)	(0.0, 10.4)
	Mild	49	1 (2.0)	(0.1, 10.9)	51	1 (2.0)	(0.0, 10.4)
	Moderate	49	3 (6.1)	(1.3, 16.9)	51	0	(0.0, 7.0)
	Severe	49	0	(0.0, 7.3)	51	0	(0.0, 7.0)
	Grade 4	49	0	(0.0, 7.3)	51	0	(0.0, 7.0)
	Vomiting[f]						
	Any	49	5 (10.2)	(3.4, 22.2)	51	2 (3.9)	(0.5, 13.5)
	Mild	49	5 (10.2)	(3.4, 22.2)	51	1 (2.0)	(0.0, 10.4)
	Moderate	49	0	(0.0, 7.3)	51	1 (2.0)	(0.0, 10.4)
	Severe	49	0	(0.0, 7.3)	51	0	(0.0, 7.0)
	Grade 4	49	0	(0.0, 7.3)	51	0	(0.0, 7.0)
	Diarrhea[g]						

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14.82. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Safety Population (Maternal) Baseline SARS-CoV-2 Status: Positive

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Any	49	6 (12.2)	(4.6, 24.8)	51	2 (3.9)	(0.5, 13.5)
	Mild	49	6 (12.2)	(4.6, 24.8)	51	2 (3.9)	(0.5, 13.5)
	Moderate	49	0	(0.0, 7.3)	51	0	(0.0, 7.0)
	Severe	49	0	(0.0, 7.3)	51	0	(0.0, 7.0)
	Grade 4	49	0	(0.0, 7.3)	51	0	(0.0, 7.0)
	New or worsened muscle pain[e]						
	Any	49	6 (12.2)	(4.6, 24.8)	51	1 (2.0)	(0.0, 10.4)
	Mild	49	2 (4.1)	(0.5, 14.0)	51	1 (2.0)	(0.0, 10.4)
	Moderate	49	4 (8.2)	(2.3, 19.6)	51	0	(0.0, 7.0)
	Severe	49	0	(0.0, 7.3)	51	0	(0.0, 7.0)
	Grade 4	49	0	(0.0, 7.3)	51	0	(0.0, 7.0)
	New or worsened joint pain[e]						
	Any	49	4 (8.2)	(2.3, 19.6)	51	1 (2.0)	(0.0, 10.4)
	Mild	49	1 (2.0)	(0.1, 10.9)	51	1 (2.0)	(0.0, 10.4)
	Moderate	49	3 (6.1)	(1.3, 16.9)	51	0	(0.0, 7.0)
	Severe	49	0	(0.0, 7.3)	51	0	(0.0, 7.0)
	Grade 4	49	0	(0.0, 7.3)	51	0	(0.0, 7.0)
	Any systemic event[h]	49	24 (49.0)	(34.4, 63.7)	51	19 (37.3)	(24.1, 51.9)
	Use of antipyretic or pain medication[i]	49	7 (14.3)	(5.9, 27.2)	51	4 (7.8)	(2.2, 18.9)
Any dose	Fever						
	Any	54	3 (5.6)	(1.2, 15.4)	58	2 (3.4)	(0.4, 11.9)
	≥38.0°C to 38.4°C	54	2 (3.7)	(0.5, 12.7)	58	1 (1.7)	(0.0, 9.2)
	>38.4°C to 38.9°C	54	0	(0.0, 6.6)	58	0	(0.0, 6.2)
	>38.9°C to 40.0°C	54	1 (1.9)	(0.0, 9.9)	58	1 (1.7)	(0.0, 9.2)
	>40.0°C	54	0	(0.0, 6.6)	58	0	(0.0, 6.2)
	Unknown[d]	54	0	(0.0, 6.6)	58	0	(0.0, 6.2)
	Fatigue/tiredness[e]						
	Any	54	29 (53.7)	(39.6, 67.4)	58	24 (41.4)	(28.6, 55.1)
	Mild	54	16 (29.6)	(18.0, 43.6)	58	14 (24.1)	(13.9, 37.2)
	Moderate	54	13 (24.1)	(13.5, 37.6)	58	9 (15.5)	(7.3, 27.4)
	Severe	54	0	(0.0, 6.6)	58	1 (1.7)	(0.0, 9.2)
	Grade 4	54	0	(0.0, 6.6)	58	0	(0.0, 6.2)
	Headache[e]						
	Any	54	22 (40.7)	(27.6, 55.0)	58	25 (43.1)	(30.2, 56.8)
	Mild	54	13 (24.1)	(13.5, 37.6)	58	13 (22.4)	(12.5, 35.3)
	Moderate	54	8 (14.8)	(6.6, 27.1)	58	11 (19.0)	(9.9, 31.4)
	Severe	54	1 (1.9)	(0.0, 9.9)	58	1 (1.7)	(0.0, 9.2)
	Grade 4	54	0	(0.0, 6.6)	58	0	(0.0, 6.2)
	Chills[e]						

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14.82. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Safety Population (Maternal) Baseline SARS-CoV-2 Status: Positive

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Any	54	7 (13.0)	(5.4, 24.9)	58	2 (3.4)	(0.4, 11.9)
	Mild	54	2 (3.7)	(0.5, 12.7)	58	2 (3.4)	(0.4, 11.9)
	Moderate	54	5 (9.3)	(3.1, 20.3)	58	0	(0.0, 6.2)
	Severe	54	0	(0.0, 6.6)	58	0	(0.0, 6.2)
	Grade 4	54	0	(0.0, 6.6)	58	0	(0.0, 6.2)
	Vomiting[f]						
	Any	54	9 (16.7)	(7.9, 29.3)	58	7 (12.1)	(5.0, 23.3)
	Mild	54	9 (16.7)	(7.9, 29.3)	58	4 (6.9)	(1.9, 16.7)
	Moderate	54	0	(0.0, 6.6)	58	3 (5.2)	(1.1, 14.4)
	Severe	54	0	(0.0, 6.6)	58	0	(0.0, 6.2)
	Grade 4	54	0	(0.0, 6.6)	58	0	(0.0, 6.2)
	Diarrhea[g]						
	Any	54	9 (16.7)	(7.9, 29.3)	58	7 (12.1)	(5.0, 23.3)
	Mild	54	9 (16.7)	(7.9, 29.3)	58	6 (10.3)	(3.9, 21.2)
	Moderate	54	0	(0.0, 6.6)	58	1 (1.7)	(0.0, 9.2)
	Severe	54	0	(0.0, 6.6)	58	0	(0.0, 6.2)
	Grade 4	54	0	(0.0, 6.6)	58	0	(0.0, 6.2)
	New or worsened muscle pain[e]						
	Any	54	13 (24.1)	(13.5, 37.6)	58	8 (13.8)	(6.1, 25.4)
	Mild	54	5 (9.3)	(3.1, 20.3)	58	6 (10.3)	(3.9, 21.2)
	Moderate	54	8 (14.8)	(6.6, 27.1)	58	2 (3.4)	(0.4, 11.9)
	Severe	54	0	(0.0, 6.6)	58	0	(0.0, 6.2)
	Grade 4	54	0	(0.0, 6.6)	58	0	(0.0, 6.2)
	New or worsened joint pain[e]						
	Any	54	4 (7.4)	(2.1, 17.9)	58	3 (5.2)	(1.1, 14.4)
	Mild	54	1 (1.9)	(0.0, 9.9)	58	3 (5.2)	(1.1, 14.4)
	Moderate	54	3 (5.6)	(1.2, 15.4)	58	0	(0.0, 6.2)
	Severe	54	0	(0.0, 6.6)	58	0	(0.0, 6.2)
	Grade 4	54	0	(0.0, 6.6)	58	0	(0.0, 6.2)
	Any systemic event[h]	54	38 (70.4)	(56.4, 82.0)	58	37 (63.8)	(50.1, 76.0)
	Use of antipyretic or pain medication[i]	54	11 (20.4)	(10.6, 33.5)	58	12 (20.7)	(11.2, 33.4)

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14.82. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Safety Population (Maternal) Baseline SARS-CoV-2 Status: Positive

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) and from any unscheduled clinical assessments from Day 1 through Day 7 after each dose. Grade 4 events were classified by the investigator or medically qualified person. Events reported as adverse events in the case report form within 7 days after the study vaccination were also included in the analysis; the severity of these events is based on the grading scale in the adverse event section of the case report form.
a. N = number of participants reporting at least 1 yes or no response for the specified event after the specified dose. These values are the denominators for the percentage calculations.
b. n = Number of participants with the specified characteristic.
c. Exact 2-sided confidence interval (CI), based on the Clopper and Pearson method.
d. This row includes counts of participants with "pyrexia" and "body temperature increased" MedDRA preferred terms with a nonmissing AE toxicity grade recorded on the AE case report form and who are also missing e-diary fever measurements.
e. Mild: does not interfere with activity; moderate: some interference with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe fatigue/tiredness, severe headache, severe chills, severe muscle pain, or severe joint pain.
f. Mild: 1 to 2 times in 24 hours; moderate: >2 times in 24 hours; severe: requires intravenous hydration; Grade 4: emergency room visit or hospitalization for severe vomiting.
g. Mild: 2 to 3 loose stools in 24 hours; moderate: 4 to 5 loose stools in 24 hours; severe: 6 or more loose stools in 24 hours; Grade 4: emergency room visit or hospitalization for severe diarrhea.
h. Any systemic event: any fever, any fatigue/tiredness, any vomiting, any chills, any diarrhea, any headache, any new or worsened muscle pain, or any new or worsened joint pain.
i. The use of antipyretic medication was included and summarized in the tables but was not considered as a systemic event. Severity was not applicable.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adfacevd Table Generation: 03MAY2023 (10:32) Output File: ./nda3/C4591015_BR/adce_s020_bscov

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14.83. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Safety Population (Maternal) Baseline SARS-CoV-2 Status: Negative

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Fever						
	Any	99	0	(0.0, 3.7)	101	1 (1.0)	(0.0, 5.4)
	≥38.0°C to 38.4°C	99	0	(0.0, 3.7)	101	1 (1.0)	(0.0, 5.4)
	>38.4°C to 38.9°C	99	0	(0.0, 3.7)	101	0	(0.0, 3.6)
	>38.9°C to 40.0°C	99	0	(0.0, 3.7)	101	0	(0.0, 3.6)
	>40.0°C	99	0	(0.0, 3.7)	101	0	(0.0, 3.6)
	Unknown[d]	99	0	(0.0, 3.7)	101	0	(0.0, 3.6)
	Fatigue/tiredness[e]						
	Any	99	53 (53.5)	(43.2, 63.6)	101	49 (48.5)	(38.4, 58.7)
	Mild	99	24 (24.2)	(16.2, 33.9)	101	23 (22.8)	(15.0, 32.2)
	Moderate	99	28 (28.3)	(19.7, 38.2)	101	26 (25.7)	(17.6, 35.4)
	Severe	99	1 (1.0)	(0.0, 5.5)	101	0	(0.0, 3.6)
	Grade 4	99	0	(0.0, 3.7)	101	0	(0.0, 3.6)
	Headache[e]						
	Any	99	35 (35.4)	(26.0, 45.6)	101	36 (35.6)	(26.4, 45.8)
	Mild	99	20 (20.2)	(12.8, 29.5)	101	25 (24.8)	(16.7, 34.3)
	Moderate	99	13 (13.1)	(7.2, 21.4)	101	11 (10.9)	(5.6, 18.7)
	Severe	99	2 (2.0)	(0.2, 7.1)	101	0	(0.0, 3.6)
	Grade 4	99	0	(0.0, 3.7)	101	0	(0.0, 3.6)
	Chills[e]						
	Any	99	5 (5.1)	(1.7, 11.4)	101	6 (5.9)	(2.2, 12.5)
	Mild	99	4 (4.0)	(1.1, 10.0)	101	6 (5.9)	(2.2, 12.5)
	Moderate	99	1 (1.0)	(0.0, 5.5)	101	0	(0.0, 3.6)
	Severe	99	0	(0.0, 3.7)	101	0	(0.0, 3.6)
	Grade 4	99	0	(0.0, 3.7)	101	0	(0.0, 3.6)
	Vomiting[f]						
	Any	99	1 (1.0)	(0.0, 5.5)	101	9 (8.9)	(4.2, 16.2)
	Mild	99	1 (1.0)	(0.0, 5.5)	101	7 (6.9)	(2.8, 13.8)
	Moderate	99	0	(0.0, 3.7)	101	2 (2.0)	(0.2, 7.0)
	Severe	99	0	(0.0, 3.7)	101	0	(0.0, 3.6)
	Grade 4	99	0	(0.0, 3.7)	101	0	(0.0, 3.6)
	Diarrhea[g]						
	Any	99	12 (12.1)	(6.4, 20.2)	101	8 (7.9)	(3.5, 15.0)
	Mild	99	11 (11.1)	(5.7, 19.0)	101	7 (6.9)	(2.8, 13.8)
	Moderate	99	1 (1.0)	(0.0, 5.5)	101	1 (1.0)	(0.0, 5.4)
	Severe	99	0	(0.0, 3.7)	101	0	(0.0, 3.6)
	Grade 4	99	0	(0.0, 3.7)	101	0	(0.0, 3.6)
	New or worsened muscle pain[e]						

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14.83. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Safety Population (Maternal) Baseline SARS-CoV-2 Status: Negative

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Any	99	8 (8.1)	(3.6, 15.3)	101	12 (11.9)	(6.3, 19.8)
	Mild	99	5 (5.1)	(1.7, 11.4)	101	5 (5.0)	(1.6, 11.2)
	Moderate	99	3 (3.0)	(0.6, 8.6)	101	7 (6.9)	(2.8, 13.8)
	Severe	99	0	(0.0, 3.7)	101	0	(0.0, 3.6)
	Grade 4	99	0	(0.0, 3.7)	101	0	(0.0, 3.6)
	New or worsened joint pain[e]						
	Any	99	3 (3.0)	(0.6, 8.6)	101	6 (5.9)	(2.2, 12.5)
	Mild	99	2 (2.0)	(0.2, 7.1)	101	2 (2.0)	(0.2, 7.0)
	Moderate	99	1 (1.0)	(0.0, 5.5)	101	4 (4.0)	(1.1, 9.8)
	Severe	99	0	(0.0, 3.7)	101	0	(0.0, 3.6)
	Grade 4	99	0	(0.0, 3.7)	101	0	(0.0, 3.6)
	Any systemic event[h]	99	61 (61.6)	(51.3, 71.2)	101	64 (63.4)	(53.2, 72.7)
	Use of antipyretic or pain medication[i]	99	15 (15.2)	(8.7, 23.8)	101	11 (10.9)	(5.6, 18.7)
2	Fever						
	Any	93	3 (3.2)	(0.7, 9.1)	92	1 (1.1)	(0.0, 5.9)
	≥38.0°C to 38.4°C	93	1 (1.1)	(0.0, 5.8)	92	1 (1.1)	(0.0, 5.9)
	>38.4°C to 38.9°C	93	1 (1.1)	(0.0, 5.8)	92	0	(0.0, 3.9)
	>38.9°C to 40.0°C	93	0	(0.0, 3.9)	92	0	(0.0, 3.9)
	>40.0°C	93	0	(0.0, 3.9)	92	0	(0.0, 3.9)
	Unknown[d]	93	1 (1.1)	(0.0, 5.8)	92	0	(0.0, 3.9)
	Fatigue/tiredness[e]						
	Any	93	51 (54.8)	(44.2, 65.2)	92	39 (42.4)	(32.1, 53.1)
	Mild	93	14 (15.1)	(8.5, 24.0)	92	13 (14.1)	(7.7, 23.0)
	Moderate	93	35 (37.6)	(27.8, 48.3)	92	26 (28.3)	(19.4, 38.6)
	Severe	93	2 (2.2)	(0.3, 7.6)	92	0	(0.0, 3.9)
	Grade 4	93	0	(0.0, 3.9)	92	0	(0.0, 3.9)
	Headache[e]						
	Any	93	46 (49.5)	(38.9, 60.0)	92	20 (21.7)	(13.8, 31.6)
	Mild	93	28 (30.1)	(21.0, 40.5)	92	12 (13.0)	(6.9, 21.7)
	Moderate	93	16 (17.2)	(10.2, 26.4)	92	8 (8.7)	(3.8, 16.4)
	Severe	93	2 (2.2)	(0.3, 7.6)	92	0	(0.0, 3.9)
	Grade 4	93	0	(0.0, 3.9)	92	0	(0.0, 3.9)
	Chills[e]						
	Any	93	13 (14.0)	(7.7, 22.7)	92	0	(0.0, 3.9)
	Mild	93	6 (6.5)	(2.4, 13.5)	92	0	(0.0, 3.9)
	Moderate	93	7 (7.5)	(3.1, 14.9)	92	0	(0.0, 3.9)
	Severe	93	0	(0.0, 3.9)	92	0	(0.0, 3.9)
	Grade 4	93	0	(0.0, 3.9)	92	0	(0.0, 3.9)

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14.83. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Safety Population (Maternal) Baseline SARS-CoV-2 Status: Negative

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Vomiting[f]						
	Any	93	8 (8.6)	(3.8, 16.2)	92	3 (3.3)	(0.7, 9.2)
	Mild	93	8 (8.6)	(3.8, 16.2)	92	2 (2.2)	(0.3, 7.6)
	Moderate	93	0	(0.0, 3.9)	92	1 (1.1)	(0.0, 5.9)
	Severe	93	0	(0.0, 3.9)	92	0	(0.0, 3.9)
	Grade 4	93	0	(0.0, 3.9)	92	0	(0.0, 3.9)
	Diarrhea[g]						
	Any	93	3 (3.2)	(0.7, 9.1)	92	5 (5.4)	(1.8, 12.2)
	Mild	93	3 (3.2)	(0.7, 9.1)	92	4 (4.3)	(1.2, 10.8)
	Moderate	93	0	(0.0, 3.9)	92	1 (1.1)	(0.0, 5.9)
	Severe	93	0	(0.0, 3.9)	92	0	(0.0, 3.9)
	Grade 4	93	0	(0.0, 3.9)	92	0	(0.0, 3.9)
	New or worsened muscle pain[e]						
	Any	93	31 (33.3)	(23.9, 43.9)	92	9 (9.8)	(4.6, 17.8)
	Mild	93	18 (19.4)	(11.9, 28.9)	92	6 (6.5)	(2.4, 13.7)
	Moderate	93	13 (14.0)	(7.7, 22.7)	92	3 (3.3)	(0.7, 9.2)
	Severe	93	0	(0.0, 3.9)	92	0	(0.0, 3.9)
	Grade 4	93	0	(0.0, 3.9)	92	0	(0.0, 3.9)
	New or worsened joint pain[e]						
	Any	93	14 (15.1)	(8.5, 24.0)	92	8 (8.7)	(3.8, 16.4)
	Mild	93	9 (9.7)	(4.5, 17.6)	92	6 (6.5)	(2.4, 13.7)
	Moderate	93	5 (5.4)	(1.8, 12.1)	92	2 (2.2)	(0.3, 7.6)
	Severe	93	0	(0.0, 3.9)	92	0	(0.0, 3.9)
	Grade 4	93	0	(0.0, 3.9)	92	0	(0.0, 3.9)
	Any systemic event[h]	93	62 (66.7)	(56.1, 76.1)	92	45 (48.9)	(38.3, 59.6)
	Use of antipyretic or pain medication[i]	93	21 (22.6)	(14.6, 32.4)	92	5 (5.4)	(1.8, 12.2)
Any dose	Fever						
	Any	99	3 (3.0)	(0.6, 8.6)	101	2 (2.0)	(0.2, 7.0)
	≥38.0°C to 38.4°C	99	1 (1.0)	(0.0, 5.5)	101	2 (2.0)	(0.2, 7.0)
	>38.4°C to 38.9°C	99	1 (1.0)	(0.0, 5.5)	101	0	(0.0, 3.6)
	>38.9°C to 40.0°C	99	0	(0.0, 3.7)	101	0	(0.0, 3.6)
	>40.0°C	99	0	(0.0, 3.7)	101	0	(0.0, 3.6)
	Unknown[d]	99	1 (1.0)	(0.0, 5.5)	101	0	(0.0, 3.6)
	Fatigue/tiredness[e]						
	Any	99	67 (67.7)	(57.5, 76.7)	101	56 (55.4)	(45.2, 65.3)
	Mild	99	19 (19.2)	(12.0, 28.3)	101	17 (16.8)	(10.1, 25.6)
	Moderate	99	46 (46.5)	(36.4, 56.8)	101	39 (38.6)	(29.1, 48.8)
	Severe	99	2 (2.0)	(0.2, 7.1)	101	0	(0.0, 3.6)

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14.83. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Safety Population (Maternal) Baseline SARS-CoV-2 Status: Negative

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Grade 4	99	0	(0.0, 3.7)	101	0	(0.0, 3.6)
	Headache[e]						
	Any	99	58 (58.6)	(48.2, 68.4)	101	44 (43.6)	(33.7, 53.8)
	Mild	99	28 (28.3)	(19.7, 38.2)	101	28 (27.7)	(19.3, 37.5)
	Moderate	99	27 (27.3)	(18.8, 37.1)	101	16 (15.8)	(9.3, 24.4)
	Severe	99	3 (3.0)	(0.6, 8.6)	101	0	(0.0, 3.6)
	Grade 4	99	0	(0.0, 3.7)	101	0	(0.0, 3.6)
	Chills[e]						
	Any	99	18 (18.2)	(11.1, 27.2)	101	6 (5.9)	(2.2, 12.5)
	Mild	99	10 (10.1)	(5.0, 17.8)	101	6 (5.9)	(2.2, 12.5)
	Moderate	99	8 (8.1)	(3.6, 15.3)	101	0	(0.0, 3.6)
	Severe	99	0	(0.0, 3.7)	101	0	(0.0, 3.6)
	Grade 4	99	0	(0.0, 3.7)	101	0	(0.0, 3.6)
	Vomiting[f]						
	Any	99	9 (9.1)	(4.2, 16.6)	101	9 (8.9)	(4.2, 16.2)
	Mild	99	9 (9.1)	(4.2, 16.6)	101	6 (5.9)	(2.2, 12.5)
	Moderate	99	0	(0.0, 3.7)	101	3 (3.0)	(0.6, 8.4)
	Severe	99	0	(0.0, 3.7)	101	0	(0.0, 3.6)
	Grade 4	99	0	(0.0, 3.7)	101	0	(0.0, 3.6)
	Diarrhea[g]						
	Any	99	13 (13.1)	(7.2, 21.4)	101	13 (12.9)	(7.0, 21.0)
	Mild	99	12 (12.1)	(6.4, 20.2)	101	11 (10.9)	(5.6, 18.7)
	Moderate	99	1 (1.0)	(0.0, 5.5)	101	2 (2.0)	(0.2, 7.0)
	Severe	99	0	(0.0, 3.7)	101	0	(0.0, 3.6)
	Grade 4	99	0	(0.0, 3.7)	101	0	(0.0, 3.6)
	New or worsened muscle pain[e]						
	Any	99	36 (36.4)	(26.9, 46.6)	101	18 (17.8)	(10.9, 26.7)
	Mild	99	20 (20.2)	(12.8, 29.5)	101	10 (9.9)	(4.9, 17.5)
	Moderate	99	16 (16.2)	(9.5, 24.9)	101	8 (7.9)	(3.5, 15.0)
	Severe	99	0	(0.0, 3.7)	101	0	(0.0, 3.6)
	Grade 4	99	0	(0.0, 3.7)	101	0	(0.0, 3.6)
	New or worsened joint pain[e]						
	Any	99	15 (15.2)	(8.7, 23.8)	101	10 (9.9)	(4.9, 17.5)
	Mild	99	9 (9.1)	(4.2, 16.6)	101	5 (5.0)	(1.6, 11.2)
	Moderate	99	6 (6.1)	(2.3, 12.7)	101	5 (5.0)	(1.6, 11.2)
	Severe	99	0	(0.0, 3.7)	101	0	(0.0, 3.6)
	Grade 4	99	0	(0.0, 3.7)	101	0	(0.0, 3.6)
	Any systemic event[h]	99	75 (75.8)	(66.1, 83.8)	101	69 (68.3)	(58.3, 77.2)

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14.83. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Safety Population (Maternal) Baseline SARS-CoV-2 Status: Negative

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Use of antipyretic or pain medication[i]	99	29 (29.3)	(20.6, 39.3)	101	13 (12.9)	(7.0, 21.0)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) and from any unscheduled clinical assessments from Day 1 through Day 7 after each dose. Grade 4 events were classified by the investigator or medically qualified person. Events reported as adverse events in the case report form within 7 days after the study vaccination were also included in the analysis; the severity of these events is based on the grading scale in the adverse event section of the case report form.
a. N = number of participants reporting at least 1 yes or no response for the specified event after the specified dose. These values are the denominators for the percentage calculations.
b. n = Number of participants with the specified characteristic.
c. Exact 2-sided confidence interval (CI), based on the Clopper and Pearson method.
d. This row includes counts of participants with "pyrexia" and "body temperature increased" MedDRA preferred terms with a nonmissing AE toxicity grade recorded on the AE case report form and who are also missing e-diary fever measurements.
e. Mild: does not interfere with activity; moderate: some interference with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe fatigue/tiredness, severe headache, severe chills, severe muscle pain, or severe joint pain.
f. Mild: 1 to 2 times in 24 hours; moderate: >2 times in 24 hours; severe: requires intravenous hydration; Grade 4: emergency room visit or hospitalization for severe vomiting.
g. Mild: 2 to 3 loose stools in 24 hours; moderate: 4 to 5 loose stools in 24 hours; severe: 6 or more loose stools in 24 hours; Grade 4: emergency room visit or hospitalization for severe diarrhea.
h. Any systemic event: any fever, any fatigue/tiredness, any vomiting, any chills, any diarrhea, any headache, any new or worsened muscle pain, or any new or worsened joint pain.
i. The use of antipyretic medication was included and summarized in the tables but was not considered as a systemic event. Severity was not applicable.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adfacevd Table Generation: 03MAY2023 (10:32) Output File: ./nda3/C4591015_BR/adce_s020_bscov

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14.84. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Safety Population (Maternal) Baseline SARS-CoV-2 Status: Missing

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Fever						
	Any	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	≥38.0°C to 38.4°C	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	>38.4°C to 38.9°C	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	>38.9°C to 40.0°C	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	>40.0°C	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Unknown[d]	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Fatigue/tiredness[e]						
	Any	8	4 (50.0)	(15.7, 84.3)	4	2 (50.0)	(6.8, 93.2)
	Mild	8	2 (25.0)	(3.2, 65.1)	4	2 (50.0)	(6.8, 93.2)
	Moderate	8	2 (25.0)	(3.2, 65.1)	4	0	(0.0, 60.2)
	Severe	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Grade 4	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Headache[e]						
	Any	8	5 (62.5)	(24.5, 91.5)	4	2 (50.0)	(6.8, 93.2)
	Mild	8	5 (62.5)	(24.5, 91.5)	4	1 (25.0)	(0.6, 80.6)
	Moderate	8	0	(0.0, 36.9)	4	1 (25.0)	(0.6, 80.6)
	Severe	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Grade 4	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Chills[e]						
	Any	8	2 (25.0)	(3.2, 65.1)	4	2 (50.0)	(6.8, 93.2)
	Mild	8	2 (25.0)	(3.2, 65.1)	4	2 (50.0)	(6.8, 93.2)
	Moderate	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Severe	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Grade 4	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Vomiting[f]						
	Any	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Mild	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Moderate	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Severe	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Grade 4	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Diarrhea[g]						
	Any	8	2 (25.0)	(3.2, 65.1)	4	0	(0.0, 60.2)
	Mild	8	2 (25.0)	(3.2, 65.1)	4	0	(0.0, 60.2)
	Moderate	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Severe	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Grade 4	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	New or worsened muscle pain[e]						

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14.84. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Safety Population (Maternal) Baseline SARS-CoV-2 Status: Missing

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Any	8	1 (12.5)	(0.3, 52.7)	4	0	(0.0, 60.2)
	Mild	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Moderate	8	1 (12.5)	(0.3, 52.7)	4	0	(0.0, 60.2)
	Severe	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Grade 4	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	New or worsened joint pain[e]						
	Any	8	1 (12.5)	(0.3, 52.7)	4	0	(0.0, 60.2)
	Mild	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Moderate	8	1 (12.5)	(0.3, 52.7)	4	0	(0.0, 60.2)
	Severe	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Grade 4	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Any systemic event[h]	8	6 (75.0)	(34.9, 96.8)	4	3 (75.0)	(19.4, 99.4)
	Use of antipyretic or pain medication[i]	8	0	(0.0, 36.9)	4	1 (25.0)	(0.6, 80.6)
2	Fever						
	Any	6	0	(0.0, 45.9)	3	0	(0.0, 70.8)
	≥38.0°C to 38.4°C	6	0	(0.0, 45.9)	3	0	(0.0, 70.8)
	>38.4°C to 38.9°C	6	0	(0.0, 45.9)	3	0	(0.0, 70.8)
	>38.9°C to 40.0°C	6	0	(0.0, 45.9)	3	0	(0.0, 70.8)
	>40.0°C	6	0	(0.0, 45.9)	3	0	(0.0, 70.8)
	Unknown[d]	6	0	(0.0, 45.9)	3	0	(0.0, 70.8)
	Fatigue/tiredness[e]						
	Any	6	3 (50.0)	(11.8, 88.2)	3	1 (33.3)	(0.8, 90.6)
	Mild	6	0	(0.0, 45.9)	3	1 (33.3)	(0.8, 90.6)
	Moderate	6	2 (33.3)	(4.3, 77.7)	3	0	(0.0, 70.8)
	Severe	6	1 (16.7)	(0.4, 64.1)	3	0	(0.0, 70.8)
	Grade 4	6	0	(0.0, 45.9)	3	0	(0.0, 70.8)
	Headache[e]						
	Any	6	1 (16.7)	(0.4, 64.1)	3	3 (100.0)	(29.2, 100.0)
	Mild	6	0	(0.0, 45.9)	3	1 (33.3)	(0.8, 90.6)
	Moderate	6	1 (16.7)	(0.4, 64.1)	3	2 (66.7)	(9.4, 99.2)
	Severe	6	0	(0.0, 45.9)	3	0	(0.0, 70.8)
	Grade 4	6	0	(0.0, 45.9)	3	0	(0.0, 70.8)
	Chills[e]						
	Any	6	2 (33.3)	(4.3, 77.7)	3	0	(0.0, 70.8)
	Mild	6	0	(0.0, 45.9)	3	0	(0.0, 70.8)
	Moderate	6	1 (16.7)	(0.4, 64.1)	3	0	(0.0, 70.8)
	Severe	6	1 (16.7)	(0.4, 64.1)	3	0	(0.0, 70.8)
	Grade 4	6	0	(0.0, 45.9)	3	0	(0.0, 70.8)
	Vomiting[f]						

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14.84. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Safety Population (Maternal) Baseline SARS-CoV-2 Status: Missing

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Any	6	0	(0.0, 45.9)	3	0	(0.0, 70.8)
	Mild	6	0	(0.0, 45.9)	3	0	(0.0, 70.8)
	Moderate	6	0	(0.0, 45.9)	3	0	(0.0, 70.8)
	Severe	6	0	(0.0, 45.9)	3	0	(0.0, 70.8)
	Grade 4	6	0	(0.0, 45.9)	3	0	(0.0, 70.8)
	Diarrhea[g]						
	Any	6	0	(0.0, 45.9)	3	1 (33.3)	(0.8, 90.6)
	Mild	6	0	(0.0, 45.9)	3	0	(0.0, 70.8)
	Moderate	6	0	(0.0, 45.9)	3	1 (33.3)	(0.8, 90.6)
	Severe	6	0	(0.0, 45.9)	3	0	(0.0, 70.8)
	Grade 4	6	0	(0.0, 45.9)	3	0	(0.0, 70.8)
	New or worsened muscle pain[e]						
	Any	6	3 (50.0)	(11.8, 88.2)	3	0	(0.0, 70.8)
	Mild	6	0	(0.0, 45.9)	3	0	(0.0, 70.8)
	Moderate	6	2 (33.3)	(4.3, 77.7)	3	0	(0.0, 70.8)
	Severe	6	1 (16.7)	(0.4, 64.1)	3	0	(0.0, 70.8)
	Grade 4	6	0	(0.0, 45.9)	3	0	(0.0, 70.8)
	New or worsened joint pain[e]						
	Any	6	2 (33.3)	(4.3, 77.7)	3	0	(0.0, 70.8)
	Mild	6	1 (16.7)	(0.4, 64.1)	3	0	(0.0, 70.8)
	Moderate	6	1 (16.7)	(0.4, 64.1)	3	0	(0.0, 70.8)
	Severe	6	0	(0.0, 45.9)	3	0	(0.0, 70.8)
	Grade 4	6	0	(0.0, 45.9)	3	0	(0.0, 70.8)
	Any systemic event[h]	6	3 (50.0)	(11.8, 88.2)	3	3 (100.0)	(29.2, 100.0)
	Use of antipyretic or pain medication[i]	6	1 (16.7)	(0.4, 64.1)	3	1 (33.3)	(0.8, 90.6)
Any dose	Fever						
	Any	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	≥38.0°C to 38.4°C	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	>38.4°C to 38.9°C	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	>38.9°C to 40.0°C	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	>40.0°C	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Unknown[d]	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Fatigue/tiredness[e]						
	Any	8	5 (62.5)	(24.5, 91.5)	4	2 (50.0)	(6.8, 93.2)
	Mild	8	1 (12.5)	(0.3, 52.7)	4	2 (50.0)	(6.8, 93.2)
	Moderate	8	3 (37.5)	(8.5, 75.5)	4	0	(0.0, 60.2)
	Severe	8	1 (12.5)	(0.3, 52.7)	4	0	(0.0, 60.2)
	Grade 4	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Headache[e]						

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14.84. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Safety Population (Maternal) Baseline SARS-CoV-2 Status: Missing

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Any	8	5 (62.5)	(24.5, 91.5)	4	3 (75.0)	(19.4, 99.4)
	Mild	8	4 (50.0)	(15.7, 84.3)	4	1 (25.0)	(0.6, 80.6)
	Moderate	8	1 (12.5)	(0.3, 52.7)	4	2 (50.0)	(6.8, 93.2)
	Severe	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Grade 4	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Chills[e]						
	Any	8	3 (37.5)	(8.5, 75.5)	4	2 (50.0)	(6.8, 93.2)
	Mild	8	1 (12.5)	(0.3, 52.7)	4	2 (50.0)	(6.8, 93.2)
	Moderate	8	1 (12.5)	(0.3, 52.7)	4	0	(0.0, 60.2)
	Severe	8	1 (12.5)	(0.3, 52.7)	4	0	(0.0, 60.2)
	Grade 4	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Vomiting[f]						
	Any	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Mild	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Moderate	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Severe	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Grade 4	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Diarrhea[g]						
	Any	8	2 (25.0)	(3.2, 65.1)	4	1 (25.0)	(0.6, 80.6)
	Mild	8	2 (25.0)	(3.2, 65.1)	4	0	(0.0, 60.2)
	Moderate	8	0	(0.0, 36.9)	4	1 (25.0)	(0.6, 80.6)
	Severe	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Grade 4	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	New or worsened muscle pain[e]						
	Any	8	4 (50.0)	(15.7, 84.3)	4	0	(0.0, 60.2)
	Mild	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Moderate	8	3 (37.5)	(8.5, 75.5)	4	0	(0.0, 60.2)
	Severe	8	1 (12.5)	(0.3, 52.7)	4	0	(0.0, 60.2)
	Grade 4	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	New or worsened joint pain[e]						
	Any	8	3 (37.5)	(8.5, 75.5)	4	0	(0.0, 60.2)
	Mild	8	1 (12.5)	(0.3, 52.7)	4	0	(0.0, 60.2)
	Moderate	8	2 (25.0)	(3.2, 65.1)	4	0	(0.0, 60.2)
	Severe	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Grade 4	8	0	(0.0, 36.9)	4	0	(0.0, 60.2)
	Any systemic event[h]	8	6 (75.0)	(34.9, 96.8)	4	3 (75.0)	(19.4, 99.4)
	Use of antipyretic or pain medication[i]	8	1 (12.5)	(0.3, 52.7)	4	1 (25.0)	(0.6, 80.6)

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14.84. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Safety Population (Maternal) Baseline SARS-CoV-2 Status: Missing

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) and from any unscheduled clinical assessments from Day 1 through Day 7 after each dose. Grade 4 events were classified by the investigator or medically qualified person. Events reported as adverse events in the case report form within 7 days after the study vaccination were also included in the analysis; the severity of these events is based on the grading scale in the adverse event section of the case report form.
a. N = number of participants reporting at least 1 yes or no response for the specified event after the specified dose. These values are the denominators for the percentage calculations.
b. n = Number of participants with the specified characteristic.
c. Exact 2-sided confidence interval (CI), based on the Clopper and Pearson method.
d. This row includes counts of participants with "pyrexia" and "body temperature increased" MedDRA preferred terms with a nonmissing AE toxicity grade recorded on the AE case report form and who are also missing e-diary fever measurements.
e. Mild: does not interfere with activity; moderate: some interference with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe fatigue/tiredness, severe headache, severe chills, severe muscle pain, or severe joint pain.
f. Mild: 1 to 2 times in 24 hours; moderate: >2 times in 24 hours; severe: requires intravenous hydration; Grade 4: emergency room visit or hospitalization for severe vomiting.
g. Mild: 2 to 3 loose stools in 24 hours; moderate: 4 to 5 loose stools in 24 hours; severe: 6 or more loose stools in 24 hours; Grade 4: emergency room visit or hospitalization for severe diarrhea.
h. Any systemic event: any fever, any fatigue/tiredness, any vomiting, any chills, any diarrhea, any headache, any new or worsened muscle pain, or any new or worsened joint pain.
i. The use of antipyretic medication was included and summarized in the tables but was not considered as a systemic event. Severity was not applicable.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adfacevd Table Generation: 03MAY2023 (10:32) Output File: ./nda3/C4591015_BR/adce_s020_bscov

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Adverse Events

14.85. Number (%) of Participants Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2 – HIV-Positive Participants – Blinded Follow-Up Period – Safety Population (Maternal)

	Vaccine Group (as Administered)	
Adverse Event	BNT162b2 (30 µg) (N[a]=12) n[b] (%)	Placebo (N[a]=10) n[b] (%)
Any adverse event	2 (16.7)	4 (40.0)
Related[c]	0	0
Severe	1 (8.3)	0
Life-threatening	0	0
Any serious adverse event	1 (8.3)	1 (10.0)
Related[c]	0	0
Severe	1 (8.3)	0
Life-threatening	0	0
Any nonserious adverse event	1 (8.3)	4 (40.0)
Related[c]	0	0
Severe	0	0
Life-threatening	0	0
Any adverse event leading to withdrawal	0	0
Related[c]	0	0
Severe	0	0
Life-threatening	0	0
Death	0	0

Note: Nonserious adverse events related to study intervention with onset within 7 days (excluding immediate adverse event and adverse events leading to withdrawal) after vaccination and identified as reactogenicity events were excluded from the analysis of adverse events. These events were included in the analysis of reactogenicity events.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event category. For "any adverse event," n = the number of participants reporting at least 1 occurrence of any adverse event.
c. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 11MAY2023 (10:32) Output File: ./nda3/C4591015_BR/adae_s091_all_pd2_hiv_saf

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14.86. Number (%) of Participants Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by Race – Blinded Follow-Up Period – Safety Population (Maternal) Race: White

	Vaccine Group (as Administered)	
Adverse Event	BNT162b2 (30 µg) (N[a]=117) n[b] (%)	Placebo (N[a]=118) n[b] (%)
Any adverse event	25 (21.4)	29 (24.6)
Related[c]	1 (0.9)	1 (0.8)
Severe	4 (3.4)	5 (4.2)
Life-threatening	0	2 (1.7)
Any serious adverse event	4 (3.4)	6 (5.1)
Related[c]	0	0
Severe	2 (1.7)	2 (1.7)
Life-threatening	0	2 (1.7)
Any nonserious adverse event	24 (20.5)	26 (22.0)
Related[c]	1 (0.9)	1 (0.8)
Severe	2 (1.7)	3 (2.5)
Life-threatening	0	0
Any adverse event leading to withdrawal	0	0
Related[c]	0	0
Severe	0	0
Life-threatening	0	0
Death	0	0

Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: Nonserious adverse events related to study intervention with onset within 7 days (excluding immediate adverse event and adverse events leading to withdrawal) after vaccination and identified as reactogenicity events were excluded from the analysis of adverse events. These events were included in the analysis of reactogenicity events.
Note: All others = American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event category. For "any adverse event," n = the number of participants reporting at least 1 occurrence of any adverse event.
c. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 03MAY2023 (10:32) Output File: ./nda3/C4591015_BR/adae_s091_all_race_saf

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14.87. Number (%) of Participants Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by Race – Blinded Follow-Up Period – Safety Population (Maternal) Race: Black or African American

Adverse Event	BNT162b2 (30 µg) (N[a]=35) n[b] (%)	Placebo (N[a]=33) n[b] (%)
Any adverse event	8 (22.9)	6 (18.2)
Related[c]	0	0
Severe	1 (2.9)	2 (6.1)
Life-threatening	0	0
Any serious adverse event	3 (8.6)	2 (6.1)
Related[c]	0	0
Severe	1 (2.9)	2 (6.1)
Life-threatening	0	0
Any nonserious adverse event	5 (14.3)	5 (15.2)
Related[c]	0	0
Severe	0	0
Life-threatening	0	0
Any adverse event leading to withdrawal	0	0
Related[c]	0	0
Severe	0	0
Life-threatening	0	0
Death	0	0

Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: Nonserious adverse events related to study intervention with onset within 7 days (excluding immediate adverse event and adverse events leading to withdrawal) after vaccination and identified as reactogenicity events were excluded from the analysis of adverse events. These events were included in the analysis of reactogenicity events.
Note: All others = American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event category. For "any adverse event," n = the number of participants reporting at least 1 occurrence of any adverse event.
c. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 03MAY2023 (10:32) Output File: ./nda3/C4591015_BR/adae_s091_all_race_saf

14.88. Number (%) of Participants Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by Race – Blinded Follow-Up Period – Safety Population (Maternal) Race: All Others

Adverse Event	BNT162b2 (30 µg) (N[a]=9) n[b] (%)	Placebo (N[a]=12) n[b] (%)
Any adverse event	5 (55.6)	2 (16.7)

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14.88. Number (%) of Participants Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by Race – Blinded Follow-Up Period – Safety Population (Maternal) Race: All Others

Adverse Event	BNT162b2 (30 µg) (N[a]=9) n[b] (%)	Placebo (N[a]=12) n[b] (%)
Related[c]	0	0
Severe	2 (22.2)	1 (8.3)
Life-threatening	0	1 (8.3)
Any serious adverse event	2 (22.2)	1 (8.3)
Related[c]	0	0
Severe	2 (22.2)	0
Life-threatening	0	1 (8.3)
Any nonserious adverse event	4 (44.4)	2 (16.7)
Related[c]	0	0
Severe	0	1 (8.3)
Life-threatening	0	0
Any adverse event leading to withdrawal	0	0
Related[c]	0	0
Severe	0	0
Life-threatening	0	0
Death	0	0

Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: Nonserious adverse events related to study intervention with onset within 7 days (excluding immediate adverse event and adverse events leading to withdrawal) after vaccination and identified as reactogenicity events were excluded from the analysis of adverse events. These events were included in the analysis of reactogenicity events.
Note: All others = American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event category. For "any adverse event," n = the number of participants reporting at least 1 occurrence of any adverse event.
c. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 03MAY2023 (10:32) Output File: ./nda3/C4591015_BR/adae_s091_all_race_saf

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14.89. Number (%) of Participants Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by Ethnicity – Blinded Follow-Up Period – Safety Population (Maternal) Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)	
Adverse Event	BNT162b2 (30 µg) (N[a]=69) n[b] (%)	Placebo (N[a]=63) n[b] (%)
Any adverse event	11 (15.9)	15 (23.8)
Related[c]	1 (1.4)	1 (1.6)
Severe	3 (4.3)	2 (3.2)
Life-threatening	0	0
Any serious adverse event	2 (2.9)	3 (4.8)
Related[c]	0	0
Severe	2 (2.9)	1 (1.6)
Life-threatening	0	0
Any nonserious adverse event	10 (14.5)	12 (19.0)
Related[c]	1 (1.4)	1 (1.6)
Severe	1 (1.4)	1 (1.6)
Life-threatening	0	0
Any adverse event leading to withdrawal	0	0
Related[c]	0	0
Severe	0	0
Life-threatening	0	0
Death	0	0

Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: Nonserious adverse events related to study intervention with onset within 7 days (excluding immediate adverse event and adverse events leading to withdrawal) after vaccination and identified as reactogenicity events were excluded from the analysis of adverse events. These events were included in the analysis of reactogenicity events.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event category. For "any adverse event," n = the number of participants reporting at least 1 occurrence of any adverse event.
c. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 03MAY2023 (10:32) Output File: ./nda3/C4591015_BR/adae_s091_all_ethnic_saf

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14.90. Number (%) of Participants Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by Ethnicity – Blinded Follow-Up Period – Safety Population (Maternal) Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=92)	Placebo (N[a]=100)
Adverse Event	n[b] (%)	n[b] (%)
Any adverse event	27 (29.3)	22 (22.0)
Related[c]	0	0
Severe	4 (4.3)	6 (6.0)
Life-threatening	0	3 (3.0)
Any serious adverse event	7 (7.6)	6 (6.0)
Related[c]	0	0
Severe	3 (3.3)	3 (3.0)
Life-threatening	0	3 (3.0)
Any nonserious adverse event	23 (25.0)	21 (21.0)
Related[c]	0	0
Severe	1 (1.1)	3 (3.0)
Life-threatening	0	0
Any adverse event leading to withdrawal	0	0
Related[c]	0	0
Severe	0	0
Life-threatening	0	0
Death	0	0

Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: Nonserious adverse events related to study intervention with onset within 7 days (excluding immediate adverse event and adverse events leading to withdrawal) after vaccination and identified as reactogenicity events were excluded from the analysis of adverse events. These events were included in the analysis of reactogenicity events.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event category. For "any adverse event," n = the number of participants reporting at least 1 occurrence of any adverse event.
c. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 03MAY2023 (10:32) Output File: ./nda3/C4591015_BR/adae_s091_all_ethnic_saf

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14.91. Number (%) of Participants Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by Baseline SARS-CoV-2 Status – Blinded Follow-Up Period – Safety Population (Maternal) Baseline SARS-CoV-2 Status: Positive

	Vaccine Group (as Administered)	
Adverse Event	BNT162b2 (30 µg) (N[a]=54) n[b] (%)	Placebo (N[a]=58) n[b] (%)
Any adverse event	10 (18.5)	9 (15.5)
Related[c]	0	1 (1.7)
Severe	2 (3.7)	2 (3.4)
Life-threatening	0	0
Any serious adverse event	4 (7.4)	3 (5.2)
Related[c]	0	0
Severe	1 (1.9)	2 (3.4)
Life-threatening	0	0
Any nonserious adverse event	6 (11.1)	7 (12.1)
Related[c]	0	1 (1.7)
Severe	1 (1.9)	0
Life-threatening	0	0
Any adverse event leading to withdrawal	0	0
Related[c]	0	0
Severe	0	0
Life-threatening	0	0
Death	0	0

Abbreviations: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: Nonserious adverse events related to study intervention with onset within 7 days (excluding immediate adverse event and adverse events leading to withdrawal) after vaccination and identified as reactogenicity events were excluded from the analysis of adverse events. These events were included in the analysis of reactogenicity events.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event category. For "any adverse event," n = the number of participants reporting at least 1 occurrence of any adverse event.
c. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 11MAY2023 (10:23) Output File: ./nda3/C4591015_BR/adae_s091_all_covbstat

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14.92. Number (%) of Participants Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by Baseline SARS-CoV-2 Status – Blinded Follow-Up Period – Safety Population (Maternal) Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=99)	Placebo (N[a]=101)
Adverse Event	n[b] (%)	n[b] (%)
Any adverse event	25 (25.3)	27 (26.7)
Related[c]	1 (1.0)	0
Severe	5 (5.1)	6 (5.9)
Life-threatening	0	3 (3.0)
Any serious adverse event	5 (5.1)	6 (5.9)
Related[c]	0	0
Severe	4 (4.0)	2 (2.0)
Life-threatening	0	3 (3.0)
Any nonserious adverse event	24 (24.2)	25 (24.8)
Related[c]	1 (1.0)	0
Severe	1 (1.0)	4 (4.0)
Life-threatening	0	0
Any adverse event leading to withdrawal	0	0
Related[c]	0	0
Severe	0	0
Life-threatening	0	0
Death	0	0

Abbreviations: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: Nonserious adverse events related to study intervention with onset within 7 days (excluding immediate adverse event and adverse events leading to withdrawal) after vaccination and identified as reactogenicity events were excluded from the analysis of adverse events. These events were included in the analysis of reactogenicity events.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event category. For "any adverse event," n = the number of participants reporting at least 1 occurrence of any adverse event.
c. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 11MAY2023 (10:23) Output File: ./nda3/C4591015_BR/adae_s091_all_covbstat

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14.93. Number (%) of Participants Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by Baseline SARS-CoV-2 Status – Blinded Follow-Up Period – Safety Population (Maternal) Baseline SARS-CoV-2 Status: Missing

	Vaccine Group (as Administered)	
Adverse Event	BNT162b2 (30 µg) (N^a=8) n^b (%)	Placebo (N^a=4) n^b (%)
Any adverse event	3 (37.5)	1 (25.0)
Related[c]	0	0
Severe	0	0
Life-threatening	0	0
Any serious adverse event	0	0
Related[c]	0	0
Severe	0	0
Life-threatening	0	0
Any nonserious adverse event	3 (37.5)	1 (25.0)
Related[c]	0	0
Severe	0	0
Life-threatening	0	0
Any adverse event leading to withdrawal	0	0
Related[c]	0	0
Severe	0	0
Life-threatening	0	0
Death	0	0

Abbreviations: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: Nonserious adverse events related to study intervention with onset within 7 days (excluding immediate adverse event and adverse events leading to withdrawal) after vaccination and identified as reactogenicity events were excluded from the analysis of adverse events. These events were included in the analysis of reactogenicity events.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event category. For "any adverse event," n = the number of participants reporting at least 1 occurrence of any adverse event.
c. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 11MAY2023 (10:23) Output File: ./nda3/C4591015_BR/adae_s091_all_covbstat

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14.94. Number (%) of Participants Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population (Maternal)

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=161)		Placebo (N[a]=163)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	38 (23.6)	(17.3, 30.9)	37 (22.7)	(16.5, 29.9)
Blood and lymphatic system disorders	3 (1.9)	(0.4, 5.3)	4 (2.5)	(0.7, 6.2)
Anaemia	2 (1.2)	(0.2, 4.4)	2 (1.2)	(0.1, 4.4)
Anaemia of pregnancy	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Iron deficiency anaemia	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Normocytic anaemia	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Cardiac disorders	2 (1.2)	(0.2, 4.4)	1 (0.6)	(0.0, 3.4)
Bradycardia foetal	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Sinus bradycardia	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Tachycardia	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Ear and labyrinth disorders	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Vertigo	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Eye disorders	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Vision blurred	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Gastrointestinal disorders	7 (4.3)	(1.8, 8.8)	10 (6.1)	(3.0, 11.0)
Abdominal pain	2 (1.2)	(0.2, 4.4)	3 (1.8)	(0.4, 5.3)
Gastrooesophageal reflux disease	1 (0.6)	(0.0, 3.4)	2 (1.2)	(0.1, 4.4)
Constipation	0	(0.0, 2.3)	2 (1.2)	(0.1, 4.4)
Dyspepsia	1 (0.6)	(0.0, 3.4)	1 (0.6)	(0.0, 3.4)
Haemorrhoids	1 (0.6)	(0.0, 3.4)	1 (0.6)	(0.0, 3.4)
Diarrhoea	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Nausea	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Toothache	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
General disorders and administration site conditions	3 (1.9)	(0.4, 5.3)	3 (1.8)	(0.4, 5.3)
Oedema peripheral	1 (0.6)	(0.0, 3.4)	1 (0.6)	(0.0, 3.4)
Chest pain	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Fatigue	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Hypothermia	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Injection site pain	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Hepatobiliary disorders	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Cholestasis	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Immune system disorders	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Hypersensitivity	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Infections and infestations	8 (5.0)	(2.2, 9.6)	4 (2.5)	(0.7, 6.2)
Urinary tract infection	4 (2.5)	(0.7, 6.2)	1 (0.6)	(0.0, 3.4)
Cystitis	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Endometritis	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)

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14.94. Number (%) of Participants Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population (Maternal)

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=161)		Placebo (N[a]=163)	
	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Gastroenteritis	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Lower respiratory tract infection	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Nasopharyngitis	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Pneumonia	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Pyelonephritis	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Urinary tract infection bacterial	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Injury, poisoning and procedural complications	2 (1.2)	(0.2, 4.4)	3 (1.8)	(0.4, 5.3)
Fall	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Lip injury	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Post lumbar puncture syndrome	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Skin laceration	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Urinary tract procedural complication	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Vulvovaginal injury	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Investigations	2 (1.2)	(0.2, 4.4)	3 (1.8)	(0.4, 5.3)
Blood pressure increased	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Blood pressure systolic increased	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Brain natriuretic peptide increased	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Electrocardiogram QT prolonged	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Foetal heart rate abnormal	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Heart rate increased	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Metabolism and nutrition disorders	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Dehydration	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Musculoskeletal and connective tissue disorders	5 (3.1)	(1.0, 7.1)	1 (0.6)	(0.0, 3.4)
Back pain	2 (1.2)	(0.2, 4.4)	0	(0.0, 2.2)
Arthralgia	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Groin pain	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Muscle spasms	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Myalgia	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Nervous system disorders	2 (1.2)	(0.2, 4.4)	3 (1.8)	(0.4, 5.3)
Headache	2 (1.2)	(0.2, 4.4)	2 (1.2)	(0.1, 4.4)
Carpal tunnel syndrome	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Presyncope	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Sciatica	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Pregnancy, puerperium and perinatal conditions	15 (9.3)	(5.3, 14.9)	15 (9.2)	(5.2, 14.7)
Foetal hypokinesia	2 (1.2)	(0.2, 4.4)	3 (1.8)	(0.4, 5.3)
Pre-eclampsia	3 (1.9)	(0.4, 5.3)	1 (0.6)	(0.0, 3.4)
Foetal distress syndrome	2 (1.2)	(0.2, 4.4)	1 (0.6)	(0.0, 3.4)
Gestational diabetes	0	(0.0, 2.3)	2 (1.2)	(0.1, 4.4)

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14.94. Number (%) of Participants Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population (Maternal)

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=161)		Placebo (N[a]=163)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Gestational hypertension	1 (0.6)	(0.0, 3.4)	1 (0.6)	(0.0, 3.4)
Haemorrhage in pregnancy	2 (1.2)	(0.2, 4.4)	0	(0.0, 2.2)
Meconium stain	1 (0.6)	(0.0, 3.4)	1 (0.6)	(0.0, 3.4)
Premature delivery	0	(0.0, 2.3)	2 (1.2)	(0.1, 4.4)
Premature separation of placenta	0	(0.0, 2.3)	2 (1.2)	(0.1, 4.4)
Uterine contractions during pregnancy	2 (1.2)	(0.2, 4.4)	0	(0.0, 2.2)
Abnormal labour	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Breech presentation	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Failed induction of labour	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Hyperemesis gravidarum	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Meconium in amniotic fluid	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Placenta accreta	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Placental insufficiency	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Polyhydramnios	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Postpartum haemorrhage	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Premature labour	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Prolonged labour	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Umbilical cord around neck	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Psychiatric disorders	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Perinatal depression	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Renal and urinary disorders	1 (0.6)	(0.0, 3.4)	1 (0.6)	(0.0, 3.4)
Glycosuria	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Renal colic	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Reproductive system and breast disorders	2 (1.2)	(0.2, 4.4)	2 (1.2)	(0.1, 4.4)
Vaginal haemorrhage	1 (0.6)	(0.0, 3.4)	2 (1.2)	(0.1, 4.4)
Cervical polyp	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Genital haemorrhage	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Vaginal discharge	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Respiratory, thoracic and mediastinal disorders	2 (1.2)	(0.2, 4.4)	2 (1.2)	(0.1, 4.4)
Cough	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Epistaxis	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Rhinorrhoea	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Tachypnoea	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Skin and subcutaneous tissue disorders	1 (0.6)	(0.0, 3.4)	1 (0.6)	(0.0, 3.4)
Pruritus	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Skin hyperpigmentation	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Surgical and medical procedures	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Episiotomy	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)

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14.94. Number (%) of Participants Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population (Maternal)

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=161)		Placebo (N[a]=163)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Vascular disorders	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Deep vein thrombosis	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)

Note: MedDRA (v25.1) coding dictionary applied.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary. Analyses for HIV-positive participants and their infants will be summarized separately.
Note: Nonserious adverse events related to study intervention with onset within 7 days (excluding immediate adverse event and adverse events leading to withdrawal) after vaccination and identified as reactogenicity events were excluded from the analysis of adverse events. These events were included in the analysis of reactogenicity events.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event. For "any event," n = number of participants reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 03MAY2023 (10:32) Output File: ./nda3/C4591015_BR/adae_s130_1md2_soc_p3_saf

14.95. Tier 2 Adverse Events Reported From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term - Blinded Follow-Up Period – Safety Population (Maternal)

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]= 161)		Placebo (N[a]= 163)		Difference	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	%[d]	(95% CI[c])
Blood and lymphatic system disorders						
Anaemia	2 (1.2)	(0.2, 4.4)	2 (1.2)	(0.1, 4.4)	0.0	(-3.3, 3.3)
Gastrointestinal disorders						
Abdominal pain	2 (1.2)	(0.2, 4.4)	3 (1.8)	(0.4, 5.3)	-0.6	(-4.2, 2.8)
Gastrooesophageal reflux disease	1 (0.6)	(0.0, 3.4)	2 (1.2)	(0.1, 4.4)	-0.6	(-3.8, 2.3)
Constipation	0	(0.0, 2.3)	2 (1.2)	(0.1, 4.4)	-1.2	(-4.4, 1.1)
Infections and infestations						
Urinary tract infection	4 (2.5)	(0.7, 6.2)	1 (0.6)	(0.0, 3.4)	1.9	(-1.2, 5.7)
Musculoskeletal and connective tissue disorders						

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14.95. Tier 2 Adverse Events Reported From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term - Blinded Follow-Up Period – Safety Population (Maternal)

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]= 161)		Placebo (N[a]= 163)		Difference	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	%[d]	(95% CI[e])
Back pain	2 (1.2)	(0.2, 4.4)	0	(0.0, 2.2)	1.2	(-1.1, 4.4)
Nervous system disorders						
Headache	2 (1.2)	(0.2, 4.4)	2 (1.2)	(0.1, 4.4)	0.0	(-3.3, 3.3)
Pregnancy, puerperium and perinatal conditions						
Foetal hypokinesia	2 (1.2)	(0.2, 4.4)	3 (1.8)	(0.4, 5.3)	-0.6	(-4.2, 2.8)
Pre-eclampsia	3 (1.9)	(0.4, 5.3)	1 (0.6)	(0.0, 3.4)	1.2	(-1.7, 4.8)
Foetal distress syndrome	2 (1.2)	(0.2, 4.4)	1 (0.6)	(0.0, 3.4)	0.6	(-2.3, 3.9)
Gestational diabetes	0	(0.0, 2.3)	2 (1.2)	(0.1, 4.4)	-1.2	(-4.4, 1.1)
Haemorrhage in pregnancy	2 (1.2)	(0.2, 4.4)	0	(0.0, 2.2)	1.2	(-1.1, 4.4)
Premature delivery	0	(0.0, 2.3)	2 (1.2)	(0.1, 4.4)	-1.2	(-4.4, 1.1)
Premature separation of placenta	0	(0.0, 2.3)	2 (1.2)	(0.1, 4.4)	-1.2	(-4.4, 1.1)
Uterine contractions during pregnancy	2 (1.2)	(0.2, 4.4)	0	(0.0, 2.2)	1.2	(-1.1, 4.4)
Reproductive system and breast disorders						
Vaginal haemorrhage	1 (0.6)	(0.0, 3.4)	2 (1.2)	(0.1, 4.4)	-0.6	(-3.8, 2.3)

Note: MedDRA (v25.1) coding dictionary applied.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary. Analyses of HIV-positive participants and their infants will be listed separately.
Note: Nonserious adverse events related to study intervention with onset within 7 days (excluding immediate adverse event and adverse events leading to withdrawal) after vaccination and identified as reactogenicity events were excluded from the analysis of adverse events. These events were included in the analysis of reactogenicity events.
Note: Tier 2 events are common adverse events with an incidence rate greater or equal to 1.0% in any vaccine group (preferred term level). No Tier 1 events were identified at this stage for this program.
Note: The 95% confidence interval quantifies the precision of the risk difference estimate. Confidence intervals are not adjusted for multiplicity. They should only be used to identify potentially important adverse events.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
d. Difference in proportions, expressed as a percentage (BNT162b2 [30 µg] - placebo).
e. 2-Sided CI, based on the Miettinen and Nurminen method for the difference in proportions, expressed as a percentage.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 03MAY2023 (10:44) Output File: ./nda3/C4591015_BR/adae_s130_1md2_soc_p3_saf_t2

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14.96. Number (%) of Participants Reporting at Least 1 Adverse Event From First Dose of BNT162b2 to 1 Month After the Second Dose of BNT162b2, by System Organ Class and Preferred Term– Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population (Maternal)

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=144)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Any event	32 (22.2)	(15.7, 29.9)
Blood and lymphatic system disorders	1 (0.7)	(0.0, 3.8)
Lymphadenopathy	1 (0.7)	(0.0, 3.8)
General disorders and administration site conditions	19 (13.2)	(8.1, 19.8)
Injection site pain	13 (9.0)	(4.9, 14.9)
Pyrexia	5 (3.5)	(1.1, 7.9)
Fatigue	3 (2.1)	(0.4, 6.0)
Injection site erythema	3 (2.1)	(0.4, 6.0)
Pain	3 (2.1)	(0.4, 6.0)
Chills	2 (1.4)	(0.2, 4.9)
Asthenia	1 (0.7)	(0.0, 3.8)
Injection site oedema	1 (0.7)	(0.0, 3.8)
Injection site swelling	1 (0.7)	(0.0, 3.8)
Malaise	1 (0.7)	(0.0, 3.8)
Infections and infestations	10 (6.9)	(3.4, 12.4)
COVID-19	2 (1.4)	(0.2, 4.9)
Gastroenteritis viral	1 (0.7)	(0.0, 3.8)
Mastitis	1 (0.7)	(0.0, 3.8)
Oral herpes	1 (0.7)	(0.0, 3.8)
Puncture site infection	1 (0.7)	(0.0, 3.8)
Skin candida	1 (0.7)	(0.0, 3.8)
Urinary tract infection	1 (0.7)	(0.0, 3.8)
Viral infection	1 (0.7)	(0.0, 3.8)
Vulvovaginal mycotic infection	1 (0.7)	(0.0, 3.8)
Injury, poisoning and procedural complications	1 (0.7)	(0.0, 3.8)
Nerve injury	1 (0.7)	(0.0, 3.8)
Musculoskeletal and connective tissue disorders	6 (4.2)	(1.5, 8.8)
Myalgia	4 (2.8)	(0.8, 7.0)
Arthralgia	2 (1.4)	(0.2, 4.9)
Pain in extremity	1 (0.7)	(0.0, 3.8)
Nervous system disorders	8 (5.6)	(2.4, 10.7)
Headache	7 (4.9)	(2.0, 9.8)
Ageusia	1 (0.7)	(0.0, 3.8)
Anosmia	1 (0.7)	(0.0, 3.8)
Dizziness	1 (0.7)	(0.0, 3.8)
Reproductive system and breast disorders	1 (0.7)	(0.0, 3.8)

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14.96. Number (%) of Participants Reporting at Least 1 Adverse Event From First Dose of BNT162b2 to 1 Month After the Second Dose of BNT162b2, by System Organ Class and Preferred Term– Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population (Maternal)

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=144)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Suppressed lactation	1 (0.7)	(0.0, 3.8)
Respiratory, thoracic and mediastinal disorders	4 (2.8)	(0.8, 7.0)
Cough	1 (0.7)	(0.0, 3.8)
Nasal congestion	1 (0.7)	(0.0, 3.8)
Productive cough	1 (0.7)	(0.0, 3.8)
Respiratory disorder	1 (0.7)	(0.0, 3.8)

Note: MedDRA (v25.1) coding dictionary applied.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary. Analyses of HIV-positive participants and their infants will be listed separately.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event. For "any event," n = number of participants reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 05MAY2023 (10:35) Output File: ./nda3/C4591015_BR/adae_s151_2_2

14.97. Number (%) of Participants Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – HIV-Positive Participants – Blinded Follow-Up Period – Safety Population (Maternal)

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12)		Placebo (N[a]=10)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	2 (16.7)	(2.1, 48.4)	4 (40.0)	(12.2, 73.8)
Blood and lymphatic system disorders	1 (8.3)	(0.2, 38.5)	0	(0.0, 30.8)
Anaemia	1 (8.3)	(0.2, 38.5)	0	(0.0, 30.8)
Gastrointestinal disorders	0	(0.0, 26.5)	1 (10.0)	(0.3, 44.5)
Dyspepsia	0	(0.0, 26.5)	1 (10.0)	(0.3, 44.5)
Infections and infestations	1 (8.3)	(0.2, 38.5)	1 (10.0)	(0.3, 44.5)
Body tinea	0	(0.0, 26.5)	1 (10.0)	(0.3, 44.5)

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14.97. Number (%) of Participants Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – HIV-Positive Participants – Blinded Follow-Up Period – Safety Population (Maternal)

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12)		Placebo (N[a]=10)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Urinary tract infection	1 (8.3)	(0.2, 38.5)	0	(0.0, 30.8)
Pregnancy, puerperium and perinatal conditions	1 (8.3)	(0.2, 38.5)	1 (10.0)	(0.3, 44.5)
Foetal death	1 (8.3)	(0.2, 38.5)	0	(0.0, 30.8)
Foetal hypokinesia	0	(0.0, 26.5)	1 (10.0)	(0.3, 44.5)
Postpartum haemorrhage	1 (8.3)	(0.2, 38.5)	0	(0.0, 30.8)
Premature separation of placenta	1 (8.3)	(0.2, 38.5)	0	(0.0, 30.8)
Renal and urinary disorders	0	(0.0, 26.5)	1 (10.0)	(0.3, 44.5)
Leukocyturia	0	(0.0, 26.5)	1 (10.0)	(0.3, 44.5)
Reproductive system and breast disorders	1 (8.3)	(0.2, 38.5)	0	(0.0, 30.8)
Vaginal discharge	1 (8.3)	(0.2, 38.5)	0	(0.0, 30.8)
Skin and subcutaneous tissue disorders	0	(0.0, 26.5)	1 (10.0)	(0.3, 44.5)
Dermatitis allergic	0	(0.0, 26.5)	1 (10.0)	(0.3, 44.5)

Note: MedDRA (v25.1) coding dictionary applied.
Note: Nonserious adverse events related to study intervention with onset within 7 days (excluding immediate adverse event and adverse events leading to withdrawal) after vaccination and identified as reactogenicity events were excluded from the analysis of adverse events. These events were included in the analysis of reactogenicity events.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event. For "any event," n = number of participants reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 10MAY2023 (14:32) Output File: ./nda3/C4591015_BR/adae_s130_1md2_soc_p3_hiv

14.98. Number (%) of Participants Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – Blinded Follow-Up Period – Safety Population (Maternal) Race: White

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=117)		Placebo (N[a]=118)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	25 (21.4)	(14.3, 29.9)	29 (24.6)	(17.1, 33.4)
Blood and lymphatic system disorders	2 (1.7)	(0.2, 6.0)	4 (3.4)	(0.9, 8.5)

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14.98. Number (%) of Participants Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – Blinded Follow-Up Period – Safety Population (Maternal) Race: White

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=117)		Placebo (N[a]=118)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Anaemia	1 (0.9)	(0.0, 4.7)	2 (1.7)	(0.2, 6.0)
Anaemia of pregnancy	0	(0.0, 3.1)	1 (0.8)	(0.0, 4.6)
Iron deficiency anaemia	0	(0.0, 3.1)	1 (0.8)	(0.0, 4.6)
Normocytic anaemia	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Cardiac disorders	2 (1.7)	(0.2, 6.0)	1 (0.8)	(0.0, 4.6)
Bradycardia foetal	0	(0.0, 3.1)	1 (0.8)	(0.0, 4.6)
Sinus bradycardia	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Tachycardia	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Ear and labyrinth disorders	0	(0.0, 3.1)	1 (0.8)	(0.0, 4.6)
Vertigo	0	(0.0, 3.1)	1 (0.8)	(0.0, 4.6)
Eye disorders	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Vision blurred	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Gastrointestinal disorders	5 (4.3)	(1.4, 9.7)	7 (5.9)	(2.4, 11.8)
Abdominal pain	1 (0.9)	(0.0, 4.7)	2 (1.7)	(0.2, 6.0)
Gastrooesophageal reflux disease	1 (0.9)	(0.0, 4.7)	2 (1.7)	(0.2, 6.0)
Dyspepsia	1 (0.9)	(0.0, 4.7)	1 (0.8)	(0.0, 4.6)
Diarrhoea	0	(0.0, 3.1)	1 (0.8)	(0.0, 4.6)
Haemorrhoids	0	(0.0, 3.1)	1 (0.8)	(0.0, 4.6)
Nausea	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Toothache	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
General disorders and administration site conditions	3 (2.6)	(0.5, 7.3)	3 (2.5)	(0.5, 7.3)
Oedema peripheral	1 (0.9)	(0.0, 4.7)	1 (0.8)	(0.0, 4.6)
Chest pain	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Fatigue	0	(0.0, 3.1)	1 (0.8)	(0.0, 4.6)
Hypothermia	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Injection site pain	0	(0.0, 3.1)	1 (0.8)	(0.0, 4.6)
Hepatobiliary disorders	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Cholestasis	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Immune system disorders	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Hypersensitivity	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Infections and infestations	4 (3.4)	(0.9, 8.5)	3 (2.5)	(0.5, 7.3)
Urinary tract infection	3 (2.6)	(0.5, 7.3)	1 (0.8)	(0.0, 4.6)
Cystitis	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Nasopharyngitis	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Pneumonia	0	(0.0, 3.1)	1 (0.8)	(0.0, 4.6)
Urinary tract infection bacterial	0	(0.0, 3.1)	1 (0.8)	(0.0, 4.6)
Injury, poisoning and procedural complications	2 (1.7)	(0.2, 6.0)	3 (2.5)	(0.5, 7.3)

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14.98. Number (%) of Participants Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – Blinded Follow-Up Period – Safety Population (Maternal) Race: White

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=117)		Placebo (N[a]=118)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Fall	0	(0.0, 3.1)	1 (0.8)	(0.0, 4.6)
Lip injury	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Post lumbar puncture syndrome	0	(0.0, 3.1)	1 (0.8)	(0.0, 4.6)
Skin laceration	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Urinary tract procedural complication	0	(0.0, 3.1)	1 (0.8)	(0.0, 4.6)
Vulvovaginal injury	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Investigations	1 (0.9)	(0.0, 4.7)	3 (2.5)	(0.5, 7.3)
Blood pressure systolic increased	0	(0.0, 3.1)	1 (0.8)	(0.0, 4.6)
Brain natriuretic peptide increased	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Electrocardiogram QT prolonged	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Foetal heart rate abnormal	0	(0.0, 3.1)	1 (0.8)	(0.0, 4.6)
Heart rate increased	0	(0.0, 3.1)	1 (0.8)	(0.0, 4.6)
Metabolism and nutrition disorders	0	(0.0, 3.1)	1 (0.8)	(0.0, 4.6)
Dehydration	0	(0.0, 3.1)	1 (0.8)	(0.0, 4.6)
Musculoskeletal and connective tissue disorders	3 (2.6)	(0.5, 7.3)	1 (0.8)	(0.0, 4.6)
Back pain	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Groin pain	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Muscle spasms	0	(0.0, 3.1)	1 (0.8)	(0.0, 4.6)
Myalgia	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Nervous system disorders	2 (1.7)	(0.2, 6.0)	3 (2.5)	(0.5, 7.3)
Headache	2 (1.7)	(0.2, 6.0)	2 (1.7)	(0.2, 6.0)
Carpal tunnel syndrome	0	(0.0, 3.1)	1 (0.8)	(0.0, 4.6)
Presyncope	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Sciatica	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Pregnancy, puerperium and perinatal conditions	10 (8.5)	(4.2, 15.2)	11 (9.3)	(4.7, 16.1)
Foetal hypokinesia	2 (1.7)	(0.2, 6.0)	3 (2.5)	(0.5, 7.3)
Pre-eclampsia	3 (2.6)	(0.5, 7.3)	0	(0.0, 3.1)
Gestational diabetes	0	(0.0, 3.1)	2 (1.7)	(0.2, 6.0)
Gestational hypertension	1 (0.9)	(0.0, 4.7)	1 (0.8)	(0.0, 4.6)
Abnormal labour	0	(0.0, 3.1)	1 (0.8)	(0.0, 4.6)
Failed induction of labour	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Foetal distress syndrome	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Haemorrhage in pregnancy	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Hyperemesis gravidarum	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Meconium in amniotic fluid	0	(0.0, 3.1)	1 (0.8)	(0.0, 4.6)
Meconium stain	0	(0.0, 3.1)	1 (0.8)	(0.0, 4.6)
Placenta accreta	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Polyhydramnios	0	(0.0, 3.1)	1 (0.8)	(0.0, 4.6)

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14.98. Number (%) of Participants Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – Blinded Follow-Up Period – Safety Population (Maternal) Race: White

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=117)		Placebo (N[a]=118)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Postpartum haemorrhage	0	(0.0, 3.1)	1 (0.8)	(0.0, 4.6)
Premature labour	0	(0.0, 3.1)	1 (0.8)	(0.0, 4.6)
Premature separation of placenta	0	(0.0, 3.1)	1 (0.8)	(0.0, 4.6)
Umbilical cord around neck	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Uterine contractions during pregnancy	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Psychiatric disorders	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Perinatal depression	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Renal and urinary disorders	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Renal colic	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Reproductive system and breast disorders	0	(0.0, 3.1)	2 (1.7)	(0.2, 6.0)
Vaginal haemorrhage	0	(0.0, 3.1)	2 (1.7)	(0.2, 6.0)
Vaginal discharge	0	(0.0, 3.1)	1 (0.8)	(0.0, 4.6)
Respiratory, thoracic and mediastinal disorders	1 (0.9)	(0.0, 4.7)	1 (0.8)	(0.0, 4.6)
Cough	0	(0.0, 3.1)	1 (0.8)	(0.0, 4.6)
Tachypnoea	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Skin and subcutaneous tissue disorders	1 (0.9)	(0.0, 4.7)	1 (0.8)	(0.0, 4.6)
Pruritus	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Skin hyperpigmentation	0	(0.0, 3.1)	1 (0.8)	(0.0, 4.6)
Surgical and medical procedures	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Episiotomy	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Vascular disorders	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Deep vein thrombosis	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)

Note: MedDRA (v25.1) coding dictionary applied.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: Nonserious adverse events related to study intervention with onset within 7 days (excluding immediate adverse event and adverse events leading to withdrawal) after vaccination and identified as reactogenicity events were excluded from the analysis of adverse events. These events were included in the analysis of reactogenicity events.
Note: All others = American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event. For "any event," n = number of participants reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
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14.99. Number (%) of Participants Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – Blinded Follow-Up Period – Safety Population (Maternal) Race: Black or African American

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=35)		Placebo (N[a]=33)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	8 (22.9)	(10.4, 40.1)	6 (18.2)	(7.0, 35.5)
Gastrointestinal disorders	0	(0.0, 10.0)	1 (3.0)	(0.1, 15.8)
Abdominal pain	0	(0.0, 10.0)	1 (3.0)	(0.1, 15.8)
Infections and infestations	2 (5.7)	(0.7, 19.2)	1 (3.0)	(0.1, 15.8)
Lower respiratory tract infection	1 (2.9)	(0.1, 14.9)	0	(0.0, 10.6)
Pyelonephritis	0	(0.0, 10.0)	1 (3.0)	(0.1, 15.8)
Urinary tract infection	1 (2.9)	(0.1, 14.9)	0	(0.0, 10.6)
Investigations	1 (2.9)	(0.1, 14.9)	0	(0.0, 10.6)
Blood pressure increased	1 (2.9)	(0.1, 14.9)	0	(0.0, 10.6)
Musculoskeletal and connective tissue disorders	2 (5.7)	(0.7, 19.2)	0	(0.0, 10.6)
Arthralgia	1 (2.9)	(0.1, 14.9)	0	(0.0, 10.6)
Back pain	1 (2.9)	(0.1, 14.9)	0	(0.0, 10.6)
Pregnancy, puerperium and perinatal conditions	2 (5.7)	(0.7, 19.2)	3 (9.1)	(1.9, 24.3)
Foetal distress syndrome	1 (2.9)	(0.1, 14.9)	1 (3.0)	(0.1, 15.8)
Breech presentation	1 (2.9)	(0.1, 14.9)	0	(0.0, 10.6)
Meconium stain	1 (2.9)	(0.1, 14.9)	0	(0.0, 10.6)
Placental insufficiency	0	(0.0, 10.0)	1 (3.0)	(0.1, 15.8)
Pre-eclampsia	0	(0.0, 10.0)	1 (3.0)	(0.1, 15.8)
Premature delivery	0	(0.0, 10.0)	1 (3.0)	(0.1, 15.8)
Renal and urinary disorders	0	(0.0, 10.0)	1 (3.0)	(0.1, 15.8)
Glycosuria	0	(0.0, 10.0)	1 (3.0)	(0.1, 15.8)
Respiratory, thoracic and mediastinal disorders	1 (2.9)	(0.1, 14.9)	1 (3.0)	(0.1, 15.8)
Epistaxis	0	(0.0, 10.0)	1 (3.0)	(0.1, 15.8)
Rhinorrhoea	1 (2.9)	(0.1, 14.9)	0	(0.0, 10.6)

Note: MedDRA (v25.1) coding dictionary applied.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: Nonserious adverse events related to study intervention with onset within 7 days (excluding immediate adverse event and adverse events leading to withdrawal) after vaccination and identified as reactogenicity events were excluded from the analysis of adverse events. These events were included in the analysis of reactogenicity events.
Note: All others = American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event. For "any event," n = number of participants reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
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14.100. Number (%) of Participants Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Race – Blinded Follow-Up Period – Safety Population (Maternal) Race: All Others

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=9)		Placebo (N[a]=12)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	5 (55.6)	(21.2, 86.3)	2 (16.7)	(2.1, 48.4)
Blood and lymphatic system disorders	1 (11.1)	(0.3, 48.2)	0	(0.0, 26.5)
Anaemia	1 (11.1)	(0.3, 48.2)	0	(0.0, 26.5)
Gastrointestinal disorders	2 (22.2)	(2.8, 60.0)	2 (16.7)	(2.1, 48.4)
Constipation	0	(0.0, 33.6)	2 (16.7)	(2.1, 48.4)
Abdominal pain	1 (11.1)	(0.3, 48.2)	0	(0.0, 26.5)
Haemorrhoids	1 (11.1)	(0.3, 48.2)	0	(0.0, 26.5)
Infections and infestations	2 (22.2)	(2.8, 60.0)	0	(0.0, 26.5)
Endometritis	1 (11.1)	(0.3, 48.2)	0	(0.0, 26.5)
Gastroenteritis	1 (11.1)	(0.3, 48.2)	0	(0.0, 26.5)
Pregnancy, puerperium and perinatal conditions	3 (33.3)	(7.5, 70.1)	1 (8.3)	(0.2, 38.5)
Haemorrhage in pregnancy	1 (11.1)	(0.3, 48.2)	0	(0.0, 26.5)
Premature delivery	0	(0.0, 33.6)	1 (8.3)	(0.2, 38.5)
Premature separation of placenta	0	(0.0, 33.6)	1 (8.3)	(0.2, 38.5)
Prolonged labour	1 (11.1)	(0.3, 48.2)	0	(0.0, 26.5)
Uterine contractions during pregnancy	1 (11.1)	(0.3, 48.2)	0	(0.0, 26.5)
Reproductive system and breast disorders	2 (22.2)	(2.8, 60.0)	0	(0.0, 26.5)
Cervical polyp	1 (11.1)	(0.3, 48.2)	0	(0.0, 26.5)
Genital haemorrhage	1 (11.1)	(0.3, 48.2)	0	(0.0, 26.5)
Vaginal haemorrhage	1 (11.1)	(0.3, 48.2)	0	(0.0, 26.5)

Note: MedDRA (v25.1) coding dictionary applied.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: Nonserious adverse events related to study intervention with onset within 7 days (excluding immediate adverse event and adverse events leading to withdrawal) after vaccination and identified as reactogenicity events were excluded from the analysis of adverse events. These events were included in the analysis of reactogenicity events.
Note: All others = American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event. For "any event," n = number of participants reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
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14.101. Number (%) of Participants Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – Blinded Follow-Up Period – Safety Population (Maternal) Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=69)		Placebo (N[a]=63)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	11 (15.9)	(8.2, 26.7)	15 (23.8)	(14.0, 36.2)
Blood and lymphatic system disorders	2 (2.9)	(0.4, 10.1)	1 (1.6)	(0.0, 8.5)
Anaemia	1 (1.4)	(0.0, 7.8)	0	(0.0, 5.7)
Anaemia of pregnancy	0	(0.0, 5.2)	1 (1.6)	(0.0, 8.5)
Normocytic anaemia	1 (1.4)	(0.0, 7.8)	0	(0.0, 5.7)
Cardiac disorders	2 (2.9)	(0.4, 10.1)	1 (1.6)	(0.0, 8.5)
Bradycardia foetal	0	(0.0, 5.2)	1 (1.6)	(0.0, 8.5)
Sinus bradycardia	1 (1.4)	(0.0, 7.8)	0	(0.0, 5.7)
Tachycardia	1 (1.4)	(0.0, 7.8)	0	(0.0, 5.7)
Gastrointestinal disorders	1 (1.4)	(0.0, 7.8)	3 (4.8)	(1.0, 13.3)
Abdominal pain	0	(0.0, 5.2)	2 (3.2)	(0.4, 11.0)
Haemorrhoids	0	(0.0, 5.2)	1 (1.6)	(0.0, 8.5)
Nausea	1 (1.4)	(0.0, 7.8)	0	(0.0, 5.7)
General disorders and administration site conditions	1 (1.4)	(0.0, 7.8)	1 (1.6)	(0.0, 8.5)
Injection site pain	0	(0.0, 5.2)	1 (1.6)	(0.0, 8.5)
Oedema peripheral	1 (1.4)	(0.0, 7.8)	0	(0.0, 5.7)
Immune system disorders	1 (1.4)	(0.0, 7.8)	0	(0.0, 5.7)
Hypersensitivity	1 (1.4)	(0.0, 7.8)	0	(0.0, 5.7)
Infections and infestations	4 (5.8)	(1.6, 14.2)	3 (4.8)	(1.0, 13.3)
Urinary tract infection	3 (4.3)	(0.9, 12.2)	1 (1.6)	(0.0, 8.5)
Endometritis	1 (1.4)	(0.0, 7.8)	0	(0.0, 5.7)
Pneumonia	0	(0.0, 5.2)	1 (1.6)	(0.0, 8.5)
Urinary tract infection bacterial	0	(0.0, 5.2)	1 (1.6)	(0.0, 8.5)
Injury, poisoning and procedural complications	2 (2.9)	(0.4, 10.1)	2 (3.2)	(0.4, 11.0)
Lip injury	1 (1.4)	(0.0, 7.8)	0	(0.0, 5.7)
Post lumbar puncture syndrome	0	(0.0, 5.2)	1 (1.6)	(0.0, 8.5)
Skin laceration	1 (1.4)	(0.0, 7.8)	0	(0.0, 5.7)
Urinary tract procedural complication	0	(0.0, 5.2)	1 (1.6)	(0.0, 8.5)
Vulvovaginal injury	1 (1.4)	(0.0, 7.8)	0	(0.0, 5.7)
Investigations	2 (2.9)	(0.4, 10.1)	2 (3.2)	(0.4, 11.0)
Blood pressure increased	1 (1.4)	(0.0, 7.8)	0	(0.0, 5.7)
Blood pressure systolic increased	0	(0.0, 5.2)	1 (1.6)	(0.0, 8.5)
Brain natriuretic peptide increased	1 (1.4)	(0.0, 7.8)	0	(0.0, 5.7)
Electrocardiogram QT prolonged	1 (1.4)	(0.0, 7.8)	0	(0.0, 5.7)
Heart rate increased	0	(0.0, 5.2)	1 (1.6)	(0.0, 8.5)
Musculoskeletal and connective tissue disorders	2 (2.9)	(0.4, 10.1)	0	(0.0, 5.7)
Back pain	1 (1.4)	(0.0, 7.8)	0	(0.0, 5.7)

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14.101. Number (%) of Participants Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – Blinded Follow-Up Period – Safety Population (Maternal) Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=69)		Placebo (N[a]=63)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Groin pain	1 (1.4)	(0.0, 7.8)	0	(0.0, 5.7)
Nervous system disorders	1 (1.4)	(0.0, 7.8)	1 (1.6)	(0.0, 8.5)
Headache	1 (1.4)	(0.0, 7.8)	1 (1.6)	(0.0, 8.5)
Presyncope	1 (1.4)	(0.0, 7.8)	0	(0.0, 5.7)
Sciatica	1 (1.4)	(0.0, 7.8)	0	(0.0, 5.7)
Pregnancy, puerperium and perinatal conditions	3 (4.3)	(0.9, 12.2)	3 (4.8)	(1.0, 13.3)
Gestational diabetes	0	(0.0, 5.2)	1 (1.6)	(0.0, 8.5)
Haemorrhage in pregnancy	1 (1.4)	(0.0, 7.8)	0	(0.0, 5.7)
Hyperemesis gravidarum	1 (1.4)	(0.0, 7.8)	0	(0.0, 5.7)
Meconium in amniotic fluid	0	(0.0, 5.2)	1 (1.6)	(0.0, 8.5)
Polyhydramnios	0	(0.0, 5.2)	1 (1.6)	(0.0, 8.5)
Pre-eclampsia	1 (1.4)	(0.0, 7.8)	0	(0.0, 5.7)
Umbilical cord around neck	1 (1.4)	(0.0, 7.8)	0	(0.0, 5.7)
Uterine contractions during pregnancy	1 (1.4)	(0.0, 7.8)	0	(0.0, 5.7)
Reproductive system and breast disorders	1 (1.4)	(0.0, 7.8)	1 (1.6)	(0.0, 8.5)
Genital haemorrhage	1 (1.4)	(0.0, 7.8)	0	(0.0, 5.7)
Vaginal haemorrhage	0	(0.0, 5.2)	1 (1.6)	(0.0, 8.5)
Respiratory, thoracic and mediastinal disorders	1 (1.4)	(0.0, 7.8)	1 (1.6)	(0.0, 8.5)
Cough	0	(0.0, 5.2)	1 (1.6)	(0.0, 8.5)
Tachypnoea	1 (1.4)	(0.0, 7.8)	0	(0.0, 5.7)
Surgical and medical procedures	1 (1.4)	(0.0, 7.8)	0	(0.0, 5.7)
Episiotomy	1 (1.4)	(0.0, 7.8)	0	(0.0, 5.7)

Note: MedDRA (v25.1) coding dictionary applied.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: Nonserious adverse events related to study intervention with onset within 7 days (excluding immediate adverse event and adverse events leading to withdrawal) after vaccination and identified as reactogenicity events were excluded from the analysis of adverse events. These events were included in the analysis of reactogenicity events.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event. For "any event," n = number of participants reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
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14.102. Number (%) of Participants Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – Blinded Follow-Up Period – Safety Population (Maternal) Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=92)		Placebo (N[a]=100)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	27 (29.3)	(20.3, 39.8)	22 (22.0)	(14.3, 31.4)
Blood and lymphatic system disorders	1 (1.1)	(0.0, 5.9)	3 (3.0)	(0.6, 8.5)
Anaemia	1 (1.1)	(0.0, 5.9)	2 (2.0)	(0.2, 7.0)
Iron deficiency anaemia	0	(0.0, 3.9)	1 (1.0)	(0.0, 5.4)
Ear and labyrinth disorders	0	(0.0, 3.9)	1 (1.0)	(0.0, 5.4)
Vertigo	0	(0.0, 3.9)	1 (1.0)	(0.0, 5.4)
Eye disorders	1 (1.1)	(0.0, 5.9)	0	(0.0, 3.6)
Vision blurred	1 (1.1)	(0.0, 5.9)	0	(0.0, 3.6)
Gastrointestinal disorders	6 (6.5)	(2.4, 13.7)	7 (7.0)	(2.9, 13.9)
Abdominal pain	2 (2.2)	(0.3, 7.6)	1 (1.0)	(0.0, 5.4)
Gastrooesophageal reflux disease	1 (1.1)	(0.0, 5.9)	2 (2.0)	(0.2, 7.0)
Constipation	0	(0.0, 3.9)	2 (2.0)	(0.2, 7.0)
Dyspepsia	1 (1.1)	(0.0, 5.9)	1 (1.0)	(0.0, 5.4)
Diarrhoea	0	(0.0, 3.9)	1 (1.0)	(0.0, 5.4)
Haemorrhoids	1 (1.1)	(0.0, 5.9)	0	(0.0, 3.6)
Toothache	1 (1.1)	(0.0, 5.9)	0	(0.0, 3.6)
General disorders and administration site conditions	2 (2.2)	(0.3, 7.6)	2 (2.0)	(0.2, 7.0)
Chest pain	1 (1.1)	(0.0, 5.9)	0	(0.0, 3.6)
Fatigue	0	(0.0, 3.9)	1 (1.0)	(0.0, 5.4)
Hypothermia	1 (1.1)	(0.0, 5.9)	0	(0.0, 3.6)
Oedema peripheral	0	(0.0, 3.9)	1 (1.0)	(0.0, 5.4)
Hepatobiliary disorders	1 (1.1)	(0.0, 5.9)	0	(0.0, 3.6)
Cholestasis	1 (1.1)	(0.0, 5.9)	0	(0.0, 3.6)
Infections and infestations	4 (4.3)	(1.2, 10.8)	1 (1.0)	(0.0, 5.4)
Cystitis	1 (1.1)	(0.0, 5.9)	0	(0.0, 3.6)
Gastroenteritis	1 (1.1)	(0.0, 5.9)	0	(0.0, 3.6)
Lower respiratory tract infection	1 (1.1)	(0.0, 5.9)	0	(0.0, 3.6)
Nasopharyngitis	1 (1.1)	(0.0, 5.9)	0	(0.0, 3.6)
Pyelonephritis	0	(0.0, 3.9)	1 (1.0)	(0.0, 5.4)
Urinary tract infection	1 (1.1)	(0.0, 5.9)	0	(0.0, 3.6)
Injury, poisoning and procedural complications	0	(0.0, 3.9)	1 (1.0)	(0.0, 5.4)
Fall	0	(0.0, 3.9)	1 (1.0)	(0.0, 5.4)
Investigations	0	(0.0, 3.9)	1 (1.0)	(0.0, 5.4)
Foetal heart rate abnormal	0	(0.0, 3.9)	1 (1.0)	(0.0, 5.4)
Metabolism and nutrition disorders	0	(0.0, 3.9)	1 (1.0)	(0.0, 5.4)

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14.102. Number (%) of Participants Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – Blinded Follow-Up Period – Safety Population (Maternal) Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=92)		Placebo (N[a]=100)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Dehydration	0	(0.0, 3.9)	1 (1.0)	(0.0, 5.4)
Musculoskeletal and connective tissue disorders	3 (3.3)	(0.7, 9.2)	1 (1.0)	(0.0, 5.4)
Arthralgia	1 (1.1)	(0.0, 5.9)	0	(0.0, 3.6)
Back pain	1 (1.1)	(0.0, 5.9)	0	(0.0, 3.6)
Muscle spasms	0	(0.0, 3.9)	1 (1.0)	(0.0, 5.4)
Myalgia	1 (1.1)	(0.0, 5.9)	0	(0.0, 3.6)
Nervous system disorders	1 (1.1)	(0.0, 5.9)	2 (2.0)	(0.2, 7.0)
Headache	1 (1.1)	(0.0, 5.9)	1 (1.0)	(0.0, 5.4)
Carpal tunnel syndrome	0	(0.0, 3.9)	1 (1.0)	(0.0, 5.4)
Pregnancy, puerperium and perinatal conditions	12 (13.0)	(6.9, 21.7)	12 (12.0)	(6.4, 20.0)
Foetal hypokinesia	2 (2.2)	(0.3, 7.6)	3 (3.0)	(0.6, 8.5)
Foetal distress syndrome	2 (2.2)	(0.3, 7.6)	1 (1.0)	(0.0, 5.4)
Pre-eclampsia	2 (2.2)	(0.3, 7.6)	1 (1.0)	(0.0, 5.4)
Gestational hypertension	1 (1.1)	(0.0, 5.9)	1 (1.0)	(0.0, 5.4)
Meconium stain	1 (1.1)	(0.0, 5.9)	1 (1.0)	(0.0, 5.4)
Premature delivery	0	(0.0, 3.9)	2 (2.0)	(0.2, 7.0)
Premature separation of placenta	0	(0.0, 3.9)	2 (2.0)	(0.2, 7.0)
Abnormal labour	0	(0.0, 3.9)	1 (1.0)	(0.0, 5.4)
Breech presentation	1 (1.1)	(0.0, 5.9)	0	(0.0, 3.6)
Failed induction of labour	1 (1.1)	(0.0, 5.9)	0	(0.0, 3.6)
Gestational diabetes	0	(0.0, 3.9)	1 (1.0)	(0.0, 5.4)
Haemorrhage in pregnancy	1 (1.1)	(0.0, 5.9)	0	(0.0, 3.6)
Placenta accreta	1 (1.1)	(0.0, 5.9)	0	(0.0, 3.6)
Placental insufficiency	0	(0.0, 3.9)	1 (1.0)	(0.0, 5.4)
Postpartum haemorrhage	0	(0.0, 3.9)	1 (1.0)	(0.0, 5.4)
Premature labour	0	(0.0, 3.9)	1 (1.0)	(0.0, 5.4)
Prolonged labour	1 (1.1)	(0.0, 5.9)	0	(0.0, 3.6)
Uterine contractions during pregnancy	1 (1.1)	(0.0, 5.9)	0	(0.0, 3.6)
Psychiatric disorders	1 (1.1)	(0.0, 5.9)	0	(0.0, 3.6)
Perinatal depression	1 (1.1)	(0.0, 5.9)	0	(0.0, 3.6)
Renal and urinary disorders	1 (1.1)	(0.0, 5.9)	1 (1.0)	(0.0, 5.4)
Glycosuria	0	(0.0, 3.9)	1 (1.0)	(0.0, 5.4)
Renal colic	1 (1.1)	(0.0, 5.9)	0	(0.0, 3.6)
Reproductive system and breast disorders	1 (1.1)	(0.0, 5.9)	1 (1.0)	(0.0, 5.4)
Vaginal haemorrhage	1 (1.1)	(0.0, 5.9)	1 (1.0)	(0.0, 5.4)
Cervical polyp	1 (1.1)	(0.0, 5.9)	0	(0.0, 3.6)
Vaginal discharge	0	(0.0, 3.9)	1 (1.0)	(0.0, 5.4)

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14.102. Number (%) of Participants Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Ethnicity – Blinded Follow-Up Period – Safety Population (Maternal) Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=92)		Placebo (N[a]=100)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Respiratory, thoracic and mediastinal disorders	1 (1.1)	(0.0, 5.9)	1 (1.0)	(0.0, 5.4)
Epistaxis	0	(0.0, 3.9)	1 (1.0)	(0.0, 5.4)
Rhinorrhoea	1 (1.1)	(0.0, 5.9)	0	(0.0, 3.6)
Skin and subcutaneous tissue disorders	1 (1.1)	(0.0, 5.9)	1 (1.0)	(0.0, 5.4)
Pruritus	1 (1.1)	(0.0, 5.9)	0	(0.0, 3.6)
Skin hyperpigmentation	0	(0.0, 3.9)	1 (1.0)	(0.0, 5.4)
Vascular disorders	1 (1.1)	(0.0, 5.9)	0	(0.0, 3.6)
Deep vein thrombosis	1 (1.1)	(0.0, 5.9)	0	(0.0, 3.6)

Note: MedDRA (v25.1) coding dictionary applied.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: Nonserious adverse events related to study intervention with onset within 7 days (excluding immediate adverse event and adverse events leading to withdrawal) after vaccination and identified as reactogenicity events were excluded from the analysis of adverse events. These events were included in the analysis of reactogenicity events.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event. For "any event," n = number of participants reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 03MAY2023 (10:40) Output File: ./nda3/C4591015_BR/adae_s130_1md2_soc_p3_eth

14.103. Number (%) of Participants Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Blinded Follow-Up Period – Safety Population (Maternal) Baseline SARS-CoV-2 Status: Positive

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=54)		Placebo (N[a]=58)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	10 (18.5)	(9.3, 31.4)	9 (15.5)	(7.3, 27.4)
Blood and lymphatic system disorders	1 (1.9)	(0.0, 9.9)	0	(0.0, 6.2)
Anaemia	1 (1.9)	(0.0, 9.9)	0	(0.0, 6.2)

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14.103. Number (%) of Participants Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Blinded Follow-Up Period – Safety Population (Maternal) Baseline SARS-CoV-2 Status: Positive

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=54)		Placebo (N[a]=58)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Gastrointestinal disorders	1 (1.9)	(0.0, 9.9)	2 (3.4)	(0.4, 11.9)
Abdominal pain	0	(0.0, 6.6)	2 (3.4)	(0.4, 11.9)
Haemorrhoids	1 (1.9)	(0.0, 9.9)	0	(0.0, 6.2)
General disorders and administration site conditions	0	(0.0, 6.6)	1 (1.7)	(0.0, 9.2)
Injection site pain	0	(0.0, 6.6)	1 (1.7)	(0.0, 9.2)
Infections and infestations	1 (1.9)	(0.0, 9.9)	1 (1.7)	(0.0, 9.2)
Lower respiratory tract infection	1 (1.9)	(0.0, 9.9)	0	(0.0, 6.2)
Pyelonephritis	0	(0.0, 6.6)	1 (1.7)	(0.0, 9.2)
Injury, poisoning and procedural complications	1 (1.9)	(0.0, 9.9)	1 (1.7)	(0.0, 9.2)
Post lumbar puncture syndrome	0	(0.0, 6.6)	1 (1.7)	(0.0, 9.2)
Vulvovaginal injury	1 (1.9)	(0.0, 9.9)	0	(0.0, 6.2)
Investigations	0	(0.0, 6.6)	1 (1.7)	(0.0, 9.2)
Blood pressure systolic increased	0	(0.0, 6.6)	1 (1.7)	(0.0, 9.2)
Metabolism and nutrition disorders	0	(0.0, 6.6)	1 (1.7)	(0.0, 9.2)
Dehydration	0	(0.0, 6.6)	1 (1.7)	(0.0, 9.2)
Musculoskeletal and connective tissue disorders	1 (1.9)	(0.0, 9.9)	0	(0.0, 6.2)
Back pain	1 (1.9)	(0.0, 9.9)	0	(0.0, 6.2)
Pregnancy, puerperium and perinatal conditions	6 (11.1)	(4.2, 22.6)	4 (6.9)	(1.9, 16.7)
Foetal distress syndrome	1 (1.9)	(0.0, 9.9)	1 (1.7)	(0.0, 9.2)
Pre-eclampsia	1 (1.9)	(0.0, 9.9)	1 (1.7)	(0.0, 9.2)
Breech presentation	1 (1.9)	(0.0, 9.9)	0	(0.0, 6.2)
Failed induction of labour	1 (1.9)	(0.0, 9.9)	0	(0.0, 6.2)
Gestational hypertension	1 (1.9)	(0.0, 9.9)	0	(0.0, 6.2)
Meconium in amniotic fluid	0	(0.0, 6.6)	1 (1.7)	(0.0, 9.2)
Meconium stain	1 (1.9)	(0.0, 9.9)	0	(0.0, 6.2)
Placenta accreta	1 (1.9)	(0.0, 9.9)	0	(0.0, 6.2)
Placental insufficiency	0	(0.0, 6.6)	1 (1.7)	(0.0, 9.2)
Premature delivery	0	(0.0, 6.6)	1 (1.7)	(0.0, 9.2)
Prolonged labour	1 (1.9)	(0.0, 9.9)	0	(0.0, 6.2)
Respiratory, thoracic and mediastinal disorders	0	(0.0, 6.6)	1 (1.7)	(0.0, 9.2)
Epistaxis	0	(0.0, 6.6)	1 (1.7)	(0.0, 9.2)
Surgical and medical procedures	1 (1.9)	(0.0, 9.9)	0	(0.0, 6.2)
Episiotomy	1 (1.9)	(0.0, 9.9)	0	(0.0, 6.2)

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14.103. Number (%) of Participants Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Blinded Follow-Up Period – Safety Population (Maternal) Baseline SARS-CoV-2 Status: Positive

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=54)		Placebo (N[a]=58)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])

Abbreviations: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: MedDRA (v25.1) coding dictionary applied.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: Nonserious adverse events related to study intervention with onset within 7 days (excluding immediate adverse event and adverse events leading to withdrawal) after vaccination and identified as reactogenicity events were excluded from the analysis of adverse events. These events were included in the analysis of reactogenicity events.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event. For "any event," n = number of participants reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 03MAY2023 (10:40) Output File: ./nda3/C4591015_BR/adae_s130_1md2_soc_p3_cov

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14.104. Number (%) of Participants Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Blinded Follow-Up Period – Safety Population (Maternal) Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=99)		Placebo (N[a]=101)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	25 (25.3)	(17.1, 35.0)	27 (26.7)	(18.4, 36.5)
Blood and lymphatic system disorders	2 (2.0)	(0.2, 7.1)	4 (4.0)	(1.1, 9.8)
Anaemia	1 (1.0)	(0.0, 5.5)	2 (2.0)	(0.2, 7.0)
Anaemia of pregnancy	0	(0.0, 3.7)	1 (1.0)	(0.0, 5.4)
Iron deficiency anaemia	0	(0.0, 3.7)	1 (1.0)	(0.0, 5.4)
Normocytic anaemia	1 (1.0)	(0.0, 5.5)	0	(0.0, 3.6)
Cardiac disorders	2 (2.0)	(0.2, 7.1)	1 (1.0)	(0.0, 5.4)
Bradycardia foetal	0	(0.0, 3.7)	1 (1.0)	(0.0, 5.4)
Sinus bradycardia	1 (1.0)	(0.0, 5.5)	0	(0.0, 3.6)
Tachycardia	1 (1.0)	(0.0, 5.5)	0	(0.0, 3.6)
Ear and labyrinth disorders	0	(0.0, 3.7)	1 (1.0)	(0.0, 5.4)
Vertigo	0	(0.0, 3.7)	1 (1.0)	(0.0, 5.4)
Eye disorders	1 (1.0)	(0.0, 5.5)	0	(0.0, 3.6)
Vision blurred	1 (1.0)	(0.0, 5.5)	0	(0.0, 3.6)
Gastrointestinal disorders	6 (6.1)	(2.3, 12.7)	7 (6.9)	(2.8, 13.8)
Abdominal pain	2 (2.0)	(0.2, 7.1)	1 (1.0)	(0.0, 5.4)
Gastrooesophageal reflux disease	1 (1.0)	(0.0, 5.5)	2 (2.0)	(0.2, 7.0)
Constipation	0	(0.0, 3.7)	2 (2.0)	(0.2, 7.0)
Dyspepsia	1 (1.0)	(0.0, 5.5)	1 (1.0)	(0.0, 5.4)
Haemorrhoids	0	(0.0, 3.7)	1 (1.0)	(0.0, 5.4)
Nausea	1 (1.0)	(0.0, 5.5)	0	(0.0, 3.6)
Toothache	1 (1.0)	(0.0, 5.5)	0	(0.0, 3.6)
General disorders and administration site conditions	2 (2.0)	(0.2, 7.1)	2 (2.0)	(0.2, 7.0)
Oedema peripheral	1 (1.0)	(0.0, 5.5)	1 (1.0)	(0.0, 5.4)
Chest pain	1 (1.0)	(0.0, 5.5)	0	(0.0, 3.6)
Fatigue	0	(0.0, 3.7)	1 (1.0)	(0.0, 5.4)
Hepatobiliary disorders	1 (1.0)	(0.0, 5.5)	0	(0.0, 3.6)
Cholestasis	1 (1.0)	(0.0, 5.5)	0	(0.0, 3.6)
Immune system disorders	1 (1.0)	(0.0, 5.5)	0	(0.0, 3.6)
Hypersensitivity	1 (1.0)	(0.0, 5.5)	0	(0.0, 3.6)
Infections and infestations	7 (7.1)	(2.9, 14.0)	3 (3.0)	(0.6, 8.4)
Urinary tract infection	4 (4.0)	(1.1, 10.0)	1 (1.0)	(0.0, 5.4)
Cystitis	1 (1.0)	(0.0, 5.5)	0	(0.0, 3.6)
Endometritis	1 (1.0)	(0.0, 5.5)	0	(0.0, 3.6)
Gastroenteritis	1 (1.0)	(0.0, 5.5)	0	(0.0, 3.6)

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14.104. Number (%) of Participants Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Blinded Follow-Up Period – Safety Population (Maternal) Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=99)		Placebo (N[a]=101)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Nasopharyngitis	1 (1.0)	(0.0, 5.5)	0	(0.0, 3.6)
Pneumonia	0	(0.0, 3.7)	1 (1.0)	(0.0, 5.4)
Urinary tract infection bacterial	0	(0.0, 3.7)	1 (1.0)	(0.0, 5.4)
Injury, poisoning and procedural complications	1 (1.0)	(0.0, 5.5)	2 (2.0)	(0.2, 7.0)
Fall	0	(0.0, 3.7)	1 (1.0)	(0.0, 5.4)
Lip injury	1 (1.0)	(0.0, 5.5)	0	(0.0, 3.6)
Skin laceration	1 (1.0)	(0.0, 5.5)	0	(0.0, 3.6)
Urinary tract procedural complication	0	(0.0, 3.7)	1 (1.0)	(0.0, 5.4)
Investigations	2 (2.0)	(0.2, 7.1)	2 (2.0)	(0.2, 7.0)
Blood pressure increased	1 (1.0)	(0.0, 5.5)	0	(0.0, 3.6)
Brain natriuretic peptide increased	1 (1.0)	(0.0, 5.5)	0	(0.0, 3.6)
Electrocardiogram QT prolonged	1 (1.0)	(0.0, 5.5)	0	(0.0, 3.6)
Foetal heart rate abnormal	0	(0.0, 3.7)	1 (1.0)	(0.0, 5.4)
Heart rate increased	0	(0.0, 3.7)	1 (1.0)	(0.0, 5.4)
Musculoskeletal and connective tissue disorders	3 (3.0)	(0.6, 8.6)	1 (1.0)	(0.0, 5.4)
Back pain	1 (1.0)	(0.0, 5.5)	0	(0.0, 3.6)
Groin pain	1 (1.0)	(0.0, 5.5)	0	(0.0, 3.6)
Muscle spasms	0	(0.0, 3.7)	1 (1.0)	(0.0, 5.4)
Myalgia	1 (1.0)	(0.0, 5.5)	0	(0.0, 3.6)
Nervous system disorders	2 (2.0)	(0.2, 7.1)	3 (3.0)	(0.6, 8.4)
Headache	2 (2.0)	(0.2, 7.1)	2 (2.0)	(0.2, 7.0)
Carpal tunnel syndrome	0	(0.0, 3.7)	1 (1.0)	(0.0, 5.4)
Presyncope	1 (1.0)	(0.0, 5.5)	0	(0.0, 3.6)
Sciatica	1 (1.0)	(0.0, 5.5)	0	(0.0, 3.6)
Pregnancy, puerperium and perinatal conditions	8 (8.1)	(3.6, 15.3)	11 (10.9)	(5.6, 18.7)
Foetal hypokinesia	2 (2.0)	(0.2, 7.1)	3 (3.0)	(0.6, 8.4)
Gestational diabetes	0	(0.0, 3.7)	2 (2.0)	(0.2, 7.0)
Haemorrhage in pregnancy	2 (2.0)	(0.2, 7.1)	0	(0.0, 3.6)
Pre-eclampsia	2 (2.0)	(0.2, 7.1)	0	(0.0, 3.6)
Premature separation of placenta	0	(0.0, 3.7)	2 (2.0)	(0.2, 7.0)
Uterine contractions during pregnancy	2 (2.0)	(0.2, 7.1)	0	(0.0, 3.6)
Abnormal labour	0	(0.0, 3.7)	1 (1.0)	(0.0, 5.4)
Gestational hypertension	0	(0.0, 3.7)	1 (1.0)	(0.0, 5.4)
Hyperemesis gravidarum	1 (1.0)	(0.0, 5.5)	0	(0.0, 3.6)
Meconium stain	0	(0.0, 3.7)	1 (1.0)	(0.0, 5.4)
Polyhydramnios	0	(0.0, 3.7)	1 (1.0)	(0.0, 5.4)
Postpartum haemorrhage	0	(0.0, 3.7)	1 (1.0)	(0.0, 5.4)

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14.104. Number (%) of Participants Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Blinded Follow-Up Period – Safety Population (Maternal) Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=99)		Placebo (N[a]=101)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Premature delivery	0	(0.0, 3.7)	1 (1.0)	(0.0, 5.4)
Premature labour	0	(0.0, 3.7)	1 (1.0)	(0.0, 5.4)
Umbilical cord around neck	1 (1.0)	(0.0, 5.5)	0	(0.0, 3.6)
Psychiatric disorders	1 (1.0)	(0.0, 5.5)	0	(0.0, 3.6)
Perinatal depression	1 (1.0)	(0.0, 5.5)	0	(0.0, 3.6)
Renal and urinary disorders	1 (1.0)	(0.0, 5.5)	1 (1.0)	(0.0, 5.4)
Glycosuria	0	(0.0, 3.7)	1 (1.0)	(0.0, 5.4)
Renal colic	1 (1.0)	(0.0, 5.5)	0	(0.0, 3.6)
Reproductive system and breast disorders	2 (2.0)	(0.2, 7.1)	2 (2.0)	(0.2, 7.0)
Vaginal haemorrhage	1 (1.0)	(0.0, 5.5)	2 (2.0)	(0.2, 7.0)
Cervical polyp	1 (1.0)	(0.0, 5.5)	0	(0.0, 3.6)
Genital haemorrhage	1 (1.0)	(0.0, 5.5)	0	(0.0, 3.6)
Vaginal discharge	0	(0.0, 3.7)	1 (1.0)	(0.0, 5.4)
Respiratory, thoracic and mediastinal disorders	2 (2.0)	(0.2, 7.1)	1 (1.0)	(0.0, 5.4)
Cough	0	(0.0, 3.7)	1 (1.0)	(0.0, 5.4)
Rhinorrhoea	1 (1.0)	(0.0, 5.5)	0	(0.0, 3.6)
Tachypnoea	1 (1.0)	(0.0, 5.5)	0	(0.0, 3.6)
Skin and subcutaneous tissue disorders	1 (1.0)	(0.0, 5.5)	1 (1.0)	(0.0, 5.4)
Pruritus	1 (1.0)	(0.0, 5.5)	0	(0.0, 3.6)
Skin hyperpigmentation	0	(0.0, 3.7)	1 (1.0)	(0.0, 5.4)
Vascular disorders	1 (1.0)	(0.0, 5.5)	0	(0.0, 3.6)
Deep vein thrombosis	1 (1.0)	(0.0, 5.5)	0	(0.0, 3.6)

Abbreviations: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: MedDRA (v25.1) coding dictionary applied.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: Nonserious adverse events related to study intervention with onset within 7 days (excluding immediate adverse event and adverse events leading to withdrawal) after vaccination and identified as reactogenicity events were excluded from the analysis of adverse events. These events were included in the analysis of reactogenicity events.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event. For "any event," n = number of participants reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 03MAY2023 (10:40) Output File: ./nda3/C4591015_BR/adae_s130_1md2_soc_p3_cov

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14.105. Number (%) of Participants Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Blinded Follow-Up Period – Safety Population (Maternal) Baseline SARS-CoV-2 Status: Missing

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8)		Placebo (N[a]=4)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	3 (37.5)	(8.5, 75.5)	1 (25.0)	(0.6, 80.6)
Gastrointestinal disorders	0	(0.0, 36.9)	1 (25.0)	(0.6, 80.6)
Diarrhoea	0	(0.0, 36.9)	1 (25.0)	(0.6, 80.6)
General disorders and administration site conditions	1 (12.5)	(0.3, 52.7)	0	(0.0, 60.2)
Hypothermia	1 (12.5)	(0.3, 52.7)	0	(0.0, 60.2)
Musculoskeletal and connective tissue disorders	1 (12.5)	(0.3, 52.7)	0	(0.0, 60.2)
Arthralgia	1 (12.5)	(0.3, 52.7)	0	(0.0, 60.2)
Pregnancy, puerperium and perinatal conditions	1 (12.5)	(0.3, 52.7)	0	(0.0, 60.2)
Foetal distress syndrome	1 (12.5)	(0.3, 52.7)	0	(0.0, 60.2)

Abbreviations: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: MedDRA (v25.1) coding dictionary applied.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: Nonserious adverse events related to study intervention with onset within 7 days (excluding immediate adverse event and adverse events leading to withdrawal) after vaccination and identified as reactogenicity events were excluded from the analysis of adverse events. These events were included in the analysis of reactogenicity events.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event. For "any event," n = number of participants reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 03MAY2023 (10:40) Output File: ./nda3/C4591015_BR/adae_s130_1md2_soc_p3_cov

14.106. Number (%) of Participants Reporting at Least 1 Adverse Event From Birth to 1 Month of Age, by System Organ Class and Preferred Term – Safety Population (Infant)

	Maternal Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=156)		Placebo (N[a]=159)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	55 (35.3)	(27.8, 43.3)	59 (37.1)	(29.6, 45.1)

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14.106. Number (%) of Participants Reporting at Least 1 Adverse Event From Birth to 1 Month of Age, by System Organ Class and Preferred Term – Safety Population (Infant)

System Organ Class Preferred Term	Maternal Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=156)		Placebo (N[a]=159)	
	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Blood and lymphatic system disorders	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Coagulopathy	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Thrombocytopenia	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Cardiac disorders	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Bradycardia	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Congenital, familial and genetic disorders	16 (10.3)	(6.0, 16.1)	8 (5.0)	(2.2, 9.7)
Ankyloglossia congenital	1 (0.6)	(0.0, 3.5)	4 (2.5)	(0.7, 6.3)
Atrial septal defect	3 (1.9)	(0.4, 5.5)	1 (0.6)	(0.0, 3.5)
Congenital naevus	3 (1.9)	(0.4, 5.5)	1 (0.6)	(0.0, 3.5)
Congenital skin dimples	0	(0.0, 2.3)	2 (1.3)	(0.2, 4.5)
Hydrocele	2 (1.3)	(0.2, 4.6)	0	(0.0, 2.3)
Congenital rubella syndrome	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
DiGeorge's syndrome	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Microcephaly	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Mucopolysaccharidosis	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Naevus flammeus	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Patent ductus arteriosus	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Phimosis	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Polydactyly	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Syndactyly	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Trisomy 21	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Ventricular septal defect	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Endocrine disorders	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Adrenal insufficiency	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Eye disorders	1 (0.6)	(0.0, 3.5)	3 (1.9)	(0.4, 5.4)
Dacryostenosis acquired	1 (0.6)	(0.0, 3.5)	1 (0.6)	(0.0, 3.5)
Conjunctival haemorrhage	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Eye discharge	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Eyelid oedema	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Gastrointestinal disorders	2 (1.3)	(0.2, 4.6)	6 (3.8)	(1.4, 8.0)
Constipation	1 (0.6)	(0.0, 3.5)	1 (0.6)	(0.0, 3.5)
Abdominal distension	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Allergic colitis	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Allergic gastroenteritis	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Dysphagia	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Infantile colic	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Intestinal perforation	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Meconium plug syndrome	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)

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14.106. Number (%) of Participants Reporting at Least 1 Adverse Event From Birth to 1 Month of Age, by System Organ Class and Preferred Term – Safety Population (Infant)

	Maternal Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=156)		Placebo (N[a]=159)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Pneumoperitoneum	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Tooth development disorder	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
General disorders and administration site conditions	2 (1.3)	(0.2, 4.6)	2 (1.3)	(0.2, 4.5)
Hypothermia	1 (0.6)	(0.0, 3.5)	2 (1.3)	(0.2, 4.5)
Macrosomia	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Hepatobiliary disorders	1 (0.6)	(0.0, 3.5)	7 (4.4)	(1.8, 8.9)
Hyperbilirubinaemia neonatal	1 (0.6)	(0.0, 3.5)	5 (3.1)	(1.0, 7.2)
Hepatic function abnormal	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Jaundice	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Infections and infestations	4 (2.6)	(0.7, 6.4)	8 (5.0)	(2.2, 9.7)
Neonatal pneumonia	1 (0.6)	(0.0, 3.5)	1 (0.6)	(0.0, 3.5)
Sepsis neonatal	0	(0.0, 2.3)	2 (1.3)	(0.2, 4.5)
Beta haemolytic streptococcal infection	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Candida infection	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Conjunctivitis	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Fungal infection	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Infection	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Ophthalmia neonatorum	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Pyelonephritis acute	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Sepsis	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Injury, poisoning and procedural complications	1 (0.6)	(0.0, 3.5)	3 (1.9)	(0.4, 5.4)
Clavicle fracture	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Contusion	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Exposure to communicable disease	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Injury to brachial plexus due to birth trauma	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Traumatic intracranial haemorrhage	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Investigations	7 (4.5)	(1.8, 9.0)	4 (2.5)	(0.7, 6.3)
Apgar score low	4 (2.6)	(0.7, 6.4)	2 (1.3)	(0.2, 4.5)
Cardiac murmur	3 (1.9)	(0.4, 5.5)	2 (1.3)	(0.2, 4.5)
Metabolism and nutrition disorders	1 (0.6)	(0.0, 3.5)	5 (3.1)	(1.0, 7.2)
Hypoglycaemia neonatal	0	(0.0, 2.3)	3 (1.9)	(0.4, 5.4)
Feeding disorder	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Hypercalcaemia	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Hypernatraemia	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Hypoglycaemia	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Hypokalaemia	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Metabolic acidosis	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)

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14.106. Number (%) of Participants Reporting at Least 1 Adverse Event From Birth to 1 Month of Age, by System Organ Class and Preferred Term – Safety Population (Infant)

	Maternal Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=156)		Placebo (N[a]=159)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Musculoskeletal and connective tissue disorders	2 (1.3)	(0.2, 4.6)	1 (0.6)	(0.0, 3.5)
Joint noise	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Newborn head moulding	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Small fontanelle	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.6)	(0.0, 3.5)	1 (0.6)	(0.0, 3.5)
Haemangioma of bone	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Melanocytic naevus	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Nervous system disorders	3 (1.9)	(0.4, 5.5)	3 (1.9)	(0.4, 5.4)
Hypotonia	2 (1.3)	(0.2, 4.6)	1 (0.6)	(0.0, 3.5)
Coma	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Encephalopathy neonatal	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Hypoxic-ischaemic encephalopathy	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Intraventricular haemorrhage neonatal	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Nervous system disorder	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Seizure	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Pregnancy, puerperium and perinatal conditions	26 (16.7)	(11.2, 23.5)	31 (19.5)	(13.6, 26.5)
Jaundice neonatal	19 (12.2)	(7.5, 18.4)	17 (10.7)	(6.4, 16.6)
Caput succedaneum	3 (1.9)	(0.4, 5.5)	4 (2.5)	(0.7, 6.3)
Small for dates baby	2 (1.3)	(0.2, 4.6)	4 (2.5)	(0.7, 6.3)
Umbilical cord around neck	0	(0.0, 2.3)	5 (3.1)	(1.0, 7.2)
Low birth weight baby	3 (1.9)	(0.4, 5.5)	1 (0.6)	(0.0, 3.5)
Large for dates baby	2 (1.3)	(0.2, 4.6)	0	(0.0, 2.3)
Shoulder dystocia	1 (0.6)	(0.0, 3.5)	1 (0.6)	(0.0, 3.5)
Birth trauma	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Foetal cardiac disorder	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Foetal macrosomia	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Hypothermia neonatal	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Meconium stain	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Postmature baby	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Premature baby	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Weight decrease neonatal	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Renal and urinary disorders	1 (0.6)	(0.0, 3.5)	1 (0.6)	(0.0, 3.5)
Pyelocaliectasis	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Renal tubular necrosis	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Vesicoureteric reflux	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Respiratory, thoracic and mediastinal disorders	8 (5.1)	(2.2, 9.9)	12 (7.5)	(4.0, 12.8)
Meconium aspiration syndrome	3 (1.9)	(0.4, 5.5)	1 (0.6)	(0.0, 3.5)

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14.106. Number (%) of Participants Reporting at Least 1 Adverse Event From Birth to 1 Month of Age, by System Organ Class and Preferred Term – Safety Population (Infant)

	Maternal Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=156)		Placebo (N[a]=159)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Tachypnoea	1 (0.6)	(0.0, 3.5)	2 (1.3)	(0.2, 4.5)
Nasal congestion	1 (0.6)	(0.0, 3.5)	1 (0.6)	(0.0, 3.5)
Neonatal respiratory distress	0	(0.0, 2.3)	2 (1.3)	(0.2, 4.5)
Respiratory distress	1 (0.6)	(0.0, 3.5)	1 (0.6)	(0.0, 3.5)
Apnoea	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Cyanosis neonatal	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Hypoxia	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Nasal obstruction	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Neonatal pneumothorax	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Neonatal respiratory distress syndrome	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Neonatal respiratory failure	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Pulmonary hypertension	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Respiratory disorder	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Respiratory failure	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Transient tachypnoea of the newborn	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Skin and subcutaneous tissue disorders	3 (1.9)	(0.4, 5.5)	4 (2.5)	(0.7, 6.3)
Dermal cyst	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Ecchymosis	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Erythema toxicum neonatorum	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Hypertrichosis	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Macule	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Seborrhoeic dermatitis	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Transient neonatal pustular melanosis	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Surgical and medical procedures	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Tongue tie operation	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Vascular disorders	1 (0.6)	(0.0, 3.5)	3 (1.9)	(0.4, 5.4)
Cyanosis	1 (0.6)	(0.0, 3.5)	1 (0.6)	(0.0, 3.5)
Hypertension	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Hypoperfusion	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Hypotension	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Renovascular hypertension	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Shock	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Subgaleal haemorrhage	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)

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14.106. Number (%) of Participants Reporting at Least 1 Adverse Event From Birth to 1 Month of Age, by System Organ Class and Preferred Term – Safety Population (Infant)

	Maternal Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=156)		Placebo (N[a]=159)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])

Note: MedDRA (v25.1) coding dictionary applied.
Note: Infants born to human immunodeficiency virus (HIV)-positive participants are not included in this summary. Analyses for HIV-positive participants and their infants will be summarized separately.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event. For "any event," n = number of participants reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
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14.107. Tier 2 Adverse Events Reported From Birth to 1 Month of Age, by System Organ Class and Preferred Term – Safety Population (Infant)

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]= 156)		Placebo (N[a]= 159)		Difference	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	%[d]	(95% CI[e])
Congenital, familial and genetic disorders						
Ankyloglossia congenital	1 (0.6)	(0.0, 3.5)	4 (2.5)	(0.7, 6.3)	-1.9	(-5.7, 1.3)
Atrial septal defect	3 (1.9)	(0.4, 5.5)	1 (0.6)	(0.0, 3.5)	1.3	(-1.7, 5.0)
Congenital naevus	3 (1.9)	(0.4, 5.5)	1 (0.6)	(0.0, 3.5)	1.3	(-1.7, 5.0)
Congenital skin dimples	0	(0.0, 2.3)	2 (1.3)	(0.2, 4.5)	-1.3	(-4.5, 1.2)
Hydrocele	2 (1.3)	(0.2, 4.6)	0	(0.0, 2.3)	1.3	(-1.1, 4.6)
General disorders and administration site conditions						
Hypothermia	1 (0.6)	(0.0, 3.5)	2 (1.3)	(0.2, 4.5)	-0.6	(-3.9, 2.4)
Hepatobiliary disorders						
Hyperbilirubinaemia neonatal	1 (0.6)	(0.0, 3.5)	5 (3.1)	(1.0, 7.2)	-2.5	(-6.6, 0.7)
Infections and infestations						
Sepsis neonatal	0	(0.0, 2.3)	2 (1.3)	(0.2, 4.5)	-1.3	(-4.5, 1.2)
Investigations						
Apgar score low	4 (2.6)	(0.7, 6.4)	2 (1.3)	(0.2, 4.5)	1.3	(-2.2, 5.3)
Cardiac murmur	3 (1.9)	(0.4, 5.5)	2 (1.3)	(0.2, 4.5)	0.7	(-2.8, 4.4)

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14.107. Tier 2 Adverse Events Reported From Birth to 1 Month of Age, by System Organ Class and Preferred Term – Safety Population (Infant)

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]= 156)		Placebo (N[a]= 159)		Difference	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	%[d]	(95% CI[e])
Metabolism and nutrition disorders						
Hypoglycaemia neonatal	0	(0.0, 2.3)	3 (1.9)	(0.4, 5.4)	-1.9	(-5.4, 0.5)
Nervous system disorders						
Hypotonia	2 (1.3)	(0.2, 4.6)	1 (0.6)	(0.0, 3.5)	0.7	(-2.3, 4.0)
Pregnancy, puerperium and perinatal conditions						
Jaundice neonatal	19 (12.2)	(7.5, 18.4)	17 (10.7)	(6.4, 16.6)	1.5	(-5.7, 8.8)
Caput succedaneum	3 (1.9)	(0.4, 5.5)	4 (2.5)	(0.7, 6.3)	-0.6	(-4.6, 3.3)
Small for dates baby	2 (1.3)	(0.2, 4.6)	4 (2.5)	(0.7, 6.3)	-1.2	(-5.2, 2.3)
Umbilical cord around neck	0	(0.0, 2.3)	5 (3.1)	(1.0, 7.2)	-3.1	(-7.2, -0.7)
Low birth weight baby	3 (1.9)	(0.4, 5.5)	1 (0.6)	(0.0, 3.5)	1.3	(-1.7, 5.0)
Large for dates baby	2 (1.3)	(0.2, 4.6)	0	(0.0, 2.3)	1.3	(-1.1, 4.6)
Respiratory, thoracic and mediastinal disorders						
Meconium aspiration syndrome	3 (1.9)	(0.4, 5.5)	1 (0.6)	(0.0, 3.5)	1.3	(-1.7, 5.0)
Tachypnoea	1 (0.6)	(0.0, 3.5)	2 (1.3)	(0.2, 4.5)	-0.6	(-3.9, 2.4)
Neonatal respiratory distress	0	(0.0, 2.3)	2 (1.3)	(0.2, 4.5)	-1.3	(-4.5, 1.2)

Note: MedDRA (v25.1) coding dictionary applied.
Note: Infants born to human immunodeficiency virus (HIV)-positive participants are not included in this summary. Analyses for HIV-positive participants and their infants will be listed separately.
Note: Tier 2 events are common adverse events with an incidence rate greater or equal to 1.0% in any vaccine group (preferred term level). No Tier 1 events were identified at this stage for this program.
Note: The 95% confidence interval quantifies the precision of the risk difference estimate. Confidence intervals are not adjusted for multiplicity. They should only be used to identify potentially important adverse events.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event. For "any event" n = number of participants reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
d. Difference in proportions, expressed as a percentage (BNT162b2 [30 µg] - placebo).
e. 2-Sided CI, based on the Miettinen and Nurminen method for the difference in proportions, expressed as a percentage.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 09MAY2023 (09:53) Output File: ./nda3/C4591015_BR/adae_s130_1md2_soc_p3_inf_t2

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14.108. Number (%) of Participants Reporting at Least 1 Adverse Event From Birth to 1 Month of Age, by System Organ Class and Preferred Term – Born to HIV-Positive Maternal Participants – Safety Population (Infant)

System Organ Class Preferred Term	Maternal Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=11)		Placebo (N[a]=9)	
	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	1 (9.1)	(0.2, 41.3)	4 (44.4)	(13.7, 78.8)
Congenital, familial and genetic disorders	0	(0.0, 28.5)	1 (11.1)	(0.3, 48.2)
Polydactyly	0	(0.0, 28.5)	1 (11.1)	(0.3, 48.2)
Infections and infestations	0	(0.0, 28.5)	1 (11.1)	(0.3, 48.2)
Neonatal pneumonia	0	(0.0, 28.5)	1 (11.1)	(0.3, 48.2)
Injury, poisoning and procedural complications	0	(0.0, 28.5)	1 (11.1)	(0.3, 48.2)
Exposure to communicable disease	0	(0.0, 28.5)	1 (11.1)	(0.3, 48.2)
Pregnancy, puerperium and perinatal conditions	1 (9.1)	(0.2, 41.3)	1 (11.1)	(0.3, 48.2)
Jaundice neonatal	0	(0.0, 28.5)	1 (11.1)	(0.3, 48.2)
Small for dates baby	1 (9.1)	(0.2, 41.3)	0	(0.0, 33.6)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event. For "any event," n = number of participants reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 10MAY2023 (14:36) Output File: ./nda3/C4591015_BR/adae_s130_1md2_soc_p3_inhiv

14.109. Number (%) of Participants Reporting at Least 1 Adverse Event From Birth to 1 Month of Age, by System Organ Class and Preferred Term, by Breastfeeding Status – Safety Population (Infant) Breastfeeding Status: Yes

System Organ Class Preferred Term	Maternal Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=142)		Placebo (N[a]=146)	
	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	53 (37.3)	(29.4, 45.8)	53 (36.3)	(28.5, 44.7)
Blood and lymphatic system disorders	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Coagulopathy	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)

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14.109. Number (%) of Participants Reporting at Least 1 Adverse Event From Birth to 1 Month of Age, by System Organ Class and Preferred Term, by Breastfeeding Status – Safety Population (Infant) Breastfeeding Status: Yes

System Organ Class Preferred Term	Maternal Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=142)		Placebo (N[a]=146)	
	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Thrombocytopenia	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Cardiac disorders	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Bradycardia	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Congenital, familial and genetic disorders	16 (11.3)	(6.6, 17.7)	8 (5.5)	(2.4, 10.5)
Ankyloglossia congenital	1 (0.7)	(0.0, 3.9)	4 (2.7)	(0.8, 6.9)
Atrial septal defect	3 (2.1)	(0.4, 6.0)	1 (0.7)	(0.0, 3.8)
Congenital naevus	3 (2.1)	(0.4, 6.0)	1 (0.7)	(0.0, 3.8)
Congenital skin dimples	0	(0.0, 2.6)	2 (1.4)	(0.2, 4.9)
Hydrocele	2 (1.4)	(0.2, 5.0)	0	(0.0, 2.5)
Congenital rubella syndrome	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
DiGeorge's syndrome	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Microcephaly	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Mucopolysaccharidosis	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Naevus flammeus	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Patent ductus arteriosus	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Phimosis	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Polydactyly	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Syndactyly	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Trisomy 21	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Ventricular septal defect	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Endocrine disorders	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Adrenal insufficiency	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Eye disorders	0	(0.0, 2.6)	3 (2.1)	(0.4, 5.9)
Conjunctival haemorrhage	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Dacryostenosis acquired	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Eye discharge	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Eyelid oedema	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Gastrointestinal disorders	2 (1.4)	(0.2, 5.0)	5 (3.4)	(1.1, 7.8)
Constipation	1 (0.7)	(0.0, 3.9)	1 (0.7)	(0.0, 3.8)
Abdominal distension	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Allergic colitis	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Allergic gastroenteritis	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Dysphagia	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Infantile colic	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Intestinal perforation	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Meconium plug syndrome	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Pneumoperitoneum	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
General disorders and administration site conditions	2 (1.4)	(0.2, 5.0)	2 (1.4)	(0.2, 4.9)

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14.109. Number (%) of Participants Reporting at Least 1 Adverse Event From Birth to 1 Month of Age, by System Organ Class and Preferred Term, by Breastfeeding Status – Safety Population (Infant) Breastfeeding Status: Yes

System Organ Class Preferred Term	Maternal Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=142)		Placebo (N[a]=146)	
	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Hypothermia	1 (0.7)	(0.0, 3.9)	2 (1.4)	(0.2, 4.9)
Macrosomia	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Hepatobiliary disorders	1 (0.7)	(0.0, 3.9)	7 (4.8)	(1.9, 9.6)
Hyperbilirubinaemia neonatal	1 (0.7)	(0.0, 3.9)	5 (3.4)	(1.1, 7.8)
Hepatic function abnormal	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Jaundice	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Infections and infestations	4 (2.8)	(0.8, 7.1)	7 (4.8)	(1.9, 9.6)
Sepsis neonatal	0	(0.0, 2.6)	2 (1.4)	(0.2, 4.9)
Beta haemolytic streptococcal infection	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Candida infection	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Conjunctivitis	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Fungal infection	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Infection	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Neonatal pneumonia	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Ophthalmia neonatorum	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Pyelonephritis acute	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Sepsis	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Injury, poisoning and procedural complications	1 (0.7)	(0.0, 3.9)	3 (2.1)	(0.4, 5.9)
Clavicle fracture	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Contusion	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Exposure to communicable disease	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Injury to brachial plexus due to birth trauma	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Traumatic intracranial haemorrhage	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Investigations	6 (4.2)	(1.6, 9.0)	4 (2.7)	(0.8, 6.9)
Apgar score low	3 (2.1)	(0.4, 6.0)	2 (1.4)	(0.2, 4.9)
Cardiac murmur	3 (2.1)	(0.4, 6.0)	2 (1.4)	(0.2, 4.9)
Metabolism and nutrition disorders	1 (0.7)	(0.0, 3.9)	4 (2.7)	(0.8, 6.9)
Hypoglycaemia neonatal	0	(0.0, 2.6)	3 (2.1)	(0.4, 5.9)
Hypercalcaemia	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Hypernatraemia	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Hypoglycaemia	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Hypokalaemia	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Metabolic acidosis	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Musculoskeletal and connective tissue disorders	2 (1.4)	(0.2, 5.0)	1 (0.7)	(0.0, 3.8)
Joint noise	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Newborn head moulding	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Small fontanelle	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)

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14.109. Number (%) of Participants Reporting at Least 1 Adverse Event From Birth to 1 Month of Age, by System Organ Class and Preferred Term, by Breastfeeding Status – Safety Population (Infant) Breastfeeding Status: Yes

System Organ Class Preferred Term	Maternal Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=142)		Placebo (N[a]=146)	
	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.7)	(0.0, 3.9)	1 (0.7)	(0.0, 3.8)
Haemangioma of bone	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Melanocytic naevus	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Nervous system disorders	3 (2.1)	(0.4, 6.0)	3 (2.1)	(0.4, 5.9)
Hypotonia	2 (1.4)	(0.2, 5.0)	1 (0.7)	(0.0, 3.8)
Coma	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Encephalopathy neonatal	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Hypoxic-ischaemic encephalopathy	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Intraventricular haemorrhage neonatal	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Nervous system disorder	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Seizure	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Pregnancy, puerperium and perinatal conditions	26 (18.3)	(12.3, 25.7)	28 (19.2)	(13.1, 26.5)
Jaundice neonatal	19 (13.4)	(8.3, 20.1)	15 (10.3)	(5.9, 16.4)
Caput succedaneum	3 (2.1)	(0.4, 6.0)	4 (2.7)	(0.8, 6.9)
Small for dates baby	2 (1.4)	(0.2, 5.0)	4 (2.7)	(0.8, 6.9)
Umbilical cord around neck	0	(0.0, 2.6)	5 (3.4)	(1.1, 7.8)
Low birth weight baby	3 (2.1)	(0.4, 6.0)	1 (0.7)	(0.0, 3.8)
Large for dates baby	2 (1.4)	(0.2, 5.0)	0	(0.0, 2.5)
Shoulder dystocia	1 (0.7)	(0.0, 3.9)	1 (0.7)	(0.0, 3.8)
Birth trauma	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Foetal cardiac disorder	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Hypothermia neonatal	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Meconium stain	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Postmature baby	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Premature baby	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Weight decrease neonatal	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Renal and urinary disorders	1 (0.7)	(0.0, 3.9)	1 (0.7)	(0.0, 3.8)
Pyelocaliectasis	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Renal tubular necrosis	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Vesicoureteric reflux	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Respiratory, thoracic and mediastinal disorders	8 (5.6)	(2.5, 10.8)	12 (8.2)	(4.3, 13.9)
Meconium aspiration syndrome	3 (2.1)	(0.4, 6.0)	1 (0.7)	(0.0, 3.8)
Tachypnoea	1 (0.7)	(0.0, 3.9)	2 (1.4)	(0.2, 4.9)
Nasal congestion	1 (0.7)	(0.0, 3.9)	1 (0.7)	(0.0, 3.8)
Neonatal respiratory distress	0	(0.0, 2.6)	2 (1.4)	(0.2, 4.9)
Respiratory distress	1 (0.7)	(0.0, 3.9)	1 (0.7)	(0.0, 3.8)
Apnoea	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)

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14.109. Number (%) of Participants Reporting at Least 1 Adverse Event From Birth to 1 Month of Age, by System Organ Class and Preferred Term, by Breastfeeding Status – Safety Population (Infant) Breastfeeding Status: Yes

	Maternal Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=142)		Placebo (N[a]=146)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Cyanosis neonatal	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Hypoxia	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Nasal obstruction	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Neonatal pneumothorax	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Neonatal respiratory distress syndrome	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Neonatal respiratory failure	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Pulmonary hypertension	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Respiratory disorder	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Respiratory failure	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Transient tachypnoea of the newborn	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Skin and subcutaneous tissue disorders	3 (2.1)	(0.4, 6.0)	4 (2.7)	(0.8, 6.9)
Dermal cyst	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Ecchymosis	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Erythema toxicum neonatorum	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Hypertrichosis	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Macule	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Seborrhoeic dermatitis	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Transient neonatal pustular melanosis	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Surgical and medical procedures	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Tongue tie operation	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Vascular disorders	1 (0.7)	(0.0, 3.9)	3 (2.1)	(0.4, 5.9)
Cyanosis	1 (0.7)	(0.0, 3.9)	1 (0.7)	(0.0, 3.8)
Hypertension	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Hypoperfusion	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Hypotension	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Renovascular hypertension	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Shock	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Subgaleal haemorrhage	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)

Note: MedDRA (v25.1) coding dictionary applied.
Note: Infants born to human immunodeficiency virus (HIV)-positive participants are not included in this summary.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event. For "any event," n = number of participants reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 09MAY2023 (09:44) Output File: ./nda3/C4591015_BR/adae_s130_1md2_brstfd

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14.110. Number (%) of Participants Reporting at Least 1 Adverse Event From Birth to 1 Month of Age, by System Organ Class and Preferred Term, by Breastfeeding Status – Safety Population (Infant) Breastfeeding Status: No

	Maternal Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=11)		Placebo (N[a]=9)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	2 (18.2)	(2.3, 51.8)	3 (33.3)	(7.5, 70.1)
Eye disorders	1 (9.1)	(0.2, 41.3)	0	(0.0, 33.6)
Dacryostenosis acquired	1 (9.1)	(0.2, 41.3)	0	(0.0, 33.6)
Investigations	1 (9.1)	(0.2, 41.3)	0	(0.0, 33.6)
Apgar score low	1 (9.1)	(0.2, 41.3)	0	(0.0, 33.6)
Metabolism and nutrition disorders	0	(0.0, 28.5)	1 (11.1)	(0.3, 48.2)
Feeding disorder	0	(0.0, 28.5)	1 (11.1)	(0.3, 48.2)
Pregnancy, puerperium and perinatal conditions	0	(0.0, 28.5)	2 (22.2)	(2.8, 60.0)
Jaundice neonatal	0	(0.0, 28.5)	2 (22.2)	(2.8, 60.0)

Note: MedDRA (v25.1) coding dictionary applied.
Note: Infants born to human immunodeficiency virus (HIV)-positive participants are not included in this summary.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event. For "any event," n = number of participants reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 09MAY2023 (09:44) Output File: ./nda3/C4591015_BR/adae_s130_1md2_brstfd

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14.111. Number (%) of Participants Reporting at Least 1 Adverse Event From Birth to 1 Month of Age, by System Organ Class and Preferred Term, by Breastfeeding Status – Safety Population (Infant) Breastfeeding Status: Missing

	Maternal Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=3)		Placebo (N[a]=4)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	0	(0.0, 70.8)	3 (75.0)	(19.4, 99.4)
Gastrointestinal disorders	0	(0.0, 70.8)	1 (25.0)	(0.6, 80.6)
Tooth development disorder	0	(0.0, 70.8)	1 (25.0)	(0.6, 80.6)
Infections and infestations	0	(0.0, 70.8)	1 (25.0)	(0.6, 80.6)
Neonatal pneumonia	0	(0.0, 70.8)	1 (25.0)	(0.6, 80.6)
Pregnancy, puerperium and perinatal conditions	0	(0.0, 70.8)	1 (25.0)	(0.6, 80.6)
Foetal macrosomia	0	(0.0, 70.8)	1 (25.0)	(0.6, 80.6)

Note: MedDRA (v25.1) coding dictionary applied.
Note: Infants born to human immunodeficiency virus (HIV)-positive participants are not included in this summary.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event. For "any event," n = number of participants reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 09MAY2023 (09:44) Output File: ./nda3/C4591015_BR/adae_s130_1md2_brstfd

14.112. Number (%) of Participants Reporting at Least 1 Immediate Adverse Event After Dose 2, by System Organ Class and Preferred Term – Safety Population (Maternal)

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=158)		Placebo (N[a]=160)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
General disorders and administration site conditions	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Injection site pain	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)

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14.112. Number (%) of Participants Reporting at Least 1 Immediate Adverse Event After Dose 2, by System Organ Class and Preferred Term – Safety Population (Maternal)

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=158)		Placebo (N[a]=160)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])

Note: MedDRA (v25.1) coding dictionary applied.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary. Analyses for HIV-positive participants and their infants will be listed separately.
Note: Immediate AE refers to an AE reported in the 30-minute observation period after vaccination.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event. For "any event," n = number of participants reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 09MAY2023 (11:08) Output File: ./nda3/C4591015_BR/adae_s130_immd_vax2_p3_saf

14.113. Number (%) of Participants Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population (Maternal)

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=161)		Placebo (N[a]=163)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	9 (5.6)	(2.6, 10.3)	9 (5.5)	(2.6, 10.2)
Infections and infestations	2 (1.2)	(0.2, 4.4)	1 (0.6)	(0.0, 3.4)
Endometritis	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Lower respiratory tract infection	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Pneumonia	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Injury, poisoning and procedural complications	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Urinary tract procedural complication	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Investigations	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Foetal heart rate abnormal	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Pregnancy, puerperium and perinatal conditions	6 (3.7)	(1.4, 7.9)	7 (4.3)	(1.7, 8.6)
Pre-eclampsia	2 (1.2)	(0.2, 4.4)	1 (0.6)	(0.0, 3.4)
Foetal distress syndrome	1 (0.6)	(0.0, 3.4)	1 (0.6)	(0.0, 3.4)

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14.113. Number (%) of Participants Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population (Maternal)

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=161)		Placebo (N[a]=163)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Foetal hypokinesia	1 (0.6)	(0.0, 3.4)	1 (0.6)	(0.0, 3.4)
Premature separation of placenta	0	(0.0, 2.3)	2 (1.2)	(0.1, 4.4)
Breech presentation	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Failed induction of labour	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Gestational hypertension	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Haemorrhage in pregnancy	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Meconium in amniotic fluid	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Meconium stain	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Placental insufficiency	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Postpartum haemorrhage	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Skin and subcutaneous tissue disorders	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Pruritus	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Vascular disorders	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Deep vein thrombosis	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)

Note: MedDRA (v25.1) coding dictionary applied.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary. Analyses of HIV-positive participants and their infants will be listed separately.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event. For "Any event," n = number of participants reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 03MAY2023 (10:43) Output File: ./nda3/C4591015_BR/adae_s151_2_3_ser

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14.114. Number (%) of Participants Reporting at Least 1 Life-Threatening Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population (Maternal)

	Maternal Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=161)		Placebo (N[a]=163)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	0	(0.0, 2.3)	3 (1.8)	(0.4, 5.3)
Investigations	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Foetal heart rate abnormal	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Pregnancy, puerperium and perinatal conditions	0	(0.0, 2.3)	2 (1.2)	(0.1, 4.4)
Postpartum haemorrhage	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Premature separation of placenta	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)

Note: MedDRA (v25.1) coding dictionary applied.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary. Analyses of HIV-positive participants and their infants will be listed separately.
Note: Nonserious adverse events related to study intervention with onset within 7 days (excluding immediate adverse event and adverse events leading to withdrawal) after vaccination and identified as reactogenicity events were excluded from the analysis of adverse events. These events were included in the analysis of reactogenicity events.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event. For "any event," n = number of participants reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 11MAY2023 (10:44) Output File: ./nda3/C4591015_BR/adae_s130_1md2_p3_life_saf

14.115. Number (%) of Participants Reporting at Least 1 Severe Adverse Event From Birth to 1 Month of Age, by System Organ Class and Preferred Term – Safety Population (Infant)

	Maternal Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=156)		Placebo (N[a]=159)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	5 (3.2)	(1.0, 7.3)	10 (6.3)	(3.1, 11.3)
Blood and lymphatic system disorders	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Coagulopathy	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Congenital, familial and genetic disorders	3 (1.9)	(0.4, 5.5)	0	(0.0, 2.3)
DiGeorge's syndrome	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)

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14.115. Number (%) of Participants Reporting at Least 1 Severe Adverse Event From Birth to 1 Month of Age, by System Organ Class and Preferred Term – Safety Population (Infant)

	Maternal Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=156)		Placebo (N[a]=159)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Microcephaly	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Trisomy 21	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Gastrointestinal disorders	0	(0.0, 2.3)	2 (1.3)	(0.2, 4.5)
Intestinal perforation	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Meconium plug syndrome	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Pneumoperitoneum	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Hepatobiliary disorders	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Hyperbilirubinaemia neonatal	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Infections and infestations	0	(0.0, 2.3)	2 (1.3)	(0.2, 4.5)
Sepsis	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Sepsis neonatal	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Injury, poisoning and procedural complications	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Injury to brachial plexus due to birth trauma	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Investigations	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Apgar score low	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Nervous system disorders	1 (0.6)	(0.0, 3.5)	2 (1.3)	(0.2, 4.5)
Coma	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Encephalopathy neonatal	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Nervous system disorder	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Pregnancy, puerperium and perinatal conditions	2 (1.3)	(0.2, 4.6)	2 (1.3)	(0.2, 4.5)
Jaundice neonatal	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Small for dates baby	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Umbilical cord around neck	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Weight decrease neonatal	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Renal and urinary disorders	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Renal tubular necrosis	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Respiratory, thoracic and mediastinal disorders	0	(0.0, 2.3)	4 (2.5)	(0.7, 6.3)
Neonatal respiratory distress	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Pulmonary hypertension	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Respiratory distress	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Respiratory failure	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Tachypnoea	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Vascular disorders	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Hypoperfusion	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Hypotension	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Shock	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)

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14.115. Number (%) of Participants Reporting at Least 1 Severe Adverse Event From Birth to 1 Month of Age, by System Organ Class and Preferred Term – Safety Population (Infant)

	Maternal Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=156)		Placebo (N[a]=159)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])

Note: MedDRA (v25.1) coding dictionary applied.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary. Analyses of HIV-positive participants and their infants will be listed separately.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event. For "any event," n = number of participants reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 09MAY2023 (09:50) Output File: ./nda3/C4591015_BR/adae_s130_1md2_sev_soc_p3

14.116. Number (%) of Participants Reporting at Least 1 Life-Threatening Adverse Event From Birth to 1 Month of Age, by System Organ Class and Preferred Term – Safety Population (Infant)

	Maternal Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=156)		Placebo (N[a]=159)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	1 (0.6)	(0.0, 3.5)	5 (3.1)	(1.0, 7.2)
Infections and infestations	1 (0.6)	(0.0, 3.5)	1 (0.6)	(0.0, 3.5)
Neonatal pneumonia	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Pyelonephritis acute	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Metabolism and nutrition disorders	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Metabolic acidosis	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Nervous system disorders	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Hypoxic-ischaemic encephalopathy	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Pregnancy, puerperium and perinatal conditions	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Premature baby	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Renal and urinary disorders	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Vesicoureteric reflux	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Respiratory, thoracic and mediastinal disorders	0	(0.0, 2.3)	2 (1.3)	(0.2, 4.5)
Neonatal pneumothorax	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)

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14.116. Number (%) of Participants Reporting at Least 1 Life-Threatening Adverse Event From Birth to 1 Month of Age, by System Organ Class and Preferred Term – Safety Population (Infant)

	Maternal Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=156)		Placebo (N[a]=159)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Neonatal respiratory distress syndrome	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Neonatal respiratory failure	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)

Note: MedDRA (v25.1) coding dictionary applied.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary. Analyses of HIV-positive participants and their infants will be listed separately.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event. For "any event," n = number of participants reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 09MAY2023 (09:51) Output File: ./nda3/C4591015_BR/adae_s130_1md2_p3_life_inf_saf

14.117. Number (%) of Participants Reporting at Least 1 Severe Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population (Maternal)

	Maternal Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=161)		Placebo (N[a]=163)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	7 (4.3)	(1.8, 8.8)	8 (4.9)	(2.1, 9.4)
Blood and lymphatic system disorders	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Anaemia	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Ear and labyrinth disorders	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Vertigo	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Infections and infestations	2 (1.2)	(0.2, 4.4)	1 (0.6)	(0.0, 3.4)
Endometritis	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Lower respiratory tract infection	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Pneumonia	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Pregnancy, puerperium and perinatal conditions	3 (1.9)	(0.4, 5.3)	5 (3.1)	(1.0, 7.0)
Pre-eclampsia	1 (0.6)	(0.0, 3.4)	1 (0.6)	(0.0, 3.4)
Abnormal labour	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)

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14.117. Number (%) of Participants Reporting at Least 1 Severe Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population (Maternal)

	Maternal Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=161)		Placebo (N[a]=163)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Foetal hypokinesia	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Haemorrhage in pregnancy	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Placental insufficiency	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Premature delivery	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Premature separation of placenta	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Renal and urinary disorders	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Renal colic	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Reproductive system and breast disorders	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Vaginal haemorrhage	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.4)
Skin and subcutaneous tissue disorders	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)
Pruritus	1 (0.6)	(0.0, 3.4)	0	(0.0, 2.2)

Note: MedDRA (v25.1) coding dictionary applied.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary. Analyses of HIV-positive participants and their infants will be listed separately.
Note: Nonserious adverse events related to study intervention with onset within 7 days (excluding immediate adverse event and adverse events leading to withdrawal) after vaccination and identified as reactogenicity events were excluded from the analysis of adverse events. These events were included in the analysis of reactogenicity events.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event. For "any event," n = number of participants reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 03MAY2023 (10:44) Output File: ./nda3/C4591015_BR/adae_s130_1md2_sev_soc_p3_inf

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14.118. Number (%) of Participants Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months Postdelivery, by System Organ Class and Preferred Term – Participants Originally Received BNT162b2 – Blinded and Open-Label Follow-Up Period – Safety Population (Maternal)

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=161)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Any event	21 (13.0)	(8.3, 19.2)
Cardiac disorders	1 (0.6)	(0.0, 3.4)
Bradycardia foetal	1 (0.6)	(0.0, 3.4)
Gastrointestinal disorders	1 (0.6)	(0.0, 3.4)
Abdominal wall haematoma	1 (0.6)	(0.0, 3.4)
Infections and infestations	3 (1.9)	(0.4, 5.3)
Endometritis	1 (0.6)	(0.0, 3.4)
Lower respiratory tract infection	1 (0.6)	(0.0, 3.4)
Pyelonephritis	1 (0.6)	(0.0, 3.4)
Musculoskeletal and connective tissue disorders	1 (0.6)	(0.0, 3.4)
Osteoarthritis	1 (0.6)	(0.0, 3.4)
Pregnancy, puerperium and perinatal conditions	13 (8.1)	(4.4, 13.4)
Pre-eclampsia	4 (2.5)	(0.7, 6.2)
Foetal distress syndrome	3 (1.9)	(0.4, 5.3)
Breech presentation	1 (0.6)	(0.0, 3.4)
Cephalo-pelvic disproportion	1 (0.6)	(0.0, 3.4)
Failed induction of labour	1 (0.6)	(0.0, 3.4)
Foetal growth restriction	1 (0.6)	(0.0, 3.4)
Foetal hypokinesia	1 (0.6)	(0.0, 3.4)
Gestational hypertension	1 (0.6)	(0.0, 3.4)
Haemorrhage in pregnancy	1 (0.6)	(0.0, 3.4)
Meconium stain	1 (0.6)	(0.0, 3.4)
Retained placenta or membranes	1 (0.6)	(0.0, 3.4)
Reproductive system and breast disorders	2 (1.2)	(0.2, 4.4)
Uterine disorder	2 (1.2)	(0.2, 4.4)
Skin and subcutaneous tissue disorders	1 (0.6)	(0.0, 3.4)
Pruritus	1 (0.6)	(0.0, 3.4)
Vascular disorders	1 (0.6)	(0.0, 3.4)
Deep vein thrombosis	1 (0.6)	(0.0, 3.4)

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14.118. Number (%) of Participants Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months Postdelivery, by System Organ Class and Preferred Term – Participants Originally Received BNT162b2 – Blinded and Open-Label Follow-Up Period – Safety Population (Maternal)

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=161)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])

Note: MedDRA (v25.1) coding dictionary applied.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary. Analyses of HIV-positive participants and their infants will be listed separately.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event. For "any event," n = number of participants reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 11MAY2023 (10:35) Output File: ./nda3/C4591015_BR/adae_s130_immd_vax2_all_p3_2_saf

14.119. Number (%) of Participants Reporting at Least 1 Serious Adverse Event From Dose 1 Through 1 Month After Delivery, by System Organ Class and Preferred Term – HIV-Positive Participants – Blinded Follow-Up Period – Safety Population (Maternal)

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12)		Placebo (N[a]=10)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	2 (16.7)	(2.1, 48.4)	4 (40.0)	(12.2, 73.8)
Blood and lymphatic system disorders	1 (8.3)	(0.2, 38.5)	0	(0.0, 30.8)
Anaemia	1 (8.3)	(0.2, 38.5)	0	(0.0, 30.8)
Pregnancy, puerperium and perinatal conditions	2 (16.7)	(2.1, 48.4)	4 (40.0)	(12.2, 73.8)
Foetal distress syndrome	1 (8.3)	(0.2, 38.5)	1 (10.0)	(0.3, 44.5)
Cephalo-pelvic disproportion	0	(0.0, 26.5)	1 (10.0)	(0.3, 44.5)
Failed trial of labour	0	(0.0, 26.5)	1 (10.0)	(0.3, 44.5)
Foetal death	1 (8.3)	(0.2, 38.5)	0	(0.0, 30.8)
Foetal hypokinesia	0	(0.0, 26.5)	1 (10.0)	(0.3, 44.5)
Postpartum haemorrhage	1 (8.3)	(0.2, 38.5)	0	(0.0, 30.8)
Premature separation of placenta	1 (8.3)	(0.2, 38.5)	0	(0.0, 30.8)

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14.119. Number (%) of Participants Reporting at Least 1 Serious Adverse Event From Dose 1 Through 1 Month After Delivery, by System Organ Class and Preferred Term – HIV-Positive Participants – Blinded Follow-Up Period – Safety Population (Maternal)

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12)		Placebo (N[a]=10)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event. For "any event," n = number of participants reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 11MAY2023 (10:34) Output File: ./nda3/C4591015_BR/adae_s130_immd_vax1_all_p3_hiv

14.120. Number (%) of Participants Reporting at Least 1 Serious Adverse Event From Dose 1 Through 1 Month After Delivery, by System Organ Class and Preferred Term, by Race – Blinded Follow-Up Period – Safety Population (Maternal) Race: White

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=117)		Placebo (N[a]=118)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	12 (10.3)	(5.4, 17.2)	14 (11.9)	(6.6, 19.1)
Cardiac disorders	1 (0.9)	(0.0, 4.7)	2 (1.7)	(0.2, 6.0)
Nonreassuring foetal heart rate pattern	0	(0.0, 3.1)	2 (1.7)	(0.2, 6.0)
Bradycardia foetal	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Gastrointestinal disorders	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Abdominal wall haematoma	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Hepatobiliary disorders	0	(0.0, 3.1)	1 (0.8)	(0.0, 4.6)
Cholelithiasis	0	(0.0, 3.1)	1 (0.8)	(0.0, 4.6)
Infections and infestations	1 (0.9)	(0.0, 4.7)	1 (0.8)	(0.0, 4.6)
Pneumonia	0	(0.0, 3.1)	1 (0.8)	(0.0, 4.6)
Pyelonephritis	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Injury, poisoning and procedural complications	0	(0.0, 3.1)	1 (0.8)	(0.0, 4.6)
Urinary tract procedural complication	0	(0.0, 3.1)	1 (0.8)	(0.0, 4.6)

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14.120. Number (%) of Participants Reporting at Least 1 Serious Adverse Event From Dose 1 Through 1 Month After Delivery, by System Organ Class and Preferred Term, by Race – Blinded Follow-Up Period – Safety Population (Maternal) Race: White

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=117)		Placebo (N[a]=118)	
	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Investigations	0	(0.0, 3.1)	2 (1.7)	(0.2, 6.0)
Foetal heart rate abnormal	0	(0.0, 3.1)	1 (0.8)	(0.0, 4.6)
Ultrasound foetal abnormal	0	(0.0, 3.1)	1 (0.8)	(0.0, 4.6)
Pregnancy, puerperium and perinatal conditions	7 (6.0)	(2.4, 11.9)	9 (7.6)	(3.5, 14.0)
Pre-eclampsia	4 (3.4)	(0.9, 8.5)	1 (0.8)	(0.0, 4.6)
Foetal hypokinesia	1 (0.9)	(0.0, 4.7)	1 (0.8)	(0.0, 4.6)
Gestational hypertension	1 (0.9)	(0.0, 4.7)	1 (0.8)	(0.0, 4.6)
Premature separation of placenta	0	(0.0, 3.1)	2 (1.7)	(0.2, 6.0)
Arrested labour	0	(0.0, 3.1)	1 (0.8)	(0.0, 4.6)
Failed induction of labour	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Foetal distress syndrome	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Foetal growth restriction	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Meconium in amniotic fluid	0	(0.0, 3.1)	1 (0.8)	(0.0, 4.6)
Omphalorrhexis	0	(0.0, 3.1)	1 (0.8)	(0.0, 4.6)
Postpartum haemorrhage	0	(0.0, 3.1)	1 (0.8)	(0.0, 4.6)
Prolonged rupture of membranes	0	(0.0, 3.1)	1 (0.8)	(0.0, 4.6)
Reproductive system and breast disorders	2 (1.7)	(0.2, 6.0)	0	(0.0, 3.1)
Uterine disorder	2 (1.7)	(0.2, 6.0)	0	(0.0, 3.1)
Skin and subcutaneous tissue disorders	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Pruritus	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Vascular disorders	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)
Deep vein thrombosis	1 (0.9)	(0.0, 4.7)	0	(0.0, 3.1)

Note: MedDRA (v25.1) coding dictionary applied.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: All others = American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event. For "any event," n = number of participants reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 03MAY2023 (10:43) Output File: ./nda3/C4591015_BR/adae_s130_immd_vax1_all_rac_saf

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14.121. Number (%) of Participants Reporting at Least 1 Serious Adverse Event From Dose 1 Through 1 Month After Delivery, by System Organ Class and Preferred Term, by Race – Blinded Follow-Up Period – Safety Population (Maternal) Race: Black or African American

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=35) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=33) n[b] (%)	 (95% CI[c])
Any event	7 (20.0)	(8.4, 36.9)	8 (24.2)	(11.1, 42.3)
Infections and infestations	1 (2.9)	(0.1, 14.9)	1 (3.0)	(0.1, 15.8)
Lower respiratory tract infection	1 (2.9)	(0.1, 14.9)	0	(0.0, 10.6)
Urinary tract infection	0	(0.0, 10.0)	1 (3.0)	(0.1, 15.8)
Musculoskeletal and connective tissue disorders	1 (2.9)	(0.1, 14.9)	0	(0.0, 10.6)
Osteoarthritis	1 (2.9)	(0.1, 14.9)	0	(0.0, 10.6)
Pregnancy, puerperium and perinatal conditions	5 (14.3)	(4.8, 30.3)	7 (21.2)	(9.0, 38.9)
Cephalo-pelvic disproportion	1 (2.9)	(0.1, 14.9)	3 (9.1)	(1.9, 24.3)
Foetal distress syndrome	2 (5.7)	(0.7, 19.2)	2 (6.1)	(0.7, 20.2)
Breech presentation	1 (2.9)	(0.1, 14.9)	0	(0.0, 10.6)
Meconium stain	1 (2.9)	(0.1, 14.9)	0	(0.0, 10.6)
Placental insufficiency	0	(0.0, 10.0)	1 (3.0)	(0.1, 15.8)
Postpartum haemorrhage	0	(0.0, 10.0)	1 (3.0)	(0.1, 15.8)
Pre-eclampsia	0	(0.0, 10.0)	1 (3.0)	(0.1, 15.8)
Preterm premature rupture of membranes	0	(0.0, 10.0)	1 (3.0)	(0.1, 15.8)
Retained placenta or membranes	1 (2.9)	(0.1, 14.9)	0	(0.0, 10.6)

Note: MedDRA (v25.1) coding dictionary applied.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: All others = American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event. For "any event," n = number of participants reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 03MAY2023 (10:43) Output File: ./nda3/C4591015_BR/adae_s130_immd_vax1_all_rac_saf

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14.122. Number (%) of Participants Reporting at Least 1 Serious Adverse Event From Dose 1 Through 1 Month After Delivery, by System Organ Class and Preferred Term, by Race – Blinded Follow-Up Period – Safety Population (Maternal) Race: All Others

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=9)		Placebo (N[a]=12)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	2 (22.2)	(2.8, 60.0)	1 (8.3)	(0.2, 38.5)
Infections and infestations	1 (11.1)	(0.3, 48.2)	0	(0.0, 26.5)
Endometritis	1 (11.1)	(0.3, 48.2)	0	(0.0, 26.5)
Pregnancy, puerperium and perinatal conditions	1 (11.1)	(0.3, 48.2)	1 (8.3)	(0.2, 38.5)
Haemorrhage in pregnancy	1 (11.1)	(0.3, 48.2)	0	(0.0, 26.5)
Premature separation of placenta	0	(0.0, 33.6)	1 (8.3)	(0.2, 38.5)

Note: MedDRA (v25.1) coding dictionary applied.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
Note: All others = American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event. For "any event," n = number of participants reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 03MAY2023 (10:43) Output File: ./nda3/C4591015_BR/adae_s130_immd_vax1_all_rac_saf

14.123. Number (%) of Participants Reporting at Least 1 Serious Adverse Event From Dose 1 Through 1 Month After Delivery, by System Organ Class and Preferred Term, by Ethnicity – Blinded Follow-Up Period – Safety Population (Maternal) Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=69)		Placebo (N[a]=63)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	8 (11.6)	(5.1, 21.6)	5 (7.9)	(2.6, 17.6)
Cardiac disorders	1 (1.4)	(0.0, 7.8)	1 (1.6)	(0.0, 8.5)
Bradycardia foetal	1 (1.4)	(0.0, 7.8)	0	(0.0, 5.7)
Nonreassuring foetal heart rate pattern	0	(0.0, 5.2)	1 (1.6)	(0.0, 8.5)
Gastrointestinal disorders	1 (1.4)	(0.0, 7.8)	0	(0.0, 5.7)

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14.123. Number (%) of Participants Reporting at Least 1 Serious Adverse Event From Dose 1 Through 1 Month After Delivery, by System Organ Class and Preferred Term, by Ethnicity – Blinded Follow-Up Period – Safety Population (Maternal) Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=69)		Placebo (N[a]=63)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Abdominal wall haematoma	1 (1.4)	(0.0, 7.8)	0	(0.0, 5.7)
Infections and infestations	1 (1.4)	(0.0, 7.8)	2 (3.2)	(0.4, 11.0)
Endometritis	1 (1.4)	(0.0, 7.8)	0	(0.0, 5.7)
Pneumonia	0	(0.0, 5.2)	1 (1.6)	(0.0, 8.5)
Urinary tract infection	0	(0.0, 5.2)	1 (1.6)	(0.0, 8.5)
Injury, poisoning and procedural complications	0	(0.0, 5.2)	1 (1.6)	(0.0, 8.5)
Urinary tract procedural complication	0	(0.0, 5.2)	1 (1.6)	(0.0, 8.5)
Musculoskeletal and connective tissue disorders	1 (1.4)	(0.0, 7.8)	0	(0.0, 5.7)
Osteoarthritis	1 (1.4)	(0.0, 7.8)	0	(0.0, 5.7)
Pregnancy, puerperium and perinatal conditions	3 (4.3)	(0.9, 12.2)	2 (3.2)	(0.4, 11.0)
Arrested labour	0	(0.0, 5.2)	1 (1.6)	(0.0, 8.5)
Foetal distress syndrome	1 (1.4)	(0.0, 7.8)	0	(0.0, 5.7)
Foetal growth restriction	1 (1.4)	(0.0, 7.8)	0	(0.0, 5.7)
Meconium in amniotic fluid	0	(0.0, 5.2)	1 (1.6)	(0.0, 8.5)
Pre-eclampsia	1 (1.4)	(0.0, 7.8)	0	(0.0, 5.7)
Reproductive system and breast disorders	2 (2.9)	(0.4, 10.1)	0	(0.0, 5.7)
Uterine disorder	2 (2.9)	(0.4, 10.1)	0	(0.0, 5.7)

Note: MedDRA (v25.1) coding dictionary applied.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event. For "any event," n = number of participants reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 03MAY2023 (10:43) Output File: ./nda3/C4591015_BR/adae_s130_immd_vax1_ethnic_saf

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14.124. Number (%) of Participants Reporting at Least 1 Serious Adverse Event From Dose 1 Through 1 Month After Delivery, by System Organ Class and Preferred Term, by Ethnicity – Blinded Follow-Up Period – Safety Population (Maternal) Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=92)		Placebo (N[a]=100)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	13 (14.1)	(7.7, 23.0)	18 (18.0)	(11.0, 26.9)
Cardiac disorders	0	(0.0, 3.9)	1 (1.0)	(0.0, 5.4)
Nonreassuring foetal heart rate pattern	0	(0.0, 3.9)	1 (1.0)	(0.0, 5.4)
Hepatobiliary disorders	0	(0.0, 3.9)	1 (1.0)	(0.0, 5.4)
Cholelithiasis	0	(0.0, 3.9)	1 (1.0)	(0.0, 5.4)
Infections and infestations	2 (2.2)	(0.3, 7.6)	0	(0.0, 3.6)
Lower respiratory tract infection	1 (1.1)	(0.0, 5.9)	0	(0.0, 3.6)
Pyelonephritis	1 (1.1)	(0.0, 5.9)	0	(0.0, 3.6)
Investigations	0	(0.0, 3.9)	2 (2.0)	(0.2, 7.0)
Foetal heart rate abnormal	0	(0.0, 3.9)	1 (1.0)	(0.0, 5.4)
Ultrasound foetal abnormal	0	(0.0, 3.9)	1 (1.0)	(0.0, 5.4)
Pregnancy, puerperium and perinatal conditions	10 (10.9)	(5.3, 19.1)	15 (15.0)	(8.6, 23.5)
Pre-eclampsia	3 (3.3)	(0.7, 9.2)	2 (2.0)	(0.2, 7.0)
Cephalo-pelvic disproportion	1 (1.1)	(0.0, 5.9)	3 (3.0)	(0.6, 8.5)
Foetal distress syndrome	2 (2.2)	(0.3, 7.6)	2 (2.0)	(0.2, 7.0)
Premature separation of placenta	0	(0.0, 3.9)	3 (3.0)	(0.6, 8.5)
Foetal hypokinesia	1 (1.1)	(0.0, 5.9)	1 (1.0)	(0.0, 5.4)
Gestational hypertension	1 (1.1)	(0.0, 5.9)	1 (1.0)	(0.0, 5.4)
Postpartum haemorrhage	0	(0.0, 3.9)	2 (2.0)	(0.2, 7.0)
Breech presentation	1 (1.1)	(0.0, 5.9)	0	(0.0, 3.6)
Failed induction of labour	1 (1.1)	(0.0, 5.9)	0	(0.0, 3.6)
Haemorrhage in pregnancy	1 (1.1)	(0.0, 5.9)	0	(0.0, 3.6)
Meconium stain	1 (1.1)	(0.0, 5.9)	0	(0.0, 3.6)
Omphalorrhexis	0	(0.0, 3.9)	1 (1.0)	(0.0, 5.4)
Placental insufficiency	0	(0.0, 3.9)	1 (1.0)	(0.0, 5.4)
Preterm premature rupture of membranes	0	(0.0, 3.9)	1 (1.0)	(0.0, 5.4)
Prolonged rupture of membranes	0	(0.0, 3.9)	1 (1.0)	(0.0, 5.4)
Retained placenta or membranes	1 (1.1)	(0.0, 5.9)	0	(0.0, 3.6)
Skin and subcutaneous tissue disorders	1 (1.1)	(0.0, 5.9)	0	(0.0, 3.6)
Pruritus	1 (1.1)	(0.0, 5.9)	0	(0.0, 3.6)
Vascular disorders	1 (1.1)	(0.0, 5.9)	0	(0.0, 3.6)
Deep vein thrombosis	1 (1.1)	(0.0, 5.9)	0	(0.0, 3.6)

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14.124. Number (%) of Participants Reporting at Least 1 Serious Adverse Event From Dose 1 Through 1 Month After Delivery, by System Organ Class and Preferred Term, by Ethnicity – Blinded Follow-Up Period – Safety Population (Maternal) Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=92)		Placebo (N[a]=100)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])

Note: MedDRA (v25.1) coding dictionary applied.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event. For "any event," n = number of participants reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 03MAY2023 (10:43) Output File: ./nda3/C4591015_BR/adae_s130_immd_vax1_ethnic_saf

14.125. Number (%) of Participants Reporting at Least 1 Serious Adverse Event From Dose 1 Through 1 Month After Delivery, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Blinded Follow-Up Period – Safety Population (Maternal) Baseline SARS-CoV-2 Status: Positive

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=54)		Placebo (N[a]=58)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	8 (14.8)	(6.6, 27.1)	10 (17.2)	(8.6, 29.4)
Cardiac disorders	0	(0.0, 6.6)	1 (1.7)	(0.0, 9.2)
Nonreassuring foetal heart rate pattern	0	(0.0, 6.6)	1 (1.7)	(0.0, 9.2)
Gastrointestinal disorders	1 (1.9)	(0.0, 9.9)	0	(0.0, 6.2)
Abdominal wall haematoma	1 (1.9)	(0.0, 9.9)	0	(0.0, 6.2)
Infections and infestations	1 (1.9)	(0.0, 9.9)	0	(0.0, 6.2)
Lower respiratory tract infection	1 (1.9)	(0.0, 9.9)	0	(0.0, 6.2)
Pregnancy, puerperium and perinatal conditions	7 (13.0)	(5.4, 24.9)	9 (15.5)	(7.3, 27.4)
Foetal distress syndrome	3 (5.6)	(1.2, 15.4)	2 (3.4)	(0.4, 11.9)
Cephalo-pelvic disproportion	1 (1.9)	(0.0, 9.9)	3 (5.2)	(1.1, 14.4)
Pre-eclampsia	1 (1.9)	(0.0, 9.9)	1 (1.7)	(0.0, 9.2)
Breech presentation	1 (1.9)	(0.0, 9.9)	0	(0.0, 6.2)
Failed induction of labour	1 (1.9)	(0.0, 9.9)	0	(0.0, 6.2)

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14.125. Number (%) of Participants Reporting at Least 1 Serious Adverse Event From Dose 1 Through 1 Month After Delivery, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Blinded Follow-Up Period – Safety Population (Maternal) Baseline SARS-CoV-2 Status: Positive

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=54)		Placebo (N[a]=58)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Meconium in amniotic fluid	0	(0.0, 6.6)	1 (1.7)	(0.0, 9.2)
Meconium stain	1 (1.9)	(0.0, 9.9)	0	(0.0, 6.2)
Placental insufficiency	0	(0.0, 6.6)	1 (1.7)	(0.0, 9.2)
Postpartum haemorrhage	0	(0.0, 6.6)	1 (1.7)	(0.0, 9.2)
Preterm premature rupture of membranes	0	(0.0, 6.6)	1 (1.7)	(0.0, 9.2)
Prolonged rupture of membranes	0	(0.0, 6.6)	1 (1.7)	(0.0, 9.2)
Retained placenta or membranes	1 (1.9)	(0.0, 9.9)	0	(0.0, 6.2)

Abbreviations: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: MedDRA (v25.1) coding dictionary applied.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event. For "any event," n = number of participants reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
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14.126. Number (%) of Participants Reporting at Least 1 Serious Adverse Event From Dose 1 Through 1 Month After Delivery, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Blinded Follow-Up Period – Safety Population (Maternal) Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=99)		Placebo (N[a]=101)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	12 (12.1)	(6.4, 20.2)	13 (12.9)	(7.0, 21.0)
Cardiac disorders	1 (1.0)	(0.0, 5.5)	1 (1.0)	(0.0, 5.4)
Bradycardia foetal	1 (1.0)	(0.0, 5.5)	0	(0.0, 3.6)
Nonreassuring foetal heart rate pattern	0	(0.0, 3.7)	1 (1.0)	(0.0, 5.4)
Hepatobiliary disorders	0	(0.0, 3.7)	1 (1.0)	(0.0, 5.4)
Cholelithiasis	0	(0.0, 3.7)	1 (1.0)	(0.0, 5.4)
Infections and infestations	2 (2.0)	(0.2, 7.1)	2 (2.0)	(0.2, 7.0)
Endometritis	1 (1.0)	(0.0, 5.5)	0	(0.0, 3.6)
Pneumonia	0	(0.0, 3.7)	1 (1.0)	(0.0, 5.4)
Pyelonephritis	1 (1.0)	(0.0, 5.5)	0	(0.0, 3.6)
Urinary tract infection	0	(0.0, 3.7)	1 (1.0)	(0.0, 5.4)
Injury, poisoning and procedural complications	0	(0.0, 3.7)	1 (1.0)	(0.0, 5.4)
Urinary tract procedural complication	0	(0.0, 3.7)	1 (1.0)	(0.0, 5.4)
Investigations	0	(0.0, 3.7)	2 (2.0)	(0.2, 7.0)
Foetal heart rate abnormal	0	(0.0, 3.7)	1 (1.0)	(0.0, 5.4)
Ultrasound foetal abnormal	0	(0.0, 3.7)	1 (1.0)	(0.0, 5.4)
Pregnancy, puerperium and perinatal conditions	6 (6.1)	(2.3, 12.7)	8 (7.9)	(3.5, 15.0)
Pre-eclampsia	3 (3.0)	(0.6, 8.6)	1 (1.0)	(0.0, 5.4)
Premature separation of placenta	0	(0.0, 3.7)	3 (3.0)	(0.6, 8.4)
Foetal hypokinesia	1 (1.0)	(0.0, 5.5)	1 (1.0)	(0.0, 5.4)
Gestational hypertension	1 (1.0)	(0.0, 5.5)	1 (1.0)	(0.0, 5.4)
Arrested labour	0	(0.0, 3.7)	1 (1.0)	(0.0, 5.4)
Foetal growth restriction	1 (1.0)	(0.0, 5.5)	0	(0.0, 3.6)
Haemorrhage in pregnancy	1 (1.0)	(0.0, 5.5)	0	(0.0, 3.6)
Omphalorrhexis	0	(0.0, 3.7)	1 (1.0)	(0.0, 5.4)
Postpartum haemorrhage	0	(0.0, 3.7)	1 (1.0)	(0.0, 5.4)
Reproductive system and breast disorders	2 (2.0)	(0.2, 7.1)	0	(0.0, 3.6)
Uterine disorder	2 (2.0)	(0.2, 7.1)	0	(0.0, 3.6)
Skin and subcutaneous tissue disorders	1 (1.0)	(0.0, 5.5)	0	(0.0, 3.6)
Pruritus	1 (1.0)	(0.0, 5.5)	0	(0.0, 3.6)
Vascular disorders	1 (1.0)	(0.0, 5.5)	0	(0.0, 3.6)
Deep vein thrombosis	1 (1.0)	(0.0, 5.5)	0	(0.0, 3.6)

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14.126. Number (%) of Participants Reporting at Least 1 Serious Adverse Event From Dose 1 Through 1 Month After Delivery, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Blinded Follow-Up Period – Safety Population (Maternal) Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=99)		Placebo (N[a]=101)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])

Abbreviations: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: MedDRA (v25.1) coding dictionary applied.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event. For "any event," n = number of participants reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
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14.127. Number (%) of Participants Reporting at Least 1 Serious Adverse Event From Dose 1 Through 1 Month After Delivery, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Blinded Follow-Up Period – Safety Population (Maternal) Baseline SARS-CoV-2 Status: Missing

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8)		Placebo (N[a]=4)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	1 (12.5)	(0.3, 52.7)	0	(0.0, 60.2)
Musculoskeletal and connective tissue disorders	1 (12.5)	(0.3, 52.7)	0	(0.0, 60.2)
Osteoarthritis	1 (12.5)	(0.3, 52.7)	0	(0.0, 60.2)

Abbreviations: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: MedDRA (v25.1) coding dictionary applied.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event. For "any event," n = number of participants reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 03MAY2023 (10:43) Output File: ./nda3/C4591015_BR/adae_s130_immd_vax1_all_cov_saf1

14.128. Number (%) of Participants Reporting at Least 1 Serious Adverse Event From Birth to 6 Months of Age, by System Organ Class and Preferred Term, by Breastfeeding Status – Safety Population (Infant) Breastfeeding Status: Yes

	Maternal Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=142)		Placebo (N[a]=146)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	21 (14.8)	(9.4, 21.7)	22 (15.1)	(9.7, 21.9)
Blood and lymphatic system disorders	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Coagulopathy	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Thrombocytopenia	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Congenital, familial and genetic disorders	9 (6.3)	(2.9, 11.7)	5 (3.4)	(1.1, 7.8)
Atrial septal defect	3 (2.1)	(0.4, 6.0)	1 (0.7)	(0.0, 3.8)
Ankyloglossia congenital	0	(0.0, 2.6)	2 (1.4)	(0.2, 4.9)
Congenital rubella syndrome	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Congenital skin dimples	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)

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14.128. Number (%) of Participants Reporting at Least 1 Serious Adverse Event From Birth to 6 Months of Age, by System Organ Class and Preferred Term, by Breastfeeding Status – Safety Population (Infant) Breastfeeding Status: Yes

System Organ Class Preferred Term	Maternal Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=142)		Placebo (N[a]=146)	
	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
DiGeorge's syndrome	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Microcephaly	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Mucopolysaccharidosis	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Patent ductus arteriosus	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Polydactyly	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Syndactyly	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Trisomy 21	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Ventricular septal defect	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Gastrointestinal disorders	1 (0.7)	(0.0, 3.9)	3 (2.1)	(0.4, 5.9)
Allergic colitis	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Allergic gastroenteritis	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Dysphagia	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Intestinal perforation	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Meconium plug syndrome	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Pneumoperitoneum	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Hepatobiliary disorders	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Hyperbilirubinaemia neonatal	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Infections and infestations	4 (2.8)	(0.8, 7.1)	5 (3.4)	(1.1, 7.8)
Bronchiolitis	2 (1.4)	(0.2, 5.0)	1 (0.7)	(0.0, 3.8)
Sepsis neonatal	0	(0.0, 2.6)	2 (1.4)	(0.2, 4.9)
Neonatal pneumonia	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Pneumonia respiratory syncytial viral	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Pyelonephritis	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Pyelonephritis acute	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Sepsis	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Injury, poisoning and procedural complications	0	(0.0, 2.6)	2 (1.4)	(0.2, 4.9)
Injury to brachial plexus due to birth trauma	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Traumatic intracranial haemorrhage	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Investigations	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Cardiac murmur	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Metabolism and nutrition disorders	0	(0.0, 2.6)	2 (1.4)	(0.2, 4.9)
Hypoglycaemia neonatal	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Metabolic acidosis	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Nervous system disorders	1 (0.7)	(0.0, 3.9)	2 (1.4)	(0.2, 4.9)
Coma	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Encephalopathy neonatal	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Hypoxic-ischaemic encephalopathy	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)

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14.128. Number (%) of Participants Reporting at Least 1 Serious Adverse Event From Birth to 6 Months of Age, by System Organ Class and Preferred Term, by Breastfeeding Status – Safety Population (Infant) Breastfeeding Status: Yes

	Maternal Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=142)		Placebo (N[a]=146)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Nervous system disorder	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Seizure	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Pregnancy, puerperium and perinatal conditions	9 (6.3)	(2.9, 11.7)	4 (2.7)	(0.8, 6.9)
Jaundice neonatal	7 (4.9)	(2.0, 9.9)	3 (2.1)	(0.4, 5.9)
Caput succedaneum	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Low birth weight baby	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Premature baby	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Small for dates baby	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Weight decrease neonatal	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Renal and urinary disorders	1 (0.7)	(0.0, 3.9)	1 (0.7)	(0.0, 3.8)
Renal tubular necrosis	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Vesicoureteric reflux	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Respiratory, thoracic and mediastinal disorders	2 (1.4)	(0.2, 5.0)	8 (5.5)	(2.4, 10.5)
Meconium aspiration syndrome	2 (1.4)	(0.2, 5.0)	0	(0.0, 2.5)
Neonatal respiratory distress	0	(0.0, 2.6)	2 (1.4)	(0.2, 4.9)
Hypoxia	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Neonatal pneumothorax	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Neonatal respiratory distress syndrome	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Neonatal respiratory failure	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Pulmonary hypertension	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Respiratory distress	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Respiratory failure	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Tachypnoea	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Vascular disorders	0	(0.0, 2.6)	2 (1.4)	(0.2, 4.9)
Hypoperfusion	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Hypotension	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Shock	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Subgaleal haemorrhage	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)

Note: MedDRA (v25.1) coding dictionary applied.
Note: Infants born to human immunodeficiency virus (HIV)-positive participants are not included in this summary.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event. For "any event," n = number of participants reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 03MAY2023 (10:43) Output File: ./nda3/C4591015_BR/adae_s130_sae_inf_brst

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14.129. Number (%) of Participants Reporting at Least 1 Serious Adverse Event From Birth to 6 Months of Age, by System Organ Class and Preferred Term, by Breastfeeding Status – Safety Population (Infant) Breastfeeding Status: No

System Organ Class Preferred Term	Maternal Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=11)		Placebo (N[a]=9)	
	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	0	(0.0, 28.5)	1 (11.1)	(0.3, 48.2)
Pregnancy, puerperium and perinatal conditions	0	(0.0, 28.5)	1 (11.1)	(0.3, 48.2)
Jaundice neonatal	0	(0.0, 28.5)	1 (11.1)	(0.3, 48.2)

Note: MedDRA (v25.1) coding dictionary applied.
Note: Infants born to human immunodeficiency virus (HIV)-positive participants are not included in this summary.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event. For "any event," n = number of participants reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 03MAY2023 (10:43) Output File: ./nda3/C4591015_BR/adae_s130_sae_inf_brst

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14.130. Number (%) of Participants Reporting at Least 1 Serious Adverse Event From Birth to 6 Months of Age, by System Organ Class and Preferred Term, by Breastfeeding Status – Safety Population (Infant) Breastfeeding Status: Missing

	Maternal Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=3)		Placebo (N[a]=4)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	0	(0.0, 70.8)	1 (25.0)	(0.6, 80.6)
Infections and infestations	0	(0.0, 70.8)	1 (25.0)	(0.6, 80.6)
Neonatal pneumonia	0	(0.0, 70.8)	1 (25.0)	(0.6, 80.6)

Note: MedDRA (v25.1) coding dictionary applied.
Note: Infants born to human immunodeficiency virus (HIV)-positive participants are not included in this summary.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event. For "any event," n = number of participants reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 03MAY2023 (10:43) Output File: ./nda3/C4591015_BR/adae_s130_sae_inf_brst

14.131. Number (%) of Participants Reporting at Least 1 Serious Adverse Event From Birth to 6 Months of Age, by System Organ Class and Preferred Term – Born to HIV-Positive Maternal Participants – Safety Population (Infant)

	Maternal Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=11)		Placebo (N[a]=9)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	1 (9.1)	(0.2, 41.3)	2 (22.2)	(2.8, 60.0)
Infections and infestations	1 (9.1)	(0.2, 41.3)	2 (22.2)	(2.8, 60.0)
Gastroenteritis	0	(0.0, 28.5)	1 (11.1)	(0.3, 48.2)
Neonatal pneumonia	0	(0.0, 28.5)	1 (11.1)	(0.3, 48.2)
Pneumonia	1 (9.1)	(0.2, 41.3)	0	(0.0, 33.6)
Urinary tract infection	0	(0.0, 28.5)	1 (11.1)	(0.3, 48.2)
Metabolism and nutrition disorders	0	(0.0, 28.5)	1 (11.1)	(0.3, 48.2)
Dehydration	0	(0.0, 28.5)	1 (11.1)	(0.3, 48.2)
Nervous system disorders	0	(0.0, 28.5)	1 (11.1)	(0.3, 48.2)
Superior sagittal sinus thrombosis	0	(0.0, 28.5)	1 (11.1)	(0.3, 48.2)

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14.131. Number (%) of Participants Reporting at Least 1 Serious Adverse Event From Birth to 6 Months of Age, by System Organ Class and Preferred Term – Born to HIV-Positive Maternal Participants – Safety Population (Infant)

	Maternal Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=11)		Placebo (N[a]=9)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event. For "any event," n = number of participants reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 10MAY2023 (14:40) Output File: ./nda3/C4591015_BR/adae_s130_1md2_soc_hivin

14.132. Number (%) of Participants Reporting at Least 1 Adverse Event of Special Interest From Birth to 6 Months of Age, by System Organ Class and Preferred Term, by Breastfeeding Status – Safety Population (Infant) Breastfeeding Status: Yes

	Maternal Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=142)		Placebo (N[a]=146)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	8 (5.6)	(2.5, 10.8)	2 (1.4)	(0.2, 4.9)
Congenital, familial and genetic disorders	8 (5.6)	(2.5, 10.8)	2 (1.4)	(0.2, 4.9)
Atrial septal defect	3 (2.1)	(0.4, 6.0)	1 (0.7)	(0.0, 3.8)
DiGeorge's syndrome	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Microcephaly	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Mucopolysaccharidosis	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Patent ductus arteriosus	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Syndactyly	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Trisomy 21	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Ventricular septal defect	0	(0.0, 2.6)	1 (0.7)	(0.0, 3.8)
Renal and urinary disorders	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)
Vesicoureteric reflux	1 (0.7)	(0.0, 3.9)	0	(0.0, 2.5)

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14.132. Number (%) of Participants Reporting at Least 1 Adverse Event of Special Interest From Birth to 6 Months of Age, by System Organ Class and Preferred Term, by Breastfeeding Status – Safety Population (Infant) Breastfeeding Status: Yes

	Maternal Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=142)		Placebo (N[a]=146)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])

Note: MedDRA (v25.1) coding dictionary applied.
Note: Adverse event of special interest terms are from the COVID-19 program targeted medical event (TME) list dated 16Nov2022.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event. For "Any event," n = number of participants reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 09MAY2023 (10:28) Output File: ./nda3/C4591015_BR/adae_s130_specint_inf_brst

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14.133. Number (%) of Participants Reporting at Least 1 Adverse Event of Special Interest From Birth to 6 Months of Age, by System Organ Class and Preferred Term, by Breastfeeding Status – Safety Population (Infant) Breastfeeding Status: No

System Organ Class Preferred Term	BNT162b2 (30 µg) (N[a]=11) n[b] (%)	(95% CI[c])	Placebo (N[a]=9) n[b] (%)	(95% CI[c])
Any event	0	(0.0, 28.5)	0	(0.0, 33.6)

Note: MedDRA (v25.1) coding dictionary applied.
Note: Adverse event of special interest terms are from the COVID-19 program targeted medical event (TME) list dated 16Nov2022.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event. For "Any event," n = number of participants reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 09MAY2023 (10:28) Output File: ./nda3/C4591015_BR/adae_s130_specint_inf_brst

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14.134. Number (%) of Participants Reporting at Least 1 Adverse Event of Special Interest From Birth to 6 Months of Age, by System Organ Class and Preferred Term, by Breastfeeding Status – Safety Population (Infant) Breastfeeding Status: Missing

System Organ Class Preferred Term	BNT162b2 (30 µg) (N[a]=3) n[b] (%)	 (95% CI[c])	Placebo (N[a]=4) n[b] (%)	 (95% CI[c])
Any event	0	(0.0, 70.8)	0	(0.0, 60.2)

Note: MedDRA (v25.1) coding dictionary applied.
Note: Adverse event of special interest terms are from the COVID-19 program targeted medical event (TME) list dated 16Nov2022.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event. For "Any event," n = number of participants reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 09MAY2023 (10:28) Output File: ./nda3/C4591015_BR/adae_s130_specint_inf_brst

14.135. Number (%) of Participants Reporting at Least 1 Adverse Events of Special Interest From Birth to 6 Months of Age, by System Organ Class and Preferred Term – Safety Population (Infant)

System Organ Class Preferred Term	Maternal Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=156) n[b] (%)	 (95% CI[c])	Placebo (N[a]=159) n[b] (%)	 (95% CI[c])
Any event	8 (5.1)	(2.2, 9.9)	2 (1.3)	(0.2, 4.5)
Congenital, familial and genetic disorders	8 (5.1)	(2.2, 9.9)	2 (1.3)	(0.2, 4.5)
Atrial septal defect	3 (1.9)	(0.4, 5.5)	1 (0.6)	(0.0, 3.5)
DiGeorge's syndrome	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Microcephaly	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Mucopolysaccharidosis	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Patent ductus arteriosus	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Syndactyly	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Trisomy 21	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Ventricular septal defect	0	(0.0, 2.3)	1 (0.6)	(0.0, 3.5)
Renal and urinary disorders	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)
Vesicoureteric reflux	1 (0.6)	(0.0, 3.5)	0	(0.0, 2.3)

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14.135. Number (%) of Participants Reporting at Least 1 Adverse Events of Special Interest From Birth to 6 Months of Age, by System Organ Class and Preferred Term – Safety Population (Infant)

	Maternal Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=156)		Placebo (N[a]=159)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])

Note: MedDRA (v25.1) coding dictionary applied.
Note: Adverse event of special interest terms are from the COVID-19 program targeted medical event (TME) list dated 16Nov2022.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this summary. Analyses of HIV-positive participants and their infants will be listed separately.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified adverse event. For "Any event," n = number of participants reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 09MAY2023 (10:27) Output File: ./nda3/C4591015_BR/adae_s130_specint_inf

14.136. Pregnancy Outcomes – Safety Population (Maternal)

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=168)	Placebo (N[a]=168)
	n[b] (%)	n[b] (%)
Duration between dose and delivery (days)		
Mean (SD)	45.3 (20.74)	44.3 (18.72)
Median	45.0	42.0
Min, max	(5, 95)	(6, 93)
Location of delivery		
Home	0	1 (0.6)
Medical facility	162 (96.4)	161 (95.8)
Other	5 (3.0)	5 (3.0)
Missing	1 (0.6)	1 (0.6)
Mode of delivery		
Vaginal delivery	116 (69.0)	111 (66.1)
Cesarean delivery	51 (30.4)	56 (33.3)
Elective	38 (22.6)	38 (22.6)
Emergency	13 (7.7)	18 (10.7)
Missing	1 (0.6)	1 (0.6)

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14.136. Pregnancy Outcomes – Safety Population (Maternal)

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=168) n[b] (%)	Placebo (N[a]=168) n[b] (%)
Outcome at delivery		
Live delivery	166 (98.8)	167 (99.4)
Stillbirth	1 (0.6)	0
Missing	1 (0.6)	1 (0.6)
Gross visual inspection of aborted fetus/stillbirth		
No observed abnormalities	1 (0.6)	0
Pathology performed	1 (0.6)	0
Group B streptococcal colonization status		
Positive	20 (11.9)	15 (8.9)
Negative	83 (49.4)	95 (56.5)
Unknown	65 (38.7)	58 (34.5)
GBS test performed		
Swab	98 (58.3)	101 (60.1)
Urine	0	2 (1.2)
Other	7 (4.2)	10 (6.0)
Not done	63 (37.5)	55 (32.7)
Intrapartum antibiotic prophylaxis given for GBS		
Yes	23 (13.7)	17 (10.1)
No	112 (66.7)	118 (70.2)
Unknown	33 (19.6)	33 (19.6)

Abbreviation: GBS = group B streptococcus.
Note: Days between dose and delivery = date of delivery - Dose 1 date + 1.
a. N = number of participants who delivered in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:02) Source Data: adrp Table Generation: 10MAY2023 (12:12) Output File: ./nda3/C4591015_BR/adrppy_s001

14.137. Birth Outcomes – Safety Population (Infant)

	Maternal Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=167)		Placebo (N[a]=168)	
	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Gestational age (weeks/days)				

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14.137. Birth Outcomes – Safety Population (Infant)

	Maternal Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=167)		Placebo (N[a]=168)	
	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
<37 weeks 0 days	2 (1.2)	(0.1, 4.3)	8 (4.8)	(2.1, 9.2)
≥37 weeks - 41 weeks 6 days	162 (97.0)	(93.2, 99.0)	157 (93.5)	(88.6, 96.7)
≥42 weeks	2 (1.2)	(0.1, 4.3)	2 (1.2)	(0.1, 4.2)
Missing	1 (0.6)	(0.0, 3.3)	1 (0.6)	(0.0, 3.3)
Apgar score – 1 minute after delivery				
0-3	4 (2.4)	(0.7, 6.0)	4 (2.4)	(0.7, 6.0)
4-6	4 (2.4)	(0.7, 6.0)	9 (5.4)	(2.5, 9.9)
7-10	157 (94.0)	(89.3, 97.1)	152 (90.5)	(85.0, 94.5)
Missing	2 (1.2)	(0.1, 4.3)	3 (1.8)	(0.4, 5.1)
Apgar score – 5 minutes after delivery				
0-3	0	(0.0, 2.2)	1 (0.6)	(0.0, 3.3)
4-6	1 (0.6)	(0.0, 3.3)	4 (2.4)	(0.7, 6.0)
7-10	164 (98.2)	(94.8, 99.6)	160 (95.2)	(90.8, 97.9)
Missing	2 (1.2)	(0.1, 4.3)	3 (1.8)	(0.4, 5.1)
Apgar score – 10 minutes after delivery				
7-10	62 (37.1)	(29.8, 44.9)	63 (37.5)	(30.2, 45.3)
Missing	105 (62.9)	(55.1, 70.2)	105 (62.5)	(54.7, 69.8)
Infant cry immediately after delivery				
Yes	152 (91.0)	(85.6, 94.9)	147 (87.5)	(81.5, 92.1)
No	12 (7.2)	(3.8, 12.2)	14 (8.3)	(4.6, 13.6)
Missing	3 (1.8)	(0.4, 5.2)	7 (4.2)	(1.7, 8.4)
Infant suckle shortly after delivery				
Yes	154 (92.2)	(87.1, 95.8)	150 (89.3)	(83.6, 93.5)
No	8 (4.8)	(2.1, 9.2)	11 (6.5)	(3.3, 11.4)
Missing	5 (3.0)	(1.0, 6.8)	7 (4.2)	(1.7, 8.4)
Infant outcome				
Normal	153 (91.6)	(86.3, 95.3)	150 (89.3)	(83.6, 93.5)
Congenital malformation/anomaly	10 (6.0)	(2.9, 10.7)	6 (3.6)	(1.3, 7.6)
Other neonatal problem	3 (1.8)	(0.4, 5.2)	11 (6.5)	(3.3, 11.4)
Missing	1 (0.6)	(0.0, 3.3)	1 (0.6)	(0.0, 3.3)

a. N = number of infant participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic.
c. Exact 2-sided confidence interval (CI), based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:02) Source Data: adscio Table Generation: 03MAY2023 (12:27) Output File: ./nda3/C4591015_BR/adfaio_s001

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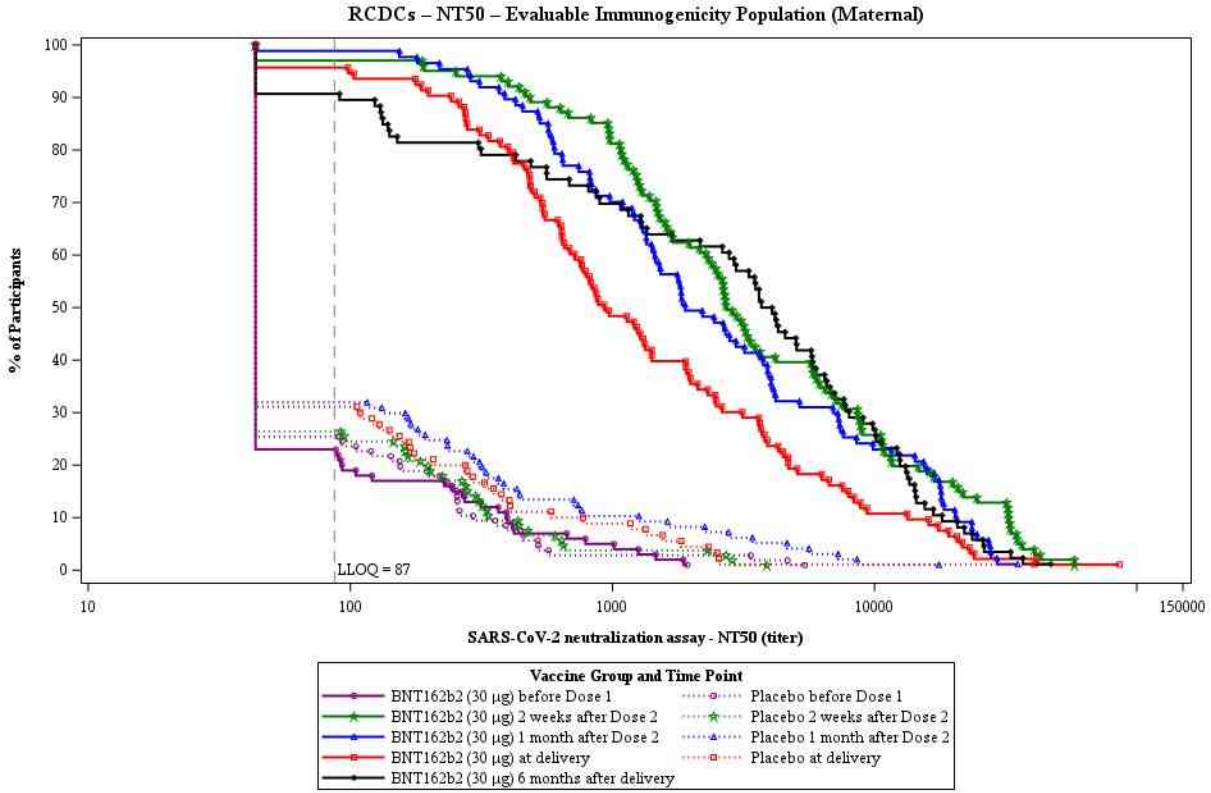
SUPPLEMENTAL FIGURES

14.1. Reverse Cumulative Distribution Curves, SARS-CoV-2 Neutralization Assay – NT50 – Evaluable Immunogenicity Population (Maternal)



Abbreviations: LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer; RCDC = reverse cumulative distribution curve; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: 6 Months after delivery was only drawn from participants originally randomized to receive BNT162b2.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this figure.
Note: LLOQ value is represented using a vertical line. Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.
PFIZER CONFIDENTIAL SDTM Creation: 12JAN2024 (03:07) Source Data: adva Table Generation: 19FEB2024 (05:00)
(Database snapshot date: Safety [29Mar2023], Immunogenicity [09Jan2024])
Output File: /nda3/C4591015_CSR/adva_f003_sars_50_p22

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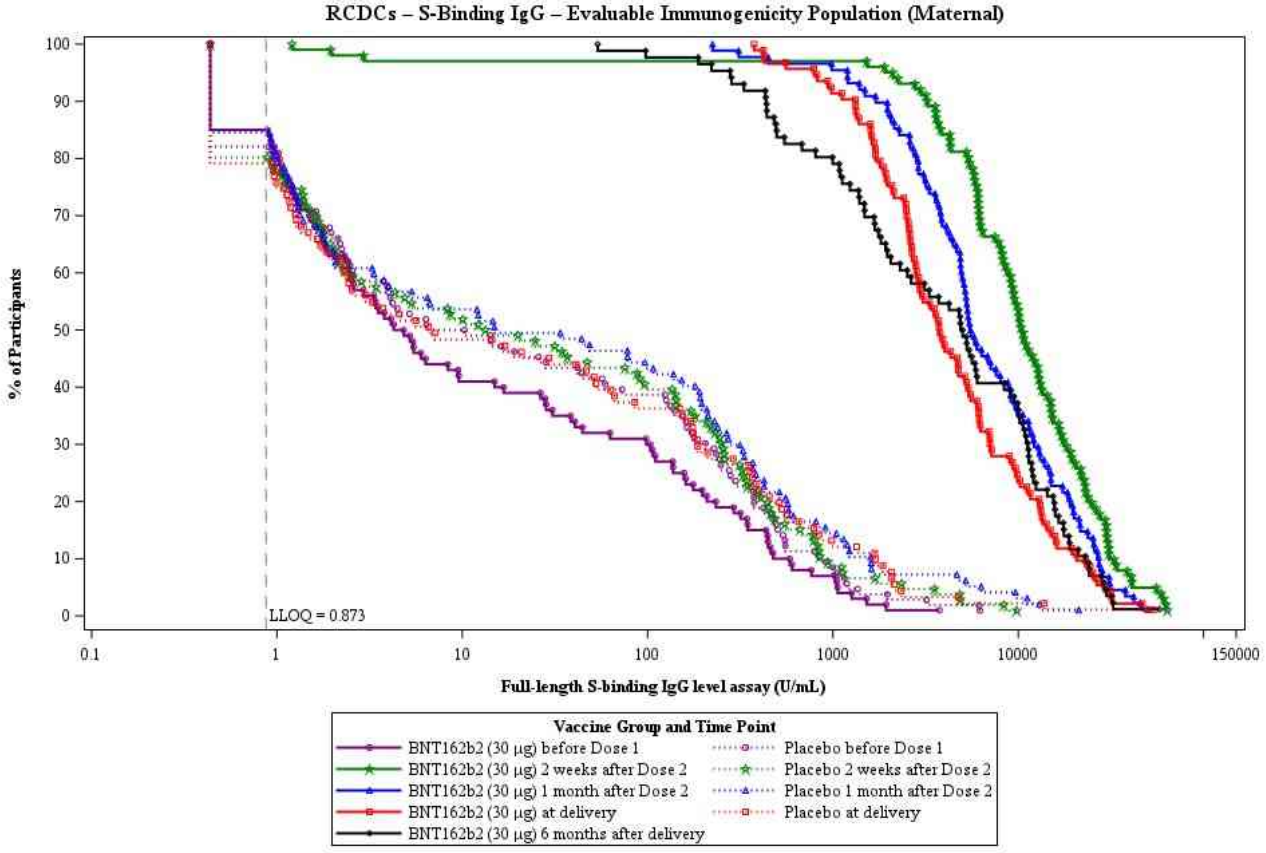
14.2. Reverse Cumulative Distribution Curves, Full-Length S-Binding IgG Level Assay – Evaluable Immunogenicity Population (Maternal)



Abbreviations: IgG = immunoglobulin G; LLOQ = lower limit of quantitation; RCDC = reverse cumulative distribution curve; S = spike protein.
Note: 6 Months after delivery was only drawn from participants originally randomized to receive BNT162b2.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this figure.
Note: LLOQ value is represented using a vertical line. Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.
PFIZER CONFIDENTIAL SDTM Creation: 12JAN2024 (03:07) Source Data: adva Table Generation: 19FEB2024 (05:05)
(Database snapshot date: Safety [29Mar2023], Immunogenicity [09Jan2024])
Output File: /nda3/C4591015_CSR/adva_f003_s1_p3

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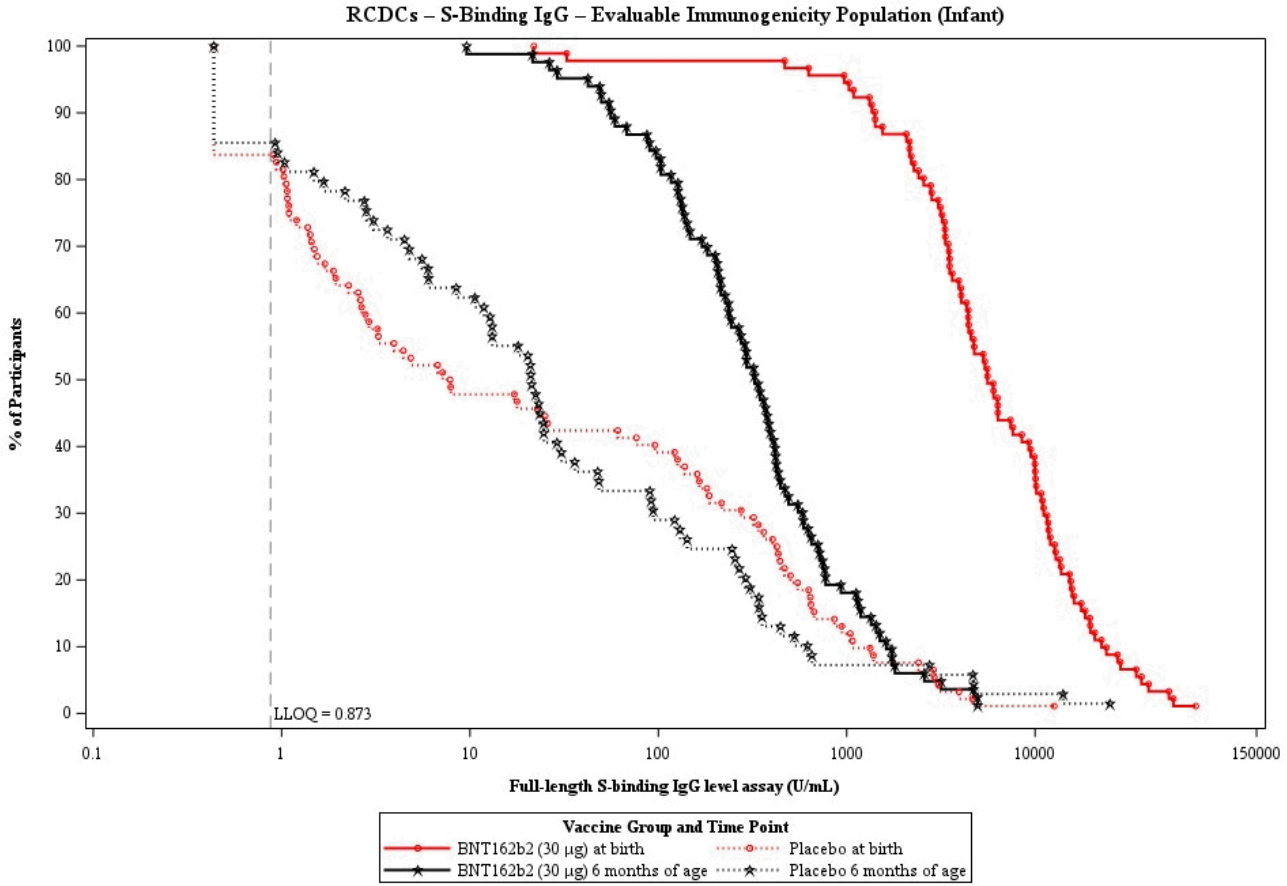
14.3. Reverse Cumulative Distribution Curves, Full-Length S-Binding IgG Level Assay – Evaluable Immunogenicity Population (Infant)



Abbreviations: IgG = immunoglobulin G; LLOQ = lower limit of quantitation; RCDC = reverse cumulative distribution curve; S = spike protein.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this figure.
Note: LLOQ value is represented using a vertical line. Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.
PFIZER CONFIDENTIAL SDTM Creation: 12JAN2024 (03:07) Source Data: adva Table Generation: 19FEB2024 (05:11)
(Database snapshot date: Safety [29Mar2023], Immunogenicity [09Jan2024])
Output File: ./nda3/C4591015_CSR/adva_f003_fullsbin_e_inf

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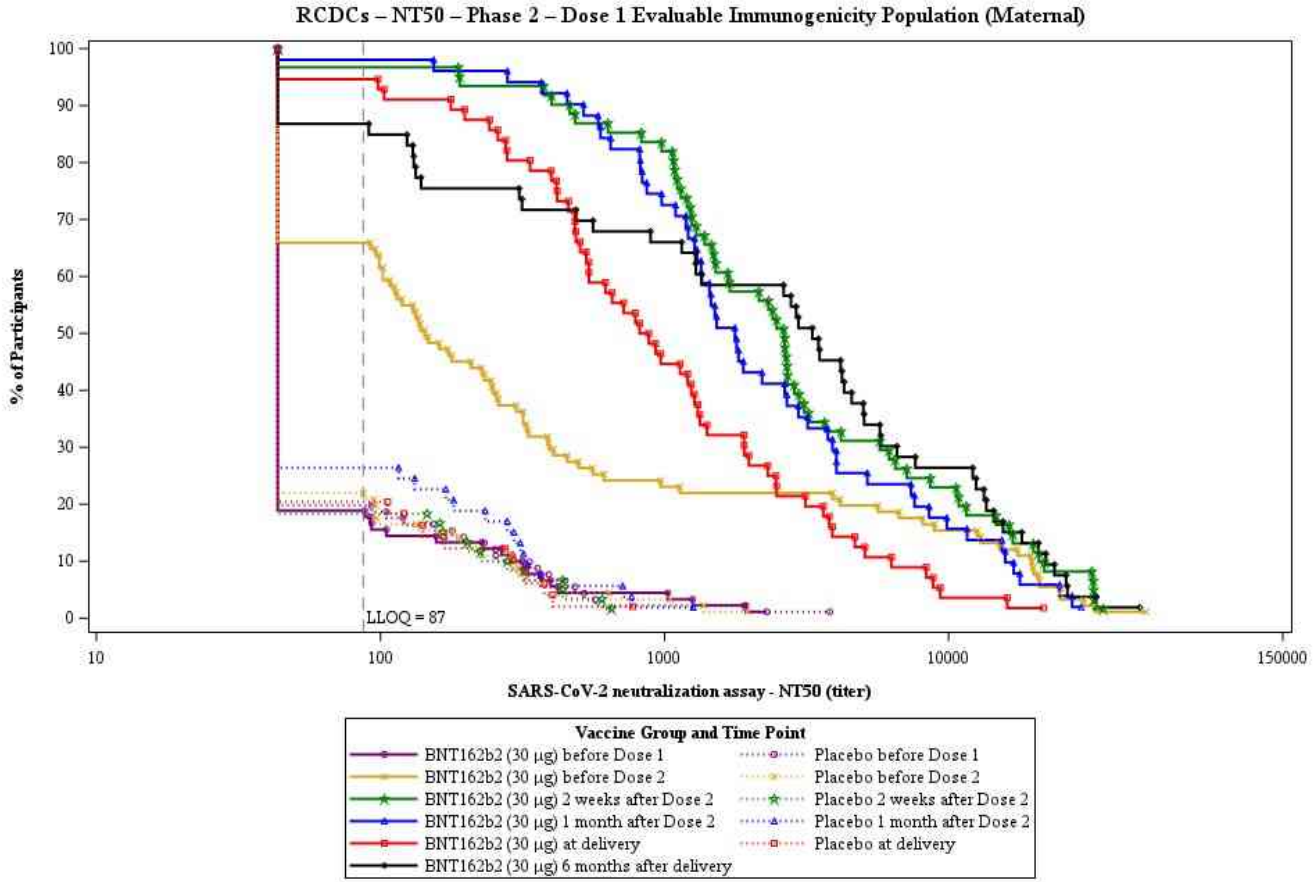
14.4. Reverse Cumulative Distribution Curves, SARS-CoV-2 Neutralization Assay – NT50 – Phase 2 – Dose 1 Evaluable Immunogenicity Population (Maternal)



Abbreviations: LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer; RCDC = reverse cumulative distribution curve; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this figure.
Note: LLOQ value is represented using a vertical line. Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.
PFIZER CONFIDENTIAL SDTM Creation: 12JAN2024 (03:07) Source Data: adva Table Generation: 20FEB2024 (23:11)
(Database snapshot date: Safety [29Mar2023], Immunogenicity [09Jan2024])
Output File: /nda3/C4591015_CSR/adva_f003_sars_50_phase2

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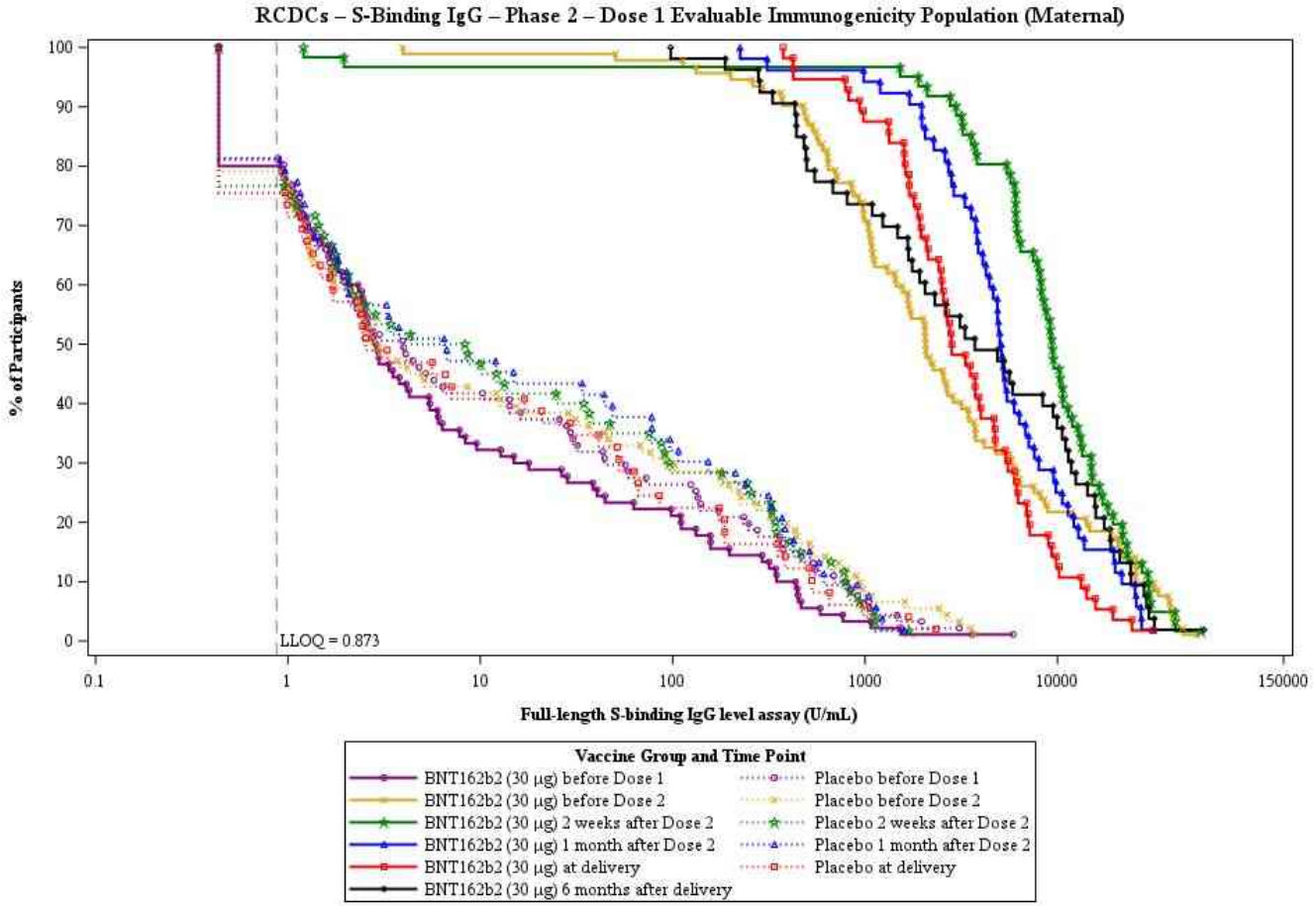
14.5. Reverse Cumulative Distribution Curves, Full-Length S-Binding IgG Level Assay – Phase 2 – Dose 1 Evaluable Immunogenicity Population (Maternal)



Abbreviations: IgG = immunoglobulin G; LLOQ = lower limit of quantitation; RCDC = reverse cumulative distribution curve; S = spike protein.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this figure.
Note: LLOQ value is represented using a vertical line. Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.
PFIZER CONFIDENTIAL SDTM Creation: 12JAN2024 (03:07) Source Data: adva Table Generation: 20FEB2024 (23:13)
(Database snapshot date: Safety [29Mar2023], Immunogenicity [09Jan2024])
Output File: /nda3/C4591015_CSR/adva_f003_fullsbin_e_phase2

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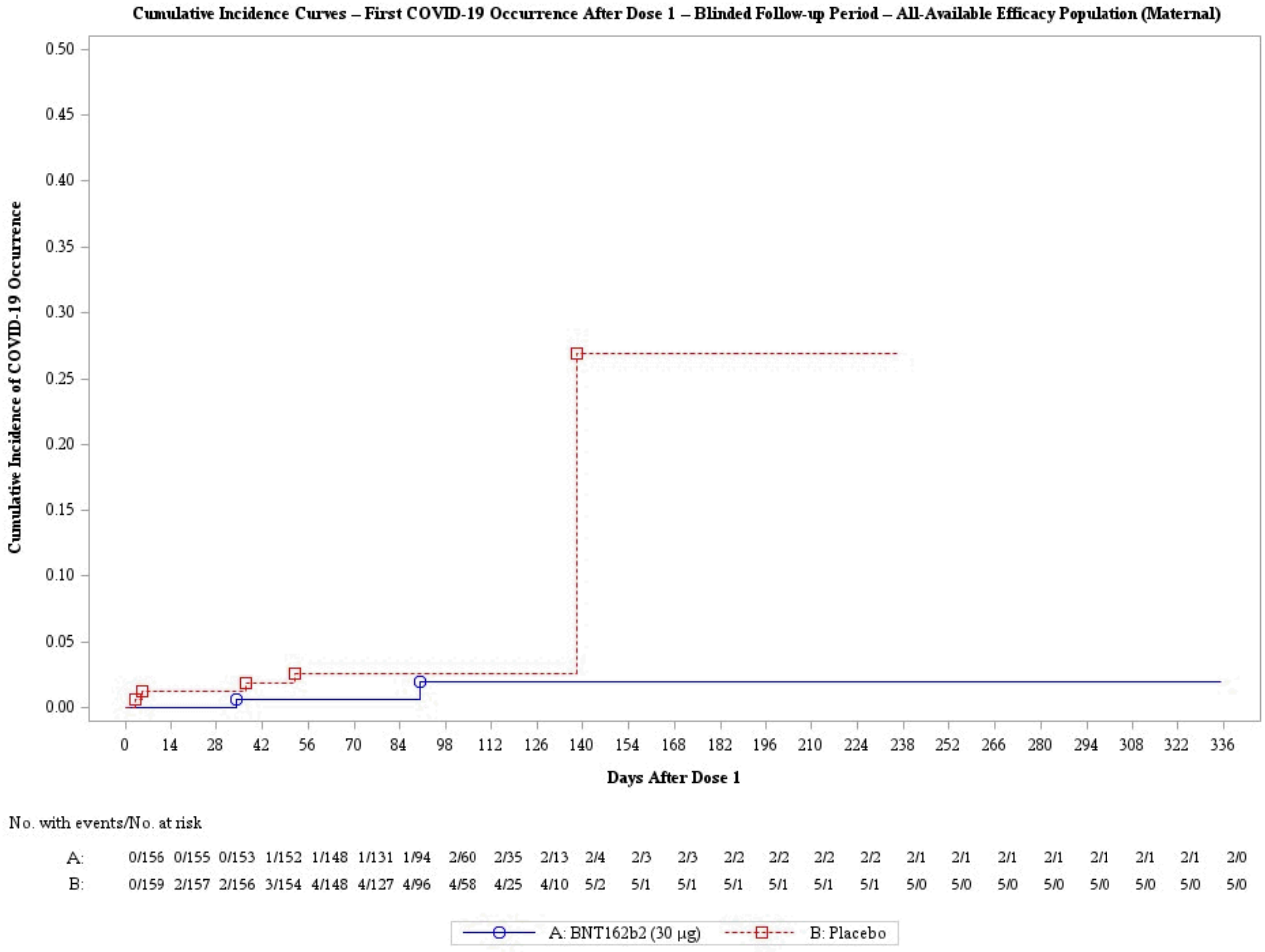
14.6. Cumulative Incidence Curves - First COVID-19 Occurrence After Dose 1 – Blinded Follow-up Period – All-Available Efficacy Population (Maternal)



PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (08:47) Source Data: adc19ef Table Generation: 05JAN2024 (09:16) Output File: . /nda3/C4591015_EFF/adc19ef_f001_km_7d2_wo_aai2m

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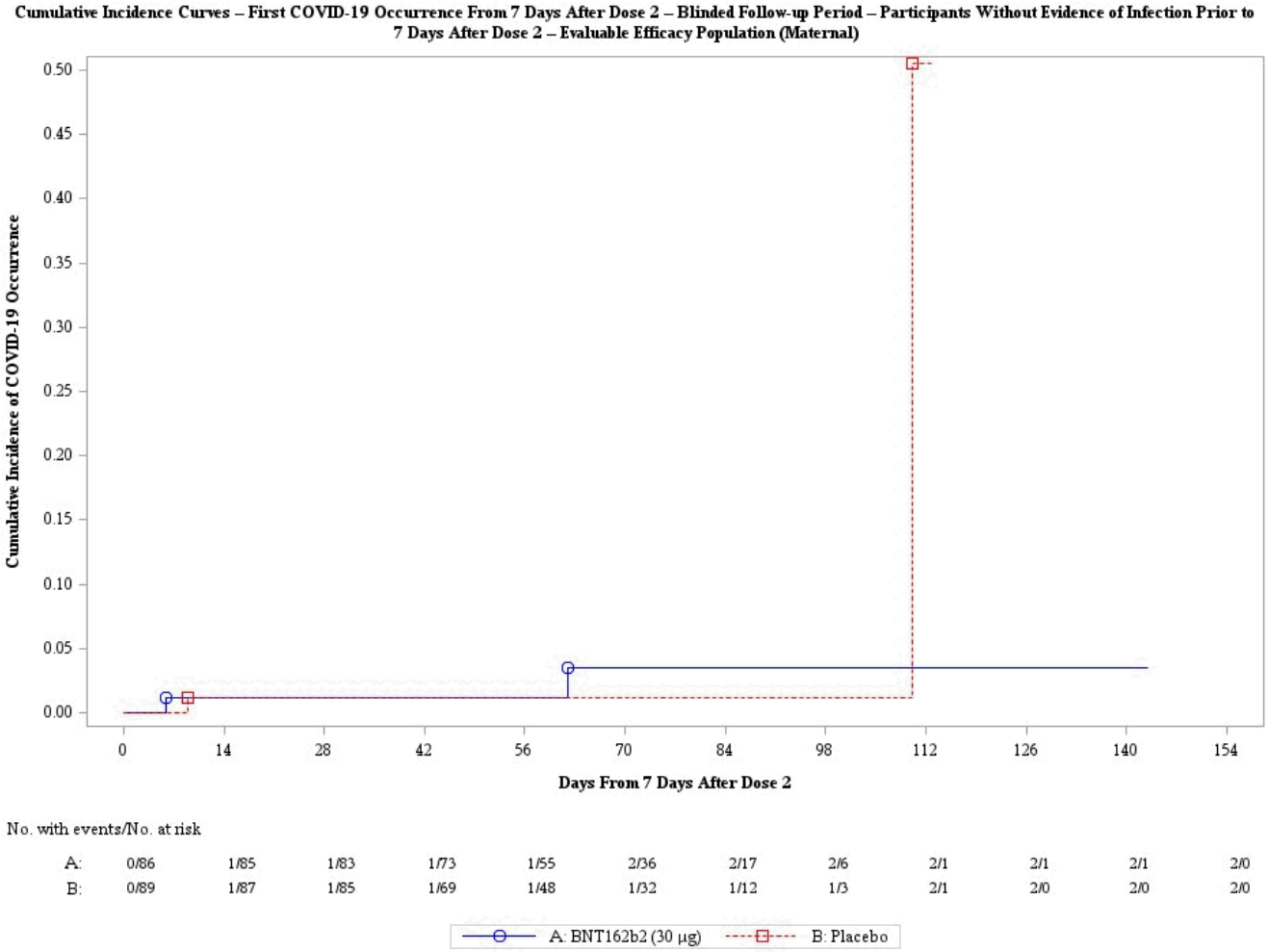
14.7. Cumulative Incidence Curves – First COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Follow-up Period – Participants Without Evidence of Infection Prior to 7 Days After Dose 2 - Evaluable Efficacy Population (Maternal)



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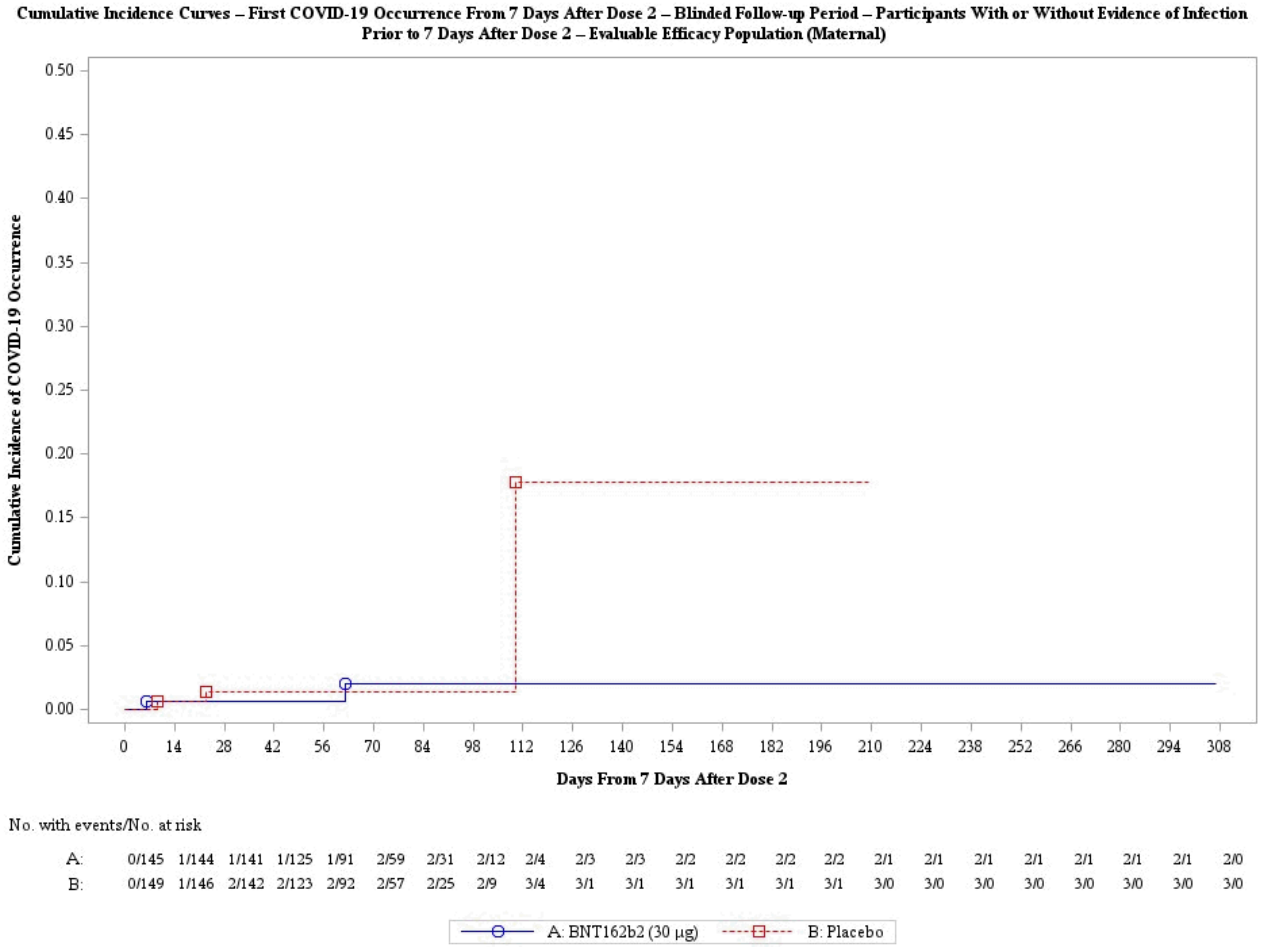
14.8. Cumulative Incidence Curves - First COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Follow-up Period – Participants With or Without Evidence of Infection Prior to 7 Days After Dose 2 - Evaluable Efficacy Population (Maternal)



PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (08:47) Source Data: adc19ef Table Generation: 12DEC2023 (23:20) Output File: . /nda3/C4591015_EFF/adc19ef_f001_km_7d2_evlm

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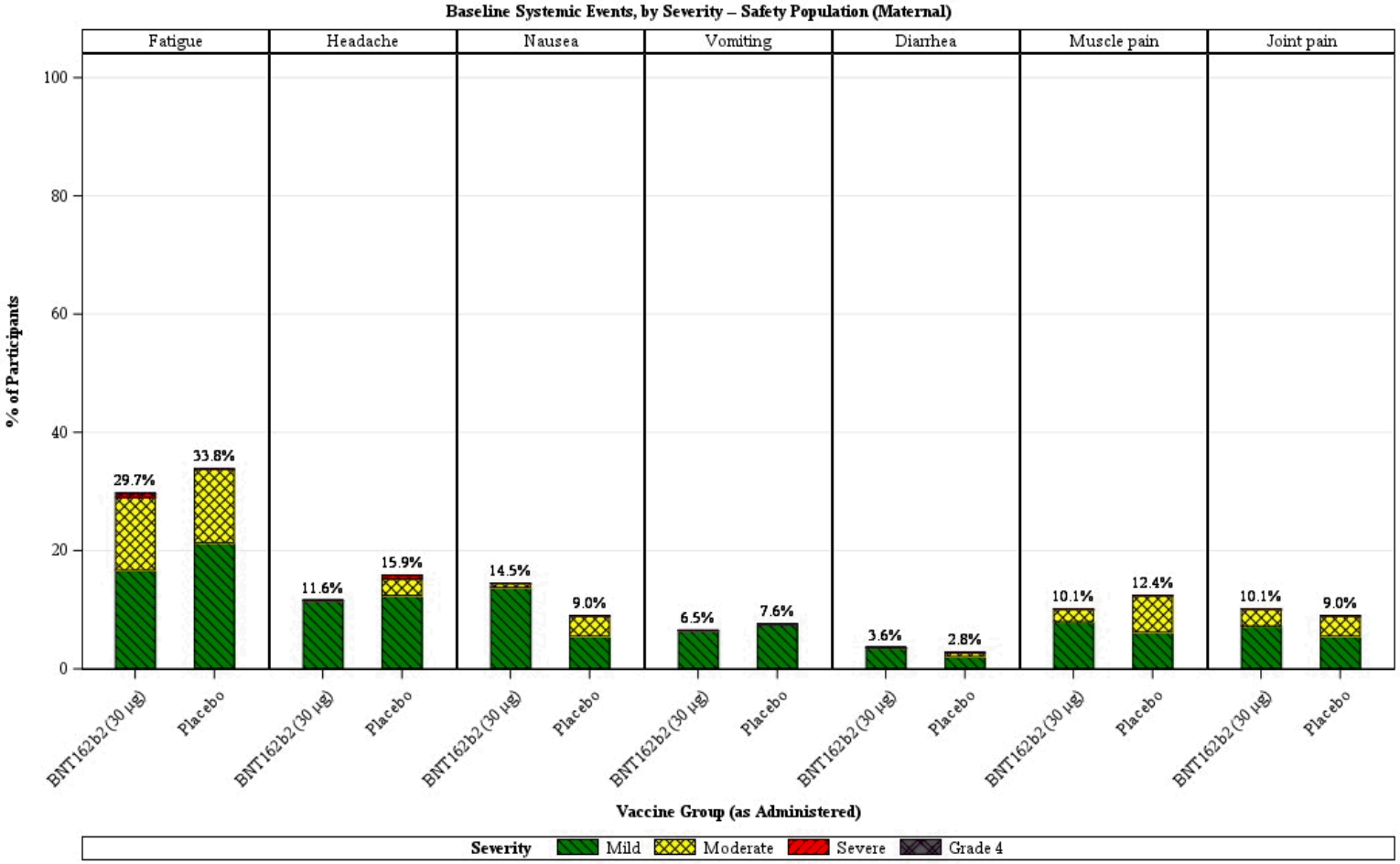
14.9. Participants Reporting Baseline Systemic Events, by Severity – Safety Population (Maternal)



Note: Prior to vaccination on Day 1, a baseline assessment of fatigue, headache, vomiting, nausea, diarrhea, muscle pain, and joint pain were recorded in the e-diary.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adfacevd Table Generation: 03MAY2023 (14:04)
Output File: /nda3/C4591015_BR/adce_f001_bs_max_p3

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PARTICIPANT NARRATIVES

Reason for Narrative	Participant Number
Death	Participant C4591015 [redacted]
	Participant C4591015
Adverse Event of Special Interest	Participant C4591015
	Participant C4591015
	Participant C4591015
	Participant C4591015
	Participant C4591015
	Participant C4591015
	Participant C4591015
	Participant C4591015
	Participant C4591015
	Participant C4591015
COVID-19 Case (Severe and/or Multiple)	Participant C4591015
	Participant C4591015
	Participant C4591015
	Participant C4591015
	Participant C4591015

Participant C4591015 [redacted]
Participant C4591015
Participant C4591015
Participant C4591015
Participant C4591015
Participant C4591015

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Table of Abbreviations		
Category	**Abbreviation**	**Text**
Action - Participant	N	No action
	O	Other
	P	Drug withdrawn (study intervention discontinued)
	TC	Concomitant drug treatment given
	TCN	Concomitant nondrug treatment given
	W	Withdrawn from study
Toxicity Grade	1	Mild
	2	Moderate
	3	Severe
	4	Life-threatening
System Organ Class	BLOOD	Blood and lymphatic system disorders
	CARD	Cardiac disorders
	CONG	Congenital, familial and genetic disorders
	EAR	Ear and labyrinth disorders
	ENDO	Endocrine disorders
	EYE	Eye disorders
	GASTR	Gastrointestinal disorders
	GENRL	General disorders and administration site conditions
	HEPAT	Hepatobiliary disorders
	IMMUN	Immune system disorders
	INFEC	Infections and infestations
	INJ&P	Injury poisoning and procedural complications
	INV	Investigations
	METAB	Metabolism and nutrition disorders
	MUSC	Musculoskeletal and connective tissue disorders
	NEOPL	Neoplasms benign, malignant and unspecified (incl cysts and polyps)
	NERV	Nervous system disorders
	PI	Product issues
	PREG	Pregnancy, puerperium and perinatal conditions
	PSYCH	Psychiatric disorders
	RENAL	Renal and urinary disorders
	REPRO	Reproductive system and breast disorders
	RESP	Respiratory, thoracic and mediastinal disorders

	SKIN	Skin and subcutaneous tissue disorders
	SOCCI	Social circumstances
	SURG	Surgical and medical procedures
	VASC	Vascular disorders

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Demography				
Date of Birth	**Gestational Age at Birth**	**Race**	**Ethnicity**	**Sex**
[redacted]	32 weeks 3 days	Black or African American	Non-Hispanic/Latino	Female

Birth Details			
Mode of Birth	**Apgar Score at 1 Minute**	**Apgar Score at 5 Minutes**	**Apgar Score at 10 Minutes**
Vaginal	8	9	--

Vital Signs - Baseline				
Body Length	**Weight**	**Diastolic Blood Pressure**	**Systolic Blood Pressure**	**Date Collected (Study Day)**
41 cm	1.7 kg			[redacted] (58)

Reason(s) for Narrative: Death
Participant: C4591015 Country: South Africa
Maternal Vaccine Group (as Administered): Placebo
Date of First Dose: Date of Last Dose:
==========

Maternal Study Vaccination(s)				
Vaccination Number	**Vaccine**	**Maternal Vaccination Date (Study Day)**	**Time of Maternal Vaccination**	**Gestational Age at Maternal Vaccination**
1	Placebo	1)	13:52:00	24 weeks 4 days
2	Placebo	(25)	12:34:00	28 weeks

Adverse Events						
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Age in Days)**	**Stop Date (Age in Days)**	**Duration (Days)**
1	INFEC	Neonatal pneumonia	neonatal pneumonia	(1)	(7)	7

Adverse Events						
AE Number	**Toxicity Grade**	**Action: Participant**	**SAE**	**AE Still Present?**	**AE Related To:**	**Narrative Event**
1	4	TC,W	Yes	FATA	NOT RELATED /OTHER; CONGENITAL INFECTION	Yes

Concomitant Medications				
Investigator Text	**WHO Drug Preferred Term**	**Start Da e**	**End Date**	**Route**
AMPICILLIN	AMPICILLIN			INTRAVENOUS

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Reason(s) for Narrative: Death
Participant: C4591015 [redacted] **Country: South Africa**
Maternal Vaccine Group (as Administered): Placebo
Date of First Dose: [redacted] **Date of Last Dose:** [redacted]

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Concomitant Medications				
Investigator Text	**WHO Drug Preferred Term**	**Start Date**	**End Date**	**Route**
GENTAMICIN	GENTAMICIN	[redacted]		INTRAVENOUS
NEVIRAPINE	NEVIRAPINE			ORAL
OXYGEN	OXYGEN			NASAL
AZT (ZIDOVUDINE)	ZIDOVUDINE			ORAL
CALCIUM GLUCONATE	CALCIUM GLUCONATE			INTRAVENOUS
ADRENALINE	EPINEPHRINE			INTRAVENOUS
sodium bicarbonate	SODIUM BICARBONATE			INTRAVENOUS

Nonstudy Vaccines
No Nonstudy Vaccines

Participant Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Withdrawn	FOLLOW-UP	[redacted]	DEATH

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Narrative Comment
Participant C4591015 a day-old Black/African American female, was born to a maternal participant by vaginal birth on at 32 weeks 3 days of gestation. Apgar scores were 8 and 9 at 1 and 5 minutes, respectively. The participant was born to a maternal participant, who, while pregnant, received Dose 1 on and Dose 2 on (Day 25). The maternal participant had an obstetric history of 1 previous pregnancy (1 live birth via cesarean delivery); she formerly drank alcohol every month but never smoked tobacco during this pregnancy. The participant was diagnosed with neonatal pneumonia on at 1 day of age. On 32 weeks and 1 day of gestation), the maternal participant tested negative for COVID-19. On (Day 1 of age), the participant was in respiratory distress with sternocostal recessions, alar flaring, and tachypnea. She was suspected to have respiratory distress syndrome or neonatal sepsis. She was hospitalized for desaturating post-birth with a saturation of 84% on room air, which subsequently increased to 90% once on nasal prongs at 1 L/min of oxygen. Initial blood culture was positive for *Enterococcus faecalis*, sensitive to ampicillin. On (Day 1 of age), the participant started treatment with intravenous (IV) ampicillin (85 mg via IV infusion, 12 hourly), IV gentamicin (9 mg dai y) and oral nevirapine and zidovudine daily (both 0.3 mL until [Day 2 of age]). The maternal participant was HIV-negative, and the prescription for nevirapine and zidovudine prophylaxis was likely an error on the part of the attending doctor (as reported). The C-reactive protein was <1 mg/L (normal range [NR] not reported) and a repeat blood culture was negative. A lumbar puncture result revealed only erythrocytes 7200/µL and a commensal coagulase-negative streptococcus. On (Day 1 of age), DNA testing for aneuploidy screening was done and the result showed normal copies of chromosome X, 13, 18, and 21. On (Day 7 of age), the participant experienced sudden apnea and received full resuscitation for more than 20 minutes. Chest compressions, bag va ve mask respiration, and 2 doses of 0.2 mL adrenaline were given. She was intubated with a size 3 endotracheal tube and an IV line was placed. Arterial blood gas was performed, and calcium gluconate in a 1:1 ratio and 2 mL of sodium bicarbonate with 2 mL of water were given. When resuscitation proceeded beyond 20 minutes, a consultant was called, and postmortem lumbar puncture and blood tests were performed. The lumbar puncture result was normal. The results of blood tests showed low hemoglobin of 11.5 × 10^{12}/L (NR: 16-25.5 × 10^{12}/L), low hematocrit of 0.414 L/L (NR: 0.430-0.680 L/L), and high mean cell volume of 125.8 fL (NR: 95-121 fL), and the results were suggestive of macrocytic anemia. On Day 7 of age), the participant died due to the progression of neonatal pneumonia. An autopsy was not performed.

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Reason(s) for Narrative: Death
Participant: C4591015[redacted]; Country: South Africa
Maternal Vaccine Group (as Administered): Placebo
Date of First Dose:[redacted]; Date of Last Dose: [redacted]
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Narrative Comment
In the opinion of the investigator, there was no reasonable possibility that the neonatal pneumonia was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Demography				
Date of Birth	Gestational Age at Birth	Race	Ethnicity	Sex
[redacted]	40 weeks	Black or African American	Non-Hispanic/Latino	Male

Birth Details			
Mode of Birth	Apgar Score at 1 Minute	Apgar Score at 5 Minutes	Apgar Score at 10 Minutes
Vaginal	9	10	--

Vital Signs - Baseline				
Body Length	Weight	Diastolic Blood Pressure	Systolic Blood Pressure	Date Collected (Study Day)
47 cm	2.5 kg			[redacted] (102)

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Reason(s) for Narrative: Death
Participant: C4591015 [redacted] Country: South Africa
Maternal Vaccine Group (as Administered): BNT162b2
Date of First Dose: [redacted] Date of Last Dose: [redacted]
==========

Maternal Study Vaccination(s)				
Vaccination Number	**Vaccine**	**Maternal Vaccination Date (Study Day)**	**Time of Maternal Vaccination**	**Gestational Age at Maternal Vaccination**
1	BNT162b2	[redacted] (1)	12:37:00	25 weeks 3 days
2	BNT162b2	[redacted] (21)	12:41:00	28 weeks 2 days

Adverse Events						
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Age in Days)**	**Stop Date (Age in Days)**	**Duration (Days)**
1	INFEC	Pneumonia	PNEUMONIA	[redacted]	[redacted]	6

Adverse Events						
AE Number	**Toxicity Grade**	**Action: Participant**	**SAE**	**AE Still Present?**	**AE Related To:**	**Narrative Event**
1	4	W	Yes	FATA [redacted]	NOT RELATED /OTHER; INFECTION	Yes

Concomitant Medications
No Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Participant Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Withdrawn	FOLLOW-UP		DEATH

Narrative Comment
Participant C4591015 a 17-weeks-old Black/African American male, was born to a maternal participant by vaginal birth on at 40 weeks of gestation. A gar scores were 9 and 10 at 1 and 5 m nutes, respectively. The participant was born to a maternal participant, who, while pregnant, received Dose 1 on and Dose 2 on (Day 21). The maternal participant had a history of tobacco use (weekly) and alcohol consumption (every month); she had no previous pregnancy The participant was diagnosed with pneumonia on , at 119 days of age. On (Day 119 of age), the participant developed a loss of appetite and cough. On Day 120 of age), he was taken to the local clinic for the illness and the clinic staff said there were no problems with the participant and sent the maternal participant home with a prescription for normal saline drops, which were given to the participant from to (Day 120 to Day 122 of age). No herbal medications were

Narrative Comment
given to the participant during his illness. The participant's cough persisted for the next 2 days, but he was fine, played normally, and was fed formula but in smaller quantities. On [redacted] (Day 123 of age), the participant was sleepier than usual, slept most of the day, and woke up occasionally to drink formula but in smaller quantities. He woke up around 20:00 but was not active; he drank some formula and fell asleep at 22:30. On [redacted] (Day 124 of age), around 03:00, the participant was struggling to breathe. While the maternal participant was arranging for an ambulance, the participant coughed and then stopped breathing. The paramedics came around 04:15 and pronounced the participant dead. Per the death notice, the primary cause of the participant's death was pneumonia. No autopsy was performed. In the opinion of the investigator, there was no reasonable possibility that the pneumonia was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Demography				
Date of Birth	Age at Enrollment	Race	Ethnicity	Sex
[redacted]	27	White	Non-Hispanic/Latino	Female

Vital Signs - Baseline					
Height	Weight	BMI	Diastolic Blood Pressure	Systolic Blood Pressure	Date Collected (Study Day)
178 cm	78 kg	24.6 kg/m2	79 mmHg	131 mmHg	[redacted] (1)

Obstetrical History Details					
Number of Previous Pregnancies	Number of Vaginal Deliveries	Number of C-Section Deliveries	Number of Live Births	Number of Spontaneous Abortions	Number of Stillbirths
2	1	0	1	1	0

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Reason(s) for Narrative: Adverse Event of Special Interest - Maternal
Participant: C4591015[redacted] Country: United Kingdom
Vaccine Group (as Administered): BNT162b2
Date of First Dose[redacted]; Date of Last Dose:[redacted]
==========

Medical History
No Medical History

Study Vaccination(s)				
Vaccination Number	**Vaccine Name**	**Gestational Age at Vaccination**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	33W 3D	[redacted] (1)	12:27
2	BNT162b2	36W 3D	[redacted] (22)	15:50

Delivery Details					
Mode of Delivery	**Date of Delivery (Relative Day From Vaccination)**	**Gestational Age at Delivery**	**Outcome of Delivery**	**Was Pathology Performed?**	**Pathology Findings**
Vaginal	[redacted] (20)	39WEEKS 0DAYS	LIVE DELIVERY	N	

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Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Gestational Age at Start Date of AE**	**Start Date (Relative Day From Vaccination)**	**Stop Date (Relative Day From Vaccination)**	**Duration (Days)**
1	GENRL	Chest pain	Chest pains	Post Delivery	[redacted] 34)	02AUG2021 (35)	2
2	VASC	Deep vein thrombosis	Occlusive thrombus in left leg common femoral vein	Post Delivery	[redacted] 34)		Continuing

Adverse Events						
AE Number	**Toxicity Grade**	**Action: Investigational Product/ Participant**	**SAE**	**AE Still Present?**	**AE Related To:**	**Narrative Event**
1	1	NA/ TC	No	RECOVERED/RESOLVED (02AUG2021)	NOT RELATED /OTHER; no underlying factors found. All tests normal ECG / Chest Xray	No
2	1	NA/ TC,TCN	Yes	RECOVERING/RESOLVING	NOT RELATED /OTHER; post natal 2 weeks	Yes

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Participant Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING		
Completed	VACCINATION		
Completed	FOLLOW-UP		

Narrative Comment
Participant C4591015 a 27-year-old White female with an obstetric history of 2 previous pregnancies (1 live birth and 1 spontaneous abortion), received Dose 1 on at 33 weeks 3 days of gestation and Dose 2 on (Day 22) at 36 weeks 3 days of gestation. Concomitant medications received within 2 weeks prior to the onset of the deep vein thrombosis included ferrous sulphate (since 10 May 2021) and sodium feredetate (since 29 Jun 2021) for low hemoglobin. On 18 days after receiving Dose 2, at 39 weeks of gestation, the participant delivered a live baby through vaginal delivery. The participant was diagnosed with deep vein thrombosis (occlusive thrombus in left leg common femoral vein) on 33 days after receiving Dose 2.

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Narrat ve Comment
On [redacted] (Day 55), the participant began experiencing left hip pain along with left leg pain, and intermittent chest pain, and visited the emergency room he next day (Day 56). On [redacted] (Day 56), her laboratory tests showed an elevated white blood cell count of 13.83 × 10^9/L, C-reactive protein of 106, and fibrin D dimer of 6766 (units and normal range were not provided). The blood culture showed no growth, and COVID nasal/throat swab tests were negative. A Doppler scan of the left leg showed occlusive thrombosis in the left common femoral vein, unable to detect blood flow in left external iliac vein, and a patent inferior vena cava. An electrocardiogram (ECG) showed sinus rhythm with marked sinus arrhythmia and possible left atrial enlargement (borderline ECG), and an x-ray of pelvis showed no acute bone injury. On examination, the participant's leg was red/purple colored, the capillary refill time was less than 2 seconds, and her vitals were normal. It was reported that the participant was struggling to bear weight and she was admitted to the hospital. She was treated with enoxaparin sodium 120 mg subcutaneously (SC) (on 02 Aug 2021), gentamicin 120 mg intravenously (IV) once, clindamycin 600 mg IV 4 times a day (QDS) (from [redacted] through [redacted], paracetamol 1 g oral (PO) QDS, and ibuprofen 400 mg PO once a day (on 03 Aug 2021). A knee compression stocking was prescribed. On [redacted] (Day 57), the participant was discharged from the hospital on clindamycin 300 mg PO (from [redacted] through [redacted]), dihydrocodeine tartrate 30-60 mg PO QDS and enoxaparin sodium 80 mg SC (since 03 Aug 2021). The participant was recovering, and the deep vein thrombosis was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the deep vein thrombosis was related to the study intervention, concomitant medications, or clinical trial procedures, but was related to the participant being 2 weeks postpartum. Pfizer concurred with the investigator's causality assessment and stated that the pregnancy associated with venous stasis, endothelial injury, and a hypercoagulable state had contributed to the thrombotic event.

Reason(s) for Narrative: Adverse Event of Special Interest - Infant

Participant: C4591015 [redacted] **Country: USA**

Maternal Vaccine Group (as Adm n stered): Placebo

Date of First Dose: [redacted] **Date of Last Dose:** [redacted]

==========

Demography				
Date of Birth	Gestational Age at Birth	Race	Ethnicity	Sex
[redacted]	38 weeks 1 day	White	Non-Hispanic/Latino	Female

Birth Details			
Mode of Birth	Apgar Score at 1 Minute	Apgar Score at 5 Minutes	Apgar Score at 10 Minutes
Vaginal	8	8	--

Vital Signs - Baseline				
Body Length	Weight	Diastolic Blood Pressure	Systolic Blood Pressure	Date Collected (Study Day)
52.5 cm	3.66 kg			[redacted] (71)

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Reason(s) for Narrative: Adverse Event of Special Interest - Infant
Participant: C4591015[redacted] Country: USA
Maternal Vaccine Group (as Administered): Placebo
Date of First Dose[redacted] Date of Last Dose:[redacted]
==========

Maternal Study Vaccination(s)				
Vaccination Number	**Vaccine**	**Maternal Vaccination Date (Study Day)**	**Time of Maternal Vaccination**	**Gestational Age at Maternal Vaccination**
1	Placebo	[redacted] (1)	16:32:00	28 weeks 1 days
2	Placebo	[redacted] (36)	11:25:00	33 weeks 1 days

Adverse Events						
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Age in Days)**	**Stop Date (Age in Days)**	**Duration (Days)**
1	RESP	Hypoxia	Hypoxia	[redacted] (1)	[redacted] (5)	5
2	CONG	Ventricular septal defect	Ventricular Septal Defect	[redacted] (1)		Continuing

Adverse Events						
AE Number	**Toxicity Grade**	**Action: Participant**	**SAE**	**AE Still Present?**	**AE Related To:**	**Narrative Event**
1	2	TC,TCN	Yes	RECOVERED/RESOLVED (17AUG2021)	NOT RELATED /OTHER; Periodic desaturations requiring CPAP to provide resipratory support.	No
2	1	NA	Yes	NOT RECOVERED/NOT RESOLVED	NOT RELATED /OTHER; congenital anamoly	Yes

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Concomitant Medications				
Investigator Text	**WHO Drug Preferred Term**	**Start Date**	**End Date**	**Route**
Oxygen	OXYGEN	[redacted]		RESPIRATORY (INHALATION)

Nonstudy Vaccines
No Nonstudy Vaccines

Participant Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Withdrawn	FOLLOW-UP	22NOV2021	WITHDRAWAL BY PARENT/GUARDIAN

Narrative Comment
Participant C4591015, a day-old White female, was born to a maternal participant by vaginal birth on at 38 weeks 1 day of gestation. Apgar scores were 8 and 8 at 1 and 5 minutes, respectively. The participant was born to a maternal participant, who, while pregnant, received Dose 1 on and Dose 2 on (Day 36). The participant was diagnosed with ventricular septal defect (VSD) on at 1 day of age. On (Day 1 of age), the participant experienced hypoxia and was admitted to the neonatal intensive care unit (NICU). A murmur was discovered, and an echocardiogram showed a small VSD, which was reported to be minimal and non-clinical important per medical practice. She was treated with intravenous dextrose 10 and supplemental oxygen (on) via continuous positive airway pressure. The participant was in NICU for 4 days, and the hypoxia was considered resolved on (Day 5 of age). The participant's parent/legal guardian requested withdrawal from the study on In the opinion of the investigator, there was no reasonable possibility that the VSD was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Demography				
Date of Birth	Gestational Age at Birth	Race	Ethnicity	Sex
	37 weeks 1 day	White	Not reported	Female

Birth Details			
Mode of Birth	Apgar Score at 1 Minute	Apgar Score at 5 Minutes	Apgar Score at 10 Minutes
Vaginal	8	9	--

Vital Signs - Baseline				
Body Length	Weight	Diastolic Blood Pressure	Systolic Blood Pressure	Date Collected (Study Day)
47 cm	2.335 kg			71)

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Maternal Study Vaccination(s)				
Vaccination Number	**Vaccine**	**Maternal Vaccination Date (Study Day)**	**Time of Maternal Vaccination**	**Gestational Age at Maternal Vaccination**
1	BNT162b2	[redacted] (1)	10:19:00	27 weeks 1 days
2	BNT162b2	[redacted] (21)	09:50:00	30 weeks

Adverse Events						
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Age in Days)**	**Stop Date (Age in Days)**	**Duration (Days)**
1	CONG	Microcephaly	microcephaly	[redacted] (1)		Continuing
2	PREG	Jaundice neonatal	neonatal jaundice	[redacted] (4)		Continuing
3	PREG	Small for dates baby	small for gestational age	[redacted] (4)		Continuing

Adverse Events						
AE Number	**Toxicity Grade**	**Action: Participant**	**SAE**	**AE Still Present?**	**AE Related To:**	**Narrative Event**
1	3	NA	Yes	NOT RECOVERED/NOT RESOLVED	NOT RELATED /OTHER; unknown etiology	Yes
2	1	NA	No	NOT RECOVERED/NOT RESOLVED	NOT RELATED /OTHER; unknown etiology	No
3	3	NA	Yes	NOT RECOVERED/NOT RESOLVED	NOT RELATED /OTHER; unknown etiology	No

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Concomitant Medications
No Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Participant Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	FOLLOW-UP	08DEC2021	

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Narrative Comment
Participant C4591015 a day-old White female, was born to a maternal participant by vaginal birth on at 37 weeks 1 day of gestation. Apgar scores were 8 and 9 at 1 and 5 minutes, respectively. The participant was born to a maternal participant, who, while pregnant, received Dose 1 on and Dose 2 on (Day 21). The maternal participant with a pertinent medical history of thyroid nodule (since 23 Jan 2013), toxic adenoma (06 Dec 2017 to 08 Feb 2018), ethanol ablation of thyroid (on 08 Feb 2018), and biopsy thyroid percutaneous needle (in Aug 2013 and Jun 2014); she was a nonsmoker with a history of alcohol consumption (weekly). The maternal participant had no previous pregnancy; she had a prenatal history of gestational hypertension. The participant was diagnosed with microcephaly on at 1 day of age. At birth, the participant's body weight was 2335 g and her head circumference was 31.1 cm. A physical examination done on (Day 2 of age) did not mention small for dates baby (small for gestational age [SGA]; important medical event) or microcephaly (congenital anomaly). The participant's body weight at the time of hospital discharge on (Day 3 of age) was 2195 g. On (Day 4 of age), the participant's body weight was 2092 g, down by 10% since birth; and her head circumference was 31 cm. Microcephaly, asymmetric was noted at this visit, with birth occipital frontal circumference in the second percentile and weight in the 10th percentile, also mentioned infant as borderline SGA. On (Day 5 of age), her body weight was 2070 g, down 11% from the birth weight. Supplemen ation with formula after each breastfeeding was recommended as the maternal participant was establishing lactation. The participant returned on (Day 7 of age) and her body weight was 2206 g, gaining about 1.5 ounces per day and the breastfeeding was going well. In the opinion of the investigator, there was no reasonable possibility that the microcephaly was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment and considered the maternal participant's medical conditions including alcohol use, thyroid disease, and gestational hypertension as the risk factors for this event.

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Demography				
Date of Birth	Gestational Age at Birth	Race	Ethnicity	Sex
[redacted]	40 weeks 2 days	White	Non-Hispanic/Latino	Female

Birth Details			
Mode of Birth	Apgar Score at 1 Minute	Apgar Score at 5 Minutes	Apgar Score at 10 Minutes
Vaginal	8	9	--

Vital Signs - Baseline				
Body Length	Weight	Diastolic Blood Pressure	Systolic Blood Pressure	Date Collected (Study Day)
49.5 cm	2.99 kg			[redacted] (75)

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Reason(s) for Narrative: Adverse Event of Special Interest - Infant
Participant: C459101[redacted] Country: USA
Maternal Vaccine Group (as Administered): BNT162b2
Date of First Dose:[redacted] Date of Last Dose:[redacted]
==========

Maternal Study Vaccination(s)				
Vaccination Number	**Vaccine**	**Maternal Vaccination Date (Study Day)**	**Time of Maternal Vaccination**	**Gestational Age at Maternal Vaccination**
1	BNT162b2	[redacted] (1)	14:52:00	29 weeks 5 days
2	BNT162b2	[redacted] 22)	15:36:00	32 weeks 5 days

Adverse Events						
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Age in Days)**	**Stop Date (Age in Days)**	**Duration (Days)**
1	CONG	Atrial septal defect	fenestrated atrial septal [redacted] defect	(1)		Continuing

Adverse Events						
AE Number	**Toxicity Grade**	**Action: Participant**	**SAE**	**AE Still Present?**	**AE Related To:**	**Narrative Event**
1	1	NA	Yes	NOT RECOVERED/NOT RESOLVED	NOT RELATED /OTHER; unknown etiology	Yes

Concomitant Medications
No Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Participant Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	FOLLOW-UP	03JAN2022	

Narrative Comment
Participant C4591015[redacted] a day-old White female, was born to a maternal participant by vaginal birth on[redacted] at 40 weeks 2 days of gestation. Apgar scores were 8 and 9 at 1 and 5 minutes, respectively. The participant was born to a maternal participant, who, while pregnant, received Dose 1 o[redacted]nd Dose 2 o[redacted] (Day 22). The maternal participant had no previous pregnancy; she never smoked tobacco or drank alcohol, and it was not reported whether she used illicit drugs. The participant had a pertinent family medical history of maternal congenital heart defect (dates not reported) and congenital pulmonary stenosis and pulmonary artery dilation (both since 1992). The maternal participant's echocardiogram (echo) done in 2008 showed stability of her lesion with no recurrence of symptoms until early pregnancy when she had intermittent chest pain, nausea, and vomiting which subsequently resolved. An echo performed on the maternal participant on 27 Jan 2021 demonstrated normal left ventricular systolic function, normal right ventricular size and systolic function, moderate pulmonic valve regurgitation, and mild pulmonic valve stenosis, overall correlating with a low risk of complications during this pregnancy. Due

Narrative Comment
to the history of maternal congenital heart defect, a fetal echo was performed on 26 Mar 2021 with no evidence of cardiac structural or biventricular functional abnormalities. The participant was diagnosed with atrial septal defect (ASD) on at 1 day of age. After birth, the participant had an echo which showed no evidence of pulmonary stenosis; however, it was notable for a fenestrated ASD with 2 small left-to-right shunts. The participant had a consultation with a cardiologist, who recommended no follow-up. In the opinion of the investigator, there was no reasonable possibility that the ASD was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Demography				
Date of Birth	Gestational Age at Birth	Race	Ethnicity	Sex
[redacted]	37 weeks 5 days	White	Hispanic/Latino	Female

Birth Details			
Mode of Birth	Apgar Score at 1 Minute	Apgar Score at 5 Minutes	Apgar Score at 10 Minutes
C-Section	8	9	9

Vital Signs - Baseline				
Body Length	Weight	Diastolic Blood Pressure	Systolic Blood Pressure	Date Collected (Study Day)
48.1 cm	2.725 kg			[redacted] 34)

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Reason(s) for Narrative: Adverse Event of Special Interest - Infant
Participant: C4591015[redacted] Country: USA
Maternal Vaccine Group (as Administered): Placebo
Date of First Dose[redacted] Date of Last Dose[redacted]
==========

Maternal Study Vaccination(s)				
Vaccination Number	**Vaccine**	**Maternal Vaccination Date (Study Day)**	**Time of Maternal Vaccination**	**Gestational Age at Maternal Vaccination**
1	Placebo	[redacted] (1)	15:58:00	34 weeks
2	Placebo	[redacted] 20)	14:00:00	36 weeks 5 days

Adverse Events						
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Age in Days)**	**Stop Date (Age in Days)**	**Duration (Days)**
1	CONG	Atrial septal defect	Patent Foramen Oval (PFO)	[redacted] (1)	[redacted] (65)	65
2	CONG	Patent ductus arteriosus	Small Patent Ductus Arteriosus	[redacted] (1)	[redacted] (65)	65

Adverse Events						
AE Number	**Toxicity Grade**	**Action: Participant**	**SAE**	**AE Still Present?**	**AE Related To:**	**Narrative Event**
1	1	NA	Yes	RECO ERED/RESOLVED [redacted]	NOT RELATED /OTHER; Genetic	Yes
2	1	NA	Yes	RECOVERED/RESOLVED [redacted]	NOT RELATED /OTHER; Genetic	Yes

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Concomitant Medications
No Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Participant Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	FOLLOW-UP	27DEC2021	

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Narrative Comment
Participant C4591015 a day-old White female, was born to a maternal participant by cesarean delivery on at 37 weeks 5 days of gestation. Apgar scores were 8, 9, and 9 at 1, 5, and 10 minutes, respectively. The participant was born to a maternal participant, who, while pregnant, received Dose 1 on and Dose 2 on (Day 20). The maternal participant had an obstetric history of 3 previous pregnancies (2 live births via cesarean delivery and 1 spontaneous abortion); she never smoked tobacco and never drank alcohol. The participant was diagnosed with an atrial septal defect (ASD) and patent ductus arteriosus (PDA) on at 1 day of age. The maternal participant was admitted on for an elective cesarean delivery. Upon admission, non-reassuring fetal heart rate tracing was noted. On cardiovascular examination at birth, the participant had diminished femoral pulses. A transthoracic echocardiography performed on the next day showed patent foramen ovale (PFO) and a small PDA with a continuous left to right shunting with a peak gradient of 9 mmHg, PFO with left to right shunting, and no evidence for coarctation of the aorta, but could not rule out the development of such in the presence of the PDA. On (Day 3 of age), the participant's diminished femoral pulses improved, and the probable cause was due to the examination difficulty encountered by the medical practitioner. Medical records were requested from the pediatrician by the site for an routine follow-up. Medical records showed no impression that the PFO was still present in the participant. On (Day 64 of age), the cardiovascular examination showed no heart murmur or any other cardiac symptom that was indicative of a small PDA or PFO. The participant's health condition was stable since In the opinion of the investigator, there was no reasonable possibility that the ASD and PDA were related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Demography				
Date of Birth	**Gestational Age at Birth**	**Race**	**Ethnicity**	**Sex**
[redacted]	39 weeks	White	Non-Hispanic/Latino	Male

Birth Details			
Mode of Birth	**Apgar Score at 1 Minute**	**Apgar Score at 5 Minutes**	**Apgar Score at 10 Minutes**
Vaginal	8	9	--

Vital Signs - Baseline				
Body Length	**Weight**	**Diastolic Blood Pressure**	**Systolic Blood Pressure**	**Date Collected (Study Day)**
51.5 cm	3.242 kg			[redacted] (79)

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Reason(s) for Narrative: Adverse Event of Special Interest - Infant
Participant: C4591015[redacted] Country: USA
Maternal Vaccine Group (as Administered): BNT162b2
Date of First Dose:[redacted] Date of Last Dose:[redacted]
==========

Maternal Study Vaccination(s)				
Vaccination Number	**Vaccine**	**Maternal Vaccination Date (Study Day)**	**Time of Maternal Vaccination**	**Gestational Age at Maternal Vaccination**
1	BNT162b2	[redacted] (1)	12:27:00	27 weeks 6 days
2	BNT162b2	[redacted] (22)	11:40:00	30 weeks 6 days

Adverse Events						
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Age in Days)**	**Stop Date (Age in Days)**	**Duration (Days)**
1	CONG	Atrial septal defect	patent foramen ovale	[redacted] (1)		Continuing

Adverse Events						
AE Number	**Toxicity Grade**	**Action: Participant**	**SAE**	**AE Still Present?**	**AE Related To:**	**Narrative Event**
1	1	NA	Yes	NOT RECOVERED/NOT RESOLVED	NOT RELATED /OTHER; common congenital abnormality	Yes

Concomitant Medications
No Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Participant Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	FOLLOW-UP	10NOV2021	

Narrative Comment
Participant C4591015 , a day-old White male, was born to a maternal participant by vaginal birth on at 39 weeks of gestation. Apgar scores were 8 and 9 at 1 and 5 minutes, respectively. The participant was born to a maternal participant, who, while pregnant, received Dose 1 on and Dose 2 on (Day 22). The maternal participant had a history of tobacco use (daily) and alcohol intake (weekly); she had had no previous pregnancy. Concomitant medications received (by the maternal participant) within 2 weeks prior to the onset of the atrial septal defect (ASD) included acetylsalicylic acid (from 30 Nov 2020 to 12 May 2021) for hypertension prophylaxis and prenatal vitamins (ascorbic acid/biotin/minerals/nicotinic acid/retinol/ tocopherol/vitamin B/vitamin D) for pregnancy health (ongoing since). The participant was diagnosed with an ASD on at 1 day of age.

Narrative Comment
On (Day 4 of age), a patent foramen ovale (PFO) was diagnosed. On (Day 6 of age), an echocardiogram confirmed PFO, and an electroca d ogram showed sinus rhythm with prominent q-wave in lead III, which was considered left septal hypertrophy, a non-specific precordial repolarization abnormality. No treatment was suggested but an annual cardiac follow-up was scheduled. In the opinion of the investigator, there was no reasonable possibility that the ASD was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment and further stated that the event was more likely associated with the infantile genetic susceptibility and environmental factors from the maternal participant including smoking and alcohol intake.

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Demography				
Date of Birth	Gestational Age at Birth	Race	Ethnicity	Sex
	39 weeks 2 days	White	Non-Hispanic/Latino	Female

Birth Details			
Mode of Birth	Apgar Score at 1 Minute	Apgar Score at 5 Minutes	Apgar Score at 10 Minutes
Vaginal	7	9	--

Vital Signs - Baseline				
Body Length	Weight	Diastolic Blood Pressure	Systolic Blood Pressure	Date Collected (Study Day)
52.71 cm	3.47 kg			(82)

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Reason(s) for Narrative: Adverse Event of Special Interest - Infant
Participant: C4591015[redacted] Country: USA
Maternal Vaccine Group (as Adm n stered): BNT162b2
Date of First Dose:[redacted] Date of Last Dose:[redacted]
==========

Maternal Study Vaccination(s)				
Vaccination Number	Vaccine	Maternal Vaccination Date (Study Day)	Time of Maternal Vaccination	Gestational Age at Maternal Vaccination
1	BNT162b2	[redacted] 1)	10:32:00	27 weeks 5 days
2	BNT162b2	[redacted] 22)	10:09:00	30 weeks 5 days

Adverse Events						
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Age in Days)	Stop Date (Age in Days)	Duration (Days)
1	CONG	Atrial septal defect	Atrial septal defect	[redacted] (1)		Continuing
2	NERV	Nervous system disorder	Neonatal central nervous system abnormality	[redacted] (1)		Continuing

Adverse Events						
AE Number	Toxicity Grade	Action: Participant	SAE	AE Still Present?	AE Related To:	Narrative Event
1	2	NA	Yes	NOT RECOVERED/NOT RESOLVED	NOT RELATED /OTHER; Unknown (this is a common abnormality seen in newborns)	Yes
2	3	TC,TCN	Yes	NOT RECOVERED/NOT RESOLVED	NOT RELATED /OTHER; Possible unknown genetic condition	No

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Concomitant Medications				
Investigator Text	**WHO Drug Preferred Term**	**Start Date**	**End Date**	**Route**
Acyclovir	ACICLOVIR	26JUL2021	[redacted]	INTRAVENOUS
Ampicillin/sterile H2O	AMPICILLIN	26JUL2021	[redacted]	INTRAVENOUS
Gentamicin	GENTAMICIN	26JUL2021	[redacted]	INTRAVENOUS
Valganciclovir	VALGANCICLOVIR	31JUL2021	05AUG 021	ORAL
Ofloxacin	OFLOXACIN	24AUG2021	09SEP2021	OPHTHALMIC
Prednisolone	PREDNISOLONE	24AUG2021	23SEP2021	OPHTHALMIC
Keppra	LEVETIRACETAM	08OCT2021	08OCT2021	ORAL
Keppra	LEVETIRACETAM	08OCT2021	09DEC2021	ORAL
Melatonin	MELATONIN	18NOV2021	ONGOING	ORAL
Keppra (levetiracetam)	LEVETIRACETAM	09DEC2021	ONGOING	ORAL
Clobazam	CLOBAZAM	15DEC2021	ONGOING	ORAL

Nonstudy Vaccines
No Nonstudy Vaccines

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Participant Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	FOLLOW-UP	17JAN2022	

Narrative Comment
Participant C4591015 [redacted] a day-old White female, was born to a maternal participant by vaginal birth on [redacted] at 39 weeks 2 days of gestation. Apgar scores were 7 and 9 at 1 and 5 m nutes, respectively. The participant was born to a maternal participant, who, while pregnant, received Dose 1 on [redacted] and Dose 2 on [redacted] (Day 22). The maternal participant was a nonsmoker with a history of alcohol consumption every month; she had an obstetric history of 3 previous pregnancies (2 live births via vaginal delivery and 1 spontaneous abortion). The participant was diagnosed with an atrial septal defect (ASD) on [redacted] at 1 day of age. The participant had a transthoracic echocardiogram (echo; test date was not reported), which showed moderate secundum ASD with predominantly left-to-right shunting. No other cardiac abnormalities were identified. On [redacted], a follow-up echo showed results consistent with the previous report. She had a 3-month follow-up appointment to assess the previously diagnosed ASD. It was noted in records that there was some very slight hemodynamic effect with borderline right heart dilatation. On [redacted], follow-up echo showed resting electrocardiogram abnormality that would be a variant of normal and of no clinical concern. No medications were prescribed, and a follow-up was scheduled to review again at 1 year of age. In the opinion of the investigator, there was no reasonable possibility that the ASD was related to the study intervention or clinical trial procedures. Pfizer causality assessment for ASD was not reported.

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Demography				
Date of Birth	Gestational Age at Birth	Race	Ethnicity	Sex
	40 weeks 3 days	Black or African American	Non-Hispanic/Latino	Male

Birth Details			
Mode of Birth	Apgar Score at 1 Minute	Apgar Score at 5 Minutes	Apgar Score at 10 Minutes
Vaginal	9	10	--

Vital Signs - Baseline				
Body Length	Weight	Diastolic Blood Pressure	Systolic Blood Pressure	Date Collected (Study Day)
55 cm	3.4 kg			(94)

Reason(s) for Narrative: Adverse Event of Special Interest - Infant

Participant: C4591015[redacted] Country: South Africa

Maternal Vaccine Group (as Administered): BNT162b2

Date of First Dose: [redacted] Date of Last Dose: [redacted]

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Maternal Study Vaccination(s)				
Vaccination Number	**Vaccine**	**Maternal Vaccination Date (Study Day)**	**Time of Maternal Vaccination**	**Gestational Age at Maternal Vaccination**
1	BNT162b2	[redacted] (1)	12:26:00	27 weeks 2 days
2	BNT162b2	[redacted] (24)	12:47:00	30 weeks 4 days

Adverse Events						
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Age in Days)**	**Stop Date (Age in Days)**	**Duration (Days)**
1	CONG	Syndactyly	Syndactyly toes,bilateral	[redacted] (1)		Continuing

Adverse Events						
AE Number	**Toxicity Grade**	**Action: Participant**	**SAE**	**AE Still Present?**	**AE Related To:**	**Narrative Event**
1	1	NA	Yes	NOT RECOVERED/NOT RESOLVED	NOT RELATED /OTHER; congenital anomaly	Yes

Concomitant Medications
No Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Participant Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	FOLLOW-UP	08JUN2022	

Narrative Comment
Participant C4591015[redacted], a day-old Black/African American male, was born to a maternal participant by vaginal birth on [redacted] at 40 weeks and 3 days of gestation. Apgar scores were 9 and 10 at 1 and 5 minutes, respectively. The participant was born to a maternal participant, who, while pregnant, received Dose 1 on [redacted] and Dose 2 on [redacted](Day 24). The maternal participant was a nonsmoker with a history of alcohol consumption every month; she had 2 previous pregnancies with 2 live births via vaginal deliveries. The participant was diagnosed with bilateral syndactyly of the toes on [redacted], at 1 day of age. During a routine study Visit 3, the participant was examined by a pediatrician and diagnosed with bilateral syndactyly (fusion of the fifth and sixth toes). Subsequently, the participant was referred to a hospital for assessment by a pediatric surgeon. No relevant tests were conducted, and no further details were reported. In the opinion of the investigator, there was no reasonable possibility that the syndactyly was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Demography				
Date of Birth	Gestational Age at Birth	Race	Ethnicity	Sex
[redacted]	38 weeks 5 days	Black or African American	Non-Hispanic/Latino	Male

Birth Details			
Mode of Birth	Apgar Score at 1 Minute	Apgar Score at 5 Minutes	Apgar Score at 10 Minutes
C-Section	7	8	--

Vital Signs - Baseline				
Body Length	Weight	Diastolic Blood Pressure	Systolic Blood Pressure	Date Collected (Study Day)
		42 mmHg	68 mmHg	[redacted] (126)
52 cm	3.1 kg			[redacted] (64)

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Reason(s) for Narrative: Adverse Event of Special Interest - Infant
Participant: C4591015 [redacted]; Country: South Africa
Maternal Vaccine Group (as Administered): BNT162b2
Date of First Dose: [redacted]; Date of Last Dose: [redacted]
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Maternal Study Vaccination(s)				
Vaccination Number	**Vaccine**	**Maternal Vaccination Date (Study Day)**	**Time of Maternal Vaccination**	**Gestational Age at Maternal Vaccination**
1	BNT162b2	[redacted] (1)	12:55:00	29 weeks 5 days
2	BNT162b2	[redacted] (20)	13:14:00	32 weeks 3 days

Adverse Events						
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Age in Days)**	**Stop Date (Age in Days)**	**Duration (Days)**
1	CONG	Congenital rubella syndrome	Congenital Rubella Syndrome	[redacted] (1)		Continuing
2	CONG	Mucopolysaccharidosis	Mucopolysaccharidosis	[redacted] (1)		Continuing
3	INFEC	Neonatal pneumonia	Neonatal Pneumonia	[redacted] (1)	[redacted] (5)	5

Adverse Events						
AE Number	**Toxicity Grade**	**Action: Participant**	**SAE**	**AE Still Present?**	**AE Related To:**	**Narrative Event**
1	2	NA	Yes	NOT RECOVERED/NOT RESOLVED	NOT RELATED /OTHER; Congenital Rubella	No

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Reason(s) for Narrative: Adverse Event of Special Interest - Infant
Participant: C4591015 [redacted]; Country: South Africa
Maternal Vaccine Group (as Administered): BNT162b2
Date of First Dose: [redacted]; Date of Last Dose: [redacted]
==========

Adverse Events						
AE Number	**Toxicity Grade**	**Action: Participant**	**SAE**	**AE Still Present?**	**AE Related To:**	**Narrative Event**
2	2	NA	Yes	NOT RECOVERED/NOT RESOLVED	NOT RELATED /OTHER; Congenital anomaly	Yes
3	2	TC,TCN	Yes	RECOVERED/RESOLVED (27DEC2021)	NOT RELATED /OTHER; Aspirated liqor in utero	No

Concomitant Medications				
Investigator Text	**WHO Drug Preferred Term**	**Start Date**	**End Date**	**Route**
Amikacin	AMIKACIN	[redacted]	ONGOING	INTRAVENOUS
Ampicillin	AMPICILLIN	[redacted]	ONGOING	INTRAVENOUS

Nonstudy Vaccines
No Nonstudy Vaccines

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Participant Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	FOLLOW-UP	01JUN2022	

Narrative Comment
Participant C4591015[redacted], a day-old Black/African American male, was born to a maternal participant by cesarean delivery on[redacted] at 38 weeks and 5 days of gestation. Apgar scores were 7 and 8 at 1 and 5 minutes, respectively. The participant was born to a maternal participant, who, while pregnant, received Dose 1 on[redacted] and Dose 2 on[redacted] (Day 20). The maternal participant never smoked tobacco or drank alcohol; she had 1 previous pregnancy with 1 live birth via cesarean delivery. The participant was diagnosed with mucopolysaccharidosis on[redacted] at 1 day of age. On[redacted], at 2 months of age, the infant participant was seen onsite. The maternal participant expressed concerns about the infant's inability to follow or focus on objects. The infant had previously been evaluated at a local clinic without a diagnosis, leading to a referral to the hospital for assessment by a pediatrician. On[redacted] a B scan was performed, and the ophthalmological findings were consistent with congenital cataract and glaucoma, and bilateral synechiolysis was scheduled at a tertiary hospital. On[redacted], at 4 months of age, the participant was assessed by the pediatrician and referred to an academic hospital for further evaluation. The primary investigator requested the maternal participant to provide the pediatrician referral letter to the academic hospital, which was delivered to the site on[redacted] Based on the referral letter, a diagnosis of congenital rubella syndrome (onset on[redacted]) and mucopolysaccharidosis was made. On[redacted] a physical examination of the participant by a pediatrician revealed the following: short stature, low lying ears, posterior fontanelle still open at 5 months and 2 weeks, coarse facial features (big lips), bilateral leukocoria with bilateral cataract, musculoskeletal hypotonia and decreased

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Narrative Comment
reflexes, short extremities, neurological head lag (delayed milestones). No further tests were conducted except for an ophthalmological examination regarding cataract. In the opinion of the investigator, there was no reasonable possibility that the mucopolysaccharidosis was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Demography				
Date of Birth	Gestational Age at Birth	Race	Ethnicity	Sex
[redacted]	38 weeks 4 days	White	Hispanic/Latino	Male

Birth Details			
Mode of Birth	Apgar Score at 1 Minute	Apgar Score at 5 Minutes	Apgar Score at 10 Minutes
Vaginal	9	10	10

Vital Signs - Baseline				
Body Length	Weight	Diastolic Blood Pressure	Systolic Blood Pressure	Date Collected (Study Day)
45.5 cm	2.42 kg			[redacted] (44)

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Reason(s) for Narrative: Adverse Event of Special Interest - Infant

Participant: C4591015[redacted] Country: Spain

Maternal Vaccine Group (as Administered): BNT162b2

Date of First Dose:[redacted] Date of Last Dose:[redacted]

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Maternal Study Vaccination(s)				
Vaccination Number	**Vaccine**	**Maternal Vaccination Date (Study Day)**	**Time of Maternal Vaccination**	**Gestational Age at Maternal Vaccination**
1	BNT162b2	[redacted] (1)	12:00:00	32 weeks 4 days
2	BNT162b2	[redacted] (21)	11:00:00	35 weeks 3 days

Adverse Events						
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Age in Days)**	**Stop Date (Age in Days)**	**Duration (Days)**
1	CONG	Trisomy 21	down's syndrome	[redacted] (2)		Continuing

Adverse Events						
AE Number	**Toxicity Grade**	**Action: Participant**	**SAE**	**AE Still Present?**	**AE Related To:**	**Narrative Event**
1	3	NA	Yes	NOT RECOVERED/NOT RESOLVED	NOT RELATED /OTHER; down's syndrome	Yes

Concomitant Medications
No Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Participant Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	FOLLOW-UP	19JAN2022	

Narrative Comment
Participant C4591015 [redacted], a day-old White male, was born to a maternal participant by vaginal birth on [redacted] at 38 weeks 4 days of gestation. Apgar scores were 9, 10, and 10 at 1, 5, and 10 minutes, respectively. The participant was born to a maternal participant, who, while pregnant, received Dose 1 on [redacted] and Dose 2 on [redacted] (Day 21). The maternal participant had an ongoing history of tobacco use but never consumed alcohol; she had an obstetric history of 1 previous pregnancy (1 live birth via vaginal delivery). The participant was diagnosed with trisomy 21 on [redacted], at 2 days of age. On [redacted] (Day 1 of age), the participant's physical exploration included: Microcephaly with brachycephaly and normotensive anterior fontanelle. Archaic reflections present. Tone preserved. Skin redundant in the cervical region. Small mouth with protrusion of the tongue. Eyelid grooves obliquely upward and outward. Small nose with flattened nasal root. Palate and clavicles were intact. Chest: without distress, eupneic. Good bilateral air inlet. No added noise. Rhythmic tones without murmurs. Palpable femoral pulses. Abdomen: soft and depressible, no masses or megaly. Not painful. Male

Narrative Comment
external genitalia with scrotal sac testes. Hypermobility of the hips. On [redacted] (Day 2 of age), the infant participant was suspected of Down syndrome and was admitted to the unit care neonatal unit to complete studies. Karyotyping showed trisomy 21. On [redacted] (Day 3 of age), transthoracic echocardiography findings included: Situs solitus, levocardia, and levoapex. Normal systemic and pulmonary venous drainage. Auriculoventricular and ventriculoarterial concordance. A differential diagnosis of atrial septal defect (ASD) type ostium secundum (OS) vs patent foramen ovale (PFO) was considered. No significant tricuspid or mitral insufficiency. Interventricular septum seemed intact and slightly rectified. Free exit tracts. Normally functioning tricuspid aortic valve. Normal bow. 2-3 mm. patent ductus arteriosus (PDA) with a preferential left to right shunt. Pulmonary tract outflow and PR interval normal. The infant participant was discharged from the hospital on [redacted] On [redacted] (Day 33 of age), a follow-up echocardiography showed interatrial communication and PDA; diagnostic judgment: ASD OS vs PFO; pulmonary hypertension PDA. In the opinion of the investigator, there was no reasonable possibility that trisomy 21 was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Demography				
Date of Birth	**Gestational Age at Birth**	**Race**	**Ethnicity**	**Sex**
[redacted]	38 weeks 4 days	White	Non-Hispanic/Latino	Male

Birth Details			
Mode of Birth	**Apgar Score at 1 Minute**	**Apgar Score at 5 Minutes**	**Apgar Score at 10 Minutes**
Vaginal	9	10	--

Vital Signs - Baseline				
Body Length	**Weight**	**Diastolic Blood Pressure**	**Systolic Blood Pressure**	**Date Collected (Study Day)**
52.7 cm	3.635 kg			[redacted](39)

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Reason(s) for Narrative: Adverse Event of Special Interest - Infant

Participant: C4591015 [redacted]; Country: Spain

Maternal Vaccine Group (as Administered): BNT162b2

Date of First Dose: [redacted]; Date of Last Dose: [redacted]

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Maternal Study Vaccination(s)				
Vaccination Number	**Vaccine**	**Maternal Vaccination Date (Study Day)**	**Time of Maternal Vaccination**	**Gestational Age at Maternal Vaccination**
1	BNT162b2	[redacted] (1)	12:19:00	33 weeks 2 days
2	BNT162b2	[redacted] (21)	13:05:00	36 weeks 1 days

Adverse Events						
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Age in Days)**	**Stop Date (Age in Days)**	**Duration (Days)**
1	CONG	DiGeorge's syndrome	Digeorge syndrome	[redacted] (1)		Continuing
2	RENAL	Vesicoureteric reflux	Vesicoureteral reflux	[redacted] (1)		Continuing
3	RENAL	Pyelocaliectasis	Right distal ureteral dilation with bilateral pyele ectasia	[redacted] (8)		Continuing
4	INFEC	Pyelonephritis acute	acute pyelonephritis	[redacted] (9)	[redacted] (14)	6
5	INFEC	Pyelonephritis	pyelonephritis	[redacted] (40)	[redacted] (44)	5
6	INFEC	Pyelonephritis	pyelonephritis	[redacted] (162)	[redacted] (164)	3

Adverse Events						
AE Number	**Toxicity Grade**	**Action: Participant**	**SAE**	**AE Still Present?**	**AE Related To:**	**Narrative Event**
1	3	NA	Yes	NOT RECOVERED/NOT RESOLVED	NOT RELATED /OTHER; congenital disease	Yes

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Reason(s) for Narrative: Adverse Event of Special Interest - Infant
Participant: C4591015[redacted]; Country: Spain
Maternal Vaccine Group (as Administered): BNT162b2
Date of First Dose:[redacted]; Date of Last Dose:[redacted]
==========

Adverse Events						
AE Number	**Toxicity Grade**	**Action: Participant**	**SAE**	**AE Still Present?**	**AE Related To:**	**Narrative Event**
2	4	NA	Yes	NOT RECOVERED/NOT RESOLVED	NOT RELATED /OTHER; UNK	Yes
3	2	NA	No	NOT RECOVERED/NOT RESOLVED	NOT RELATED /OTHER; congenital anomaly	No
4	4	TC	Yes	RECOVERED/RESOLVED (28JUL2021)	NOT RELATED /OTHER; Bacterial infection. Urineculture with E. coli and Enterococcus faecalis.	No
5	3	TC	Yes	RECOVERED/RESOLVED (27AUG2021)	NOT RELATED /OTHER; infection	No
6	3	TC	Yes	RECOVERED/RESOLVED (25DEC2021)	NOT RELATED /OTHER; infection	No

Concomitant Medications				
Investigator Text	**WHO Drug Preferred Term**	**Start Date**	**End Date**	**Route**
Ampiciline	AMPICILLIN	[redacted]	[redacted]	INTRAVENOUS
Cefotaxime	CEFOTAXIME			INTRAVENOUS
Amoxicilin-clavulanic	AMOXICILLIN;CLAVULANIC ACID			INTRAVENOUS
AmpicilinE	AMPICILLIN	[redacted]	[redacted]	INTRAVENOUS
CefuroximE	CEFUROXIME			INTRAVENOUS
Gentamicine	GENTAMICIN			INTRAVENOUS

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Concomitant Medications				
Investigator Text	**WHO Drug Preferred Term**	**Start Date**	**End Date**	**Route**
Trimetoprim-sulfametoxazol	SULFAMETHOXAZOLE;TRIMETHOPRIM	[redacted]	ONGOING	ORAL
ampicillin	AMPICILLIN		ONGOING	INTRAVENOUS
cefuroxime.	CEFUROXIME		ONGOING	INTRAVENOUS

Nonstudy Vaccines
No Nonstudy Vaccines

Participant Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	FOLLOW-UP	07JAN2022	

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Narrative Comment
Participant C4591015 [redacted], a day-old White male, was born to a maternal participant by vaginal birth on [redacted] at 38 weeks 4 days of gestation. Apgar scores were 9 and 10 at 1 and 5 minutes, respectively. The infant participant was born to a maternal participant, who, while pregnant, received Dose 1 on [redacted] and Dose 2 on [redacted] (Day 21). The maternal participant was a nonsmoker with a history of alcohol consumption (weekly); she had an obstetric history of 1 previous pregnancy (1 live birth via vaginal delivery). The participant was diagnosed with DiGeorge's syndrome (22q11.2 deletion syndrome) and vesicoureteral reflux on [redacted], at 1 day of age. On [redacted] (Day 1 of age), the participant underwent array comparative genomic hybridization (CGH) analysis test, which showed 22q11.2 deletion syndrome. The participant was asymptomatic for this congenital disease since birth (the result of the array CGH was not available until [redacted]), and the suspected diagnosis was due to his family history (father and brother) of this disease. On the same day (Day 1 of age), the participant was taken to the emergency room and the physician's office. Prenatal ultrasound diagnosis of suspected renal duplication was not confirmed in postnatal ultrasound, in which only mild pyelocaliceal ectasia, a consequence of vesicoureteral reflux, was observed on both sides. The participant was diagnosed with pyelocaliectasis (right distal ureteral dilation with bilateral pyelectasis) on [redacted] at 8 days of age. The pyelocaliectasis and vesicoureteric reflux were ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that DiGeorge's syndrome and vesicoureteric reflux were related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Table of Abbreviations		
Category	**Abbreviation**	**Text**
Action - Participant	N	No action
	O	Other
	P	Drug withdrawn (study intervention discontinued)
	TC	Concomitant drug treatment given
	TCN	Concomitant nondrug treatment given
	W	Withdrawn from study
Toxicity Grade	1	Mild
	2	Moderate
	3	Severe
	4	Life-threatening
System Organ Class	BLOOD	Blood and lymphatic system disorders
	CARD	Cardiac disorders
	CONG	Congenital, familial and genetic disorders
	EAR	Ear and labyrinth disorders
	ENDO	Endocrine disorders
	EYE	Eye disorders
	GASTR	Gastrointestinal disorders
	GENRL	General disorders and administration site conditions
	HEPAT	Hepatobiliary disorders
	IMMUN	Immune system disorders
	INFEC	Infections and infestations
	INJ&P	Injury poisoning and procedural complications
	INV	Investigations
	METAB	Metabolism and nutrition disorders
	MUSC	Musculoskeletal and connective tissue disorders
	NEOPL	Neoplasms benign, malignant and unspecified (incl cysts and polyps)
	NERV	Nervous system disorders
	PI	Product issues
	PREG	Pregnancy, puerperium and perinatal conditions
	PSYCH	Psychiatric disorders
	RENAL	Renal and urinary disorders
	REPRO	Reproductive system and breast disorders
	RESP	Respiratory, thoracic and mediastinal disorders
	SKIN	Skin and subcutaneous tissue disorders

Table of Abbreviations		
Category	**Abbreviation**	**Text**
	SOCCI	Social circumstances
	SURG	Surgical and medical procedures
	VASC	Vascular disorders

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Demography				
Date of Birth	**Gestational Age at Birth**	**Race**	**Ethnicity**	**Sex**
[redacted]	39 weeks 1 day	White	Non-Hispanic/Latino	Male

Birth Details			
Mode of Birth	**Apgar Score at 1 Minute**	**Apgar Score at 5 Minutes**	**Apgar Score at 10 Minutes**
Vaginal	8	9	--

Vital Signs - Baseline			
Body Length	**Weight**	**Date Collected (Study Day)**	**Infant age in Days**
50.5 cm	3.3 kg	[redacted] (47)	1

Maternal Study Vaccination(s)				
Vaccination Number	**Vaccine**	**Maternal Vaccination Date (Study Day)**	**Time of Maternal Vaccination**	**Gestational Age at Maternal Vaccination**
1	Placebo	[redacted] (1)	16:01:00	32 weeks 4 days
2	Placebo	[redacted] (22)	17:16:00	35 weeks 4 days

Adverse Events
No Adverse Events

Concomitant Medications
No Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Case Details				
Visit	**>7 Days After Dose 2**	**Severe**	**Infant Age**	**Visit Date (Study Day)**
COVID Illness Visit 1	Yes	Yes	5 Weeks	[redacted] (85)

Signs and Symptoms of Potential COVID-19						
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**	**Protocol and/or CDC Defined**	**Infant age in Days (Date First Symptom Started)**	**Narrative Event**
COVID Illness Visit 1 /[redacted](85)/ [redacted](84)/ [redacted](88)	YES	FEVER		Protocol and CDC Defined Symptoms Present	38	Yes
	YES	NEW OR INCREASED COUGH		Protocol and CDC Defined Symptoms Present	38	Yes

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Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis (Study Day)**	**MedDRA Preferred Term**	**Infant Age in days**
COVID Illness Visit 1	[redacted] (85)	COVID-19 like illness	[redacted] (84)	Suspected COVID-19	38
COVID Illness Visit 1	[redacted] (85)	Covid 19 Illness	[redacted] (85)	COVID-19	39

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	[redacted] (85)	[redacted] (85)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**
1	COVID Illness Visit 1	[redacted] (85)	[redacted] (84)	SWABBED MATERIAL

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SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Specimen Collection Location**	**Test Result**	**Comments/Findings/Details**	**Trade Name**
1	NASOPHARYNX	POSITIVE		BIOFIRE COVID-19 TEST

Health Care Utilization						
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**	**Infant age in days**
COVID Illness Visit 1	[redacted](85)	HOSPITAL	NO		NA	39
		SPECIALIST	NO		NA	39
		EMERGENCY ROOM	YES	1	NA	39
		PRIMARY CARE PHYSICIAN	NO		NA	39
		URGENT CARE	NO		NA	39
		TELEPHONE CONSULTATION	NO		NA	39
		OTHER	NO		NA	39

Hospitalization Details
No Hospitalization Details

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Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology								
Visit	**Visit Date (Study Day)**	**Date of Test (Study Day)**	**Laboratory Test**	**Result**	**Units**	**Lower Limit Range**	**Upper Limit Range**	**Infant age in Days**
COVID Illness Visit 1	[redacted] (85)	[redacted] (84)	Basophils	0.40†	%	0	2	38
			Eosinophils	3.30†	%	1	9	38
			Hematocrit	0.33	L/L	0.3	0.4	38
			Hemoglobin	115	g/L	100	150	38
			Lymphocytes	50.40†	%	40	70	38
			Monocytes	29.2†	%	1	9	38
			Neutrophils	1.3	10^9/L	23	43	38
			Platelets	387	10^9/L	200	473	38
			Erythrocytes	3.47	10^12/L	3.8	5.5	38
			Leukocytes	7.8	10^9/L	6	17	38

Note: † = Original results and units are displayed for UNCONVERTED Standard lab results.

Vital Signs - COVID-19								
Visit	**Visit Date (Study Day)**	**Date Collected (Study Day)**	**Record Identifier**	**Respiratory Rate**	**Heart Rate**	**Oxygen Saturation**	**Diastolic Blood Pressure**	**Systolic Blood Pressure**
COVID Illness Visit 1	[redacted] (85)	[redacted] (84)	1			96 %		
		[redacted] (85)	2	50 breaths/min	184 beats/min			

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Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging								
Assessment Number	Visit	Visit Date (Study Day)	Date of Assessment	Location of Assessment	If Other, Specify	Type of Imaging Exam	If Other, Specify	Overall Assessment
1	COVID Illness Visit 1	[redacted] (85)	[redacted]	CHEST	.	X-RAY	NA	NORMAL

Participant Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	FOLLOW-UP	04JAN2022	

PFIZER CONFIDENTIAL SDTM Creation: 12JAN2024 (04:07) Source Data: dm, vs, mh, ex, ae, mb, co, di, is, face, ce, ho, faho, ds, cm, mo, pr, lb (Snapshot Date: 09Jan2024) Output File: ./nda2/C4591015_COVID_NARR/profile_inf Date of Generation: 20MAR2024 (10:46)

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Narrative Comment
Participant C4591015 [redacted] a 5-week 3-day-old White male with no reported medical history, was born to a maternal participant by vaginal birth on [redacted] at 39 weeks 1 day gestational age, with Apgar scores of 8 and 9 at 1 and 5 minutes, respectively. The maternal participant, while pregnant, received Dose 1 on [redacted] at 32 weeks 4 days of gestation and Dose 2 on [redacted] (Day 22) at 35 weeks 4 days of gestation. On [redacted] (Day 39 of age), the participant was diagnosed with severe COVID-19 and his parent/legal guardian reported fever and new or increased cough, with the first symptom starting on [redacted], 37 days after birth, and the last symptom resolved on [redacted] (Day 42 of age). The participant was taken to the emergency room (once). The local laboratory SARS-CoV-2 test result at the time of the COVID-19 illness on [redacted] (Day 38 of age) was positive. On [redacted] (Day 38 of age), the participant had an oxygen saturation of 96% on room air. On the same day (Day 38 of age), a chest radiograph revealed normal findings. On the same day (Day 38 of age), blood investigations revealed the following results: neutrophils: 1.3×10^9/L (normal range [NR]: 23-43 $\times 10^9$/L), basophils: 0.40% (NR: 0%-2%), eosinophils: 3.30% (NR: 1%-9%), lymphocytes: 50.40% (NR: 40%-70%), monocytes: 29.2% (NR: 1%-9%), erythrocytes: 3.47×10^{12}/L (NR: 3.8-5.5 $\times 10^{12}$/L), hematocrit: 0.33 L/L (NR: 0.3-0.4 L/L), hemoglobin: 115 g/L (NR: 100-150 g/L), platelets: 387×10^9/L (NR: 200-473 $\times 10^9$/L), and leukocytes: 7.8×10^9/L (NR: 6-17 $\times 10^9$/L). The central laboratory SARS-CoV-2 NAAT result at the time of COVID-19 illness on [redacted] (Day 39 of age) was positive. On [redacted] (Day 39 of age), the participant had a heart rate (HR) of 184 beats/min and a respiratory rate (RR) of 50 breaths/min. The participant therefore had severe COVID-19 illness per protocol criteria (ie, had clinical signs at rest indicative of severe systemic illness [HR: >180 beats/min and RR: ≥34 breaths/min from 1 month to 6 months of age]).

Demography				
Date of Birth	**Gestational Age at Birth**	**Race**	**Ethnicity**	**Sex**
[redacted]	40 weeks 2 days	White	Non-Hispanic/Latino	Male

Birth Details			
Mode of Birth	**Apgar Score at 1 Minute**	**Apgar Score at 5 Minutes**	**Apgar Score at 10 Minutes**
Vaginal	8	9	--

Vital Signs - Baseline			
Body Length	**Weight**	**Date Collected (Study Day)**	**Infant age in Days**
49.5 cm	3.04 kg	[redacted] (73)	1

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Maternal Study Vaccination(s)				
Vaccination Number	**Vaccine**	**Maternal Vaccination Date (Study Day)**	**Time of Maternal Vaccination**	**Gestational Age at Maternal Vaccination**
1	BNT162b2	[redacted] 1)	11:36:00	30 weeks
2	BNT162b2	[redacted] 24)	13:06:00	33 weeks 2 days

Adverse Events
No Adverse Events

Concomitant Medications
No Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Case Details				
Visit	**>7 Days After Dose 2**	**Severe**	**Infant Age**	**Visit Date (Study Day)**
COVID Illness Visit 1	Yes	Yes	23 Weeks	[redacted]234)

Signs and Symptoms of Potential COVID-19						
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**	**Protocol and/or CDC Defined**	**Infant age in Days (Date First Symptom Started)**	**Narrative Event**
COVID Illness Visit 1 /[redacted](234)/ [redacted](230)/ [redacted](245)	YES	NEW OR INCREASED COUGH		Protocol and CDC Defined Symptoms Present	158	Yes

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Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis (Study Day)**	**MedDRA Preferred Term**	**Infant Age in days**
COVID Illness Visit 1	[redacted] (234)	COVID-19 like illness	[redacted] (230)	Suspected COVID-19	158
COVID Illness Visit 1	[redacted] (234)	Covid 19	[redacted] (233)	COVID-19	161

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	[redacted] (234)	[redacted] (234)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**
1	COVID Illness Visit 1	[redacted] (234)	[redacted] (233)	SWABBED MATERIAL

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Specimen Collection Location**	**Test Result**	**Comments/Findings/Details**	**Trade Name**
1	NASOPHARYNX	POSITIVE		ABBOTT DIAGNOSTICS ID NOW COVID-19

Health Care Utilization						
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**	**Infant age in days**
COVID Illness Visit 1	[redacted] (234)	HOSPITAL	NO		NA	162
		SPECIALIST	NO		NA	162
		EMERGENCY ROOM	NO		NA	162
		PRIMARY CARE PHYSICIAN	YES	1	NA	162
		URGENT CARE	NO		NA	162
		TELEPHONE CONSULTATION	NO		NA	162
		OTHER	NO		NA	162

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Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

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Note: † = Original results and units are displayed for UNCONVERTED Standard lab results.

Vital Signs - COVID-19

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Respiratory Rate	Heart Rate	Oxygen Saturation	Diastolic Blood Pressure	Systolic Blood Pressure
COVID Illness Visit 1	[redacted] (234)	[redacted] (234)	1	46 breaths/min	130 beats/min			

Oxygenation Parameters

No Oxygenation Parameters

Concomitant Medications - Vasopressors

No Concomitant Medications - Vasopressors

Imaging

No Imaging

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Participant Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	FOLLOW-UP	01MAR2022	

Narrative Comment
Participant C4591015 [redacted], a 22-week 4-day-old White male with no reported medical history, was born to a maternal participant by vaginal birth on [redacted] at 40 weeks 2 days gestational age, with Apgar scores of 8 and 9 at 1 and 5 minutes, respectively. The maternal participant, while pregnant, received Dose 1 on [redacted] at 30 weeks of gestation and Dose 2 on [redacted] (Day 24) at 33 weeks 2 days of gestation. On [redacted] (Day 161 of age), the participant was diagnosed with severe COVID-19 and his parent/legal guardian reported a new or increased cough, with the symptom starting on [redacted] 157 days after birth, and the symptom resolved on [redacted] (Day 173 of age). The participant was taken to his primary care physician (once). The local laboratory SARS-CoV-2 test result at the time of the COVID-19 illness on [redacted] (Day 161 of age) was positive. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on [redacted] (Day 162 of age) was positive. On [redacted] (Day 162 of age), the participant had a heart rate of 130 beats/min and a respiratory rate (RR) of 46 breaths/min. The participant therefore had severe COVID-19 illness per protocol criteria (ie, had clinical signs at rest indicative of severe systemic illness [RR: ≥34 breaths/min from 1 month to 6 months of age]).

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Demography				
Date of Birth	**Gestational Age at Birth**	**Race**	**Ethnicity**	**Sex**
	38 weeks 2 days	White	Non-Hispanic/Latino	Male

Birth Details			
Mode of Birth	**Apgar Score at 1 Minute**	**Apgar Score at 5 Minutes**	**Apgar Score at 10 Minutes**
Vaginal	8	9	--

Vital Signs - Baseline			
Body Length	**Weight**	**Date Collected (Study Day)**	**Infant age in Days**
50.8 cm	2.7 kg	(64)	1

Maternal Study Vaccination(s)				
Vaccination Number	**Vaccine**	**Maternal Vaccination Date (Study Day)**	**Time of Maternal Vaccination**	**Gestational Age at Maternal Vaccination**
1	Placebo	[redacted](1)	11:20:00	29 weeks 2 days
2	Placebo	[redacted](20)	15:47:00	32 weeks

Adverse Events
No Adverse Events

Concomitant Medications
No Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Case Details				
Visit	**>7 Days After Dose 2**	**Severe**	**Infant Age**	**Visit Date (Study Day)**
COVID Illness Visit 1	Yes	Yes	20 Weeks	[redacted](208)

Signs and Symptoms of Potential COVID-19						
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**	**Protocol and/or CDC Defined**	**Infant age in Days (Date First Symptom Started)**	**Narrative Event**
COVID Illness Visit 1 / [redacted](208)/ [redacted](208)/ [redacted](223)	YES	NEW OR INCREASED COUGH		Protocol and CDC Defined Symptoms Present	145	Yes

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis (Study Day)**	**MedDRA Preferred Term**	**Infant Age in days**
COVID Illness Visit 1	[redacted] (208)	COVID-19 like illness	[redacted] (208)	Suspected COVID-19	145

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	[redacted] (208)	[redacted] (208)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

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Health Care Utilization						
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**	**Infant age in days**
COVID Illness Visit 1	[redacted](208)	HOSPITAL	NO		NA	145
		SPECIALIST	NO		NA	145
		EMERGENCY ROOM	NO		NA	145
		PRIMARY CARE PHYSICIAN	NO		NA	145
		URGENT CARE	NO		NA	145
		TELEPHONE CONSULTATION	NO		NA	145
		OTHER	NO		NA	145

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

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Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Note: † = Original results and units are displayed for UNCONVERTED Standard lab results.

Vital Signs - COVID-19								
Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Respiratory Rate	Heart Rate	Oxygen Saturation	Diastolic Blood Pressure	Systolic Blood Pressure
COVID Illness Visit 1	[redacted] (208)	[redacted] (208)	1	40 breaths/min	141 beats/min	97 %		

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Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Participant Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	FOLLOW-UP	22FEB2022	

Narrative Comment
Participant C4591015 [redacted], a 20-week 5-day-old White male with no reported medical history, was born to a maternal participant by vaginal birth on [redacted] at 38 weeks 2 days gestational age, with Apgar scores of 8 and 9 at 1 and 5 minutes, respectively. The maternal participant, while pregnant, received Dose 1 on [redacted] at 29 weeks 2 days of gestation and Dose 2 on [redacted] (Day 20) at 32 weeks of gestation. On [redacted] (Day 145 of age), the participant was diagnosed with severe suspected COVID-19 and his parent/legal guardian reported a new or increased cough, with the symptom starting on [redacted], 144 days after birth, and the symptom resolved on [redacted] (Day 160 of age). The participant did not have any healthcare contact. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on [redacted] (Day 145 of age) was positive. No local laboratory SARS-CoV-2 NAAT was done. On [redacted] (Day 145 of age), the participant had a heart rate of 141 beats/min, respiratory rate (RR) of 40 breaths/min, and oxygen saturation of 97% on room air. The participant therefore had severe COVID-19 illness per protocol criteria (ie, had clinical signs at rest indicative of severe systemic illness [RR: ≥34 breaths/min from 1 month to 6 months of age]).

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Demography				
Date of Birth	**Gestational Age at Birth**	**Race**	**Ethnicity**	**Sex**
[redacted]	36 weeks 3 days	White	Hispanic/Latino	Male

Birth Details			
Mode of Birth	**Apgar Score at 1 Minute**	**Apgar Score at 5 Minutes**	**Apgar Score at 10 Minutes**
Vaginal	8	9	--

Vital Signs - Baseline			
Body Length	**Weight**	**Date Collected (Study Day)**	**Infant age in Days**
46 cm	2.4 kg	[redacted] (63)	1

Maternal Study Vaccination(s)				
Vaccination Number	**Vaccine**	**Maternal Vaccination Date (Study Day)**	**Time of Maternal Vaccination**	**Gestational Age at Maternal Vaccination**
1	BNT162b2	[redacted] (1)	16:24:00	27 weeks 4 days
2	BNT162b2	[redacted] (22)	11:23:00	30 weeks 4 days

Adverse Events
No Adverse Events

Concomitant Medications
No Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: COVID-19 Case (Severe and/or Multiple)
Participant: C4591015 [redacted]; Country: USA
Maternal Vaccine Group (as Administered): BNT162b2
Date of First Dose: [redacted]; Date of Last Dose: [redacted]
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Case Details				
Visit	**>7 Days After Dose 2**	**Severe**	**Infant Age**	**Visit Date (Study Day)**
COVID Illness Visit 1	Yes	Yes	23 Weeks	[redacted] (228)

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Signs and Symptoms of Potential COVID-19						
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**	**Protocol and/or CDC Defined**	**Infant age in Days (Date First Symptom Started)**	**Narrative Event**
COVID Illness Visit 1 / (228)/ (224)/ (232)	YES	FEVER		Protocol and CDC Defined Symptoms Present	162	Yes
	YES	NEW OR INCREASED SHORTNESS OF BREATH		Protocol and CDC Defined Symptoms Present	162	Yes
	YES	NEW OR INCREASED COUGH		Protocol and CDC Defined Symptoms Present	162	Yes
	YES	DIARRHEA		Protocol and CDC Defined Symptoms Present	162	Yes

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Reason(s) for Narrative: COVID-19 Case (Severe and/or Multiple)
Participant: C4591015[redacted]; Country: USA
Maternal Vaccine Group (as Administered): BNT162b2
Date of First Dose: [redacted]; Date of Last Dose: [redacted]
==========

Signs and Symptoms of Potential COVID-19						
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**	**Protocol and/or CDC Defined**	**Infant age in Days (Date First Symptom Started)**	**Narrative Event**
	NO		CHILLS	Protocol and CDC Defined Symptoms Present	162	Yes
	YES	VOMITING		Protocol and CDC Defined Symptoms Present	162	Yes

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Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis (Study Day)**	**MedDRA Preferred Term**	**Infant Age in days**
COVID Illness Visit 1	[redacted] (228)	COVID-19 like illness	[redacted] (224)	Suspected COVID-19	162

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	[redacted] (228)	[redacted] (228)	NASAL SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

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Health Care Utilization						
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**	**Infant age in days**
COVID Illness Visit 1	[redacted](228)	HOSPITAL	NO		NA	166
		SPECIALIST	NO		NA	166
		EMERGENCY ROOM	YES	1	NA	166
		PRIMARY CARE PHYSICIAN	NO		NA	166
		URGENT CARE	NO		NA	166
		TELEPHONE CONSULTATION	NO		NA	166
		OTHER	NO		NA	166

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

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Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Note: † = Original results and units are displayed for UNCONVERTED Standard lab results.

Vital Signs - COVID-19								
Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Respiratory Rate	Heart Rate	Oxygen Saturation	Diastolic Blood Pressure	Systolic Blood Pressure
COVID Illness Visit 1	[redacted] (228)	[redacted] (228)	1	42 breaths/min	147 beats/min	99 %		

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Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Participant Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	FOLLOW-UP	01APR2022	

Narrative Comment
Participant C4591015 [redacted], a 23-week 1-day-old White male with no reported medical history, was born to a maternal participant by vaginal birth on [redacted] at 36 weeks 3 days gestational age, with Apgar scores of 8 and 9 at 1 and 5 minutes, respectively. The maternal participant, while pregnant, received Dose 1 on [redacted] at 27 weeks 4 days of gestation and Dose 2 on [redacted] (Day 22) at 30 weeks 4 days of gestation. On [redacted] (Day 162 of age), the participant was diagnosed with severe suspected COVID-19 and his parent/legal guardian reported fever, new or increased shortness of breath, new or increased cough, diarrhea, chills, and vomiting, with the first symptom starting on [redacted], 161 days after birth, and the last symptom resolved on [redacted] (Day 170 of age). The participant was taken to the emergency room (once) The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on [redacted] (Day 166 of age) was positive. No local laboratory SARS-CoV-2 NAAT was done. On [redacted] (Day 166 of age), the participant had a heart rate of 147 beats/min, respiratory rate (RR) of 42 breaths/min, and oxygen saturation of 99% on room air. The participant therefore had severe COVID-19 illness per protocol criteria (ie, had clinical signs at rest indicative of severe systemic illness [RR: ≥34 breaths/min from 1 month to 6 months of age]).

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Demography				
Date of B rth	Gestational Age at Birth	Race	Ethnicity	Sex
[redacted]	38 weeks 6 days	White	Non-Hispanic/Latino	Male

Birth Details			
Mode of Birth	Apgar Score at 1 Minute	Apgar Score at 5 Minutes	Apgar Score at 10 Minutes
Vaginal	8	9	--

Vital Signs - Baseline			
Body Length	Weight	Date Collected (Study Day)	Infant age in Days
50.04 cm	3.01 kg	[redacted] (43)	1

Maternal Study Vaccination(s)				
Vaccination Number	**Vaccine**	**Maternal Vaccination Date (Study Day)**	**Time of Maternal Vaccination**	**Gestational Age at Maternal Vaccination**
1	Placebo	[redacted] (1)	16:50:00	32 weeks 6 days
2	Placebo	[redacted] (20)	07:43:00	35 weeks 4 days

Adverse Events						
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Age in Days)**	**Stop Date (Age in Days)**	**Duration (Days)**
1	Congenital, familial and genetic disorders	Ankyloglossia congenital	mild congenital ankyloglossia	[redacted] (1)	[redacted] (3)	3
2	Congenital, familial and genetic disorders	Congenital skin dimples	Simple Sacral dimple	[redacted] (1)		Continuing

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Adverse Events					
AE Number	**Toxicity Grade**	**Action: Participant**	**SAE**	**AE Still Present?**	**AE Related To:**
1	1	NA	No	RECOVERED/RESOLVED (19062021)	NOT RELATED /OTHER; Frenectomy performed
2	1	NA	Yes	RECOVERING/RESOLVING	NOT RELATED /OTHER; congenital anomaly

Concomitant Medications
No Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: COVID-19 Case (Severe and/or Multiple)
Participant: C4591015 [redacted]; Country: USA
Maternal Vaccine Group (as Administered): Placebo
Date of First Dose: [redacted]; Date of Last Dose: [redacted]
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Case Details				
Visit	**>7 Days After Dose 2**	**Severe**	**Infant Age**	**Visit Date (Study Day)**
COVID Illness Visit 1	Yes	Yes	6 Weeks	[redacted] (87)

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Signs and Symptoms of Potential COVID-19						
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**	**Protocol and/or CDC Defined**	**Infant age in Days (Date First Symptom Started)**	**Narrative Event**
COVID Illness Visit 1 [redacted](88)/ [redacted](86)/ [redacted] (99)	YES	NEW OR INCREASED COUGH		Protocol and CDC Defined Symptoms Present	44	Yes
	YES	FEVER		Protocol and CDC Defined Symptoms Present	44	Yes
	NO		DECREASED APPETITE	Protocol and CDC Defined Symptoms Present	44	Yes

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Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis (Study Day)**	**MedDRA Preferred Term**	**Infant Age in days**
COVID Illness Visit 1	[redacted] (88)	COVID-19 like illness	[redacted] (86)	Suspected COVID-19	44
COVID Illness Visit 1	[redacted] (88)	SARS COVID-19 Illness	[redacted] (88)	COVID-19	46

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	[redacted] (88)	[redacted] (99)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**
1	COVID Illness Visit 1	[redacted] (88)	[redacted] (88)	SWABBED MATERIAL

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SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Specimen Collection Location**	**Test Result**	**Comments/Findings/Details**	**Trade Name**
1	NASOPHARYNX	POSITIVE		BIOFIRE COVID-19 TEST

Health Care Utilization						
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**	**Infant age in days**
COVID Illness Visit 1	[redacted] (88)	HOSPITAL	YES		NA	46
		INTENSIVE CARE	NO		NA	46
		SPECIALIST	NO		NA	46
		EMERGENCY ROOM	YES	1	NA	46
		PRIMARY CARE PHYSICIAN	NO		NA	46
		URGENT CARE	NO		NA	46
		TELEPHONE CONSULTATION	NO		NA	46
		OTHER	NO		NA	46

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Hospitalization Details						
Visit	**Visit Date (Study Day)**	**Hospitalization Category**	**Hospitalization Term**	**Admission Date (Study Day)**	**Discharge Date or Ongoing (Study Day)**	**Infant age in days**
COVID Illness Visit 1	[redacted] (88)	HOSPITALIZATION STATUS	HOSPITAL	[redacted] (88)	[redacted] (99)	46

Respiratory Treatment							
Visit	**Visit Date (Study Day)**	**Treatment Identifier**	**Prespecified Concomitant Nondrug Treatment**	**Treatment**	**Start Date (Study Day)**	**End Date or Ongoing (Study Day)**	**Infant age in days**
COVID Illness Visit 1	[redacted] (88)	1	YES	OXYGEN THERAPY	[redacted] (90)	[redacted] (97)	48

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

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Laboratory Results - Clinical Chemistry								
Visit	**Visit Date (Study Day)**	**Date of Test (Study Day)**	**Laboratory Test**	**Result**	**Units**	**Lower Limit Range**	**Upper Limit Range**	**Infant age in Days**
COVID Illness Visit 1	[redacted] (88)	[redacted] (90)	Alkaline Phosphatase	5.55	ukat/L	1.67	7.25	48
			Bilirubin	5.1	umol/L	3.4	17.1	48
			Creatinine	<13.3	umol/L	8.8	35.4	48
			C Reactive Protein	<3	mg/L	0	3	48
			Urea Nitrogen	5	mmol/L	2.5	6.43	48

Laboratory Results - Hematology								
Visit	**Visit Date (Study Day)**	**Date of Test (Study Day)**	**Laboratory Test**	**Result**	**Units**	**Lower Limit Range**	**Upper Limit Range**	**Infant age in Days**
COVID Illness Visit 1	[redacted] (88)	[redacted] (88)	Basophils	0.12	10^9/L	0	0.6	46
			Eosinophils	1.09	10^9/L	1.2	4.4	46
			Hematocrit	0.3	L/L	0.26	0.35	46
			Hemoglobin	105	g/L	89	119	46
			Lymphocytes	3.99	10^9/L	3.3	8.3	46
			Monocytes	1.93	10^9/L	0.5	1.1	46
			Neutrophils	1.02	10^9/L	1.2	4.4	46
			Platelets	315	10^9/L	275	567	46

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Note: † = Original results and units are displayed for UNCONVERTED Standard lab results.

Vital Signs - COVID-19

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Respiratory Rate	Heart Rate	Oxygen Saturation	Diastolic Blood Pressure	Systolic Blood Pressure
COVID Illness Visit 1	[redacted] (88)	[redacted] (87)	1	50 breaths/min	145 beats/min	99 %	48 mmHg	96 mmHg

Oxygenation Parameters

No Oxygenation Parameters

Concomitant Medications - Vasopressors

No Concomitant Medications - Vasopressors

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Imaging								
Assessment Number	**Visit**	**Visit Date (Study Day)**	**Date of Assessment**	**Location of Assessment**	**If Other, Specify**	**Type of Imaging Exam**	**If Other, Specify**	**Overall Assessment**
1	COVID Illness Visit 1	[redacted] (88)	[redacted]	CHEST	.	OTHER		INDETERMINATE
2	COVID Illness Visit 1	[redacted] (88)	[redacted]	CHEST	.	X-RAY	NA	NORMAL
3	COVID Illness Visit 1	[redacted] (88)	[redacted]	OTHER	.	X-RAY	NA	NORMAL

Participant Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	FOLLOW-UP	21DEC2021	

Narrative Comment
Participant C4591015[redacted], a 6-week 2-day-old White male with no reported medical history, was born to a maternal participant by vaginal birth on [redacted] at 38 weeks 6 days gestational age, with Apgar scores of 8 and 9 at 1 and 5 minutes, respectively. The maternal participant, while pregnant, rece ved Dose 1 on [redacted] at 32 weeks 6 days of gestation and Dose 2 on [redacted] (Day 20) at 35 weeks 4 days of gestation.

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Narrative Comment
On [redacted] (Day 46 of age), the participant was diagnosed with severe COVID-19 and his parent/legal guardian reported new or increased cough, fever, and decreased appetite, with the first symptom starting on [redacted] 43 days after birth, and the last symptom resolved on [redacted] (Day 57 of age). The participant was taken to the emergency room (once). On [redacted] (Day 45 of age; a day before the COVID-19 diagnosis), the participant had a heart rate of 145 beats/min, blood pressure (BP) of 96/48 mmHg, respiratory rate (RR) of 50 breaths/min, and oxygen saturation of 99% on room air. The local laboratory SARS-CoV-2 test result at the time of the COVID-19 illness on [redacted] (Day 46 of age) was positive. The participant was hospitalized on [redacted] (Day 46 of age) for 12 days and discharged on [redacted] (Day 57 of age). On [redacted] (Day 46 of age), a chest radiograph revealed normal findings. On the same day (Day 46 of age), the eosinophils was 1.09 × 10^9/L (normal range [NR]:1 2-4.4 × 10^9/L), neutrophils was 1.02 × 10^9/L (NR: 1.2-4.4 × 10^9/L), monocytes was 1.93 × 10^9/L (NR: 0.5-1.1 × 10^9/L), basophils was 0.12 × 10^9/L (NR: 0-0.6× 10^9/L), hematocrit was 0.3 L/L (NR: 0.26-0.35 L/L), hemoglobin was 105 g/L (NR: 89-119 g/L), lymphocytes was 3.99 × 10^9/L (NR: 3.3-8.3 × 10^9/L), and platelets was 315 × 10^9/L (NR: 275-567 × 10^9/L). The participant required supplemental oxygen from [redacted] to [redacted] (Day 48 to Day 55 of age). On [redacted] (Day 48 of age), the alkaline phosphatase was 5.55 µkat/L (NR: 1.67-7.25 µkat/L), bilirubin was 5.1 µmol/L (NR: 3.4-17.1 µmol/L), creatinine was <13.3 µmol/L (NR: 8.8-35.4 µmol/L), C reactive protein was <3 mg/L (NR: 0-3 mg/L), and blood urea nitrogen was 5 mmol/L (NR: 2.5-6.43 mmol/L). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on [redacted] (Day 57 of age) was positive. The participant therefore had severe COVID-19 illness per protocol criteria (ie, had clinical signs at rest indicative of severe systemic illness [RR: ≥34 breaths/min from 1 month to 6 months of age], presented evidence of shock [systolic BP <100 mmHg from 1 month to 6 months of age]).

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Demography				
Date of Birth	**Gestational Age at Birth**	**Race**	**Ethnicity**	**Sex**
[redacted]	40 weeks 6 days	White	Hispanic/Latino	Male

Birth Details			
Mode of Birth	**Apgar Score at 1 Minute**	**Apgar Score at 5 Minutes**	**Apgar Score at 10 Minutes**
C-Section	1	3	7

Vital Signs - Baseline			
Body Length	**Weight**	**Date Collected (Study Day)**	**Infant age in Days**
48 cm	3.43 kg	[redacted] (52)	1

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Maternal Study Vaccination(s)				
Vaccination Number	**Vaccine**	**Maternal Vaccination Date (Study Day)**	**Time of Maternal Vaccination**	**Gestational Age at Maternal Vaccination**
1	Placebo	[redacted] (1)	15:58:00	33 weeks 4 days
2	Placebo	[redacted] (21)	16:40:00	36 weeks 3 days

Adverse Events						
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Age in Days)**	**Stop Date (Age in Days)**	**Duration (Days)**
1	Investigations	Apgar score low	Low Apgar score	[redacted] (1)	[redacted] (1)	1
2	Infections and infestations	Infection	Infection of unknown origin	[redacted] (1)	[redacted] (3)	3

Adverse Events						
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Age in Days)**	**Stop Date (Age in Days)**	**Duration (Days)**
3	Respiratory, thoracic and mediastinal disorders	Neonatal pneumothorax	pneumothorax in infant	[redacted] (1)	[redacted] (1)	1
4	Respiratory, thoracic and mediastinal disorders	Neonatal respiratory failure	Respiratory failure in newborn	[redacted] (1)	[redacted] (3)	3

Adverse Events					
AE Number	**Toxicity Grade**	**Action: Participant**	**SAE**	**AE Still Present?**	**AE Related To:**
1	3	NA	No	RECOVERED/RESOLVED (29052021)	NOT RELATED /OTHER; pneumothorax in infant
2	1	TC	No	RECOVERED/RESOLVED (31052021)	NOT RELATED /OTHER; unknown etiology

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Adverse Events					
AE Number	**Toxicity Grade**	**Action: Participant**	**SAE**	**AE Still Present?**	**AE Related To:**
3	4	TC,TCN	Yes	RECOVERED/RESOLVED (29052021)	NOT RELATED /OTHER; unknown etiology
4	4	TCN	Yes	RECOVERED/RESOLVED (31052021)	NOT RELATED /OTHER; Pneumothorax

Concomitant Medications				
Investigator Text	**WHO Drug Preferred Term**	**Start Date**	**End Date**	**Route**
ampicilin	AMPICILLIN SODIUM	29MAY2021	[redacted]	INTRAVENOUS
fentanyl	FENTANYL	29MAY2021	[redacted]	INTRAVENOUS
gentamicin	GENTAMICIN	29MAY2021	[redacted]	INTRAVENOUS
sucrose	SUCROSE	30MAY2021	[redacted]	ORAL

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: COVID-19 Case (Severe and/or Multiple)
Participant: C4591015 [redacted]; Country: USA
Maternal Vaccine Group (as Administered): Placebo
Date of First Dose: [redacted]; Date of Last Dose:[redacted]
==========

Case Details				
Visit	**>7 Days After Dose 2**	**Severe**	**Infant Age**	**Visit Date (Study Day)**
COVID Illness Visit 1	Yes	Yes	6 Weeks	[redacted] (97)

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Signs and Symptoms of Potential COVID-19						
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**	**Protocol and/or CDC Defined**	**Infant age in Days (Date First Symptom Started)**	**Narrative Event**
COV D Illness Visit 1 [redacted] (99)/ [redacted](96)/ [redacted](112)	YES	VOMITING		Protocol and CDC Defined Symptoms Present	45	Yes
	NO		NASAL CONGESTION	Protocol and CDC Defined Symptoms Present	45	Yes
	NO		FATIGUE	Protocol and CDC Defined Symptoms Present	45	Yes
	YES	FEVER		Protocol and CDC Defined Symptoms Present	45	Yes

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Signs and Symptoms of Potential COVID-19						
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**	**Protocol and/or CDC Defined**	**Infant age in Days (Date First Symptom Started)**	**Narrative Event**
	YES	DIARRHEA		Protocol and CDC Defined Symptoms Present	45	Yes
COVID Illness Visit 2 [redacted] (216)/ [redacted](211)/ [redacted](221)	NO		RASH	Protocol and CDC Defined Symptoms Present	160	No
	NO		NASAL CONGESTION	Protocol and CDC Defined Symptoms Present	160	No
	YES	NEW OR INCREASED COUGH		Protocol and CDC Defined Symptoms Present	160	No

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Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis (Study Day)**	**MedDRA Preferred Term**	**Infant Age in days**
COVID Illness Visit 1	[redacted] (99)	COVID-19	[redacted] (97	COVID-19	46
COVID Illness Visit 1	[redacted] (99)	COVID-19 like illness	[redacted] (96)	Suspected COVID-19	45
COVID Illness Visit 2	[redacted] (216)	COVID-19 like illness	[redacted] (211)	Suspected COVID-19	160

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	[redacted] (99)	[redacted] (99)	NASAL_SWAB	POSITIVE
2	COVID Illness Visit 2	[redacted] (216)	[redacted] (216)	NASAL_SWAB	NEGATIVE

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SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**
1	COVID Illness Visit 1	[redacted] (99)	[redacted] (97)	SWABBED MATERIAL

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Specimen Collection Location**	**Test Result**	**Comments/Findings/Details**	**Trade Name**
1	NASOPHARYNX	POSITIVE		CLIA-certified lab

Health Care Utilization						
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**	**Infant age in days**
COVID Illness Visit 1	[redacted] (99)	HOSPITAL	NO		NA	48
		SPECIALIST	NO		NA	48
		EMERGENCY ROOM	YES	1	NA	48
		PRIMARY CARE PHYSICIAN	YES	2	NA	48
		URGENT CARE	NO		NA	48
		TELEPHONE CONSULTATION	NO		NA	48
		OTHER	NO		NA	48

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Health Care Utilization						
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**	**Infant age in days**
COVID Illness Visit 2	[redacted] (216)	SPECIALIST	NO		NA	165
		EMERGENCY ROOM	NO		NA	165
		PRIMARY CARE PHYSICIAN	NO		NA	165
		URGENT CARE	NO		NA	165
		TELEPHONE CONSULTATION	YES	1	NA	165
		OTHER	NO		NA	165

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

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Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range	Infant age in Days
COVID Illness Visit 1	[redacted] (99)	[redacted] (97)	Hematocrit	0.34	L/L	0.42	0.6	46
			Hemoglobin	121	g/L	135	195	46
			Platelets	496	10^9/L	159	439	46

Note: † = Original results and units are displayed for UNCONVERTED Standard lab results.

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Vital Signs - COVID-19

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Respiratory Rate	Heart Rate	Oxygen Saturation	Diastolic Blood Pressure	Systolic Blood Pressure
COVID Illness Visit 1	[redacted] (99)	[redacted] (97)	1	36 breaths/min	164 beats/min	96 %	40 mmHg	90 mmHg

Oxygenation Parameters

No Oxygenation Parameters

Concomitant Medications - Vasopressors

No Concomitant Medications - Vasopressors

Imaging

No Imaging

Participant Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	FOLLOW-UP	[redacted]	

Narrative Comment
Participant C4591015 [redacted], a 6-week 3-day-old White male with no reported medical history, was born to a maternal participant by emergency cesarean delivery on [redacted] at 40 weeks 6 days gestational age, with Apgar scores of 1, 3, and 7 at 1, 5, and 10 minutes, respectively. The maternal participant, while pregnant, received Dose 1 on [redacted] at 33 weeks 4 days of gestation and Dose 2 on [redacted] (Day 21) at 36 weeks 3 days of gestation. The participant developed low Apgar score, infection (of an unknown origin), neonatal pneumothorax, and neonatal respiratory failure on [redacted], at 1 day of age. On [redacted] (Day 1 of age), a chest x-ray revealed a moderate-sized left pneumothorax, with mediastinal shift to the right exacerbated by the collapse of the right upper lobe. An emergent needle thoracostomy was performed within 40 minutes of birth to drain the air. He received treatment with intravenous fentanyl, ampicillin sodium, gentamicin, and oral sucrose. After receiving care in the neonatal intensive care unit and subsequent follow-up in the intermediate care nursery, the participant made a full recovery. The low Apgar score and neonatal pneumo horax were considered resolved on [redacted] (Day 1 of age), and the infection and neonatal respiratory failure were considered resolved on [redacted] (Day 3 of age). On [redacted] (Day 46 of age), the participant was diagnosed with severe COVID-19 and his parent/legal guardian reported vomiting, nasal congestion, fatigue, fever, and diarrhea, with the first symptom starting on [redacted], 44 days after birth, and the last symptom resolved on [redacted] (Day 61 of age). The participant was taken to his primary care physician (twice) and to the emergency room (once). The local laboratory SARS-CoV-2 test result at the time of the COVID-19 illness on [redacted] (Day 46 of age) was positive.

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Reason(s) for Narrative: COVID-19 Case (Severe and/or Multiple)
Participant: C4591015[redacted]; Country: USA
Maternal Vaccine Group (as Administered): Placebo
Date of First Dose:[redacted]; Date of Last Dose:[redacted]

==========

Narrative Comment
On [redacted] (Day 46 of age), the participant had a heart rate of 164 beats/min, blood pressure (BP) of 90/40 mmHg, respiratory rate [RR] of 36 breaths/min, and oxygen saturation of 96% on room air. On [redacted] (Day 46 of age), the hematocrit was 0.34 L/L (normal range [NR]: 0.42-0.6 L/L), hemoglobin was 121 g/L (NR: 135-195 g/L), and platelet count was 496 × 10^9/L (NR: 159-439 × 10^9/L). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on [redacted] (Day 48 of age) was positive. The participant therefore had severe COVID-19 illness per protocol criteria (ie, had clinical signs at rest indicative of severe systemic illness [RR: ≥34 breaths/min from 1 month to 6 months of age] and presented evidence of shock [systolic BP <100 mmHg from 1 month to 6 months of age]).

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Demography				
Date of Birth	**Gestational Age at Birth**	**Race**	**Ethnicity**	**Sex**
[redacted]	39 weeks 1 day	Black or African American	Non-Hispanic/Latino	Male

Birth Details			
Mode of Birth	**Apgar Score at 1 Minute**	**Apgar Score at 5 Minutes**	**Apgar Score at 10 Minutes**
C-Section	9	10	--

Vital Signs - Baseline			
Body Length	**Weight**	**Date Collected (Study Day)**	**Infant age in Days**
51 cm	3.3 kg	[redacted](86)	1

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Reason(s) for Narrative: COVID-19 Case (Severe and/or Multiple)
Participant: C4591015 [redacted]; Country: South Africa
Maternal Vaccine Group (as Administered): Placebo
Date of First Dose:[redacted]; Date of Last Dose:[redacted]
==========

Maternal Study Vaccination(s)				
Vaccination Number	**Vaccine**	**Maternal Vaccination Date (Study Day)**	**Time of Maternal Vaccination**	**Gestational Age at Maternal Vaccination**
1	Placebo	[redacted] (1)	11:29:00	27 weeks
2	Placebo	[redacted] (24)	11:17:00	30 weeks 2 days

Adverse Events
No Adverse Events

Concomitant Medications
No Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: COVID-19 Case (Severe and/or Multiple)
Participant: C4591015 [redacted]; Country: South Africa
Maternal Vaccine Group (as Adm nistered): Placebo
Date of First Dose: [redacted]; Date of Last Dose: [redacted]
==========

Case Details				
Visit	**>7 Days After Dose 2**	**Severe**	**Infant Age**	**Visit Date (Study Day)**
COVID Illness Visit 2	Yes	Yes	6 Weeks	[redacted] (130)

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Signs and Symptoms of Potential COVID-19						
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**	**Protocol and/or CDC Defined**	**Infant age in Days (Date First Symptom Started)**	**Narrative Event**
COVID Illness Visit 1 (94)/ 90)/ 97)	NO		NASAL CONGESTION	Protocol and CDC Defined Symptoms Present	5	No
	YES	NEW OR INCREASED COUGH		Protocol and CDC Defined Symptoms Present	5	No
COVID Illness Visit 2 (130)/ (127)/ (133)	YES	DIARRHEA		Protocol and CDC Defined Symptoms Present	42	Yes
COVID Illness Visit 3 (149)/ 147)/ (180)	YES	DIARRHEA		Protocol and CDC Defined Symptoms Present	62	No

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Signs and Symptoms of Potential COVID-19						
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**	**Protocol and/or CDC Defined**	**Infant age in Days (Date First Symptom Started)**	**Narrative Event**
COVID Illness Visit 4 [redacted](193)/ [redacted](190)/ [redacted]214)	NO		NASAL CONGESTIO N	Protocol and CDC Defined Symptoms Present	105	No
	YES	NEW OR INCREASED COUGH		Protocol and CDC Defined Symptoms Present	105	No
COVID Illness Visit 5 [redacted](212)/ [redacted](193)/ [redacted]214)	NO		NASAL CONGESTIO N	Protocol and CDC Defined Symptoms Present	108	No
	YES	NEW OR INCREASED COUGH		Protocol and CDC Defined Symptoms Present	108	No

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Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis (Study Day)**	**MedDRA Preferred Term**	**Infant Age in days**
COVID Illness Visit 1	[redacted] (94)	COVID-19 like illness	[redacted] (90)	Suspected COVID-19	5
COVID Illness Visit 2	[redacted] 130)	COVID-19 like illness	[redacted] (127)	Suspected COVID-19	42
COVID Illness Visit 3	[redacted] 149)	COVID-19 like illness	[redacted] (147)	Suspected COVID-19	62
COVID Illness Visit 4	[redacted] (193)	COVID-19 like illness	[redacted] (190)	Suspected COVID-19	105
COVID Illness Visit 4	[redacted] (193)	UPPER RESPIRATORY TRACT INFECTION	[redacted] (193)	Upper respiratory tract infection	108
COVID Illness Visit 5	[redacted] (212)	COVID-19 like illness	[redacted] (193)	Suspected COVID-19	108

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	[redacted] (94)	[redacted] (94)	NASAL_SWAB	NEGATIVE

PFIZER CONFIDENTIAL SDTM Creation: 12JAN2024 (04:07) Source Data: dm, vs, mh, ex, ae, mb, co, di, is, face, ce, ho, faho, ds, cm, mo, pr, lb (Snapshot Date: 09Jan2024) Output File: ./nda2/C4591015_COVID_NARR/profile_inf Date of Generation: 20MAR2024 (10:46)

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
2	COVID Illness Visit 2	[redacted] (130)	[redacted] (130)	NASAL_SWAB	POSITIVE
3	COVID Illness Visit 3	[redacted] (149)	[redacted] (149)	NASAL_SWAB	NEGATIVE
4	COVID Illness Visit 4	[redacted] (193)	[redacted] (193)	NASAL_SWAB	NEGATIVE
5	COVID Illness Visit 5	[redacted] (212)	[redacted] (212)	NASAL_SWAB	NEGATIVE

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**
1	COVID Illness Visit 1	[redacted] (94)	[redacted] (95)	SWABBED MATERIAL
2	COVID Illness Visit 2	[redacted] (130)	[redacted] (131)	SWABBED MATERIAL
3	COVID Illness Visit 3	[redacted] (149)	[redacted] (150)	SWABBED MATERIAL
4	COVID Illness Visit 4	[redacted] (193)	[redacted] (197)	SWABBED MATERIAL
5	COVID Illness Visit 5	[redacted] (212)	[redacted] (213)	SWABBED MATERIAL

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SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Specimen Collection Location**	**Test Result**	**Comments/Findings/Details**	**Trade Name**
1	NASOPHARYNX	POSITIVE		CDC 2019-NCOV REAL-TIME RT-PCR DIAGNOSTIC PANEL
2	NASOPHARYNX	NEGATIVE		CDC 2019-NCOV REAL-TIME RT-PCR DIAGNOSTIC PANEL
3	NASOPHARYNX	NEGATIVE		CDC 2019-NCOV REAL-TIME RT-PCR DIAGNOSTIC PANEL
4	NASOPHARYNX	NEGATIVE		CDC 2019-NCOV REAL-TIME RT-PCR DIAGNOSTIC PANEL
5	NASOPHARYNX	NEGATIVE		CDC 2019-NCOV REAL-TIME RT-PCR DIAGNOSTIC PANEL

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Health Care Utilization						
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**	**Infant age in days**
COVID Illness Visit 1	[redacted] (94)	HOSPITAL	NO		NA	9
		SPECIALIST	NO		NA	9
		EMERGENCY ROOM	NO		NA	9
		PRIMARY CARE PHYSICIAN	NO		NA	9
		URGENT CARE	NO		NA	9
		TELEPHONE CONSULTATION	NO		NA	9
		OTHER	NO		NA	9
COVID Illness Visit 2	[redacted] (130)	SPECIALIST	NO		NA	45
		EMERGENCY ROOM	NO		NA	45
		PRIMARY CARE PHYSICIAN	YES	1	NA	45
		URGENT CARE	NO		NA	45
		TELEPHONE CONSULTATION	NO		NA	45
		OTHER	NO		NA	45
COVID Illness Visit 3	[redacted] (149)	SPECIALIST	NO		NA	64
		EMERGENCY ROOM	NO		NA	64
		PRIMARY CARE PHYSICIAN	YES	1	NA	64
		URGENT CARE	NO		NA	64
		TELEPHONE CONSULTATION	NO		NA	64
		OTHER	NO		NA	64

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Health Care Utilization						
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**	**Infant age in days**
COVID Illness Visit 4	[redacted] (193)	SPECIALIST	NO		NA	108
		EMERGENCY ROOM	NO		NA	108
		PRIMARY CARE PHYSICIAN	YES	1	NA	108
		URGENT CARE	NO		NA	108
		TELEPHONE CONSULTATION	NO		NA	108
		OTHER	NO		NA	108
COVID Illness Visit 5	[redacted] (212)	SPECIALIST	NO		NA	127
		EMERGENCY ROOM	NO		NA	127
		PRIMARY CARE PHYSICIAN	YES	1	NA	127
		URGENT CARE	NO		NA	127
		TELEPHONE CONSULTATION	NO		NA	127
		OTHER	NO		NA	127

Hospitalization Details
No Hospitalization Details

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Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Note: † = Original results and units are displayed for UNCONVERTED Standard lab results.

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Vital Signs - COVID-19								
Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Respiratory Rate	Heart Rate	Oxygen Saturation	Diastolic Blood Pressure	Systolic Blood Pressure
COVID Illness Visit 1	[redacted] (94)	09DEC2021 (94)	1	48 breaths/min	144 beats/min	99 %		
COVID Illness Visit 2	[redacted] (130)	14JAN2022 (130)	2	46 breaths/min	134 beats/min	97 %		
COVID Illness Visit 3	[redacted] (149)	02FEB2022 (149)	3	42 breaths/min	138 beats/min	98 %		
COVID Illness Visit 4	[redacted] (193)	18MAR2022 (193)	4	41 breaths/min	166 beats/min	98 %		
COVID Illness Visit 5	[redacted] (212)	06APR2022 (212)	5	45 breaths/min	142 beats/min	99 %		

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

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Participant Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	FOLLOW-UP	18MAY2022	

Narrative Comment
Participant C4591015 [redacted], a 6-week-old Black/African American male with no reported medical history, was born to a maternal participant by cesarean delivery on [redacted] at 39 weeks 1 day gestational age, with Apgar scores of 9 and 10 at 1 and 5 minutes, respectively. The maternal participant, while pregnant, received Dose 1 on [redacted] at 27 weeks of gestation and Dose 2 on [redacted] (Day 24) at 30 weeks 2 days of gestation. On [redacted] (Day 42 of age), the participant was diagnosed with severe suspected COVID-19 and his parent/legal guardian reported diarrhea, with the symptom starting on [redacted], 41 days after birth, and resolving on [redacted] (Day 48 of age). The participant was taken to his primary care physician (once). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on [redacted] (Day 45 of age) was positive. On [redacted] (Day 45 of age), the participant had a heart rate of 134 beats/min, RR of 46 breaths/min, and oxygen saturation of 97% on room air. The local laboratory SARS-CoV-2 test result at the time of the COVID-19 illness on [redacted] (Day 46 of age) was negative. The participant therefore had severe COVID-19 illness per protocol criteria (ie, had clinical signs at rest indicative of severe systemic illness [RR: ≥34 breaths/min from 1 month to 6 months of age]).

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Demography				
Date of Birth	**Gestational Age at Birth**	**Race**	**Ethnicity**	**Sex**
[redacted]	40 weeks 5 days	Black or African American	Non-Hispanic/Latino	Male

Birth Details			
Mode of Birth	**Apgar Score at 1 Minute**	**Apgar Score at 5 Minutes**	**Apgar Score at 10 Minutes**
C-Section	7	9	--

Vital Signs - Baseline			
Body Length	**Weight**	**Date Collected (Study Day)**	**Infant age in Days**
52 cm	2.95 kg	[redacted] (69)	1

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Maternal Study Vaccination(s)				
Vaccination Number	**Vaccine**	**Maternal Vaccination Date (Study Day)**	**Time of Maternal Vaccination**	**Gestational Age at Maternal Vaccination**
1	BNT162b2	[redacted] (1)	11:43:00	30 weeks 5 days
2	BNT162b2	[redacted] (24)	12:12:00	34 weeks

Adverse Events
No Adverse Events

Concomitant Medications
No Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: COVID-19 Case (Severe and/or Multiple)
Participant: C4591015 [redacted]; Country: South Africa
Maternal Vaccine Group (as Adm n stered): BNT162b2
Date of First Dose: [redacted]; Date of Last Dose: [redacted]
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Case Details				
Visit	**>7 Days After Dose 2**	**Severe**	**Infant Age**	**Visit Date (Study Day)**
COVID Illness Visit 3	Yes	Yes	20 Weeks	[redacted] 213)

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Signs and Symptoms of Potential COVID-19						
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**	**Protocol and/or CDC Defined**	**Infant age in Days (Date First Symptom Started)**	**Narrative Event**
COVID Illness Visit 1 [redacted] (128)/ [redacted] (126)/ [redacted] (135)	NO		NASAL CONGESTION	Protocol and CDC Defined Symptoms Present	58	No
	YES	NEW OR INCREASED COUGH		Protocol and CDC Defined Symptoms Present	58	No
	YES	FEVER		Protocol and CDC Defined Symptoms Present	58	No

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Signs and Symptoms of Potential COVID-19						
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**	**Protocol and/or CDC Defined**	**Infant age in Days (Date First Symptom Started)**	**Narrative Event**
COV D Illness Visit 2 [redacted] (157)/ (152)/ (160)	NO		NASAL CONGESTION	Protocol and CDC Defined Symptoms Present	84	No
	YES	NEW OR INCREASED COUGH		Protocol and CDC Defined Symptoms Present	84	No
COVID Illness Visit 3 [redacted] (213)/ (203)/ (216)	YES	NEW OR INCREASED COUGH		Protocol and CDC Defined Symptoms Present	135	Yes
	NO		NASAL CONGESTION	Protocol and CDC Defined Symptoms Present	135	Yes

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Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis (Study Day)**	**MedDRA Preferred Term**	**Infant Age in days**
COVID Illness Visit 1	[redacted] (128)	COVID-19 like illness	[redacted] (126)	Suspected COVID-19	58
COVID Illness Visit 1	[redacted] (128)	upper respiratory tract infection	[redacted] (128)	Upper respiratory tract infection	60
COVID Illness Visit 2	[redacted] (157)	COVID-19 like illness	[redacted] (152)	Suspected COVID-19	84
COVID Illness Visit 2	[redacted] (157)	UPPER RESPIRATORY TRACT INFECTION	[redacted] (157)	Upper respiratory tract infection	89
COVID Illness Visit 3	[redacted] (213)	COVID-19 like illness	[redacted] (203	Suspected COVID-19	135
COVID Illness Visit 3	[redacted] (213)	upper respiratory tract infection	[redacted] (213)	Upper respiratory tract infection	145

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	[redacted] (128)	[redacted] (128)	NASAL_SWAB	NEGATIVE
2	COVID Illness Visit 2	[redacted] (157)	[redacted] (157)	NASAL_SWAB	NEGATIVE
3	COVID Illness Visit 3	[redacted] (213)	[redacted] (213)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**
1	COVID Illness Visit 2	[redacted] (157)	[redacted] (157)	SWABBED MATERIAL
2	COVID Illness Visit 3	[redacted] (213)	[redacted] (213)	SWABBED MATERIAL

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Specimen Collection Location**	**Test Result**	**Comments/Findings/Details**	**Trade Name**
1	NASOPHARYNX	NEGATIVE		CDC 2019-NCOV REAL-TIME RT-PCR DIAGNOSTIC PANEL
2	NASOPHARYNX	NEGATIVE		CDC 2019-NCOV REAL-TIME RT-PCR DIAGNOSTIC PANEL

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Health Care Utilization						
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**	**Infant age in days**
COVID Illness Visit 1	[redacted] (128)	HOSPITAL	NO		NA	60
		SPECIALIST	NO		NA	60
		EMERGENCY ROOM	NO		NA	60
		PRIMARY CARE PHYSICIAN	NO		NA	60
		URGENT CARE	NO		NA	60
		TELEPHONE CONSULTATION	NO		NA	60
		site visit - sub investigator	YES	1	site visit - sub investigator	60
COVID Illness Visit 2	[redacted] (157)	SPECIALIST	NO		NA	89
		EMERGENCY ROOM	NO		NA	89
		PRIMARY CARE PHYSICIAN	YES	1	NA	89
		URGENT CARE	NO		NA	89
		TELEPHONE CONSULTATION	NO		NA	89
		OTHER	NO		NA	89

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Health Care Utilization						
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**	**Infant age in days**
COVID Illness Visit 3	[redacted](213)	SPECIALIST	NO		NA	145
		EMERGENCY ROOM	NO		NA	145
		PRIMARY CARE PHYSICIAN	YES	1	NA	145
		URGENT CARE	NO		NA	145
		TELEPHONE CONSULTATION	NO		NA	145
		OTHER	NO		NA	145

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

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Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Note: † = Original results and units are displayed for UNCONVERTED Standard lab results.

Vital Signs - COVID-19								
Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Respiratory Rate	Heart Rate	Oxygen Saturation	Diastolic Blood Pressure	Systolic Blood Pressure
COVID Illness Visit 1	[redacted] (128)	[redacted] (128)	1	46 breaths/min	148 beats/min	98 %		
COVID Illness Visit 2	[redacted] (157)	[redacted] (157)	2	44 breaths/min	127 beats/min	99 %		
COVID Illness Visit 3	[redacted] (213)	[redacted] (213)	3	46 breaths/min	143 beats/min	100 %		

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Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Participant Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	FOLLOW-UP	02JUN2022	

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Narrative Comment
Participant C4591015[redacted], a 19-week 2-day-old Black/African American male with no reported medical history, was born to a maternal participant by cesarean delivery on [redacted] at 40 weeks 5 _ays gestational age, with Apgar scores of 7 and 9 at 1 and 5 minutes, respectively. The maternal participant, while pregnant, received Dose 1 on [redacted] at 30 weeks 5 days of gestation and Dose 2 on [redacted] (Day 24) at 34 weeks of gestation. On [redacted] (Day 145 of age), the participant was diagnosed with severe upper respiratory tract infection and his parent/legal guardian reported new or increased cough and nasal congestion, with the first symptom starting on [redacted], 134 days after birth, and the last symptom resolved on [redacted] (Day 148 of age). The participant was taken to his primary care physician (once). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on [redacted] (Day 145 of age) was positive. The local laboratory SARS-CoV-2 test result at the time of the COVID-19 illness on [redacted], (Day 145 of age) was negative. On [redacted] (Day 145 of age), the participant had a heart rate of 143 beats/min, respiratory rate (RR) of 46 breaths/min, and oxygen saturation of 100% on room air The participant therefore had severe COVID-19 illness per protocol criteria (ie, had clinical signs at rest indicative of severe systemic illness [RR: ≥34 breaths/min from 1 month to 6 months of age]).

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Demography				
Date of Birth	**Gestational Age at Birth**	**Race**	**Ethnicity**	**Sex**
[redacted]	39 weeks 1 day	Black or African American	Non-Hispanic/Latino	Female

Birth Details			
Mode of Birth	**Apgar Score at 1 Minute**	**Apgar Score at 5 Minutes**	**Apgar Score at 10 Minutes**
C-Section	9	10	--

Vital Signs - Baseline			
Body Length	**Weight**	**Date Collected (Study Day)**	**Infant age in Days**
47 cm	3.13 kg	[redacted] (76)	1

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Maternal Study Vaccination(s)				
Vaccination Number	**Vaccine**	**Maternal Vaccination Date (Study Day)**	**Time of Maternal Vaccination**	**Gestational Age at Maternal Vaccination**
1	Placebo	[redacted] (1)	13:46:00	30 weeks 6 days
2	Placebo	[redacted] (21)	11:07:00	33 weeks 5 days

Adverse Events						
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Age in Days)**	**Stop Date (Age in Days)**	**Duration (Days)**
1	Skin and subcutaneous tissue disorders	Dermatitis diaper	nappy rash	[redacted] (29)	[redacted] (41)	13
2	Pregnancy, puerperium and perinatal conditions	Jaundice neonatal	neonatal jaundice	[redacted] (8)	[redacted] (8)	1

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Adverse Events					
AE Number	**Toxicity Grade**	**Action: Participant**	**SAE**	**AE Still Present?**	**AE Related To:**
1	1	TC	No	RECOVERED/RESOLVED (07022022)	NOT RELATED /OTHER; unknown
2	1	NA	No	RECOVERED/RESOLVED (05012022)	NOT RELATED /OTHER; physiological

Concomitant Medications				
Investigator Text	**WHO Drug Preferred Term**	**Start Date**	**End Date**	**Route**
clotrimazole	CLOTRIMAZOLE	02FEB2022	ONGOING	TOPICAL

Nonstudy Vaccines
No Nonstudy Vaccines

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Case Details				
Visit	**>7 Days After Dose 2**	**Severe**	**Infant Age**	**Visit Date (Study Day)**
COVID Illness Visit 5	Yes	Yes	21 Weeks	[redacted] (225)

Signs and Symptoms of Potential COVID-19						
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**	**Protocol and/or CDC Defined**	**Infant age in Days (Date First Symptom Started)**	**Narrative Event**
COV D Illness Visit 1 [redacted] (83)/ [redacted] (79)/ [redacted] (83)	YES	DIARRHEA		Protocol and CDC Defined Symptoms Present	4	No

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Signs and Symptoms of Potential COVID-19						
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**	**Protocol and/or CDC Defined**	**Infant age in Days (Date First Symptom Started)**	**Narrative Event**
COVID Illness Visit 2 [redacted] (130)/ (126)/ (135)	NO		NASAL CONGESTION	Protocol and CDC Defined Symptoms Present	51	No
	YES	NEW OR INCREASED COUGH		Protocol and CDC Defined Symptoms Present	51	No
	YES	FEVER		Protocol and CDC Defined Symptoms Present	51	No

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Signs and Symptoms of Potential COVID-19						
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**	**Protocol and/or CDC Defined**	**Infant age in Days (Date First Symptom Started)**	**Narrative Event**
COVID Illness Visit 3 [redacted] (159)/ 147)/ 162)	NO		NASAL CONGESTION	Protocol and CDC Defined Symptoms Present	72	No
	YES	NEW OR INCREASED COUGH		Protocol and CDC Defined Symptoms Present	72	No
COVID Illness Visit 4 [redacted] (173)/ 169)/ (177)	YES	NEW OR INCREASED COUGH		Protocol and CDC Defined Symptoms Present	94	No

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Signs and Symptoms of Potential COVID-19						
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**	**Protocol and/or CDC Defined**	**Infant age in Days (Date First Symptom Started)**	**Narrative Event**
COVID Illness Visit 5 [redacted] (225)/ [redacted]222)/ ONGOING	NO		NASAL CONGESTION	Protocol and CDC Defined Symptoms Present	147	Yes
	YES	NEW OR INCREASED COUGH		Protocol and CDC Defined Symptoms Present	147	Yes

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Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis (Study Day)**	**MedDRA Preferred Term**	**Infant Age in days**
COVID Illness Visit 1	[redacted] (83)	COVID-19 like illness	[redacted] (79)	Suspected COVID-19	4
COVID Illness Visit 2	[redacted] (130)	COVID-19 like illness	[redacted] (126	Suspected COVID-19	51
COVID Illness Visit 2	[redacted] (130)	upper respiratory tract infection	[redacted] (130)	Upper respiratory tract infection	55
COVID Illness Visit 3	[redacted] (159)	COVID-19 like illness	[redacted] (147	Suspected COVID-19	72
COVID Illness Visit 3	[redacted] (159)	upper respiratory tract infection	[redacted] (159	Upper respiratory tract infection	84
COVID Illness Visit 4	[redacted] (173)	COVID-19 like illness	[redacted] (169	Suspected COVID-19	94
COVID Illness Visit 5	[redacted] (225)	COVID-19	[redacted] (227)	COVID-19	152
COVID Illness Visit 5	[redacted] 225)	COVID-19 like illness	[redacted] (222	Suspected COVID-19	147

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SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	[redacted] (83)	[redacted] (83)	NASAL_SWAB	NEGATIVE
2	COVID Illness Visit 2	[redacted] (130)	[redacted] (130)	NASAL_SWAB	NEGATIVE
3	COVID Illness Visit 3	[redacted] (159)	[redacted] (159)	NASAL_SWAB	NEGATIVE
4	COVID Illness Visit 4	[redacted] (173)	[redacted] (173)	NASAL_SWAB	NEGATIVE
5	COVID Illness Visit 5	[redacted] (225)	[redacted] (225)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**
1	COVID Illness Visit 1	[redacted] (83)	[redacted] (83)	SWABBED MATERIAL
2	COVID Illness Visit 2	[redacted] (130)	[redacted] (130)	SWABBED MATERIAL
3	COVID Illness Visit 3	[redacted] (159)	[redacted] (159)	SWABBED MATERIAL
4	COVID Illness Visit 4	[redacted] (173)	[redacted] (173)	SWABBED MATERIAL
5	COVID Illness Visit 5	[redacted] (225)	[redacted] (227)	SWABBED MATERIAL

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SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Specimen Collection Location**	**Test Result**	**Comments/Findings/Details**	**Trade Name**
1	NASOPHARYNX	NEGATIVE		CDC 2019-NCOV REAL-TIME RT-PCR DIAGNOSTIC PANEL
2	NASOPHARYNX	NEGATIVE		CDC 2019-NCOV REAL-TIME RT-PCR DIAGNOSTIC PANEL
3	NASOPHARYNX	NEGATIVE		CDC 2019-NCOV REAL-TIME RT-PCR DIAGNOSTIC PANEL
4	NASOPHARYNX	NEGATIVE		CDC 2019-NCOV REAL-TIME RT-PCR DIAGNOSTIC PANEL
5	NASOPHARYNX	POSITIVE		CDC 2019-NCOV REAL-TIME RT-PCR DIAGNOSTIC PANEL

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Health Care Utilization						
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**	**Infant age in days**
COVID Illness Visit 1	[redacted] (83)	HOSPITAL	NO		NA	8
		SPECIALIST	NO		NA	8
		EMERGENCY ROOM	NO		NA	8
		PRIMARY CARE PHYSICIAN	YES	1	NA	8
		URGENT CARE	NO		NA	8
		TELEPHONE CONSULTATION	NO		NA	8
		OTHER	NO		NA	8
COVID Illness Visit 2	[redacted] (130)	SPECIALIST	NO		NA	55
		EMERGENCY ROOM	NO		NA	55
		PRIMARY CARE PHYSICIAN	YES	1	NA	55
		URGENT CARE	NO		NA	55
		TELEPHONE CONSULTATION	NO		NA	55
		OTHER	NO		NA	55
COVID Illness Visit 3	[redacted] (159)	SPECIALIST	NO		NA	84
		EMERGENCY ROOM	NO		NA	84
		PRIMARY CARE PHYSICIAN	YES	1	NA	84
		URGENT CARE	NO		NA	84
		TELEPHONE CONSULTATION	NO		NA	84
		OTHER	NO		NA	84

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Health Care Utilization						
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**	**Infant age in days**
COVID Illness Visit 4	[redacted] (173)	SPECIALIST	NO		NA	98
		EMERGENCY ROOM	NO		NA	98
		PRIMARY CARE PHYSICIAN	YES	1	NA	98
		URGENT CARE	NO		NA	98
		TELEPHONE CONSULTATION	NO		NA	98
		OTHER	NO		NA	98
COVID Illness Visit 5	[redacted] (225)	SPECIALIST	NO		NA	150
		EMERGENCY ROOM	NO		NA	150
		PRIMARY CARE PHYSICIAN	YES	1	NA	150
		URGENT CARE	NO		NA	150
		TELEPHONE CONSULTATION	NO		NA	150
		OTHER	NO		NA	150

Hospitalization Details
No Hospitalization Details

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Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Note: † = Original results and units are displayed for UNCONVERTED Standard lab results.

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Vital Signs - COVID-19								
Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Respiratory Rate	Heart Rate	Oxygen Saturation	Diastolic Blood Pressure	Systolic Blood Pressure
COVID Illness Visit 1	[redacted] 83)	[redacted] 83)	1	44 breaths/min	140 beats/min	100 %		
COVID Illness Visit 2	[redacted] 130)	[redacted] 130)	2	46 breaths/min	144 beats/min	98 %		
COVID Illness Visit 3	[redacted] (159)	[redacted] (159)	3	38 breaths/min	136 beats/min	97 %		
COVID Illness Visit 4	[redacted] (173)	[redacted] 173)	4	66 breaths/min	142 beats/min	100 %		
COVID Illness Visit 5	[redacted] (225)	[redacted] (225)	5	41 breaths/min	136 beats/min	99 %		

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

PFIZER CONFIDENTIAL SDTM Creation: 12JAN2024 (04:07) Source Data: dm, vs, mh, ex, ae, mb, co, di, is, face, ce, ho, faho, ds, cm, mo, pr, lb (Snapshot Date: 09Jan2024) Output File: ./nda2/C4591015_COVID_NARR/profile_inf Date of Generation: 20MAR2024 (10:46)

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Participant Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	FOLLOW-UP	24JUN2022	

Narrative Comment
Participant C4591015[redacted], a 21-week-old Black/African American female with no reported medical history, was born to a maternal participant by cesarean delivery on [redacted] at 39 weeks 1 day gestational age, with Apgar scores of 9 and 10 at 1 and 5 minutes, respectively. The maternal participant, while pregnant, received Dose 1 on [redacted] at 30 weeks 6 days of gestation and Dose 2 on [redacted] (Day 21) at 33 weeks 5 days of gestation. On [redacted] (Day 152 of age), the participant was diagnosed with severe COVID-19 and her parent/legal guardian reported nasal congestion and new or increased cough, with the first symptom starting on 24 May 2022, 146 days after birth, and the last symptom was ongoing as of the last available report. The participant was taken to her primary care physician (once). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on [redacted] (Day 150 of age) was positive. On [redacted] (Day 150 of age), the participant had a heart rate of 136 beats/min, respiratory rate (RR) of 41 breaths/min, and oxygen saturation of 99% on room air The local laboratory SARS-CoV-2 test result at the time of the COVID-19 illness on [redacted] (Day 152 of age) was positive.

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Reason(s) for Narrative: COVID-19 Case (Severe and/or Multiple)
Participant: C4591015[redacted]; Country: South Africa
Maternal Vaccine Group (as Administered): Placebo
Date of First Dose:[redacted] Date of Last Dose:[redacted]
==========

Narrative Comment
The participant therefore had severe COVID-19 illness per protocol criteria (ie, had clinical signs at rest indicative of severe systemic illness [RR: ≥34 breaths/min from 1 month to 6 months of age]).

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Demography				
Date of Birth	**Gestational Age at Birth**	**Race**	**Ethnicity**	**Sex**
	40 weeks 4 days	White	Hispanic/Latino	Female

Birth Details			
Mode of Birth	**Apgar Score at 1 Minute**	**Apgar Score at 5 Minutes**	**Apgar Score at 10 Minutes**
Vaginal	8	10	--

Vital Signs - Baseline				
Body Length	**Weight**	**Date Collected (Study Day)**		**Infant age in Days**
56 cm	3.31 kg		(53)	2

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Reason(s) for Narrative: COVID-19 Case (Severe and/or Multiple)
Participant: C4591015[redacted]; Country: Spain
Maternal Vaccine Group (as Administered): BNT162b2
Date of First Dose: [redacted] Date of Last Dose: [redacted]
==========

Maternal Study Vaccination(s)				
Vaccination Number	**Vaccine**	**Maternal Vaccination Date (Study Day)**	**Time of Maternal Vaccination**	**Gestational Age at Maternal Vaccination**
1	BNT162b2	[redacted] 1)	16:40:00	33 weeks 5 days
2	BNT162b2	[redacted] (22)	15:40:00	36 weeks 5 days

Adverse Events						
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Age in Days)**	**Stop Date (Age in Days)**	**Duration (Days)**
1	Gastrointestinal disorders	Constipation	constipation	[redacted] (2)	[redacted] (4)	3

Adverse Events					
AE Number	**Toxicity Grade**	**Action: Participant**	**SAE**	**AE Still Present?**	**AE Related To:**
1	1	NA	No	RECOVERED/RESOLVED (14092021)	NOT RELATED /OTHER; intestinal immaturity

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Concomitant Medications
No Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Case Details				
Visit	>7 Days After Dose 2	Severe	Infant Age	Visit Date (Study Day)
COVID Illness Visit 1	Yes	Yes	17 Weeks	[redacted] (174)

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Reason(s) for Narrative: COVID-19 Case (Severe and/or Multiple)
Participant: C4591015[redacted] Country: Spain
Maternal Vaccine Group (as Administered): BNT162b2
Date of First Dose[redacted] Date of Last Dose[redacted]
==========

Signs and Symptoms of Potential COVID-19						
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**	**Protocol and/or CDC Defined**	**Infant age in Days (Date First Symptom Started)**	**Narrative Event**
COVID Illness Visit 1 [redacted] (174)/ [redacted] (173)/ [redacted] (180)	YES	NEW OR INCREASED COUGH		Protocol and CDC Defined Symptoms Present	122	Yes
	YES	FEVER		Protocol and CDC Defined Symptoms Present	122	Yes

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Reason(s) for Narrative: COVID-19 Case (Severe and/or Multiple)
Participant: C4591015[redacted]; Country: Spain
Maternal Vaccine Group (as Administered): BNT162b2
Date of First Dose:[redacted]; Date of Last Dose: [redacted]
==========

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis (Study Day)**	**MedDRA Preferred Term**	**Infant Age in days**
COVID Illness Visit 1	[redacted] (174)	COVID-19 like illness	[redacted] (173	Suspected COVID-19	122
COVID Illness Visit 1	[redacted] (174)	HIGH RESPIRATORY INFECTION	[redacted] (174)	Respiratory tract infection	123

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	[redacted] (174)	[redacted] (174)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

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Health Care Utilization						
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**	**Infant age in days**
COVID Illness Visit 1	[redacted] (174)	HOSPITAL	NO		NA	123
		SPECIALIST	NO		NA	123
		EMERGENCY ROOM	NO		NA	123
		PRIMARY CARE PHYSICIAN	NO		NA	123
		URGENT CARE	NO		NA	123
		TELEPHONE CONSULTATION	NO		NA	123
		OTHER	NO		NA	123

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

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Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Note: † = Original results and units are displayed for UNCONVERTED Standard lab results.

Vital Signs - COVID-19								
Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Respiratory Rate	Heart Rate	Oxygen Saturation	Diastolic Blood Pressure	Systolic Blood Pressure
COVID Illness Visit 1	[redacted] (174)	[redacted] (174)	1	48 breaths/min	153 beats/min	95 %	60 mmHg	84 mmHg

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Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Participant Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	FOLLOW-UP	19FEB2022	

Narrative Comment
Participant C4591015, a 17-week 3-day-old White female with no reported medical history, was born to a maternal participant by vaginal birth on at 40 weeks 4 days gestational age, with Apgar scores of 8 and 10 at 1 and 5 minutes, respectively. The maternal participant, while pregnant, received Dose 1 on at 33 weeks 5 days of gestation and Dose 2 on (Day 22) at 36 weeks 5 days of gestation. On (Day 123 of age), the participant was diagnosed with severe respiratory tract infection and her parent/legal guardian reported new or increased cough and fever, with the first symptom starting on 121 days after birth, and the last symptom resolved on (Day 129 of age). The participant did not have any healthcare contact. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on (Day 123 of age) was positive. No local laboratory SARS CoV-2 NAAT was done. On (Day 123 of age), the participant had a heart rate of 153 beats/min, blood pressure (BP) of 84/60 mmHg, respiratory rate (RR) of 48 breaths/min, and oxygen saturation of 95% on room air. The participant therefore had severe COVID-19 illness per protocol criteria (ie, had clinical signs at rest indicative of severe systemic illness [RR: ≥34 breaths/min from 1 month to 6 months of age] and presented evidence of shock [systolic BP <100 mmHg from 1 month to 6 months of age]).

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Demography				
Date of B rth	Gestational Age at Birth	Race	Ethnicity	Sex
[redacted]	37 weeks	American Indian or Alaskan native	Hispanic/Latino	Female

Birth Details			
Mode of Birth	Apgar Score at 1 Minute	Apgar Score at 5 Minutes	Apgar Score at 10 Minutes
Vaginal	9	10	10

Vital Signs - Baseline			
Body Length	Weight	Date Collected (Study Day)	Infant age in Days
43.9 cm	2.305 kg	[redacted] (49)	2

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Reason(s) for Narrative: COV_D_19 Case (Severe and/or Multiple)
Participant: C4591015 [redacted]; Country: Spain
Maternal Vaccine Group (as Administered): BNT162b2
Date of First Dose: [redacted]; Date of Last Dose: [redacted]
==========

Maternal Study Vaccination(s)				
Vaccination Number	**Vaccine**	**Maternal Vaccination Date (Study Day)**	**Time of Maternal Vaccination**	**Gestational Age at Maternal Vaccination**
1	BNT162b2	[redacted] (1)	12:13:00	30 weeks 2 days
2	BNT162b2	[redacted] (21)	12:48:00	33 weeks 1 days

Adverse Events						
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Age in Days)**	**Stop Date (Age in Days)**	**Duration (Days)**
1	Pregnancy, puerperium and perinatal conditions	Jaundice neonatal	Hyperbilirubinaemia neonatal - neonatal jaundice	[redacted] (2)	[redacted] (5)	4

Adverse Events					
AE Number	**Toxicity Grade**	**Action: Participant**	**SAE**	**AE Still Present?**	**AE Related To:**
1	3	NA	Yes	RECOVERED/RESOLVED (07082021)	NOT RELATED /OTHER; Unknown

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Reason(s) for Narrative: COVID-19 Case (Severe and/or Multiple)
Participant: C4591015 [redacted]; Country: Spain
Maternal Vaccine Group (as Administered): BNT162b2
Date of First Dose: [redacted]; Date of Last Dose: [redacted]
==========

Concomitant Medications				
Investigator Text	**WHO Drug Preferred Term**	**Start Date**	**End Date**	**Route**
paracetamol	PARACETAMOL	[redacted]	[redacted]	ORAL

Nonstudy Vaccines
No Nonstudy Vaccines

Case Details				
Visit	**>7 Days After Dose 2**	**Severe**	**Infant Age**	**Visit Date (Study Day)**
COVID Illness Visit 1	Yes	Yes	20 Weeks	[redacted] (188)

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Signs and Symptoms of Potential COVID-19						
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**	**Protocol and/or CDC Defined**	**Infant age in Days (Date First Symptom Started)**	**Narrative Event**
COVID Illness Visit 1 [redacted] (188)/ 187)/ 191)	NO		RHINORRHOEA	Protocol and CDC Defined Symptoms Present	140	Yes
	YES	FEVER		Protocol and CDC Defined Symptoms Present	140	Yes

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Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis (Study Day)**	**MedDRA Preferred Term**	**Infant Age in days**
COVID Illness Visit 1	[redacted] (188)	COVID-19 like illness	[redacted] (187	Suspected COVID-19	140
COVID Illness Visit 1	[redacted] (188)	covid-19	[redacted] (189)	COVID-19	142

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	[redacted] (188)	[redacted] (188)	NASAL_SWAB	POSITIVE
2	COVID Illness Visit 1 - Repeat Swab	[redacted] (188)	[redacted] (188)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**
1	COVID Illness Visit 1	[redacted] (188)	[redacted] (188)	RESPIRATORY SECRETIONS

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SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Specimen Collection Location**	**Test Result**	**Comments/Findings/Details**	**Trade Name**
1	NASOPHARYNX	POSITIVE		HOLOGIC PANTHER FUSION SARS-COV-2

Health Care Utilization						
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**	**Infant age in days**
COVID Illness Visit 1	[redacted] (188)	HOSPITAL	NO		NA	141
		SPECIALIST	NO		NA	141
		EMERGENCY ROOM	YES	1	NA	141
		PRIMARY CARE PHYSICIAN	NO		NA	141
		URGENT CARE	NO		NA	141
		TELEPHONE CONSULTATION	NO		NA	141
		OTHER	NO		NA	141

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Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

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Note: † = Original results and units are displayed for UNCONVERTED Standard lab results.

Vital Signs - COVID-19								
Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Respiratory Rate	Heart Rate	Oxygen Saturation	Diastolic Blood Pressure	Systolic Blood Pressure
COVID Illness Visit 1	[redacted] (188)	[redacted] (188)	1	36 breaths/min	153 beats/min	99 %	58 mmHg	97 mmHg

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

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Participant Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	FOLLOW-UP	03FEB2022	

Narrative Comment
Participant C4591015 [redacted], a 20-week-old American Indian/Alaskan native female with no reported medical history, was born to a maternal participant by vaginal birth on [redacted] at 37 weeks gestat onal age, with Apgar scores of 9, 10, and 10 at 1, 5, and 10 minutes, respectively. The maternal participant, while pregnant, received Dose 1 on [redacted] at 30 weeks 2 days of gestation and Dose 2 on [redacted] (Day 21) at 33 weeks 1 day of gestation. On [redacted] (Day 142 of age), the participant was diagnosed with severe COVID-19 and her parent/legal guardian reported rhinorrhea and fever, with the first symptom starting on [redacted], 139 days after birth, and the last symptom resolved on [redacted] (Day 144 of age). The participant was taken to the emergency room (once). She was treated with paracetamol from [redacted] to [redacted] (Day 141 to Day 143 of age). The central laboratory SARS-CoV-2 NAAT results at the time of the COVID-19 illness on [redacted] (Day 141 of age) were positive. The local laboratory SARS-CoV-2 test result at the time of the COVID-19 illness on [redacted] (Day 141 of age) was positive. On [redacted] (Day 141 of age), the participant had a heart rate of 153 beats/min, blood pressure (BP) of 97/58 mmHg, respiratory rate (RR) of 36 brea hs/m n, and oxygen saturation of 99% on room air.

Reason(s) for Narrative: COV_D_19 Case (Severe and/or Multiple)
Participant: C4591015[redacted]; Country: Spain
Maternal Vaccine Group (as Administered): BNT162b2
Date of First Dose:[redacted] Date of Last Dose: [redacted]
==========

Narrative Comment
The participant therefore had severe COVID-19 illness per protocol criteria (ie, had clinical signs at rest indicative of severe systemic illness [RR: ≥34 breaths/min from 1 month to 6 months of age] and presented evidence of shock [systolic BP <100 mmHg from 1 month to 6 months of age]).

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CLINICAL STUDY REPORT ERRATA

Protocol Number: C4591015

Study Report Title:	Final Report: A Phase 2/3, Placebo-Controlled, Randomized, Observer-Blind Study to Evaluate the Safety, Tolerability, and Immunogenicity of a SARS-CoV-2 RNA Vaccine Candidate (BNT162b2) Against COVID-19 in Healthy Pregnant Women 18 Years of Age and Older

Minor errors were identified in the Clinical Study Report (CSR). Those errors are listed below.

Although these errors do not affect the conclusions of the study, they have been included in this Erratum to ensure the accuracy of the report.

Section	Description of Error
Tables 14.17 and 14.18	Subjects [redacted] and [redacted] mistakenly had serology samples drawn at Visit 2 which were then used for immunogenicity testing instead of being destroyed. The N-binding antibody assay result from subject [redacted] was negative, while the results for the SARS-CoV-2 neutralization assay and full-length S-binding IgG levels did not have valid readings. The sample taken from subject [redacted] did not have valid readings for any of the three assay tes s performed. The test results were then included in the final Immunogenicity Blood Samples Drawn tables for maternal and nonpregnant female participants.
Appendix 16.2.6.1.1	Subjects [redacted] and [redacted] mistakenly had serology samples drawn at Visit 2, which were then used for immunogenicity testing instead of being destroyed. The N-binding antibody assay result from subject [redacted] was negative, while the results for the SARS-CoV-2 neutralization assay and full-length S-binding IgG levels did not have valid readings. The sample taken from subject [redacted] did not have valid readings for any of the three assay tes s performed. The test results were then included in the final Listing of Assay Data for maternal participants.

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A PHASE 2/3, PLACEBO-CONTROLLED, RANDOMIZED, OBSERVER-BLIND STUDY TO EVALUATE THE SAFETY, TOLERABILITY, AND IMMUNOGENICITY OF A SARS-COV-2 RNA VACCINE CANDIDATE (BNT162b2) AGAINST COVID-19 IN HEALTHY PREGNANT WOMEN 18 YEARS OF AGE AND OLDER

Study Sponsor:	BioNTech
Study Conducted By:	Pfizer
Study Intervention Number:	PF-07302048
Study Intervention Name:	RNA-Based COVID-19 Vaccines
US IND Number:	19736
EudraCT Number:	2020-005444-35
Protocol Number:	C4591015
Phase:	Phase 2/3

Short Title: A Phase 2/3 Study to Evaluate the Safety, Tolerability, and Immunogenicity of SARS-CoV-2 RNA Vaccine Candidate (BNT162b2) Against COVID-19 in Healthy Pregnant Women 18 Years of Age and Older

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Protocol Amendment Summary of Changes Table

Document History		
Document	**Version Date**	**Summary and Rationale for Changes**
Protocol amendment 5	08 March 2022	• Enrollment of study participants was terminated with fewer study participants enrolled than originally planned due to enrollment challenges into a placebo-controlled trial as a result of universal recommendations for COVID-19 vaccination of pregnant women and the increased global availability of COVID-19 vaccines. • Modified the primary immunogenicity objectives and estimands from hypothesis testing analysis to descriptive analysis as a result of the significantly reduced final number of study participants enrolled than originally planned. • Modified an exploratory immunogenicity estimand by removing the calculation of incidence rate after 1 month after delivery for crossover participants because there is no COVID-19 surveillance for these participants after 1 month after delivery. • Modified appropriate statistical sections due to updates to the primary immunogenicity objectives and estimands. • Updated Sections 2.2.1 and 2.3 to reflect current recommendations and to provide details of the recent safety and efficacy analysis results for study C4591001.
Protocol amendment 4	06 August 2021	• Added procedures in Section 8.14 to capture data pertaining to myocarditis and pericarditis in response to commitments made to CBER.

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Document History		
Document	**Version Date**	**Summary and Rationale for Changes**
		• Added myocarditis and pericarditis in Sections 8.14 and 2.3.1 in response to commitments made to CBER. • Added a procedure to any visit that occurs sooner than 1 month after any vaccination in Sections 8.11 and 8.17 in response to commitments made to CBER. • Added myocarditis and pericarditis as AESIs in Section 8.3.8. • Added a statement on diversity in Section 5. • Added clarification to the infant SoA (Section 1.3.3) to collect the e-diary or assist the maternal participant to delete the application at Visit 3. • Administrative update in Section 8.11.1.7 to add collection of the e-diary or assist the participant to delete the application. • Corrected typographical errors throughout.
Protocol amendment 3	14 May 2021	• Reduced the study sample size based on regulatory feedback and evolving global availability of COVID-19 vaccines for pregnant women. • Modified the study objectives to align with the reduced sample size. • Removed the hypothesis-based efficacy objective, estimands, and endpoints. • Modified the statistical analysis timing to align with the reduced sample size and changes in the objectives.

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Document History		
Document	**Version Date**	**Summary and Rationale for Changes**
		• Updated a typographical error in the SoA regarding the need to collect AE information during the 1-week postdelivery follow-up call. • Clarified that, if pregnancy outcome information was not obtained at the time of delivery, updated information should be provided at Visit 6. • Added a modifier to inclusion criterion 8 regarding the need for a telephone as method of contact in Mozambique, so that the population is reachable based on location despite lack of routine access to telephones. • Removed the collection of CD4 count and HIV viral load at Visit 101 in Sections 1.3.2 and 8.17.1 since this is duplicate information and will already be collected at Visit 7 in Section 1.3.1. • Added "chills" to the definition of confirmed COVID-19 in maternal participants in Section 8.1.1.
Protocol amendment 2	02 March 2021	• Sections 1.3.1 and 1.3.2: expanded the 1-month postdelivery visit window by 1 week to allow for potential earlier vaccination of BNT162b2 to participants originally randomized to receive placebo. • Section 1.3.3: removed "equivalent visit number for maternal participants" from the Infant SoA since this will differ for maternal participants originally randomized to placebo who will go on to receive BNT162b2 at 1 month after delivery and follow a different SoA. • Section 2.3: added a sentence to clarify that the protocol is a PASS.

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Document	**Version Date**	**Summary and Rationale for Changes**

		• Section 5.1.1: corrected the calculation of GA in the third trimester, replacing "second trimester" with "third trimester," and updated the discrepancy of days between the LMP-determined GA from >10 to >21 days.
		  • Removed references to thumbprinting the ICD, since illiterate participants will not be enrolled from certain regions.
		• Clarified in Section 8.2.2 that field workers would be used in the case of poor network connection for e-diary completion.
		• Sections 5.1.1, 8.17.3, and 10.4: added criteria for inclusion of maternal participants with stable HIV, hepatitis B, or hepatitis C in Phase 3.
		• Updated the Objectives, Estimands, and Endpoints to add a safety objective for the first 600 randomized maternal participants to support interim analysis/submission report.
		  • Per CBER feedback, updated the term "NI" to "immunobridging" to describe the immunogenicity comparison between nonrandomized populations in the protocol.
		  • Added a footnote to clarify that HIV-infected participants will not be included in analyses of the objectives. Analyses among HIV-infected women and their infants will be summarized separately.

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		• Sections 8.1.1 and 8.13.1: added a second definition of symptoms of severe COVID-19 disease per the CDC definition.
		• Section 8.2.3: clarified that stopping rules are in place during Phase 2 only, with no overlap into Phase 3.
		  • Clarified that a study pause may not prevent administration of Dose 2 for enrolled participants.
		  • Modified stopping rule 7 to include a trigger of preterm premature rupture of membranes.
		  • Stopping rule 4: removed assessment of laboratory abnormalities, as these data are not collected in this study.
		• Section 8.11.1, Visit 1: removed the requirement of a repeat fetal scan to clarify that an earlier scan done at ≥18 weeks' GA can be used to confirm singleton pregnancy and rule out fetal anomalies.
		• Section 8.16: clarified that exclusion criterion 2 is not met if the participant meets the criteria for confirmed COVID-19 with or without symptoms and can receive Vaccination 2.
		• Section 8.17: to align with current recommendations, investigators may exercise judgment on review of inclusion and exclusion criteria ahead of vaccination with BNT162b2 for participants who originally received placebo.
		• Sections 8.3.1 and 8.3.7: inserted language to clarify that potential COVID-19/MIS-C illnesses and their sequelae that are consistent with the clinical endpoint definition should not be recorded as AEs.

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Document History		
Document	**Version Date**	**Summary and Rationale for Changes**
		• Appendix 3: removed an erroneous partially completed sentence from the second paragraph.
Protocol amendment 1	28 January 2021	• Based on availability of BNT162b2 in high-risk pregnant women and evidence of safety in the real-world setting, the sentinel cohort of N=50 in Phase 2 was removed. • Based on feedback from an external advisory board, inclusion criterion 10 was updated to allow enrollment of participants with a prepregnancy BMI of ≤40 kg/m^2. • Clarified language in inclusion criterion 1 that GA dating for maternal participants who underwent assisted reproduction technology can be referenced in the SRM. • Corrected the list of prohibited medications under Section 6.5.1. • Clarified language in the Objectives, Estimands, and Endpoints table for consistency. • Added exploratory objectives to evaluate incidence rates of COVID-19 and asymptomatic SARS-CoV-2 infection through the entire follow-up among the maternal participants receiving BNT162b2. • Updated the VE assessment to reflect the reduced accrual of time following the unblinding of participants at 1 month after delivery. • Clarified the unblinding at 1 month after delivery for participants originally randomized to placebo who go on to receive BNT162b2.

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Document History		
Document	**Version Date**	**Summary and Rationale for Changes**
		• Updated Section 2.3, Benefit-Risk Assessment, to include data from the DART studies. • In line with current recommendations, removed the requirement to discontinue study intervention because of a diagnosis of COVID-19 during the study. • Added the requirement to record antipyretic medication in the e-diary during the 7-day vaccination period, as this was omitted in error. • Added editorial changes in the document to clarify where field workers/site staff may be required to call/visit maternal participants at home (applicable to regions where illiterate participants may be enrolled). • Clarified that participants originally randomized to placebo who go on to receive BNT162b2 at 1 month after delivery will not participate in COVID-19 surveillance. • Clarified that AEs will be collected from the signing of the ICD to 1 month after Vaccination 4 (Visit 103) for those maternal participants who originally received placebo and who go on to receive BNT162b2 at 1 month after delivery.
Original protocol	21 December 2020	N/A

This amendment incorporates all revisions to date, including amendments made at the request of country health authorities and IRBs/ECs.

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1. PROTOCOL SUMMARY

1.1. Synopsis

Short Title: A Phase 2/3 Study to Evaluate the Safety, Tolerability, and Immunogenicity of a SARS-CoV-2 RNA Vaccine Candidate (BNT162b2) Against COVID-19 in Healthy Pregnant Women 18 Years of Age and Older

Rationale

In December 2019, a pneumonia outbreak of unknown cause occurred in Wuhan, China. In January 2020, it became clear that a novel coronavirus (2019-nCoV) was the underlying cause. Later in January, the genetic sequence of the 2019-nCoV became available to the WHO and public (MN908947.3), and the virus was categorized in the *Betacoronavirus* subfamily. By sequence analysis, the phylogenetic tree revealed a closer relationship to SARS virus isolates than to another coronavirus infecting humans, the MERS virus. SARS-CoV-2 infections and the resulting disease, COVID-19, have spread globally, affecting a growing number of countries.

On 11 March 2020, the WHO characterized the COVID-19 outbreak as a pandemic. Global case rates and deaths have continued to increase, with the United States reporting the most cases and deaths of any other country. At the time of this communication, the number of confirmed cases continues to rise globally. There are currently no licensed vaccines or effective antiviral drugs to prevent SARS-CoV-2 infections or the disease it causes, COVID-19.

Pregnant women are at risk for acquiring SARS-CoV-2 infection and COVID-19. Pregnancy may confer increased risk of severe COVID-19 because of physiological changes during pregnancy that can increase susceptibility to respiratory infections and subsequent rapid progression to respiratory failure. Additionally, pregnant women with COVID-19 have been reported to have higher rates of preterm birth, cesarean delivery, fetal distress, and infants requiring neonatal intensive care. Prevention of SARS-CoV-2 infection and COVID-19 is critically important in pregnant women.

Given the rapid transmission of COVID-19 and incidence of disease in the United States and elsewhere, the rapid development of an effective vaccine is of utmost importance.

BNT162b2 is a SARS-CoV-2–RNA-LNP vaccine based on a platform of modRNA with blunted innate immune sensor–activating capacity and augmented expression encoding the P2 S.

This study will describe the safety of BNT162b2 in pregnant women and their infants. It will also assess the immunogenicity of BNT162b2 in pregnant women, the transfer of antibody to their infants, and the kinetics of antibody transfer in the infant.

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Objectives, Estimands, and Endpoints

Objectives[a]	Estimands	Endpoints
Primary Safety	**Primary Safety**	**Primary Safety**
To describe the safety and tolerability of prophylactic BNT162b2 when administered to maternal participants 18 years of age or older vaccinated at 24 to 34 weeks' gestation.	In maternal participants receiving at least 1 dose of study intervention from each vaccine group, the percentage of maternal participants reporting: • Local reactions for up to 7 days following each dose • Systemic events for up to 7 days following each dose • AEs from Dose 1 through 1 month after Dose 2 • SAEs from Dose 1 through 1 month after delivery	• Prompted local reactions (redness, swelling, and pain at the injection site) • Prompted systemic events (fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain) • AEs • SAEs
Primary Immunogenicity	**Primary Immunogenicity**	**Primary Immunogenicity**
To describe the immune response to prophylactic BNT162b2 in maternal participants 18 years of age or older vaccinated at 24 to 34 weeks' gestation and reference to the immune response in nonpregnant women 18 years of age or older from the C4591001 study without evidence of past SARS-CoV-2 infection.	In female participants complying with the key protocol criteria (evaluable participants) and no serological or virological evidence (up to 1 month after receipt of the second dose) of past SARS-CoV-2 infection: • GMR, estimated by the ratio of the geometric mean of SARS-CoV-2 neutralizing titers in pregnant women to those in nonpregnant women 1 month after Dose 2	• SARS-CoV-2 neutralizing titers
To describe the immune response to prophylactic BNT162b2 in maternal participants 18 years of age or older vaccinated at 24 to 34 weeks' gestation and reference to the immune response in nonpregnant women 18 years of age or older from the C4591001 study with and without evidence of prior SARS-CoV-2 infection.	In female participants complying with the key protocol criteria (evaluable participants): • GMR, estimated by the ratio of the geometric mean of SARS-CoV-2 neutralizing titers in pregnant women to those in nonpregnant female participants 1 month after Dose 2	• SARS-CoV-2 neutralizing titers

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Objectives[a]	Estimands	Endpoints
Secondary	**Secondary**	**Secondary**
To describe the efficacy of prophylactic BNT162b2 against confirmed COVID19 occurring from 7 days after Dose 2 through 1 month after delivery in maternal participants 18 years of age or older vaccinated at 24 to 34 weeks' gestation without evidence of prior SARS-CoV-2 infection.	In maternal participants complying with the key protocol criteria (evaluable participants) and no serological or virological evidence (prior to 7 days after receipt of Dose 2) of past SARS-CoV-2 infection: • 100 × (1 – IRR) [ratio of active vaccine to placebo]	• COVID-19 incidence per 1000 person-years of blinded follow-up based on central laboratory or locally confirmed NAAT
To describe the efficacy of prophylactic BNT162b2 against confirmed COVID-19 occurring from 7 days after Dose 2 through 1 month after delivery in maternal participants 18 years of age or older vaccinated at 24 to 34 weeks' gestation with and without evidence of prior SARS-CoV-2 infection.	In maternal participants complying with the key protocol criteria (evaluable participants): • 100 × (1 – IRR) [ratio of active vaccine to placebo]	• COVID-19 incidence per 1000 person-years of blinded follow-up based on central laboratory or locally confirmed NAAT
To describe the efficacy of prophylactic BNT162b2 against asymptomatic SARS-CoV-2 infection through 1 month after delivery in maternal participants 18 years of age or older vaccinated at 24 to 34 weeks' gestation without evidence of prior SARS-CoV-2 infection.	In evaluable maternal participants without serological or virological evidence of prior SARS-CoV-2 infection: • 100 × (1 – IRR) [ratio of active vaccine to placebo]	• Incidence of asymptomatic infection of SARS-CoV-2 based on N-binding antibody seroconversion
To describe the immune response over time and persistence of prophylactic BNT162b2 when administered to maternal participants 18 years of age or older vaccinated at 24 to 34 weeks' gestation.	In maternal participants complying with the key protocol criteria (evaluable maternal participants) from each vaccine group: • GMCs/GMTs, at baseline (before Dose 1), 2 weeks after Dose 2, 1 month after Dose 2, at delivery, and 6 months after delivery • GMFRs from baseline through 2 weeks after Dose 2, 1 month after Dose 2, at delivery, and 6 months after delivery	• Full-length S-binding IgG levels • SARS-CoV-2 neutralizing titers

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Objectives[a]	Estimands	Endpoints
To assess the safety of maternal immunization in infants born to maternal participants 18 years of age or older who were vaccinated with BNT162b2 during pregnancy.	In infants born to maternal participants receiving at least 1 dose of study intervention from each vaccine group, the percentage of infants with: • Specific birth outcomes • AEs from birth through 1 month of age • SAEs and AESIs (major congenital anomalies, developmental delay) through 6 months of age	• Specific birth outcomes • AEs from birth through 1 month of age • SAEs and AESIs (major congenital anomalies, developmental delay) through 6 months of age
To describe the immune response in infants born to maternal participants vaccinated with prophylactic BNT162b2 during pregnancy.	In infants born to evaluable maternal participants from each vaccine group: • GMCs and GMFRs, at birth and 6 months after delivery	• Full-length S-binding IgG levels
Exploratory	**Exploratory**	**Exploratory**
To describe the incidence of confirmed COVID-19 among maternal participants who were vaccinated with BNT162b2.	In maternal participants who received BNT162b2 at initial randomization: • Incidence per 1000 person-years of follow-up	• COVID-19 incidence per 1000 person-years of follow-up based on central laboratory or locally confirmed NAAT
To describe the incidence of asymptomatic SARS-CoV-2 infection through 6 months after delivery in maternal participants 18 years of age or older vaccinated at 24 to 34 weeks' gestation with BNT162b2 at initial randomization and without evidence of prior SARS-CoV-2 infection.	In maternal participants who received BNT162b2 at initial randomization and without evidence of prior SARS-CoV-2 infection: • Incidence per 1000 person-years of follow-up	• Incidence of asymptomatic SARS-CoV-2 infection per 1000 person-years of follow-up based on N-binding antibody seroconversion
To describe the serological responses among maternal participants to the BNT162b2 vaccine candidate in cases of: • Confirmed COVID-19 • Confirmed severe COVID-19 • SARS-CoV-2 infection without confirmed COVID-19	In each subset of evaluable maternal participants from each vaccine group with: • Confirmed COVID-19 • Confirmed severe COVID-19 • SARS-CoV-2 infection but no confirmed COVID-19 • GMCs/GMTs and GMFRs at baseline, 1 month after Dose 2, at delivery, and 6 months after delivery	• Full-length S-binding IgG levels • SARS-CoV-2 neutralizing titers

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Objectives[a]	Estimands	Endpoints
To describe the immune response to prophylactic BNT162b2 between Dose 1 and Dose 2 when administered to maternal participants 18 years of age or older vaccinated at 27 to 34 weeks' gestation in the Phase 2 portion of the study.	In evaluable maternal participants: • GMCs/GMTs at baseline and before Dose 2 • GMFRs from baseline to before Dose 2	• Full-length S-binding IgG levels • SARS-CoV-2 neutralizing titers
To describe the immune response in infants born to breastfeeding maternal participants vaccinated with prophylactic BNT162b2 during pregnancy.	In infants born to maternal participants from each vaccine group, based on the breastfeeding status: • GMCs and GMFRs, at birth and 6 months after delivery	• Full-length S-binding IgG levels
To describe the safety of maternal immunization in infants born to breastfeeding maternal participants vaccinated with prophylactic BNT162b2 during pregnancy.	In infants born to maternal participants receiving at least 1 dose of study intervention from each vaccine group, based on the breastfeeding status, the percentage of infants with: • AEs from birth through 1 month of age • SAEs and AESIs (major congenital anomalies, developmental delay) through 6 months of age	• AEs from birth through 1 month of age • SAEs and AESIs (major congenital anomalies, developmental delay) through 6 months of age
To describe the incidence of confirmed COVID-19 in infants born to maternal participants who were vaccinated with BNT162b2 during pregnancy.	In infants born to maternal participants from each vaccine group: • Incidence rate of infant participants with confirmed COVID-19	• COVID-19 incidence per 1000 person-years of follow-up based on central laboratory or locally confirmed NAAT
To describe MIS-C cases in infants born to maternal participants who were vaccinated with BNT162b2 during pregnancy.	In infants born to maternal participants from each vaccine group: • Incidence rate of MIS-C	• MIS-C incidence per 1000 person-years of follow-up

a. HIV-infected participants will not be included in analyses of the objectives, but in separate exploratory analyses. Analyses among HIV-infected women and their infants will be summarized separately.

Overall Design

This will be a global Phase 2/3, randomized, placebo-controlled, observer-blind study evaluating the safety, tolerability, and immunogenicity of 30 µg of BNT162b2 or placebo administered in 2 doses, 21 days apart, in approximately 350 healthy pregnant women 18 years of age or older vaccinated at 24 to 34 weeks' gestation. Participants will be randomized 1:1 to receive BNT162b2 or placebo (saline).

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The Phase 2 portion of the study will include approximately 200 pregnant women randomized 1:1 to receive BNT162b2 or placebo (saline) at 27 to 34 weeks' gestation. The IRC will review safety data through 7 days after the second dose for all Phase 2 participants.

The Phase 3 portion of this study will assess the safety, tolerability, and immunogenicity of BNT162b2 among pregnant women enrolled at 24 to 34 weeks' gestation. Phase 3 will proceed after the first 200 maternal participants have been enrolled in Phase 2.

Maternal participants who originally received placebo will receive BNT162b2 at defined time points as part of the study.

Number of Participants

Approximately 200 healthy pregnant women will be enrolled in the Phase 2 portion of the study. Approximately 150 healthy pregnant women will be enrolled in the Phase 3 portion.

Intervention Groups and Duration

This study will evaluate a 2-dose (separated by 21 days) schedule of 30 µg of the investigational BNT162b2 RNA vaccine candidate (BNT162 RNA-LNP vaccine utilizing modRNA and encoding the P2 S) for active immunization against COVID-19.

Healthy pregnant women will be randomized in a 1:1 ratio to receive a 2-dose schedule of either:

- BNT162b2 (BNT162 RNA-LNP vaccine utilizing modRNA and encoding the P2 S) at a dose of 30 µg OR
- Normal saline solution for injection (0.9% NaCl injection).

Each maternal participant will participate in the study for approximately up to 10 months depending on the vaccine group to which she was randomized. Her infant will participate in the study for approximately 6 months. The study duration will be approximately 14 months.

Data Monitoring Committee or Other Independent Oversight Committee

The study will utilize an IRC, an internal Pfizer committee that will be used during the Phase 2 portion of the study to closely monitor safety.

The study will include stopping rules, which may result in a pause to study vaccination followed by a review and recommendation by the IRC.

The study will use an external DMC to monitor vaccine safety throughout the study.

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Statistical Methods

The primary safety objective will be evaluated by descriptive summary statistics for local reactions, systemic events, AEs, and SAEs, for each vaccine group. Descriptive summary statistics will include counts and percentages of participants with the indicated endpoint and the associated Clopper-Pearson 95% CIs. A 3-tier approach will be used to summarize AEs. The AEs, including SAEs, reported in the open-label follow-up period will be summarized separately from those reported during the blinded follow-up period for maternal participants. The safety objective related to infants born to maternal participants, including birth outcomes, AEs, SAEs, and AESIs, will be evaluated in a similar way.

There are 2 primary immunogenicity objectives, one for participants without evidence of SARS-CoV-2 infection up to 1 month after Dose 2, and the other for participants with and without evidence of prior SARS-CoV-2 infection; each will be evaluated by describing SARS-CoV-2 neutralizing titers induced by BNT162b2 at 1 month after Dose 2 in maternal participants and in a group of randomly selected nonpregnant women within the same age group from the C4591001 study. GMRs will be provided along with associated 2-sided 95% CIs.

Other immunogenicity objectives will be evaluated descriptively by GMTs/GMCs and GMFRs of full-length S-binding IgG levels and/or SARS-CoV-2 neutralizing titers and associated 2-sided 95% CIs.

The secondary efficacy objectives are to describe VE against the confirmed COVID-19 illness during the blinded follow-up period, which is defined as VE = 100 × (1 – IRR). IRR is calculated as the ratio of first confirmed COVID-19 illness rate in the vaccine group to the corresponding illness rate in the placebo group.

VE against asymptomatic infection will be evaluated descriptively, in a similar way.

The incidence rates of confirmed COVID-19 and asymptomatic infection per 1000 person-years of follow-up in maternal participants after their receipt of BNT162b2 throughout the study will be provided with the associated 2-sided 95% CIs.

The incidence rate of confirmed COVID-19 and incidence rate of confirmed MIS-C in infant participants, and associated 2-sided 95% CIs, will also be provided according to the vaccine group to which the maternal participants were randomized.

1.2. Schema

Not applicable.

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1.3. Schedule of Activities

The SoA table provides an overview of the protocol visits and procedures. Refer to the Study Assessments and Procedures section of the protocol for detailed information on each procedure and assessment required for compliance with the protocol.

The investigator may schedule visits (unplanned visits) in addition to those listed in the SoA table, in order to conduct evaluations or assessments required to protect the well-being of the participant.

An unplanned potential COVID-19 illness visit and unplanned potential COVID-19 convalescent visit are required at any time between Visit 1 (Vaccination 1) and Visit 8 (6-month postdelivery visit, the final study visit) that potential COVID-19 symptoms are reported, including MIS C.

1.3.1. Schedule of Activities for Maternal Participants

Visit Number (Maternal Participants)	1	2	3	4	5	6	7	8	Unplanned	Unplanned
Visit Description	Screening: -28 Days to Vaccination 1	Vaccination 2	2-Week Post–Vaccination 2 Follow-up[a]	1-Month Post–Vaccination 2 Follow-up[a]	Delivery	1-Week Postdelivery Follow-up Call	1-Month Postdelivery Follow-up[b]	6-Month Postdelivery Follow-up For Participants Originally Randomized to Receive BNT162b2	Potential COVID-19 Illness Visit[c]	Potential COVID-19 Convalescent Visit
Visit Window (Days)	Day 1 Visit 1	19 to 23 Days After Visit 1	11 to 17 Days After Visit 2	28 to 35 Days After Visit 2	Varies	7 to 10 Days After Delivery	21 to 35 Days After Delivery	160 to 200 Days After Delivery	Optimally Within 3 Days After Potential COVID-19 Illness Onset	28 to 35 Days After Potential COVID-19 Illness Visit
Type of Visit	**Clinic**	**Clinic**	**Clinic**	**Clinic**	**Hospital**	**Phone Call**	**Clinic**	**Clinic**		
Obtain informed consent	X									
Assign single participant identifier	X									
Obtain demography	X									

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Visit Number (Maternal Participants)	1	2	3	4	5	6	7	8	Unplanned	Unplanned
Visit Description	**Screening: -28 Days to Vaccination 1**	**Vaccination 2**	**2-Week Post–Vaccination 2 Follow-up[a]**	**1-Month Post–Vaccination 2 Follow-up[a]**	**Delivery**	**1-Week Postdelivery Follow-up Call**	**1-Month Postdelivery Follow-up[b]**	**6-Month Postdelivery Follow-up For Participants Originally Randomized to Receive BNT162b2**	**Potential COVID-19 Illness Visit[c]**	**Potential COVID-19 Convalescent Visit**
Visit Window (Days)	**Day 1 Visit 1**	**19 to 23 Days After Visit 1**	**11 to 17 Days After Visit 2**	**28 to 35 Days After Visit 2**	**Varies**	**7 to 10 Days After Delivery**	**21 to 35 Days After Delivery**	**160 to 200 Days After Delivery**	**Optimally Within 3 Days After Potential COVID-19 Illness Onset**	**28 to 35 Days After Potential COVID-19 Illness Visit**
Type of Visit	**Clinic**	**Clinic**	**Clinic**	**Clinic**	**Hospital**	**Phone Call**	**Clinic**	**Clinic**		
Record current alcohol and tobacco usage	X									
Obtain medical history, including obstetric and gestational history	X									
Phase 3 only: For participants who are HIV-positive, record latest CD4 count and HIV viral load	X		X	X	X		X	X		
Record LMP and EDD	X									
Measure vital signs	X	X		X						
Perform physical examination	X									
Perform targeted physical examination		X		X						
Perform obstetric examination	X	X		X						
Perform obstetric ultrasound	X									
Record nonstudy vaccine information	X	X	X	X	X	X	X	X		
Record concomitant medication associated with an adverse event or serious adverse event	X	X	X	X	X	X	X	X[d]		
Record prohibited medications									X	X

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Visit Number (Maternal Participants)	1	2	3	4	5	6	7	8	Unplanned	Unplanned
Visit Description	**Screening: -28 Days to Vaccination 1**	**Vaccination 2**	**2-Week Post–Vaccination 2 Follow-up[a]**	**1-Month Post–Vaccination 2 Follow-up[a]**	**Delivery**	**1-Week Postdelivery Follow-up Call**	**1-Month Postdelivery Follow-up[b]**	**6-Month Postdelivery Follow-up For Participants Originally Randomized to Receive BNT162b2**	**Potential COVID-19 Illness Visit[c]**	**Potential COVID-19 Convalescent Visit**
Visit Window (Days)	**Day 1 Visit 1**	**19 to 23 Days After Visit 1**	**11 to 17 Days After Visit 2**	**28 to 35 Days After Visit 2**	**Varies**	**7 to 10 Days After Delivery**	**21 to 35 Days After Delivery**	**160 to 200 Days After Delivery**	**Optimally Within 3 Days After Potential COVID-19 Illness Onset**	**28 to 35 Days After Potential COVID-19 Illness Visit**
Type of Visit	**Clinic**	**Clinic**	**Clinic**	**Clinic**	**Hospital**	**Phone Call**	**Clinic**	**Clinic**		
Review eligibility criteria	X	X								
Review temporary delay criteria	X	X								
Review continued eligibility			X	X	X	X	X	X		
Explain/review participant communication methods (including for e-diary completion), assist the participant with downloading the app, or issue provisioned device, if required	X									
Record systemic events at baseline in the e-diary	X									
Assign participant randomization and container number	X									
Collect blood sample for immunogenicity assessment (~20 mL per blood sample)	X	X[e]	X	X	X			X		X
Obtain nasal (midturbinate swab)	X	X							X[d]	
Administer study intervention	X	X								

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Visit Number (Maternal Participants)	1	2	3	4	5	6	7	8	Unplanned	Unplanned
Visit Description	**Screening: -28 Days to Vaccination 1**	**Vaccination 2**	**2-Week Post–Vaccination 2 Follow-up[a]**	**1-Month Post–Vaccination 2 Follow-up[a]**	**Delivery**	**1-Week Postdelivery Follow-up Call**	**1-Month Postdelivery Follow-up[b]**	**6-Month Postdelivery Follow-up For Participants Originally Randomized to Receive BNT162b2**	**Potential COVID-19 Illness Visit[c]**	**Potential COVID-19 Convalescent Visit**
Visit Window (Days)	**Day 1 Visit 1**	**19 to 23 Days After Visit 1**	**11 to 17 Days After Visit 2**	**28 to 35 Days After Visit 2**	**Varies**	**7 to 10 Days After Delivery**	**21 to 35 Days After Delivery**	**160 to 200 Days After Delivery**	**Optimally Within 3 Days After Potential COVID-19 Illness Onset**	**28 to 35 Days After Potential COVID-19 Illness Visit**
Type of Visit	**Clinic**	**Clinic**	**Clinic**	**Clinic**	**Hospital**	**Phone Call**	**Clinic**	**Clinic**		
Assess acute reactions for at least 30 minutes after study intervention administration	X	X								
Provide/ensure participant has a thermometer and measuring device	X	X								
Review reactogenicity e-diary data (daily review is optimal during the active diary period of 7 days following study intervention administration)	◄——►	◄——►								
Review ongoing reactogenicity e-diary symptoms with participant and obtain stop dates		X	X							
Record pregnancy outcome information					X	X				
Record AEs and SAEs as appropriate[f]	X	X	X	X	X[d]	X	X[d]	X[d]	X[d]	X[d]
Collect e-diary or assist the participant to delete application								X		

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Visit Number (Maternal Participants)	1	2	3	4	5	6	7	8	Unplanned	Unplanned
Visit Description	Screening: -28 Days to Vaccination 1	Vaccination 2	2-Week Post–Vaccination 2 Follow-up[a]	1-Month Post–Vaccination 2 Follow-up[a]	Delivery	1-Week Postdelivery Follow-up Call	1-Month Postdelivery Follow-up[b]	6-Month Postdelivery Follow-up For Participants Originally Randomized to Receive BNT162b2	Potential COVID-19 Illness Visit[c]	Potential COVID-19 Convalescent Visit
Visit Window (Days)	Day 1 Visit 1	19 to 23 Days After Visit 1	11 to 17 Days After Visit 2	28 to 35 Days After Visit 2	Varies	7 to 10 Days After Delivery	21 to 35 Days After Delivery	160 to 200 Days After Delivery	Optimally Within 3 Days After Potential COVID-19 Illness Onset	28 to 35 Days After Potential COVID-19 Illness Visit
Type of Visit	Clinic	Clinic	Clinic	Clinic	Hospital	Phone Call	Clinic	Clinic		
Collection of COVID-19–related clinical and laboratory information (including local diagnosis)									X	X

Abbreviations: EDD = estimated delivery date; HIV = human immunodeficiency virus; LMP = last menstrual period.

a. The 2-week postvaccination follow-up and 1-month postvaccination follow-up visits will not be performed if delivery occurs before the visits. If delivery occurs before Vaccination 2, the second dose should be given as soon as possible after delivery. Once delivery occurs, the visit windows are calculated based on the delivery date.
b. All maternal participants will be unblinded. Placebo recipients will be given BNT162b2 and move to follow the procedures in Section 1.3.2.
c. The COVID-19 illness visit may be conducted as an in-person or telehealth visit.
d. Only AEs occurring up to 48 hours after each blood draw and nasal midturbinate swab collection must be recorded.
e. Prevaccination blood samples for immunogenicity will be drawn from maternal participants in Phase 2 only.
f. The investigator and site staff will ensure the active elicitation and collection of AEs and SAEs through 1 month after Vaccination 2. From 1 month after Vaccination 2 until the 6-month postdelivery follow-up, SAEs will be collected.

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1.3.2. Schedule of Activities for Maternal Participants Who Were Originally Assigned to Placebo

Visit Number (Maternal Participants)	101	102	103
Visit Description	**1-Month Postdelivery Follow-up Vaccination 3**	**Vaccination 4**	**1-Month Telephone Contact Follow-up**
Visit Window (Days)	**21 to 35 Days After Delivery**	**19 to 23 Days After Visit 101**	**28 to 35 Days After Visit 102**
Type of Visit	**Clinic**	**Clinic**	**Phone Call**
Confirm the participant originally received only placebo at Vaccination 1/2. Secondary confirmation by another site staff member is required	X		
Collect prohibited medication use	X	X	X
For participants who are HIV-positive, record latest CD4 count and HIV viral load			X
Review and consider eligibility	X	X	
Review temporary delay criteria	X	X	
Collect blood sample for immunogenicity assessment	~20 mL		
Obtain nasal (midturbinate) swab	X	X	
Obtain vaccine vial allocation via IRT	X	X	
Administer BNT162b2	X	X	
Assess acute reactions for at least 30 minutes after study intervention administration	X	X	
Collect AEs and SAEs as appropriate	X	X	X
Contact the participant by telephone			X

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1.3.3. Schedule of Activities for Infant Participants

Visit Number (Infant Participants)	1	2	3		
				Unplanned	Unplanned
Visit Description	Delivery	1-Week Postdelivery Follow-up	6-Months-of-Age Follow-up	Potential COVID-19 Illness Visit	Potential COVID-19 Convalescent Visit
Visit Window (Days)	Varies	7 to 10 Days After Delivery	160 to 200 Days After Delivery	Optimally Within 3 Days After Potential COVID-19 Illness Onset	28 to 35 Days After Potential COVID-19 Illness Visit
Type of Visit	Hospital	Phone Call	Clinic		
Assign single participant identifier	X				
Record demography and available birth information	X				
Measure vital signs	X				
Perform physical examination	X				
Record concomitant medication associated with an adverse event/serious adverse event	X	X	X		
Review eligibility	X				
Review continued eligibility		X	X		
Record breastfeeding information		X	X		
Collect blood sample for immunogenicity assessment (up to ~5 mL per blood sample depending on weight)			X		X
Cord blood sample (~10 mL) for immunogenicity assessment	X[a]				
Record adverse events	X	X[b]	X[b]	X	X
Record serious adverse events and adverse events of special interest	X	X	X	X	X
Collect prohibited medication use				X	X
Obtain nasal swab				X	
Collection of COVID-19–related clinical and laboratory information (including local diagnosis)				X	X
Collect e-diary or assist the maternal participant to delete application			X		

Abbreviations: HIV = human immunodeficiency virus; IRT = interactive response technology.

a. If cord blood is unavailable, a blood sample may be collected from the infant participant up to 72 hours after birth but preferably within 24 hours after birth.
b. Active AE collection through 1 month of age.

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2. INTRODUCTION

The BNT162b2 RNA-based COVID-19 vaccine is currently being investigated for prevention of COVID-19 in healthy pregnant women.

2.1. Study Rationale

The purpose of the study is to describe the safety, tolerability, and immunogenicity of BNT162b2 RNA-based COVID-19 vaccine against COVID-19 in healthy pregnant women. There are currently no licensed vaccines to prevent infection with SARS-CoV-2 or COVID-19. Pregnant women are at risk of acquiring SARS-CoV-2 infection, developing COVID-19 and COVID-19–associated complications. Given the global crisis of COVID-19 and fast expansion of the disease globally, the rapid development of an effective vaccine for use in this population is of utmost importance.

2.2. Background

In December 2019, a pneumonia outbreak of unknown cause occurred in Wuhan, China. In January 2020, it became clear that a novel coronavirus (2019-nCoV) was the underlying cause. Later in January, the genetic sequence of the 2019-nCoV became available to the WHO and public (MN908947.3), and the virus was categorized in the *Betacoronavirus* subfamily. By sequence analysis, the phylogenetic tree revealed a closer relationship to SARS virus isolates than to another coronavirus infecting humans, the MERS virus.[1,2]

SARS-CoV-2 infections and the resulting disease, COVID-19, have spread globally, affecting a growing number of countries, and on 11 March 2020, the WHO characterized the COVID-19 outbreak as a pandemic.[3] On 16 December 2020, The Center for Systems Science and Engineering at Johns Hopkins University reported more than 73 million cases globally, with over 1.6 million deaths from 191 countries. Global case rates and deaths have continued to increase, with the United States reporting the most cases and deaths of any other country. There are currently no vaccines broadly available to prevent SARS-CoV-2 infections or the disease it causes, COVID-19.[4]

Pregnant women are at risk for acquiring SARS-CoV-2 infection and COVID-19.[5,6,7] Pregnancy may confer increased risk of severe COVID-19 because of physiological changes during pregnancy that can increase susceptibility to respiratory infections and subsequent rapid progression to respiratory failure.[8] Additionally, pregnant women with COVID-19 have been reported to have higher rates of preterm birth, cesarean delivery, fetal distress, and infants requiring neonatal intensive care.[8,9,10,11] While COVID-19 in children is reported less commonly than in adults, infants <1 year of age, if infected with SARS-CoV-2, may be at increased risk of severe disease, and younger age groups have increasing rates of COVID-19–associated hospitalization.[12,13] Prevention of SARS-CoV-2 infection and COVID-19 is critically important in pregnant women, and maternal immunization may confer some protection to their infants.

Given the rapid transmission of COVID-19 and incidence of disease in the United States and elsewhere, the rapid development of an effective vaccine is of utmost importance.

A prophylactic, RNA-based SARS-CoV-2 vaccine provides one of the most flexible and fastest approaches available to immunize against the emerging virus.[14,15] The development of an RNA-based vaccine encoding a viral antigen, which is then expressed by the vaccine recipient as a protein capable of eliciting protective immune responses, provides significant advantages over more traditional vaccine approaches. Unlike live attenuated vaccines, RNA vaccines do not carry the risks associated with infection and may be given to people who cannot be administered live virus (eg, pregnant women and immunocompromised persons). RNA-based vaccines are manufactured via a cell-free in vitro transcription process, which allows an easy and rapid production and the prospect of producing high numbers of vaccination doses within a shorter time period than achieved with traditional vaccine approaches. This capability is pivotal to enable the most effective response in outbreak scenarios.[14,15]

There are no ongoing randomized controlled COVID-19 vaccine studies including pregnant women. Vaccination of pregnant women has been used globally to protect both women and their infants against influenza and as a mechanism to protect infants against pertussis. Several studies have demonstrated that maternal immunization is safe for both mother and infant and an important strategy to protect pregnant women and their infants against infectious diseases. Currently maternal immunization studies are being conducted as part of the development of novel RSV and GBS vaccines.[16,17]

BNT162b2 is a SARS-CoV-2–RNA-LNP vaccine based on a platform of modRNA with blunted innate immune sensor–activating capacity and augmented expression encoding the P2 S.

This study will describe the safety of BNT162b2 in pregnant women and their infants. It will also assess the immunogenicity of BNT162b2 in pregnant women, the transfer of antibody to their infants, and the kinetics of antibody transfer in the infant.

2.2.1. Clinical Overview

Prior to this study, clinical data from BNT162b2 established a favorable safety profile characterized by mild, localized, and transient effects. Study C4591001 (NCT04368728) is an ongoing Phase 1/2/3 trial in ~46,000 participants designed to generate safety, tolerability, immunogenicity, and efficacy data from a novel RNA-based vaccine candidate.[18] The trial is being conducted in a heterogeneous study population: eligible healthy participants ≥12 years of age, including those participants with stable chronic medical conditions, including HIV-, HCV-, and HBV-positive participants. The study consists of 2 parts: Phase 1: to identify the preferred vaccine candidate (BNT162b1 or BNT162b2) and dose level (10 µg, 20 µg, 30 µg, or 100 µg [for BNT162b1]); Phase 2/3: an expanded-cohort and efficacy part for the selected vaccine candidate (BNT162b2).

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The available immunogenicity data from Phase 1 participants show that BNT162b2 induced a robust IgG-binding response to S1 and a SARS-CoV-2–neutralizing response. Immunogenicity substantially increased following the second dose of vaccine. BNT162b2 induces a strong antigen-specific Th1-skewed CD4+ response and a strong antigen-specific CD8+ response. BNT162b2 was selected from the Phase 1 part of the study based on the overall safety, tolerability, and immunogenicity. In a mid-November 2020 analysis of 36,621 participants randomized 1:1 to vaccine or placebo, who were included in the per-protocol efficacy analysis population of participants without evidence of SARS-CoV-2 infection prior to 7 days after completion of the vaccination schedule, the efficacy in preventing confirmed COVID-19 occurring at least 7 days after the second dose of vaccine was 95.0%, with 8 COVID-19 cases in the active vaccine group and 162 COVID-19 cases in the placebo group. Subgroup analyses of the primary efficacy endpoint showed similar efficacy point estimates across age groups, sexes, racial and ethnic groups, and participants with medical comorbidities associated with high risk of severe COVID-19. Secondary efficacy analyses suggested benefit of the vaccine in preventing severe COVID-19, in preventing COVID-19 following the first dose, and in preventing COVID-19 in individuals with prior SARS-CoV-2 infection, although available data for these outcomes did not allow for firm conclusions.[19]

In a subsequent analysis of 927 confirmed symptomatic cases of COVID-19, an efficacy rate of 91.3% was observed for BNT162b2 in preventing such cases occurring between 7 days to 6 months after the second dose.[20] Furthermore, from the same analysis, BNT162b2 was shown to have an efficacy of:

- 100% in preventing severe disease as defined by the CDC.
- 95.3% in preventing severe disease as defined by the FDA.
- 100% in preventing COVID-19 cases in South Africa, where the B.1.351 lineage is prevalent.

Safety data from approximately 38,000 participants at least 16 years of age randomized 1:1 to vaccine or placebo with a median of 2 months of follow-up after the second dose demonstrated a favorable safety profile. Available safety data from all participants enrolled through the 14 November 2020 data cutoff (N = 43,252, which includes late enrollment of additional adolescent and adult participants) were consistent with the safety profile for the approximately 38,000 participants with a median follow-up of 2 months and also did not raise specific safety concerns.[19]

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The most common solicited adverse reactions were injection site reactions (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), and fever (14.2%); severe adverse reactions occurred in 0.0% to 4.6% of participants, were more frequent after Dose 2 than after Dose 1, and were generally less frequent in participants ≥55 years of age (≤2.8%) as compared to younger participants (≤4.6%). The frequency of SAEs was low (<0.5%), without meaningful imbalances between study arms. Lymphadenopathy was observed in 0.3% of vaccine recipients as compared to <0.1% of those who received placebo. Otherwise, there were no notable patterns or numerical imbalances between vaccine groups for specific categories of nonserious AEs (including other neurologic, neuroinflammatory, and thrombotic events) that would suggest a causal relationship to BNT162b2. With the exception of more frequent, generally mild to moderate reactogenicity in participants <55 years of age, the safety profile of BNT162b2 was generally similar across age groups, sexes, ethnic and racial groups, participants with or without medical comorbidities, and participants with or without evidence of prior SARS-CoV-2 infection at enrollment.[19]

Numerous COVID-19 vaccines are currently in development globally, and several candidate COVID-19 vaccines (eg, mRNA vaccines and adenovirus-vectored vaccines expressing the S protein) have been shown to be efficacious in the prevention of COVID-19 in clinical studies and are now available under temporary or emergency authorizations.[21] BNT162b2, an RNA-based COVID-19 vaccine given as a 2-dose series administered 21 days apart, was shown to be safe and effective in a Phase 1/2/3 study and has received authorizations for temporary or emergency use or marketing authorizations in multiple countries and has been fully licensed for use in individuals 16 years of age and above in the US as of 23 August 2021.[22,23]

On 22 September 2021, based on safety and immunogenicity data from approximately 300 immunocompetent adult booster-dose recipients from Study C4591001, the FDA issued the EUA for a single booster dose of BNT162b2 30 µg for 1) individuals 65 years of age and older; 2) individuals 18 through 64 years of age at high risk of severe COVID-19; and 3) individuals 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19, including severe COVID-19.[24] On 19 November 2021, the FDA amended the EUA, authorizing use of a single booster dose for all individuals 18 years of age and older after completion of primary vaccination with an FDA-approved COVID-19 vaccine.[25] On 09 December 2021, the FDA again amended the EUA to authorize the use of a single booster dose for administration to individuals 16 and 17 years of age at least 6 months after completion of primary vaccination with BNT162b2.[26] In addition, a booster dose of the vaccine is authorized in the EU and other countries, with recommendations for populations varying based on local health authority guidance.[27,28]

The currently available safety and immunogenicity data are presented in the BNT162 IB.

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2.3. Benefit/Risk Assessment

There is an ongoing global pandemic of COVID-19, however, numerous COVID-19 vaccines are currently in development globally, and several candidate COVID-19 vaccines (eg, mRNA vaccines and adenovirus-vectored vaccines expressing the S protein) have been shown to be efficacious in the prevention of COVID-19 in clinical studies and are now available under temporary or emergency authorizations or have licenses or conditional marketing authorizations. While there were no data available from clinical trials on the use of BNT162 vaccines in pregnant women, preliminary data are available from the ongoing Phase 1/2/3 clinical trial evaluating the use of BNT162b2 30-µg doses administered 21 days apart in nonpregnant adults.

In the C4591001 study, BNT162b2 has been shown to elicit increased local and systemic adverse reactions as compared to those in the placebo arm, usually lasting a few days. The most common solicited adverse reactions were injection site reactions (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), and fever (14.2%).[19] Adverse reactions characterized as reactogenicity were generally mild to moderate. The number of participants reporting hypersensitivity-related AEs was numerically higher in the vaccine group compared with the placebo group (137 [0.63%] vs 111 [0.51%]). Severe adverse reactions occurred in 0.0% to 4.6% of participants, were more frequent after Dose 2 than after Dose 1, and were generally less frequent in older adults (>55 years of age) (≤2.8%) as compared to younger participants (≤4.6%). Among reported unsolicited AEs, lymphadenopathy occurred much more frequently in the active vaccine group than the placebo group and is plausibly related to vaccination. SAEs, while uncommon (<1.0%), represented medical events that occur in the general population at similar frequency as observed in the study.[19]

No specific safety concerns were identified in subgroup analyses by age, race, ethnicity, medical comorbidities, or prior SARS-CoV-2 infection. The risks are based on the observed safety profile to date, which shows mostly mild reactogenicity, low incidence of severe or serious events, and no clinically concerning safety observations. The preponderance of severe cases of COVID-19 in the placebo group relative to the BNT162b2 group (9 of 10) suggests no evidence of VAED.[19]

In the latest analysis from C4591001, vaccine safety has been evaluated in more than 44,000 participants ≥16 years of age, with more than 12,000 vaccinated participants having at least 6 months follow-up after their second dose. No serious safety concerns have been observed in this timeframe. Side effects observed in this analysis were generally consistent with previously reported results.[20]

Continued clinical investigation is justified, given:

- the threat posed by the increasing number of globally distributed outbreaks of SARS-CoV-2 infection.

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- the potential of the BioNTech platform of RNA-based vaccines to deliver high numbers of vaccine doses rapidly in a single production campaign.

- the threat posed by the SARS-CoV-2 variants emerging worldwide.

- the potential need for enhancing immunoresponses to overcome waning immunity.

These data suggest a favorable risk/benefit profile in pregnant women. Anticipated AEs after vaccination in maternal participants are expected to be manageable using routine symptom-driven standard of care as determined by the investigators. As a result, the profile of these vaccine candidates supported initiation of this PASS clinical study. This interventional study is designated as a PASS, identified as Category 3 in the EU RMP, and is conducted as a conditional marketing approval commitment to the EMA and Swissmedic and an emergency use authorization commitment to the US FDA and numerous other health authorities under respective national emergency use legislation.

DART studies have been completed. In summary, administration of BNT162b2 to female rats twice before the start of mating and twice during gestation at the human clinical dose was associated with nonadverse effects (body weight, food consumption, and effects localized to the injection site) after each dose administration. However, there were no effects of BNT162b2 administration on mating performance, fertility, or any ovarian or uterine parameters in the female rats or on embryo-fetal or postnatal survival, growth, or development in the offspring. An immune response was confirmed in female rats following administration of each vaccine candidate and these responses were also detectable in the offspring (fetuses and pups). Additional details are included in the IB.

More detailed information about the known and expected benefits and risks and reasonably expected AEs of BNT162b2 may be found in the IB, which is the SRSD for this study.

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2.3.1. Risk Assessment

Potential Risk of Clinical Significance	Summary of Data/Rationale for Risk	Mitigation Strategy
Study Intervention: BNT162 RNA-Based COVID-19 Vaccine		
Potential for local reactions (injection site redness, injection site swelling, and injection site pain) and systemic events (fever, fatigue, headache, chills, vomiting, diarrhea, muscle pain, and joint pain) following vaccination.	These are common adverse reactions seen with other vaccines, as noted in the FDA CBER guidelines on toxicity grading scales for healthy adult volunteers enrolled in preventive vaccine clinical trials.[29]	• Phase 1 data from the C4591001 study demonstrated that the 30-µg dose had a tolerable reactogenicity profile.[30] • This study employs the use of a reactogenicity e-diary to monitor local reactions and systemic events in real time. • All participants will be observed for at least 30 minutes after vaccination. • In addition, the study will enroll a smaller subset of pregnant women in Phase 2 (N=200) and have a review of 7-day safety data by an IRC.
Unknown AEs with a novel vaccine.	There are limited data available because of the ongoing C4591001 study (Phase 1 completed, Phase 2/3 ongoing). To date, the safety and tolerability profile of BNT162b2 is consistent with what has been expected from nonclinical studies and clinical studies in other RNA-based compounds.[31,32]	• An IRC (in Phase 2) will review safety. Stopping rules will be in place for Phase 2, which may result in a pause to study vaccination followed by a review and recommendation by the IRC. • A DMC will be used throughout the study to review all safety data. • All participants will be observed for at least 30 minutes after vaccination. • AE and SAE reports will be collected from the signing of the ICD through 1 month after the second dose of vaccine.

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Potential Risk of Clinical Significance	Summary of Data/Rationale for Risk	Mitigation Strategy
		• In maternal participants who receive BNT162b2 1 month after delivery, AEs will be collected from the signing of the ICD to 1 month after Vaccination 4 (Visit 103) for those maternal participants who originally received placebo and go on to receive BNT162b2.
Potential for COVID-19 enhancement.	Disease enhancement has been seen following vaccination with RSV, feline coronavirus, and Dengue virus vaccines.	• Eligibility criteria will exclude any pregnant participants who have had a previous clinical (signs/symptoms only) or microbiological (signs/symptoms and positive SARS-CoV-2 NAAT result) diagnosis of COVID-19. • Monitoring for cases of COVID-19 developing during the study will be reported.
Potential for adverse obstetric and/or neonatal outcomes following vaccination.	There are no ongoing COVID-19 vaccine studies including pregnant women and, therefore, the potential for adverse obstetric and/or neonatal outcomes following vaccination while pregnant is unknown.	• Stopping rules for obstetric and neonatal AEs occurring after study vaccination and/or possibly deemed related to study vaccination in the Phase 2 portion of the trial. If a stopping rule is triggered, a pause of study vaccination will be put in place until there is a review of all relevant safety events and evaluation by the IRC.
Very rare cases of anaphylaxis, myocarditis, and pericarditis have been reported after authorization in recipients of BNT162b2.	Anaphylaxis: The estimated rate is 5.0 per million doses administered. Myocarditis and pericarditis: Very rare cases of myocarditis and pericarditis have been reported following vaccination with mRNA COVID-19 vaccines. Typically, the cases have occurred more often in younger men and after the second dose of the vaccine and within 14 days after vaccination. These are generally mild cases, and individuals tend to recover within a short time following standard treatment and rest.	• Specific reference to these risks is made within the ICD, with instruction to contact a healthcare professional if a case is suspected. • For anaphylaxis, there is an on-site 30-minute observation period after vaccination. • Instructions for handling suspected cases of myocarditis and pericarditis are found in Section 8.1.4.

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Potential Risk of Clinical Significance	Summary of Data/Rationale for Risk	Mitigation Strategy
	Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis in vaccine recipients.	
Study Procedures		
Participants will be required to attend healthcare facilities during the global SARS-CoV-2 pandemic.	Without appropriate social distancing and PPE, there is a potential for increased exposure to SARS-CoV-2.	• Pfizer will work with sites to ensure an appropriate COVID-19 prevention strategy. • Potential COVID-19 illness visits can be conducted via telehealth, without the need for an in-person visit, if required, with the maternal participant performing a self-swab or obtaining a swab from her infant.
Venipuncture will be performed during the study.	There is the risk of bleeding, bruising, hematoma formation, and infection at the venipuncture site.	• Only appropriately qualified personnel will obtain the blood draw.

2.3.2. Benefit Assessment

Benefits to individual maternal participants may include:

- Receipt of a potentially efficacious COVID-19 vaccine during a global pandemic.
- Access to COVID-19 diagnostic and antibody testing.
- Contributing to research to help others in a time of global pandemic.
- Potential antibody protection for infants born to mothers who were vaccinated with COVID-19 vaccine.

2.3.3. Overall Benefit/Risk Conclusion

Taking into account the measures taken to minimize risk to participants participating in this study, the potential risks identified in association with BNT162 RNA-based COVID-19 vaccine are justified by the anticipated benefits that may be afforded to healthy participants.

3. OBJECTIVES, ESTIMANDS, AND ENDPOINTS

Objectives[a]	Estimands	Endpoints
Primary Safety	**Primary Safety**	**Primary Safety**
To describe the safety and tolerability of prophylactic BNT162b2 when administered to maternal participants 18 years of age or older vaccinated at 24 to 34 weeks' gestation.	In maternal participants receiving at least 1 dose of study intervention from each vaccine group, the percentage of maternal participants reporting: • Local reactions for up to 7 days following each dose • Systemic events for up to 7 days following each dose • AEs from Dose 1 through 1 month after Dose 2 • SAEs from Dose 1 through 1 month after delivery	• Prompted local reactions (redness, swelling, and pain at the injection site) • Prompted systemic events (fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain) • AEs • SAEs

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Objectives[a]	Estimands	Endpoints
Primary Immunogenicity	**Primary Immunogenicity**	**Primary Immunogenicity**
To describe the immune response to prophylactic BNT162b2 in maternal participants 18 years of age or older vaccinated at 24 to 34 weeks' gestation and reference to the immune response in nonpregnant women 18 years of age or older from the C4591001 study without evidence of past SARS-CoV-2 infection.	In female participants complying with the key protocol criteria (evaluable participants) and no serological or virological evidence (up to 1 month after receipt of the second dose) of past SARS-CoV-2 infection: • GMR, estimated by the ratio of the geometric mean of SARS-CoV-2 neutralizing titers in pregnant women to those in nonpregnant women 1 month after Dose 2	• SARS-CoV-2 neutralizing titers
To describe the immune response to prophylactic BNT162b2 in maternal participants 18 years of age or older vaccinated at 24 to 34 weeks' gestation and reference to the immune response in nonpregnant women 18 years of age or older from the C4591001 study with and without evidence of prior SARS-CoV-2 infection.	In female participants complying with the key protocol criteria (evaluable participants): • GMR, estimated by the ratio of the geometric mean of SARS-CoV-2 neutralizing titers in pregnant women to those in nonpregnant female participants 1 month after Dose 2	• SARS-CoV-2 neutralizing titers
Secondary	**Secondary**	**Secondary**
To describe the efficacy of prophylactic BNT162b2 against confirmed COVID-19 occurring from 7 days after Dose 2 through 1 month after delivery in maternal participants 18 years of age or older vaccinated at 24 to 34 weeks' gestation without evidence of prior SARS-CoV-2 infection.	In maternal participants complying with the key protocol criteria (evaluable participants) and no serological or virological evidence (prior to 7 days after receipt of Dose 2) of past SARS-CoV-2 infection: • 100 × (1 – IRR) [ratio of active vaccine to placebo]	• COVID-19 incidence per 1000 person-years of blinded follow-up based on central laboratory or locally confirmed NAAT
To describe the efficacy of prophylactic BNT162b2 against confirmed COVID-19 occurring from 7 days after Dose 2 through 1 month after delivery in maternal participants 18 years of age or older vaccinated at 24 to 34 weeks' gestation with and without evidence of prior SARS-CoV-2 infection.	In maternal participants complying with the key protocol criteria (evaluable participants): • 100 × (1 – IRR) [ratio of active vaccine to placebo]	• COVID-19 incidence per 1000 person-years of blinded follow-up based on central laboratory or locally confirmed NAAT

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Objectives[a]	Estimands	Endpoints
To describe the efficacy of prophylactic BNT162b2 against asymptomatic SARS-CoV-2 infection through 1 month after delivery in maternal participants 18 years of age or older vaccinated at 24 to 34 weeks' gestation without evidence of prior SARS-CoV-2 infection.	In evaluable maternal participants without serological or virological evidence of prior SARS-CoV-2 infection: • 100 × (1 – IRR) [ratio of active vaccine to placebo]	• Incidence of asymptomatic infection of SARS-CoV-2 based on N-binding antibody seroconversion
To describe the immune response over time and persistence of prophylactic BNT162b2 when administered to maternal participants 18 years of age or older vaccinated at 24 to 34 weeks' gestation.	In maternal participants complying with the key protocol criteria (evaluable maternal participants) from each vaccine group: • GMCs/GMTs, at baseline (before Dose 1), 2 weeks after Dose 2, 1 month after Dose 2, at delivery, and 6 months after delivery • GMFRs from baseline through 2 weeks after Dose 2, 1 month after Dose 2, at delivery, and 6 months after delivery	• Full-length S-binding IgG levels • SARS-CoV-2 neutralizing titers
To assess the safety of maternal immunization in infants born to maternal participants 18 years of age or older who were vaccinated with BNT162b2 during pregnancy.	In infants born to maternal participants receiving at least 1 dose of study intervention from each vaccine group, the percentage of infants with: • Specific birth outcomes • AEs from birth through 1 month of age • SAEs and AESIs (major congenital anomalies, developmental delay) through 6 months of age	• Specific birth outcomes • AEs from birth through 1 month of age • SAEs and AESIs (major congenital anomalies, developmental delay) through 6 months of age
To describe the immune response in infants born to maternal participants vaccinated with prophylactic BNT162b2 during pregnancy.	In infants born to evaluable maternal participants from each vaccine group: • GMCs and GMFRs, at birth and 6 months after delivery	• Full-length S-binding IgG levels

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Objectives[a]	Estimands	Endpoints
Exploratory	**Exploratory**	**Exploratory**
To describe the incidence of confirmed COVID-19 among maternal participants who were vaccinated with BNT162b2.	In maternal participants who received BNT162b2 at initial randomization: • Incidence per 1000 person-years of follow-up	• COVID-19 incidence per 1000 person-years of follow-up based on central laboratory or locally confirmed NAAT
To describe the incidence of asymptomatic SARS-CoV-2 infection through 6 months after delivery in maternal participants 18 years of age or older vaccinated at 24 to 34 weeks' gestation with BNT162b2 at initial randomization and without evidence of prior SARS-CoV-2 infection.	In maternal participants who received BNT162b2 at initial randomization and without evidence of prior SARS-CoV-2 infection: • Incidence per 1000 person-years of follow-up	• Incidence of asymptomatic SARS-CoV-2 infection per 1000 person-years of follow-up based on N-binding antibody seroconversion
To describe the serological responses among maternal participants to the BNT162b2 vaccine candidate in cases of: • Confirmed COVID-19 • Confirmed severe COVID-19 • SARS-CoV-2 infection without confirmed COVID-19	In each subset of evaluable maternal participants from each vaccine group with: • Confirmed COVID-19 • Confirmed severe COVID-19 • SARS-CoV-2 infection but no confirmed COVID-19 • GMCs/GMTs and GMFRs at baseline, 1 month after Dose 2, at delivery, and 6 months after delivery	• Full-length S-binding IgG levels • SARS-CoV-2 neutralizing titers
To describe the immune response to prophylactic BNT162b2 between Dose 1 and Dose 2 when administered to maternal participants 18 years of age or older vaccinated at 27 to 34 weeks' gestation in the Phase 2 portion of the study.	In evaluable maternal participants: • GMCs/GMTs at baseline and before Dose 2 • GMFRs from baseline to before Dose 2	• Full-length S-binding IgG levels • SARS-CoV-2 neutralizing titers
To describe the immune response in infants born to breastfeeding maternal participants vaccinated with prophylactic BNT162b2 during pregnancy.	In infants born to maternal participants from each vaccine group, based on the breastfeeding status: • GMCs and GMFRs, at birth and 6 months after delivery	• Full-length S-binding IgG levels

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Objectives[a]	Estimands	Endpoints
To describe the safety of maternal immunization in infants born to breastfeeding maternal participants vaccinated with prophylactic BNT162b2 during pregnancy.	In infants born to maternal participants receiving at least 1 dose of study intervention from each vaccine group, based on the breastfeeding status, the percentage of infants with: • AEs from birth through 1 month of age • SAEs and AESIs (major congenital anomalies, developmental delay) through 6 months of age	• AEs from birth through 1 month of age • SAEs and AESIs (major congenital anomalies, developmental delay) through 6 months of age
To describe the incidence of confirmed COVID-19 in infants born to maternal participants who were vaccinated with BNT162b2 during pregnancy.	In infants born to maternal participants from each vaccine group: • Incidence rate of infant participants with confirmed COVID-19	• COVID-19 incidence per 1000 person-years of follow-up based on central laboratory or locally confirmed NAAT
To describe MIS-C cases in infants born to maternal participants who were vaccinated with BNT162b2 during pregnancy.	In infants born to maternal participants from each vaccine group: • Incidence rate of MIS-C	• MIS-C incidence per 1000 person-years of follow-up

a. HIV-infected participants will not be included in analyses of the objectives, but in separate exploratory analyses. Analyses among HIV-infected women and their infants will be summarized separately.

4. STUDY DESIGN

4.1. Overall Design

This will be a global Phase 2/3, randomized, placebo-controlled, observer-blind study in approximately 350 healthy pregnant women 18 years of age or older vaccinated during their 24 to 34 weeks' gestation. This study will evaluate the safety, tolerability, and immunogenicity of 2 doses of BNT162b2 or placebo administered 21 days apart. The Phase 2 portion of the study will include approximately 200 pregnant women randomized 1:1 to receive BNT162b2 or placebo (saline) during their 27 to 34 weeks' gestation. Safety data through 7 days after the second dose (where Day 1 is the day of vaccination) for all Phase 2 participants will be reviewed by the Pfizer IRC. The Phase 3 portion of this study will assess the safety, tolerability, and immunogenicity of BNT162b2 in approximately 150 pregnant women enrolled during their 24 to 34 weeks' gestation who will be randomized in a 1:1 ratio to receive BNT162b2 or placebo (saline). Phase 3 will proceed after the first 200 maternal participants have been enrolled in Phase 2. Maternal participants who originally received placebo will receive BNT162b2 at defined time points as part of the study.

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Enrollment in this study was terminated on 25 Oct 2021 with approximately 350 participants enrolled. Enrollment was terminated due to enrollment challenges into a placebo-controlled study as a result of universal recommendations for COVID-19 vaccination of pregnant women and the increased global availability of COVID-19 vaccines. Enrollment numbers within this protocol have been modified accordingly.

The study is observer-blinded, as the physical appearance of the investigational vaccine and the placebo may differ. The participant, investigator, study coordinator, and other site staff will be blinded through the 1-month postdelivery visit for each maternal participant. At the study site, only the dispenser(s)/administrator(s) are unblinded.

Each maternal participant will participate in the study for approximately up to 10 months depending on the vaccine group to which she was randomized. Her infant will participate in the study for approximately 6 months. The study duration will be approximately 14 months.

For each placebo recipient who will go on to receive BNT162b2 and follow a new visit schedule (Section 1.3.2), she will participate in the study for up to 7 months, and her infant will participate in the study for approximately 6 months.

The study will use an external DMC throughout study conduct. A Pfizer IRC will be used during the Phase 2 portion of the study to closely monitor safety.

The study will include stopping rules, which may result in a pause to study vaccination followed by a review and recommendation by the IRC.

4.2. Scientific Rationale for Study Design

There are currently no licensed vaccines to prevent infection with SARS-CoV-2 or COVID-19. Pregnant women are at risk of acquiring SARS-CoV-2 infection, developing COVID-19 and COVID-19–associated complications. Given the global crisis of COVID-19 and fast expansion of the disease globally, the rapid development of an effective vaccine for use in this population is of utmost importance.

This study is being conducted as a standard maternal immunization safety and immunogenicity clinical trial; however, additional surveillance for COVID-19 has been included as part of the study to assess efficacy (based on a minimal number of cases) as well as to monitor the potential risk of disease enhancement and severe disease in pregnant women and their infants with COVID-19. If a participant experiences symptoms, as detailed in Section 8.13, a COVID-19 illness and subsequent convalescent visit will occur. As part of these visits, samples (nasal swab and blood) will be taken for antigen and antibody assessment as well as recording of COVID-19–related clinical and laboratory information (including local diagnosis).

4.3. Justification for Dose

Based on data from the Phase 1 component of clinical trial C4591001, the BNT162b2 vaccine candidate was selected at a dose of 30 µg for Phase 2/3 evaluation in C4591001.

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4.4. End of Study Definition

A participant and her infant are considered to have completed the study if they have completed all phases of the study, including the last visit.

The end of the study is defined as the date of the last visit of the last participant in the study.

5. STUDY POPULATION

This study can fulfill its objectives only if appropriate participants are enrolled, including participants across diverse and representative racial and ethnic backgrounds. Use of a prescreener for study recruitment purposes will include collection of information that reflects the enrollment of a diverse participant population including, where permitted under local regulations, age, sex, race, and ethnicity. The following eligibility criteria are designed to select participants for whom participation in the study is considered appropriate. All relevant medical and nonmedical conditions should be taken into consideration when deciding whether a particular participant is suitable for this protocol.

Prospective approval of protocol deviations to recruitment and enrollment criteria, also known as protocol waivers or exemptions, is not permitted.

5.1. Inclusion Criteria

Participants are eligible to be included in the study only if all of the following criteria apply.

NOTE: In countries/locales where certain prenatal assessments are not routinely performed, prerandomization assessments and test results to confirm maternal participant eligibility for this clinical trial can be obtained and reviewed by the investigator or qualified designee up to 28 days prior to vaccination.

Maternal participants must provide informed consent prior to performing any procedures, including those that are being done exclusively to meet study eligibility criteria.

5.1.1. Maternal Participants

Age and Sex:

1. Healthy women ≥18 years of age who are between 24 0/7 and 34 0/7 weeks' gestation on the day of planned first vaccination, with an uncomplicated, singleton pregnancy, who are at no known increased risk for complications.

    a. **Phase 2** participants will include healthy women ≥18 years of age who are between **27 0/7 and 34 0/7** weeks' gestation on the day of planned vaccination, with an uncomplicated, singleton pregnancy, who are at no known increased risk for complications.

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GA will be documented based on one of the following composite criteria based on timing and availability of data on the LMP, ultrasound examination, and physical examination, for natural pregnancies. Please refer to the SRM for GA dating among women who underwent assisted reproduction technology. The earliest ultrasound data available during the current pregnancy should be used to establish GA:

a. **First-Trimester Data Available** (data obtained at ≤13 6/7 weeks):

- The date of the first day of the reported LMP may be used to establish the GA if corroborated by a first-trimester ultrasound.
- If there is a discrepancy of >7 days between the LMP-determined GA and a first-trimester ultrasound OR the LMP is uncertain/unknown, then the GA should be determined using the first-trimester ultrasound.

b. **Second-Trimester Data Available (data obtained at 14 0/7 to 27 6/7 weeks):**

- The date of the first day of the reported LMP may be used to establish the GA if corroborated by a second-trimester ultrasound or a physical examination including fundal height.
- If there is a discrepancy of >10 days between the LMP-determined GA and the second-trimester ultrasound OR if the LMP is uncertain/unknown, then the GA should be determined using the second-trimester ultrasound.

c. **Third-Trimester Data Available (data obtained at ≥28 weeks):**

- The date of the first day of the reported LMP may be used to establish the GA if corroborated by a third-trimester ultrasound or a physical examination including fundal height.
- If there is a discrepancy of >21 days between the LMP-determined GA and the third-trimester ultrasound OR if the LMP is uncertain/unknown, then the GA should be determined using the third-trimester ultrasound.

Type of Participant and Disease Characteristics:

2. Participants who are willing and able to comply with scheduled visits, treatment plan, laboratory tests, and other study procedures.

3. Receiving prenatal standard of care based on country requirements.

4. Had an ultrasound examination performed at ≥18 weeks of pregnancy with no significant fetal abnormalities observed, based on the investigator's judgment.

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5. Healthy participants who are determined by medical history, physical examination, and clinical judgment to be appropriate for inclusion in the study. Note: Participants with preexisting stable disease, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 6 weeks before enrollment, can be included. Specific criteria for Phase 3 participants with known stable infection with HIV, HCV, or HBV can be found in Section 10.4.

6. Documented negative HIV antibody test (Phase 2 only), syphilis test, and HBV surface antigen test during this pregnancy and prior to randomization (Visit 1).

7. Intention to deliver at a hospital or birthing facility where study procedures can be conducted.

8. Expected to be available for the duration of the study and can be contacted by telephone during study participation. Country-specific modification for Mozambique: Participants are expected to be available for the duration of the study and to reside in the Manhiça study area.

9. Participant is willing to give informed consent for her infant to participate in the study.

Weight:

10. Prepregnancy BMI of ≤40 kg/m^2. If prepregnancy BMI is not available, the BMI at the time of the first obstetric visit during the current pregnancy may be used.

Informed Consent:

11. Capable of giving signed informed consent as described in Appendix 1, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol.

5.1.2. Infant Participants

1. Evidence of a signed and dated ICD signed by the parent(s).

    - The maternal participant must sign an ICD for herself and her fetus/infant before taking part in the study. The father of the fetus/infant must sign an ICD if required by local requirements.

2. Parent(s) willing and able to comply with scheduled visits, treatment plan, laboratory tests, and other study procedures.

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5.2. Exclusion Criteria

Participants are excluded from the study if any of the following criteria apply:

5.2.1. Maternal Participants

Medical Conditions:

1. Other medical or psychiatric condition including recent (within the past year) or active suicidal ideation/behavior or laboratory abnormality that may increase the risk of study participation or, in the investigator's judgment, make the participant inappropriate for the study.

2. Previous clinical (based on COVID-19 symptoms/signs alone, if a SARS-CoV-2 NAAT result was not available) or microbiological (based on COVID-19 symptoms/signs and a positive SARS-CoV-2 NAAT result) diagnosis of COVID-19.

3. History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention or any related vaccine.

4. Participants with known or suspected immunodeficiency.

5. Bleeding diathesis or condition associated with prolonged bleeding that would in the opinion of the investigator contraindicate intramuscular injection.

6. **Phase 2 only: A prior or current** major illness of the mother or conditions of the fetus that, in the investigator's judgment, will substantially increase the risk associated with the participant's participation in, and completion of, the study or could preclude the evaluation of the participant's response, including but not limited to the following:

    - Gestational hypertension or preeclampsia-eclampsia
    - Placental abnormality
    - Polyhydramnios or oligohydramnios
    - Significant bleeding or blood clotting disorder
    - Gestational diabetes
    - Any signs of premature labor with the current pregnancy or having ongoing intervention (medical/surgical) in the current pregnancy to prevent preterm birth
    - Prior stillbirth or neonatal death, prior low birth weight or preterm delivery, prior history of at least 3 miscarriages, prior pregnancies numbering greater than 5, or previous infant with a known genetic disorder or major congenital anomaly

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7. **For Phase 2 only**: Maternal participants with a history of stable chronic diseases that are known to be associated with increased risk of obstetrical or neonatal complications (as defined above in exclusion criterion 6) should not be included.

8. **Phase 3: Current** major illness of the mother or conditions of the fetus that, in the investigator's judgment, will substantially increase the risk associated with the participant's participation in, and completion of, the study or could preclude the evaluation of the participant's response, including but not limited to the following:

    - Uncontrolled gestational hypertension
    - Preeclampsia-eclampsia
    - Placental abnormality
    - Polyhydramnios or oligohydramnios
    - Significant bleeding or blood clotting disorder
    - Uncontrolled gestational diabetes
    - Any signs of premature labor with the current pregnancy or having ongoing intervention (medical/surgical) in the current pregnancy to prevent preterm birth
    - Prior stillbirth or neonatal death, preterm delivery (≤34 weeks), or previous infant with a known genetic disorder or major congenital anomaly.

Prior/Concomitant Therapy:

9. Previous vaccination with any coronavirus vaccine.

10. Receipt of medications intended to prevent COVID-19.

11. Receipt of blood/plasma products or immunoglobulin, from 60 days before administration of study intervention, or planned receipt through delivery, with 1 exception, anti-D immunoglobulin (eg, RhoGAM), which can be given at any time.

12. Current alcohol abuse or illicit drug use.

13. Participants who receive treatment with immunosuppressive therapy, including cytotoxic agents or systemic corticosteroids, eg, for cancer or an autoimmune disease, or planned receipt through the postvaccination blood draw.

Prior/Concurrent Clinical Study Experience:

14. Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation.

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15. Previous participation in other studies involving study intervention containing LNPs.

Diagnostic Assessments:

16. Not applicable.

Other Exclusions:

17. Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members.

18. Participants whose unborn baby has been fathered by investigational site staff members directly involved in the conduct of the study or their family members, site staff members otherwise supervised by the investigator, or Pfizer employees directly involved in the conduct of the study.

5.2.2. Infant Participants

1. Infant who is a direct descendant (eg, child or grandchild) of the study personnel.

5.3. Lifestyle Considerations

No restrictions required.

5.4. Screen Failures

Screen failures are defined as maternal participants who consent to participate in the clinical study but are not subsequently randomly assigned to study intervention. A minimal set of screen failure information is required to ensure transparent reporting of screen failure participants to meet the CONSORT publishing requirements and to respond to queries from regulatory authorities. Minimal information includes demography, screen failure details, eligibility criteria, and any SAE.

Maternal participants who do not meet the criteria for participation in this study (screen failure) may be rescreened.

5.5. Criteria for Temporarily Delaying Randomization/Study Intervention Administration

The following conditions are temporary or self-limiting and a maternal participant may be vaccinated once the condition(s) has/have resolved and no other exclusion criteria are met.

1. Current febrile illness (temperature 38.0°C [100.4°F]) or other acute illness within 48 hours before study intervention administration. This includes current symptoms that could represent a potential COVID-19 illness:

    - New or increased cough;

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- New or increased shortness of breath;
- Chills;
- New or increased muscle pain;
- New loss of taste/smell;
- Sore throat;
- Diarrhea;
- Vomiting.

2. Receipt of any seasonal or pandemic influenza vaccine in the previous 14 days.
3. Anticipated receipt of any seasonal or pandemic influenza vaccine in the 7 days after study intervention administration.
4. Receipt of a tetanus-, diphtheria-, and/or pertussis-containing vaccine in the previous 14 days.
5. Anticipated receipt of a tetanus-, diphtheria-, and/or pertussis-containing vaccine in the 7 days after study intervention administration.
6. Receipt of short-term (<14 days) systemic corticosteroids. Study intervention administration should be delayed until systemic corticosteroid use has been discontinued for at least 28 days. Inhaled/nebulized, intra-articular, intrabursal, or topical (skin or eyes) corticosteroids are permitted.

6. STUDY INTERVENTION

Study intervention is defined as any investigational intervention(s), marketed product(s), placebo, medical device(s), or study procedure(s) intended to be administered to a study participant according to the study protocol.

The study will evaluate 2 doses of BNT162b2 or placebo administered 21 days apart for active immunization against COVID-19 in healthy pregnant women 18 years of age or older vaccinated during their 24 to 34 weeks' gestation. The Phase 2 portion of the study will include a subset (N=200) of pregnant women during their 27 to 34 weeks' gestation.

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The investigational RNA vaccine candidate or saline placebo are the 2 potential study interventions that may be administered to pregnant maternal participants (randomized 1:1):

- BNT162b2 (BNT162 RNA-LNP vaccine utilizing modRNA and encoding the P2 S): 30 µg
- Normal saline (0.9% NaCl solution for injection)

6.1. Study Intervention(s) Administered

Intervention Name	BNT162b2 (BNT162 RNA-LNP Vaccine Utilizing modRNA)	Saline Placebo
Type	Vaccine	Placebo
Dose Formulation	modRNA	Normal saline (0.9% NaCl solution for injection)
Unit Dose Strength(s)	250 µg/0.5 mL	N/A
Dosage Level(s)	30-µg	N/A
Route of Administration	Intramuscular injection	Intramuscular injection
Use	Experimental	Placebo
IMP or NIMP	IMP	IMP
Sourcing	Provided centrally by the sponsor	Provided centrally by the sponsor
Packaging and Labeling	Study intervention will be provided in a glass vial as open-label supply. Each vial will be labeled as required per country requirement.	Study intervention will be provided in a glass or plastic vial as open-label supply. Each vial will be labeled as required per country requirement.

6.1.1. Administration

Maternal participants will receive 1 dose of study intervention as randomized at each vaccination visit (Visits 1 and 2) in accordance with the study's SoA (Section 1.3.1). Full details are described in the IP manual.

At 1 month after delivery, maternal participants who originally received placebo will receive 1 dose of BNT162b2 at each additional vaccination visit (Visits 101 and 102) in accordance with the SoA in Section 1.3.2.

Study intervention should be administered intramuscularly into the deltoid muscle, preferably of the nondominant arm, by an unblinded administrator.

Standard vaccination practices must be observed and vaccine must not be injected into blood vessels. Appropriate medication and other supportive measures for management of an acute hypersensitivity reaction should be available in accordance with local guidelines for standard immunization practices.

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Administration of study interventions should be performed by an appropriately qualified, GCP-trained, and vaccine-experienced member of the study staff (eg, physician, nurse, physician's assistant, nurse practitioner, pharmacist, or medical assistant) as allowed by local, state, and institutional guidance.

Study intervention administration details will be recorded on the CRF.

6.2. Preparation/Handling/Storage/Accountability

1. The investigator or designee must confirm that appropriate temperature conditions have been maintained during transit for all study interventions received and any discrepancies are reported and resolved before use of the study intervention.

2. Only maternal participants enrolled in the study may receive study intervention and only authorized site staff may supply or administer study intervention. All study interventions must be stored in a secure, environmentally controlled, and monitored (manual or automated recording) area in accordance with the labeled storage conditions with access limited to the investigator and authorized site staff. At a minimum, daily minimum and maximum temperatures for all site storage locations must be documented and available upon request. Data for nonworking days must indicate the minimum and maximum temperatures since previously documented for all site storage locations upon return to business.

3. Any excursions from the study intervention label storage conditions should be reported to Pfizer upon discovery along with any actions taken. The site should actively pursue options for returning the study intervention to the storage conditions described in the labeling, as soon as possible. Once an excursion is identified, the study intervention must be quarantined and not used until Pfizer provides permission to use the study intervention. Specific details regarding the definition of an excursion and information the site should report for each excursion will be provided to the site in the IP manual.

4. Any storage conditions stated in the SRSD will be superseded by the storage conditions stated on the label.

5. Study interventions should be stored in their original containers.

6. See the IP manual for storage conditions of the study intervention.

7. The investigator, institution, or the head of the medical institution (where applicable) is responsible for study intervention accountability, reconciliation, and record maintenance (ie, receipt, reconciliation, and final disposition records), such as the IPAL or sponsor-approved equivalent. All study interventions will be accounted for using a study intervention accountability form/record.

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8. Further guidance and information for the final disposition of unused study interventions are provided in the IP manual. All destruction must be adequately documented. If destruction is authorized to take place at the investigator site, the investigator must ensure that the materials are destroyed in compliance with applicable environmental regulations, institutional policy, and any special instructions provided by Pfizer.

Upon identification of a product complaint, notify the sponsor within 1 business day of discovery as described in the IP manual.

6.2.1. Preparation and Dispensing

See the IP manual for instructions on how to prepare the study intervention for administration. Study intervention should be prepared and dispensed by an appropriately qualified and experienced member of the study staff (eg, physician, nurse, physician's assistant, nurse practitioner, pharmacy assistant/technician, or pharmacist) as allowed by local, state, and institutional guidance. A second staff member will verify the dispensing.

Study intervention and placebo will be prepared by qualified unblinded site personnel according to the IP manual. The study intervention will be administered in such a way as to ensure that the maternal participants remain blinded.

6.3. Measures to Minimize Bias: Randomization and Blinding

6.3.1. Allocation to Study Intervention

Maternal participants will be allocated (randomized) to a vaccine group as described below. The infants of the maternal participants will be assigned a participant number at birth.

Allocation of maternal participants to vaccine groups will proceed through the use of an IRT system (IWR). The site personnel (study coordinator or specified designee) will be required to enter or select information including but not limited to the user's ID and password, the protocol number, and the maternal participant number. The site personnel will then be provided with a vaccine assignment, randomization number, and DU or container number when study intervention is being supplied via the IRT system. The IRT system will provide a confirmation report containing the maternal participant number, randomization number, and DU or container number assigned. The confirmation report must be stored in the site's files.

Study intervention will be dispensed at the study visits summarized in the SoA.

The study-specific IRT reference manual and IP manual will provide the contact information and further details on the use of the IRT system.

Maternal participants will be assigned to receive study intervention according to randomization scheme. Investigators will remain blinded to each maternal participant's assigned study intervention until 1 month after delivery.

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6.3.2. Blinding of Site Personnel Until the 1-Month Postdelivery Visit

In this observer-blinded study, the study staff receiving, storing, dispensing, preparing, and administering the study interventions will be unblinded. All other study and site personnel, including the investigator, investigator staff, and maternal participants, will be blinded to study intervention assignments. In particular, the individuals who evaluate maternal participant safety will be blinded. Because the BNT162 RNA-based COVID-19 vaccine candidate and placebo are different in physical appearance, the study intervention syringes will be administered in a manner that prevents the maternal study participants from identifying the study intervention type based on its appearance.

The responsibility of the unblinded dispenser and administrator must be assigned to an individual or individuals who will not participate in the evaluation of any maternal study participants. Contact between the unblinded dispenser and maternal study participants and unblinded administrator and maternal study participants should be kept to a minimum. The remaining site personnel must not know study intervention assignments.

In the event of a Quality Assurance audit, the auditor(s) will be allowed access to unblinded study intervention records at the site(s) to verify that randomization/dispensing has been done accurately.

To allow administration of BNT162b2 to maternal participants who originally received placebo, site staff will be unblinded to individual participants' original study intervention allocation at the 1-month postdelivery visit.

6.3.3. Blinding of Site Personnel Prior to the 1-Month Postdelivery Visit

To allow administration of BNT162b2 to maternal participants who originally received placebo, site staff will be unblinded to individual participants' original study intervention allocation at the 1-month postdelivery visit. Prior to unblinding maternal participants at the 1-month postdelivery visit, this is an observer-blinded study. The study staff receiving, storing, dispensing, preparing, and administering the study interventions will be unblinded. All other study and site personnel, including the investigator, investigator staff, and maternal participants, will be blinded to study intervention assignments until the 1-month postdelivery visit for each participant. In particular, the individuals who evaluate maternal participant safety prior to unblinding maternal participants at the 1-month postdelivery visit will be blinded.

Because the BNT162 RNA-based COVID-19 vaccine candidate and placebo are different in physical appearance, the study intervention syringes will be administered in a manner that prevents the maternal study participants from identifying the study intervention type based on its appearance during the blinded portion of the study.

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The responsibility of the unblinded dispenser and administrator must be assigned to an individual or individuals who will not participate in the evaluation of any maternal study participants prior to the maternal participant being unblinded. Contact between the unblinded dispenser and blinded maternal study participants and unblinded administrator and blinded maternal study participants should be kept to a minimum. The remaining site personnel must not know study intervention assignments until the maternal participant is unblinded at the 1-month postdelivery visit.

In the event of a Quality Assurance audit, the auditor(s) will be allowed access to unblinded study intervention records at the site(s) to verify that randomization/dispensing has been done accurately.

6.3.4. Blinding of the Sponsor

The study team will be unblinded to the participant's study intervention allocation when maternal participants complete the 1-month postdelivery visit. Prior to unblinding the maternal participants at the 1-month postdelivery visit the majority of sponsor staff will be blinded to study intervention allocation. All laboratory testing personnel performing serology assays will remain blinded to study intervention assigned/received. The following sponsor staff, who will have no part in the blinded conduct of the study, will be unblinded (further details will be provided in a data blinding plan):

- Those study team members who are involved in ensuring that protocol requirements for study intervention preparation, handling, allocation, and administration are fulfilled at the site will be unblinded for the duration of the study (eg, unblinded study manager, unblinded clinical research associate).

- Unblinded clinician(s) who are not direct members of the study team and will not participate in any other study-related activities will review unblinded protocol deviations.

- An unblinded team supporting interactions with, and analyses for, the DMC (see Section 9.6). This will comprise a statistician, programmer(s), and a medical monitor and/or a clinical scientist who will review cases of severe COVID-19 as they are received, and will review AEs at least weekly for additional potential cases of severe COVID-19 (see Section 8.2.4).

- An unblinded submissions team will be responsible for preparing unblinded analyses and documents to support regulatory activities that may be required while the study is ongoing. This team will only be unblinded at the group level and not have access to individual participant assignments. The programs that produce the summary tables will be developed and validated by the blinded study team, and these programs will be run by the unblinded DMC team.

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6.3.5. Breaking the Blind

The IRT will be programmed with blind-breaking instructions. In case of an emergency, the investigator has the sole responsibility for determining if unblinding of a maternal participant's vaccine assignment is warranted. Participant safety must always be the first consideration in making such a determination. If the investigator decides that unblinding is warranted, the investigator should make every effort to contact the sponsor prior to unblinding a maternal participant's vaccine assignment unless this could delay further management of the participant.

If a maternal participant's vaccine assignment is unblinded, the sponsor must be notified within 24 hours after breaking the blind. The date and reason that the blind was broken must be recorded in the source documentation and CRF.

The study-specific IRT reference manual and IP manual will provide the contact information and further details on the use of the IRT system.

Instructions on how to unblind participants ahead of administration of BNT162b2 to placebo recipients will be provided separately: this unblinding will NOT be performed in the IRT.

6.4. Study Intervention Compliance

When maternal participants are dosed at the site, they will receive study intervention directly from the investigator or designee, under medical supervision. The date and time of each dose administered in the clinic will be recorded in the source documents and recorded in the CRF. The dose of study intervention and maternal study participant identification will be confirmed at the time of dosing by a member of the study site staff other than the person administering the study intervention.

6.5. Concomitant Therapy

6.5.1. Prohibited During the Study – Maternal Participants

Receipt of the following vaccines and medications during the time periods listed below may exclude a maternal participant from the per-protocol analysis from that point onwards, and may require vaccinations to be discontinued in that participant; however, it is anticipated that the maternal participant would not be withdrawn from the study (see Section 7). Medications should not be withheld if required for a maternal participant's medical care.

- Unless considered medically necessary, no vaccines other than study intervention should be administered within 14 days before and 7 days after each study vaccination, including seasonal and pandemic influenza vaccines.

- Receipt of chronic systemic treatment with known immunosuppressant medications within 60 days before enrollment through conclusion of the study.

- Receipt of systemic corticosteroids (≥20 mg/day of prednisone or equivalent) for ≥14 days is prohibited from 28 days prior to enrollment through Visit 3.

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- Receipt of blood/plasma products or immunoglobulins within 60 days before enrollment through conclusion of the study.

- Receipt of any other (nonstudy) coronavirus vaccine at any time prior to or during study participation is prohibited.

- Prophylactic antipyretics and other pain medication to prevent symptoms associated with study intervention administration are not permitted. However, if a maternal participant is taking a medication for another condition, even if it may have antipyretic or pain-relieving properties, it should not be withheld prior to study vaccination.

6.5.2. Permitted During the Study – Maternal Participants

- The use of antipyretics and other pain medication to treat symptoms associated with study intervention administration or ongoing conditions is permitted.

- Medication other than that described as prohibited in Section 6.5.1 required for treatment of preexisting stable conditions is permitted.

- Inhaled, topical, or localized injections of corticosteroids (eg, intra-articular or intrabursal administration) are permitted.

6.5.3. Recording Nonstudy Vaccinations and Concomitant Medications – Maternal Participants

The following concomitant medications and vaccinations will be recorded in the CRF:

- All vaccinations received from 14 days prior to study enrollment until the 6-month follow-up visit for participants originally randomized to receive BNT162b2.

- Any medication taken to treat AEs from the signing of the ICD through the final study visit be recorded in the CRF.

- Prohibited medications listed in Section 6.5.1 will be recorded in the CRF, to include start and stop dates, name of the medication, dose, unit, route, and frequency from the signing of the ICD through the final study visit.

6.5.4. Prohibited During the Study – Infant Participants

- Investigational vaccines, drugs, or medical devices are prohibited during the course of the study.

6.5.5. Permitted During the Study – Infant Participants

- ONLY routine treatments, routine vaccinations, and routine procedures (eg, circumcision) are permitted at any time during the study, in accordance with national recommendations, medical standard of care, or accepted practice.

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- Prescription and nonprescription medications, vitamins, minerals, and herbal remedies are permitted during infant participant participation in the study.

- Local anesthetic may be applied to the site of the blood draw, as appropriate.

6.5.6. Recording Concomitant Medications – Infant Participants

The following concomitant medications will be recorded in the CRF:

- Any medications taken to treat AEs and/or SAEs from Visit 1 through the final study visit.

6.6. Dose Modification

Dose modification is not applicable in this study.

6.7. Intervention After the End of the Study

No intervention will be provided to maternal or infant study participants at the end of the study.

7. DISCONTINUATION OF STUDY INTERVENTION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

7.1. Discontinuation of Study Intervention

In rare instances, it may be necessary for a participant to permanently discontinue study intervention (definitive discontinuation). Reasons for definitive discontinuation of study intervention include the following: AEs; participant request; investigator request; protocol deviation (including no longer meeting all the inclusion criteria, or meeting 1 or more exclusion criteria). In general, unless the investigator considers it unsafe to administer the second dose, or the maternal participant does not wish to receive it, it is preferred that the second dose be administered. Note: following Vaccination 1, a positive SARS-CoV-2 NAAT result without symptoms or a COVID-19 diagnosis (signs/symptoms only or signs/symptoms and a positive SARS-CoV-2 NAAT result) should not result in discontinuation from the study intervention.

Note that discontinuation of study intervention does not represent withdrawal from the study. Per the study estimands if study intervention is definitively discontinued, the participant will remain in the study to be evaluated for safety, tolerability, and immunogenicity. See the SoA for data to be collected at the time of discontinuation of study intervention and follow-up for any further evaluations that need to be completed.

In the event of discontinuation of study intervention, it must be documented on the appropriate CRF/in the medical records whether the participant is discontinuing further receipt of study intervention or also from study procedures, postvaccination study follow-up, and/or future collection of additional information.

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7.2. Participant Discontinuation/Withdrawal From the Study

A maternal participant may withdraw from the study at any time at her own request or the infant participant may be withdrawn at any time at the request of his/her parent(s). Reasons for discontinuation from the study include the following:

- Refused further follow-up;
- Lost to follow-up;
- Death;
- Study terminated by sponsor;
- AEs;
- Maternal participant request;
- Investigator request;
- Protocol deviation.

If a participant does not return for a scheduled visit, every effort should be made to contact the participant. All attempts to contact the participant and information received during contact attempts must be documented in the participant's source document. In any circumstance, every effort should be made to document participant outcome, if possible.

The investigator or his or her designee should capture the reason for withdrawal in the CRF for all participants.

If a participant withdraws from the study, she may request destruction of any remaining samples taken and not tested, and the investigator must document any such requests in the site study records and notify the sponsor accordingly.

If the participant withdraws from the study and also withdraws consent (see Section 7.2.1) for disclosure of future information, no further evaluations should be performed and no additional data should be collected. The sponsor may retain and continue to use any data collected before such withdrawal of consent.

Lack of completion of all or any of the withdrawal/early termination procedures will not be viewed as protocol deviations so long as the participant's safety was preserved.

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7.2.1. Withdrawal of Consent

Participants who request to discontinue receipt of study intervention will remain in the study and must continue to be followed for protocol-specified follow-up procedures. The only exception to this is when a participant specifically withdraws consent for any further contact with her. Participants should notify the investigator in writing of the decision to withdraw consent from future follow-up, whenever possible. The withdrawal of consent should be explained in detail in the medical records by the investigator, as to whether the withdrawal is only from further receipt of study intervention or also from study procedures and/or postvaccination study follow-up, and entered on the appropriate CRF page. In the event that vital status (whether the participant is alive or dead) is being measured, publicly available information should be used to determine vital status only as appropriately directed in accordance with local law.

7.3. Lost to Follow-up

A maternal participant will be considered lost to follow-up if she repeatedly fails to return for scheduled visits and is unable to be contacted by the study site.

The following actions must be taken if a participant fails to return for scheduled visits and is unable to be contacted by the study site:

- The site must attempt to contact the participant and reschedule the missed visit as soon as possible and counsel the participant on the importance of maintaining the assigned visit schedule and ascertain whether or not the participant wishes to and/or should continue in the study.

- Before a participant is deemed lost to follow-up, the investigator or designee must make every effort to regain contact with the participant (where possible, 3 telephone calls and, if necessary, a certified letter to the participant's last known mailing address or local equivalent methods). These contact attempts should be documented in the participant's medical record.

- Should the participant continue to be unreachable, she will be considered to have withdrawn from the study.

8. STUDY ASSESSMENTS AND PROCEDURES

The investigator (or an appropriate delegate at the investigator site) must obtain a signed and dated ICD before performing any study-specific procedures.

Study procedures and their timing are summarized in the SoA. Protocol waivers or exemptions are not allowed.

The full date of birth will be collected to critically evaluate the immune response and safety profile by age.

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Safety issues should be discussed with the sponsor immediately upon occurrence or awareness to determine whether the participant should continue or discontinue study intervention.

Adherence to the study design requirements, including those specified in the SoA, is essential and required for study conduct.

All screening evaluations must be completed and reviewed to confirm that potential maternal participants meet all eligibility criteria. The investigator will maintain a screening log to record details of all maternal participants screened and to confirm eligibility or record reasons for screening failure, as applicable.

Procedures conducted as part of the maternal participant's routine clinical management and obtained before signing of the ICD may be utilized for baseline and/or screening purposes provided the procedures met the protocol-specified criteria and were performed within the time frame defined in the SoA.

Every effort should be made to ensure that protocol-required tests and procedures are completed as described. However, it is anticipated that from time to time there may be circumstances outside the control of the investigator that may make it unfeasible to perform the test. In these cases, the investigator must take all steps necessary to ensure the safety and well-being of the participant. When a protocol-required test cannot be performed, the investigator will document the reason for the missed test and any corrective and preventive actions that he or she has taken to ensure that required processes are adhered to as soon as possible. The study team must be informed of these incidents in a timely manner.

For samples being collected and shipped, detailed collection, processing, storage, and shipment instructions and contact information will be provided to the investigator site prior to initiation of the study.

The total blood sampling volume in this study is dependent on when a maternal participant is enrolled and which vaccine she is given while pregnant. It is expected that most maternal participants will have to give up to 6 blood samples (20 mL each).

Additionally, 20 mL of blood for maternal participants will be taken at an unplanned convalescent visit at any time a maternal participant develops respiratory symptoms indicating a potential COVID-19 infection. Maternal participants would therefore have a total blood sampling volume of approximately up to 140 mL during the study period. Additional blood samples may be taken for safety assessments at times specified by Pfizer, provided the total volume taken during the study does not exceed 550 mL during any period of 60 consecutive days. Approximately 10 mL of cord blood will be taken from each infant participant; if cord blood is unavailable, a blood sample of up to 5 mL (based on weight) will be collected. A 5-mL blood sample will be collected from each infant at the 6-month postdelivery visit; in addition, a blood sample of up to 5 mL will be collected at each convalescent illness visit.

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8.1. Efficacy and/or Immunogenicity Assessments

Surveillance for potential cases of COVID-19 will occur throughout a maternal and infant participant's involvement in the study. If, at any time, a maternal or infant participant develops acute respiratory illness (see Section 8.13), for the purposes of the study he or she will be considered to potentially have a COVID-19 illness. In this circumstance, the maternal participant should contact the site, an in-person or telehealth visit should occur, and assessments should be conducted as specified in the SoA. The assessments will include collection of a nasal swab, which will be tested at a central laboratory using an RT-PCR test (Cepheid; FDA approved under EUA), or other equivalent nucleic acid amplification–based test (ie, NAAT), to detect SARS-CoV-2. In addition, clinical information and results from local standard-of-care tests (as detailed in Section 8.13) will be assessed. The central laboratory NAAT result will be used for the case definition, unless no result is available from the central laboratory, in which case a local NAAT result may be used if it was obtained using 1 of the following assays:

- Cepheid Xpert Xpress SARS-CoV-2
- Roche cobas SARS-CoV-2 real-time RT-PCR test (EUA200009/A001)
- Abbott Molecular/RealTime SARS-CoV-2 assay (EUA200023/A001)

8.1.1. Maternal Participants

Two definitions of SARS-CoV-2–related cases, and SARS-CoV-2–related severe cases, will be considered (for both, the onset date of the case will be the date that symptoms were first experienced by the **maternal participant**; if new symptoms are reported within 4 days after resolution of all previous symptoms, they will be considered as part of a single illness):

Confirmed COVID-19, first definition: presence of at least 1 of the following symptoms and SARS-CoV-2 NAAT-positive during, or within 4 days before or after, the symptomatic period, either at the central laboratory or at a local testing facility (using an acceptable test):

- Fever;
- New or increased cough;
- New or increased shortness of breath;
- Chills;
- New or increased muscle pain;
- New loss of taste or smell;
- Sore throat;

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- Diarrhea;
- Vomiting.

The second definition, which may be updated as more is learned about COVID-19, will include the following additional symptoms defined by the CDC (listed at https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html):

- Fatigue;
- Headache;
- Nasal congestion or runny nose;
- Nausea.

Confirmed Severe COVID-19: confirmed COVID-19 and presence of at least 1 of the following:

- Clinical signs at rest indicative of severe systemic illness (RR ≥30 breaths/min, HR ≥125 beats/min, SpO_2 ≤93% on room air at sea level, or PaO_2/FiO_2 <300 mm Hg);
- Respiratory failure (defined as needing high-flow oxygen, noninvasive ventilation, mechanical ventilation, or ECMO);
- Evidence of shock (SBP <90 mm Hg, DBP <60 mm Hg, or requiring vasopressors);
- Significant acute renal, hepatic, or neurologic dysfunction*;
- Admission to an ICU;
- Death.

The second definition, which may be updated as more is learned about COVID-19, will include the following additional outcomes defined by the CDC (listed at https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html):

- Hospitalization;
- Admission to the ICU;
- Intubation or mechanical ventilation;
- Death.

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8.1.2. Infant Participants

Two definitions of SARS-CoV-2–related cases, and SARS-CoV-2–related severe cases, will be considered (for both, the onset date of the case will be the date that symptoms were first experienced by the **infant participant**; if new symptoms are reported within 4 days after resolution of all previous symptoms, they will be considered as part of a single illness). Signs and symptoms of an acute respiratory illness will not be considered a potential COVID-19–related illness if they occur within the first 72 hours after birth.

Confirmed COVID-19, first definition: presence of at least 1 of the following symptoms and SARS-CoV-2 NAAT-positive during, or within 4 days before or after, the symptomatic period, either at the central laboratory or at a local testing facility (using an acceptable test):

- Fever;
- New or increased cough;
- New or increased shortness of breath;
- Diarrhea;
- Vomiting.

The second definition, which may be updated as more is learned about COVID-19, will include the following additional symptoms defined by the CDC (listed at https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html) but does not trigger a potential COVID-19 illness visit unless, in the opinion of PI, it is deemed necessary:

- Nasal congestion or runny nose;
- Poor appetite or poor feeding;
- Abdominal pain (colic).

Confirmed Severe Infant COVID-19: confirmed COVID-19 and presence of at least 1 of the following:

- Clinical signs at rest indicative of severe systemic illness:
  - RR (breaths/min): >50 from birth to 1 week of age, ≥40 from 1 week to 1 month of age, ≥34 from 1 month to 6 months of age;
  - HR (beats/min): >180;
  - SpO_2 ≤92% on room air or >50% FiO_2 to maintain ≥92%, or PaO_2/FiO_2 <300 mm Hg;[33]

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- Respiratory failure (defined as needing high-flow oxygen including nasal CPaP/BiPaP, noninvasive ventilation, mechanical ventilation, or ECMO);
- Evidence of shock or cardiac failure:
    - SBP (mm Hg) (<5th percentile for age):
        - <65 from birth to 1 week of age, <75 from 1 week to 1 month of age, <100 from 1 month to 6 months of age;

OR

    - Requiring vasoactive drugs to maintain BP in the normal range;
- Significant acute renal failure: serum creatinine >2 times ULN for age or 2-fold increase in baseline creatinine;
- Significant GI/hepatic failure: total bilirubin >4 mg/dL or ALT 2 times ULN for age;
- Significant neurologic dysfunction: Glasgow Coma Scale score <11 or acute change in mental status with a decrease in Glasgow Coma Scale score ≥3 points from abnormal baseline;
- Admission to an ICU;
- Death.

Confirmed Multisystem Inflammatory Syndrome in Children (MIS-C) definition[34]:
as per the CDC MIS-C case definition:

- An infant presenting with fever (≥38.0°C for ≥24 hours or report of subjective fever lasting ≥24 hours); AND
- Laboratory evidence of inflammation (based on local laboratory ranges) including, but not limited to, 1 or more of the following: an elevated CRP, ESR, fibrinogen, procalcitonin, D-dimer, ferritin, LDH, or IL-6, elevated neutrophils, reduced lymphocytes, and low albumin; AND
- Evidence of clinically severe illness requiring hospitalization (definition as noted above for severe disease), with multisystem (≥2) organ involvement:
    - Cardiac (eg, shock, elevated troponin, elevated BNP, abnormal echocardiogram, arrhythmia);
    - Renal (eg, acute kidney injury or renal failure);

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- Respiratory (eg, pneumonia, ARDS, pulmonary embolism);
- Hematologic (eg, elevated D-dimers, thrombophilia, or thrombocytopenia);
- GI/hepatic (eg, elevated bilirubin, elevated liver enzymes, or diarrhea);
- Dermatologic (eg, rash, mucocutaneous lesions);
- Neurological (eg, CVA, aseptic meningitis, encephalopathy); AND

- No alternative plausible diagnoses; AND
- Positive for current or recent SARS-CoV-2 infection by RT-PCR, serology, or antigen test; OR
- COVID-19 exposure within the 4 weeks prior to the onset of symptoms.

The following are applicable for both maternal and infant participants:

The DMC may recommend modification of the definition of severe disease according to emerging information.

* A small group of blinded case reviewers (medically qualified Pfizer staff members) will review all potential COVID-19 illness events. If a NAAT-confirmed case in Phase 2/3 may be considered severe, or not, solely on the basis of these criteria, the blinded data will be reviewed by the case reviewers to assess whether the criterion is met; the majority opinion will prevail.

In addition, a serological definition will be used for participants without clinical presentation of COVID-19:

- Confirmed seroconversion to SARS-CoV-2 without confirmed COVID-19: a positive N-binding antibody result in a participant with a prior negative N-binding antibody result.

8.1.3. Immunogenicity

Serum samples will be obtained for immunogenicity testing at the visits specified in the SoA. The following assays will be performed:

- SARS-CoV-2 neutralization assay
- Full-length S-binding IgG levels
- N-binding antibody assay

Note that all immunogenicity analyses will be based upon samples analyzed at the **central laboratory**.

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8.1.4. Total Volume of Blood Collected – Maternal Participants

The total volume of blood collected for antibody assessment over the course of the study will be up to approximately 120 mL (~20 mL/visit) and an additional 20 mL during each unplanned convalescent visit at any time a participant develops respiratory symptoms indicating a potential COVID-19 infection.

8.1.5. Total Volume of Blood Collected – Infant Participants

Blood samples will be collected according to the directive 2001/20/EC: Ethical considerations for clinical trials on medicinal products conducted with minors.[35]

All infants will have a cord blood sample collected at birth. The total volume of cord blood to be collected for antibody assessment in this study will be approximately 10 mL.

If cord blood is unavailable, a blood sample may be collected from the infant participant up to 72 hours after birth but preferably within 24 hours after birth. The infant's weight must be used to determine the volume of blood that can be collected (see Table 1).

The maximum volume of blood collected from the infant in the absence of cord blood will be no more than 5 mL at planned study visits (based on weight). An additional sample of up to 5 mL may be collected during each unplanned convalescent visit at any time an infant participant develops respiratory symptoms indicating a potential COVID-19 infection.

Table 1. Guideline for Infant Blood Draw, if Cord Blood Sample Was Not Obtained

Body Weight (in kg)	Approximate Volume of Blood (in mL) to Be Collected
<1.3	No blood draw
1.3 - ≤2.4	1.0
>2.4 - ≤3.7	2.0
>3.7 - ≤4.9	3.0
>4.9 - ≤6.2	4.0
>6.2	5.0

8.1.6. Biological Samples

Blood and nasal swab samples will be used only for scientific research. Each sample will be labeled with a code so that the laboratory personnel testing the samples will not know the participant's identity. Samples that remain after performing assays outlined in the protocol may be stored by Pfizer. Unless a time limitation is required by local regulations or ethical requirements, the samples will be stored for up to 15 years after the end of the study and then destroyed. If allowed by the ICD, stored samples may be used for additional testing to better understand the immune responses to the vaccine(s) under study in this protocol, to inform the development of other products, and/or for vaccine-related assay work supporting vaccine programs. No testing of the participant's DNA material will be performed.

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The maternal participant may request that her or her infant's samples, if still identifiable, be destroyed at any time; however, any data already collected from those samples will still be used for this research. The biological samples may be shared with other researchers as long as confidentiality is maintained and no testing of the participant's DNA material is performed.

8.2. Safety Assessments

Planned time points for all safety assessments are provided in the SoA. Unscheduled clinical laboratory measurements may be obtained at any time during the study to assess any perceived safety issues.

A clinical assessment, including medical history, will be performed on all maternal participants at the first visit to establish a baseline. Significant medical history and observations from any physical examination will be documented in the CRF.

AEs and SAEs are collected, recorded, and reported as defined in Section 8.3.

Acute reactions within the first 30 minutes after vaccination will be assessed and documented in the AE CRF.

The safety parameters also include reactogenicity e-diary reports of local reactions and systemic events (including fever) and use of antipyretic medication that occur in the 7 days after administration of the study intervention, where Day 1 is the day of vaccination. Reactogenicity will not be collected in the e-diary for placebo recipients who subsequently receive BNT162b2 1 month following delivery. These prospectively self-reported occurrences of local reactions and systemic events are graded as described in Section 8.2.2.

8.2.1. Clinical Safety Laboratory Assessments

Clinical safety laboratory assessments will not be collected in this study.

8.2.2. Electronic Diary

Maternal participants will be required to complete a reactogenicity e-diary through an application (see Section 8.15) installed on a provisioned device or on the maternal participant's own personal device. Maternal participants will be asked to monitor and record local reactions, systemic events, and antipyretic medication usage for 7 days following administration of the study intervention, where Day 1 is the day of vaccination. The reactogenicity e-diary allows recording of these assessments only within a fixed time window, thus providing the accurate representation of the participant's experience at that time. Data on local reactions, systemic events, and antipyretic medication usage reported in the reactogenicity e-diary will be transferred electronically to a third-party vendor, where they will be available for review by investigators and the Pfizer clinicians at all times via an internet-based portal.

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Maternal participants originally randomized to placebo who subsequently receive BNT162b2 1 month following delivery, will not complete a reactogenicity e-diary but will have their local reactions and systemic events detected and reported as AEs in accordance with Section 8.3.2.

If the maternal participant lives in an area with poor network connection (certain countries only), a study staff/field worker may visit the maternal participant in her home or contact her via phone daily after vaccination to assess and record local reactions, systemic events, and temperature each day (beginning in the morning) for 6 days following vaccination (Day 2 through Day 7) where this system of follow-up is well established. Maternal participants may call the site and report additional local reactions and systemic events at any time during the Day 1 through Day 7 reporting period. The study staff/field worker will be required to record these data on a provisioned device or an application on a personal device, thus providing the accurate representation of the maternal participant's experience at that time. For events persisting on Day 7 and use of antipyretic medication continuing on Day 7, the field worker will continue to visit the participant and record information until resolution.

At intervals agreed to by the vendor and Pfizer, these data will be transferred electronically into Pfizer's database for analysis and reporting. These data do not need to be reported by the investigator in the CRF as AEs.

Investigators (or designee) will be required to review the reactogenicity e-diary data online at frequent intervals as part of the ongoing safety review.

The investigator or designee must obtain stop dates from the participant for any ongoing local reactions, systemic events, or use of antipyretic medication on the last day that the reactogenicity e-diary was completed. The stop dates should be documented in the source documents and the information entered in the CRF.

8.2.2.1. Grading Scales

The grading scales used in this study to assess local reactions and systemic events as described below are derived from the FDA CBER guidelines on toxicity grading scales for healthy adult volunteers enrolled in preventive vaccine clinical trials.[29]

8.2.2.2. Local Reactions

During the reactogenicity e-diary reporting period, maternal participants/study staff member/field worker will be asked to assess redness, swelling, and pain at the injection site and to record the symptoms in the reactogenicity e-diary. If a local reaction persists beyond the end of the reactogenicity e-diary period following vaccination, the maternal participant will be requested to report that information. The investigator/field staff will enter this additional information in the CRF.

Redness and swelling will be measured and recorded by the maternal participants/study staff member/field worker in measuring device units (range: 1 to 21) and then categorized during analysis as absent, mild, moderate, or severe based on the grading scale in Table 2.

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Measuring device units can be converted to centimeters according to the following formula: 1 measuring device unit = 0.5 cm. Pain at the injection site will be assessed by the participant as absent, mild, moderate, or severe according to the grading scale in Table 2.

If a Grade 3 local reaction is reported in the reactogenicity e-diary, a telephone contact should occur to ascertain further details and determine whether a site visit is clinically indicated. Only an investigator or medically qualified person is able to classify a participant's local reaction as Grade 4. If a participant experiences a confirmed Grade 4 local reaction, the investigator must immediately notify the sponsor and, if it is determined to be related to the administration of the study intervention, further vaccinations will be discontinued in that participant.

Where appropriate, the site staff/field worker will educate the maternal participant regarding signs and symptoms that would prompt site contact.

Table 2. Local Reaction Grading Scale

	Mild (Grade 1)	Moderate (Grade 2)	Severe (Grade 3)	Potentially Life Threatening (Grade 4)
Pain at the injection site	Does not interfere with activity	Interferes with activity	Prevents daily activity	Emergency room visit or hospitalization for severe pain
Redness	>2.0 cm to 5.0 cm (5 to 10 measuring device units)	>5.0 cm to 10.0 cm (11 to 20 measuring device units)	>10 cm (≥21 measuring device units)	Necrosis or exfoliative dermatitis
Swelling	>2.0 cm to 5.0 cm (5 to 10 measuring device units)	>5.0 cm to 10.0 cm (11 to 20 measuring device units)	>10 cm (≥21 measuring device units)	Necrosis

8.2.2.3. Systemic Events

Prior to vaccination on Day 1, a baseline assessment of fatigue, headache, vomiting, nausea, diarrhea, muscle pain, and joint pain will be recorded in the e-diary.

During the reactogenicity e-diary reporting period, maternal participants will be asked to assess vomiting, diarrhea, headache, fatigue, chills, new or worsened muscle pain, and new or worsened joint pain and to record the symptoms in the reactogenicity e-diary. Based on local practice in certain countries/locales, a study staff member/field worker will call or visit maternal participants daily after vaccination to assess the presence of systemic events during the reactogenicity reporting period. The symptoms will be assessed by the maternal participant as absent, mild, moderate, or severe according to the grading scale in Table 3.

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Maternal participants will also be instructed to contact site staff if they visit the emergency room or are hospitalized for severe fatigue, headache, vomiting, nausea, diarrhea, muscle pain, or joint pain within 7 days after vaccination. Based on local practice in certain countries/locales, maternal participants will be referred to the appropriate healthcare facility at the discretion of the study staff/field worker if there are any concerns, as appropriate. In the event that the maternal participant does not call, the investigator or qualified designee will contact the maternal participant. The study staff/field worker may also contact the maternal participant to obtain additional information on events entered into the e-diary.

If a Grade 3 systemic event is reported in the reactogenicity e-diary, a telephone contact should occur to ascertain further details and determine whether a site visit is clinically indicated. Only an investigator or medically qualified person is able to classify a maternal participant's systemic event as Grade 4. If a maternal participant experiences a confirmed Grade 4 systemic event, the investigator must immediately notify the sponsor and, if it is determined to be related to the administration of the study intervention, further vaccinations will be discontinued in that maternal participant.

Table 3. Systemic Event Grading Scale

	Mild (Grade 1)	Moderate (Grade 2)	Severe (Grade 3)	Potentially Life Threatening (Grade 4)
Vomiting	1-2 times in 24 hours	>2 times in 24 hours	Requires IV hydration	Emergency room visit or hospitalization for hypotensive shock
Diarrhea	2 to 3 loose stools in 24 hours	4 to 5 loose stools in 24 hours	6 or more loose stools in 24 hours	Emergency room visit or hospitalization for severe diarrhea
Headache	Does not interfere with activity	Some interference with activity	Prevents daily routine activity	Emergency room visit or hospitalization for severe headache
Fatigue/tiredness	Does not interfere with activity	Some interference with activity	Prevents daily routine activity	Emergency room visit or hospitalization for severe fatigue
Chills	Does not interfere with activity	Some interference with activity	Prevents daily routine activity	Emergency room visit or hospitalization for severe chills
New or worsened muscle pain	Does not interfere with activity	Some interference with activity	Prevents daily routine activity	Emergency room visit or hospitalization for severe new or worsened muscle pain

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Table 3. Systemic Event Grading Scale

	Mild (Grade 1)	Moderate (Grade 2)	Severe (Grade 3)	Potentially Life Threatening (Grade 4)
New or worsened joint pain	Does not interfere with activity	Some interference with activity	Prevents daily routine activity	Emergency room visit or hospitalization for severe new or worsened joint pain

Abbreviation: IV = intravenous.

8.2.2.4. Fever

In order to record information on fever, a thermometer will be given to maternal participants with instructions on how to measure oral temperature at home. Temperature will be collected in the reactogenicity e-diary in the evening daily during the reactogenicity e-diary reporting period. It will also be collected at any time during the reactogenicity e-diary data collection periods when fever is suspected. Similarly, based on local practice in certain countries/locales, the study staff/field worker will call or visit maternal participants daily during the reactogenicity reporting period to collect the temperature.

Fever is defined as an oral temperature of ≥38.0°C (100.4°F). The highest temperature for each day will be recorded in the reactogenicity e-diary. Temperature will be measured and recorded to 1 decimal place. Temperatures recorded in degrees Fahrenheit will be programmatically converted to degrees Celsius and then categorized during analysis according to the scale shown in Table 4.

If a fever of ≥39.0°C (102.1°F) is reported in the reactogenicity e-diary, a telephone contact should occur to ascertain further details and determine whether a site visit is clinically indicated. Only an investigator or medically qualified person is able to confirm a maternal participant's fever as >40.0°C (>104.0°F). If a maternal participant experiences a confirmed fever >40.0°C (>104.0°F), the investigator must immediately notify the sponsor and, if it is determined to be related to the administration of the study intervention, further vaccinations will be discontinued in that maternal participant.

Table 4. Scale for Fever

≥38.0-38.4°C (100.4-101.1°F)
>38.4-38.9°C (101.2-102.0°F)
>38.9-40.0°C (102.1-104.0°F)
>40.0°C (>104.0°F)

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8.2.2.5. Antipyretic Medication

The use of antipyretic medication to treat symptoms associated with study intervention administration will be recorded in the reactogenicity e-diary daily during the reporting period (Day 1 through Day 7).

8.2.3. Stopping Rules

The following stopping rules are in place for all Phase 2 maternal participants, based on review of AE data and e-diary reactogenicity data, until the start of Phase 3. Stopping rules do not apply to maternal participants who initially received placebo and subsequently receive BNT162b2. These data will be monitored on an ongoing basis by the investigator (or medically qualified designee) and sponsor in order to promptly identify and flag any event that potentially contributes to a stopping rule.

In the event that sponsor personnel confirm that a stopping rule is met, the following actions will commence:

- The IRC will review all appropriate data.
- The stopping rule will PAUSE randomization and study intervention administration for participants receiving the first dose. Maternal participants scheduled to receive Dose 2 at the time of a study pause may proceed with vaccination.
- The DMC will review all appropriate data.
- For all participants vaccinated, all other routine study conduct activities, including ongoing data entry, reporting of AEs, participant reactogenicity e-diary completion, blood sample collection, and participant follow-up, will continue during the pause.

A stopping rule is met if any of the following rules occur after administration of investigational BNT162b2; data from placebo recipients will not contribute to the stopping rules. Reactogenicity e-diary data confirmed by the investigator as being entered by the participant in error will not contribute toward a stopping rule.

Stopping Rule Criteria:

1. If any participant vaccinated with BNT162b2 develops an SAE that is assessed by the investigator as possibly related, or for which there is no alternative, plausible, attributable cause.
2. If any participant vaccinated with BNT162b2 develops a Grade 4 local reaction or systemic event after vaccination that is assessed as possibly related by the investigator, or for which there is no alternative, plausible, attributable cause.

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3. If any participant vaccinated with BNT162b2 develops a fever >40.0°C (>104.0°F) for at least 1 daily measurement after vaccination that is assessed as possibly related by the investigator, or for which there is no alternative, plausible, attributable cause.

4. If any 2 participants vaccinated with BNT162b2 report the same or similar severe (Grade 3) AE after vaccination, assessed as possibly related by the investigator, or for which there is no alternative, plausible, attributable cause.

5. If any participant dies or requires ICU admission due to SARS-CoV-2 infection; if this stopping rule is met, all available clinical and preclinical safety and immunogenicity data should be reviewed to evaluate for enhanced COVID-19.

6. If any participant vaccinated with BNT162b2 experiences any of the following within 7 days after vaccination, where Day 1 is the day of vaccination: severe vaginal bleeding (eg, partial abruption); severe preeclampsia; eclampsia; HELLP syndrome; life-threatening sequelae of preeclampsia (eg, pulmonary edema); stillbirth; or fetal loss.

7. If ≥2 maternal participants vaccinated with BNT162b2 experience premature delivery or preterm premature rupture of membranes within 14 days after vaccination.

8.2.4. Surveillance of Events That Could Represent Enhanced COVID-19

The unblinded team supporting the DMC, including an unblinded medical monitor, will review cases of severe COVID-19 as they are received and will review AEs at least weekly for additional potential cases of severe COVID-19. At any point, the unblinded team may discuss with the DMC chair whether the DMC should review cases.

The purpose of these reviews will be to identify whether any features of each case appear unusual, in particular, greater in severity, compared to available information at the time of review. Indicators of severity may include accelerated deterioration, need for hospitalization, need for ventilation, or death.

Observed rates of these indicators will be compared with what could be expected in a population similar to the study participants based upon available information at the time of review.

8.2.5. Clinical Safety Laboratory Assessments

Clinical safety laboratory assessments will not be collected in this study.

8.3. Adverse Events and Serious Adverse Events

The definitions of an AE and an SAE can be found in Appendix 2.

AEs will be reported by the maternal participant (or the parent[s] for the infant participant).

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The investigator and any qualified designees are responsible for detecting, documenting, and recording events that meet the definition of an AE or SAE and remain responsible to pursue and obtain adequate information both to determine the outcome and to assess whether the event meets the criteria for classification as an SAE or caused the participant to discontinue the study intervention (see Section 7.1).

Each maternal participant and parent of the infant participant will be questioned about the occurrence of AEs in a nonleading manner.

In addition, the investigator may be requested by Pfizer Safety to obtain specific follow-up information in an expedited fashion.

The procedures described in this section pertain to both the infant participant and maternal participant, unless otherwise indicated.

8.3.1. Time Period and Frequency for Collecting AE and SAE Information

The time period for actively eliciting and collecting AEs and SAEs ("active collection period") for each maternal participant including her fetus begins from the time the maternal participant provides informed consent, which is obtained before participation in the study (ie, before undergoing any study-related procedure and/or receiving study intervention), through and including a minimum of 28 calendar days after the last administration of the study intervention.

In this study, the investigator and site staff will ensure the active elicitation and collection of AEs and SAEs through Visit 4.

From Visit 4 through Visit 8, SAEs will be collected for maternal participants originally randomized to BNT162b2. In addition, AEs occurring up to 48 hours after blood draws and collection of nasal swabs that are related to study procedures must be reported in the CRF.

Additionally, for those maternal participants who originally received placebo but go on to receive BNT162b2 at Visit 101 and Visit 102, AEs and SAEs will be collected through and 1 month after the second dose of BNT162b2 (Visit 103).

For the infant participant, the time period for actively eliciting and collecting nonserious AEs ("active collection period") begins at birth and continues through and including 1 month after birth. SAEs and AESIs will be collected from birth through and including 6 months of age.

Follow-up by the investigator continues throughout and after the active collection period and until the AE or SAE or its sequelae resolve or stabilize at a level acceptable to the investigator and Pfizer concurs with that assessment.

For maternal participants who are screen failures, the active collection period ends when screen failure status is determined.

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If the participant withdraws from the study and also withdraws consent for the collection of future information, the active collection period ends when consent is withdrawn.

If a participant definitively discontinues or temporarily discontinues study intervention because of an AE or SAE, the AE or SAE must be recorded on the CRF and the SAE reported using the Vaccine SAE Reporting Form.

Investigators are not obligated to actively seek AEs or SAEs after the participant has concluded study participation. However, if the investigator learns of any SAE, including a death, at any time after a participant has completed the study, and he/she considers the event to be reasonably related to the study intervention, the investigator must promptly report the SAE to Pfizer using the Vaccine SAE Reporting Form.

Note: Potential COVID-19/MIS-C illnesses and their sequelae that are consistent with the clinical endpoint definition (Section 8.1) should not be recorded as AEs. These data will be captured to describe disease endpoints for lack-of-efficacy assessment data only on the relevant pages of the CRF, as these are expected endpoints.

8.3.1.1. Reporting SAEs to Pfizer Safety

All SAEs occurring in a participant during the active collection period as described in Section 8.3.1 are reported to Pfizer Safety on the Vaccine SAE Reporting Form, if applicable, immediately upon awareness and under no circumstance should this exceed 24 hours.

If the outcome of the pregnancy meets the criteria for an SAE (ie, ectopic pregnancy, spontaneous abortion, including miscarriage and missed abortion, intrauterine fetal demise, neonatal death defined as those that occur within 1 month of birth, or congenital anomaly [in a live-born baby, a terminated fetus, an intrauterine fetal demise, or a neonatal death]), the investigator should follow the procedures for reporting SAEs. In addition, infant deaths after 1 month of age should be reported as SAEs.

Further follow-up may be requested by the sponsor and will be handled on a case-by-case basis (eg, follow-up on preterm infants to identify developmental delays).

SAEs occurring in the mother after the active collection period has ended are reported to Pfizer Safety if the investigator becomes aware of them; at a minimum, all SAEs that the investigator believes have at least a reasonable possibility of being related to study intervention must be reported to Pfizer Safety.

For those SAEs or deaths that occur to the infant after the active collection period should be reported when the investigator believes the SAE or death has at least a reasonable possibility of being related to study intervention.

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8.3.1.2. Recording Nonserious AEs and SAEs in the CRF

All nonserious AEs and SAEs occurring in a participant during the active collection period, which begins after obtaining informed consent as described in Section 8.3.1, will be recorded on the AE section of the CRF.

The investigator is to record on the CRF all directly observed and all spontaneously reported AEs and SAEs reported by the participant.

The investigator obtains general information on the pregnancy and its outcome for all study participants. The investigator will follow the pregnancy until completion (or until pregnancy termination). In the case of a live birth, the structural integrity of the neonate can be assessed at the time of birth. In the event of a termination, the reason(s) for termination should be specified and, if clinically possible, the structural integrity of the terminated fetus should be assessed by gross visual inspection (unless preprocedure test findings are conclusive for a congenital anomaly and the findings are reported).

If the outcome of the pregnancy meets the criteria for an SAE (ie, ectopic pregnancy, spontaneous abortion, including miscarriage and missed abortion, intrauterine fetal demise, neonatal death defined as those deaths that occur within 1 month of birth, or congenital anomaly (in a live-born baby, a terminated fetus, an intrauterine fetal demise, or a neonatal death), the investigator should record this information in the CRF. In addition, infant deaths after 1 month of age should be recorded in the CRF as SAEs.

8.3.2. Method of Detecting AEs and SAEs

The method of recording, evaluating, and assessing causality of AEs and SAEs and the procedures for completing and transmitting SAE reports are provided in Appendix 2.

Care will be taken not to introduce bias when detecting AEs and/or SAEs. Open-ended and nonleading verbal questioning of the participant is the preferred method to inquire about AE occurrences.

8.3.3. Follow-up of AEs and SAEs

After the initial AE/SAE report, the investigator is required to proactively follow each participant at subsequent visits/contacts. For each event, the investigator must pursue and obtain adequate information until resolution, stabilization, the event is otherwise explained, or the participant is lost to follow-up (as defined in Section 7.3).

In general, follow-up information will include a description of the event in sufficient detail to allow for a complete medical assessment of the case and independent determination of possible causality. Any information relevant to the event, such as concomitant medications and illnesses, must be provided. In the case of a participant death, a summary of available autopsy findings must be submitted as soon as possible to Pfizer Safety.

Further information on follow-up procedures is given in Appendix 2.

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8.3.4. Regulatory Reporting Requirements for SAEs

Prompt notification by the investigator to the sponsor of an SAE is essential so that legal obligations and ethical responsibilities towards the safety of participants and the safety of a study intervention under clinical investigation are met.

The sponsor has a legal responsibility to notify both the local regulatory authority and other regulatory agencies about the safety of a study intervention under clinical investigation. The sponsor will comply with country-specific regulatory requirements relating to safety reporting to the regulatory authority, IRBs/ECs, and investigators.

Investigator safety reports must be prepared for SUSARs according to local regulatory requirements and sponsor policy and forwarded to investigators as necessary.

An investigator who receives SUSARs or other specific safety information (eg, summary or listing of SAEs) from the sponsor will review and then file it along with the SRSD(s) for the study and will notify the IRB/EC, if appropriate according to local requirements.

8.3.5. Additional Exposure Scenarios That May Result From the Exposure to the Study Intervention

8.3.5.1. Environmental Exposure During Pregnancy

Environmental exposure occurs when, during the performance of job duties, a person (whether a healthcare professional or otherwise) gets in unplanned direct contact with the study intervention, which may or may not lead to the occurrence of an AE. Such persons may include HCPs, family members, and other roles that are involved in the trial participant's care.

Note: This does NOT apply to maternal participants enrolled in this trial.

- The scenarios below describe environmental exposures that could lead to an EDP:
    - A female is found to be pregnant while being exposed or having been exposed to study intervention by environmental exposure. Below are some examples:
        - A female family member or healthcare provider reports that she is pregnant after having been exposed to the study intervention by inadvertent product administration via needlestick.
        - A male family member or healthcare provider who has been exposed to the study intervention then exposes his female partner prior to or around the time of conception.

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The investigator must report EDP to Pfizer Safety within 24 hours of the investigator's awareness, irrespective of whether an SAE has occurred. The investigator must report information to Pfizer Safety using the Vaccine SAE Reporting Form and EDP Supplemental Form. The initial information submitted should include the anticipated date of delivery (see below for information related to termination of pregnancy). Since the exposure information does not pertain to the participant enrolled in the study, the information is not recorded on a CRF; however, a copy of the completed Vaccine SAE Reporting Form is maintained in the investigator site file.

Follow-up is conducted to obtain general information on the pregnancy and its outcome for all EDP reports with an unknown outcome. The investigator will follow the pregnancy until completion (or until pregnancy termination) and notify Pfizer Safety of the outcome as a follow-up to the initial EDP Supplemental Form.

In the case of a live birth, the structural integrity of the neonate can be assessed at the time of birth. In the event of a termination, the reason(s) for termination should be specified and, if clinically possible, the structural integrity of the terminated fetus should be assessed by gross visual inspection (unless preprocedure test findings are conclusive for a congenital anomaly and the findings are reported).

Abnormal pregnancy outcomes are considered SAEs. If the outcome of the pregnancy meets the criteria for an SAE (ie, ectopic pregnancy, spontaneous abortion, intrauterine fetal demise, neonatal death, or congenital anomaly [in a live-born baby, a terminated fetus, an intrauterine fetal demise, or a neonatal death]), the investigator should follow the procedures for reporting SAEs.

Additional information about pregnancy outcomes that are reported to Pfizer Safety as SAEs follows:

- Spontaneous abortion including miscarriage and missed abortion;
- Neonatal deaths that occur within 1 month of birth should be reported, without regard to causality, as SAEs. In addition, infant deaths after 1 month should be reported as SAEs when the investigator assesses the infant death as related or possibly related to exposure to the study intervention.

Additional information regarding the EDP may be requested by the sponsor. Further follow-up of birth outcomes will be handled on a case-by-case basis (eg, follow-up on preterm infants to identify developmental delays).

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8.3.5.2. Exposure During Breastfeeding

Exposure-during-breastfeeding reports are not expected for maternal participants who breastfeed a child delivered during the study.

Environmental exposure during breastfeeding occurs when a female family member or healthcare provider who reports that she is breastfeeding after having been exposed to the study intervention (eg, by inhalation or skin contact). The investigator must report exposure during breastfeeding to Pfizer Safety within 24 hours of the investigator's awareness, irrespective of whether an SAE has occurred. The information must be reported using the Vaccine SAE Reporting Form. When exposure during breastfeeding occurs in the setting of environmental exposure, the exposure information does not pertain to the participant enrolled in the study**,** so the information is not recorded on a CRF. However, a copy of the completed Vaccine SAE Reporting Form is maintained in the investigator site file.

An exposure-during-breastfeeding report is not created when a Pfizer drug specifically approved for use in breastfeeding women (eg, vitamins) is administered in accord with authorized use. However, if the infant experiences an SAE associated with such a drug, the SAE is reported together with the exposure during breastfeeding.

8.3.5.3. Occupational Exposure

An occupational exposure occurs when a person receives unplanned direct contact with the study intervention, which may or may not lead to the occurrence of an AE. Such persons may include healthcare providers, family members, and other roles that are involved in the trial participant's care.

The investigator must report occupational exposure to Pfizer Safety within 24 hours of the investigator's awareness, regardless of whether there is an associated SAE. The information must be reported using the Vaccine SAE Reporting Form. Since the information does not pertain to a participant enrolled in the study, the information is not recorded on a CRF; however, a copy of the completed Vaccine SAE Reporting Form is maintained in the investigator site file.

8.3.6. Cardiovascular and Death Events

Not applicable.

8.3.7. Disease-Related Events and/or Disease-Related Outcomes Not Qualifying as AEs or SAEs

Potential COVID-19/MIS-C illnesses and their sequelae that are consistent with the clinical endpoint definition should **not** be recorded as AEs. These data will be captured as efficacy assessment data only on the relevant pages of the CRF, as these are expected endpoints.

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Potential COVID-19/MIS-C illnesses and their sequelae will not be reported according to the standard process for expedited reporting of SAEs, even though the event may meet the definition of an SAE. These events will be recorded on the COVID-19 illness pages in the participant's CRF within 1 day.

NOTE: However, if either of the following conditions applies, then the event must be recorded and reported as an SAE (instead of a disease-related event):

The event is, in the investigator's opinion, of greater intensity, frequency, or duration than expected for the individual participant.

OR

The investigator considers that there is a reasonable possibility that the event was related to study intervention.

Potential COVID-19/MIS-C illness events and their sequelae will be reviewed by a group of internal blinded case reviewers. Any SAE that is determined by the internal case reviewers NOT to meet endpoint criteria is reported back to the investigator site of incidence. The investigator must report the SAE to Pfizer Safety within 24 hours of being made aware that the SAE did not meet endpoint criteria. The investigator's SAE awareness date is the date on which the investigator site of incidence receives the SAE back from the internal case reviewers.

8.3.8. Adverse Events of Special Interest

This section provides information on AESIs that may be detected during the study. The following events are considered AESIs:

- A confirmed diagnosis of myocarditis or pericarditis. See Section 8.14 for additional procedures for monitoring of potential myocarditis or pericarditis.

For Infant Participants:

- Major congenital anomaly
- Developmental delay

All AESIs must be reported as an AE or SAE following the procedures described in Section 8.3.1 through Section 8.3.4. An AESI is to be recorded as an AE or SAE on the CRF. In addition, an AESI that is also an SAE must be reported using the Vaccine SAE Reporting Form.

8.3.8.1. Lack of Efficacy

This section is not applicable, as efficacy is yet to be demonstrated in the study population.

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8.3.9. Medical Device Deficiencies

Not applicable.

8.3.10. Medication Errors

Medication errors may result from the administration or consumption of the study intervention by the wrong participant, or at the wrong time, or at the wrong dosage strength.

Other exposures to the study intervention under study may occur in clinical trial settings, such as medication errors.

Safety Event	Recorded on the CRF	Reported on the Vaccine SAE Reporting Form to Pfizer Safety Within 24 Hours of Awareness
Medication errors	All (regardless of whether associated with an AE)	Only if associated with an SAE

Medication errors include:

- Medication errors involving participant exposure to the study intervention;
- Potential medication errors or uses outside of what is foreseen in the protocol that do or do not involve the study participant.

Such medication errors occurring to a study participant are to be captured on the medication error page of the CRF, which is a specific version of the AE page.

In the event of a medication dosing error, the sponsor should be notified within 24 hours.

Whether or not the medication error is accompanied by an AE, as determined by the investigator, the medication error is recorded on the medication error page of the CRF and, if applicable, any associated AE(s), serious and nonserious, are recorded on the AE page of the CRF.

Medication errors should be reported to Pfizer Safety within 24 hours on a Vaccine SAE Reporting Form **only when associated with an SAE**.

Other examples include, but are not limited to:

- The administration of expired study intervention;
- The administration of an incorrect study intervention;
- The administration of an incorrect dosage;

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- The administration of study intervention that has undergone temperature excursion from the specified storage range, unless it is determined by the sponsor that the study intervention under question is acceptable for use.

8.4. Treatment of Overdose

For this study, any dose of study intervention greater than 1 dose of study intervention within a 24-hour time period will be considered an overdose.

Pfizer does not recommend specific treatment for an overdose.

In the event of an overdose, the investigator should:

1. Contact the medical monitor within 24 hours.
2. Closely monitor the participant for any AEs/SAEs.
3. Document the quantity of the excess dose as well as the duration of the overdose in the CRF.
4. Overdose is reportable to Safety **only when associated with an SAE.**

Decisions regarding dose interruptions or modifications will be made by the investigator in consultation with the medical monitor based on the clinical evaluation of the participant.

8.5. Pharmacokinetics

Pharmacokinetic parameters are not evaluated in this study.

8.6. Pharmacodynamics

Pharmacodynamic parameters are not evaluated in this study.

8.7. Genetics

Genetics (specified analyses) are not evaluated in this study.

8.8. Biomarkers

Biomarkers are not evaluated in this study.

8.9. Immunogenicity Assessments

Immunogenicity assessments are described in Section 8.1.

8.10. Health Economics

Health economics/medical resource utilization and health economics parameters are not evaluated in this study.

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8.11. Study Procedures – Maternal Participants

The following procedures apply to both Phase 2 and Phase 3 maternal participants.

8.11.1. Visit 1: Screening (-28 Days to Vaccination 1)

Before enrollment and before any study-related procedures are performed, voluntary, written study-specific informed consent will be obtained from the maternal participant. Each signature on the ICD must be personally dated by the signatory. The investigator or his or her designee will also sign the ICD. A copy of the signed and dated ICD must be given to the maternal participant. The source data must reflect that the informed consent was obtained before participation in the study.

Standard-of-care procedures performed prior to informed consent can be considered for use in the study provided they follow guidance around the timing of procedures stipulated in the protocol.

In countries/locales where procedures to confirm maternal participant eligibility for this clinical trial are not routinely performed, the procedures must be obtained and reviewed by the investigator or qualified designee up to 28 days prior to vaccination.

It is anticipated that the procedures below will be conducted in a stepwise manner; ensure that procedures listed prior to administration of the vaccine are conducted prior to vaccination.

The following procedures will be performed:

- Obtain and record the participant demography (including complete date of birth [dd-Mmm-YYYY], sex, race, racial designation, and ethnicity). The date of birth will be collected to critically evaluate the immune response and safety profile by age.
- Obtain and record current alcohol and tobacco usage.
- Phase 3 only: For participants who are HIV-infected, record HIV viral load and CD4 count results from the most recent test performed in the previous 6 months.
- Obtain and record the LMP and EDD.
- Measure and record vital signs, including oral temperature, seated blood pressure, and heart rate.
- Perform physical examination including but not limited to weight and height, evaluating any clinically significant abnormalities within the following body systems: general appearance; skin; head, eyes, ears, nose, and throat; heart; lungs; abdomen; musculoskeletal; extremities; neurological; and lymph nodes.

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- Perform obstetric examination including but not limited to fetal heart tones and fetal movement. Note: Repeat and conduct targeted physical and obstetric examination if it was last performed greater than 7 days prior to vaccination.
- Perform an obstetric ultrasound scan and/or record findings to confirm singleton pregnancy and rule out fetal abnormalities.
- Record nonstudy vaccinations as described in Section 6.5.
- Collect and record concomitant medication associated with AE/SAEs.
- Ensure and document that all of the inclusion criteria and none of the exclusion criteria are met.
- Ensure that the participant meets none of the temporary delay criteria as described in Section 5.5.
- Explain the e-diary technologies available for this study (see Section 8.15) and assist the participant in downloading the study application onto her own device or issue a provisioned device if required.
- Record systemic events at baseline in the e-diary.
- Assign a single participant identifier using the IRT system.
- Collect a blood sample (approximately 20 mL) for immunogenicity testing.
- Obtain a nasal (midturbinate) swab (collected by site staff).
- Obtain the participant's randomization number and study intervention allocation using the IRT system.
- Unblinded site staff member(s) will dispense/administer 1 dose of study intervention into the deltoid muscle of the (preferably) nondominant arm. Please refer to the IP manual for further instruction on this process.
- Blinded site staff must observe the participant for at least 30 minutes after study intervention administration for any acute reactions. Record any acute reactions (including time of onset) in the participant's source documents and on the AE page of the CRF, and on an SAE form as applicable.
- Ask the participant to contact the site staff or investigator if the participant experiences acute chest pain, shortness of breath, or palpitations (see Section 8.14).

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- Issue a measuring device to measure local reactions at the injection site and a thermometer for recording daily temperatures and provide instructions on their use. Provide instructions on e-diary completion and ask the participant to complete the reactogenicity e-diary from Day 1 through Day 7, with Day 1 being the day of vaccination, OR explain to the maternal participant that a study staff member/field worker will call or visit her every day from Day 2 through Day 7 after vaccination (where Day 1 is the day of vaccination) to collect or take her temperature and record systemic events, acute local reactions, and use of antipyretic medication in a diary (if applicable).

- Provide instructions on COVID-19 illness e-diary completion and ask the participant to complete the COVID-19 illness e-diary at least weekly, if she is diagnosed with COVID-19 or has possible new or increased symptoms, or when she receives a reminder. See Section 8.15 for further details.

- Ask the participant to contact the site staff or investigator immediately if she experiences any of the following from Day 1 through Day 7 after vaccination (where Day 1 is the day of vaccination) to determine if an unscheduled reactogenicity visit or COVID-19 illness visit is required:

  - Fever ≥39.0°C (≥102.1°F).

  - Redness or swelling at the injection site measuring greater than 10 cm (>20 measuring device units).

  - Severe pain at the injection site.

  - Any severe systemic event.

- Ask the participant to contact the site staff or investigator if a medically attended event (eg, doctor's visit, emergency room visit) or hospitalization occurs.

- Ask the participant to contact the site staff or investigator (this could be via the COVID-19 illness e-diary) immediately if she experiences any respiratory symptoms as detailed in Section 8.13.

- Record AEs and SAEs as described in Section 8.3.

- Schedule an appointment for the participant to return for the next study visit.

- Remind the participant to bring the e-diary to the next visit.

- Complete the source documents.

- The investigator or an authorized designee completes the CRFs and an unblinded dispenser/administrator updates the study intervention accountability records.

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- The investigator or appropriately qualified designee reviews the reactogenicity e-diary data online following vaccination to evaluate participant compliance and as part of the ongoing safety review. Daily review is optimal during the active diary period.

8.11.1.1. Visit 2 – Vaccination 2 (Clinic: 19-23 Days After Vaccination 1)

If delivery occurs before this visit, this visit will be conducted as soon as possible after delivery. It is anticipated that the procedures below will be conducted in a stepwise manner; ensure that procedures listed prior to administration of the vaccine are conducted prior to vaccination.

- Measure vital signs (body temperature, pulse rate, and seated blood pressure).
- Perform targeted physical examination evaluating/noting any clinically significant abnormalities within the following body systems: general appearance; skin; head, eyes, ears, nose, and throat; heart; lungs; abdomen; musculoskeletal; extremities; neurological; and lymph nodes. Significant medical and surgical history and abnormal observations from the physical examination will be documented and recorded in the CRF.
- Perform obstetric examination including but not limited to fetal heart tones and fetal movement.
- Record AEs and SAEs as described in Section 8.3.
- Review the participant's reactogenicity e-diary data. Collect stop dates of any reactogenicity e-diary events ongoing on the last day that the reactogenicity e-diary was completed and record stop dates in the CRF if required.
- Record nonstudy vaccinations as described in Section 6.5.
- Collect and record concomitant medication associated with AE/SAEs.
- Ensure and document that the participant is still eligible for continued participation.
- Ensure that the maternal participant meets none of the temporary delay criteria as described in Section 5.5.
- Collect a blood sample (approximately 20 mL) for immunogenicity testing.
  Note: blood samples for immunogenicity will be drawn in Phase 2 maternal participants only.
- Obtain a nasal swab (collected by site staff).
- Unblinded site staff member(s) will dispense/administer 1 dose of study intervention into the deltoid muscle of the (preferably) nondominant arm. Please refer to the IP manual for further instruction on this process.

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- Blinded site staff must observe the participant for at least 30 minutes after study intervention administration for any acute reactions. Record any acute reactions (including time of onset) in the participant's source documents and on the AE page of the CRF, and on an SAE form as applicable.

- Ask the participant to contact the site staff or investigator if the participant experiences acute chest pain, shortness of breath, or palpitations (see Section 8.14).

- Ensure the participant remains comfortable with the chosen e-diary platform, confirm instructions on e-diary completion, and ask the participant to complete the reactogenicity e-diary from Day 1 through Day 7, with Day 1 being the day of vaccination.

- Ask the participant to contact the site staff or investigator immediately if she experiences any of the following from Day 1 through Day 7 after vaccination (where Day 1 is the day of vaccination) to determine if an unscheduled reactogenicity visit is required:

  - Fever ≥39.0°C (≥102.1°F).

  - Redness or swelling at the injection site measuring greater than 10 cm (>20 measuring device units).

  - Severe pain at the injection site.

  - Any severe systemic event.

- Ask the participant to contact the site staff or investigator if a medically attended event (eg, doctor's visit, emergency room visit) or hospitalization occurs.

- Ask the participant to contact the site staff or investigator (this could be via the COVID-19 illness e-diary) immediately if she experiences any COVID-19 illness symptoms as detailed in Section 8.13.

- Schedule an appointment for the participant to return for the next study visit.

- Remind the participant to bring the e-diary to the next visit.

- Complete the source documents.

- The investigator or an authorized designee completes the CRFs and an unblinded dispenser/administrator updates the study intervention accountability records.

The investigator or appropriately qualified designee reviews the reactogenicity e-diary data online following vaccination to evaluate participant compliance and as part of the ongoing safety review. Daily review is optimal during the active diary period.

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8.11.1.2. Visit 3 – 2-Week Postvaccination Follow-up (Clinic)

If delivery occurs before this visit, this visit will not be conducted.

- Phase 3 only: For participants who are HIV-infected, record HIV viral load and CD4 count results from the most recent test performed since their last visit (if any).
- Record nonstudy vaccinations as described in Section 6.5.
- Collect and record concomitant medication associated with AE/SAEs.
- Review the participant's reactogenicity e-diary data. Collect stop dates of any reactogenicity e-diary events ongoing on the last day that the reactogenicity e-diary was completed and record stop dates in the CRF if required.
- Ensure and document that the participant is still eligible for continued participation.
- Collect a blood sample (approximately 20 mL) for immunogenicity testing.
- Record AEs and SAEs as described in Section 8.3.
- Ask the participant to contact the site staff or investigator if an emergency room visit or hospitalization occurs.
- Ask the participant to contact the site staff or investigator if the participant experiences acute chest pain, shortness of breath, or palpitations (see Section 8.14).
- Ask the participant to contact the site staff or investigator (this could be via the COVID-19 illness e-diary) immediately if she experiences any COVID-19 illness symptoms as detailed in Section 8.13.
- Schedule an appointment for the participant to return for the next study visit.
- Complete the source documents.
- The investigator or an authorized designee completes the CRFs.

8.11.1.3. Visit 4 – 1-Month Postvaccination Follow-up Visit (Clinic: 28-35 Days After Visit 2)

If delivery occurs before this visit, this visit will not be conducted.

- Phase 3 only: For participants who are HIV-infected, record HIV viral load and CD4 count results from the most recent test performed since their last visit (if any).
- Measure vital signs (body temperature, pulse rate, and seated blood pressure).

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- Perform targeted physical examination evaluating/noting any clinically significant abnormalities within the following body systems: general appearance; skin; head, eyes, ears, nose, and throat; heart; lungs; abdomen; musculoskeletal; extremities; neurological; and lymph nodes. Significant medical and surgical history and abnormal observations from the physical examination will be documented and recorded in the CRF.

- Perform obstetric examination including but not limited to fetal heart tones and fetal movement.

- Record nonstudy vaccinations as described in Section 6.5.

- Collect and record concomitant medication associated with an AE.

- Ensure and document that the participant is still eligible for continued participation. Collect a blood sample (approximately 20 mL) for immunogenicity testing.

- Record AEs and SAEs as described in Section 8.3.

- Ask the participant to contact the site staff or investigator if an emergency room visit or hospitalization occurs.

- Ask the participant to contact the site staff or investigator if the participant experiences acute chest pain, shortness of breath, or palpitations (see Section 8.14).

- Ask the participant to contact the site staff or investigator (this could be via the COVID-19 illness e-diary) immediately if she experiences any COVID-19 illness symptoms as detailed in Section 8.13.

- Schedule an appointment for the participant to return for the next study visit.

- Complete the source documents.

- The investigator or an authorized designee completes the CRFs.

8.11.1.4. Visit 5 – Delivery

The delivery visit spans the time from when a participant is admitted in labor through discharge following delivery of her infant. Protocol-specified procedures associated with this delivery visit may be done at any time during this period.

- Phase 3 only: For participants who are HIV-infected, record HIV viral load and CD4 count results from the most recent test performed since their last visit (if any).

- Record nonstudy vaccinations as described in Section 6.5.

- Collect and record concomitant medication associated with AE/SAEs.

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- Ensure and document that the participant is still eligible for continued participation.
- Collect a blood sample (approximately 20 mL) for immunogenicity testing. If a sample for this purpose has already been collected in the previous 7 days (eg, per the procedures at Visit 4 for Phase 2/3 participants), a second sample need not be collected.
    - Note: A cord blood sample of approximately 10 mL for immunogenicity assessments must also be collected. Please refer to Section 8.18.1 for details of the infant delivery visit.
- Record pregnancy outcome information, including vital status of the infant (live, stillbirth, etc), mode of delivery (vaginal delivery or cesarean delivery), and the use of any assisted devices (forceps or vacuum).
- Record AEs and SAEs as described in Section 8.3.
- If Visit 5 occurs within 1 month after study vaccination: Ask the participant to contact the site staff or investigator if the participant experiences acute chest pain, shortness of breath, or palpitations (see Section 8.14).
- Ask the participant to contact the site staff or investigator (this could be via the COVID-19 illness e-diary) immediately if she experiences any COVID-19 illness symptoms as detailed in Section 8.13.
- Schedule a telephone call for the participant's next study visit.
- Complete the source documents.
- The investigator or an authorized designee completes the CRFs.

8.11.1.5. Visit 6 – 1-Week Postdelivery Follow-up (Telephone Call: 7-10 Days After Delivery)

- Record nonstudy vaccinations as described in Section 6.5.
- Collect and record concomitant medication associated with AE/SAEs.
- Ensure and document that the participant is still eligible for continued participation.
- If not obtained at the time of delivery, update pregnancy outcome information, including vital status of the infant (live, stillbirth, etc), mode of delivery (vaginal delivery or cesarean delivery), and the use of any assisted devices (forceps or vacuum).
- Record AEs and SAEs as described in Section 8.3.

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- If Visit 6 occurs within 1 month after study vaccination: Ask the participant to contact the site staff or investigator if the participant experiences acute chest pain, shortness of breath, or palpitations (see Section 8.14).

- Ask the participant to contact the site staff or investigator (this could be via the COVID-19 illness e-diary) immediately if she experiences any COVID-19 illness symptoms as detailed in Section 8.13.

- Schedule an appointment for the participant to return for the next study visit.

- Complete the source documents.

- The investigator or an authorized designee completes the CRFs.

8.11.1.6. Visit 7 – 1-Month Postdelivery Follow-up (Clinic: 21 to 35 Days After Delivery)

- All participants will be unblinded. Maternal participants who received BNT162b2 will follow the procedures below and those who received placebo will follow the procedures in Section 8.17.

- Phase 3 only: For participants who are HIV-infected, record HIV viral load and CD4 count results from the most recent test performed since their last visit (if any).

- Record nonstudy vaccinations as described in Section 6.5.

- Collect and record concomitant medication associated with AE/SAEs.

- Ensure and document that the participant is still eligible for continued participation.

- Record AEs and SAEs as described in Section 8.3.

- Ask the participant to contact the site staff or investigator (this could be via the COVID-19 illness e-diary) immediately if she experiences any COVID-19 illness symptoms as detailed in Section 8.13.

- Schedule an appointment for the participant to return for the next study visit.

- Complete the source documents.

- The investigator or an authorized designee completes the CRFs.

8.11.1.7. Visit 8 – 6-Month Postdelivery Follow-up (Clinic: 160-200 Days After Delivery)

- Phase 3 only: For participants who are HIV-infected, record HIV viral load and CD4 count results from the most recent test performed since their last visit (if any).

- Record nonstudy vaccinations as described in Section 6.5.

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- Collect and record concomitant medication associated with AE/SAEs.
- Collect a blood sample (approximately 20 mL) for immunogenicity testing.
- Record SAEs as described in Section 8.3.
- Collect the e-diary or assist the participant to delete the application.
- Complete the source documents.
- The investigator or an authorized designee completes the CRFs.

8.12. Unscheduled Visit for Reactogenicity Events

If a Grade 3 local reaction (Section 8.2.2.2), systemic event (Section 8.2.2.3), or fever (≥39.0°C [102.1°F]) (Section 8.2.2.4) is reported in the reactogenicity e-diary, a telephone contact should occur to ascertain further details and determine whether a site visit is clinically indicated. If suspected Grade 4 local reaction (Section 8.2.2.2), systemic event (Section 8.2.2.3), or fever (>40.0°C [>104.0°F]) (Section 8.2.2.4) is reported in the reactogenicity e-diary, a telephone contact or site visit should occur to confirm the fever and whether the event meets the criteria for Grade 4.

A site visit must be scheduled as soon as possible to assess the participant unless any of the following is true:

- The participant is unable to attend the unscheduled visit.
- The local reaction/systemic event is no longer present at the time of the telephone contact.
- The participant recorded an incorrect value in the reactogenicity e-diary (confirmation of a reactogenicity e-diary data entry error).
- The PI or authorized designee determined it was not needed.

This telephone contact will be recorded in the participant's source documentation and the CRF.

If the participant is unable to attend the unscheduled visit, or the PI or authorized designee determined it was not needed, any ongoing local reactions/systemic events must be assessed at the next study visit.

During the unscheduled visit, the reactions should be assessed by the investigator or a medically qualified member of the study staff such as a study physician or a study nurse, as applicable to the investigator's local practice, who will:

- Measure body temperature (°F/°C).

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- Measure minimum and maximum diameters of redness (if present).
- Measure minimum and maximum diameters of swelling (if present).
- Assess injection site pain (if present) in accordance with the grades provided in Section 8.2.2.2.
- Assess systemic events (if present) in accordance with the grades provided in Section 8.2.2.3.
- Assess for other findings associated with the reaction and record on the AE page of the CRF, if appropriate.

The investigator or an authorized designee will complete the unscheduled visit assessment page of the CRF.

8.13. COVID-19 Surveillance (All Maternal Participants)

If a participant experiences any of the following from the time of vaccination (irrespective of perceived etiology or clinical significance), she is instructed to contact the site immediately and, if confirmed, participate in an in-person or telehealth visit as soon as possible, optimally within 3 days after symptom onset (and at the latest 4 days after symptom resolution).
Note that:

- If new symptoms are reported within 4 days after resolution of all previous symptoms, they will be considered as part of a single illness and a second illness visit is not required;
- Surveillance of potential COVID-19 symptoms should continue even if a participant has a positive SARS-CoV-2 test earlier in the study.

During the 7 days following each vaccination, potential COVID-19 symptoms that overlap with specific systemic events (ie, fever, chills, new or increased muscle pain, diarrhea, vomiting) should not trigger a potential COVID-19 illness visit unless, in the investigator's opinion, the clinical picture is more indicative of a possible COVID-19 illness than vaccine reactogenicity.

If, in the investigator's opinion, the symptoms are considered more likely to be vaccine reactogenicity, but a participant is required to demonstrate that they are SARS-CoV-2–negative, a local SARS-CoV-2 test may be performed: if positive, the symptoms should be recorded as a potential COVID-19 illness; if not, the symptoms should be recorded as AEs (unless already captured in the reactogenicity e-diary).

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Maternal participants may utilize a COVID-19 illness e-diary through an application (see Section 8.15) installed on a provisioned device or on the participant's own personal device to prompt her to report any symptoms. Note that this does not substitute for a participant's routine medical care. Therefore, participants should be encouraged to seek care, if appropriate, from their usual provider.

- A diagnosis of COVID-19;
- Fever;
- New or increased cough;
- New or increased shortness of breath;
- Chills;
- New or increased muscle pain;
- New loss of taste/smell;
- Sore throat;
- Diarrhea;
- Vomiting.

8.13.1. Potential Maternal COVID-19 Illness Visit (Optimally Within 3 Days After Potential COVID-19 Illness Onset)

This visit may be conducted as an in-person or telehealth visit; a telehealth visit involves the sharing of healthcare information and services via telecommunication technologies (eg, audio, video, videoconferencing software) remotely, thus allowing the participant and investigator to communicate on aspects of clinical care.

As a participant's COVID-19 illness may evolve over time, several contacts may be required to obtain the following information:

- Record AEs, as appropriate as described in Section 8.3. Note: Potential COVID-19 illnesses that are consistent with the clinical endpoint definition should not be recorded as AEs. These data will be captured as efficacy assessment data only on the relevant pages of the CRF, as these are expected endpoints.
- Record details of any of the prohibited medications specified in Section 6.5.1 received by the participant if required for her clinical care.

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- If the visit is conducted in person, obtain a nasal (midturbinate) swab (collected by site staff). Alternatively, if conducted by telehealth, instruct the participant to self-collect a nasal (midturbinate) swab and ship for assessment at the central laboratory.

- Collect COVID-19–related standard-of-care clinical and laboratory information. This includes, but is not limited to:

- Symptoms and signs, including:

    - Clinical signs at rest indicative of severe systemic illness (RR ≥30 breaths/min, HR ≥125 beats/min, SpO_2 ≤93% on room air at sea level, or PaO_2/FiO_2 <300 mm Hg)

    - Evidence of shock (SBP <90 mm Hg, DBP <60 mm Hg, or requiring vasopressors)

    - Significant acute renal, hepatic, or neurologic dysfunction

    - Respiratory failure (defined as needing high-flow oxygen, noninvasive ventilation, mechanical ventilation, or ECMO)

    - Clinical diagnosis

    - Local laboratory SARS-CoV-2 test result(s)

      Note that if it is routine practice to perform a repeat local SARS-CoV-2 test for any reason, then a repeat nasal (midturbinate) swab should also be obtained and shipped for assessment at the central laboratory.

    - Full blood count

    - Blood chemistry, specifically creatinine, urea, LFTs, and CRP

    - Imaging results (eg, CT or MRI scan) to document neurologic dysfunction

    - Hospitalization

    - Admission to the ICU

    - Death

- Schedule an appointment for the participant to return for the potential COVID-19 convalescent visit once she has recovered.

- Complete the source documents.

- The investigator or an authorized designee completes the CRFs.

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8.13.2. Potential Maternal COVID-19 Convalescent Visit (28 to 35 Days After Potential COVID-19 Illness Visit)

- Record AEs, as appropriate as described in Section 8.3. Note: Potential COVID-19 illnesses that are consistent with the clinical endpoint definition should not be recorded as AEs. These data will be captured as efficacy assessment data only on the relevant pages of the CRF, as these are expected endpoints.
- Record details of any of the prohibited medications specified in Section 6.5.1 received by the participant if required for her clinical care.
- Collect a blood sample (approximately 20 mL) for immunogenicity testing.
- Collect/update COVID-19–related clinical and laboratory information (detailed in Section 8.13.1).
- Complete the source documents.
- The investigator or an authorized designee completes the CRFs.
- Record any AEs that occur within the 48 hours after the blood draw as described in Section 8.3.

8.14. Additional Procedures for Monitoring of Potential Myocarditis or Pericarditis

Any study participant who reports acute chest pain, shortness of breath, palpitations, or any other symptom(s) that might be indicative of myocarditis or pericarditis within 4 weeks after a study vaccination should be specifically evaluated, preferably by a cardiologist, for possible myocarditis or pericarditis.

In addition to a clinical evaluation, the following should be performed:

- ECG and
- Measurement of the troponin level

If myocarditis or pericarditis is suspected based upon the initial evaluation, the following should also be performed:

- Cardiac echocardiogram and/or
- Cardiac magnetic resonance study

Details of the symptoms reported, and results of the investigations performed, will be recorded in the CRF.

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8.15. Communication and Use of Technology

In a study of this nature that requires illness events to be reported outside of scheduled study visits, it is vital that communication between the study site and the maternal participant is maintained to ensure that endpoint events are not missed for her or her infant. This study will employ various methods, tailored to the individual participant, to ensure that communication is maintained and study information can be transmitted securely. Using appropriate technology, such as a study application, a communication pathway between the participant and the study site staff will be established. The participant may be able to utilize her own devices to access this technology, or use a device provided by the sponsor.

Traditional methods of telephone communication will also be available. The technology solution may facilitate the following:

- Contact with the investigator, including the ability of the participant to report whether or not the participant has experienced symptoms that could represent a potential COVID-19 illness (COVID-19 illness e-diary; see Section 8.13).
- An alert in the event that the participant is hospitalized.
- Visit reminders.
- Messages of thanks and encouragement from the study team.
- A platform for recording local reactions and systemic events (reactogenicity e-diary) – see Section 8.2.2.

If a maternal participant is not actively completing either the reactogenicity or COVID-19 illness e-diary, the investigator or designee is required to contact the participant to ascertain why and also to obtain details of any missed events.

8.16. SARS-CoV-2 NAAT Results From Visits 1 and 2 and Potential COVID-19 Illness Visits

Nasal (midturbinate) swabs for SARS-CoV-2 NAAT are obtained at:

- Visits 1 and 2: To determine whether a participant will be included in efficacy analyses of those with no serological or virological evidence (up to 7 days after receipt of the second dose) of past SARS-CoV-2 infection.
- Potential COVID-19 illness visits: To determine whether symptoms experienced by the participant fulfill the COVID-19 case definition.

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Research laboratory–generated positive results from the Visit 1 and Visit 2 swabs, and all results from the illness visit swabs, will be provided to the site once available, but this will not be in real time and cannot be relied upon to direct clinical care. Therefore, the participant should be directed to seek additional testing through her primary healthcare providers at a licensed clinical laboratory when exhibiting potential COVID-19 symptoms or otherwise receiving a positive result and counseled on whether to take any precautionary measures pending confirmatory testing.

Participants who have a positive SARS-CoV-2 NAAT result prior to Visit 2 should be handled as follows:

- Positive SARS-CoV-2 test with no symptoms, either at Visit 1 or any time between Visit 1 and Visit 2: A positive test in an asymptomatic participant does not meet exclusion criterion 2; therefore, Vaccination 2 should proceed as normal.

- Confirmed COVID-19 (ie, symptoms and positive SARS-CoV-2 test) diagnosed at Visit 1 or any time between Visit 1 and Visit 2 does not meet exclusion criterion 2; therefore, Vaccination 2 should proceed as normal.

8.17. Procedures for Administration of BNT162b2 to Those Originally Assigned to Placebo

Maternal participants will be given BNT162b2 at the 1-month postdelivery visit, and will follow the procedures listed in this section for the remainder of their participation in the study.

8.17.1. Visit 101 – Vaccination 3 – 1-Month Postdelivery Follow-up (Clinic: 21 to 35 Days After Delivery)

- Confirm that the participant originally received only placebo at Vaccination 1/2. Secondary confirmation by another site staff member is required.

- Before vaccination and before any study-related procedures are performed: Review and consider inclusion criteria 2, 5, and 11 and exclusion criteria 1, 3, 4, 5, 9, 13, 14, 15, and 17 prior to vaccination. If, in the investigator's judgment, vaccination is in the best interests of the participant, vaccination may proceed, even if inclusion criteria are not met and exclusion criteria are met. Such exceptions should be recorded in the participant's source documents.

- Record details of any of the prohibited medications specified in Section 6.5.1 received by the participant if required for her clinical care.

- Ensure that the participant meets none of the temporary delay criteria as described in Section 5.5.

- Record AEs as described in Section 8.3.

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- Collect a blood sample (approximately 20 mL) for immunogenicity testing.
- Obtain a nasal (midturbinate) swab (collected by site staff).
- Obtain the participant's vaccine vial allocation using the IRT system.
- Site staff member(s) will dispense/administer 1 dose of BNT162b2 into the deltoid muscle of the (preferably) nondominant arm.
- Site staff must observe the participant for at least 30 minutes after BNT162b2 administration for any acute reactions. Record any acute reactions (including time of onset) in the participant's source documents and on the AE page of the CRF, and on an SAE form as applicable.
- Ask the participant to contact the site staff or investigator if the participant experiences acute chest pain, shortness of breath, or palpitations (see Section 8.14).
- Ask the participant to contact the site staff or investigator if a medically attended event (eg, doctor's visit, emergency room visit) or hospitalization occurs.
- Schedule an appointment for the participant to return for the next study visit.
- Complete the source documents.
- The investigator or an authorized designee completes the CRFs and the dispenser/administrator updates the study intervention accountability records.

8.17.2. Visit 102 – Vaccination 4 (19 to 23 Days After Visit 101)

It is anticipated that the procedures below will be conducted in a stepwise manner.

- Record AEs as described in Section 8.3.
- Record details of any of the prohibited medications specified in Section 6.5.1 received by the participant if required for her clinical care.
- Before vaccination and before any study-related procedures are performed: Review and consider inclusion criteria 2, 5, and 11 and exclusion criteria 1, 3, 4, 5, 9, 13, 14, 15, and 17 prior to vaccination. If, in the investigator's judgment, vaccination is in the best interests of the participant, vaccination may proceed, even if inclusion criteria are not met and exclusion criteria are met. Such exceptions should be recorded in the participant's source documents.
- Ensure that the participant meets none of the temporary delay criteria as described in Section 5.5.

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- Obtain a nasal (midturbinate) swab (collected by site staff).
- Obtain the participant's vaccine vial allocation using the IRT system.
- Site staff member(s) will dispense/administer 1 dose of study intervention into the deltoid muscle of the (preferably) nondominant arm. Please refer to the IP manual for further instruction on this process.
- Site staff must observe the participant for at least 30 minutes after study intervention administration for any acute reactions. Record any acute reactions (including time of onset) in the participant's source documents and on the AE page of the CRF, and on an SAE form as applicable.
- Ask the participant to contact the site staff or investigator if the participant experiences acute chest pain, shortness of breath, or palpitations (see Section 8.14).
- Ask the participant to contact the site staff or investigator if a medically attended event (eg, doctor's visit, emergency room visit) or hospitalization occurs.
- Schedule an appointment to call the participant by telephone for the next study contact.
- Complete the source documents.
- The investigator or an authorized designee completes the CRFs and the dispenser/administrator updates the study intervention accountability records.

8.17.3. Visit 103 – 1-Month Follow-up Telephone Contact (After Vaccination 4) (28 to 35 Days After Visit 102)

- Contact the participant by telephone.
- Record AEs as described in Section 8.3.
- Record details of any of the prohibited medications specified in Section 6.5.1 received by the participant if required for her clinical care.
- Phase 3 only: For participants who are HIV-infected, record HIV viral load and CD4 count results from the most recent test performed since Visit 101 (if any).
- Ask the participant to contact the site staff or investigator if a medically attended event (eg, doctor's visit, emergency room visit) or hospitalization occurs.
- Ask the participant to contact the site staff or investigator if the participant experiences acute chest pain, shortness of breath, or palpitations (see Section 8.14).
- Complete the source documents.

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- The investigator or an authorized designee completes the CRFs.

8.18. Study Procedures – Infant Participants

8.18.1. Infant Participants: Visit 1 – Delivery

- Manually assign a single infant participant identifier. This will be assigned manually by the site using the following convention: the infant participant's identifier will be the maternal participant's IRT-generated numeric ID but with the fifth digit changed to a 2 (eg, if the maternal participant is given number 10011001, then the infant will be 10012001).

- Collect demography (including complete date of birth [ie, dd-Mmm-YYYY], sex, race, and ethnicity). The date of birth will be collected to critically evaluate the immune response.

- Measure vital signs, including temperature, heart rate, oxygen saturation by pulse oximetry, and respiratory rate.

- Standard-of-care vital signs and examination procedures can be considered for use in the study provided they were performed within 48 hours after birth. Note: Please reference the physical examination procedures below for details.

- Perform a physical examination, if not performed as part of standard of care, noting any clinically significant abnormalities within the following body systems: general appearance; skin; head, eyes, ears, nose, and throat; heart; lungs; abdomen; back; musculoskeletal; extremities; genitourinary; neurological; and lymph nodes. Abnormal results must be recorded on source documents as well as the physical examination pages of the CRF; only if the abnormal finding is deemed to be clinically significant should this be recorded on the AE pages of the CRF.

- Collect and record concomitant medication associated with AE/SAEs.

- Ensure and document that the infant is eligible.

- Collect a cord blood sample of approximately 10 mL for immunogenicity assessments. Cord blood is collected from the umbilical cord vein attached to the placenta prior to the blood clotting within the cord and after the umbilical cord has been clamped and cut.

- If cord blood is unavailable, a blood sample may be collected from the infant participant preferably within 72 hours. The volume of blood collected will be based on the weight of the infant (refer to Table 1).

- Record AEs, SAEs, and AESIs as described in Section 8.3.

- Schedule an appointment for the participant for the next study visit.

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- Ask the maternal participant to contact the site staff or investigator (this could be via the COVID-19 illness e-diary) immediately if the infant participant experiences any COVID-19 illness symptoms as detailed in Section 8.19.
- Complete the source documents.
- The investigator or an authorized designee completes the CRFs.

8.18.2. Visit 2 – 1-Week Postdelivery Follow-up (Telephone Call: 7-10 Days After Visit 1)

- Ensure and document that the infant is still eligible.
- Record breastfeeding information.
- Collect and record concomitant medication associated with AE/SAEs.
- Record AEs, SAEs, and AESIs as described in Section 8.3.
- Schedule an appointment for the participant to return for the next study visit.
- Ask the maternal participant to contact the site staff or investigator (this could be via the COVID-19 illness e-diary) immediately if the infant participant experiences any COVID-19 illness symptoms as detailed in Section 8.19.
- Complete the source documents.
- The investigator or an authorized designee completes the CRFs.

8.18.3. Visit 3 – 6-Months-of-Age Follow-up (Clinic: 160-200 Days After Visit 1)

- Record concomitant medication associated with SAEs.
- Record breastfeeding information.
- Collect a blood sample (approximately 5 mL) for immunogenicity testing. The volume of blood collected will be based on the weight of the infant (refer to Table 1).
- Record AEs, SAEs, and AESIs as described in Section 8.3.
- Collect e-diary or assist the maternal participant to delete application.
- Complete the source documents.
- The investigator or an authorized designee completes the CRFs.

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8.19. COVID-19 Surveillance (All Infant Participants)

If an infant participant experiences any of the following (irrespective of perceived etiology or clinical significance), the maternal participant is instructed to contact the site immediately and, if confirmed, participate in an in-person or telehealth visit as soon as possible, optimally within 3 days after symptom onset (and at the latest 4 days after symptom resolution). Note that this does not substitute for an infant participant's routine medical care. Therefore, maternal participants should be encouraged to seek care, if appropriate, from their infant's usual provider.

Additionally:

- If new symptoms are reported within 4 days after resolution of all previous symptoms, they will be considered as part of a single illness and a second illness visit is not required;
- Surveillance of potential COVID-19 symptoms should continue even if a participant has a positive SARS-CoV-2 test earlier in the study.

Signs and symptoms of an acute respiratory illness in the infant will not be considered a potential COVID-19–related illness if they occur within the first 72 hours after birth and should not trigger an illness visit.

- A diagnosis of COVID-19;
- Fever;
- New or increased cough;
- New or increased shortness of breath;
- Diarrhea;
- Vomiting.

8.19.1. Potential Infant COVID-19/MIS-C Illness Visit (Optimally Within 3 Days After Potential COVID-19 Illness Onset)

This visit may be conducted as an in-person or telehealth visit; a telehealth visit involves the sharing of healthcare information and services via telecommunication technologies (eg, audio, video, videoconferencing software) remotely, thus allowing the parent and investigator to communicate on aspects of the infant's clinical care.

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As a participant's COVID-19 illness may evolve over time, several contacts may be required to obtain the following information:

- Record AEs, as appropriate as described in Section 8.3. Note: Potential COVID-19 illnesses that are consistent with the clinical endpoint definition should not be recorded as AEs. These data will be captured as efficacy assessment data only on the relevant pages of the CRF, as these are expected endpoints.

- Record details of any of the prohibited medications specified in Section 6.5.1 received by the participant if required for his/her clinical care.

- If the visit is conducted in person, obtain a nasal swab (collected by site staff). Alternatively, if conducted by telehealth, instruct the maternal participant to collect a nasal swab from the infant and ship for assessment at the central laboratory.

- Collect COVID-19–related standard-of-care clinical and laboratory information. This includes, but is not limited to:

    - Clinical signs at rest indicative of severe systemic illness:

        - RR (breaths/min): >50 in birth to 1 week of age, ≥40 in 1 week to 1 month of age, ≥34 in 1 month to 6 months of age;

        - HR (beats/min): >180;

        - SpO_2 ≤92% on room air or >50% FiO_2 to maintain ≥92% or PaO_2/FiO_2 <300 mm Hg;

        - Respiratory failure (defined as needing high-flow oxygen including nasal CPaP/BiPaP, noninvasive ventilation, mechanical ventilation, or ECMO);

        - Evidence of shock or cardiac failure;

        - SBP (mm Hg):

        - <65 from birth to 1 week of age, <75 from 1 week to 1 month of age, <100 from 1 month to 6 months of age;

        OR

        - Requiring vasoactive drugs to maintain BP in the normal range;

        - Significant acute renal failure: serum creatinine >2 times ULN for age or 2-fold increase in baseline creatinine;

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- Significant GI/hepatic failure: total bilirubin >4 mg/dL or ALT 2 times ULN for age;
- Significant neurologic dysfunction: Glasgow Coma Scale score <11 or acute change in mental status with a decrease in Glasgow Coma Scale score ≥3 points from abnormal baseline;
- Admission to an ICU;
- Death;
- Clinical diagnosis;
- Local laboratory SARS-CoV-2 test result(s). Note that if it is routine practice to perform a repeat local SARS-CoV-2 test for any reason, then a repeat nasal swab should also be obtained and shipped for assessment at the central laboratory.
    - Full blood count, blood chemistry, specifically creatinine, urea, liver function tests, and CRP, ESR, fibrinogen, procalcitonin, D-dimer, ferritin, LDH, or IL-6 if available.

- Number and type of any healthcare contact; duration of hospitalization and ICU stay.

8.19.2. Potential Infant COVID-19 Convalescent Visit (28 to 35 Days After Potential COVID-19 Illness Visit)

- Record AEs, as appropriate as described in Section 8.3. Note: Potential COVID-19 illnesses that are consistent with the clinical endpoint definition should not be recorded as AEs. These data will be captured as efficacy assessment data only on the relevant pages of the CRF, as these are expected endpoints.
- Record details of any of the prohibited medications specified in Section 6.5.1 received by the participant if required for her clinical care.
- Collect a blood sample (up to 5 mL based on weight [Table 1]) for immunogenicity testing.
- Collect/update COVID-19–related clinical and laboratory information (detailed in Section 8.13.1).
- Complete the source documents.
- The investigator or an authorized designee completes the CRFs.
- Record any AEs that occur within the 48 hours after the blood draw as described in Section 8.3.

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9. STATISTICAL CONSIDERATIONS

Methodology for summary and statistical analyses of the data collected in this study is described here and further detailed in a SAP, which will be maintained by the sponsor. The SAP may modify what is outlined in the protocol where appropriate; however, any major modifications of the primary endpoint definitions or their analyses will also be reflected in a protocol amendment.

9.1. Estimands and Statistical Hypotheses

9.1.1. Estimands

The estimands corresponding to each primary, secondary, and exploratory objective are described in the table in Section 3.

In the primary safety objective evaluations, missing reactogenicity e-diary data will not be imputed. Missing AE start dates will be imputed according to Pfizer safety rules. No other missing information will be imputed in the safety analysis.

The estimands to evaluate the immunogenicity objectives are based on the evaluable immunogenicity populations (Section 9.3). These estimands estimate the vaccine effect in the hypothetical settings where participants follow the study schedules and protocol requirements as directed. Missing antibody results will not be imputed. Immunogenicity results that are below the LLOQ will be set to 0.5 × LLOQ in the analysis; this may be adjusted once additional data on the assay characteristics become available.

The estimands to evaluate the efficacy objectives are based on the evaluable efficacy populations (Section 9.3). These estimands estimate the vaccine effect in the hypothetical setting where participants follow the study schedules and protocol requirements as directed. In addition, VE will also be analyzed by the all-available efficacy (mITT) populations. Missing laboratory results will not be imputed.

9.1.2. Statistical Hypotheses

Due to early enrollment termination and reduced sample size, all endpoints will be analyzed descriptively without formal hypothesis tests.

9.2. Sample Size Determination

The sample size for the Phase 2 portion of the study and for the entire study is not driven by statistical hypothesis testing.

For safety outcomes, Table 5 shows the probability of observing at least 1 AE for a given true event rate of a particular AE, for various sample sizes. For example, if the true AE rate is 2%, with 100 participants in a vaccine group, there is 95% probability of observing at least 1 AE in Phase 2. If the true AE rate is 1%, with 175 participants in a vaccine group, there is 83% probability of observing at least 1 AE in Phase 3.

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Table 5. Probability of Observing at Least 1 AE by Assumed True Event Rates With Different Sample Sizes

Assumed True Event Rate of an AE	N=100	N=175
0.1%	0.10	0.16
0.3%	0.26	0.41
0.5%	0.39	0.58
0.8%	0.55	0.75
1.0%	0.63	0.83
2.0%	0.87	0.97
3.0%	0.95	>0.99

Note: N = number of participants in a vaccine group.

9.3. Analysis Sets

For purposes of analysis, the following analysis sets are defined:

Population	Description
Enrolled	All participants who have a signed ICD.
Randomized	All participants who are assigned a randomization number in the IWR system.
Evaluable immunogenicity (maternal)	All eligible randomized participants who receive 2 doses of the vaccine to which they are randomized with Dose 2 received within the predefined window, have at least 1 valid and determinate immunogenicity result from the blood sample collected within an appropriate window, and have no other important protocol deviations as determined by the clinician.
Dose 1 evaluable immunogenicity (maternal)	All eligible randomized participants who receive Dose 1 of the vaccine to which they are randomized, have at least 1 valid and determinate immunogenicity result from the blood sample collected after Dose 1 and before Dose 2, and have no other important protocol deviations before Dose 2 as determined by the clinician.
Evaluable immunogenicity (infant)	All infant participants born to evaluable immunogenicity maternal participants and have no important protocol deviations as determined by the clinician.
All-available immunogenicity (maternal)	All participants who receive at least 1 dose of the study intervention with at least 1 valid and determinate immunogenicity result after vaccination.
All-available immunogenicity (infant)	All infant participants born to all-available immunogenicity maternal participants.
Evaluable efficacy (maternal)	All eligible randomized participants who receive all vaccination(s) as randomized within the predefined window and have no other important protocol deviations as determined by the clinician.
All-available efficacy (mITT) (maternal)	Dose 1 all-available efficacy: All randomized participants who receive at least 1 vaccination. Dose 2 all-available efficacy: All randomized participants who complete 2 vaccination doses.
All-available efficacy (mITT) (infant)	All infant participants born to Dose 1 all-available maternal participants.

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Population	Description
Safety (maternal)	All randomized participants who receive at least 1 dose of the study intervention.
Safety (infant)	All infant participants born to maternal participants who receive at least 1 dose of the study intervention.

9.4. Statistical Analyses

The SAP will be developed and finalized before any analyses are performed and will describe the analyses and procedures for accounting for missing, unused, and spurious data. This section is a summary of the planned statistical analyses of the primary and secondary endpoints.

9.4.1. General Considerations

CIs for all endpoints in the statistical analysis will be presented as 2-sided at the 95% level unless specified otherwise.

The safety analyses are based on the safety populations. Participants will be summarized by vaccine group according to the study intervention they (or their mothers) actually received. Missing reactogenicity e-diary data will not be imputed; missing AE dates will be handled according to the Pfizer safety rules.

For all the immunogenicity endpoints, the analysis will be based on the evaluable immunogenicity populations. An additional analysis may be performed based on the all-available immunogenicity populations if there is a large enough difference in sample size between the all-available immunogenicity populations and the evaluable immunogenicity populations. Participants will be summarized according to the vaccine group to which they (or their mothers) were randomized. Missing serology data will not be imputed.

9.4.1.1. Analyses for Binary Data

Descriptive statistics for categorical variables (eg, proportions) are the percentage (%), the numerator (n) and the denominator (N) used in the percentage calculation, and the 95% CIs where applicable.

The exact 95% CI for binary endpoints for each group will be computed using the F distribution (Clopper-Pearson). The 95% CI for the between-group difference for binary endpoints will be calculated using the Miettinen and Nurminen method.

The 3-tier approach will be used to summarize AEs. For both Tier 1 (if any are identified during the study) and Tier 2 events, a 95% CI for the between-group difference in proportions will be calculated based on the Miettinen and Nurminen method. In addition, for Tier 1 events (if any), the asymptotic p-values will also be presented for the difference in proportions, based on the same test statistic and under the assumption that the test statistic is asymptotically normally distributed. For Tier 3 events, counts and percentages for each vaccine group will be provided.

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9.4.1.2. Analyses for Continuous Data

Unless otherwise stated, descriptive statistics for continuous variables are n, mean, median, standard deviation, minimum, and maximum.

9.4.1.2.1. Geometric Means

The geometric means will be calculated as the mean of the assay results after making the logarithm transformation and then exponentiating the mean to express results on the original scale. Two-sided 95% CIs will be obtained by taking log transforms of assay results, calculating the 95% CI with reference to Student's t-distribution, and then exponentiating the confidence limits.

9.4.1.2.2. Geometric Mean Fold Rises

GMFRs are defined as ratios of the results after vaccination to the results before vaccination. GMFRs are limited to participants with nonmissing values at both time points.

GMFRs will be calculated as the mean of the difference of logarithmically transformed neutralization titers or antibody levels (later time point minus earlier time point) and exponentiating the mean. The associated 2-sided 95% CIs are obtained by constructing CIs using Student's t-distribution for the mean difference on the logarithm scale and exponentiating the confidence limits.

9.4.1.2.3. Geometric Mean Ratios

The GMR will be calculated as the mean of the difference of logarithmically transformed assay results (eg, SARS-CoV-2 neutralizing titers in pregnant women minus that in nonpregnant women) and exponentiating the mean. Two-sided CIs will be obtained by calculating CIs using Student's t-distribution for the mean difference of the logarithmically transformed assay results and exponentiating the confidence limits.

9.4.1.2.4. Reverse Cumulative Distribution Curves

Empirical RCDCs will plot proportions of participants with values equal to or exceeding a specified assay value versus the indicated assay value, for all observed assay values. Data points will be joined by a step function with data points on the left side of the step.

9.4.2. Primary Endpoint(s)

Endpoint	Statistical Analysis Methods
Safety (maternal participants)	Descriptive statistics will be provided for each reactogenicity endpoint for each dose and vaccine group. Local reactions and systemic events from Day 1 through Day 7 after each vaccination (where Day 1 is the day of vaccination) will be presented by severity and cumulatively across severity levels. Descriptive summary statistics will include counts and percentages of participants with the indicated endpoint and the associated Clopper-Pearson 95% CIs (see Section 9.4.1.1).

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Endpoint	Statistical Analysis Methods
	AEs will be categorized according to MedDRA terms. Counts, percentages, and the associated Clopper-Pearson 95% CIs of AEs from Dose 1 to 1 month after Dose 2 will be provided for each vaccine group. A 3-tier approach will be used to summarize AEs in Phase 2/3. Under this approach AEs are classified into 1 of 3 tiers: (1) Tier 1 events are prespecified events of clinical importance and are identified in a list in the product's safety review plan; (2) Tier 2 events are those that are not Tier 1 but are considered "relatively common"; a MedDRA preferred term is defined as a Tier 2 event if there are at least 1% of participants in at least 1 vaccine group reporting the event; and (3) Tier 3 events are those that are neither Tier 1 nor Tier 2 events. Analysis methods are described in Section 9.4.1.1. SAEs will be categorized according to MedDRA terms. Counts, percentages, and the associated Clopper-Pearson 95% CIs of SAEs from Dose 1 through 1 month after delivery will be provided for each vaccine group. AEs and SAEs reported for maternal participants during the open-label follow-up period will be summarized separately.
Immunogenicity in participants without evidence of prior SARS-CoV-2 infection (maternal participants)	GMR, estimated by the ratio of the geometric mean of SARS-CoV-2 neutralizing titers in pregnant women to nonpregnant women 1 month after Dose 2 will be provided along with associated 2-sided 95% CIs (see Section 9.4.1.2.3). Only participants with no serological or virological evidence (up to 1 month after receipt of the second dose) of past SARS-CoV-2 infection will be included in the analysis. The nonpregnant women will be randomly selected from the female participants from study C4591001 in the same age group as the pregnant women.
Immunogenicity in participants with and without evidence of prior SARS-CoV-2 infection (maternal participants)	This endpoint will be analyzed the same way as for the participants without evidence of infection.

9.4.3. Secondary Endpoint(s)

Endpoint	Statistical Analysis Methods
Vaccine efficacy	**Ratio of confirmed COVID-19 illness from 7 days after Dose 2 through 1 month after delivery per 1000 person-years of blinded follow-up in participants without evidence of infection (prior to 7 days after receipt of Dose 2) for the active vaccine group to the placebo group** VE will be estimated by 100 × (1 - IRR), where IRR is the calculated ratio of first confirmed COVID-19 illness per 1000 person-years of blinded follow-up in the active vaccine group to the corresponding illness rate in the placebo group from 7 days after Dose 2. The 2-sided 95% CI for VE will be derived using the Clopper-Pearson method. **Ratio of confirmed COVID-19 illness from 7 days after Dose 2 through 1 month after delivery per 1000 person-years of blinded follow-up in maternal participants with and without evidence of infection (prior to 7 days after receipt of Dose 2) for the active vaccine group to the placebo group** The same analysis method used for the first VE endpoint will be applied.

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Endpoint	Statistical Analysis Methods
	Ratio of incidence of asymptomatic infection of SARS-CoV-2 in evaluable participants without evidence of prior SARS-CoV-2 infection for the active vaccine group to the placebo group VE will be estimated by 100 × (1 - IRR), where IRR is the calculated ratio of asymptomatic infection in the active vaccine group to the corresponding infection in the placebo group. The 2-sided 95% CI for VE will be provided using the Clopper-Pearson method. The analyses will be based on the evaluable efficacy population and the all-available efficacy population. Missing efficacy data will not be imputed.
Immunogenicity (maternal participants)	**GMTs/GMCs of SARS-CoV-2 neutralizing titers and full-length S-binding IgG levels at baseline, 2 weeks after Dose 2, 1 month after Dose 2, and 6 months after delivery** For SARS-CoV-2 neutralizing titers and full-length S-binding IgG levels, GMTs/GMCs and 2-sided 95% CIs will be provided for each vaccine group before vaccination and at each subsequent time point after vaccination. Statistical methods are described in Section 9.4.1.2.1. Empirical RCDCs will be provided for SARS-CoV-2 neutralizing titers (Section 9.4.1.2.4). **GMFRs of SARS-CoV-2 neutralizing titers and full-length S-binding IgG levels from before vaccination through 2 weeks after Dose 2, 1 month after Dose 2, and 6 months after delivery** For SARS-CoV-2 neutralizing titers and full-length S-binding IgG levels, the GMFRs and 2-sided 95% CIs will be provided for each vaccine group from before vaccination to each subsequent time point after vaccination. GMFRs will be limited to participants with nonmissing values prior to the first dose and at the postvaccination time point. The statistical methods are described in Section 9.4.1.2.2.
Safety (infant participants)	Counts, percentages, and the associated Clopper-Pearson 95% CIs for infant participants with specific birth outcomes, AEs from birth through 1 month of age, and SAEs and AESIs through 6 months of age will be provided by vaccine group according to the study intervention the maternal participants received. A 3-tier approach will be used to summarize AEs.
Immunogenicity (infant participants)	GMCs at birth and 6 months after delivery, and GMFRs for full-length S-binding IgG levels, will be summarized for infant participants using the same statistical analysis method described for the secondary immunogenicity endpoints for maternal participants.

9.4.4. Exploratory Endpoint(s)

Endpoint	Statistical Analysis Methods
COVID-19 incidence rate (maternal participants)	Incidence rate (per 1000 person-years of follow-up) and 2-sided 95% CI for confirmed COVID-19 illness from 7 days after the second dose of BNT162b2 will be provided for participants who received BNT162b2 at initial randomization.

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Endpoint	Statistical Analysis Methods
Asymptomatic SARS-CoV-2 infection (maternal participants)	Incidence rate (per 1000 person-years of follow-up) and 2-sided 95% CI for asymptomatic SARS-CoV-2 infection based on the N-binding antibody seroconversion for participants who received BNT162b2 at initial randomization and have no serological or virological evidence of prior SARS-CoV-2 infection.
Serological responses by COVID-19 and SARS-CoV-2 infection status (maternal participants)	In each subset of participants with confirmed COVID-19, confirmed severe COVID-19, and SARS-CoV-2 infection without confirmed COVID-19, GMTs/GMCs and GMFRs of SARS-CoV-2 neutralizing titers and full-length S-binding IgG levels will be summarized using the same statistical analysis method described for the secondary immunogenicity endpoints (maternal).
Immunogenicity from baseline to before Dose 2 (Phase 2 maternal participants)	In maternal participants enrolled in the Phase 2 portion of the study, GMTs/GMCs and GMFRs of SARS-CoV-2 neutralizing titers and full-length S-binding IgG levels at baseline and before Dose 2 will be summarized using the same statistical analysis method described for the secondary immunogenicity endpoints (maternal).
Immunogenicity (infant participants by breastfeeding status)	For infants breastfed and not breastfed, respectively, GMCs at birth and 6 months after delivery, and GMFRs for full-length S-binding IgG levels, will be summarized using the same statistical analysis method described for the secondary immunogenicity endpoints for maternal participants.
Safety (infant participants by breastfeeding status)	For infants breastfed and not breastfed, respectively, counts, percentages, and the associated Clopper-Pearson 95% CIs for infant participants with AEs from birth through 1 month of age, and SAEs and AESIs through 6 months of age, will be provided by vaccine group according to the study intervention the maternal participants received.
COVID-19 incidence rate (infant participants)	Counts, incidence of COVID-19 per 1000 person-years of follow-up, and the associated 2-sided 95% CIs will be provided for each vaccine group in the infants participants.
MIS-C cases (infant participants)	Counts, incidence of MIS-C per 1000 person-years of follow-up, and the associated 2-sided 95% CIs will be provided for each vaccine group in the infants participants.

9.5. Interim Analyses

No formal interim analysis will be conducted for this study. Statistical analyses will be carried out when the final data for specified objectives are available while the study is ongoing. The timing of these planned analysis and reporting events is described in the section below.

9.5.1. Analysis Timing

Statistical analyses will be carried out when the following data are available:

- Immunogenicity data through 1 month after Dose 2 from all randomized maternal participants for assessment of SARS-CoV-2 neutralizing titers.
- Complete safety and immunogenicity analysis after complete data are available or at the end of the study.

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Additional analyses may be conducted if required for regulatory purposes. All analyses conducted while the study is ongoing will be performed by an unblinded statistical team.

9.6. Data Monitoring Committee or Other Independent Oversight Committee

This study will use an IRC, a DMC, and a group of internal case reviewers. The IRC is independent of the study team and includes only internal members. The DMC is independent of the study team and includes only external members. The IRC and DMC charters describe the role of the IRC and DMC in more detail.

The DMC will be responsible for ongoing monitoring of the safety of participants in the study according to the charter. The recommendations made by the DMC to alter the conduct of the study will be forwarded to the appropriate Pfizer personnel for final decision. Pfizer will forward such decisions, which may include summaries of aggregate analyses of safety data, to regulatory authorities, as appropriate.

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10. SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

10.1. Appendix 1: Regulatory, Ethical, and Study Oversight Considerations

10.1.1. Regulatory and Ethical Considerations

This study will be conducted in accordance with the protocol and with the following:

- Consensus ethical principles derived from international guidelines including the Declaration of Helsinki and CIOMS International Ethical Guidelines;
- Applicable ICH GCP guidelines;
- Applicable laws and regulations, including applicable privacy laws.

The protocol, protocol amendments, ICD, SRSD(s), and other relevant documents (eg, advertisements) must be reviewed and approved by the sponsor and submitted to an IRB/EC by the investigator and reviewed and approved by the IRB/EC before the study is initiated.

Any amendments to the protocol will require IRB/EC approval before implementation of changes made to the study design, except for changes necessary to eliminate an immediate hazard to study participants.

The investigator will be responsible for the following:

- Providing written summaries of the status of the study to the IRB/EC annually or more frequently in accordance with the requirements, policies, and procedures established by the IRB/EC;
- Notifying the IRB/EC of SAEs or other significant safety findings as required by IRB/EC procedures;
- Providing oversight of the conduct of the study at the site and adherence to requirements of 21 CFR, ICH guidelines, the IRB/EC, European regulation 536/2014 for clinical studies (if applicable), and all other applicable local regulations.

10.1.1.1. Reporting of Safety Issues and Serious Breaches of the Protocol or ICH GCP

In the event of any prohibition or restriction imposed (ie, clinical hold) by an applicable regulatory authority in any area of the world, or if the investigator is aware of any new information that might influence the evaluation of the benefits and risks of the study intervention, Pfizer should be informed immediately.

In addition, the investigator will inform Pfizer immediately of any urgent safety measures taken by the investigator to protect the study participants against any immediate hazard, and of any serious breaches of this protocol or of ICH GCP that the investigator becomes aware of.

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10.1.2. Financial Disclosure

Investigators and subinvestigators will provide the sponsor with sufficient, accurate financial information as requested to allow the sponsor to submit complete and accurate financial certification or disclosure statements to the appropriate regulatory authorities. Investigators are responsible for providing information on financial interests during the course of the study and for 1 year after completion of the study.

10.1.3. Informed Consent Process

The investigator or his/her representative will explain the nature of the study to the participant and answer all questions regarding the study. The participant should be given sufficient time and opportunity to ask questions and to decide whether or not to participate in the trial.

Participants must be informed that their participation is voluntary. Participants will be required to sign a statement of informed consent that meets the requirements of 21 CFR 50, local regulations, ICH guidelines, HIPAA requirements, where applicable, and the IRB/EC or study center.

The investigator must ensure that each study participant is fully informed about the nature and objectives of the study, the sharing of data related to the study, and possible risks associated with participation, including the risks associated with the processing of the participant's personal data.

The participant must be informed that her personal study-related data will be used by the sponsor in accordance with local data protection law. The level of disclosure must also be explained to the participant.

The participant must be informed that her medical records may be examined by Clinical Quality Assurance auditors or other authorized personnel appointed by the sponsor, by appropriate IRB/EC members, and by inspectors from regulatory authorities.

The investigator further must ensure that each study participant is fully informed about her right to access and correct her personal data and to withdraw consent for the processing of her personal data.

The medical record must include a statement that written informed consent was obtained before the participant was enrolled in the study and the date the written consent was obtained. The authorized person obtaining the informed consent must also sign the ICD.

Participants must be reconsented to the most current version of the ICD(s) during their participation in the study.

A copy of the ICD(s) must be provided to the participant.

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Before any study-specific activity is performed, the investigator, or a person designated by the investigator, will obtain written informed consent from each maternal participant. This will include written informed consent for the mother and the fetus during the pregnancy, and the infant's continuation in the study after delivery. Informed consent will be obtained from the father of the fetus/infant if mandated by local requirements.

Participants who are rescreened are required to sign a new ICD.

Unless prohibited by local requirements or IRB/EC decision, the ICD will contain a separate section that addresses the use of samples for optional additional research. The optional additional research does not require the collection of any further samples. The investigator or authorized designee will explain to each participant the objectives of the additional research. Participants will be told that they are free to refuse to participate and may withdraw their consent at any time and for any reason during the storage period.

10.1.4. Data Protection

All parties will comply with all applicable laws, including laws regarding the implementation of organizational and technical measures to ensure protection of participant data.

Participants' personal data will be stored at the study site in encrypted electronic and/or paper form and will be password protected or secured in a locked room to ensure that only authorized study staff have access. The study site will implement appropriate technical and organizational measures to ensure that the personal data can be recovered in the event of disaster. In the event of a potential personal data breach, the study site will be responsible for determining whether a personal data breach has in fact occurred and, if so, providing breach notifications as required by law.

To protect the rights and freedoms of participants with regard to the processing of personal data, participants will be assigned a single, participant-specific numerical code. Any participant records or data sets that are transferred to the sponsor will contain the numerical code; participant names will not be transferred. All other identifiable data transferred to the sponsor will be identified by this single, participant-specific code. The study site will maintain a confidential list of participants who participated in the study, linking each participant's numerical code to her actual identity and medical record identification. In case of data transfer, the sponsor will protect the confidentiality of participants' personal data consistent with the clinical study agreement and applicable privacy laws.

10.1.5. Dissemination of Clinical Study Data

Pfizer fulfills its commitment to publicly disclose clinical study results through posting the results of studies on www.clinicaltrials.gov (ClinicalTrials.gov), the EudraCT, and/or www.pfizer.com, and other public registries in accordance with applicable local laws/regulations. In addition, Pfizer reports study results outside of the requirements of local laws/regulations pursuant to its SOPs.

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In all cases, study results are reported by Pfizer in an objective, accurate, balanced, and complete manner and are reported regardless of the outcome of the study or the country in which the study was conducted.

www.clinicaltrials.gov

Pfizer posts clinical trial results on www.clinicaltrials.gov for Pfizer-sponsored interventional studies (conducted in patients) that evaluate the safety and/or efficacy of a product, regardless of the geographical location in which the study is conducted. These results are submitted for posting in accordance with the format and timelines set forth by US law.

EudraCT

Pfizer posts clinical trial results on EudraCT for Pfizer-sponsored interventional studies in accordance with the format and timelines set forth by EU requirements.

www.pfizer.com

Pfizer posts public disclosure synopses (CSR synopses in which any data that could be used to identify individual participants have been removed) on www.pfizer.com for Pfizer-sponsored interventional studies at the same time the corresponding study results are posted to www.clinicaltrials.gov.

Documents Within Marketing Authorization Packages/Submissions

Pfizer complies with the European Union Policy 0070, the proactive publication of clinical data to the EMA website. Clinical data, under Phase 1 of this policy, includes clinical overviews, clinical summaries, CSRs, and appendices containing the protocol and protocol amendments, sample CRFs, and statistical methods. Clinical data, under Phase 2 of this policy, includes the publishing of individual participant data. Policy 0070 applies to new marketing authorization applications submitted via the centralized procedure since 01 January 2015 and applications for line extensions and for new indications submitted via the centralized procedure since 01 July 2015.

Data Sharing

Pfizer provides researchers secure access to patient-level data or full CSRs for the purposes of "bona-fide scientific research" that contributes to the scientific understanding of the disease, target, or compound class. Pfizer will make available data from these trials 24 months after study completion. Patient-level data will be anonymized in accordance with applicable privacy laws and regulations. CSRs will have personally identifiable information redacted.

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Data requests are considered from qualified researchers with the appropriate competencies to perform the proposed analyses. Research teams must include a biostatistician. Data will not be provided to applicants with significant conflicts of interest, including individuals requesting access for commercial/competitive or legal purposes.

10.1.6. Data Quality Assurance

All participant data relating to the study will be recorded on printed or electronic CRF unless transmitted to the sponsor or designee electronically (eg, laboratory data). The investigator is responsible for verifying that data entries are accurate and correct by physically or electronically signing the CRF.

The investigator must maintain accurate documentation (source data) that supports the information entered in the CRF.

The investigator must ensure that the CRFs are securely stored at the study site in encrypted electronic and/or paper form and are password protected or secured in a locked room to prevent access by unauthorized third parties.

The investigator must permit study-related monitoring, audits, IRB/EC review, and regulatory agency inspections and provide direct access to source data documents. This verification may also occur after study completion. It is important that the investigator(s) and their relevant personnel are available during the monitoring visits and possible audits or inspections and that sufficient time is devoted to the process.

Monitoring details describing strategy (eg, risk-based initiatives in operations and quality such as risk management and mitigation strategies and analytical risk-based monitoring), methods, responsibilities, and requirements, including handling of noncompliance issues and monitoring techniques (central, remote, or on-site monitoring), are provided in the monitoring plan.

The sponsor or designee is responsible for the data management of this study, including quality checking of the data.

Study monitors will perform ongoing source data verification to confirm that data entered into the CRF by authorized site personnel are accurate, complete, and verifiable from source documents; that the safety and rights of participants are being protected; and that the study is being conducted in accordance with the currently approved protocol and any other study agreements, ICH GCP, and all applicable regulatory requirements.

Records and documents, including signed ICDs, pertaining to the conduct of this study must be retained by the investigator for 15 years after study completion unless local regulations or institutional policies require a longer retention period. No records may be destroyed during the retention period without the written approval of the sponsor. No records may be transferred to another location or party without written notification to the sponsor. The investigator must ensure that the records continue to be stored securely for as long as they are maintained.

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When participant data are to be deleted, the investigator will ensure that all copies of such data are promptly and irrevocably deleted from all systems.

The investigator(s) will notify the sponsor or its agents immediately of any regulatory inspection notification in relation to the study. Furthermore, the investigator will cooperate with the sponsor or its agents to prepare the investigator site for the inspection and will allow the sponsor or its agent, whenever feasible, to be present during the inspection. The investigator site and investigator will promptly resolve any discrepancies that are identified between the study data and the participant's medical records. The investigator will promptly provide copies of the inspection findings to the sponsor or its agent. Before response submission to the regulatory authorities, the investigator will provide the sponsor or its agents with an opportunity to review and comment on responses to any such findings.

10.1.7. Source Documents

Source documents provide evidence for the existence of the participant and substantiate the integrity of the data collected. Source documents are filed at the investigator site.

Data reported on the CRF or entered in the eCRF that are from source documents must be consistent with the source documents or the discrepancies must be explained. The investigator may need to request previous medical records or transfer records, depending on the study. Also, current medical records must be available.

Definition of what constitutes source data can be found in the clinical monitoring plan.

Description of the use of computerized system is documented in the Data Management Plan.

10.1.8. Study and Site Start and Closure

The study start date is the date on which the clinical study will be open for recruitment of participants.

The first act of recruitment is the date of the first participant’s first visit and will be the study start date.

The sponsor designee reserves the right to close the study site or terminate the study at any time for any reason at the sole discretion of the sponsor. Study sites will be closed upon study completion. A study site is considered closed when all required documents and study supplies have been collected and a study-site closure visit has been performed.

The investigator may initiate study-site closure at any time upon notification to the sponsor or designee if requested to do so by the responsible IRB/EC or if such termination is required to protect the health of study participants.

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Reasons for the early closure of a study site by the sponsor may include but are not limited to:

- Failure of the investigator to comply with the protocol, the requirements of the IRB/EC or local health authorities, the sponsor's procedures, or GCP guidelines;
- Inadequate recruitment of participants by the investigator;
- Discontinuation of further study intervention development.

If the study is prematurely terminated or suspended, the sponsor shall promptly inform the investigators, the ECs/IRBs, the regulatory authorities, and any CRO(s) used in the study of the reason for termination or suspension, as specified by the applicable regulatory requirements. The investigator shall promptly inform the participant and should assure appropriate participant therapy and/or follow-up.

Study termination is also provided for in the clinical study agreement. If there is any conflict between the contract and this protocol, the contract will control as to termination rights.

10.1.9. Publication Policy

The results of this study may be published or presented at scientific meetings by the investigator after publication of the overall study results or 1 year after the end of the study (or study termination), whichever comes first.

The investigator agrees to refer to the primary publication in any subsequent publications such as secondary manuscripts, and submits all manuscripts or abstracts to the sponsor 30 days before submission. This allows the sponsor to protect proprietary information and to provide comments and the investigator will, on request, remove any previously undisclosed confidential information before disclosure, except for any study- or Pfizer intervention-related information necessary for the appropriate scientific presentation or understanding of the study results.

For all publications relating to the study, the investigator will comply with recognized ethical standards concerning publications and authorship, including those established by the International Committee of Medical Journal Editors.

The sponsor will comply with the requirements for publication of the overall study results covering all investigator sites. In accordance with standard editorial and ethical practice, the sponsor will support publication of multicenter studies only in their entirety and not as individual site data. In this case, a coordinating investigator will be designated by mutual agreement.

Authorship of publications for the overall study results will be determined by mutual agreement and in line with International Committee of Medical Journal Editors authorship requirements.

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If publication is addressed in the clinical study agreement, the publication policy set out in this section will not apply.

10.1.10. Sponsor's Qualified Medical Personnel

The contact information for the sponsor's appropriately qualified medical personnel for the study is documented in the study contact list located in the supporting study documentation.

To facilitate access to appropriately qualified medical personnel on study-related medical questions or problems, participants are provided with a contact card at the time of informed consent. The contact card contains, at a minimum, protocol and study intervention identifiers, participant numbers, contact information for the investigator site, and contact details for a contact center in the event that the investigator site staff cannot be reached to provide advice on a medical question or problem originating from another healthcare professional not involved in the participant's participation in the study. The contact number can also be used by investigator staff if they are seeking advice on medical questions or problems; however, it should be used only in the event that the established communication pathways between the investigator site and the study team are not available. It is therefore intended to augment, but not replace, the established communication pathways between the investigator site and the study team for advice on medical questions or problems that may arise during the study. The contact number is not intended for use by the participant directly, and if a participant calls that number, she will be directed back to the investigator site.

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10.2. Appendix 2: Adverse Events: Definitions and Procedures for Recording, Evaluating, Follow-up, and Reporting

For maternal immunization clinical studies conducted in pregnant women, data on the EDP as well as pregnancy outcome are collected and analyzed in the clinical database. For these studies, in general, EDP cases are not reportable unless associated with SAEs/nonserious AEs.

The term "participant" in this section refers to (1) the maternal participant and her fetus; and after delivery (2) the maternal participant and (3) the infant participant.

10.2.1. Definition of AE

AE Definition
• An AE is any untoward medical occurrence in a patient or clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. • NOTE: An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of study intervention.

Events <u>Meeting</u> the AE Definition

• Any abnormal laboratory test results (hematology, clinical chemistry, or urinalysis) or other safety assessments (eg, ECG, radiological scans, vital sign measurements), including those that worsen from baseline, considered clinically significant in the medical and scientific judgment of the investigator. Any abnormal laboratory test results that meet any of the conditions below must be recorded as an AE:
  • Is associated with accompanying symptoms;
  • Requires additional diagnostic testing or medical/surgical intervention;
  • Leads to a change in study dosing (outside of any protocol-specified dose adjustments) or discontinuation from the study, significant additional concomitant drug treatment, or other therapy.
• Exacerbation of a chronic or intermittent preexisting condition including either an increase in frequency and/or intensity of the condition.
• New conditions detected or diagnosed after study intervention administration even though it may have been present before the start of the study.
• Signs, symptoms, or the clinical sequelae of a suspected drug-drug interaction.

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- Signs, symptoms, or the clinical sequelae of a suspected overdose of either study intervention or a concomitant medication. Overdose per se will not be reported as an AE/SAE unless it is an intentional overdose taken with possible suicidal/self-harming intent. Such overdoses should be reported regardless of sequelae.

Events NOT Meeting the AE Definition

- Any clinically significant abnormal laboratory findings or other abnormal safety assessments which are associated with the underlying disease, unless judged by the investigator to be more severe than expected for the participant's condition.
- The disease/disorder being studied or expected progression, signs, or symptoms of the disease/disorder being studied, unless more severe than expected for the participant's condition.
- Medical or surgical procedure (eg, endoscopy, appendectomy): the condition that leads to the procedure is the AE.
- Situations in which an untoward medical occurrence did not occur (social and/or convenience admission to a hospital).
- Anticipated day-to-day fluctuations of preexisting disease(s) or condition(s) present or detected at the start of the study that do not worsen.

10.2.2. Definition of SAE

If an event is not an AE per definition above, then it cannot be an SAE even if serious conditions are met (eg, hospitalization for signs/symptoms of the disease under study, death due to progression of disease).

An SAE is defined as any untoward medical occurrence that, at any dose:

a. **Results in death**

b. **Is life-threatening**

The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event. It does not refer to an event that hypothetically might have caused death if it were more severe.

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c. **Requires inpatient hospitalization or prolongation of existing hospitalization**

In general, hospitalization signifies that the participant has been detained (usually involving at least an overnight stay) at the hospital or emergency ward for observation and/or treatment that would not have been appropriate in the physician's office or outpatient setting. Complications that occur during hospitalization are AEs. If a complication prolongs hospitalization or fulfills any other serious criteria, the event is serious. When in doubt as to whether "hospitalization" occurred or was necessary, the AE should be considered serious.

Hospitalization for elective treatment of a preexisting condition that did not worsen from baseline is not considered an AE.

d. **Results in persistent disability/incapacity**

- The term disability means a substantial disruption of a person's ability to conduct normal life functions.
- This definition is not intended to include experiences of relatively minor medical significance such as uncomplicated headache, nausea, vomiting, diarrhea, influenza, and accidental trauma (eg, sprained ankle) which may interfere with or prevent everyday life functions but do not constitute a substantial disruption.

e. **Is a congenital anomaly/birth defect**

f. **Other situations:**

- Medical or scientific judgment should be exercised in deciding whether SAE reporting is appropriate in other situations such as important medical events that may not be immediately life-threatening or result in death or hospitalization but may jeopardize the participant or may require medical or surgical intervention to prevent one of the other outcomes listed in the above definition. These events should usually be considered serious.
- Examples of such events include invasive or malignant cancers, intensive treatment in an emergency room or at home for allergic bronchospasm, blood dyscrasias or convulsions that do not result in hospitalization, or development of drug dependency or drug abuse.
- Suspected transmission via a Pfizer product of an infectious agent, pathogenic or non-pathogenic, is considered serious. The event may be suspected from clinical symptoms or laboratory findings indicating an infection in a patient exposed to a Pfizer product. The terms "suspected transmission" and "transmission" are considered synonymous. These cases are considered unexpected and handled as serious expedited cases by pharmacovigilance personnel. Such cases are also considered for reporting as product defects, if appropriate.

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10.2.3. Recording/Reporting and Follow-up of AEs and/or SAEs

AE and SAE Recording/Reporting

The table below summarizes the requirements for recording safety events on the CRF and for reporting safety events on the Vaccine SAE Reporting Form to Pfizer Safety. These requirements are delineated for 3 types of events: (1) SAEs; (2) nonserious AEs; and (3) occupational exposure.

It should be noted that the Vaccine SAE Reporting Form for reporting of SAE information is not the same as the AE page of the CRF. When the same data are collected, the forms must be completed in a consistent manner. AEs should be recorded using concise medical terminology and the same AE term should be used on both the CRF and the Vaccine SAE Reporting Form for reporting of SAE information.

Safety Event	Recorded on the CRF	Reported on the Vaccine SAE Reporting Form to Pfizer Safety Within 24 Hours of Awareness
SAE	All	All
Nonserious AE	All	None
Exposure to the study intervention under study via occupational exposure	Occupational exposure is not recorded.	Occupational exposure (regardless of whether associated with an AE) Note: Include all AEs/SAEs associated with occupational exposure.

- When an AE/SAE occurs, it is the responsibility of the investigator to review all documentation (eg, hospital progress notes, laboratory reports, and diagnostic reports) related to the event.
- The investigator will then record all relevant AE/SAE information in the CRF.
- It is **not** acceptable for the investigator to send photocopies of the participant's medical records to Pfizer Safety in lieu of completion of the Vaccine SAE Reporting Form/AE/SAE CRF page.
- There may be instances when copies of medical records for certain cases are requested by Pfizer Safety. In this case, all participant identifiers, with the exception of the participant number, will be redacted on the copies of the medical records before submission to Pfizer Safety.
- The investigator will attempt to establish a diagnosis of the event based on signs, symptoms, and/or other clinical information. Whenever possible, the diagnosis (not the individual signs/symptoms) will be documented as the AE/SAE.

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Assessment of Intensity

The investigator will make an assessment of intensity for each AE and SAE reported during the study and assign it to 1 of the following categories:

GRADE	If required on the AE page of the CRF, the investigator will use the adjectives MILD, MODERATE, SEVERE, or LIFE-THREATENING to describe the maximum intensity of the AE. For purposes of consistency, these intensity grades are defined as follows:	
1	MILD	Does not interfere with participant's usual function.
2	MODERATE	Interferes to some extent with participant's usual function.
3	SEVERE	Interferes significantly with participant's usual function.
4	LIFE-THREATENING	Life-threatening consequences; urgent intervention indicated.

An event is defined as "serious" when it meets at least 1 of the predefined outcomes as described in the definition of an SAE, NOT when it is rated as severe.

Assessment of Causality

- The investigator is obligated to assess the relationship between study intervention and each occurrence of each AE/SAE.
- A "reasonable possibility" of a relationship conveys that there are facts, evidence, and/or arguments to suggest a causal relationship, rather than a relationship cannot be ruled out.
- The investigator will use clinical judgment to determine the relationship.
- Alternative causes, such as underlying disease(s), concomitant therapy, and other risk factors, as well as the temporal relationship of the event to study intervention administration, will be considered and investigated.
- The investigator will also consult the IB and/or product information, for marketed products, in his/her assessment.
- For each AE/SAE, the investigator **must** document in the medical notes that he/she has reviewed the AE/SAE and has provided an assessment of causality.
- There may be situations in which an SAE has occurred and the investigator has minimal information to include in the initial report to the sponsor. However, **it is very important that the investigator always make an assessment of causality for every event before the initial transmission of the SAE data to the sponsor.**

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- The investigator may change his/her opinion of causality in light of follow-up information and send an SAE follow-up report with the updated causality assessment.
- The causality assessment is one of the criteria used when determining regulatory reporting requirements.
- If the investigator does not know whether or not the study intervention caused the event, then the event will be handled as "related to study intervention" for reporting purposes, as defined by the sponsor. In addition, if the investigator determines that an SAE is associated with study procedures, the investigator must record this causal relationship in the source documents and CRF, and report such an assessment in the dedicated section of the Vaccine SAE Reporting Form and in accordance with the SAE reporting requirements.

Follow-up of AEs and SAEs

- The investigator is obligated to perform or arrange for the conduct of supplemental measurements and/or evaluations as medically indicated or as requested by the sponsor to elucidate the nature and/or causality of the AE or SAE as fully as possible. This may include additional laboratory tests or investigations, histopathological examinations, or consultation with other healthcare providers.
- If a participant dies during participation in the study or during a recognized follow-up period, the investigator will provide Pfizer Safety with a copy of any postmortem findings including histopathology.
- New or updated information will be recorded in the originally completed CRF.
- The investigator will submit any updated SAE data to the sponsor within 24 hours of receipt of the information.

10.2.4. Reporting of SAEs

SAE Reporting to Pfizer Safety via an Electronic Data Collection Tool

- The primary mechanism for reporting an SAE to Pfizer Safety will be the electronic data collection tool.
- If the electronic system is unavailable, then the site will use the paper SAE data collection tool (see next section) in order to report the event within 24 hours.

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- The site will enter the SAE data into the electronic system as soon as the data become available.
- After the study is completed at a given site, the electronic data collection tool will be taken off-line to prevent the entry of new data or changes to existing data.
- If a site receives a report of a new SAE from a study participant or receives updated data on a previously reported SAE after the electronic data collection tool has been taken off-line, then the site can report this information on a paper SAE form (see next section) or to Pfizer Safety by telephone.

SAE Reporting to Pfizer Safety via Vaccine SAE Reporting Form

- Facsimile transmission of the Vaccine SAE Reporting Form is the preferred method to transmit this information to Pfizer Safety.
- In circumstances when the facsimile is not working, notification by telephone is acceptable with a copy of the Vaccine SAE Reporting Form sent by overnight mail or courier service.
- Initial notification via telephone does not replace the need for the investigator to complete and sign the Vaccine SAE Reporting Form pages within the designated reporting time frames.

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10.3. Appendix 3: Liver Safety: Suggested Actions and Follow-up Assessments

Potential Cases of Drug Induced Liver Injury

Humans exposed to a drug who show no sign of liver injury (as determined by elevations in transaminases) are termed “tolerators,” while those who show transient liver injury, but adapt are termed “adaptors.” In some participants, transaminase elevations are a harbinger of a more serious potential outcome. These participants fail to adapt and therefore are "susceptible" to progressive and serious liver injury, commonly referred to as DILI. Participants who experience a transaminase elevation above 3 × ULN should be monitored more frequently to determine if they are an “adaptor” or are “susceptible.”

LFTs are not required as a routine safety monitoring procedure in this study. However, should an investigator deem it necessary to assess LFTs because a participant presents with clinical signs/symptoms, such LFT results should be managed and followed as described below.

Studies that include more detailed hepatic safety assessments (eg, an external hepatic expert panel or DMC that has separate definitions and charter) will still need to follow the reporting guidelines described below for applicable cases.

In the majority of DILI cases, elevations in AST and/or ALT precede TBili elevations (>2 × ULN) by several days or weeks. The increase in TBili typically occurs while AST/ALT is/are still elevated above 3 × ULN (ie, AST/ALT and TBili values will be elevated within the same laboratory sample). In rare instances, by the time TBili elevations are detected, AST/ALT values might have decreased. This occurrence is still regarded as a potential DILI. Therefore, abnormal elevations in either AST OR ALT in addition to TBili that meet the criteria outlined below are considered potential DILI (assessed per Hy’s law criteria) cases and should always be considered important medical events, even before all other possible causes of liver injury have been excluded.

The threshold of laboratory abnormalities for a potential DILI case depends on the participant’s individual baseline values and underlying conditions. Participants who present with the following laboratory abnormalities should be evaluated further as potential DILI (Hy’s law) cases to definitively determine the etiology of the abnormal laboratory values:

Participants with AST/ALT and TBili baseline values within the normal range who subsequently present with AST OR ALT values >3 × ULN AND a TBili value >2 × ULN with no evidence of hemolysis and an alkaline phosphatase value <2 × ULN or not available.

For participants with baseline AST OR ALT OR TBili values above the ULN, the following threshold values are used in the definition mentioned above, as needed, depending on which values are above the ULN at baseline:

Preexisting AST or ALT baseline values above the normal range: AST or ALT values >2 times the baseline values AND >3 × ULN; or >8 × ULN (whichever is smaller).

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Preexisting values of TBili above the normal range: TBili level increased from baseline value by an amount of at least 1 × ULN or if the value reaches >3 × ULN (whichever is smaller).

Rises in AST/ALT and TBili separated by more than a few weeks should be assessed individually based on clinical judgment; any case where uncertainty remains as to whether it represents a potential Hy's law case should be reviewed with the sponsor. The Hepatic Injury Council (HIC) should be informed if such a situation occurs during the study; the HIC will provide the necessary support to the study team.

The participant should return to the investigator site and be evaluated as soon as possible, preferably within 48 hours from awareness of the abnormal results. This evaluation should include laboratory tests, detailed history, and physical assessment. For oncology studies, the possibility of hepatic neoplasia (primary or secondary) should be considered.

In addition to repeating measurements of AST and ALT and TBili for suspected cases of Hy's law, additional laboratory tests should include albumin, CK, direct and indirect bilirubin, GGT, PT/INR, total bile acids, and alkaline phosphatase. Consideration should also be given to drawing a separate tube of clotted blood and an anticoagulated tube of blood for further testing, as needed, for further contemporaneous analyses at the time of the recognized initial abnormalities to determine etiology. A detailed history, including relevant information, such as review of ethanol, acetaminophen/paracetamol (either by itself or as a coformulated product in prescription or over the counter medications), recreational drug, supplement (herbal) use and consumption, family history, sexual history, travel history, history of contact with a jaundiced person, surgery, blood transfusion, history of liver or allergic disease, and potential occupational exposure to chemicals, should be collected. Further testing for acute hepatitis A, B, C, D, and E infection and liver imaging (eg, biliary tract) and collection of serum samples for acetaminophen/paracetamol drug and/or protein adduct levels may be warranted.

All cases demonstrated on repeat testing as meeting the laboratory criteria of AST/ALT and TBili elevation defined above should be considered potential DILI (Hy's law) cases if no other reason for the LFT abnormalities has yet been found. Such potential DILI (Hy's law) cases are to be reported as SAEs, irrespective of availability of all the results of the investigations performed to determine etiology of the LFT abnormalities.

A potential DILI (Hy's law) case becomes a confirmed case only after all results of reasonable investigations have been received and have excluded an alternative etiology.

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10.4. Appendix 4: Criteria for Allowing Inclusion of Participants With Chronic Stable HIV, HCV, or HBV Infection

Potential participants with chronic stable HIV, HCV, or HBV infection may be considered for inclusion if they fulfill the following respective criteria.

Known HIV infection

- Confirmed stable HIV disease defined as documented viral load <50 copies/mL and CD4 count >200 cells/mm3 within 6 months before enrollment, and on stable antiretroviral therapy for at least 6 months.

Known HCV infection

- History of chronic HCV with evidence of sustained virological response (defined as undetectable HCV RNA) for ≥12 weeks following HCV treatment or without evidence of HCV RNA viremia (undetectable HCV viral load).

Known HBV infection

Confirmed inactive chronic HBV infection, defined as HBsAg present for ≥6 months and the following:

- HBeAg negative, anti-HBe positive
- Serum HBV DNA <2000 IU/mL
- Persistently normal ALT and/or AST levels
- In those who have had a liver biopsy performed, findings that confirm the absence of significant necroinflammation.

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10.5. Appendix 5: Abbreviations

The following is a list of abbreviations that may be used in the protocol.

Abbreviation	Term
2019-nCoV	novel coronavirus 2019
AE	adverse event
AESI	adverse event of special interest
app	application
ALT	alanine aminotransferase
ARDS	adult respiratory distress syndrome
AST	aspartate aminotransferase
BiPaP	bilevel positive airway pressure
BMI	body mass index
BNP	brain natriuretic peptide
BP	blood pressure
CBER	Center for Biologics Evaluation and Research
CDC	Centers for Disease Control and Prevention (United States)
CI	confidence interval
CIOMS	Council for International Organizations of Medical Sciences
CK	creatine kinase
CONSORT	Consolidated Standards of Reporting Trials
COVID-19	coronavirus disease 2019
CPaP	continuous positive airway pressure
CRF	case report form
CRO	contract research organization
CRP	C-reactive protein
CSR	clinical study report
CT	computed tomography
CVA	cerebrovascular accident
DART	developmental and reproductive toxicology
DBP	diastolic blood pressure
DILI	drug-induced liver injury
DMC	data monitoring committee
DNA	deoxyribonucleic acid
DU	dispensable unit
EC	ethics committee
ECG	electrocardiogram
ECMO	extracorporeal membrane oxygenation
eCRF	electronic case report form
EDD	estimated delivery date
e-diary	electronic diary
EDP	exposure during pregnancy
EMA	European Medicines Agency

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Abbreviation	Term
ESR	erythrocyte sedimentation rate
EU	European Union
EUA	emergency use authorization
EudraCT	European Clinical Trials Database
FDA	Food and Drug Administration
FiO_2	fraction of inspired oxygen
GA	gestational age
GBS	group B streptococcus
GCP	Good Clinical Practice
GGT	gamma-glutamyl transferase
GI	gastrointestinal
GMC	geometric mean concentration
GMFR	geometric mean fold rise
GMR	geometric mean ratio
GMT	geometric mean titer
HBV	hepatitis B virus
HCP	healthcare provider
HCV	hepatitis C virus
HELLP	hemolysis, elevated liver enzymes, and low platelet count
HIC	Hepatic Injury Council
HIPAA	Health Insurance Portability and Accountability Act
HIV	human immunodeficiency virus
HR	heart rate
IB	investigator's brochure
ICD	informed consent document
ICH	International Council for Harmonisation
ICU	intensive care unit
ID	identification
IgG	immunoglobulin G
IL-6	interleukin 6
IMP	investigational medicinal product
IND	investigational new drug
INR	international normalized ratio
IP manual	investigational product manual
IPAL	Investigational Product Accountability Log
IRB	institutional review board
IRC	internal review committee
IRR	illness rate ratio
IRT	interactive response technology
IWR	interactive Web-based response
LDH	lactate dehydrogenase
LFT	liver function test

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Abbreviation	Term
LLOQ	lower limit of quantitation
LMP	last menstrual period
LNP	lipid nanoparticle
LS	least squares
MERS	Middle East respiratory syndrome
MIS-C	multisystem inflammatory syndrome in children
mITT	modified intent-to-treat
modRNA	nucleoside-modified messenger ribonucleic acid
MRI	magnetic resonance imaging
mRNA	messenger ribonucleic acid
N	SARS-CoV-2 nucleoprotein
N/A	not applicable
NAAT	nucleic acid amplification test
NaCl	sodium chloride
NI	noninferiority
NIMP	noninvestigational medicinal product
PASS	postauthorization safety study
P2 S	SARS-CoV-2 full-length, P2 mutant, “heads up,” prefusion spike glycoprotein
PaO_2	partial pressure of oxygen, arterial
PD	pharmacodynamic(s)
PI	principal investigator
PPE	personal protective equipment
PT	prothrombin time
RCDC	reverse cumulative distribution curve
RMP	risk management plan
RNA	ribonucleic acid
RR	respiratory rate
RSV	respiratory syncytial virus
RT-PCR	reverse transcription–polymerase chain reaction
S	spike protein
S1	spike protein S1 subunit
SAE	serious adverse event
SAP	statistical analysis plan
SARS	severe acute respiratory syndrome
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
SBP	systolic blood pressure
SoA	schedule of activities
SOP	standard operating procedure
SpO_2	oxygen saturation as measured by pulse oximetry
SRM	study reference manual
SRSD	single reference safety document

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Abbreviation	Term
SUSAR	suspected unexpected serious adverse reaction
TBili	total bilirubin
T_H1	T-helper type 1
ULN	upper limit of normal
US	United States
VAED	vaccine-associated enhanced disease
VE	vaccine efficacy
WHO	World Health Organization

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11. REFERENCES

1 National Center for Biotechnology Information. Severe acute respiratory syndrome coronavirus 2 isolate Wuhan-Hu-1, complete genome. Available from: https://www.ncbi.nlm.nih.gov/nuccore/MN908947. Accessed: 11 Dec 2020.

2 Zhu N, Zhang D, Wang W, et al. A novel coronavirus from patients with pneumonia in China, 2019. N Engl J Med. 2020;382(8):727-33.

3 World Health Organization. WHO Director-General's opening remarks at the media briefing on COVID-19. Available from: https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020. Published: 11 Mar 2020. Accessed: 01 Apr 2020.

4 Johns Hopkins University & Medicine, Coronavirus Resource Center. COVID-19 dashboard by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University (JHU). Available from: https://coronavirus.jhu.edu/map.html. Accessed: 16 Dec 2020.

5 Sutton D, Fuchs K, D'Alton M, et al. Universal screening for SARS-CoV-2 in women admitted for delivery [letter]. N Engl J Med. 2020;382(22):2163-4.

6 Ellington S, Strid P, Tong VT, et al. Characteristics of women of reproductive age with laboratory-confirmed SARS-CoV-2 infection by pregnancy status - United States, January 22-June 7, 2020. MMWR Morbid Mortal Wkly Rep. 2020;69(25):769-75.

7 Yu N, Kang Q, Xiong Z, et al. Clinical features and obstetric and neonatal outcomes of pregnant patients with COVID-19 in Wuhan, China: a retrospective, single-centre, descriptive study. Lancet Infect Dis. 2020;20(5):559-64.

8 Smith V, Seo D, Warty R, et al. Maternal and neonatal outcomes associated with COVID-19 infection: a systematic review. PLoS ONE. 2020;15(6):e0234187.

9 Di Mascio D, Khalil A, Saccone G, et al. Outcome of coronavirus spectrum infections (SARS, MERS, COVID-19) during pregnancy: a systematic review and meta-analysis. Am J Obstet Gynecol MFM. 2020;2(2):100107.

10 Khalil A, Kalafat E, Benlioglu C, et al. SARS-CoV-2 infection in pregnancy: a systematic review and meta-analysis of clinical features and pregnancy outcomes. Eclin Med. 2020;Aug;25:100446.

11 Khalil A, von Dadelszen P, Draycott T, et al. Change in the incidence of stillbirth and preterm delivery during the COVID-19 pandemic [letter]. JAMA. 2020;324(N7):705-6.

090177e1998bdef\Approved\Approved On: 09-Mar-2022 13:23 (GMT)

[12] Centers for Disease Control and Prevention. COVID-19 (coronavirus disease): information for pediatric healthcare providers. Available from: https://www.cdc.gov/coronavirus/2019-ncov/hcp/pediatric-hcp.html. Updated: 03 Dec 2020. Accessed: 16 Dec 2020.

[13] Kim L, Whitaker M, O'Halloran A, et al; COVID-NET Surveillance Team. Hospitalization rates and characteristics of children aged <18 years hospitalized with laboratory-confirmed COVID-19 – COVID-NET, 14 states, March 1–July 25, 2020. MMWR Morbid Mortal Wkly Rep. 2020;69(32):1081-8. DOI: http://dx.doi.org/10.15585/mmwr.mm6932e3.

[14] Rauch S, Jasny E, Schmidt KE, et al. New vaccine technologies to combat outbreak situations. Front Immunol. 2018;9:1963.

[15] Sahin U, Karikó K, Türeci Ö. mRNA-based therapeutics—developing a new class of drugs. Nat Rev Drug Discov. 2014;13(10):759-80.

[16] Swamy GK, Beigi RH. Maternal benefits of immunization during pregnancy. Vaccine. 2015;33(47):6436-40.

[17] Englund JA. The influence of maternal immunization on infant immune responses. J Comp Pathol. 2007;137(Suppl 1):S16-S19.

[18] Polack FP, Thomas SJ, Kitchin N, et al. Safety and efficacy of the BNT162b2 mRNA Covid-19 vaccine. N Engl J Med. 2020;383(27):2603-15.

[19] Pfizer and BioNTech. FDA briefing document: Pfizer-BioNTech COVID-19 vaccine. Available from: https://www.fda.gov/media/144245/download. Accessed: 30 Apr 2021.

[20] Pfizer. Pfizer and BioNTech confirm high efficacy and no serious safety concerns through up to six months following second dose in updated topline analysis of landmark COVID-19 vaccine study [press release]. Available from: https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-confirm-high-efficacy-and-no-serious. Accessed: 27 Apr 2021.

[21] McGill COVID19 Vaccine Tracker Team. COVID19 vaccine tracker. Available from: https://covid19.trackvaccines.org/vaccines/. Accessed: 04 May 2021.

[22] Food and Drug Administration. Comirnaty and Pfizer-BioNTech COVID-19 vaccine. BLA approval letter dated August 23, 2021. Available from: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine. Accessed: 26 Oct 2021.

090177e1998bdef\Approved\Approved On: 09-Mar-2022 13:23 (GMT)

[23] Comirnaty [package insert]. BioNTech and Pfizer; August 2021. Available from: https://www.fda.gov/media/151707/download. Accessed: 26 Oct 2021.

[24] Food and Drug Administration. FDA authorizes booster dose of Pfizer-BioNTech COVID-19 vaccine for certain populations. Available from: https://www.fda.gov/news-events/press-announcements/fda-authorizes-booster-dose-pfizer-biontech-covid-19-vaccine-certain-populations. Accessed: 19 Dec 2021.

[25] Pfizer. Pfizer and BioNTech receive expanded U.S. FDA emergency use authorization of COVID-19 vaccine booster to include individuals 18 and older [press release]. Available from: https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-receive-expanded-us-fda-emergency-use. Accessed: 19 Dec 2021.

[26] Food and Drug Administration. Coronavirus (COVID-19) update: FDA expands eligibility for Pfizer-BioNTech COVID-19 booster dose to 16- and 17-year-olds. Available from: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-expands-eligibility-pfizer-biontech-covid-19-booster-dose-16-and-17. Accessed: 19 Dec 2021.

[27] Pfizer and BioNTech. Pfizer and BioNTech receive CHMP positive opinion for COVID-19 vaccine booster in the European Union [press release]. Available from: https://cdn.pfizer.com/pfizercom/2021-10/COVID19_Booster_CHMP_Opinion_FINAL.pdf. Accessed: 20 Dec 2021.

[28] Bar-On YM, Goldberg Y, Mandel M, et al. Protection of BNT162b2 vaccine booster against COVID-19 in Israel. N Engl J Med. 2021;385(15):1393-400.

[29] US Food and Drug Administration. Guidance for industry: toxicity grading scale for healthy adult and adolescent volunteers enrolled in preventive vaccine clinical trials. Rockville, MD: Center for Biologics Evaluation and Research; September 2007.

[30] Polack FP, Thomas SJ, Kitchin N, et al. Safety and efficacy of the BNT162b2 mRNA Covid-19 vaccine. N Engl J Med. 2020 Dec 10. DOI: 10.1056/NEJMoa2034577.

[31] Jackson LA, Anderson EJ, Rouphael NG, et al; mRNA-1273 Study Group. An mRNA vaccine against SARS-CoV-2 - preliminary report. N Engl J Med. 2020;383(20):1920-31. DOI: 10.1056/NEJMoa2022483.

[32] Feldman RA, Fuhr R, Smolenov L, et al. mRNA vaccines against H10N8 and H7N9 influenza viruses of pandemic potential are immunogenic and well tolerated in healthy adults in phase 1 randomized clinical trials. Vaccine. 2019;37(25):3326-3334. DOI: 10.1016/j.vaccine.2019.04.074.

090177e1998bbdef\Approved\Approved On: 09-Mar-2022 13:23 (GMT)

[33] Goldstein B, Giroir B, Randolph A; International Consensus Conference on Pediatric Sepsis. International pediatric sepsis consensus conference: definitions for sepsis and organ dysfunction in pediatrics. Pediatr Crit Care Med. 2005;6(1):2-8. DOI: 10.1097/01.PCC.0000149131.72248.E6.

[34] Godfred-Cato S, Bryant B, Leung J, et al. COVID-19–associated multisystem inflammatory syndrome in children—United States, March–July 2020. MMWR Morb Mortal Wkly Rep. 2020;69(32):1074-80.

[35] European Commission. Ethical considerations for clinical trials on medicinal products conducted with minors. 18 Sep 2017. Available from: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/2017_09_18_ethical_consid_ct_with_minors.pdf. Accessed: 21 Feb 2019.

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C4591015: ADVERSE EVENT REPORT (AE) - Repeating Form

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Toxicity Grade	Serious	Is AE a Result of a Medication Error	Relationship to Study Treatment	Action Taken with Study Treatment	Concomitant Medication Given	Non-Drug Treatment Given	Outcome	Caused Study Discontinuation
1														

1.	Category: [Category]	○ ADVERSE EVENT ○ AE OF SPECIAL INTEREST
2.	AE ID: [AE Identifier]	
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms) [Adverse Event]	
4.	Start Date: [Start Date]	/ / : *24-hour clock*
5.	Is the adverse event still ongoing? [Is the Adverse Event Still Ongoing]	○ YES ○ NO End Date: / / : *24-hour clock*
6.	Toxicity Grade: [Toxicity Grade]	○ 1 ○ 2 ○ 3 ○ 4
7.	Is the adverse event serious? If Yes, NOTIFY [1] IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes). [Serious]	○ YES Is this serious event associated with congenital anomaly or birth defect? ○ YES ○ NO Did this serious event result in death? ○ YES ○ NO Did this serious event require or prolong hospitalization? ○ YES ○ NO Did this serious event result in persistent or significant disability/incapacity? ○ YES ○ NO Is this serious event life threatening? ○ YES ○ NO Other medically important serious event ○ YES ○ NO ○ NO Is this non-serious event reportable? ○ YES ○ NO
8.	Is this adverse event the result of a study medication error? If Yes, record the type of medication error on the Medication Error Log. [Is AE a Result of a Medication Error]	○ YES ○ NO
9.	Is this event related to study treatment: [Relationship to Study Treatment]	○ NOT RELATED If Not Related to study treatment(s), this event is due to: ○ CONCOMITANT DRUG TREATMENT ○ CONCOMITANT NON-DRUG TREATMENT ○ OTHER If Other, specify: ○ RELATED
10.	Latest Action Taken with Study Treatment: [Action Taken with Study Treatment]	○ DRUG WITHDRAWN ○ NOT APPLICABLE
11.	Was a Concomitant Medication given? If yes, record on the Concomitant Medications page [Concomitant	○ YES ○ NO

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	Medication Given]	
12.	Was a Non-Drug Treatment given? If yes, record on the Non-Drug Treatment page [Non-Drug Treatment Given]	◯ YES ◯ NO
13.	What was the outcome of this adverse event?: [Outcome]	◯ FATAL ◯ NOT RECOVERED/NOT RESOLVED ◯ RECOVERED/RESOLVED ◯ RECOVERED/RESOLVED WITH SEQUELAE ◯ RECOVERING/RESOLVING ◯ UNKNOWN
14.	Did the adverse event cause the subject to be discontinued from the study? [Caused Study Discontinuation]	◯ YES ◯ NO

Note: Hidden items are not displayed.

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C4591015: LAB CHEMISTRY - BIOMARKER (BIO CHEM) - Repeating Form

#	Category for Lab Test	Vendor Name	Specimen Type	Collection Date Time:	Lab Result
1					

1.	Lab Panel: [Category for Lab Test]	○ CLINICAL CHEMISTRY
2.	Laboratory Name and Address [Vendor Name]	
3.	Specimen Type: [Specimen Type]	○ BLOOD
4.	Collection Date: [Collection Date Time:]	/ /

Lab Result

# ✔	Sponsor-Defined Identifier	Test	Result	Not Done:	LNMT
5.a		C Reactive Protein_PX329			
5.b		Albumin_PX25			
5.c		Lactate Dehydrogenase_PX32			
5.d		Fibrinogen_PX136			
5.e		Ferritin_PX362			
5.f		Interleukin 6_PX779			
5.g		D Dimer_PX1588			
5.h		Procalcitonin_PX3257			

Lab Result Entry

5.1	Sponsor ID: [Sponsor-Defined Identifier]	
5.2	Test: [Test]	
5.3	Result: [Result]	
5.4	Not Done: [Not Done:]	○ NOT DONE
5.5	LNMT [LNMT]	High Low Unit

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C4591015: LABORATORY DATA - HEMATOLOGY BIOMARKER (BIO HEM) - Repeating Form

#	Category for Lab Test	Vendor Name	Specimen Type	Collection Date Time:	Lab Result
1					

1.	Lab Panel: [Category for Lab Test]	○ HEMATOLOGY
2.	Laboratory Name and Address [Vendor Name]	
3.	Specimen Type: [Specimen Type]	○ BLOOD
4.	Collection Date: [Collection Date Time:]	/ /

Lab Result

# ✔	Sponsor-Defined Identifier	Test	Result	Not Done:	LNMT
5.a		Hemoglobin_PX1			
5.b		Hematocrit_PX2			
5.c		Erythrocytes_PX3			
5.d		Platelets_PX5			
5.e		Leukocytes_PX7			
5.f		Erythrocyte Sedimentation Rate_PX14			
5.g		Neutrophils_PX608			
5.h		Eosinophils_PX609			
5.i		Lymphocytes_PX611			

Lab Result Entry

5.1	Sponsor ID: [Sponsor-Defined Identifier]	
5.2	Test: [Test]	
5.3	Result: [Result]	
5.4	Not Done: [Not Done:]	○ NOT DONE
5.5	LNMT [LNMT]	High Low Unit

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C4591015: OUTCOME OF LIVE BIRTH (BTH OUTCM)		
1.	Associated Parent ID: [Associated Parent ID]	
2.	Gestational Age [Gestational Age]	Gestational age in weeks: Gestational age in days:
3.	APGAR Score - 1 Minute: [APGAR Score - 1 Minute]	
4.	APGAR Score - 5 Minutes: [APGAR Score - 5 Minutes]	
5.	APGAR Score - 10 Minutes: [APGAR Score - 10 Minutes]	
6.	Did the infant cry immediately after delivery? [Cry Immediately After Delivery]	YES NO
7.	Did the infant suckle shortly after delivery? [Suckle Shortly After Delivery]	YES NO
8.	Infant Outcome [Infant Outcome]	NORMAL CONGENITAL MALFORMATION/ANOMALY OTHER NEONATAL PROBLEM

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C4591015: LABORATORY DATA - HEMATOLOGY CD4 (CD4)		
1.	Lab Panel: [Category for Lab Test]	○ HEMATOLOGY
2.	Laboratory Name and Address [Vendor Name]	
3.	Specimen Type: [Specimen Type]	○ BLOOD
4.	Collection Date: [Collection Date Time:]	/ /

Lab Result

# ✔	Sponsor-Defined Identifier	Test:	Result:	Not Done:	LNMT
5.a		CD4_PX4722			

Lab Result Entry		
5.1	Sponsor ID: [Sponsor-Defined Identifier]	
5.2	Test: [Test:]	○ CD4_PX4722
5.3	Result: [Result:]	
5.4	Not Done: [Not Done:]	○ NOT DONE
5.5	LNMT [LNMT]	Low High Unit ○ /uL ○ CELLS/MM3 ○ % ○ 10^3/mm3

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C4591015: Trigger Form (COHORT MAT)		
Trigger Form Details		
1.	Select appropriate response - [What cohort does the subject belong to?] [Trigger Response 10]	○ THE SUBJECT BELONGS TO PHASE 2 COHORT ○ THE SUBJECT BELONGS TO PHASE 3 COHORT

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C4591015: CONCOMITANT MEDICATIONS (CONMED) - Repeating Form

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Medication to Treat Adverse Event	Dose Description	Dose Unit	Dose Frequency	Route	Start Date	Ongoing
1											

1.	What is the medication identifier? [Sponsor-Defined Identifier]	
2.	Category: [Category for Medication]	○ GENERAL CONCOMITANT MEDICATIONS
3.	Concomitant Medications Pre-specified: [Concomitant Medications Pre-specified]	○ NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation). [Name of Medication]	
5.	Was this medication given to treat an Adverse Event? [Medication to Treat Adverse Event]	○ YES AE Identifier: AE Identifier: AE Identifier: AE Identifier: AE Identifier: ○ NO
6.	Dose: [Dose Description]	
7.	Dose Unit: [Dose Unit]	
8.	Dose Frequency: [Dose Frequency]	
9.	Route: [Route]	
10.	Start Date: [Start Date]	/ /
11.	Ongoing? [Ongoing]	○ YES ○ NO End Date: / /

Note: Hidden items are not displayed.

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C4591015: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS (CONMED VAX) - Repeating Form

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date
1					

1.	What is the medication identifier? [Sponsor-Defined Identifier]	
2.	Category: [Category for Medication]	○ VACCINATIONS
3.	Concomitant Medications Pre-specified: [Concomitant Medications Pre-specified]	○ NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation). [Name of Medication]	
5.	Start Date: [Start Date]	/ /

Note: Hidden items are not displayed.

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C4591015: CONTACT OUTCOME - UNPLANNED (CONTACT UV)		
1.	Follow-Up Contact Category [Follow Up Contact Category]	◯ CONTACT OUTCOME
2.	Contact Type: [Type of Contact/Visit]	◯ TELEPHONE VISIT
3.	Was contact made? [Was Contact Made]	◯ YES Date of Contact: / / Contact Outcome: ◯ VISIT ARRANGED ◯ VISIT ARRANGED, BUT NOT ATTENDED ◯ VISIT NOT ARRANGED, REACTION NO LONGER PRESENT ◯ VISIT NOT ARRANGED, UNABLE TO ATTEND ◯ VISIT NOT REQUIRED, DATA ENTRY ERROR IN E-DIARY ◯ VISIT NOT REQUIRED, INVESTIGATOR DECISION ◯ NO If No, why?
4.	Comments: [Comments/Findings/Details]	

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C4591015: MICROBIOLOGY SPECIMEN - SEROLOGY MIS-C (COV19 SERO) - Repeating Form

#	Date of Collection	Specimen Type	Assay Code and Description	Device Type	Trade Name	Trade Name Other, Specify	Result	Comments/Findings
1								

1.	Actual Date of Collection: [Date of Collection]	/ /
2.	Specimen Type: [Specimen Type]	SERUM BLOOD PLASMA
3.	Assay Code and Description: [Assay Code and Description]	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
4.	Device Type: [Device Type]	SARS-COV-2 DIAGNOSTIC TEST
5.	Trade Name: [Trade Name]	
6.	Trade Name Other, Specify: [Trade Name Other, Specify]	
7.	Test Result: [Result]	POSITIVE NEGATIVE INDETERMINATE
8.	Comments/Findings/Details: [Comments/Findings]	

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C4591015: MICROBIOLOGY SPECIMEN (COVID TEST) - Repeating Form

#	Date of Collection	Specimen Type	Specimen Location	Assay Code and Description	Device Type	Trade Name	Trade Name Other, Specify	Result	Comments/Findings
1									

1.	Actual Date of Collection: [Date of Collection]	/ /
2.	Specimen Type: [Specimen Type]	SWABBED MATERIAL RESPIRATORY SECRETIONS
3.	Specimen Sample Location: [Specimen Location]	NASOPHARYNX LOWER RESPIRATORY SYSTEM THROAT
4.	Assay Code and Description: [Assay Code and Description]	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type: [Device Type]	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name: [Trade Name]	
7.	Trade Name Other, Specify: [Trade Name Other, Specify]	
8.	Test Result: [Result]	POSITIVE NEGATIVE INDETERMINATE
9.	Comments/Findings/Details: [Comments/Findings]	

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C4591015: ELECTRONIC SAMPLING TRACKING - CORD BLOOD (CRD BLOOD)		
1.	Data Origin [Data Origin]	○ SITE
2.	Sample Type [Sample Type]	○ UMBILICAL_CORD_SERUM ○ SERUM
3.	Sample Collected? [Sample Collected]	○ YES Date of Collection: / / ○ NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason: [Reason sample not collected]	

	Sample ID
5.	

Aliquot Entry Entry		
Please enter barcode for each aliquot.		
5.1	Sample ID [Sample ID]	

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C4591015: CONTACT OUTCOME - FOLLOW UP TELEPHONE (CTACT FUP)		
1.	Follow-Up Contact Category [Follow Up Contact Category]	○ CONTACT OUTCOME
2.	Contact Type: [Type of Contact/Visit]	○ TELEPHONE VISIT
3.	Was contact made? [Was Contact Made]	○ YES Date of Contact: / / ○ NO If No, why?
4.	Comments: [Comments/Findings/Details]	

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C4591015: DEATH DETAILS CODED (DD CODED)

1.	Date of Collection / Notification of Death: [Date of Collection / Notification of Death]	/ /

	Cause of Death Status	Cause of Death
2.		

2.1	Cause of Death Status: [Cause of Death Status]	PRIMARY CAUSE OF DEATH SECONDARY CAUSE OF DEATH
2.2	Cause of Death: [Cause of Death]	

Note: Hidden items are not displayed.

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C4591015: NON-DRUG TREATMENTS DELIVERY (DELIV PR)

# ✔	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Ongoing?	Treatment given?
1.a		YES	Forceps Delivery				
1.b		YES	Vacuum Extractor Delivery				

1.1	What is the treatment Identifier? [Treatment Identifier]	
1.2	Concomitant Non-drug Treatment Pre-specified: [Con Non-Drug Treatments Pre-specified]	◯ YES
1.3	Treatment: [Treatment]	◯ Forceps Delivery ◯ Vacuum Extractor Delivery
1.4	Treatment: [Treatment]	
1.5	Start Date: [Start Date]	/ /
1.6	Ongoing? [Ongoing?]	◯ YES ◯ NO End Date: / /
1.7	Treatment given? [Treatment given?]	◯ YES ◯ NO

Note: Hidden items are not displayed.

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C4591015: DEMOGRAPHY (DEMOG)		
1.	Subject ID [Subject ID]	
2.	Birth Year: [Birth Year]	/ / : *24-hour clock*
3.	Sex: [Sex]	FEMALE MALE
4.	Ethnicity: [Ethnicity]	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN NOT REPORTED
5.	Race: (Check X all that apply): [Race Of Subject]	BLACK OR AFRICAN AMERICAN AMERICAN INDIAN OR ALASKA NATIVE ASIAN NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER WHITE NOT REPORTED
6.	Racial Designation: [Racial Designation]	

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C4591015: DISPOSITION - SCREENING (DISP SCR)		
1.	Phase of Disposition: [Disposition Phase]	◯ SCREENING
2.	Date of Completion/Discontinuation/Death [Date of Completion/Discontinuation/Death]	/ /
3.	Status: [Status]	◯ COMPLETED ◯ ADVERSE EVENT ◯ SCREEN FAILURE ◯ STUDY TERMINATED BY SPONSOR ◯ OTHER
4.	Specify Status: [Specify Status]	

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C4591015: DISPOSITION - TREATMENT VACCINATION (DISP TRT)		
1.	Phase of Disposition: [Disposition Phase]	◯ VACCINATION ◯ OPEN LABEL TREATMENT
2.	Date of Completion/Discontinuation/Death : [Date of Completion/Discontinuation/Death :]	/ /
3.	Status: [Status]	
4.	Specify Status: [Specify Status]	

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C4591015: DATE OF VISIT (DOV)		
1.	Date of Visit [Date of Visit]	/ /
2.	Erroneous Visit [Visit Error]	ERRONEOUS VISIT

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C4591015: DATE OF VISIT - ILLNESS CONVALESCENT (DOV CONV)		
1.	Date of Visit [Date of Visit]	/ /
2.	Erroneous Visit [Visit Error]	ERRONEOUS VISIT
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit: [COVID-19 Illness Visit]	

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C4591015: DATE OF VISIT - ILLNESS (DOV ILL)		
1.	Date of Visit [Date of Visit]	/ /
2.	Erroneous Visit [Visit Error]	ERRONEOUS VISIT
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit: [COVID-19 Illness Visit]	

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C4591015: DATE OF VISIT - REPEAT SWAB (DOV SWAB)		
1.	Date of Visit [Date of Visit]	/ /
2.	Erroneous Visit [Visit Error]	ERRONEOUS VISIT
3.	COVID-19 Illness Visit: [COVID-19 Illness Visit]	

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C4591015: CARDIAC FUNCTION EVALUATION (ECHOREP) - Repeating Form

#	Method	Date of Evaluation	Right Ventricular Function	LVEF (%)	LVEF Lower Limit Of Normal	End Diastolic Interventricular Septal Wall Thickness (mm)	End Diastolic Left Ventricular Posterior Wall Thickness (mm)	Left Ventricular Stroke Volume (mL)	Left Ventricular Fractional Shortening (%)	Left Atrial Diameter, Anterior-Posterior (mm)	Left Atrial Diameter, Medio-Lateral (mm)	Left Atrial Diameter, Superior-Inferior (mm)	Left Ventricular End Systolic Diameter (mm)	Left Ventricular End Systolic Volume (mL)	Left Ventricular End Diastolic Diameter (mm)	Ver
1																

Cardiac Function Evaluation

1.	Method: [Method]	ECHOCARDIOGRAPHY
2.	Date of Evaluation: [Date of Evaluation]	/ / : *24-hour clock*
3.	Right Ventricular Function: [Right Ventricular Function]	ABNORMAL NORMAL
4.	LVEF (%): [LVEF (%)]	
5.	LVEF Lower Limit Of Normal: [LVEF Lower Limit Of Normal]	
6.	End Diastolic Interventricular Septal Wall Thickness (mm): [End Diastolic Interventricular Septal Wall Thickness (mm)]	
7.	End Diastolic Left Ventricular Posterior Wall Thickness (mm): [End Diastolic Left Ventricular Posterior Wall Thickness (mm)]	
8.	Left Ventricular Stroke Volume (mL): [Left Ventricular Stroke Volume (mL)]	
9.	Left Ventricular Fractional Shortening (%): [Left Ventricular Fractional Shortening (%)]	
10.	Left Atrial Diameter, Anterior-Posterior (mm): [Left Atrial Diameter, Anterior-Posterior (mm)]	
11.	Left Atrial Diameter, Medio-Lateral (mm): [Left Atrial Diameter, Medio-Lateral (mm)]	
12.	Left Atrial Diameter, Superior-Inferior (mm): [Left Atrial Diameter, Superior-Inferior (mm)]	
13.	Left Ventricular End Systolic Diameter (mm): [Left Ventricular End Systolic Diameter (mm)]	
14.	Left Ventricular End Systolic Volume (mL): [Left Ventricular End Systolic Volume (mL)]	
15.	Left Ventricular End Diastolic Diameter (mm): [Left Ventricular End Diastolic Diameter (mm)]	
16.	Left Ventricular End Diastolic Volume (mL): [Left Ventricular End Diastolic Volume (mL)]	
17.	Left Ventricular Mass (g): [Left Ventricular Mass (g)]	
18.	E/A Ratio: [E/A Ratio]	
19.	E/E' Ratio: [E/E' Ratio]	
20.	Pericardial Effusion: [Pericardial Effusion]	ABSENT PRESENT NOT EVALUABLE
21.	Intracavitary Thrombus: [Intracavitary Thrombus]	ABSENT PRESENT
22.	Echocardiogram Interpretation: [Echocardiogram Interpretation]	ABNORMAL NORMAL
23.	Clinically Significant: [Clinically Significant]	YES NO
24.	Comments: [Comments/Findings/Details]	

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C4591015: INFORM ENROLLMENT (ENROLL)		
1.	Subject ID [Subject ID]	

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C4591015: ENROLLMENT (ENROLL)		
1.	Enrollment Date: [Enrollment Date:]	/ /
2.	Enrollment Number: [Reference ID]	

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C4591015: DISPOSITION - FOLLOW-UP INF (FUP INF)		
1.	Phase of Disposition: [Disposition Phase]	○ FOLLOW-UP
2.	Date of Completion/Discontinuation/Death : [Date of Completion/Discontinuation/Death :]	/ /
3.	Status: [Status]	
4.	Specify Status: [Specify Status]	

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C4591015: DISPOSITION - FOLLOW-UP MATERNAL (FUP MAT)		
1.	Phase of Disposition: [Disposition Phase]	FOLLOW-UP
2.	Date of Completion/Discontinuation/Death : [Date of Completion/Discontinuation/Death :]	/ /
3.	Status: [Status]	
4.	Specify Status: [Specify Status]	

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C4591015: GCS NINDS VERSION - GLASGOW COMA SCORE (GCS)		
1.	Date and Time of Assessment: [Date and Time of Assessment]	/ / : *24-hour clock*
2.	Total Score: [Total Score]	

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C4591015: TRIGGER FORM - HIV STATUS (HIV)		
Trigger Form Details		
1.	Select appropriate response - What is the subject HIV status? [Trigger Response 3]	○ The subject is known to be HIV POSITIVE ○ The subject is NOT known to be HIV POSITIVE

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C4591015: LABORATORY DATA - CHEMISTRY HIV (HIV RNA)		
1.	Lab Panel: [Category for Lab Test]	◯ CLINICAL CHEMISTRY
2.	Laboratory Name and Address [Vendor Name]	
3.	Specimen Type: [Specimen Type]	◯ BLOOD
4.	Collection Date: [Collection Date Time:]	/ /

Lab Result

# ✔	Sponsor-Defined Identifier	Test:	Result:	Not Done:	LNMT
5.a		HIV RNA (Ultrasensitive)_PX2124			

Lab Result Entry		
5.1	Sponsor ID: [Sponsor-Defined Identifier]	
5.2	Test: [Test:]	◯ HIV RNA (Ultrasensitive)_PX2124
5.3	Result: [Result:]	
5.4	Not Done: [Not Done:]	◯ NOT DONE
5.5	LNMT [LNMT]	Low High Unit ◯ /mL

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C4591015: HEALTH CARE UTILIZATION (HLTHCARE)

1.	Evaluation Interval: [Evaluation Interval]	○ SINCE THE START OF THE RESPIRATORY ILLNESS EPISODE
2.	Disease Name: [Disease Name]	○ RESPIRATORY ILLNESS

# ✔	Type of Practitioner	Occurrence of Visits or Contacts
3.a	SPECIALIST	
3.b	EMERGENCY ROOM	
3.c	PRIMARY CARE PHYSICIAN	
3.d	URGENT CARE	
3.e	TELEPHONE CONSULTATION	
3.f	OTHER	

3.1	Physician or Healthcare Professional: [Type of Practitioner]	○ SPECIALIST ○ EMERGENCY ROOM ○ PRIMARY CARE PHYSICIAN ○ URGENT CARE ○ TELEPHONE CONSULTATION ○ OTHER
3.2	Occurrence of Visits or Contacts: [Occurrence of Visits or Contacts]	○ YES Number of Visits or Contacts: [ ] ○ NO

Health Care Utilization Other

4.	Other Type of Practitioner Specify: [Other Type of Practitioner Specify]	

Health Care Utilization

5.	Has the subject been hospitalized due to potential COVID-19 illness? [Been Hospitalized]	○ YES Has the subject been in intensive care due to potential COVID-19 illness? ○ YES ○ NO ○ NO

Note: Hidden items are not displayed.

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C4591015: HOSPITALIZATION DETAILS (HOSP) - Repeating Form				
#	Hospitalization Category	Hospitalization Term	Admission Date	Ongoing
1				

1.	Hospitalization Category: [Hospitalization Category]	○ HOSPITALIZATION STATUS
2.	Hospitalization Term: [Hospitalization Term]	○ ICU ○ HOSPITAL
3.	Admission Date: [Admission Date]	/ /
4.	Ongoing? [Ongoing]	○ YES ○ NO Discharge Date: / /

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C4591015: INCLUSION/EXCLUSION CRITERIA - P2 A2 (IE P2A2)

Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclusion criteria (NO).

Inclusion Criteria

# ✔	Inclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
1.a	1	Women >=18 years old and between 27 (P2) or 24 (P3) and 34 wks gestation the day of planned vaccination, with an uncomplicated, singleton pregnancy, who are at no known increased risk for complication		IN01A00
1.b	2	Participants who are willing and able to comply with scheduled visits, treatment plan, laboratory tests, and other study procedures		IN02A00
1.c	3	Receiving prenatal standard of care based on country requirements		IN03A00
1.d	4	Had an ultrasound examination performed at >=18 weeks of pregnancy with no significant fetal abnormalities observed, based on the investigator's judgment		IN04A00
1.e	6	Documented negative HIV antibody test (Phase 2 only), syphilis test, and hepatitis B virus (HBV) surface antigen test during this pregnancy and prior to randomization (Visit 1)		IN06A02
1.f	7	Intention to deliver at a hospital or birthing facility where study procedures can be obtained		IN07A00
1.g	8	Expected to be available for the duration of the study and can be contacted by telephone during study participation		IN08A00
1.h	9	Participant is willing to give informed consent for her infant to participate in the study		IN09A00
1.i	10	Pre-pregnancy body mass index (BMI) of <= 40 kg/m2 at enrollment. If pre-pregnancy BMI is not available, the BMI at the time of the first obstetric visit during the current pregnancy may be used		IN10A01
1.j	11	Capable giving signed IC, includes compliance with requirements/restrictions in ICD/protocol		IN11A02

Inclusion Criteria Entry

1.1	Inclusion Number: [Inclusion Number]	
1.2	Criterion Description: [Criterion Description]	
1.3	Criterion met? [Criterion met?]	YES NO Describe details if relevant
1.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	

Exclusion Criteria

# ✔	Exclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
2.a	1	Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation		EX01A00
2.b	2	Previous clinical (based on COVID-19 symptoms/signs alone) or microbiological (based on COVID-19 symptoms/signs and a positive SARS-CoV-2 NAAT result) diagnosis of COVID 19		EX02A00
2.c	3	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the investigational product or any related vaccine		EX03A00
2.d	4	Participants with known or suspected immunodeficiency		EX04A00
2.e	5	Bleeding diathesis or condition associated with prolonged bleeding that would in the opinion of the investigator contraindicate intramuscular injection		EX05A00
2.f	6	Phase 2: Major illness of maternal pt or condition of fetus that, will increase risk associated with maternal pt's participation in/completion of study or preclude evaluation of the pt's response		EX06A00
2.g	7	Phase 2: Maternal participants with a history of stable chronic diseases that are known to increase the risk of obstretrical/neonatal complications (as defined in the protocol) should not be included		EX07A00
2.h	9	Previous vaccination with any coronavirus vaccine		EX09A00
2.i	10	Receipt of medications intended to prevent COVID 19		EX10A00
2.j	11	Receipt of blood/plasma products or immunoglobulin, from 60 days before IP administration, or planned receipt through delivery, with 1 exception, anti D immunoglobulin, which can be given at any time		EX11A00
2.k	12	Current alcohol abuse or illicit drug use		EX12A00
2.l	13	Individuals who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids. Inhaled/nebulized, Intra-articular, intrabursal, or topical corticosteroids are permitted		EX13A00
2.m	14	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation		EX14A00
2.n	15	Previous participation in other studies involving study intervention containing lipid nanoparticles		EX15A00
2.o	17	Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members		EX17A00
2.p	18	Pts whose unborn baby has been fathered by investigator site staff or Pfizer employees directly involved in study conduct, site staff otherwise supervised by the PI, and their respective family		EX18A00

Exclusion Criteria Entry

2.1	Exclusion Number: [Exclusion Number]	
2.2	Criterion Description: [Criterion Description]	
2.3	Criterion met? [Criterion met?]	YES Describe details if relevant

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		○ NO
2.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	

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C4591015: INCLUSION/EXCLUSION CRITERIA - P3 AMENDED (IE P3 AM)

Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclusion criteria (NO).

Inclusion Criteria

# ✔	Inclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
1.a	1	Women >=18 years old and between 27 (P2) or 24 (P3) and 34 wks gestation the day of planned vaccination, with an uncomplicated, singleton pregnancy, who are at no known increased risk for complication		IN01A00
1.b	2	Participants who are willing and able to comply with scheduled visits, treatment plan, laboratory tests, and other study procedures		IN02A00
1.c	3	Receiving prenatal standard of care based on country requirements		IN03A00
1.d	4	Had an ultrasound examination performed at >=18 weeks of pregnancy with no significant fetal abnormalities observed, based on the investigator's judgment		IN04A00
1.e	5	Healthy participants who are determined by medical history, physical examination, and clinical judgment to be appropriate for inclusion in the study. Criteria for P3 participants is in Section 10.4		IN05A02
1.f	7	Intention to deliver at a hospital or birthing facility where study procedures can be obtained		IN07A00
1.g	8	Expected to be available for the duration of the study and can be contacted by telephone during study participation		IN08A00
1.h	9	Participant is willing to give informed consent for her infant to participate in the study		IN09A00
1.i	10	Pre-pregnancy body mass index (BMI) of <= 40 kg/m2 at enrollment. If pre-pregnancy BMI is not available, the BMI at the time of the first obstetric visit during the current pregnancy may be used		IN10A01
1.j	11	Capable giving signed IC, includes compliance with requirements/restrictions in ICD/protocol		IN11A02

Inclusion Criteria Entry

1.1	Inclusion Number: [Inclusion Number]	
1.2	Criterion Description: [Criterion Description]	
1.3	Criterion met? [Criterion met?]	◯ YES ◯ NO Describe details if relevant
1.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	

Exclusion Criteria

# ✔	Exclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
2.a	1	Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation		EX01A00
2.b	2	Previous clinical (based on COVID-19 symptoms/signs alone) or microbiological (based on COVID-19 symptoms/signs and a positive SARS-CoV-2 NAAT result) diagnosis of COVID 19		EX02A00
2.c	3	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the investigational product or any related vaccine		EX03A00
2.d	4	Participants with known or suspected immunodeficiency		EX04A00
2.e	5	Bleeding diathesis or condition associated with prolonged bleeding that would in the opinion of the investigator contraindicate intramuscular injection		EX05A00
2.f	8	Phase 3: Current Major illness of maternal pt or condition of fetus that, will increase risk associated with maternal pt's participation in/completion of study or preclude evaluation of pt's response		EX08A00
2.g	9	Previous vaccination with any coronavirus vaccine		EX09A00
2.h	10	Receipt of medications intended to prevent COVID 19		EX10A00
2.i	11	Receipt of blood/plasma products or immunoglobulin, from 60 days before IP administration, or planned receipt through delivery, with 1 exception, anti D immunoglobulin, which can be given at any time		EX11A00
2.j	12	Current alcohol abuse or illicit drug use		EX12A00
2.k	13	Individuals who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids. Inhaled/nebulized, Intra-articular, intrabursal, or topical corticosteroids are permitted		EX13A00
2.l	14	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation		EX14A00
2.m	15	Previous participation in other studies involving study intervention containing lipid nanoparticles		EX15A00
2.n	17	Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members		EX17A00
2.o	18	Pts whose unborn baby has been fathered by investigator site staff or Pfizer employees directly involved in study conduct, site staff otherwise supervised by the PI, and their respective family		EX18A00

Exclusion Criteria Entry

2.1	Exclusion Number: [Exclusion Number]	
2.2	Criterion Description: [Criterion Description]	
2.3	Criterion met? [Criterion met?]	◯ YES Describe details if relevant

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		○ NO
2.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	

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C4591015: INCLUSION/EXCLUSION CRITERIA - P3 AMENDED 2 (IE P3 AM2)

Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclusion criteria (NO).

Inclusion Criteria

# ✔	Inclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
1.a	1	Women >=18 years old and between 27 (P2) or 24 (P3) and 34 wks gestation the day of planned vaccination, with an uncomplicated, singleton pregnancy, who are at no known increased risk for complication		IN01A00
1.b	2	Participants who are willing and able to comply with scheduled visits, treatment plan, laboratory tests, and other study procedures		IN02A00
1.c	3	Receiving prenatal standard of care based on country requirements		IN03A00
1.d	4	Had an ultrasound examination performed at >=18 weeks of pregnancy with no significant fetal abnormalities observed, based on the investigator's judgment		IN04A00
1.e	5	Healthy participants who are determined by medical history, physical examination, and clinical judgment to be appropriate for inclusion in the study. Criteria for P3 participants is in Section 10.4		IN05A02
1.f	6	Documented negative HIV antibody test (Phase 2 only), syphilis test, and hepatitis B virus (HBV) surface antigen test during this pregnancy and prior to randomization (Visit 1)		IN06A02
1.g	7	Intention to deliver at a hospital or birthing facility where study procedures can be obtained		IN07A00
1.h	8	Expected to be available for the duration of the study and can be contacted by telephone during study participation		IN08A00
1.i	9	Participant is willing to give informed consent for her infant to participate in the study		IN09A00
1.j	10	Pre-pregnancy body mass index (BMI) of <= 40 kg/m2 at enrollment. If pre-pregnancy BMI is not available, the BMI at the time of the first obstetric visit during the current pregnancy may be used		IN10A01
1.k	11	Capable giving signed IC, includes compliance with requirements/restrictions in ICD/protocol		IN11A02

Inclusion Criteria Entry

1.1	Inclusion Number: [Inclusion Number]	
1.2	Criterion Description: [Criterion Description]	
1.3	Criterion met? [Criterion met?]	○ YES ○ NO Describe details if relevant
1.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	

Exclusion Criteria

# ✔	Exclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
2.a	1	Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation		EX01A00
2.b	2	Previous clinical (based on COVID-19 symptoms/signs alone) or microbiological (based on COVID-19 symptoms/signs and a positive SARS-CoV-2 NAAT result) diagnosis of COVID 19		EX02A00
2.c	3	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the investigational product or any related vaccine		EX03A00
2.d	4	Participants with known or suspected immunodeficiency		EX04A00
2.e	5	Bleeding diathesis or condition associated with prolonged bleeding that would in the opinion of the investigator contraindicate intramuscular injection		EX05A00
2.f	8	Phase 3: Current Major illness of maternal pt or condition of fetus that, will increase risk associated with maternal pt's participation in/completion of study or preclude evaluation of pt's response		EX08A00
2.g	9	Previous vaccination with any coronavirus vaccine		EX09A00
2.h	10	Receipt of medications intended to prevent COVID 19		EX10A00
2.i	11	Receipt of blood/plasma products or immunoglobulin, from 60 days before IP administration, or planned receipt through delivery, with 1 exception, anti D immunoglobulin, which can be given at any time		EX11A00
2.j	12	Current alcohol abuse or illicit drug use		EX12A00
2.k	13	Individuals who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids. Inhaled/nebulized, Intra-articular, intrabursal, or topical corticosteroids are permitted		EX13A00
2.l	14	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation		EX14A00
2.m	15	Previous participation in other studies involving study intervention containing lipid nanoparticles		EX15A00
2.n	17	Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members		EX17A00
2.o	18	Pts whose unborn baby has been fathered by investigator site staff or Pfizer employees directly involved in study conduct, site staff otherwise supervised by the PI, and their respective family		EX18A00

Exclusion Criteria Entry

2.1	Exclusion Number: [Exclusion Number]	
2.2	Criterion Description: [Criterion Description]	
2.3	Criterion met? [Criterion met?]	○ YES Describe details if relevant

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		NO
2.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	

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C4591015: INCLUSION/EXCLUSION CRITERIA - P3 A2 (IE P3A2)

Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclusion criteria (NO).

Inclusion Criteria

# ✔	Inclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
1.a	1	Women >=18 years old and between 27 (P2) or 24 (P3) and 34 wks gestation the day of planned vaccination, with an uncomplicated, singleton pregnancy, who are at no known increased risk for complication		IN01A00
1.b	2	Participants who are willing and able to comply with scheduled visits, treatment plan, laboratory tests, and other study procedures		IN02A00
1.c	3	Receiving prenatal standard of care based on country requirements		IN03A00
1.d	4	Had an ultrasound examination performed at >=18 weeks of pregnancy with no significant fetal abnormalities observed, based on the investigator's judgment		IN04A00
1.e	5	Healthy participants who are determined by medical history, physical examination, and clinical judgment to be appropriate for inclusion in the study. Criteria for P3 participants is in Section 10.4		IN05A02
1.f	7	Intention to deliver at a hospital or birthing facility where study procedures can be obtained		IN07A00
1.g	8	Expected to be available for the duration of the study and can be contacted by telephone during study participation		IN08A00
1.h	9	Participant is willing to give informed consent for her infant to participate in the study		IN09A00
1.i	10	Pre-pregnancy body mass index (BMI) of <= 40 kg/m2 at enrollment. If pre-pregnancy BMI is not available, the BMI at the time of the first obstetric visit during the current pregnancy may be used		IN10A01
1.j	11	Capable giving signed IC, includes compliance with requirements/restrictions in ICD/protocol		IN11A02

Inclusion Criteria Entry

1.1	Inclusion Number: [Inclusion Number]	
1.2	Criterion Description: [Criterion Description]	
1.3	Criterion met? [Criterion met?]	◯ YES ◯ NO Describe details if relevant
1.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	

Exclusion Criteria

# ✔	Exclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
2.a	1	Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation		EX01A00
2.b	2	Previous clinical (based on COVID-19 symptoms/signs alone) or microbiological (based on COVID-19 symptoms/signs and a positive SARS-CoV-2 NAAT result) diagnosis of COVID 19		EX02A00
2.c	3	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the investigational product or any related vaccine		EX03A00
2.d	4	Participants with known or suspected immunodeficiency		EX04A00
2.e	5	Bleeding diathesis or condition associated with prolonged bleeding that would in the opinion of the investigator contraindicate intramuscular injection		EX05A00
2.f	6	Phase 2: Major illness of maternal pt or condition of fetus that, will increase risk associated with maternal pt's participation in/completion of study or preclude evaluation of the pt's response		EX06A00
2.g	7	Phase 2: Maternal participants with a history of stable chronic diseases that are known to increase the risk of obstretrical/neonatal complications (as defined in the protocol) should not be included		EX07A00
2.h	9	Previous vaccination with any coronavirus vaccine		EX09A00
2.i	10	Receipt of medications intended to prevent COVID 19		EX10A00
2.j	11	Receipt of blood/plasma products or immunoglobulin, from 60 days before IP administration, or planned receipt through delivery, with 1 exception, anti D immunoglobulin, which can be given at any time		EX11A00
2.k	12	Current alcohol abuse or illicit drug use		EX12A00
2.l	13	Individuals who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids. Inhaled/nebulized, Intra-articular, intrabursal, or topical corticosteroids are permitted		EX13A00
2.m	14	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation		EX14A00
2.n	15	Previous participation in other studies involving study intervention containing lipid nanoparticles		EX15A00
2.o	17	Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members		EX17A00
2.p	18	Pts whose unborn baby has been fathered by investigator site staff or Pfizer employees directly involved in study conduct, site staff otherwise supervised by the PI, and their respective family		EX18A00

Exclusion Criteria Entry

2.1	Exclusion Number: [Exclusion Number]	
2.2	Criterion Description: [Criterion Description]	
2.3	Criterion met? [Criterion met?]	◯ YES Describe details if relevant

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		NO
2.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	

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C4591015: ILLNESS DETAILS - POTENTIAL COVID-19 (ILL POTEN)		
1.	Category of Clinical Event: [Category of Clinical Event:]	○ POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness? [Diagnosis Obtained]	○ YES Respiratory Illness Diagnosis: Date of Diagnosis: / / ○ NO
3.	Toxicity Grade: [Toxicity Grade]	
Note: Hidden items are not displayed.		

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C4591015: ILLNESS DETAILS - COVID-19 SEVERE (ILL SEVERE) - Repeating Form

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Diagnosis Term	Toxicity Grade
1					

1.	Category of Clinical Event: [Category of Clinical Event:]	○ SEVERE COVID-19 ILLNESS
2.	Subcategory of Clinical Event: [Subcategory of Clinical Event]	○ SIGNIFICANT ACUTE RENAL DYSFUNCTION ○ SIGNIFICANT ACUTE HEPATIC DYSFUNCTION ○ SIGNIFICANT ACUTE NEUROLOGIC DYSFUNCTION
3.	Was a diagnosis obtained [for protocol specified illness/disease]? [Diagnosis Obtained]	○ YES Start Date: / / Ongoing?: ○ YES ○ NO End Date: / / ○ NO
4.	Diagnosis: [Diagnosis Term]	
5.	Toxicity Grade: [Toxicity Grade]	

Note: Hidden items are not displayed.

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C4591015: IMAGING (IMAGING) - Repeating Form

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment
1				

1.	Date of Assessment: [Date of Assessment]	/ /
2.	Location of Assessment: [Location of Assessment]	○ CHEST ○ HEAD ○ OTHER If other, specify:
3.	Type of Imaging Exam: [Imaging Method]	○ CT SCAN ○ X-RAY ○ ULTRASOUND ○ MRI ○ OTHER
4.	Assessment: [Overall Assessment]	○ ABNORMAL If abnormal, specify findings: ○ INDETERMINATE ○ NORMAL ○ UNKNOWN ○ NOT EVALUABLE

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C4591015: IMAGING - CARDIAC MRI (IMAGINGCAR) - Repeating Form				
#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment
1				

Imaging		
1.	Date of Assessment: [Date of Assessment]	/ / : *24-hour clock*
2.	Location of Assessment: [Location of Assessment]	CARDIOVASCULAR SYSTEM
3.	Type of Imaging Exam: [Imaging Method]	MRI
4.	Assessment: [Overall Assessment]	ABNORMAL If abnormal, specify findings: INDETERMINATE NORMAL UNKNOWN

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C4591015: IMAGING - MIS-C (IMG MISC) - Repeating Form

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Significant Change Detail
1					

Imaging

1.	Date of Assessment: [Date of Assessment]	/ /
2.	Location of Assessment: [Location of Assessment]	○ CHEST ○ OTHER If other, specify:
3.	Type of Imaging Exam: [Imaging Method]	○ CT SCAN ○ X-RAY ○ ULTRASOUND ○ MRI If MRI, was a gadolinium enhancement done? ○ YES ○ NO ○ OTHER If other, specify:
4.	Assessment: [Overall Assessment]	○ ABNORMAL If abnormal, specify findings: ○ INDETERMINATE ○ NORMAL ○ UNKNOWN ○ NOT EVALUABLE
5.	If Yes, specify: [Significant Change Detail]	

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C4591015: INCLUSION/EXCLUSION CRITERIA - INF (INF IE)

Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclusion criteria (NO).

Inclusion Criteria

#	Inclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
1.a	1	ICD signed/dated by parent(s)/legal guardian(s) OR thumbprinted IC, signed, dated by impartial witness present through IC process. ICD from father of fetus/infant if mandated by local requirements		IN12A00
1.b	2	Parent(s) willing and able to comply with scheduled visits, treatment plan, laboratory tests, and other study procedures		IN13A00

Inclusion Criteria Entry

1.1	Inclusion Number: [Inclusion Number]	○ 1 ○ 2
1.2	Criterion Description: [Criterion Description]	○ ICD signed/dated by parent(s)/legal guardian(s) OR thumbprinted IC, signed, dated by impartial witness present through IC process. ICD from father of fetus/infant if mandated by local requirements ○ Parent(s) willing and able to comply with scheduled visits, treatment plan, laboratory tests, and other study procedures
1.3	Criterion met? [Criterion met?]	○ YES ○ NO Describe details if relevant
1.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	○ IN12A00 ○ IN13A00

Exclusion Criteria

#	Exclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
2.a	1	Infant who is a direct descendant (eg, child or grandchild) of the study personnel		EX18A00

Exclusion Criteria Entry

2.1	Exclusion Number: [Exclusion Number]	○ 1
2.2	Criterion Description: [Criterion Description]	○ Infant who is a direct descendant (eg, child or grandchild) of the study personnel
2.3	Criterion met? [Criterion met?]	○ YES Describe details if relevant ○ NO
2.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	○ EX18A00

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C4591015: VITAL SIGNS - INFANT (INF VIT)		
1.	Date Time: [Date Time:]	/ /
2.	Weight: [Weight]	
3.	Unit: [Weight Unit]	kg LB
4.	Body Length: [Body Length]	
5.	Unit: [Body Length Unit]	cm in
6.	Head Circumference: [Head Circumference]	
7.	Unit: [Head Circumference Unit]	cm in

Vital Signs Details

# ✔	Record Identifier:	Temperature	Temperature Unit	Heart Rate	Respiratory Rate	Oxygen Saturation
8.a	1					

Vital Signs Details Entry		
8.1	Record Identifier: [Record Identifier:]	1
8.2	Temperature: [Temperature]	
8.3	Unit: [Temperature Unit]	F C
8.4	Heart Rate: [Heart Rate]	
8.5	Respiratory Rate: [Respiratory Rate]	
8.6	SPO2 Pulse Oximetry % [Oxygen Saturation]	

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C4591015: CASEBOOK SIGNATURE FORM (INVSIG)		
1.	Casebook Signature [Casebook Signature]	Click Here to Enable

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C4591015: LAB CHEMISTRY (LAB CHEM) - Repeating Form

#	Category for Lab Test	Vendor Name	Specimen Type	Collection Date Time:	Lab Result
1					

Lab Chemistry Details

1.	Lab Panel: [Category for Lab Test]	○ CLINICAL CHEMISTRY
2.	Laboratory Name and Address [Vendor Name]	
3.	Specimen Type: [Specimen Type]	○ BLOOD
4.	Collection Date: [Collection Date Time:]	/ /

Lab Result

# ✔	Sponsor-Defined Identifier	Test	Result	Not Done:	LNMT
5.a		C Reactive Protein_PX329			
5.b		Alanine Aminotransferase_PX30			
5.c		Aspartate Aminotransferase_PX28			
5.d		Alkaline Phosphatase_PX35			
5.e		Bilirubin_PX21			
5.f		Blood Urea Nitrogen_PX47			
5.g		Creatinine_PX48			

Lab Result Entry

5.1	Sponsor ID: [Sponsor-Defined Identifier]	
5.2	Test: [Test]	
5.3	Result: [Result]	
5.4	Not Done: [Not Done:]	○ NOT DONE
5.5	LNMT [LNMT]	High Low Unit ○ mg/L ○ mg/dL ○ g/L ○ U/L

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C4591015: LABORATORY DATA - HEMATOLOGY (LAB HEM) - Repeating Form

#	Category for Lab Test	Vendor Name	Specimen Type	Collection Date Time:	Lab Result
1					

Laboratory Data Hematology

1.	Lab Panel: [Category for Lab Test]	○ HEMATOLOGY
2.	Laboratory Name and Address [Vendor Name]	
3.	Specimen Type: [Specimen Type]	○ BLOOD
4.	Collection Date: [Collection Date Time:]	/ /

Lab Result

# ✔	Sponsor-Defined Identifier	Test	Result	Not Done:	LNMT
5.a		Hemoglobin_PX1			
5.b		Hematocrit_PX2			
5.c		Erythrocytes_PX3			
5.d		Platelets_PX5			
5.e		Leukocytes_PX7			
5.f		Neutrophils_PX608			
5.g		Eosinophils_PX609			
5.h		Monocytes_PX612			
5.i		Basophils_PX610			
5.j		Lymphocytes_PX611			

Lab Result Entry

5.1	Sponsor ID: [Sponsor-Defined Identifier]	
5.2	Test: [Test]	
5.3	Result: [Result]	
5.4	Not Done: [Not Done:]	○ NOT DONE
5.5	LNMT [LNMT]	High Low Unit

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C4591015: LAB CHEMISTRY - TROPONIN (LAB TROPO) - Repeating Form

#	Category for Lab Test	Vendor Name	Specimen Type	Collection Date Time:	Lab Result
1					

Lab Chemistry Details

1.	Lab Panel: [Category for Lab Test]	○ CLINICAL CHEMISTRY
2.	Laboratory Name and Address [Vendor Name]	
3.	Specimen Type: [Specimen Type]	○ BLOOD
4.	Collection Date Time: [Collection Date Time:]	/ / : *24-hour clock*

Lab Result

# ✔	Sponsor-Defined Identifier	Test	Result	Not Done:	LNMT
5.a		Troponin I_PX1580			
5.b		Troponin T_PX1139			

Lab Result Entry

5.1	Sponsor ID: [Sponsor-Defined Identifier]	
5.2	Test: [Test]	○ Troponin I_PX1580 ○ Troponin T_PX1139
5.3	Result: [Result]	
5.4	Not Done: [Not Done:]	○ NOT DONE
5.5	LNMT [LNMT]	High Low Unit

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C4591015: LOCALLY READ ECGs REPEATING (LOCALECGR) - Repeating Form

#	ECG Date Time:	ECG Interpretation	ECG Results	ECG Findings
1				

Locally Read ECGs Repeating

1.	ECG Date Time: [ECG Date Time:]	/ / : *24-hour clock*
2.	Was ECG: [ECG Interpretation]	ABNORMAL If abnormal, was the overall ECG clinically significant? YES NO INDETERMINATE NORMAL UNKNOWN

ECG Results

# ✔	ECG Test Name	Result	Unit
3.a	ECG MEAN HEART RATE		beats/min

ECG Results Entry

3.1	ECG Test Name: [ECG Test Name]	ECG MEAN HEART RATE
3.2	Result: [Result]	
3.3	Unit: [Unit]	beats/min

	Findings
4. ✔	

ECG Findings Entry

4.1	Findings: [Findings]	

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C4591015: MAIN INFORMED CONSENT (MAIN IC)		
1.	Consent Was: [Consent Was:]	OBTAINED Date Written Consent Obtained / /

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C4591015: INCLUSION/EXCLUSION CRITERIA - MATERNAL PHASE 2 (MAT IEP2)

Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclusion criteria (NO).

Inclusion Criteria

# ✔	Inclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
1.a	1	Women >=18 years old and between 27 (P2) or 24 (P3) and 34 wks gestation the day of planned vaccination, with an uncomplicated, singleton pregnancy, who are at no known increased risk for complication		IN01A00
1.b	2	Participants who are willing and able to comply with scheduled visits, treatment plan, laboratory tests, and other study procedures		IN02A00
1.c	3	Receiving prenatal standard of care based on country requirements		IN03A00
1.d	4	Had an ultrasound examination performed at >=18 weeks of pregnancy with no significant fetal abnormalities observed, based on the investigator's judgment		IN04A00
1.e	5	Healthy participants who are determined by medical history, physical examination, and clinical judgment to be appropriate for inclusion in the study		IN05A00
1.f	6	Documented negative HIV antibody test, syphilis test, and hepatitis B virus (HBV) surface antigen test during this pregnancy and prior to randomization (Visit 1)		IN06A00
1.g	7	Intention to deliver at a hospital or birthing facility where study procedures can be obtained		IN07A00
1.h	8	Expected to be available for the duration of the study and can be contacted by telephone during study participation		IN08A00
1.i	9	Participant is willing to give informed consent for her infant to participate in the study		IN09A00
1.j	10	Pre-pregnancy body mass index (BMI) of <= 40 kg/m2 at enrollment. If pre-pregnancy BMI is not available, the BMI at the time of the first obstetric visit during the current pregnancy may be used		IN10A01
1.k	11	Capable giving signed IC, includes compliance with reqmnts/restrictions in ICD/protocol OR if maternal pt is illiterate, thumbprinted IC, signed, dated by impartial witness present through IC process		IN11A00

Inclusion Criteria Entry

1.1	Inclusion Number: [Inclusion Number]	
1.2	Criterion Description: [Criterion Description]	
1.3	Criterion met? [Criterion met?]	YES NO Describe details if relevant
1.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	

Exclusion Criteria

# ✔	Exclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
2.a	1	Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation		EX01A00
2.b	2	Previous clinical (based on COVID-19 symptoms/signs alone) or microbiological (based on COVID-19 symptoms/signs and a positive SARS-CoV-2 NAAT result) diagnosis of COVID 19		EX02A00
2.c	3	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the investigational product or any related vaccine		EX03A00
2.d	4	Participants with known or suspected immunodeficiency		EX04A00
2.e	5	Bleeding diathesis or condition associated with prolonged bleeding that would in the opinion of the investigator contraindicate intramuscular injection		EX05A00
2.f	6	Phase 2: Major illness of maternal pt or condition of fetus that, will increase risk associated with maternal pt's participation in/completion of study or preclude evaluation of the pt's response		EX06A00
2.g	7	Phase 2: Maternal participants with a history of stable chronic diseases that are known to increase the risk of obstretrical/neonatal complications (as defined in the protocol) should not be included		EX07A00
2.h	9	Previous vaccination with any coronavirus vaccine		EX09A00
2.i	10	Receipt of medications intended to prevent COVID 19		EX10A00
2.j	11	Receipt of blood/plasma products or immunoglobulin, from 60 days before IP administration, or planned receipt through delivery, with 1 exception, anti D immunoglobulin, which can be given at any time		EX11A00
2.k	12	Current alcohol abuse or illicit drug use		EX12A00
2.l	13	Individuals who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids. Inhaled/nebulized, Intra-articular, intrabursal, or topical corticosteroids are permitted		EX13A00
2.m	14	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation		EX14A00
2.n	15	Previous participation in other studies involving study intervention containing lipid nanoparticles		EX15A00
2.o	17	Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members		EX17A00
2.p	18	Pts whose unborn baby has been fathered by investigator site staff or Pfizer employees directly involved in study conduct, site staff otherwise supervised by the PI, and their respective family		EX18A00

Exclusion Criteria Entry

2.1	Exclusion Number: [Exclusion Number]	
2.2	Criterion Description:	

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	[Criterion Description]	
2.3	Criterion met? [Criterion met?]	○ YES Describe details if relevant ○ NO
2.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	

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C4591015: INCLUSION/EXCLUSION CRITERIA - MATERNAL PHASE 3 (MAT IEP3)

Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclusion criteria (NO).

Inclusion Criteria

# ✔	Inclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
1.a	1	Women >=18 years old and between 27 (P2) or 24 (P3) and 34 wks gestation the day of planned vaccination, with an uncomplicated, singleton pregnancy, who are at no known increased risk for complication		IN01A00
1.b	2	Participants who are willing and able to comply with scheduled visits, treatment plan, laboratory tests, and other study procedures		IN02A00
1.c	3	Receiving prenatal standard of care based on country requirements		IN03A00
1.d	4	Had an ultrasound examination performed at >=18 weeks of pregnancy with no significant fetal abnormalities observed, based on the investigator's judgment		IN04A00
1.e	5	Healthy participants who are determined by medical history, physical examination, and clinical judgment to be appropriate for inclusion in the study		IN05A00
1.f	6	Documented negative HIV antibody test, syphilis test, and hepatitis B virus (HBV) surface antigen test during this pregnancy and prior to randomization (Visit 1)		IN06A00
1.g	7	Intention to deliver at a hospital or birthing facility where study procedures can be obtained		IN07A00
1.h	8	Expected to be available for the duration of the study and can be contacted by telephone during study participation		IN08A00
1.i	9	Participant is willing to give informed consent for her infant to participate in the study		IN09A00
1.j	10	Pre-pregnancy body mass index (BMI) of <= 40 kg/m2 at enrollment. If pre-pregnancy BMI is not available, the BMI at the time of the first obstetric visit during the current pregnancy may be used		IN10A01
1.k	11	Capable giving signed IC, includes compliance with reqmnts/restrictions in ICD/protocol OR if maternal pt is illiterate, thumbprinted IC, signed, dated by impartial witness present through IC process		IN11A00

Inclusion Criteria Entry

1.1	Inclusion Number: [Inclusion Number]	
1.2	Criterion Description: [Criterion Description]	
1.3	Criterion met? [Criterion met?]	YES NO Describe details if relevant
1.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	

Exclusion Criteria

# ✔	Exclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
2.a	1	Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation		EX01A00
2.b	2	Previous clinical (based on COVID-19 symptoms/signs alone) or microbiological (based on COVID-19 symptoms/signs and a positive SARS-CoV-2 NAAT result) diagnosis of COVID 19		EX02A00
2.c	3	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the investigational product or any related vaccine		EX03A00
2.d	4	Participants with known or suspected immunodeficiency		EX04A00
2.e	5	Bleeding diathesis or condition associated with prolonged bleeding that would in the opinion of the investigator contraindicate intramuscular injection		EX05A00
2.f	8	Phase 3: Current Major illness of maternal pt or condition of fetus that, will increase risk associated with maternal pt's participation in/completion of study or preclude evaluation of pt's response		EX08A00
2.g	9	Previous vaccination with any coronavirus vaccine		EX09A00
2.h	10	Receipt of medications intended to prevent COVID 19		EX10A00
2.i	11	Receipt of blood/plasma products or immunoglobulin, from 60 days before IP administration, or planned receipt through delivery, with 1 exception, anti D immunoglobulin, which can be given at any time		EX11A00
2.j	12	Current alcohol abuse or illicit drug use		EX12A00
2.k	13	Individuals who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids. Inhaled/nebulized, Intra-articular, intrabursal, or topical corticosteroids are permitted		EX13A00
2.l	14	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation		EX14A00
2.m	15	Previous participation in other studies involving study intervention containing lipid nanoparticles		EX15A00
2.n	17	Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members		EX17A00
2.o	18	Pts whose unborn baby has been fathered by investigator site staff or Pfizer employees directly involved in study conduct, site staff otherwise supervised by the PI, and their respective family		EX18A00

Exclusion Criteria Entry

2.1	Exclusion Number: [Exclusion Number]	
2.2	Criterion Description: [Criterion Description]	
2.3	Criterion met?	YES

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	[Criterion met?]	Describe details if relevant NO
2.4	Criterion ID: (For Pfizer use only) [Criterion ID: (For Pfizer use only)]	

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C4591015: VITAL SIGNS - MATERNAL (MAT VIT)		
1.	Date Time: [Date Time:]	/ /
2.	Height: [Height]	
3.	Unit: [Height Unit]	cm in
4.	Weight: [Weight]	
5.	Unit: [Weight Unit]	kg LB
6.	Body Mass Index: [Body Mass Index]	

Vital Signs Details

#	Record Identifier:	Temperature	Temperature Unit	Systolic:	Diastolic:	BP Position	Pulse:
7.a	1					SITTING	

Vital Signs Details Entry		
7.1	Record Identifier: [Record Identifier:]	1
7.2	Temperature: [Temperature]	
7.3	Unit: [Temperature Unit]	C F
7.4	Systolic: [Systolic:]	
7.5	Diastolic: [Diastolic:]	
7.6	BP Position: [BP Position]	SITTING
7.7	Pulse: [Pulse:]	

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C4591015: MEDICATION ERROR (MED ERROR) - Repeating Form

#	Category	Medication Error	Incorrect package ID	Start Date	Is the medication error Still Ongoing	End Date & Time	Study Medication Errors Action	Concomitant Medication Given	Non-Drug Treatment Given	Caused Study Discontinuation	Medication Error Associated With AE
1											

1.	Category: [Category]	○ MEDICATION ERROR
2.	Medication Error: (If possible specify diagnosis, not individual symptoms) [Medication Error]	
3.	If this is a dispensing error, record the incorrect package ID that was dispensed/administered to the subject: [Incorrect package ID]	
4.	Start Date: [Start Date]	/ /
5.	Is the medication error still ongoing? [Is the medication error Still Ongoing]	○ YES ○ NO
6.	End Date: [End Date & Time]	/ /
7.	Latest Action Taken with Study Treatment: [Study Medication Errors Action]	○ NO ACTION TAKEN ○ PERMANENTLY DISCONTINUED
8.	Was a Concomitant Medication given? If yes, record on the Concomitant Medications page [Concomitant Medication Given]	○ YES ○ NO
9.	Was a Non-Drug Treatment given? If yes, record on the Non-Drug Treatment page [Non-Drug Treatment Given]	○ YES ○ NO
10.	Did the Medication Error cause the subject to be discontinued from the study? [Caused Study Discontinuation]	○ YES ○ NO
11.	Was this medication error associated with any adverse events? [Medication Error Associated With AE]	○ YES AE ID: AE ID: AE ID: AE ID: AE ID: ○ NO

Note: Hidden items are not displayed.

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C4591015: GENERAL MEDICAL HISTORY (MEDHX)

	Line/MH Number	Medical History Term	Start Date	Ongoing
1.				

Medical History Details Entry

1.1	Line/MH Number: [Line/MH Number]	
1.2	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies: [Medical History Term]	
1.3	Start Date: [Start Date]	/ /
1.4	Ongoing: [Ongoing]	YES NO End Date: / /

Note: Hidden items are not displayed.

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C4591015: CONCOMITANT MEDICATIONS - MIS-C (MISC) - Repeating Form

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Ongoing
1						

1.	What is the medication identifier? [Sponsor-Defined Identifier]	
2.	Category: [Category for Medication]	◯ GENERAL CONCOMITANT MEDICATIONS
3.	Concomitant Medications Pre-specified: [Concomitant Medications Pre-specified]	◯ NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation). [Name of Medication]	
5.	Start Date: [Start Date]	/ /
6.	Ongoing? [Ongoing]	◯ YES ◯ NO End Date: / /

Note: Hidden items are not displayed.

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C4591015: TRIGGER FORM - MIS-C CASE CRITERIA (MISC CASE)		
Trigger Form Details		
1.	Select appropriate response - Reason for subject hospitalized [Trigger Response 2]	◯ Yes - the subject is hospitalized for confirmed case of MISC ◯ Yes - the subject is hospitalized for suspected case of MISC ◯ No - the subject is hospitalized for alternate diagnosis

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C4591015: TRIGGER FORM - MIS-C ILLNESS SYMPTOMS (MISCILL)		
Trigger Form Details		
1.	Select appropriate response - As response to evidence of clinically severe illness requiring hospitalization, with multisystem (>=2) organ involvement is yes, then select applicable organ system [Trigger Response 2]	○ Subject has Cardiac Symptoms
2.	Select appropriate response - As response to evidence of clinically severe illness requiring hospitalization, with multisystem (>=2) organ involvement is yes, then select applicable organ system [Trigger Response 3]	○ Subject has Renal Symptoms
3.	Select appropriate response - As response to evidence of clinically severe illness requiring hospitalization, with multisystem (>=2) organ involvement is yes, then select applicable organ system [Trigger Response 4]	○ Subject has Respiratory Symptoms
4.	Select appropriate response - As response to evidence of clinically severe illness requiring hospitalization, with multisystem (>=2) organ involvement is yes, then select applicable organ system [Trigger Response 5]	○ Subject has Hematologic Symptoms
5.	Select appropriate response - As response to evidence of clinically severe illness requiring hospitalization, with multisystem (>=2) organ involvement is yes, then select applicable organ system [Trigger Response 6]	○ Subject has Gastrointestinal Symptoms
6.	Select appropriate response - As response to evidence of clinically severe illness requiring hospitalization, with multisystem (>=2) organ involvement is yes, then select applicable organ system [Trigger Response 7]	○ Subject has Dermatologic Symptoms
7.	Select appropriate response - As response to evidence of clinically severe illness requiring hospitalization, with multisystem (>=2) organ involvement is yes, then select applicable organ system [Trigger Response 8]	○ Subject has Neurological Symptoms

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C4591015: TRIGGER FORM - MIS-C INCLUSION (MISCINCL)		
Trigger Form Details		
1.	Select appropriate response - Does the subject have Fever >38.0°C for >=24 hours, or report of subjective fever lasting >=24 hours? [Trigger Response 2]	◯ Yes - Subject has Fever >= 38.0°C for >= 24 hours ◯ Yes - Subject has subjective Fever for >=24 hours ◯ No - Subject does not have Fever for >=24 hours
2.	Select appropriate response - Does the subject Laboratory markers show one or more inflammation? [Trigger Response 3]	◯ Yes - Laboratory marker test results show inflammation ◯ No - Laboratory marker test results does not show inflammation
3.	Select appropriate response - Evidence of clinically severe illness requiring hospitalization, with multisystem (>=2) organ involvement? [Trigger Response 4]	◯ Yes - Subject is hospitalized with evidence of severe illness in 2 or more organ systems ◯ No - Subject is hospitalized with evidence of severe illness WITHOUT 2 or more organ systems
4.	Select appropriate response - Positive for current or recent SARS-COV-2 infection by [Trigger Response 6]	◯ SARS-COV-2 infection tested by RT-PCR test ◯ SARS-COV-2 infection tested by Serology test ◯ SARS-COV-2 infection tested by Antigen test
5.	Select appropriate response - COVID-19 exposure within the 4 weeks prior to the onset of symptoms [Trigger Response 7]	◯ YES - Maternal Subject confirms that Infant exposure to COVID-19 within 4 weeks of symptom onset ◯ NO - Maternal Subject is unaware of Infant exposure to COVID-19 within 4 weeks of symptom onset

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C4591015: NON-DRUG TREATMENTS - MIS-C (NONDRG TX) - Repeating Form

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Ongoing?
1					

NON-DRUG TREATMENTS

1.	What is the treatment Identifier? [Treatment Identifier]	
2.	Concomitant Non-drug Treatment Pre-specified: [Con Non-Drug Treatments Pre-specified]	○ NO
3.	Treatment: [Treatment]	
4.	Start Date: [Start Date]	/ /
5.	Ongoing? [Ongoing?]	○ YES ○ NO End Date: / /

Note: Hidden items are not displayed.

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C4591015: OBSTETRIC EXAMINATION (OB EXAM)		
1.	Last menstrual period start date: [Last Menstrual Period Start Date]	/ /
2.	First trimester ultrasound date: [First Trimester Ultrasound Date]	/ /
3.	Second trimester ultrasound date: [Second Trimester Ultrasound Date]	/ /
4.	Third trimester ultrasound date: [Third trimester ultrasound date:]	/ /
5.	Gestational Age [Gestational Age]	Gestational Age in Weeks Gestational Age in Days
6.	Method used to determine gestational age: [Method Used to Determine Gestational Age]	FIRST TRIMESTER ULTRASOUND SECOND TRIMESTER ULTRASOUND THIRD TRIMESTER ULTRASOUND
7.	Estimated due date: [Estimated due date:]	/ /
8.	Fetal Heart Tones: [Fetal Heart Tones]	PRESENT ABSENT
9.	Has the subject felt any fetal movements? [Felt Fetal Movements]	YES NO
10.	Investigator's clinical assessment of reported fetal movement: [Clinical Assessment Fetal Movement]	ABNORMAL NORMAL

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C4591015: OBSTETRIC EXAMINATION (OB EXAM)		
Obstetric Examination		
1.	Fetal Heart Tones: [Fetal Heart Tones]	○ PRESENT ○ ABSENT
2.	Has the subject felt any fetal movements? [Felt Fetal Movements]	○ YES ○ NO
3.	Investigator's clinical assessment of reported fetal movement: [Clinical Assessment Fetal Movement]	○ ABNORMAL ○ NORMAL

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C4591015: OBSTETRICAL HISTORY (OBSHX)		
1.	Date of Assessment [Date]	/ /

Obstetrical History Details

#	Obstetrical History	Number
2.a	NUMBER OF PREVIOUS PREGNANCIES	
2.b	NUMBER OF LIVE BIRTHS	
2.c	NUMBER OF STILLBIRTHS	
2.d	NUMBER OF VAGINAL DELIVERIES	
2.e	NUMBER OF C-SECTIONS	
2.f	NUMBER OF SPONTANEOUS ABORTIONS	

Obstetrical History Details Entry

2.1	Obstetrical History [Obstetrical History]	
2.2	Number [Number]	

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C4591015: OXYGENATION PARAMETERS (OXYGEN) - Repeating Form			
#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)
1			

1.	Date Time of Assessment: [Date Time of Assessment]	/ / : *24-hour clock*
2.	Arterial Blood Gases PaO2 (mmHg): [Arterial Blood Gases PaO2]	
3.	FiO2 (Fraction of Inhaled Oxygen): [FiO2 (Fraction of Inhaled Oxygen)]	

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C4591015: PHYSICAL EXAMINATION (PHYS EXAM)

1.	Exam Date: [Exam Date]	/ /

Physical Examination Result

#	Body System Examined	Result
2.a	GENERAL APPEARANCE	
2.b	SKIN	
2.c	HEAD	
2.d	EARS	
2.e	EYES	
2.f	NOSE	
2.g	THROAT	
2.h	HEART	
2.i	LUNGS	
2.j	ABDOMEN	
2.k	MUSCULOSKELETAL	
2.l	EXTREMITIES	
2.m	NEUROLOGICAL	
2.n	LYMPH NODES	

Physical Examination Result Entry

2.1	Body System Examined: [Body System Examined]	
2.2	Result: [Result]	○ NORMAL ○ ABNORMAL If abnormal findings, specify: (If clinically significant, record on the Medical History page). Are there clinically significant findings? ○ YES ○ NO ○ NOT DONE

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C4591015: PHYSICAL EXAMINATION (PHYS EXAM)

1.	Exam Date: [Exam Date]	/ /

Physical Examination Result

#	Body System Examined	Result
2.a	GENERAL APPEARANCE	
2.b	SKIN	
2.c	HEAD	
2.d	EARS	
2.e	EYES	
2.f	NOSE	
2.g	THROAT	
2.h	HEART	
2.i	LUNGS	
2.j	ABDOMEN	
2.k	MUSCULOSKELETAL	
2.l	EXTREMITIES	
2.m	NEUROLOGICAL	
2.n	LYMPH NODES	

Physical Examination Result Entry

2.1	Body System Examined: [Body System Examined]	
2.2	Result: [Result]	○ NORMAL ○ ABNORMAL If abnormal findings, specify: (If clinically significant, record on the Adverse Event page). Are there clinically significant findings? ○ YES ○ NO ○ NOT DONE

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C4591015: PREGNANCY OUTCOME (PREG OUT)		
1.	Date of delivery: [Date of Delivery]	/ /
2.	Location of delivery: [Location of Delivery]	MEDICAL FACILITY HOME OTHER Other location of delivery specify:
3.	Mode of delivery: [Mode of delivery]	VAGINAL DELIVERY CESAREAN SECTION Cesarean section type: ELECTIVE EMERGENCY
4.	Were there any complications experienced during delivery? [Occurrence of Delivery Complications]	YES NO
5.	Indicate the number of births from this pregnancy: [Number of Births]	
6.	Outcome at delivery: [Outcome at Delivery]	LIVE DELIVERY STILLBIRTH Stillbirth: Gestational age at delivery in (weeks): Stillbirth: Gestational age at delivery (days): INDUCED/ELECTIVE ABORTION Induced/elective abortion medical reason, specify:
7.	Gross visual inspection of aborted fetus/stillbirth: [Gross Visual Inspection]	NOT DONE NO OBSERVED ABNORMALITIES OBSERVED ABNORMALITIES If observed abnormalities, specify:
8.	Was pathology performed? [Pathology Performed]	YES Describe any pathology findings: NO
9.	Group B Streptococcal Colonization Status: [Streptococcal Colonization Status]	POSITIVE NEGATIVE UNKNOWN
10.	GBS Test Performed: [Test Performed]	SWAB URINE OTHER
11.	Intrapartum Antibiotic Prophylaxis Given for GBS: [Antibiotic Prophylaxis Given for GBS]	YES NO UNKNOWN

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C4591015: Trigger Form (PROT VER)		
Trigger Form Details		
1.	Select appropriate response - Protocol version [Trigger Response 1]	
2.	Select appropriate response - Will subject continue to participate in the study? [Trigger Response 2]	○ SUBJECT CONTINUING PARTICIPATION IN STUDY ○ SUBJECT NOT CONTINUING PARTICIPATION IN STUDY

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C4591015: RANDOMIZATION (RAND)		
1.	Randomization Date : [Randomization Date :]	/ /
2.	Randomization Number: [Randomization Number]	

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C4591015: NON-DRUG TREATMENTS - RESPIRATORY (RESP TX) - Repeating Form

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Ongoing?	Treatment given?
1						

1.	What is the treatment Identifier? [Treatment Identifier]	
2.	Concomitant Non-drug Treatment Pre-specified: [Con Non-Drug Treatments Pre-specified]	○ YES
3.	Treatment: [Treatment]	○ NON-INVASIVE POSITIVE PRESSURE VENTILATION ○ CPAP ○ INTUBATION ○ OXYGEN THERAPY ○ BIPAP ○ MECHANICAL VENTILATION ○ EXTRACORPOREAL MEMBRANE OXYGENATION (ECMO)
4.	Start Date: [Start Date]	/ /
5.	Ongoing? [Ongoing?]	○ YES ○ NO End Date: / /
6.	Treatment given? [Treatment given?]	○ YES ○ NO

Note: Hidden items are not displayed.

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C4591015: RISK DETERMINANTS - BACKGROUND FACTORS POST BIRTH (RSK FUP)		
1.	Date of assessment: [Date of assessment]	/ /
2.	Maintenance of any breastfeeding since last visit? [Been Breastfed]	YES NO
3.	Use of any formula since last visit? [Use formula]	YES NO

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C4591015: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB (RSWAB)		
1.	Data Origin [Data Origin]	○ SITE
2.	Sample Type [Sample Type]	○ NASAL_SWAB ○ NASAL_SWAB_SELF
3.	Sample Collected? [Sample Collected]	○ YES Date of Collection: / / ○ NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason: [Reason sample not collected]	
		Sample ID
5.		
Aliquot Entry Entry		
5.1	Sample ID [Sample ID]	

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C4591015: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY INF (SAMP INF)		
1.	Data Origin [Data Origin]	○ SITE
2.	Sample Type [Sample Type]	○ SERUM
3.	Sample Collected? [Sample Collected]	○ YES Date of Collection: / / ○ NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason: [Reason sample not collected]	
	Sample ID	
5.		
Aliquot Entry Entry		
Please enter barcode for each aliquot.		
5.1	Sample ID [Sample ID]	

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C4591015: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY MAT (SAMP MAT)		
1.	Data Origin [Data Origin]	○ SITE
2.	Sample Type [Sample Type]	○ SERUM
3.	Sample Collected? [Sample Collected]	○ YES Date of Collection: / / ○ NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason: [Reason sample not collected]	
	Sample ID	
5.		
Aliquot Entry		
Please enter barcode for each aliquot.		
5.1	Sample ID [Sample ID]	

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C4591015: INFORM SCREENING (SCREEN)		
1.	Birth Year: [Birth Year]	/ / : *24-hour clock*

Note: Hidden items are not displayed.

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C4591015: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF (SELF SWAB)		
1.	Data Origin [Data Origin]	○ SITE
2.	Sample Type [Sample Type]	○ NASAL_SWAB_SELF
3.	Sample Collected? [Sample Collected]	○ YES Date of Collection: / / ○ NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason: [Reason sample not collected]	
	Sample ID	
5.		
Aliquot Entry Entry		
Please enter barcode for each aliquot.		
5.1	Sample ID [Sample ID]	

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C4591015: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 (SOD)

If new symptoms are experienced during the SAME illness period, the symptoms should be added to the existing Signs and Symptoms form. A new COVID-19 Illness visit should not be initiated.

1.	Date of Assessment: [Date of Assessment]	/ /
2.	Date of First Symptom Started: [First Symptom Started Date]	/ /
3.	Symptoms Ongoing? [Symptoms Ongoing]	YES NO Date of Last Symptom Resolved: / /

Symptoms

# ✔	Symptoms	Symptom Present
4.a	FEVER	
4.b	NEW OR INCREASED COUGH	
4.c	NEW OR INCREASED SHORTNESS OF BREATH	
4.d	NEW LOSS OF TASTE OR SMELL	
4.e	NEW OR INCREASED SORE THROAT	
4.f	CHILLS	
4.g	NEW OR INCREASED MUSCLE PAIN	
4.h	DIARRHEA	
4.i	VOMITING	

Symptoms Entry

4.1	Symptoms: [Symptoms]	
4.2	Was symptom present? [Symptom Present]	YES NO

	Symptoms - Other
5. ✔	

CESOD03006 Entry

5.1	Symptoms - Other Text: [Symptoms - Other]	

Note: Hidden items are not displayed.

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C4591015: SIGNS AND SYMPTOMS OF MIS-C CARDIAC (SOD CARDIO)

If new symptoms are experienced during the SAME illness period, the symptoms should be added to the existing Signs and Symptoms form. A new COVID-19 Illness visit should not be initiated.

Signs and Symptoms

1.	Date of Assessment: [Date of Assessment]	/ /
2.	Date of First Symptom Started: [First Symptom Started Date]	/ /
3.	Symptoms Ongoing? [Symptoms Ongoing]	YES NO Date of Last Symptom Resolved: / /

Symptoms

# ✔	Symptoms	Symptom Present
4.a	SHOCK	
4.b	ELEVATED TROPONIN	
4.c	ELEVATED BNP / NT-PROBNP	
4.d	VENTRICULAR ARRHYTHMIA	
4.e	SUPRAVENTRICULAR ARRHYTHMIA	
4.f	CONGESTIVE HEART FAILURE	
4.g	MYOCARDITIS	

Symptoms Entry

4.1	Symptoms: [Symptoms]	
4.2	Was symptom present? [Symptom Present]	YES NO

	Symptoms - Other
5. ✔	

5.1	Symptoms - Other Text: [Symptoms - Other]	

Note: Hidden items are not displayed.

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C4591015: SIGNS AND SYMPTOMS OF MIS-C DERMATOLOGIC (SOD DERMA)

If new symptoms are experienced during the SAME illness period, the symptoms should be added to the existing Signs and Symptoms form. A new COVID-19 Illness visit should not be initiated.

Signs and Symptoms

1.	Date of Assessment: [Date of Assessment]	/ /
2.	Date of First Symptom Started: [First Symptom Started Date]	/ /
3.	Symptoms Ongoing? [Symptoms Ongoing]	YES NO Date of Last Symptom Resolved: / /

Symptoms

# ✔	Symptoms	Symptom Present
4.a	RASH	
4.b	MUCOCUTANEOUS LESIONS	

Symptoms Entry

4.1	Symptoms: [Symptoms]	RASH MUCOCUTANEOUS LESIONS
4.2	Was symptom present? [Symptom Present]	YES NO

	Symptoms - Other
5. ✔	

5.1	Symptoms - Other Text: [Symptoms - Other]	

Note: Hidden items are not displayed.

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C4591015: SIGNS AND SYMPTOMS OF MIS-C FEVER (SOD FEVER)

If new symptoms are experienced during the SAME illness period, the symptoms should be added to the existing Signs and Symptoms form. A new COVID-19 Illness visit should not be initiated.

Signs and Symptoms

1.	Date of Assessment: [Date of Assessment]	/ /
2.	Date of First Symptom Started: [First Symptom Started Date]	/ /
3.	Symptoms Ongoing? [Symptoms Ongoing]	YES NO Date of Last Symptom Resolved: / /

Symptoms

# ✔	Symptoms	Symptom Present
4.a	FEVER	

Symptoms Entry

4.1	Symptoms: [Symptoms]	FEVER
4.2	Was symptom present? [Symptom Present]	YES NO

Note: Hidden items are not displayed.

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C4591015: SIGNS AND SYMPTOMS OF MIS-C GASTROINTESTINAL (SOD GI)

If new symptoms are experienced during the SAME illness period, the symptoms should be added to the existing Signs and Symptoms form. A new COVID-19 Illness visit should not be initiated.

Signs and Symptoms

1.	Date of Assessment: [Date of Assessment]	/ /
2.	Date of First Symptom Started: [First Symptom Started Date]	/ /
3.	Symptoms Ongoing? [Symptoms Ongoing]	YES NO Date of Last Symptom Resolved: / /

Symptoms

# ✔	Symptoms	Symptom Present
4.a	VOMITING	
4.b	DIARRHEA	
4.c	ELEVATED BILIRUBIN	
4.d	ELEVATED LIVER ENZYME	

Symptoms Entry

4.1	Symptoms: [Symptoms]	VOMITING DIARRHEA ELEVATED BILIRUBIN ELEVATED LIVER ENZYME
4.2	Was symptom present? [Symptom Present]	YES NO

	Symptoms - Other
5. ✔	

5.1	Symptoms - Other Text: [Symptoms - Other]	

Note: Hidden items are not displayed.

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C4591015: SIGNS AND SYMPTOMS OF MIS-C HEMATOLOGIC (SOD HEM)

If new symptoms are experienced during the SAME illness period, the symptoms should be added to the existing Signs and Symptoms form. A new COVID-19 Illness visit should not be initiated.

Signs and Symptoms

1.	Date of Assessment: [Date of Assessment]	/ /
2.	Date of First Symptom Started: [First Symptom Started Date]	/ /
3.	Symptoms Ongoing? [Symptoms Ongoing]	YES NO Date of Last Symptom Resolved: / /

Symptoms

# ✔	Symptoms	Symptom Present
4.a	ELEVATED D-DIMERS	
4.b	THROMBOPHILIA	
4.c	THROMBOCYTOPENIA	

Symptoms Entry

4.1	Symptoms: [Symptoms]	ELEVATED D-DIMERS THROMBOPHILIA THROMBOCYTOPENIA
4.2	Was symptom present? [Symptom Present]	YES NO

	Symptoms - Other
5. ✔	

5.1	Symptoms - Other Text: [Symptoms - Other]	

Note: Hidden items are not displayed.

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C4591015: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 (SOD INF)

If new symptoms are experienced during the SAME illness period, the symptoms should be added to the existing Signs and Symptoms form. A new COVID-19 Illness visit should not be initiated.

Signs and Symptoms

1.	Date of Assessment: [Date of Assessment]	/ /
2.	Date of First Symptom Started: [First Symptom Started Date]	/ /
3.	Symptoms Ongoing? [Symptoms Ongoing]	YES NO Date of Last Symptom Resolved: / /

Symptoms

# ✔	Symptoms	Symptom Present
4.a	FEVER	
4.b	NEW OR INCREASED COUGH	
4.c	NEW OR INCREASED SHORTNESS OF BREATH	
4.d	DIARRHEA	
4.e	VOMITING	

Symptoms Entry

4.1	Symptoms: [Symptoms]	FEVER NEW OR INCREASED COUGH NEW OR INCREASED SHORTNESS OF BREATH DIARRHEA VOMITING
4.2	Was symptom present? [Symptom Present]	YES NO

Symptoms - Other

5. ✔	

CESOD03006 Entry

5.1	Symptoms - Other Text: [Symptoms - Other]	

Note: Hidden items are not displayed.

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C4591015: SIGNS AND SYMPTOMS OF MIS-C NEUROLOGICAL (SOD NEURO)

If new symptoms are experienced during the SAME illness period, the symptoms should be added to the existing Signs and Symptoms form. A new COVID-19 Illness visit should not be initiated.

Signs and Symptoms

1.	Date of Assessment: [Date of Assessment]	/ /
2.	Date of First Symptom Started: [First Symptom Started Date]	/ /
3.	Symptoms Ongoing? [Symptoms Ongoing]	YES NO Date of Last Symptom Resolved: / /

Symptoms

# ✔	Symptoms	Symptom Present
4.a	CEREBROVASCULAR ACCIDENT	
4.b	ASEPTIC MENINGITIS	
4.c	ENCEPHALOPATHY	

Symptoms Entry

4.1	Symptoms: [Symptoms]	CEREBROVASCULAR ACCIDENT ASEPTIC MENINGITIS ENCEPHALOPATHY
4.2	Was symptom present? [Symptom Present]	YES NO

	Symptoms - Other
5. ✔	

5.1	Symptoms - Other Text: [Symptoms - Other]	

Note: Hidden items are not displayed.

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C4591015: SIGNS AND SYMPTOMS OF MIS-C RENAL (SOD RENAL)

If new symptoms are experienced during the SAME illness period, the symptoms should be added to the existing Signs and Symptoms form. A new COVID-19 Illness visit should not be initiated.

Signs and Symptoms

1.	Date of Assessment: [Date of Assessment]	/ /
2.	Date of First Symptom Started: [First Symptom Started Date]	/ /
3.	Symptoms Ongoing? [Symptoms Ongoing]	YES NO Date of Last Symptom Resolved: / /

Symptoms

# ✔	Symptoms	Symptom Present
4.a	ACUTE KIDNEY INJURY	

Symptoms Entry

4.1	Symptoms: [Symptoms]	ACUTE KIDNEY INJURY
4.2	Was symptom present? [Symptom Present]	YES NO

Symptoms - Other

5. ✔	
5.1	Symptoms - Other Text: [Symptoms - Other]

Note: Hidden items are not displayed.

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C4591015: SIGNS AND SYMPTOMS OF MIS-C RESPIRATORY (SOD RESP)

If new symptoms are experienced during the SAME illness period, the symptoms should be added to the existing Signs and Symptoms form. A new COVID-19 Illness visit should not be initiated.

Signs and Symptoms

1.	Date of Assessment: [Date of Assessment]	/ /
2.	Date of First Symptom Started: [First Symptom Started Date]	/ /
3.	Symptoms Ongoing? [Symptoms Ongoing]	YES NO Date of Last Symptom Resolved: / /

Symptoms

# ✔	Symptoms	Symptom Present
4.a	COUGH	
4.b	SHORTNESS OF BREATH	
4.c	PNEUMONIA	
4.d	ATELECTASIS	
4.e	PLEURAL EFFUSION	
4.f	ACUTE RESPIRATORY DISTRESS SYNDROME	
4.g	PULMONARY EMBOLISM	

Symptoms Entry

4.1	Symptoms: [Symptoms]	
4.2	Was symptom present? [Symptom Present]	YES NO

	Symptoms - Other
5. ✔	

5.1	Symptoms - Other Text: [Symptoms - Other]	

Note: Hidden items are not displayed.

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C4591015: SIGNS AND SYMPTOMS OF POTENTIAL CARDIAC DISEASE (SODCARDIAC)

If new symptoms are experienced during the SAME illness period, the symptoms should be added to the existing Signs and Symptoms form. A new COVID-19 Illness visit should not be initiated.

Signs and Symptoms

1.	Date of Assessment: [Date of Assessment]	/ /
2.	Date of First Symptom Started: [First Symptom Started Date]	/ /
3.	Symptoms Ongoing? [Symptoms Ongoing]	YES NO Date of Last Symptom Resolved: / /
4.	AE ID: [AE Identifier]	

Symptoms

# ✔	Event Pre-specified	Symptoms	Symptom Present
5.a	YES	CHEST PAIN	
5.b	YES	SHORTNESS OF BREATH	
5.c	YES	HEART PALPITATIONS	

Symptoms Entry

5.1	Event Pre-specified: [Event Pre-specified]	YES
5.2	Symptoms: [Symptoms]	CHEST PAIN SHORTNESS OF BREATH HEART PALPITATIONS
5.3	Was symptom present? [Symptom Present]	YES NO

Symptoms - Other

6. ✔	

CESOD03006_10 Entry

6.1	Symptoms - Other Text: [Symptoms - Other]	

Note: Hidden items are not displayed.

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C4591015: Trigger Form (STDYPOP)		
1.	Select appropriate response - Study Population [Trigger Response 3]	○ MATERNAL SUBJECT ○ INFANT SUBJECT

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C4591015: SUBJECT STATUS (SUB STATU)		
1.	Subject Status [Subject Status]	
2.	Subject Status Date [Status Date]	/ /

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C4591015: SUBSTANCE USE (SUBST USE)

#	Category	Has the subject ever used the substance?	Frequency
1.a	TOBACCO		
1.b	ALCOHOL		

1.1	Category [Category]	◯ TOBACCO ◯ ALCOHOL
1.2	Has the subject ever used the substance? [Has the subject ever used the substance?]	◯ NEVER ◯ CURRENT ◯ FORMER
1.3	Frequency [Frequency]	◯ QD ◯ EVERY WEEK ◯ QM

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C4591015: ELECTRONIC SAMPLE TRACKING - NASAL SWAB (SWAB PFE)		
1.	Data Origin [Data Origin]	○ SITE
2.	Sample Type [Sample Type]	○ NASAL_SWAB
3.	Sample Collected? [Sample Collected]	○ YES Date of Collection: / / ○ NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason: [Reason sample not collected]	
	Sample ID	
5.		
Aliquot Entry Entry		
Please enter barcode for each aliquot.		
5.1	Sample ID [Sample ID]	

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C4591015: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES (SYMPRDATE)

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed? [Fever/Pain Medication on Last Diary Day]	○ YES Ongoing? ○ YES ○ NO Stop Date: / / ○ NO

Symptoms

# ✔	Symptom:	Were fever or systemic symptoms present on the last day the Subject Diary was completed?
2.a	FEVER	
2.b	FATIGUE	
2.c	HEADACHE	
2.d	CHILLS	
2.e	VOMITING	
2.f	DIARRHEA	
2.g	NEW OR WORSENED MUSCLE PAIN	
2.h	NEW OR WORSENED JOINT PAIN	

Symptoms Entry

2.1	Symptom: [Symptom:]	
2.2	Were fever or systemic symptoms present on the last day the Subject Diary was completed? [Were fever or systemic symptoms present on the last day the Subject Diary was completed?]	○ YES Ongoing? ○ YES ○ NO Stop Date: / / ○ NO

Injection

3.	Injection Site Location: [Injection Site Location:]	○ DELTOID MUSCLE
4.	Injection Site Body Side: [Injection Site Body Side:]	○ LEFT ○ RIGHT

Injection Site

# ✔	Injection Site Reaction:	Were injection site reactions present on the last day the Subject Diary was completed?
5.a	REDNESS	
5.b	SWELLING	
5.c	PAIN AT INJECTION SITE	

Injection Site Entry

5.1	Injection Site Reaction: [Injection Site Reaction:]	○ REDNESS ○ SWELLING ○ PAIN AT INJECTION SITE
5.2	Were injection site reactions present on the last day the Subject Diary was completed? [Were injection site reactions present on the last day the Subject Diary was completed?]	○ YES Ongoing? ○ YES ○ NO Stop Date: / / ○ NO

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C4591015: TRANSFUSIONS (TRANSFUSE) - Repeating Form		
#	Transfusion Type	Date of Transfusion
1		

1.	Transfusion Type: [Transfusion Type]	○ PACKED RBC ○ PLATELETS ○ WHOLE BLOOD ○ PLASMA ○ OTHER Specify:
2.	Date of Transfusion: [Date of Transfusion]	/ /

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C4591015: TREATMENT UNBLINDED (TRN UNBLN)		
Treatment Unblinded		
1.	Date Treatment Unblinded : [Date Treatment Unblinded :]	/ /
2.	Primary Reason for Unblinding: [Primary Reason for Unblinding]	○ SUBJECT SAFETY CONCERN ○ ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION ○ OTHER If other, specify:

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C4591015: UNPLANNED ASSESSMENT OF LOCAL REACTION (U REACT)

1.	Category for Clinical Event [Category for Clinical Event]	○ UNPLANNED ASSESSMENT OF LOCAL REACTION/SYSTEMIC EVENT
2.	Date of Assessment: [Date of Assessment]	/ /
3.	Injection Site Location [Injection Site Location]	○ DELTOID MUSCLE
4.	Injection Site Body Side: [Injection Site Body Side]	○ LEFT ○ RIGHT

Reaction

# ✔	Reaction:	Reaction Present:
5.a	REDNESS	
5.b	SWELLING	

Reaction Entry

5.1	Reaction: [Reaction:]	○ REDNESS ○ SWELLING
5.2	Reaction Present: [Reaction Present:]	○ YES Maximum Diameter (cm): Minimum Diameter (cm): Meets Grade 4 Reaction Criteria: ○ YES ○ NO ○ NO

Symptom

# ✔	Symptom:	Symptom Present:
6.a	PAIN AT INJECTION SITE	
6.b	FATIGUE/TIREDNESS	
6.c	HEADACHE	
6.d	VOMITING	
6.e	DIARRHEA	
6.f	NEW OR WORSENED MUSCLE PAIN	
6.g	NEW OR WORSENED JOINT PAIN	
6.h	CHILLS	

Symptom Entry

6.1	Symptom: [Symptom:]	
6.2	Symptom Present: [Symptom Present:]	○ YES Symptom Grade: ○ 1 ○ 2 ○ 3 ○ 4 Event related to Study Treament? ○ YES ○ NO ○ NO

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C4591015: Trigger Form (UNBLN TRT)		
Trigger Form Details		
1.	Select appropriate response - [What cohort does the subject belong to?] [Trigger Response 10]	○ SUBJECT RECEIVED THE SALINE INJECTION ○ SUBJECT RECEIVED THE VACCINE

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C4591015: UNPLANNED VISIT (UNPL)		
1.	Assessments [Assessments]	☐ CONTACT OUTCOME - UNPLANNED

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C4591015: VACCINATION (VACIN TRT)		
1.	Was there a temporary delay of vaccination? [Temporary Delay of Vaccination]	○ YES Date of First Delay: [ ] / [ ] / [ ] Reason(s) for Temporary Delay of Vaccination ☐ FEVER OR ACUTE ILLNESS ☐ RECENT SYSTEMIC CORTICOSTEROID TREATMENT ☐ RECENT NON-STUDY VACCINATION ☐ ANTICIPATED NON-STUDY VACCINATION ○ NO
2.	Treatment Name [Treatment Name]	
3.	Formulation: [Formulation:]	○ INJECTION
4.	Dose Date Time: [Dose Date Time:]	[ ] / [ ] / [ ] [ ] : [ ] *24-hour clock*
5.	Anatomical Location: [Anatomical Location:]	○ DELTOID MUSCLE
6.	Body Side: [Body Side:]	○ LEFT ○ RIGHT
7.	Route: [Route:]	○ INTRAMUSCULAR
8.	Actual Dose: [Actual Dose:]	
9.	Unit: [Unit:]	○ ug
10.	Was the subject observed for at least the protocol specified observation period after investigational product administration? [Observed Post Dose For Specified Time]	○ YES ○ NO If No, specify reason:

Note: Hidden items are not displayed.

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C4591015: CONCOMITANT MEDICATIONS - VASOACTIVE (VASOACTIVE) - Repeating Form

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Name of Medication	Start Date	Ongoing
1							

1.	What is the medication identifier? [Sponsor-Defined Identifier]	
2.	Category: [Category for Medication]	○ GENERAL CONCOMITANT MEDICATIONS
3.	Concomitant Medications Pre-specified: [Concomitant Medications Pre-specified]	○ NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation). [Name of Medication]	
5.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation). [Name of Medication]	
6.	Start Date: [Start Date]	/ /
7.	Ongoing? [Ongoing]	○ YES ○ NO End Date: / /

Note: Hidden items are not displayed.

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C4591015: CONCOMITANT MEDICATIONS - VASOPRESSORS (VASOPRESS) - Repeating Form

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Ongoing
1						

1.	What is the medication identifier? [Sponsor-Defined Identifier]	
2.	Category: [Category for Medication]	○ VASOPRESSORS
3.	Concomitant Medications Pre-specified: [Concomitant Medications Pre-specified]	○ NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation). [Name of Medication]	
5.	Start Date: [Start Date]	/ /
6.	Ongoing? [Ongoing]	○ YES ○ NO End Date: / /

Note: Hidden items are not displayed.

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C4591015: VITAL SIGNS - TEMPERATURE (VITAL TEMP)					
1.	Date Time: [Date Time:]	/ /			
Vital Signs Details					
# ✔	**Record Identifier:**	**Temperature**	**Temperature Unit**	**Temperature Location:**	
2.a	1				
Vital Signs Details Entry					
2.1	Record Identifier: [Record Identifier:]	○ 1			
2.2	Temperature: [Temperature]				
2.3	Unit: [Temperature Unit]	○ F ○ C			
2.4	Temperature Location: [Temperature Location:]	○ ORAL CAVITY ○ EAR ○ RECTUM ○ AXILLA ○ FOREHEAD			

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C4591015: VITAL SIGNS - COVID (VITALS COV) - Repeating Form						
#	Date Time:				Vital Signs Details	
1						
1.	Date Time: [Date Time:]	/ /				
Vital Signs Details						
# ✔	Record Identifier:	Systolic:	Diastolic:	Heart Rate:	Respiratory Rate:	
2.a	1					
Vital Signs Details Entry						
2.1	Record Identifier: [Record Identifier:]	1				
2.2	Systolic: [Systolic:]					
2.3	Diastolic: [Diastolic:]					
2.4	Heart Rate: [Heart Rate:]					
2.5	Respiratory Rate: [Respiratory Rate:]					

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C4591015: VITAL SIGNS - PULSE OX (VITALS PUL) - Repeating Form		
#	Date Time:	Vital Signs Details
1		

1.	Date Time: [Date Time:]	/ /

Vital Signs Details

# ✔	Record Identifier:	Oxygen Saturation
2.a	1	

Vital Signs Details Entry

2.1	Record Identifier: [Record Identifier:]	1
2.2	SPO2 Pulse Oximetry % [Oxygen Saturation]	

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C4591015: WITHDRAWAL OF CONSENT (WOC)		
1.	Withdrawal of Consent Date : [Withdrawal of Consent Date :]	/ /

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A-1426-0111 / C4591015
App Subject Facing Screen Report

Localized texts are displayed in English (US).

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Localized months and days of the week will display throughtout the app.

Month	January	February	March	April	May	June	July	August	September	October	November	December
Abbr.	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec

Days	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Abbr.	Mon	Tue	Wed	Thu	Fri	Sat	Sun

Note: Text below the screens/messages is for information purposes only and gives instruction on when particular wording on a screen/message may display or what a computed value may display.

1 Notifications / Subject card

Email notification/Subject card to provisioned device subjects:

Welcome to the C4591015 study!

Email notification only: [Hello, **]**

The information below will guide you on how to start using the [redacted] App.

On the phone provided to you by the study clinic, open the [redacted] App and type in the following code to activate it:
[Activation Code]

Then log in with your temporary PIN provided by your study clinic personnel. You will be asked to change the PIN to a new personal one.

During your study clinic visit, the study personnel will help you with any questions related to the [redacted] App activation.

You must activate the App with the provided activation code during your study clinic visit. If you need any help with the activation, contact your study clinic or the Helpdesk.

If you contact your study clinic or the Helpdesk, you may need to give the following information:

Subject card only: [Participant number: XXXXXXXX **]**

Subject card only: [Site number: XXXX **]**

Trial ID: C4591015

Email notification only: [----------
This is an automatic e-mail message sent by [redacted], an electronic patient diary provider for clinical trials. This email message and its contents are for the sole use of the intended recipient(s) and may contain confidential and privileged information. Any unauthorized review, use, disclosure or distribution is strictly prohibited. Please do not reply to this email; the email address cannot receive messages. If you need any assistance, please contact the Helpdesk. **]**

SMS Body for Provisioned Devices:
Welcome to the C4591015 Study! Activate the [redacted] App with code:
[Activation Code]

090177e1a08e8b06\Approved\Approved On: 30-Apr-2024 04:32 (GMT)

Email notification/Subject card to BYOD subjects:

Welcome to the C4591015 study!

Email notification only: [Hello, **]**

The information below will guide you on how to install the [redacted] App onto your cell phone and how to start using the [redacted] App after the installation.

Email notification only: [To install the [redacted] App, tap the link below and follow the on-screen instructions. **]**

Subject card only: [To install the [redacted] App, tap the link in the installation text message (SMS) or email you will receive in a few minutes, and follow the on-screen instructions.

If you have not received the text message or email, enter the following internet address into the web browser of your device: **]**
[Link]

After the installation has completed, open the [redacted] App and type in the following code to activate it:
[Activation Code]

Then log in with your temporary PIN provided by your study clinic personnel. You will be asked to change the PIN to a new personal one.

During your study clinic visit, the study clinic personnel will help you with any questions related to the [redacted] App installation.

You must activate the App with the provided activation code during your study clinic visit. If you need any help with the installation, contact your study clinic or the Helpdesk.

If you contact your study clinic or the Helpdesk, you may need to give the following information:

Subject card only: [Participant number: XXXXXXXX **]**

Subject card only: [Site number: XXXX **]**

Trial ID: C4591015

Email notification only: [----------
This is an automatic e-mail message sent by [redacted], an electronic patient diary provider for clinical trials. This email message and its contents are for the sole use of the intended recipient(s) and may contain confidential and privileged information. Any unauthorized review, use, disclosure or distribution is strictly prohibited. Please do not reply to this email; the email address cannot receive messages. If you need any assistance, please contact the Helpdesk. **]**

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SMS Body for BYOD subjects:

Welcome to the C4591015 Study! To install the [redacted] App, select the link:
[Link]
Activate the [redacted] App with code:
[Activation Code]

App notification:

Please fill in your diary!

Email notification subject :
COVID-19 Illness Diary Reminder

Email and SMS Body for COVID-19 Illness Diary Reminder:

Please continue to complete the illness diary weekly or if you experience COVID-19 symptoms or have a COVID-19 diagnosis. Contact your study doctor with any suspected COVID-19 symptoms.

Email notification only: [----------
This is an automatic e-mail message sent by [redacted] an electronic patient diary provider for clinical trials. This email message and its contents are for the sole use of the intended recipient(s) and may contain confidential and privileged information. Any unauthorized review, use, disclosure or distribution is strictly prohibited. Please do not reply to this email; the email address cannot receive messages. If you need any assistance, please contact the Helpdesk. **]**

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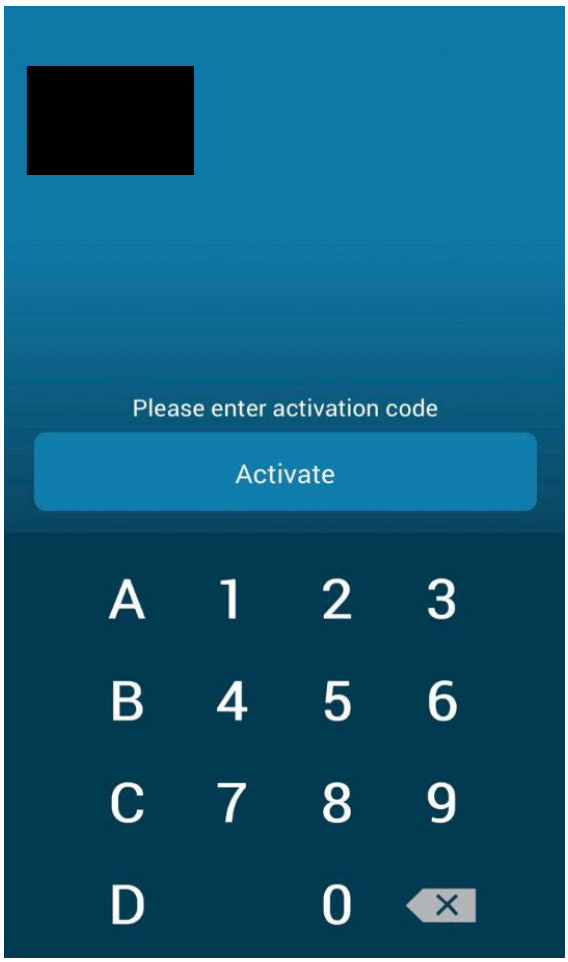
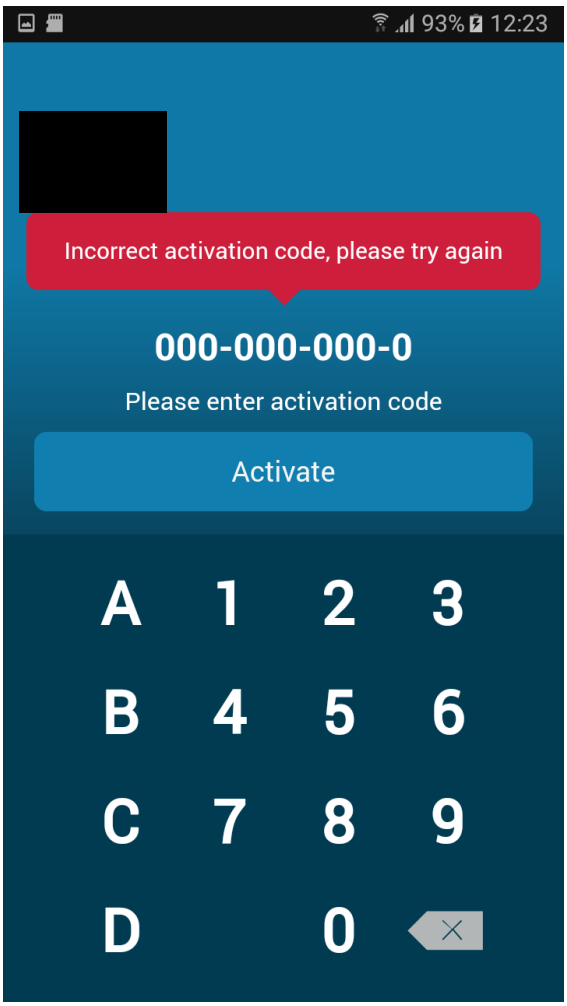
2 Common



Screen 1



Screen 2

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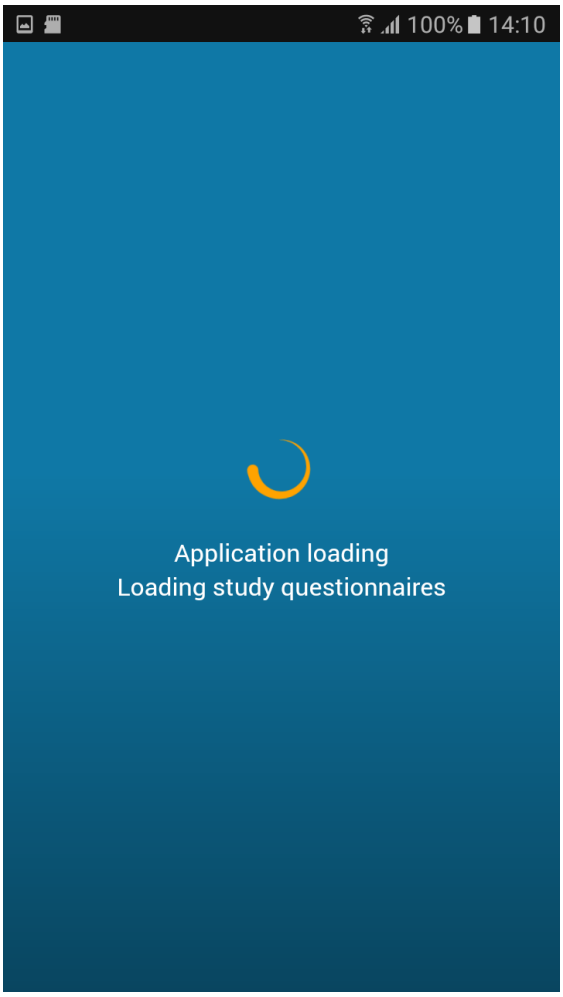
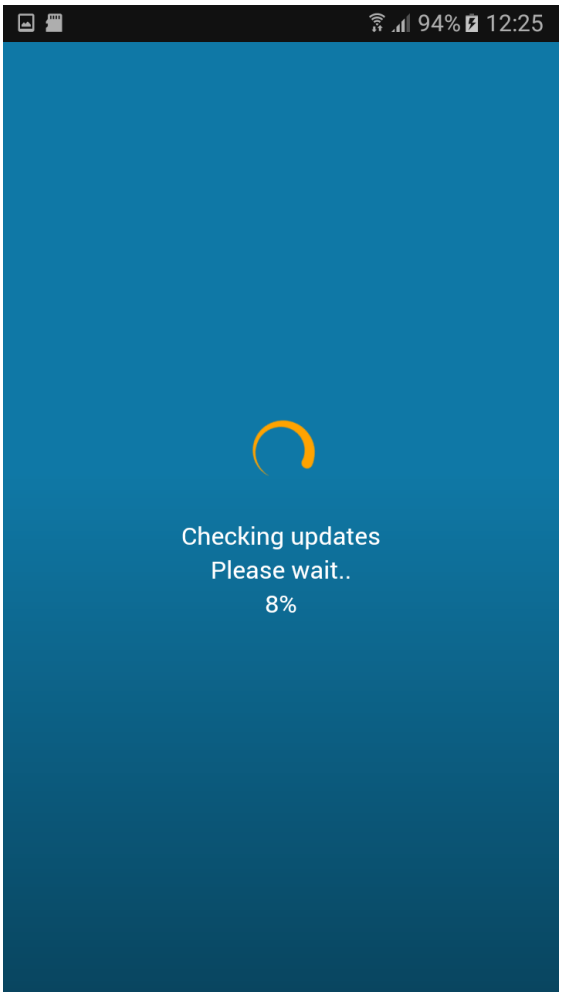


Screen 3



Screen 4

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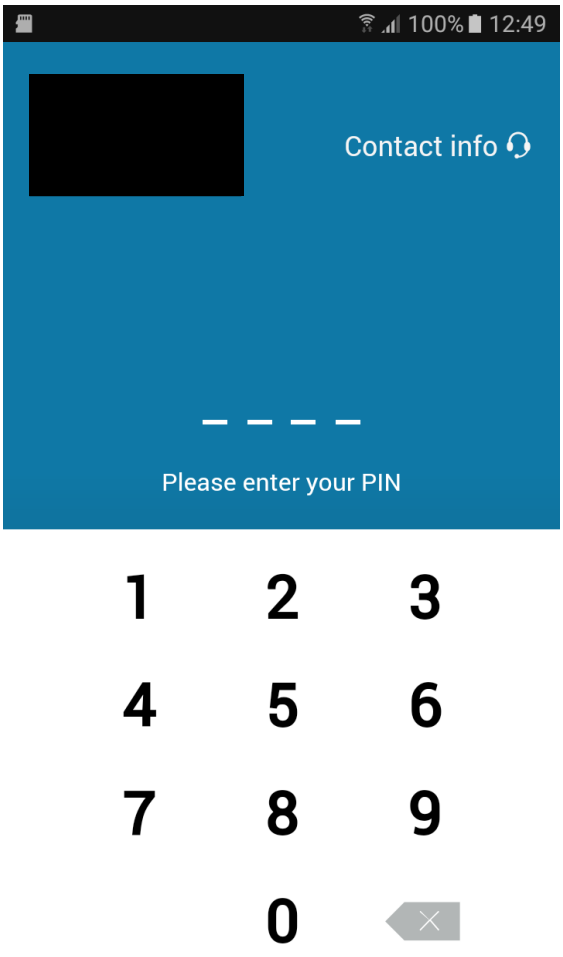
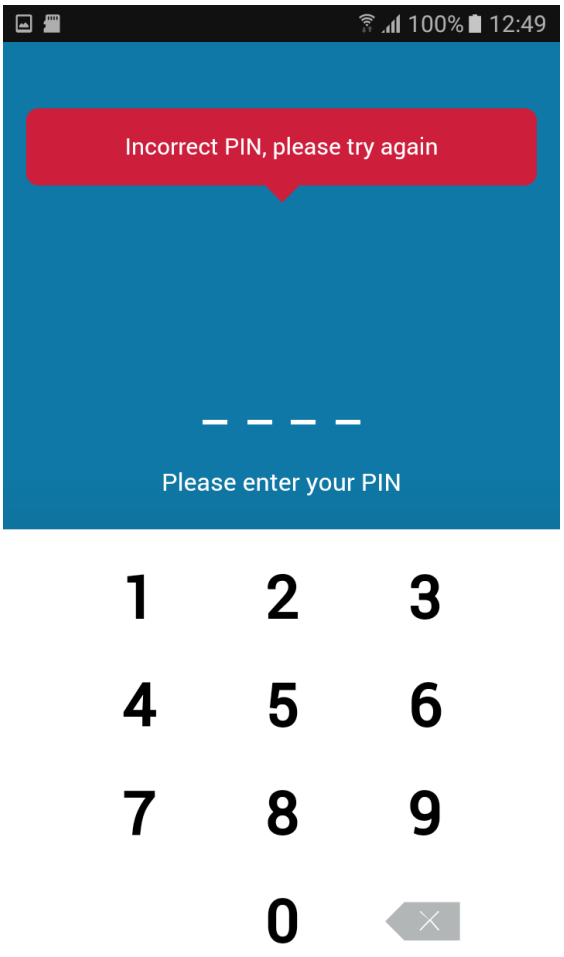


Screen 5



Screen 6

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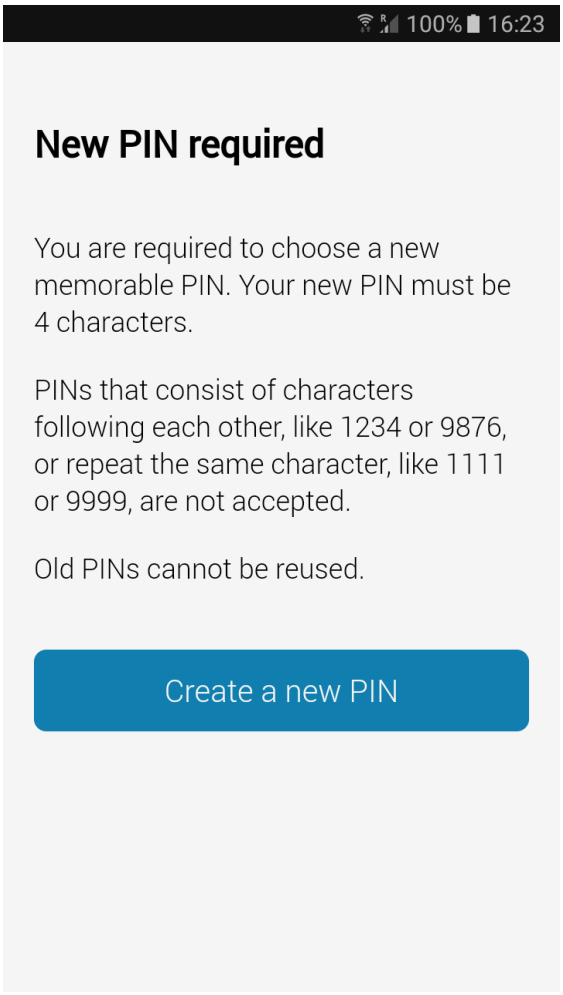
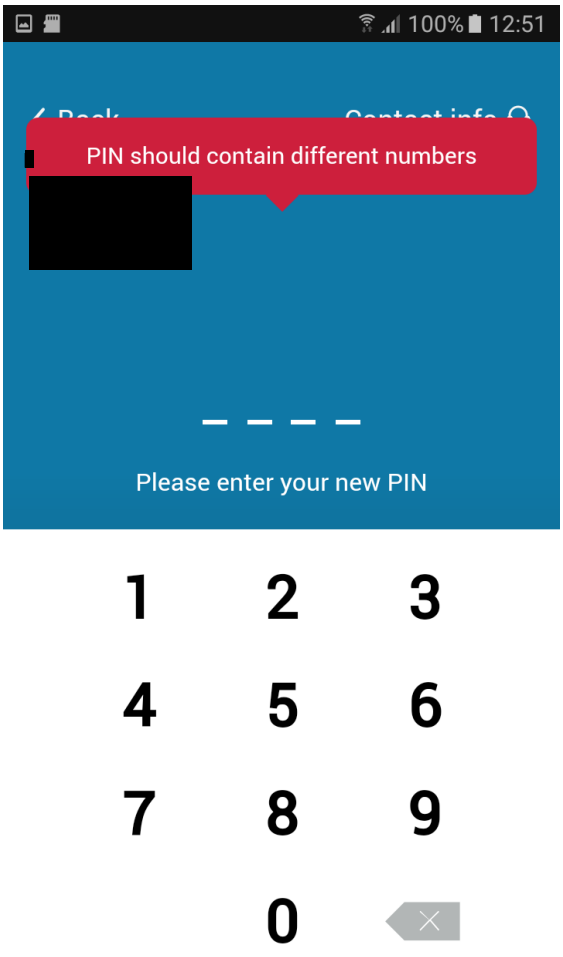


Screen 7

Screen 8

090177e1a08e8b06\Approved\Approved On: 30-Apr-2024 04:32 (GMT)



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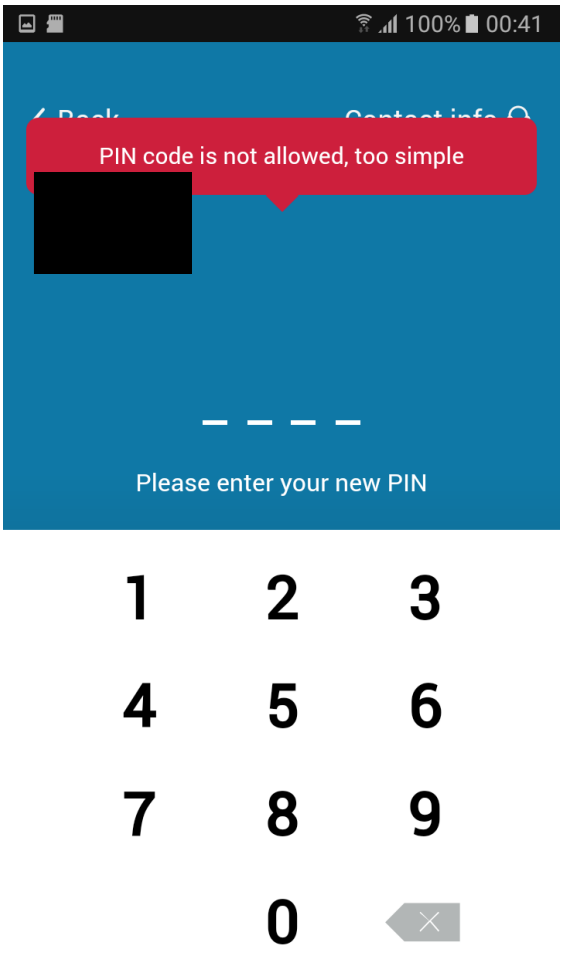

Screen 10

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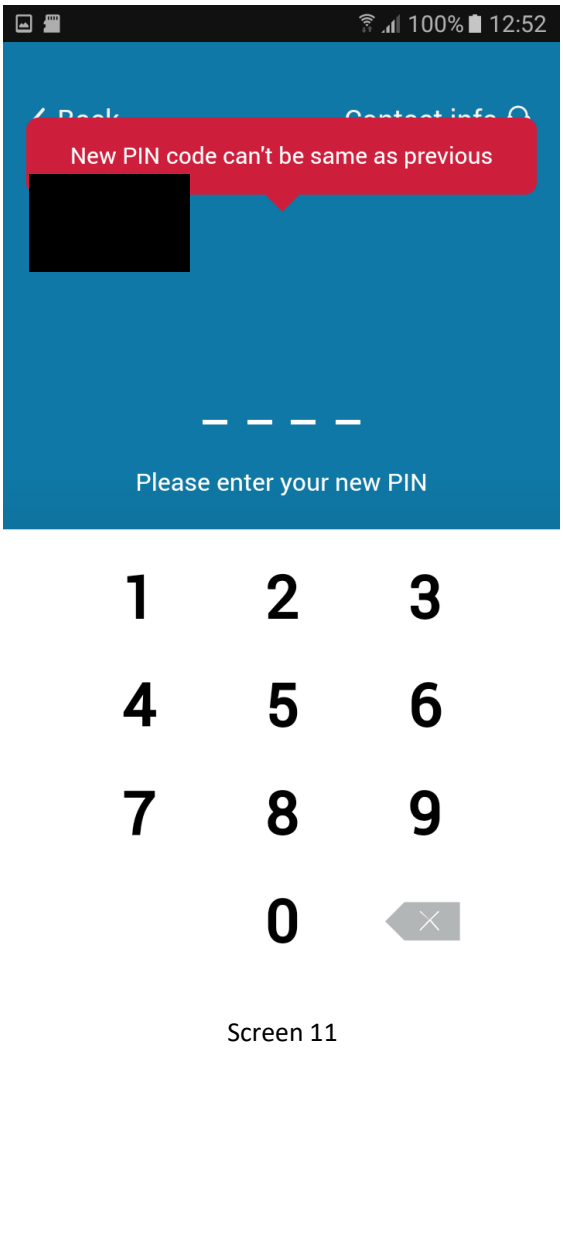

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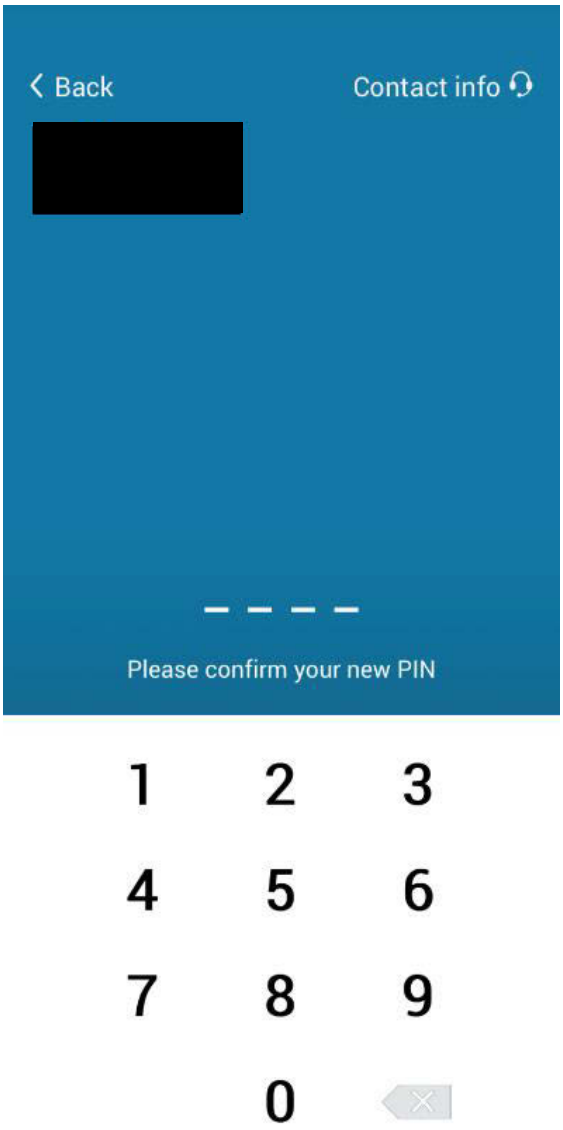

Screen 12

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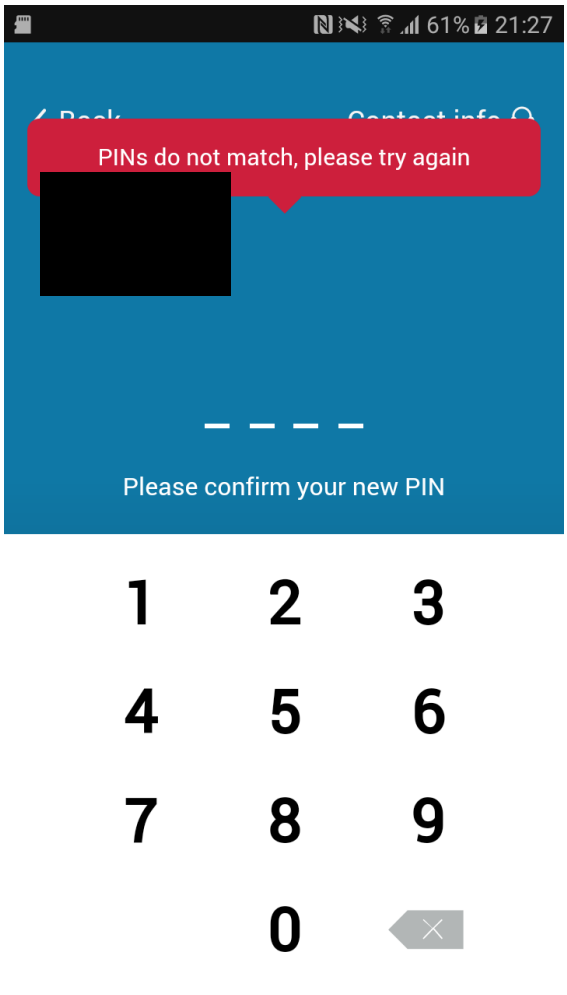
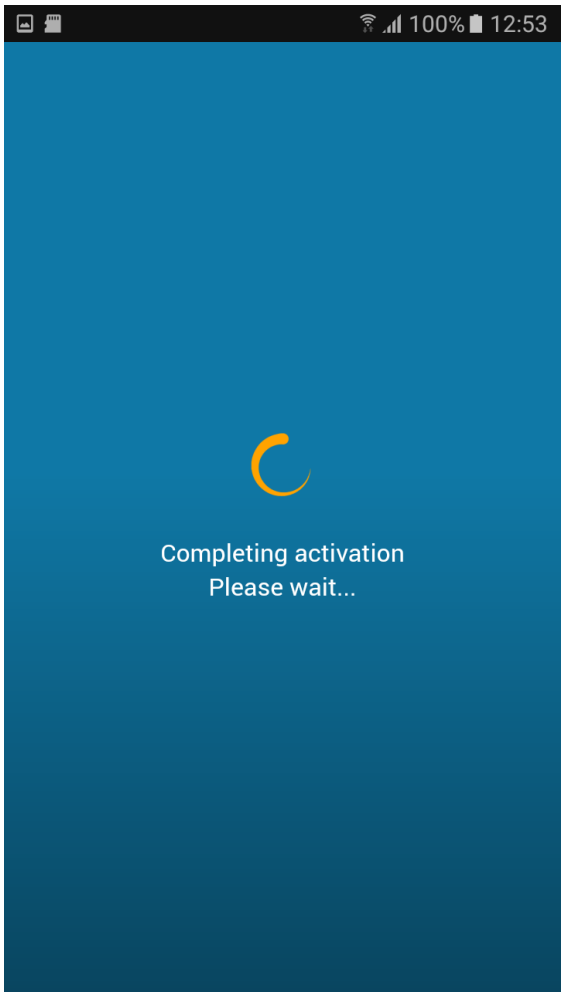


Screen 13



Screen 14

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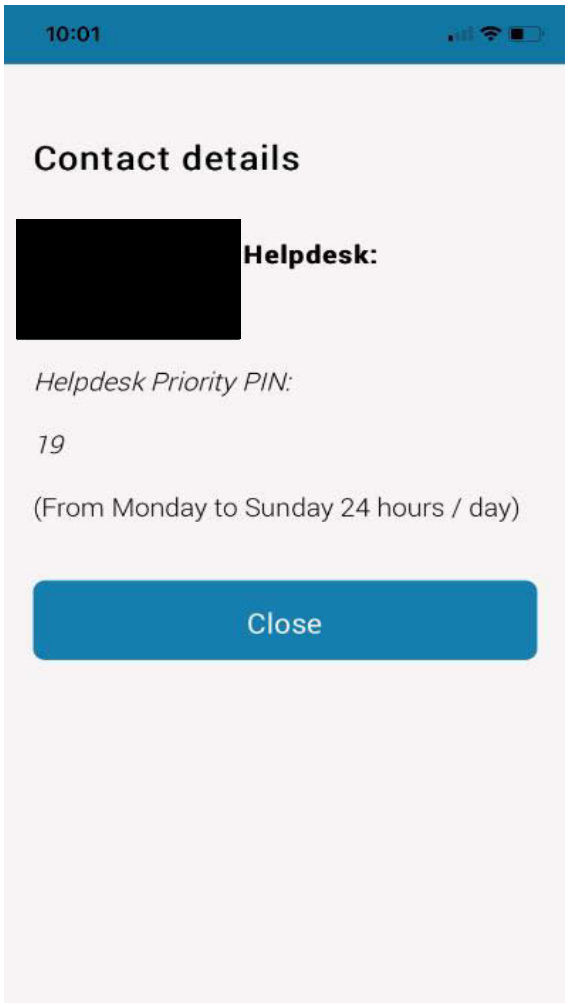
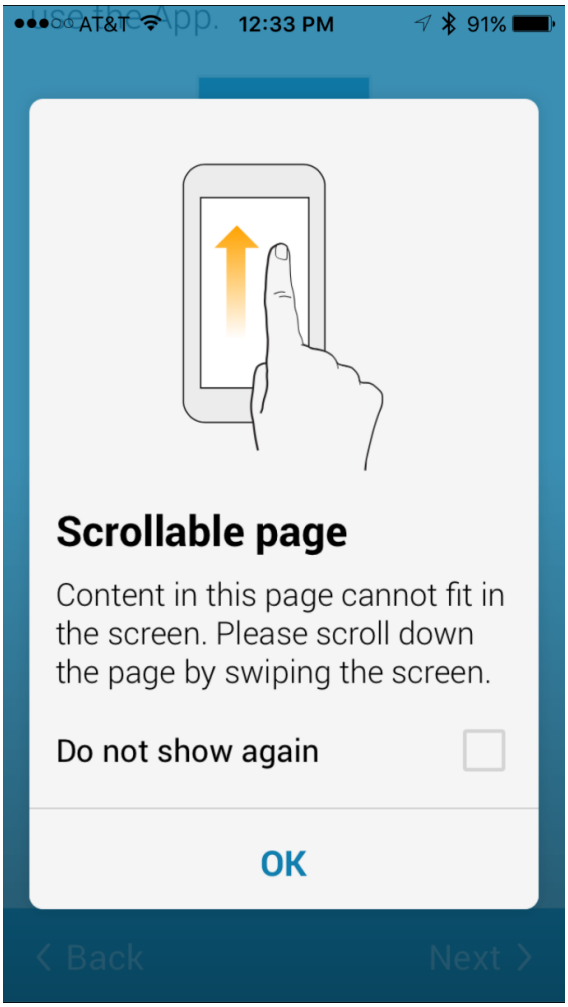


Screen 15



Screen 16

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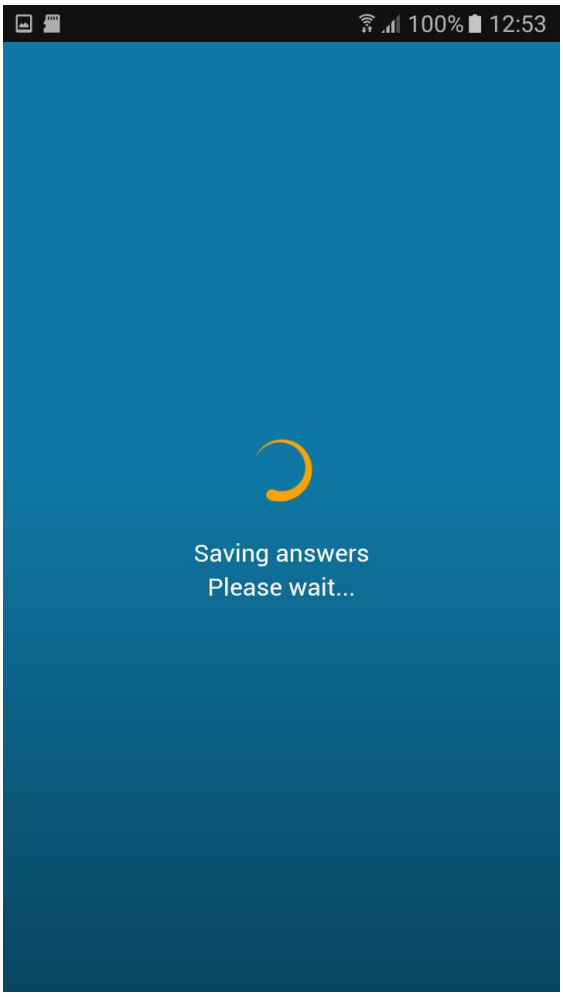
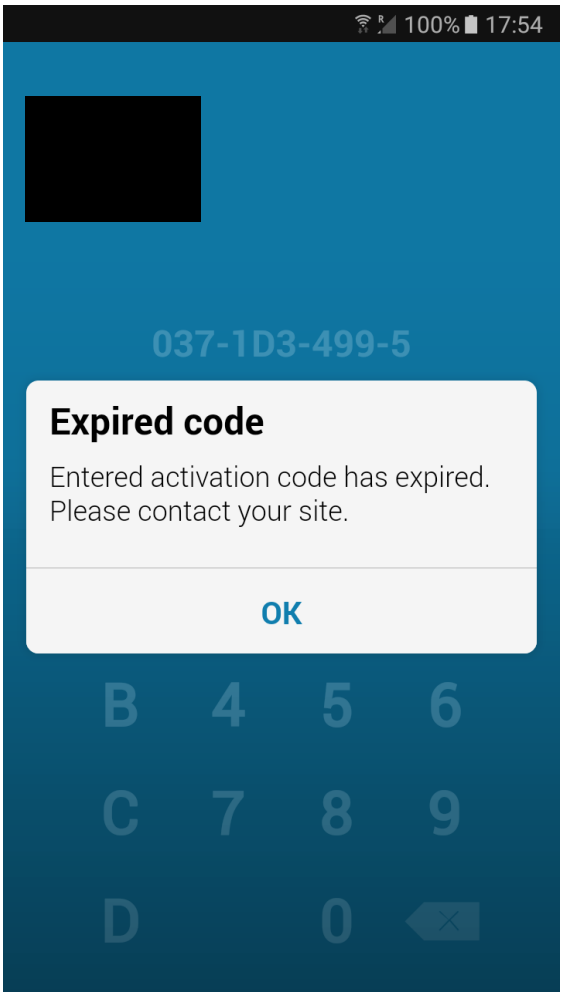


Screen 17



Screen 18

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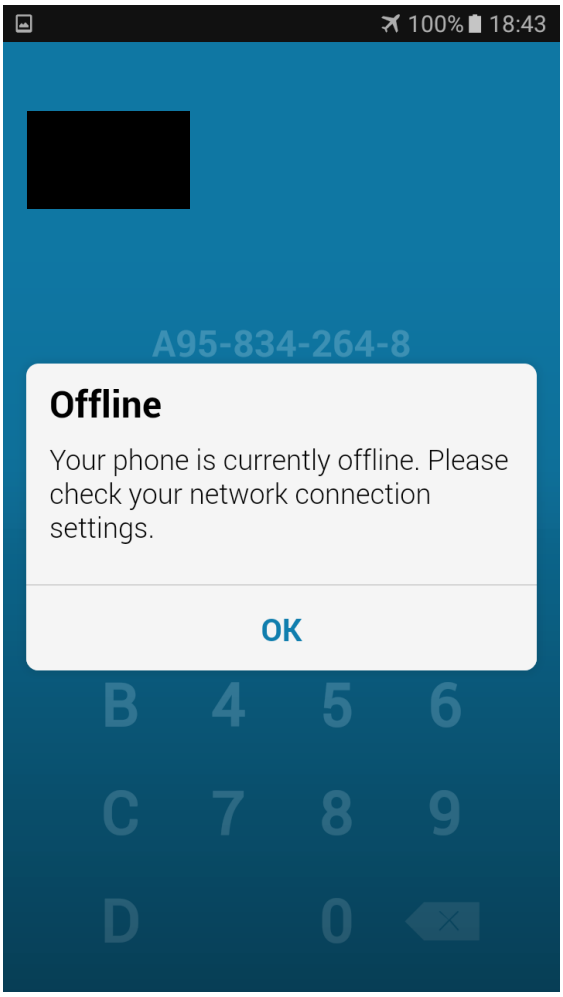
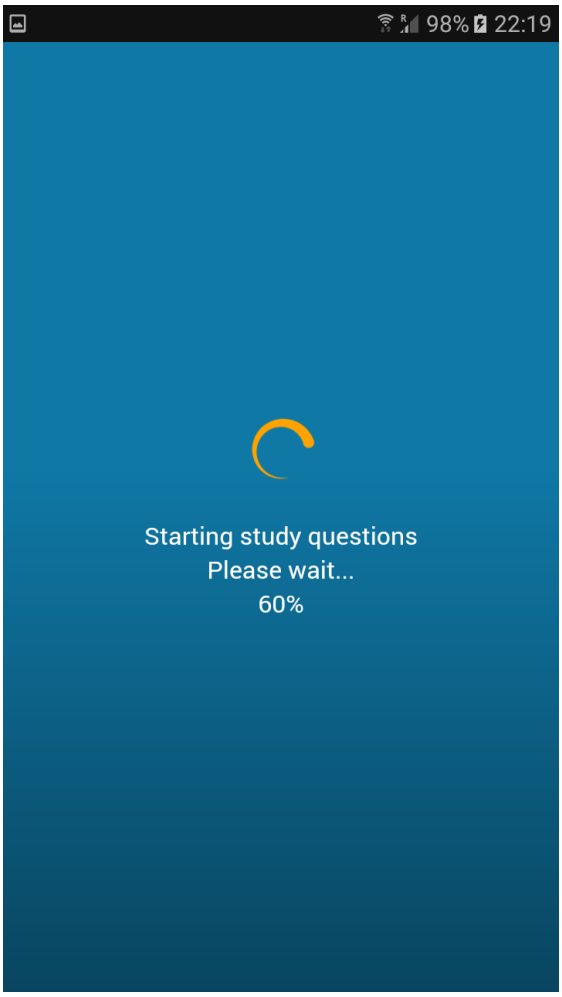


Screen 19



Screen 20

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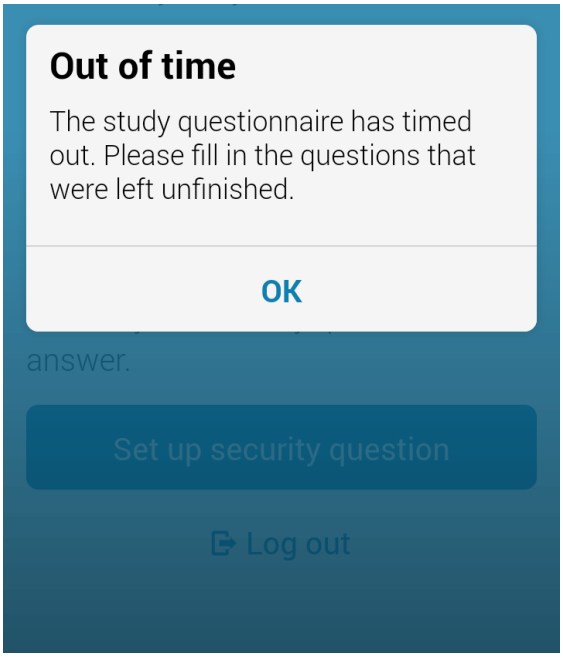
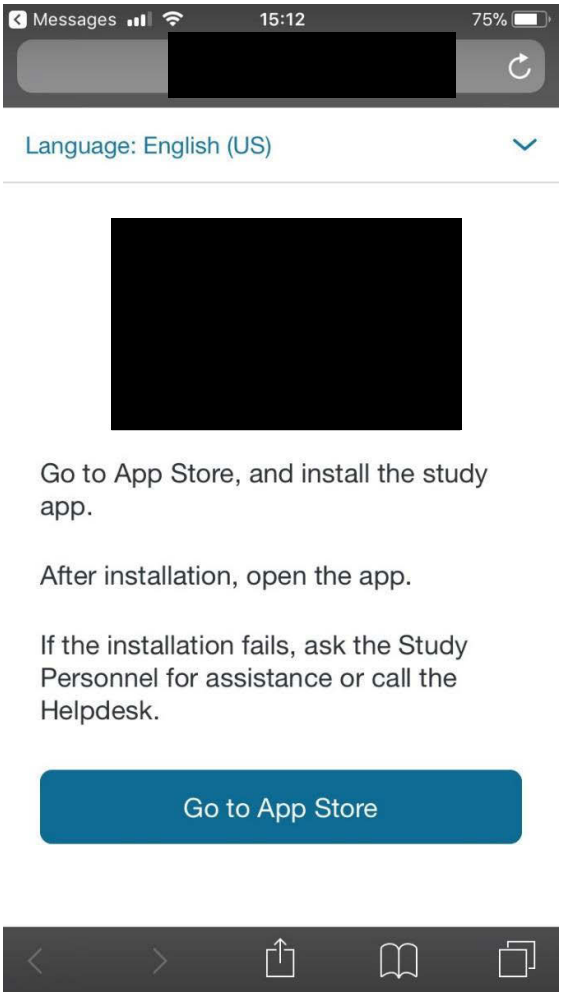


Screen 21



Screen 22

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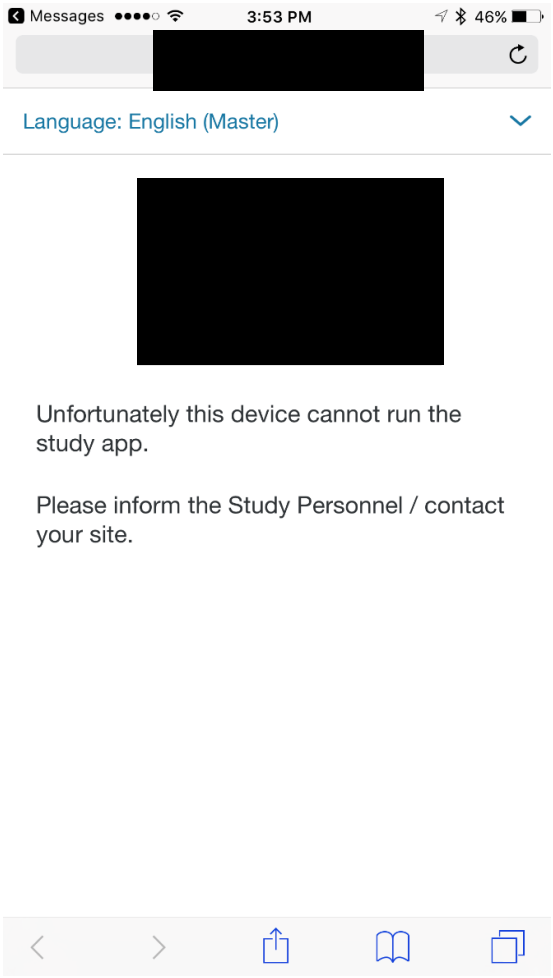
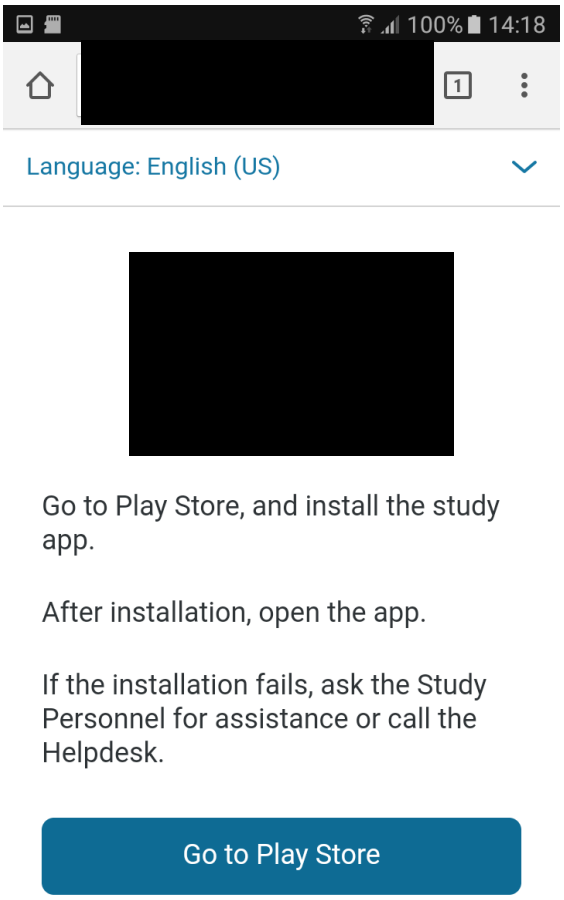


Screen 23



Screen 24

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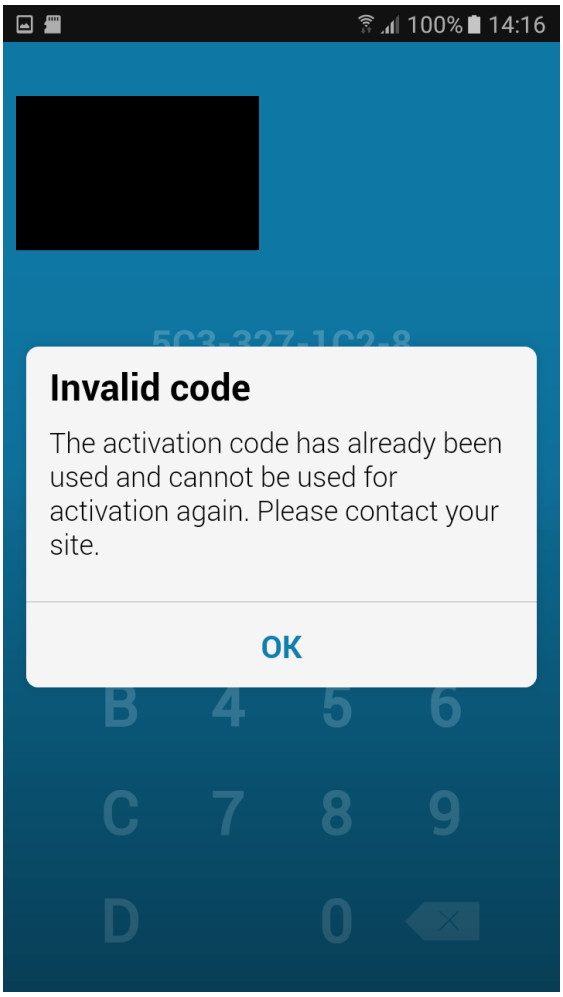
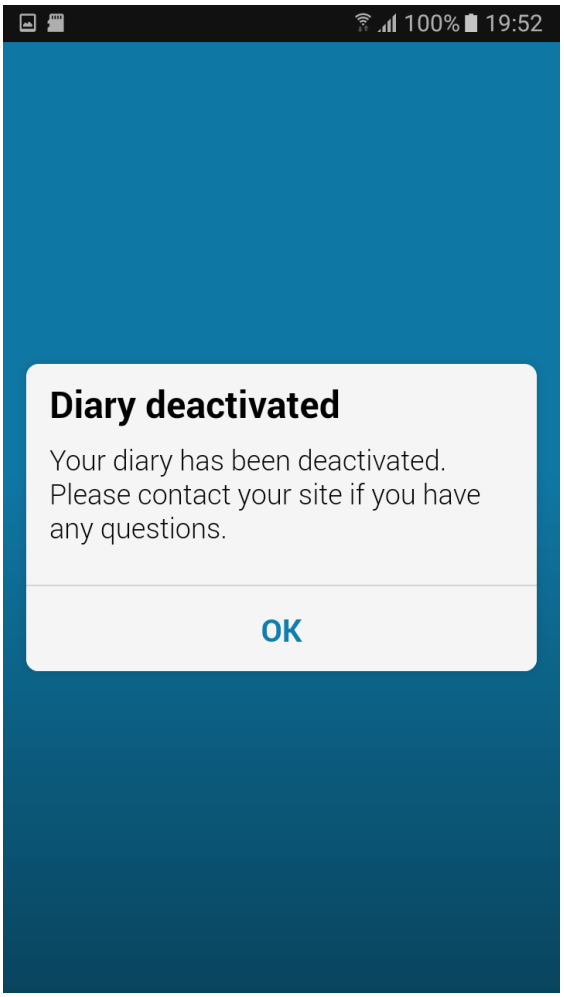


Screen 25



Screen 26

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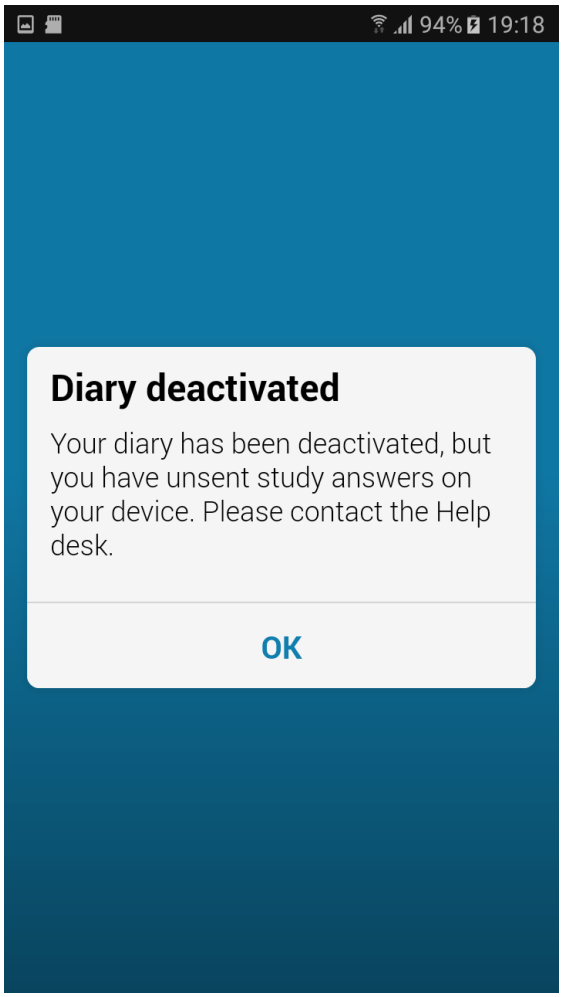
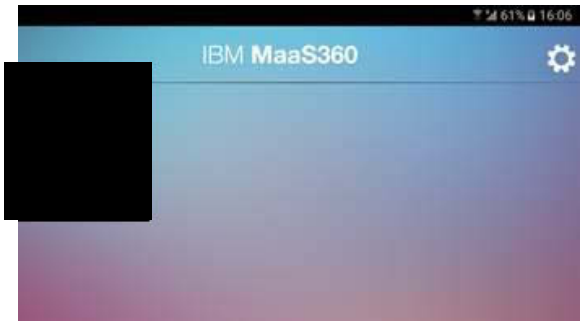


Screen 27



Screen 28

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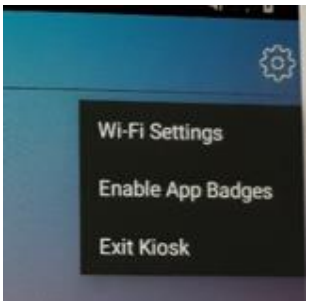
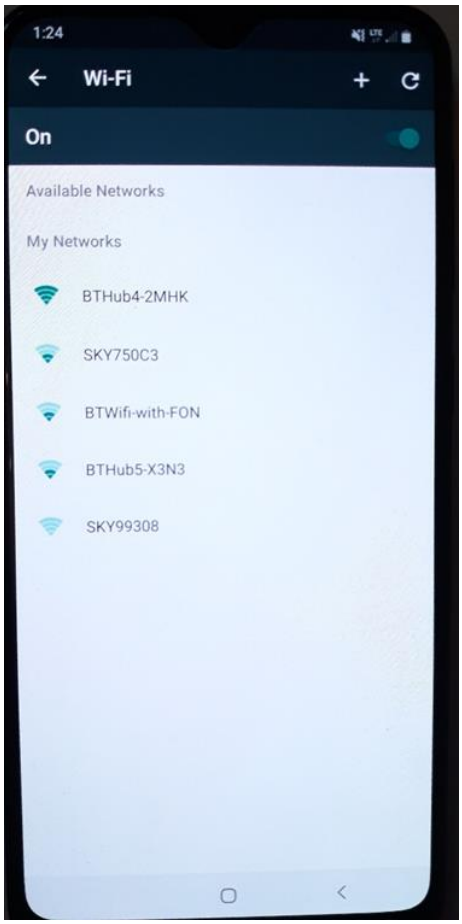


Screen 29



Screen 30

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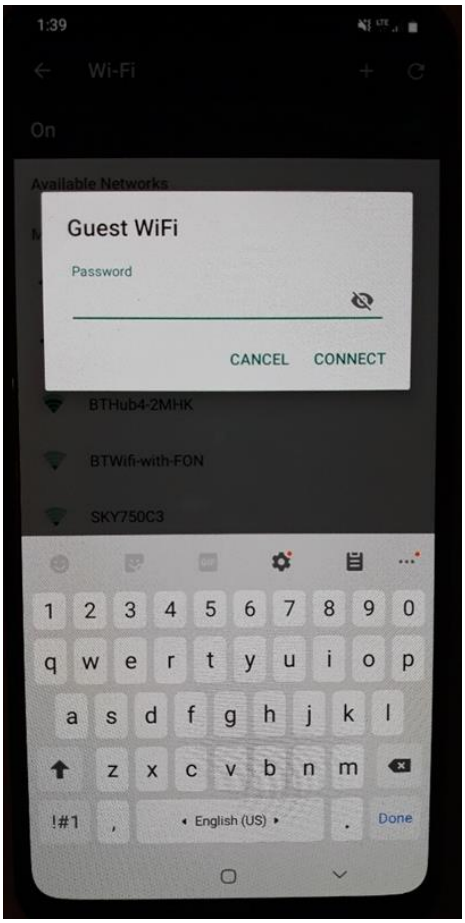
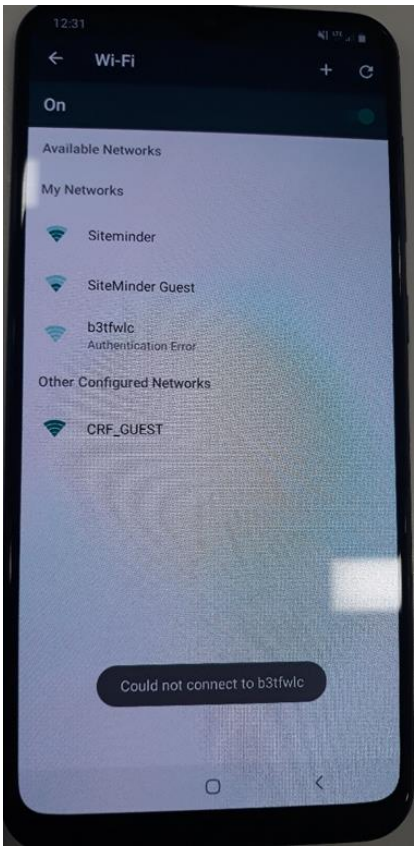


Screen 31



Screen 32

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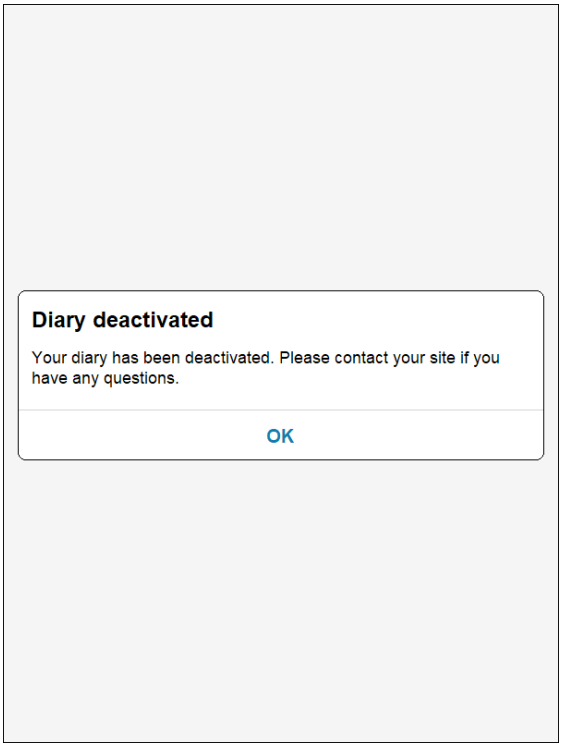

Message 1

Note: Other messages that could appear on the device include:

'Invalid PIN'

'Installing study questions'

'Securing study questions'

'Unsent answers'

'There are a lot of unsent study answers. Please make sure your device is connected to the Internet.'

'The limit of unsent study answers has been reached. Please connect your device to the Internet to fill in the diary again.'

'Oops!'

'Something went wrong, please try again or contact the Help desk.'

'Unsuccessful sending'

'Cannot safely send the study answers, please contact the Help desk.'

'Study ended'

'You no longer need to fill in the diary. Thank you for your help.'

'Updating'

'System is updating, please try again later.'

'Connection error'

'No Internet connection. Please check your Internet connection and try again.'

'Time out'

'Please check your Internet connection and try again.'

'Low storage space'

'Your device is running out of available storage. Please free some storage space and try again.'

'Error'

'Something went wrong, please contact the Help desk or click OK to try again.'

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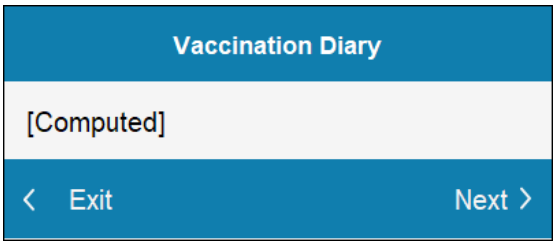
2 Form: Vaccination Diary



Screen 1

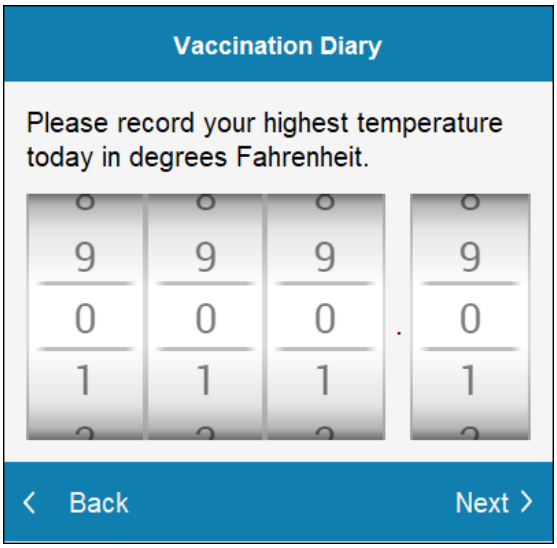
Message 1

[Computed] Text will display “Hello, welcome to the vaccination diary. You will be answering the following questions about how you have been feeling since your vaccination on {1}. You will answer these questions for {2} day(s).”

{1} Will display a date

{2} Will display a number of days.

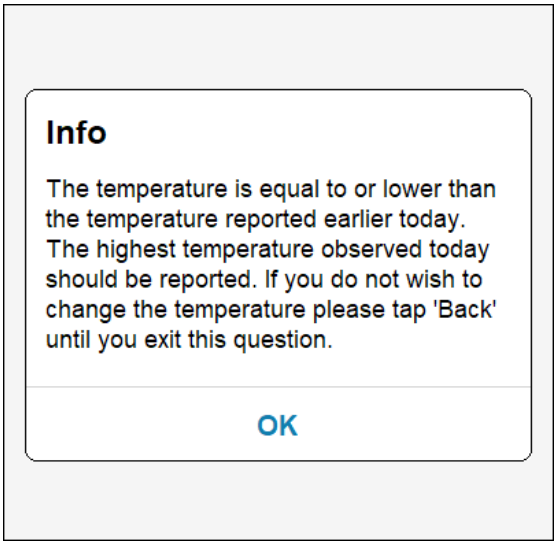
Example: Hello, welcome to the vaccination diary. You will be answering the following questions about how you have been feeling since your vaccination on Mar-27-2020. You will answer these questions for 7 day(s).



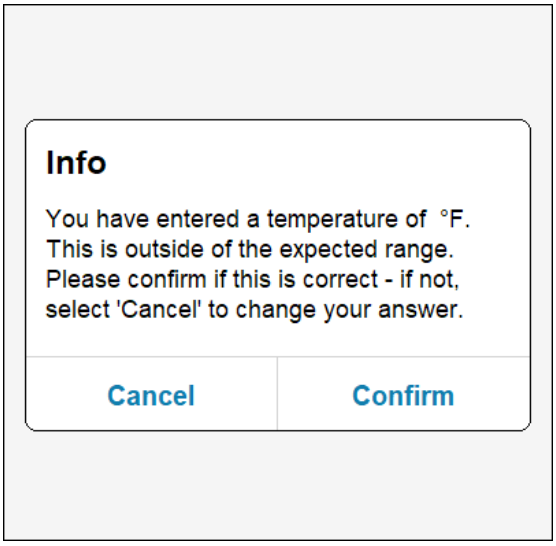
Screen 3

090177e1a08e8b06\Approved\Approved On: 30-Apr-2024 04:32 (GMT)

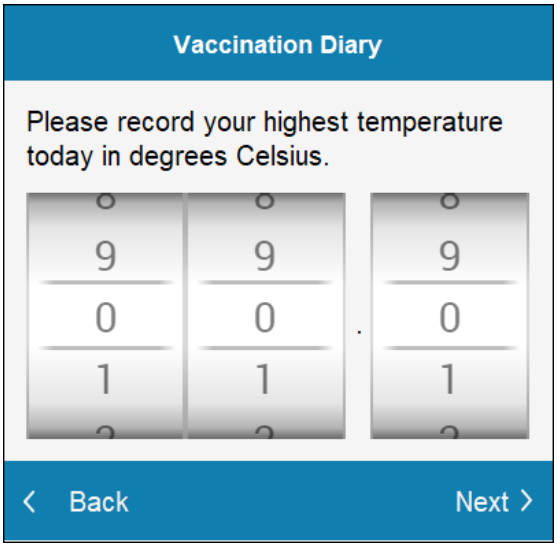
Message 1



Message 2



Message 3



Screen 4

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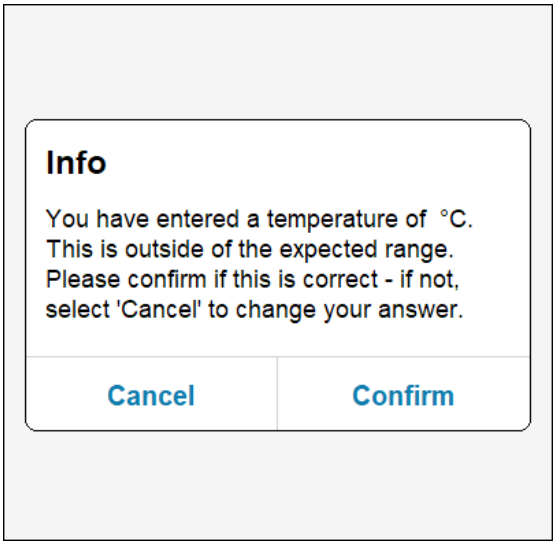
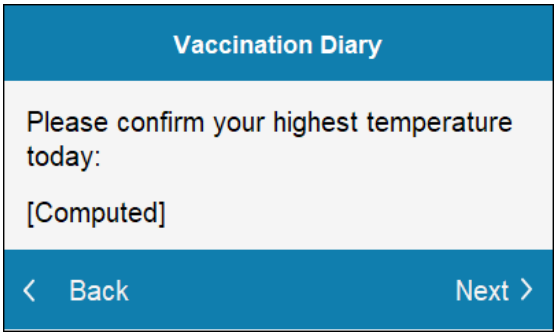
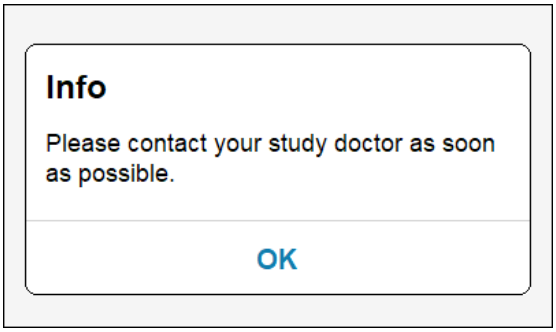


Message 3

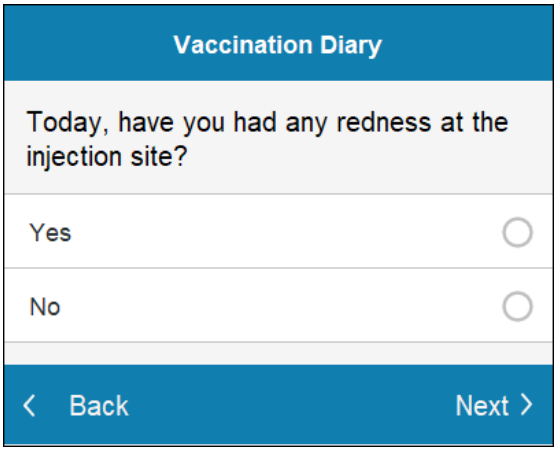


Screen 5

[Computed] will display the temperature selected on Screen 3 or Screen 4

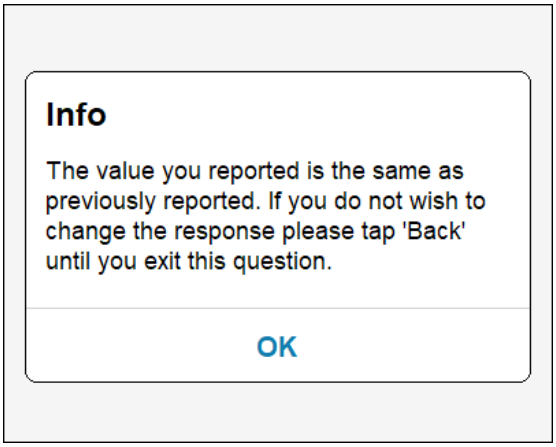


Message 1

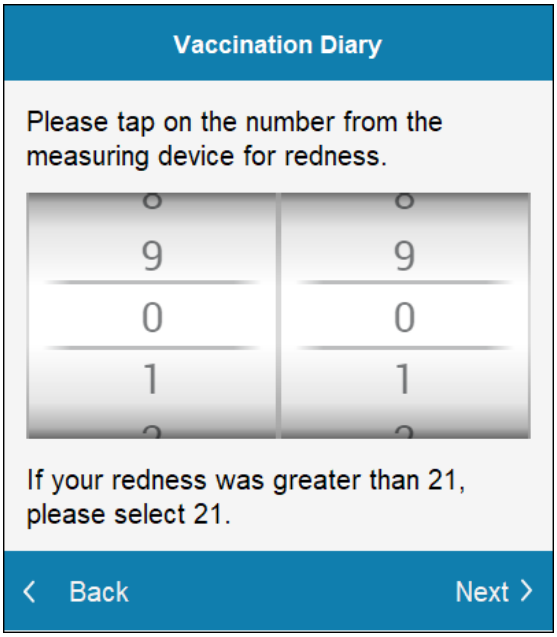


Screen 6

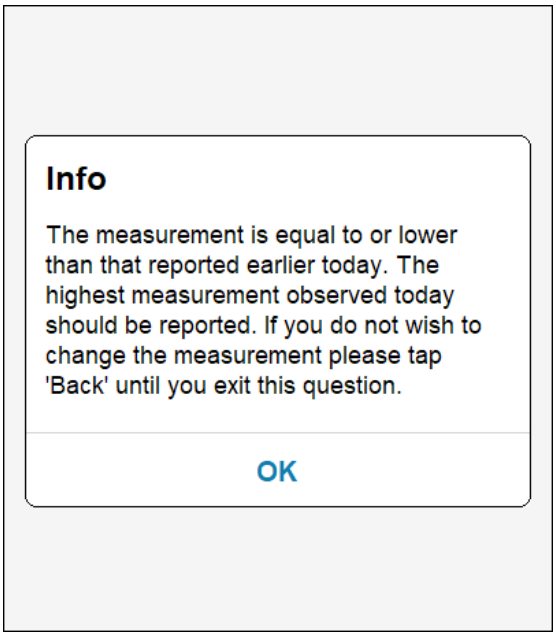
090177e1a08e8b06\Approved\Approved On: 30-Apr-2024 04:32 (GMT)



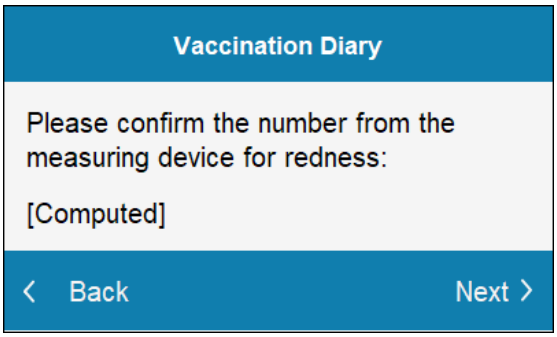
Message 2



Screen 7



Message 2



Screen 8

[Computed] will display the number selected on Screen 7.

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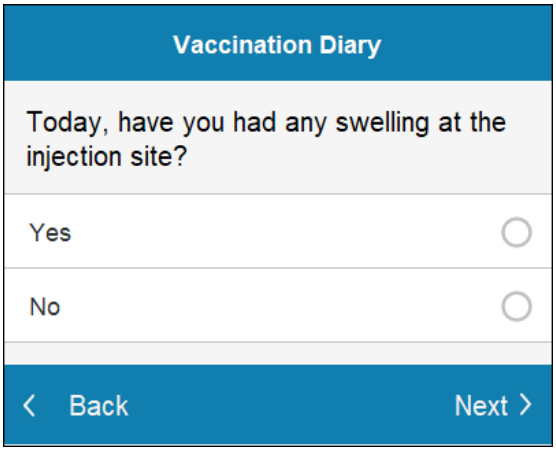
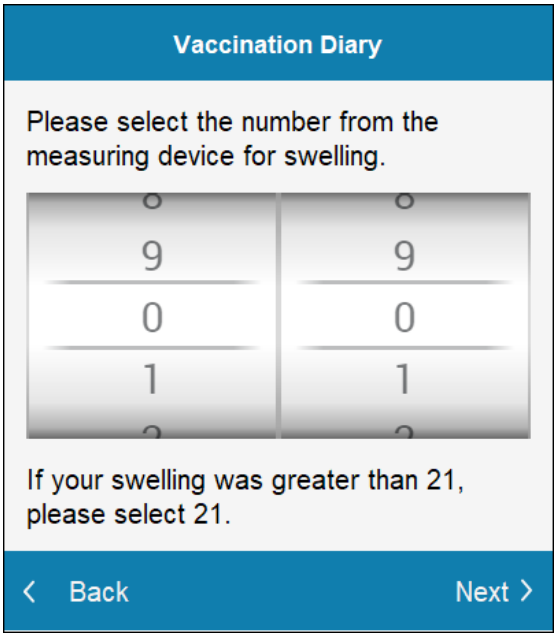
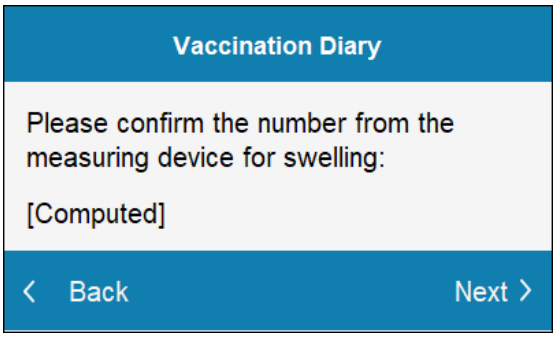


Screen 9

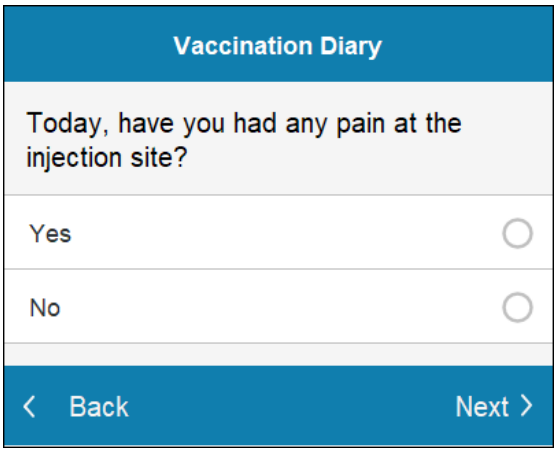


Screen 10



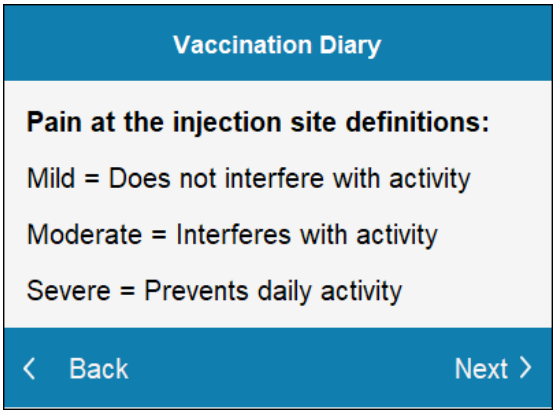
Screen 11

[Computed] will display the number selected on Screen 10.

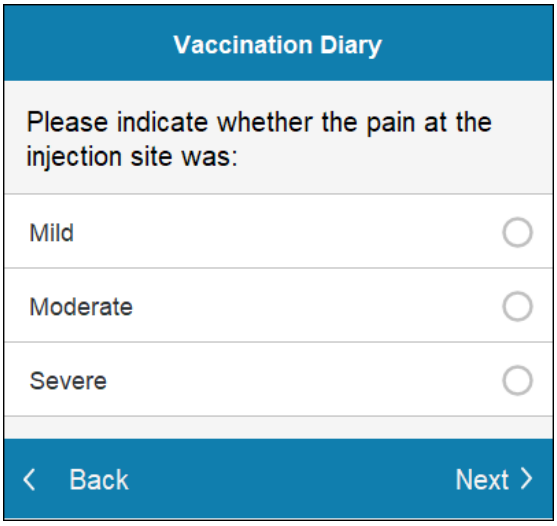


Screen 12

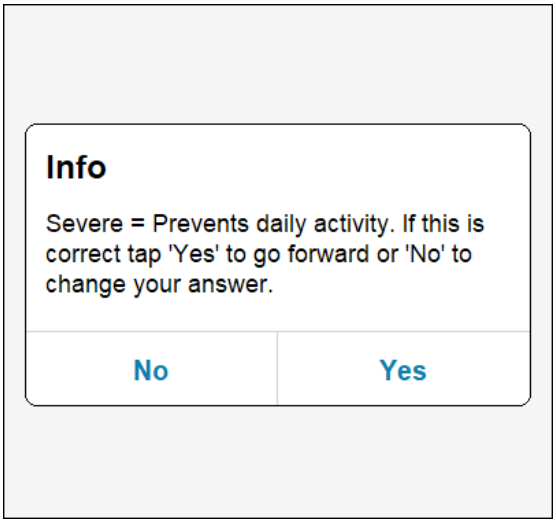
090177e1a08e8b06\Approved\Approved On: 30-Apr-2024 04:32 (GMT)



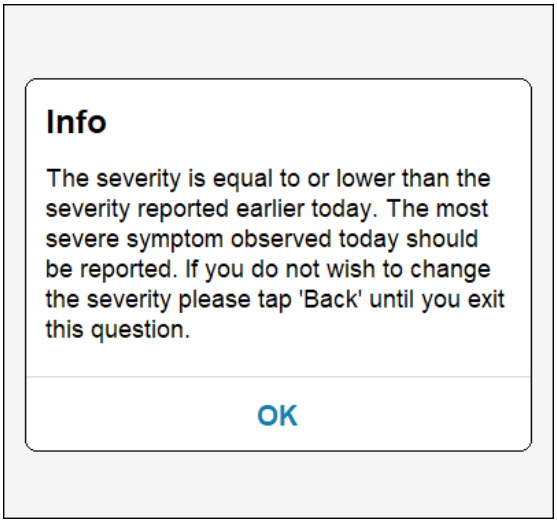
Screen 13



Screen 14

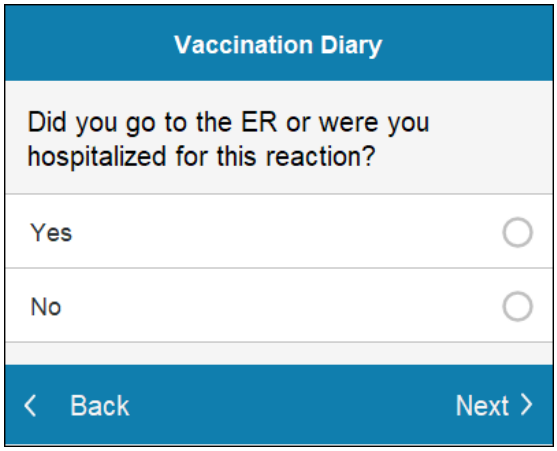


Message 2

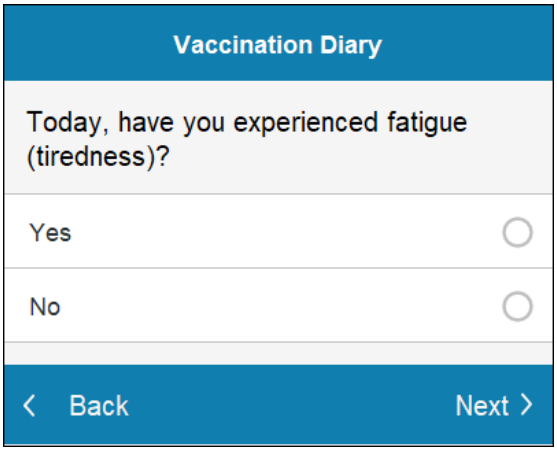


Message 4

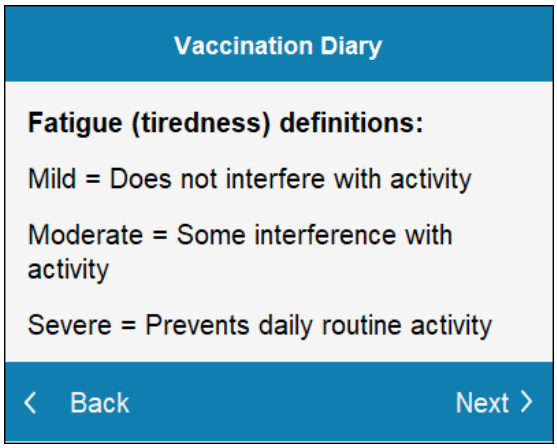
090177e1a08e8b06\Approved\Approved On: 30-Apr-2024 04:32 (GMT)



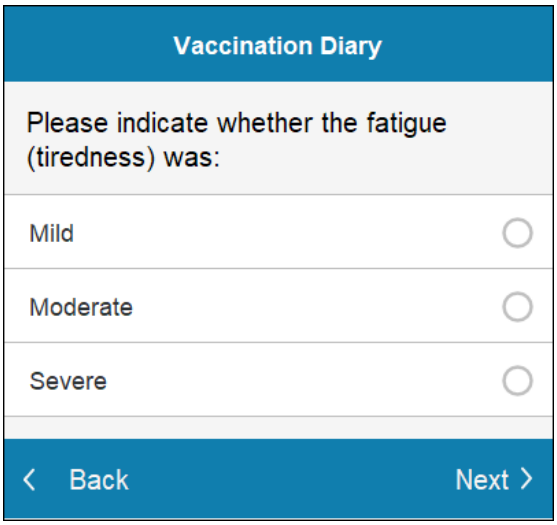
Screen 15



Screen 16

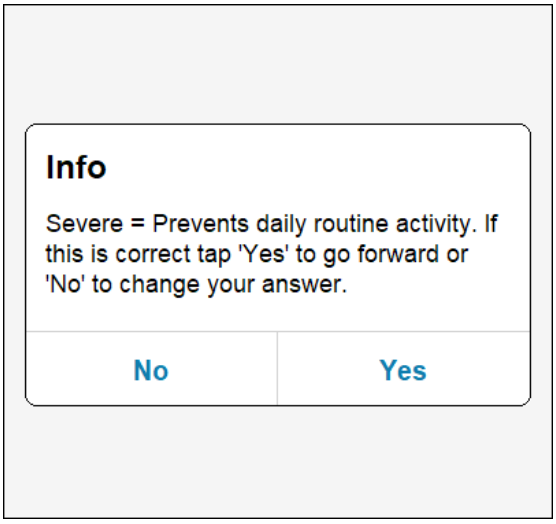


Screen 17

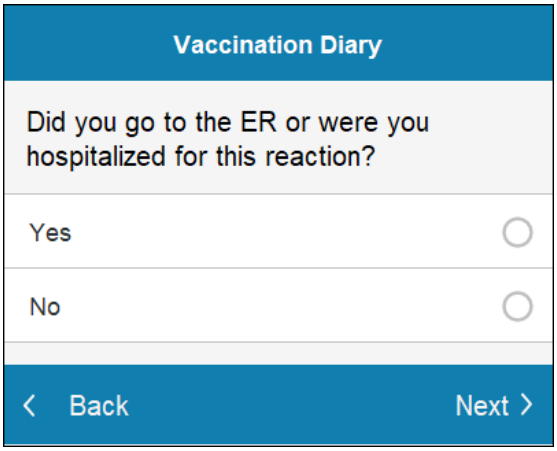


Screen 18

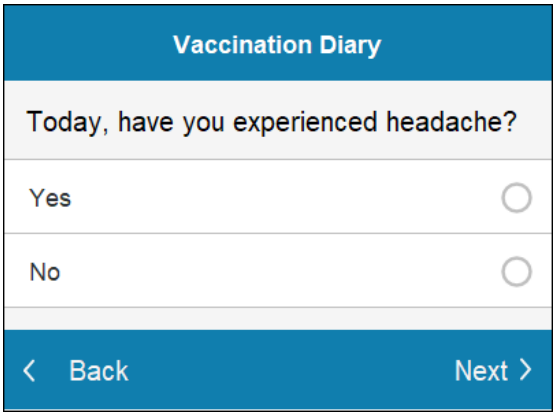
090177e1a08e8b06\Approved\Approved On: 30-Apr-2024 04:32 (GMT)



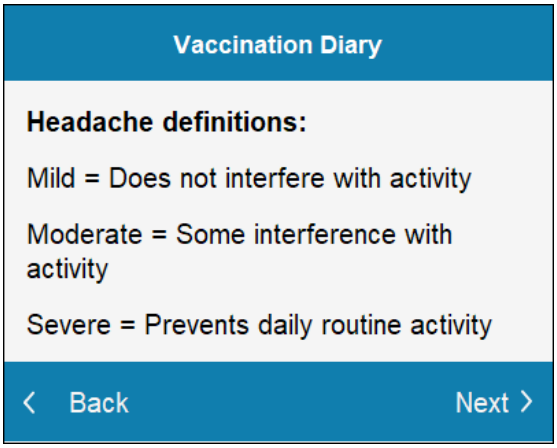
Message 2



Screen 19

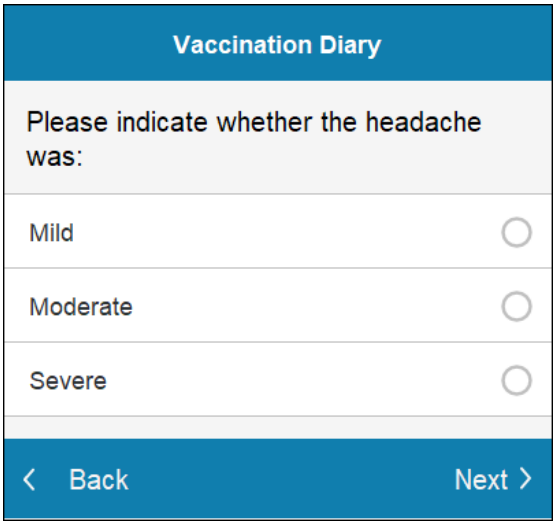


Screen 20

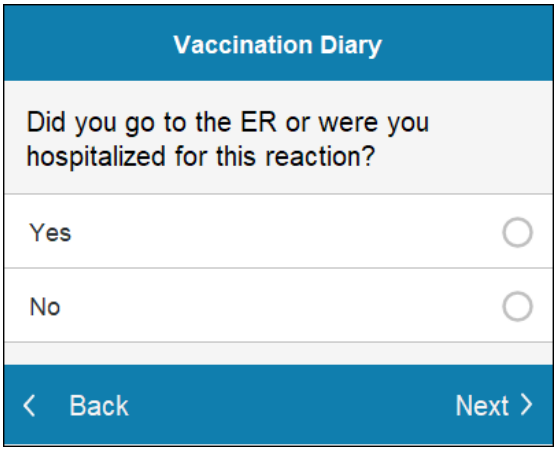


Screen 21

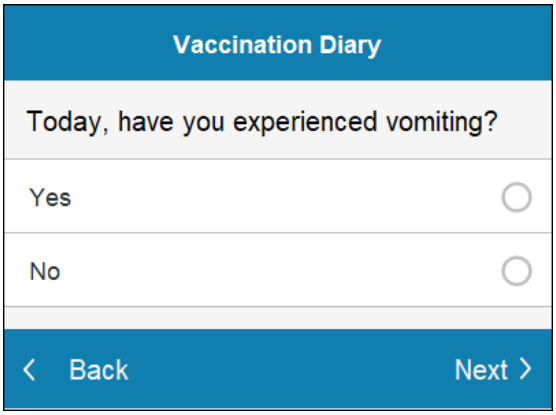
090177e1a08e8b06\Approved\Approved On: 30-Apr-2024 04:32 (GMT)



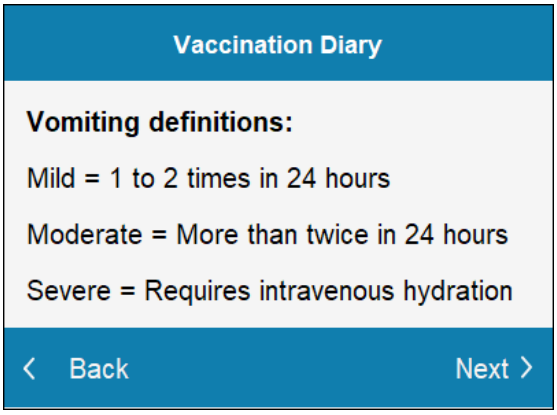
Screen 22



Screen 23

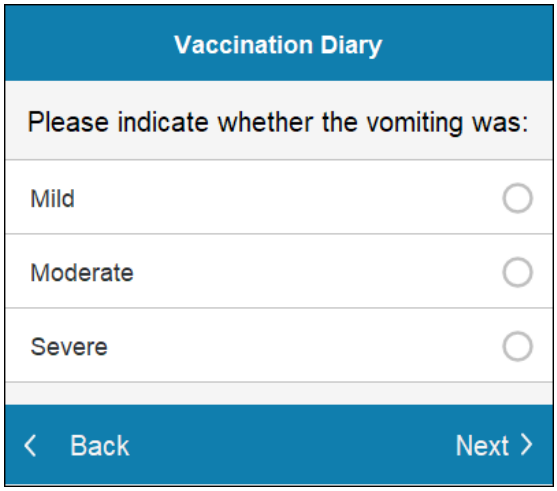


Screen 24

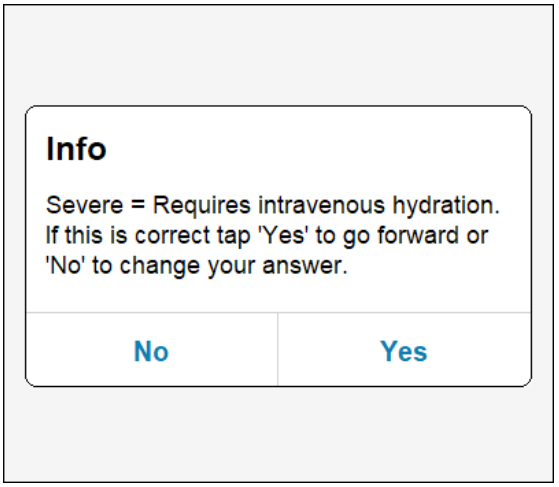


Screen 25

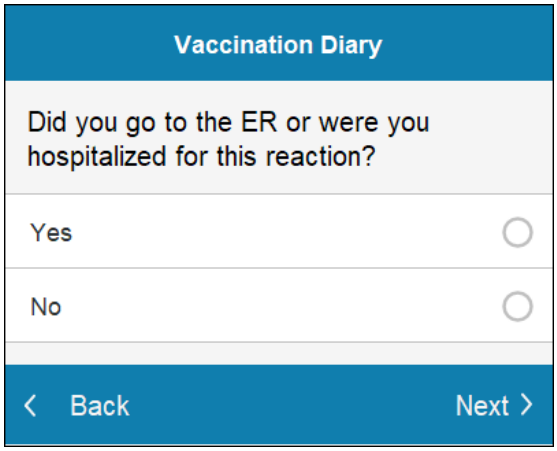
090177e1a08e8b06\Approved\Approved On: 30-Apr-2024 04:32 (GMT)



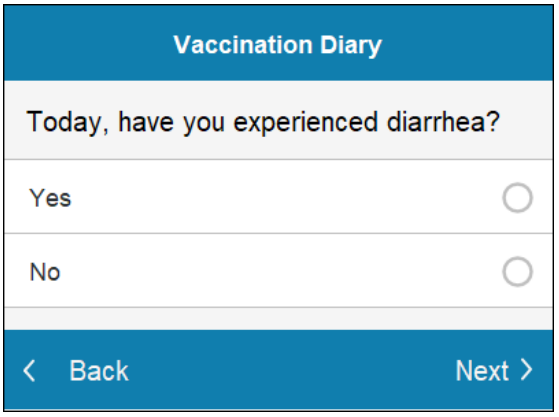
Screen 26



Message 2

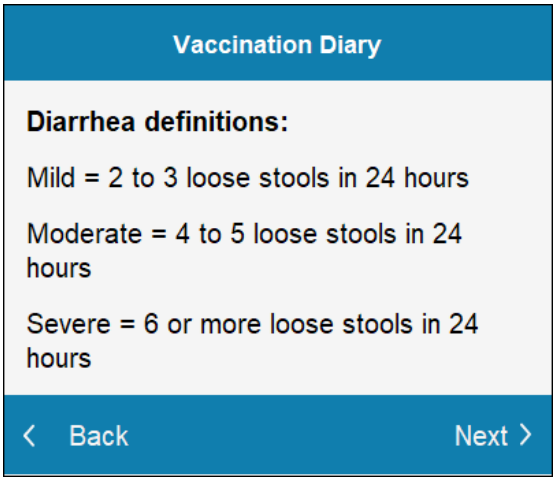


Screen 27

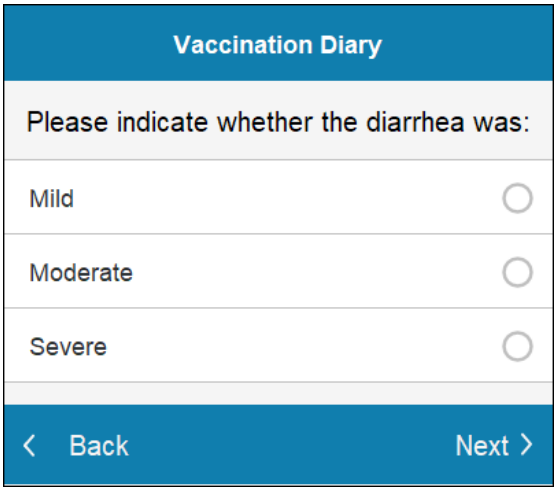


Screen 28

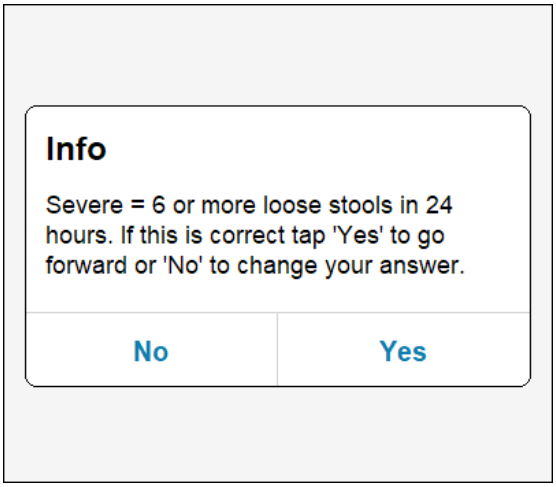
090177e1a08e8b06\Approved\Approved On: 30-Apr-2024 04:32 (GMT)



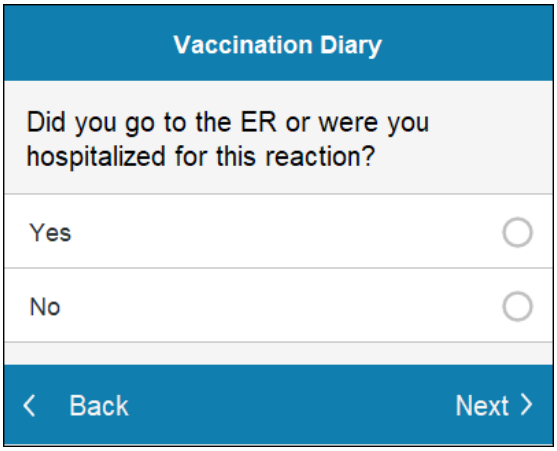
Screen 29



Screen 30

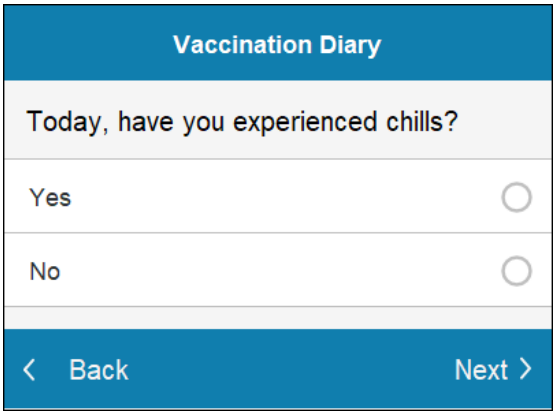


Message 2

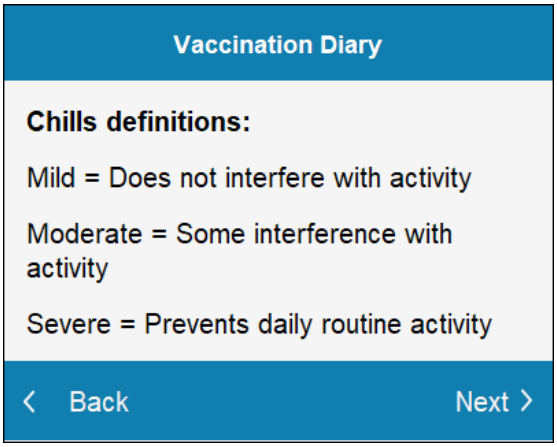


Screen 31

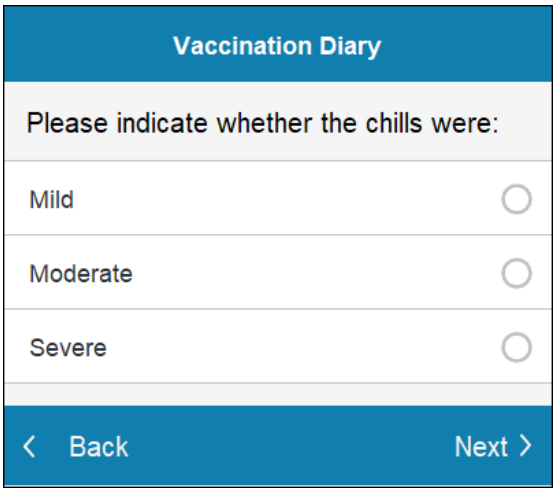
090177e1a08e8b06\Approved\Approved On: 30-Apr-2024 04:32 (GMT)



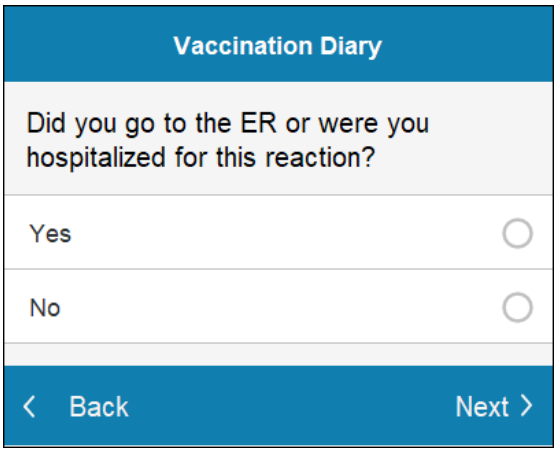
Screen 32



Screen 33

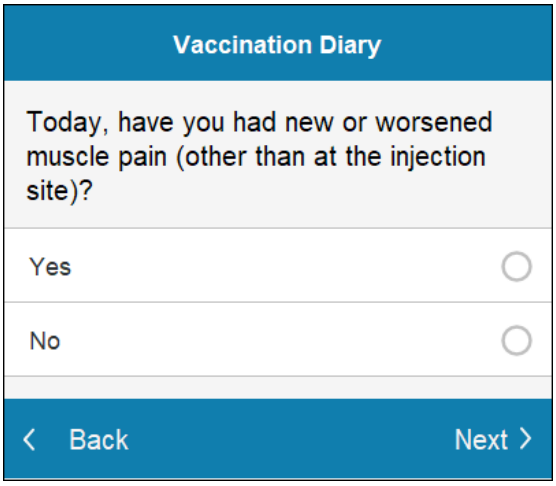


Screen 34

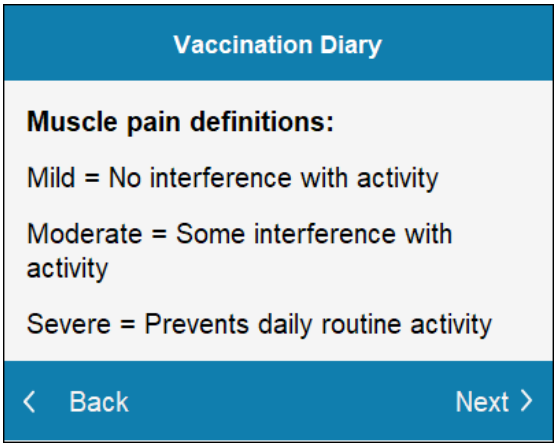


Screen 35

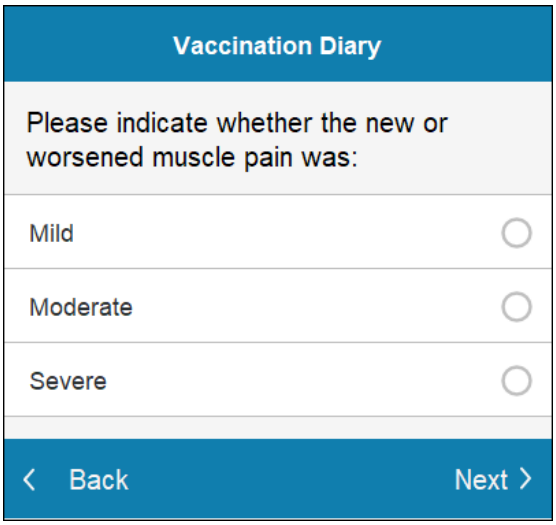
090177e1a08e8b06\Approved\Approved On: 30-Apr-2024 04:32 (GMT)



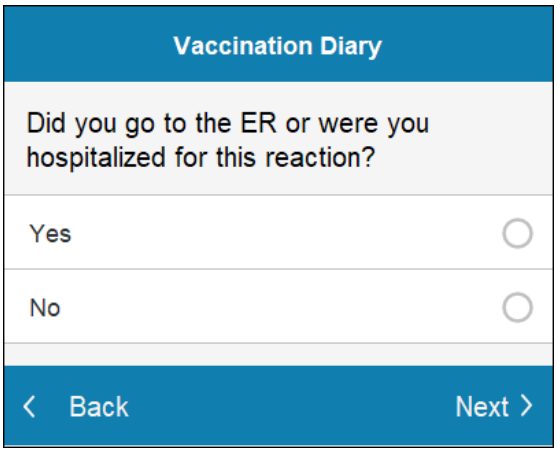
Screen 36



Screen 37

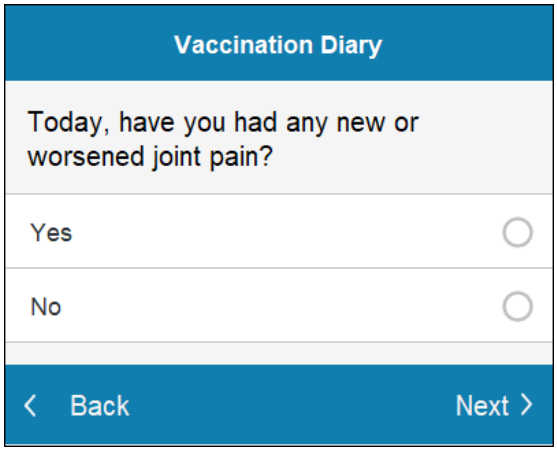


Screen 38

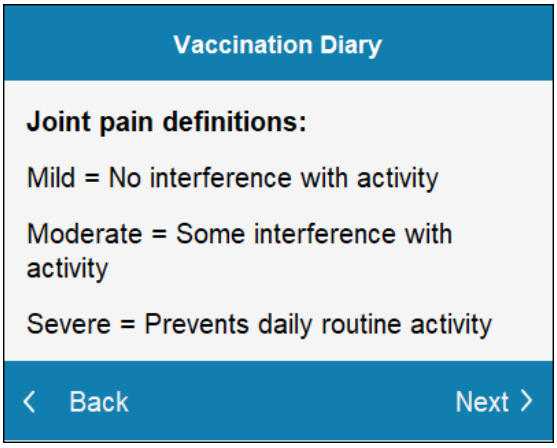


Screen 39

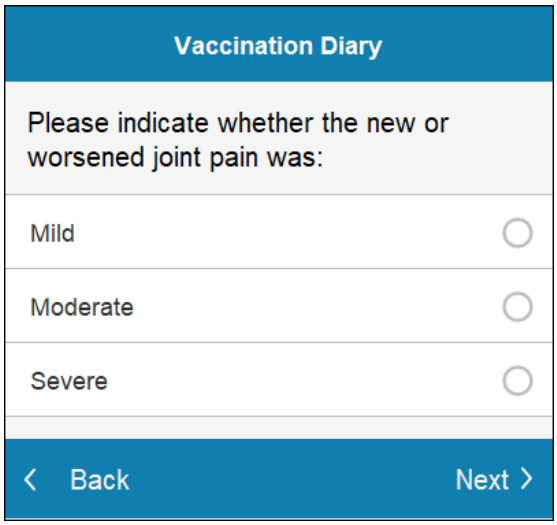
090177e1a08e8b06\Approved\Approved On: 30-Apr-2024 04:32 (GMT)



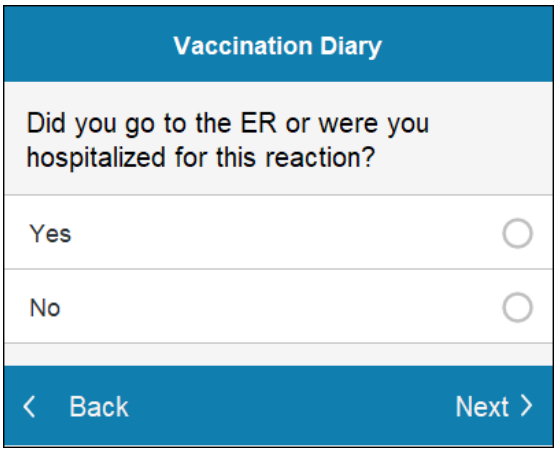
Screen 40



Screen 41

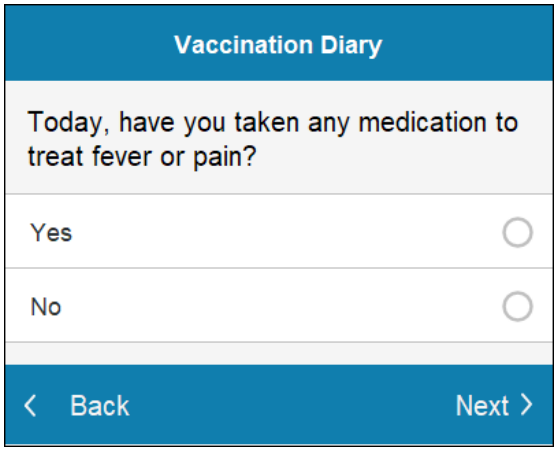


Screen 42

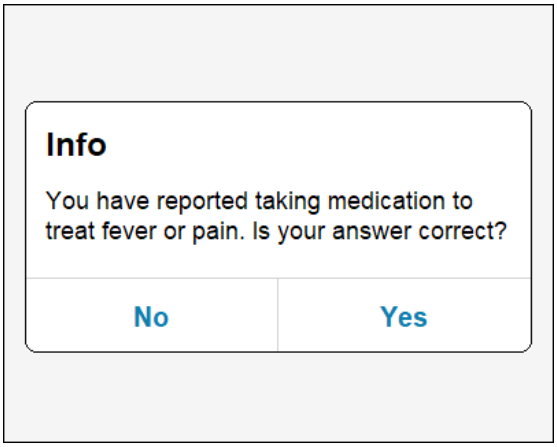


Screen 43

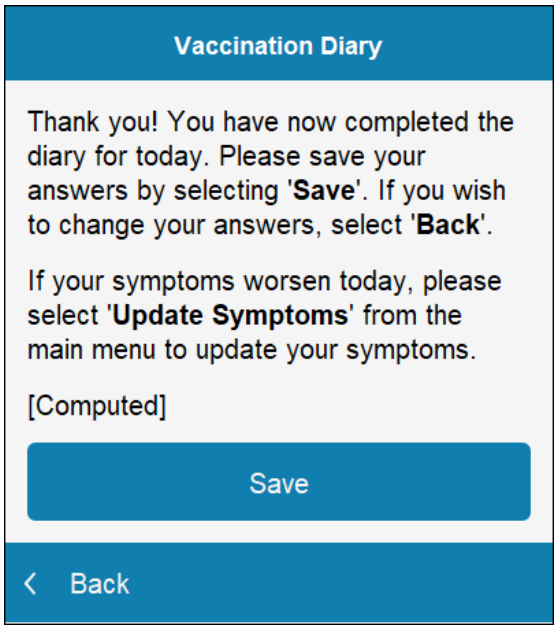
090177e1a08e8b06\Approved\Approved On: 30-Apr-2024 04:32 (GMT)



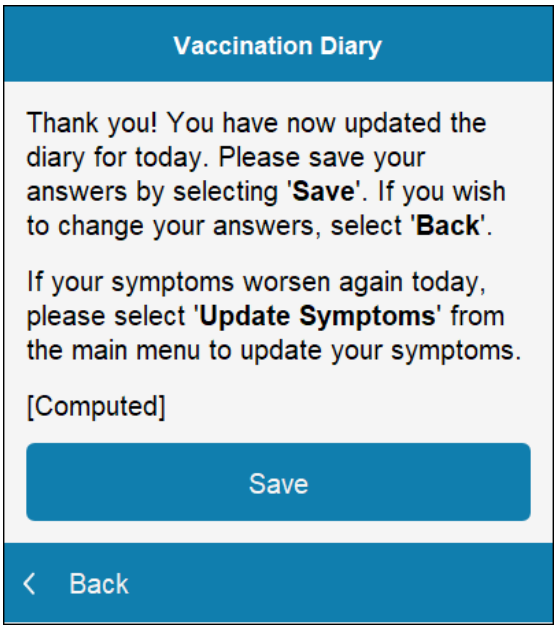
Screen 44



Message 2



Screen 45



Screen 46

[Computed] will display “Please continue to fill out your diary for the next {1} day(s).”

Where {1} = a number of days

Example: Please continue to fill out your diary for the next 4 day(s).

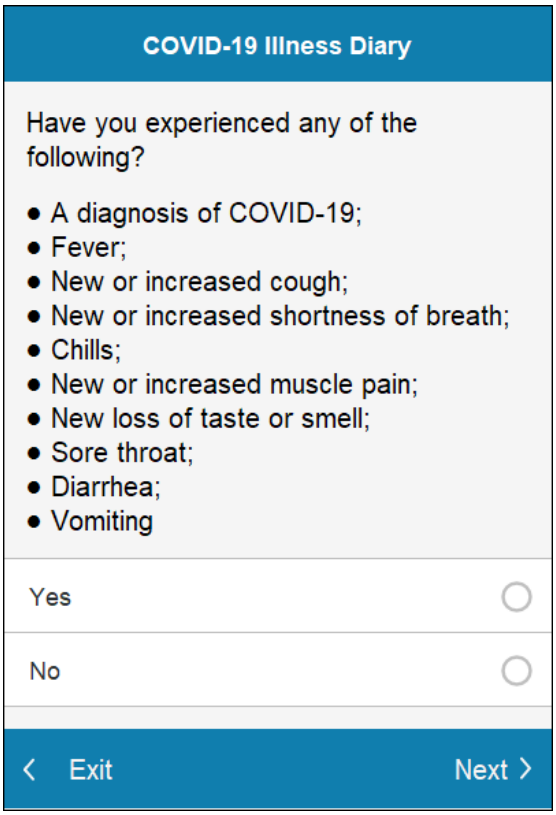
[Computed] will display “Please continue to fill out your diary for the next {1} day(s).”

Where {1} = a number of days

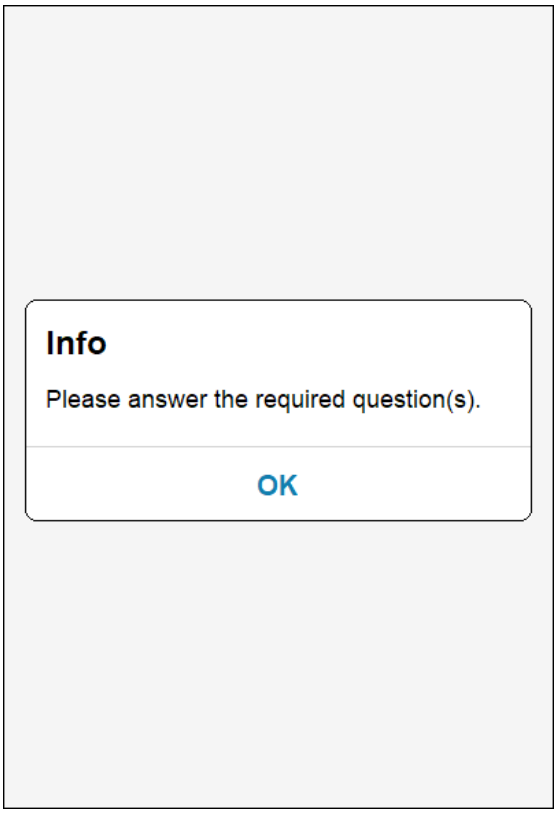
Example: Please continue to fill out your diary for the next 4 day(s).

090177e1a08e8b06\Approved\Approved On: 30-Apr-2024 04:32 (GMT)

3 Form: COVID-19 Illness Diary

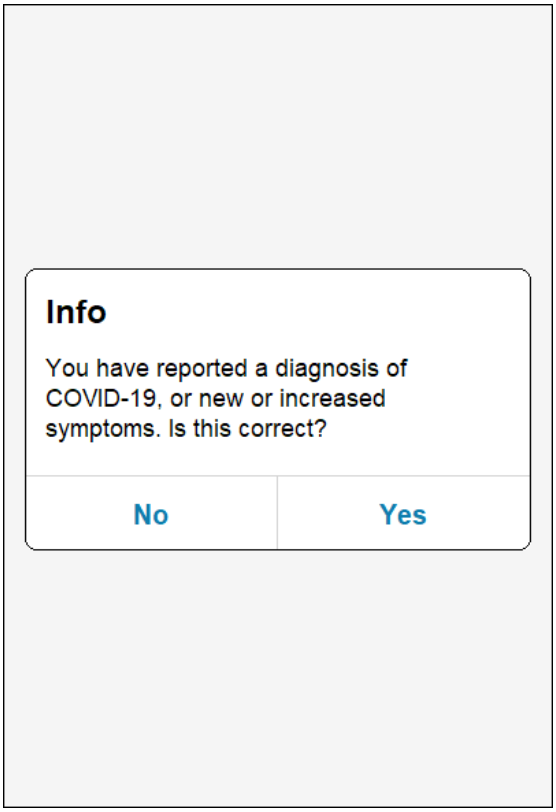


Screen 1



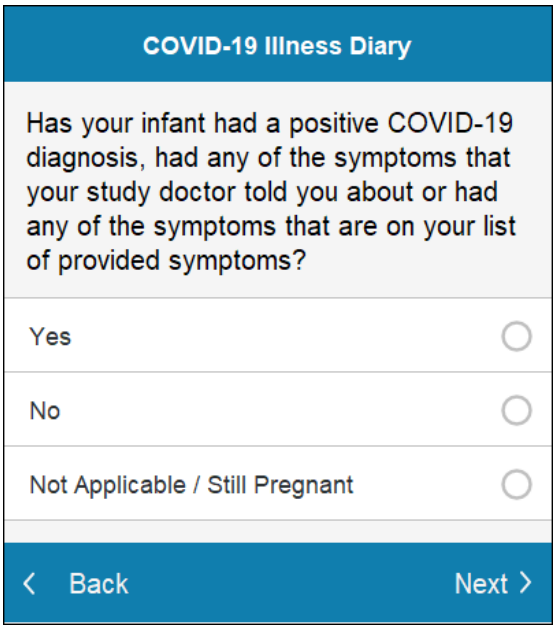
Message 1

090177e1a08e8b06\Approved\Approved On: 30-Apr-2024 04:32 (GMT)

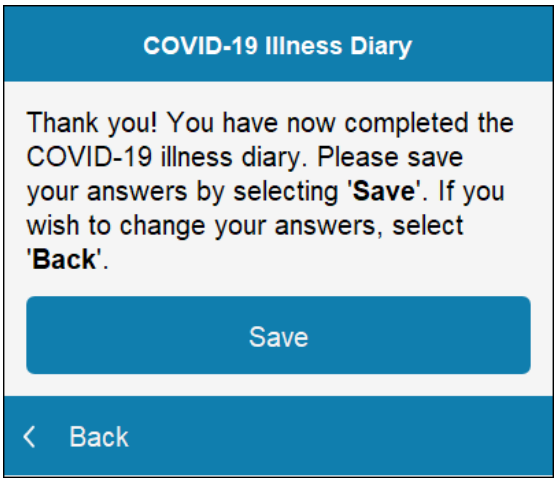


Message 2

Message 3

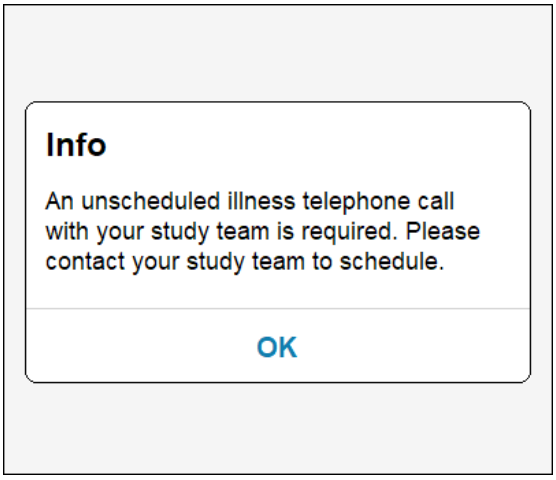


Screen 2

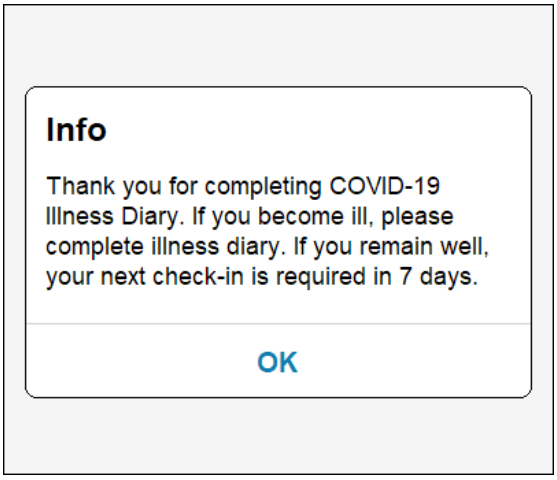


Screen 3

090177e1a08e8b06\Approved\Approved On: 30-Apr-2024 04:32 (GMT)



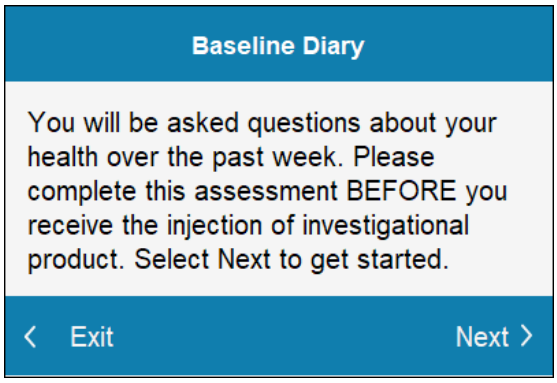
Message 1



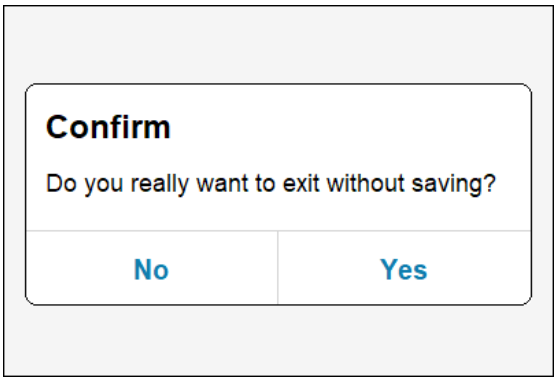
Message 2

090177e1a08e8b06\Approved\Approved On: 30-Apr-2024 04:32 (GMT)

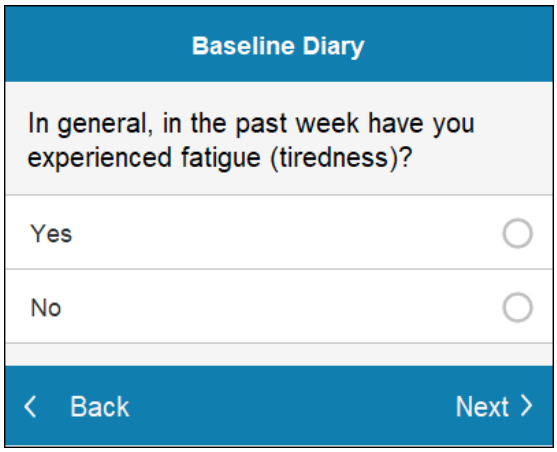
4 Form: Baseline Diary



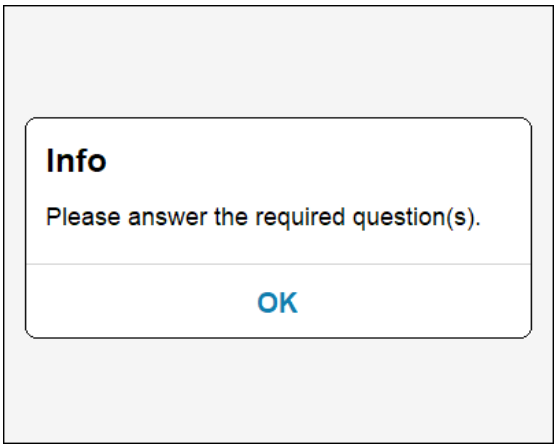
Screen 1



Message 1



Screen 2



Message 1

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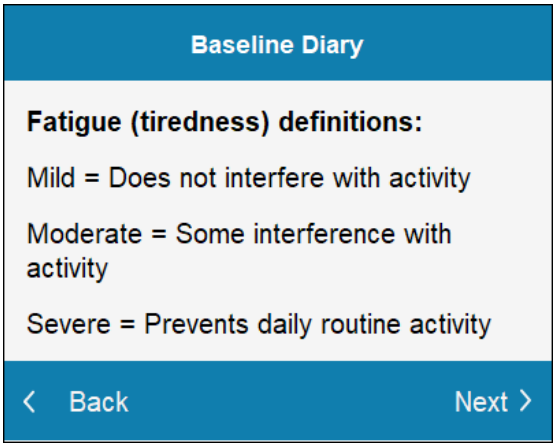
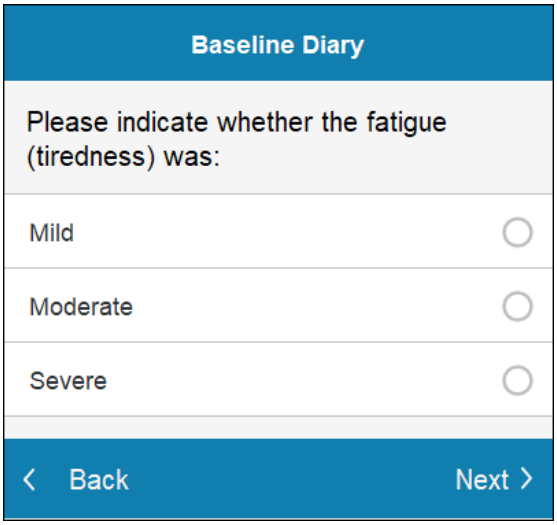
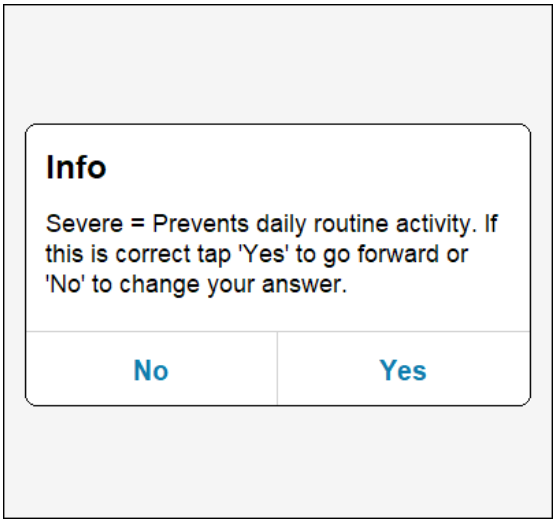


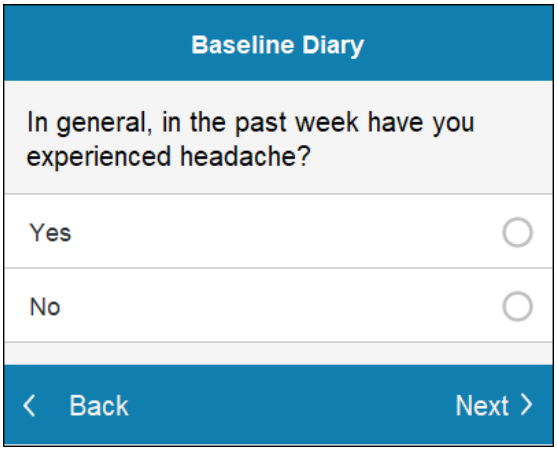
Screen 3



Screen 4



Message 2



Screen 5

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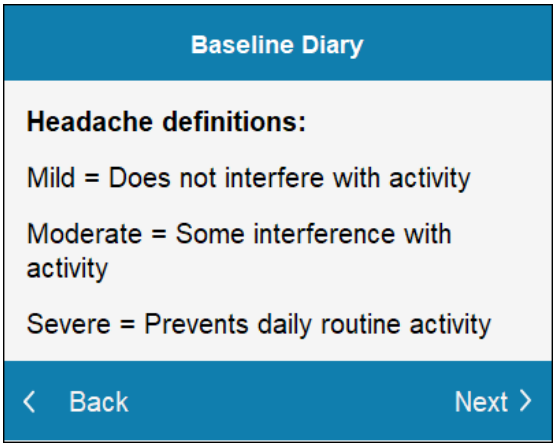
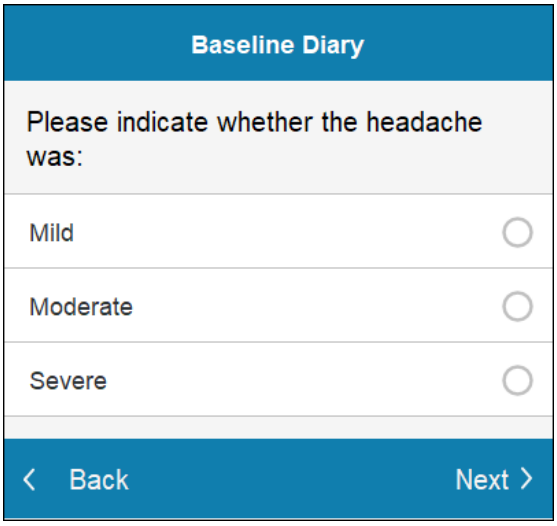
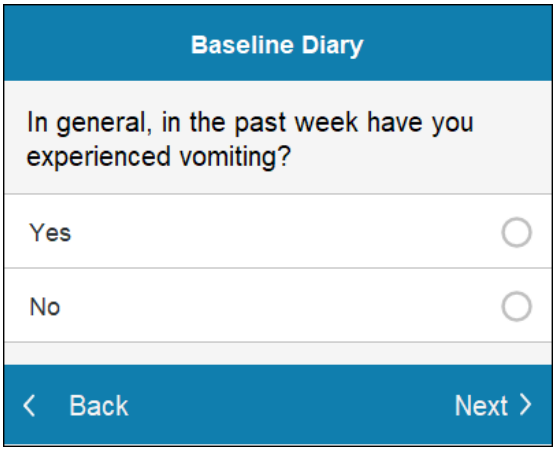


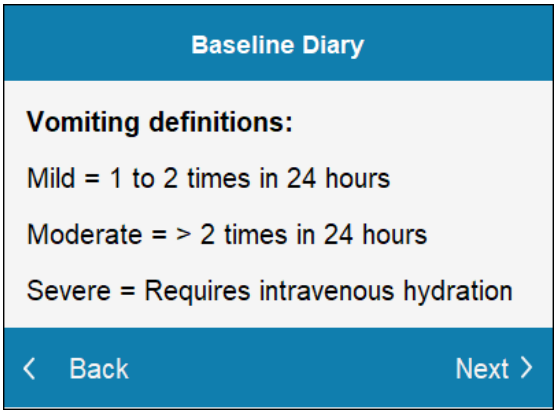
Screen 6



Screen 7



Screen 8



Screen 9

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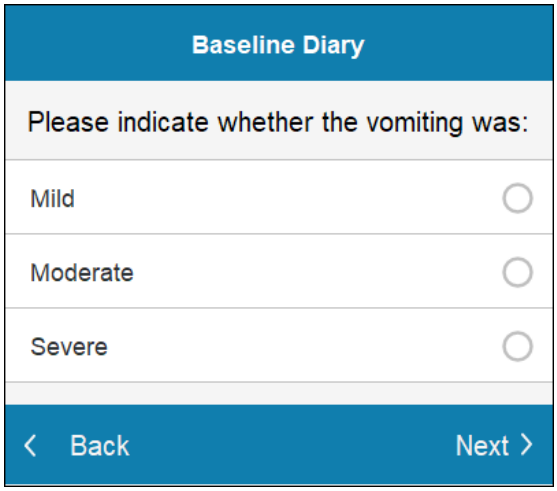
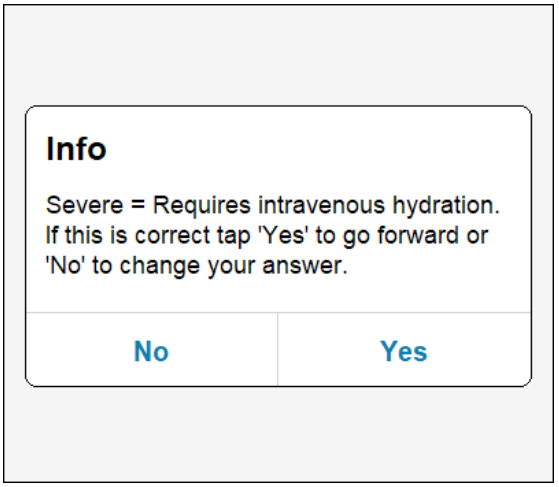
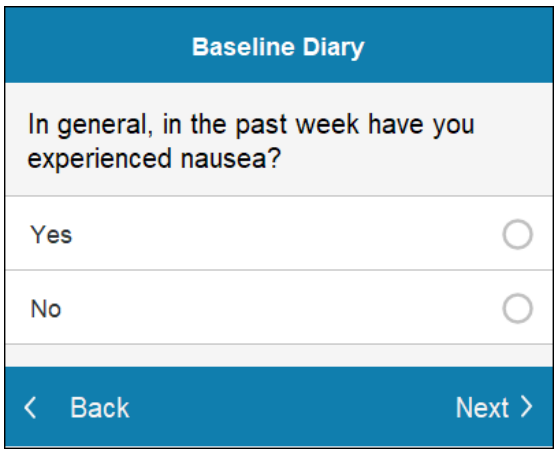


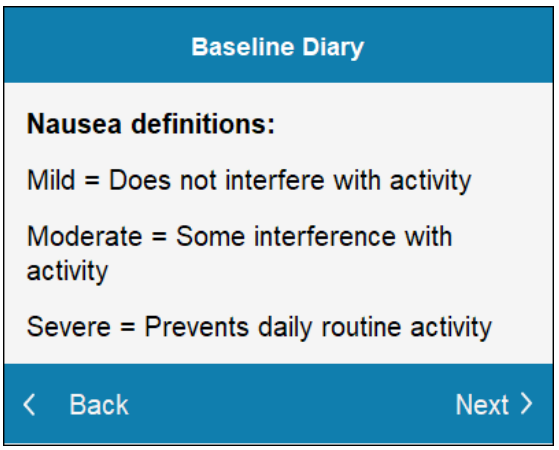
Screen 10



Message 2



Screen 11



Screen 12

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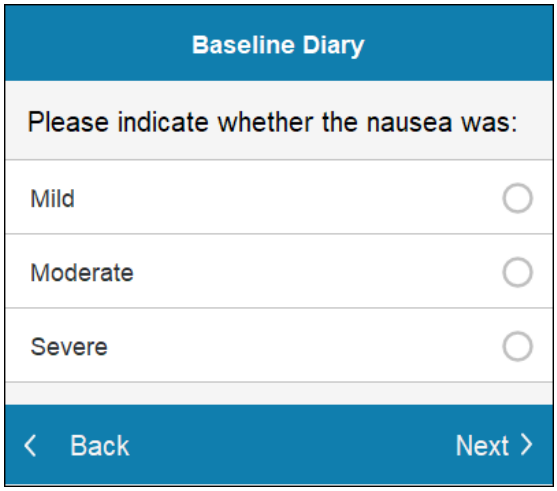
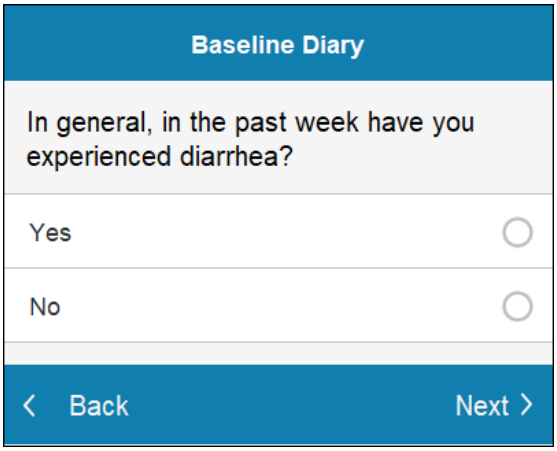
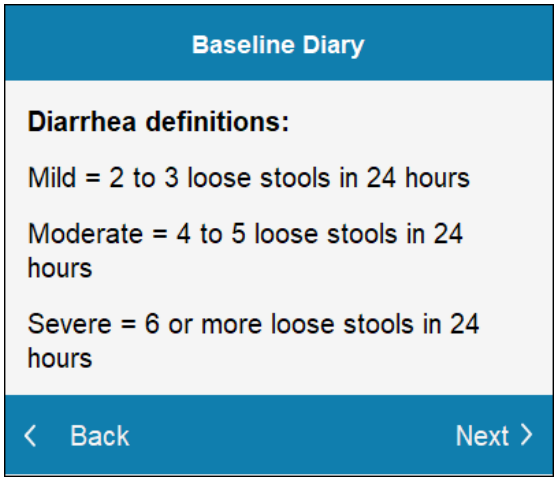


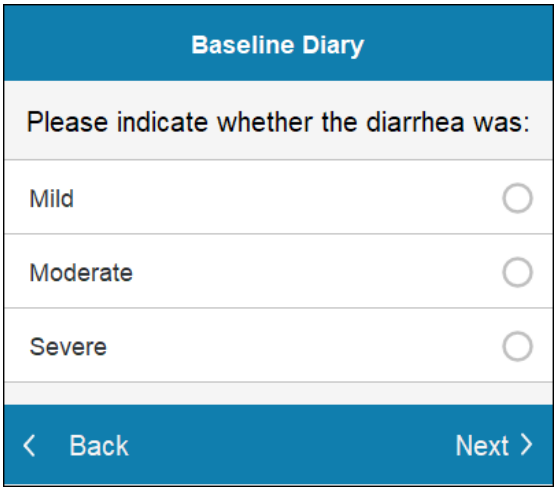
Screen 13



Screen 14



Screen 15



Screen 16

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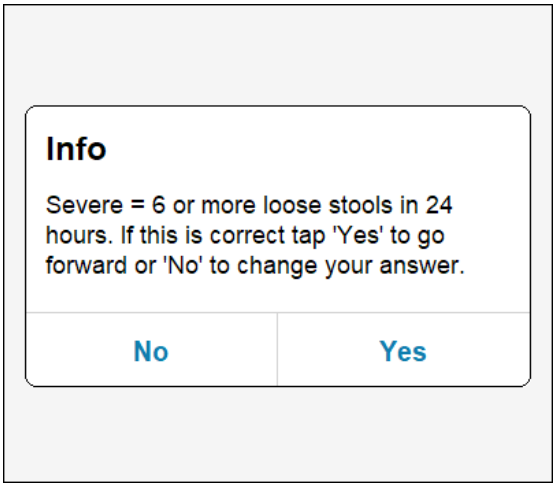
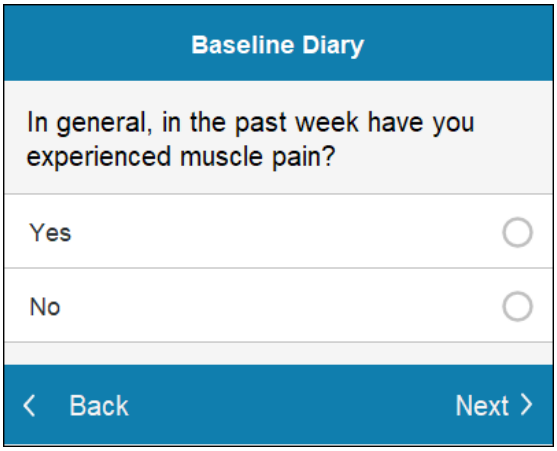
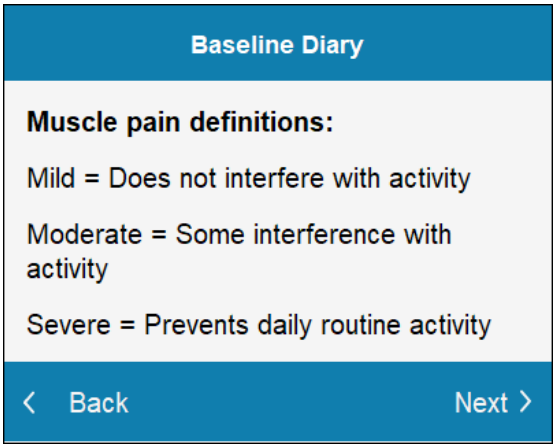


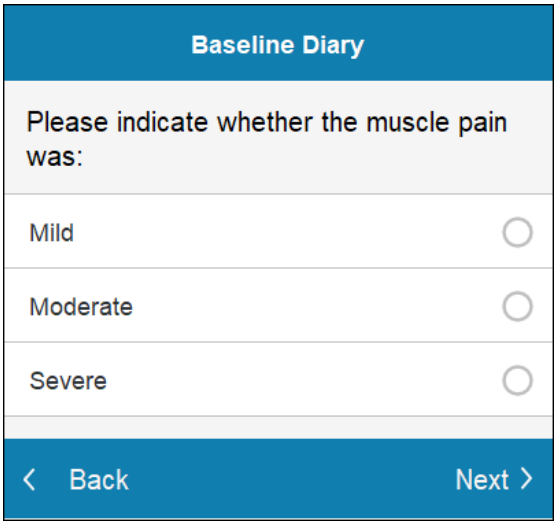
Message 2



Screen 17

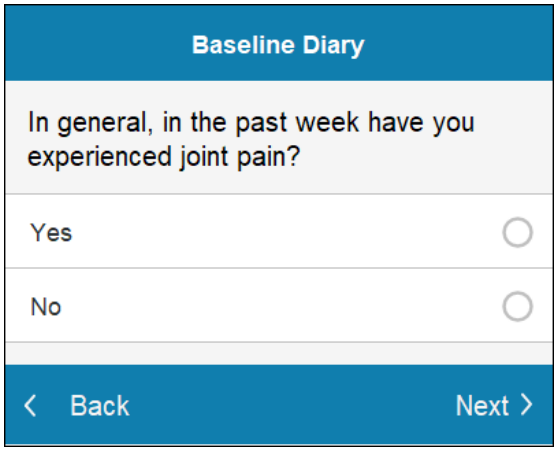


Screen 18

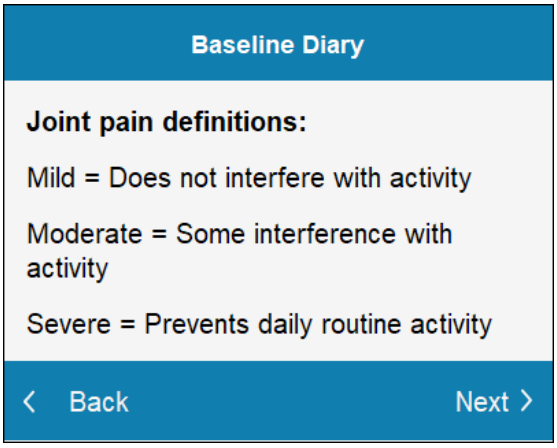


Screen 19

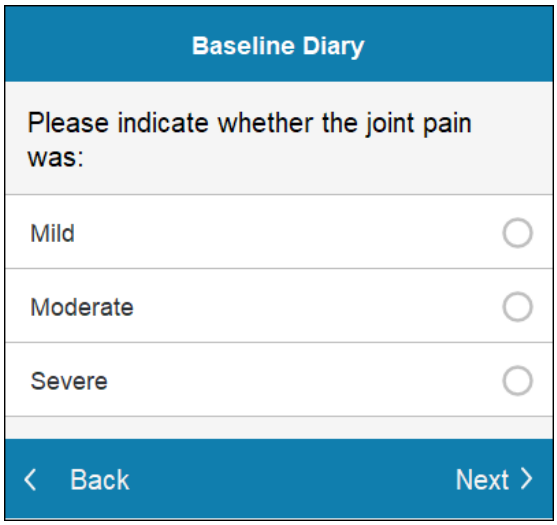
090177e1a08e8b06\Approved\Approved On: 30-Apr-2024 04:32 (GMT)



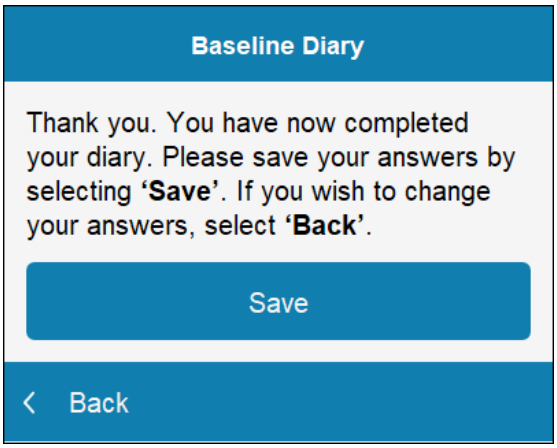
Screen 20



Screen 21



Screen 22



Screen 23

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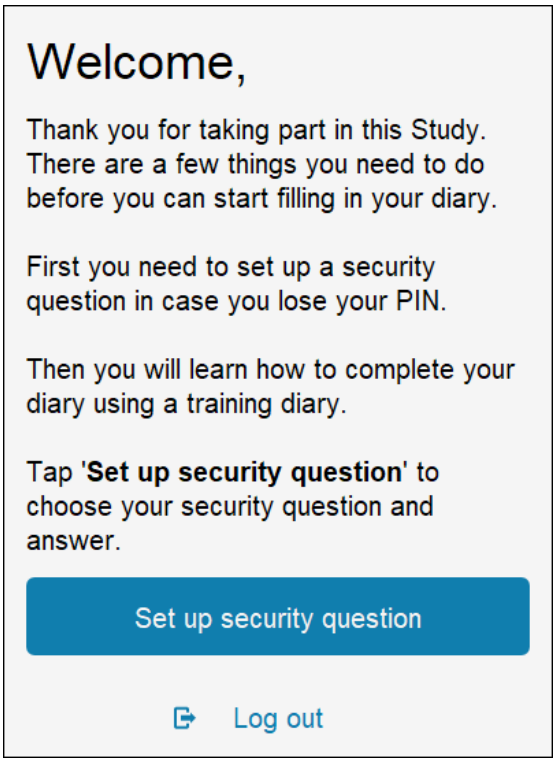
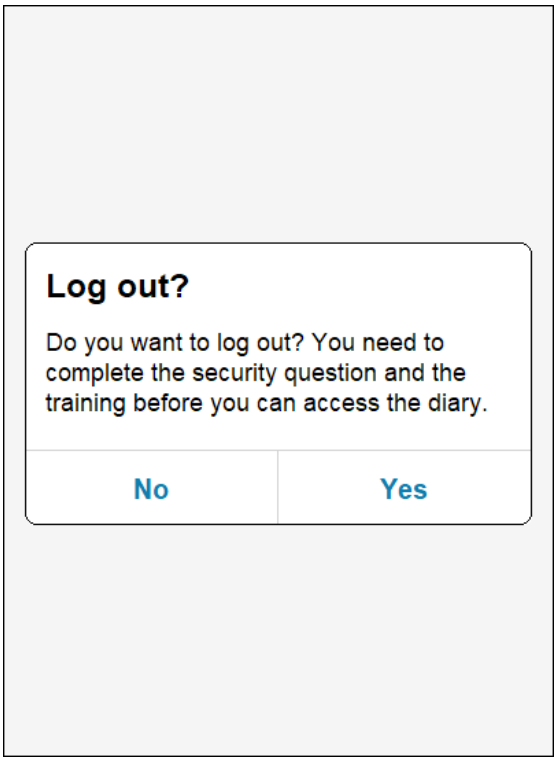
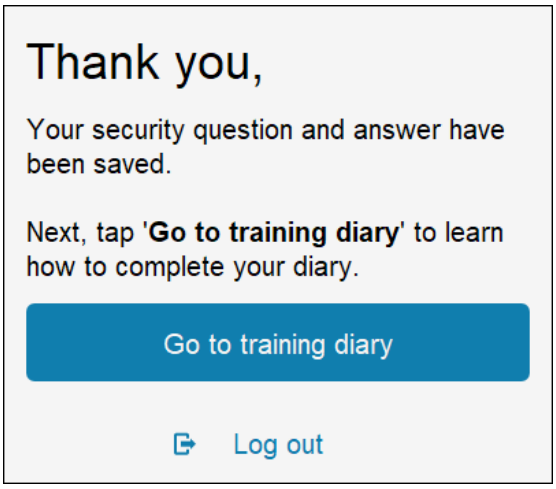
5 Form: Patient main menu



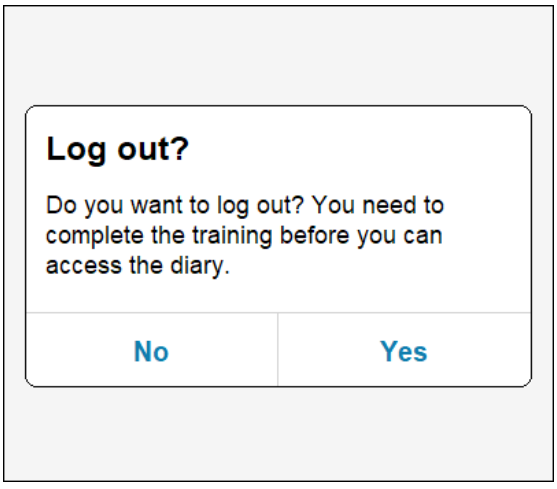
Screen 1



Message 1



Screen 2



Message 1

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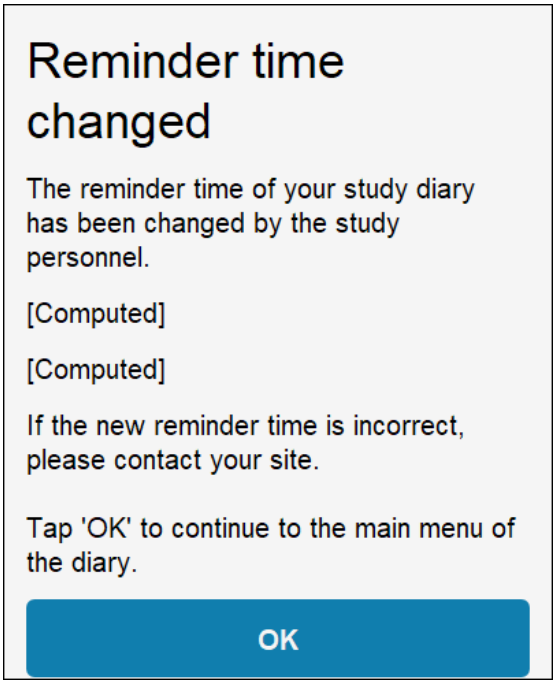
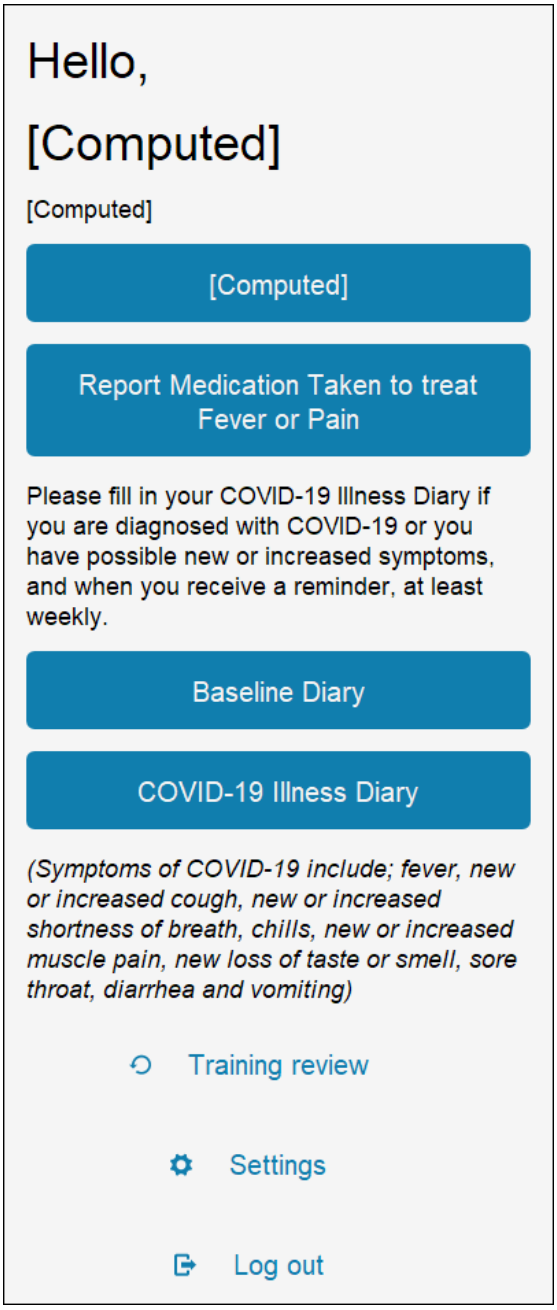


Screen 3

First [Computed] will show 'Old reminder time: {1}' where {1} will be the old reminder time

Second [Computed] will show 'New reminder time: {1}' where {1} will be the new reminder time



Screen 4

First [Computed] text below Hello, will either display: "You are being reminded to complete your weekly COVID-19 Illness Diary." or "You are being reminded to complete your daily <u>Vaccination Diary</u>."

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Second [Computed] text below Hello, will either display: “You have completed today's Vaccination Diary.”, “You have completed today's Vaccination Diary. Please remember to log in again tomorrow." or “Please fill in your daily Vaccination Diary before midnight.”

[Computed] text within the button will read: “Update Symptoms” or “Vaccination Diary”

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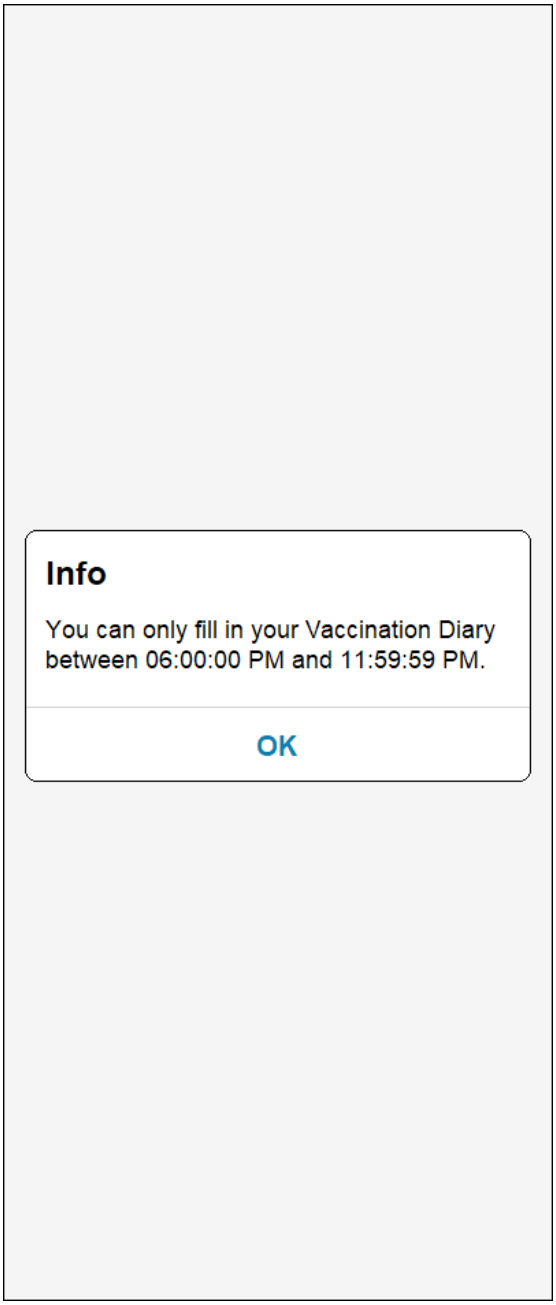
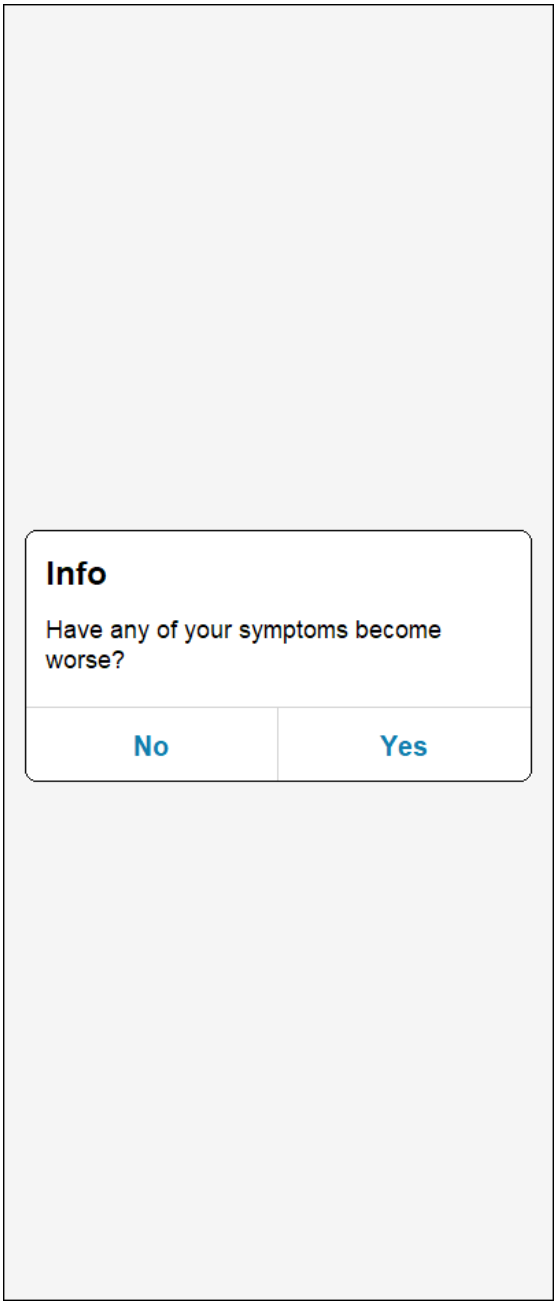


Message 1



Message 2

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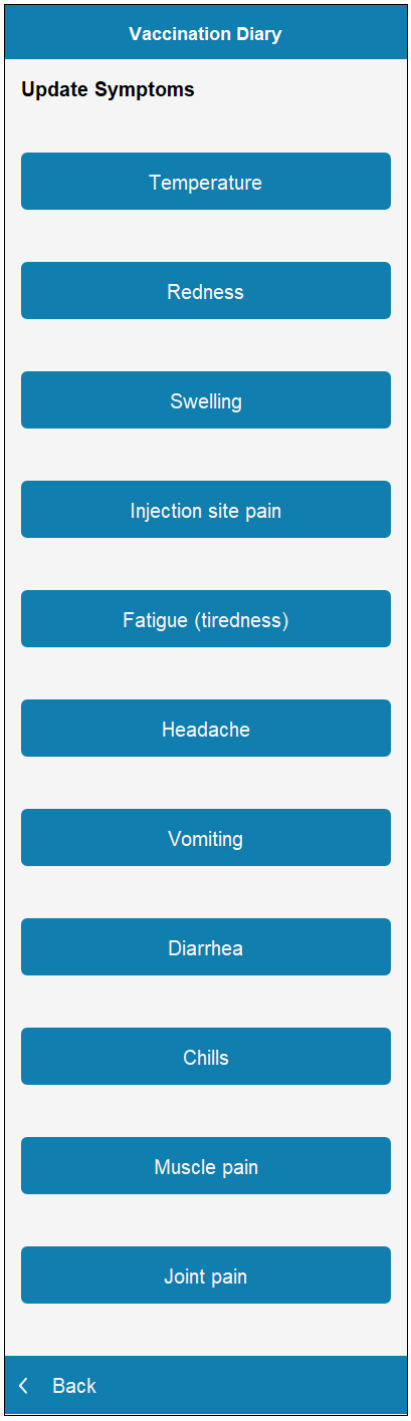
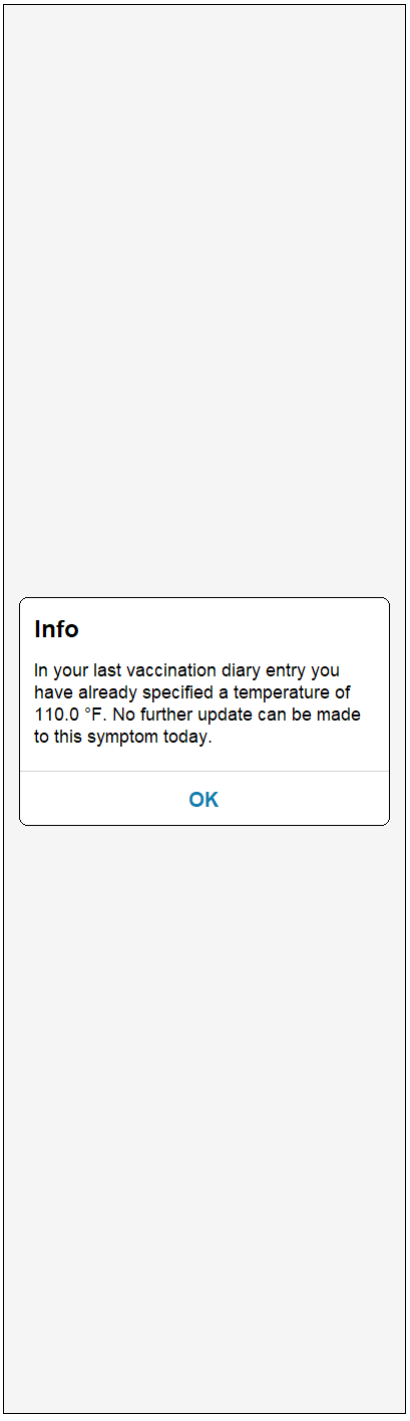
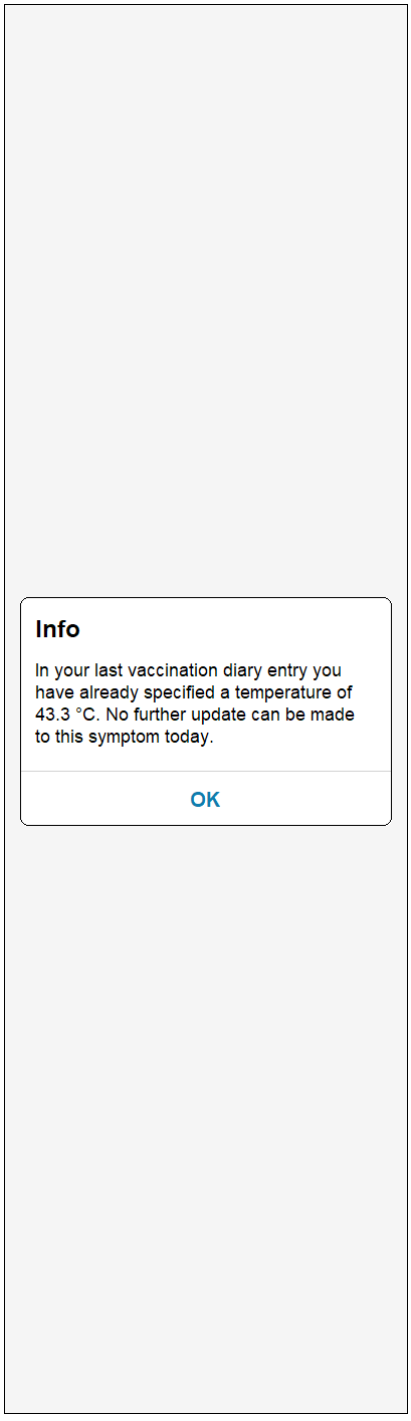


Screen 5

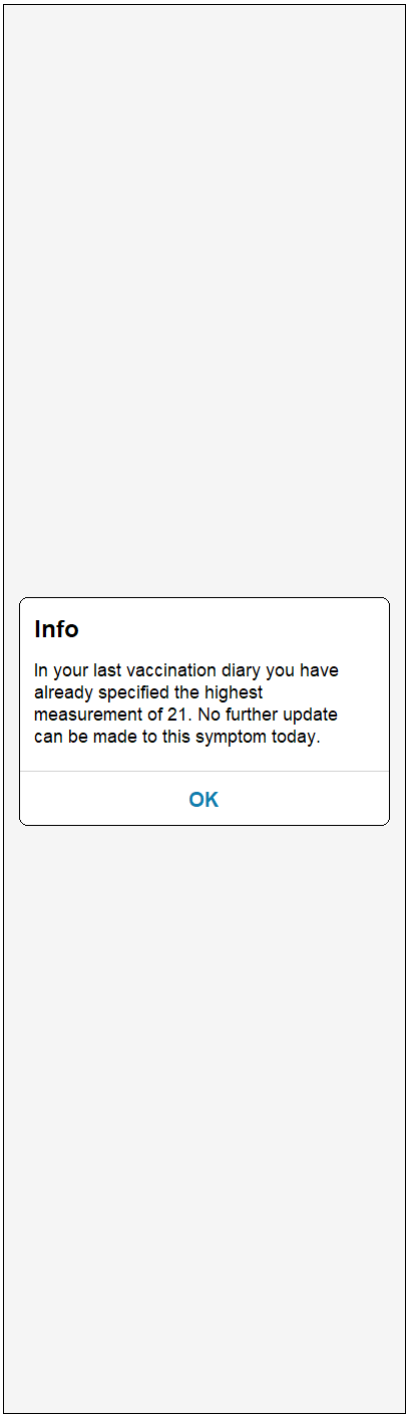


Message 2

090177e1a08e8b06\Approved\Approved On: 30-Apr-2024 04:32 (GMT)



Message 3



Message 5

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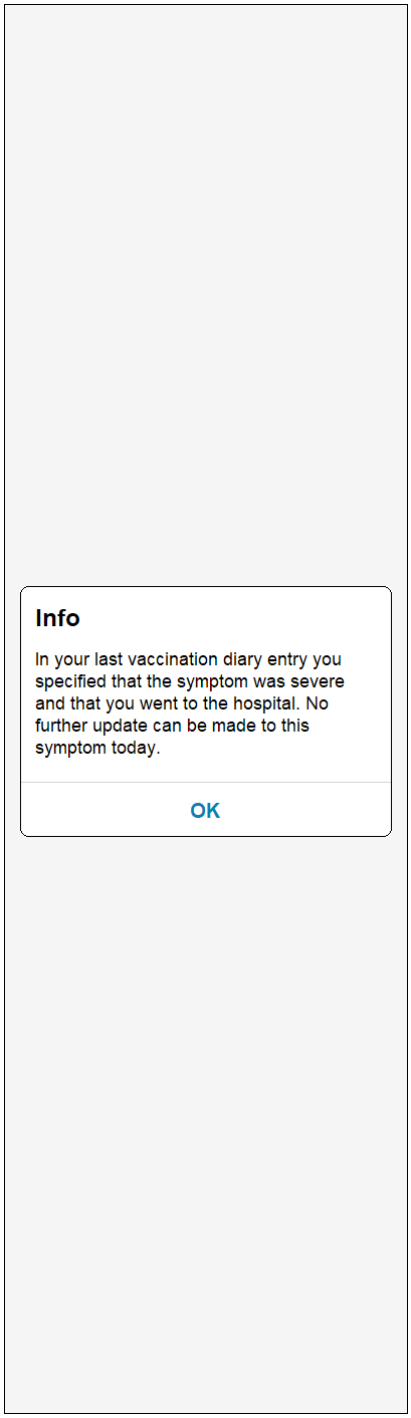

Message 9

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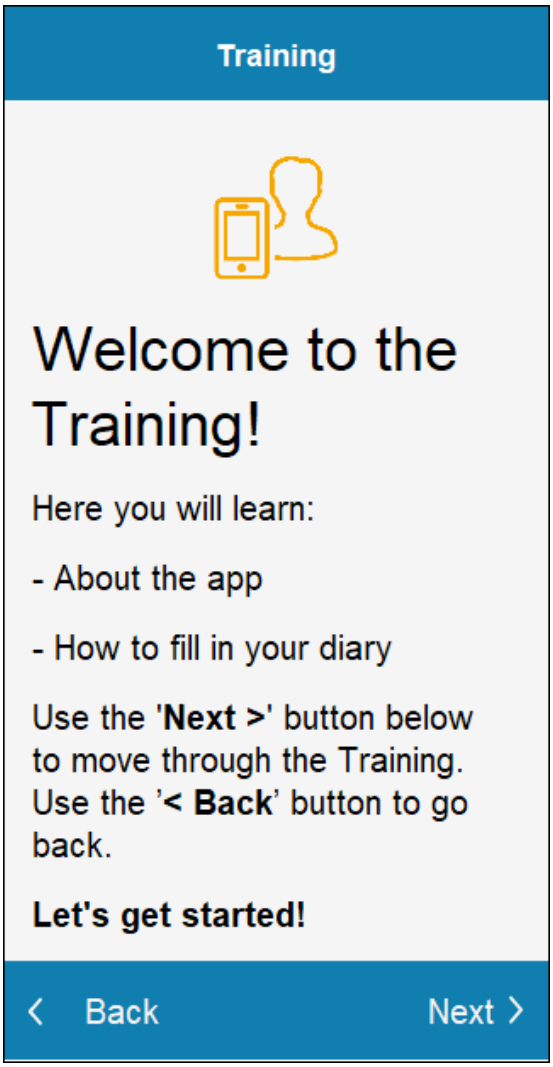
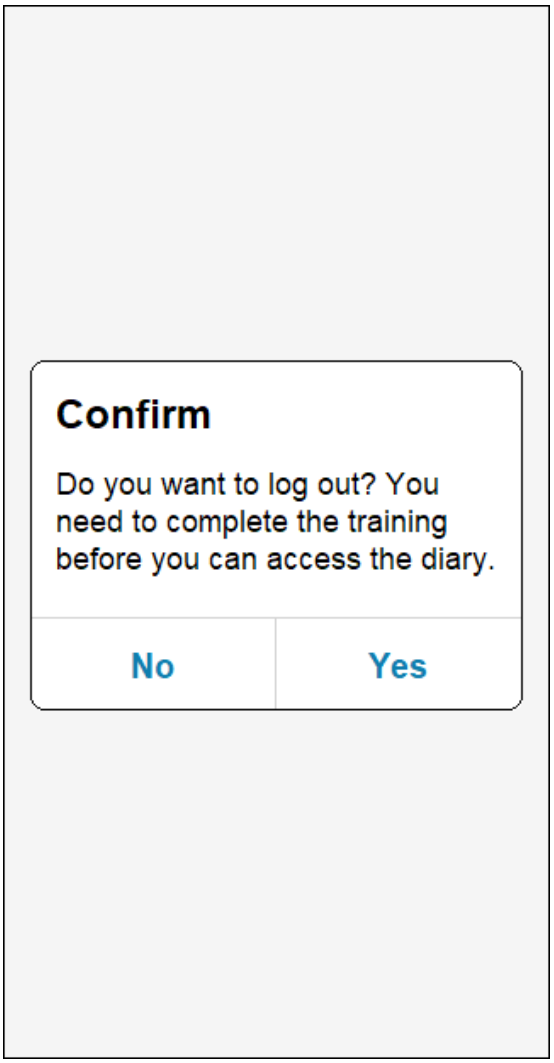
6 Form: Subject training diary

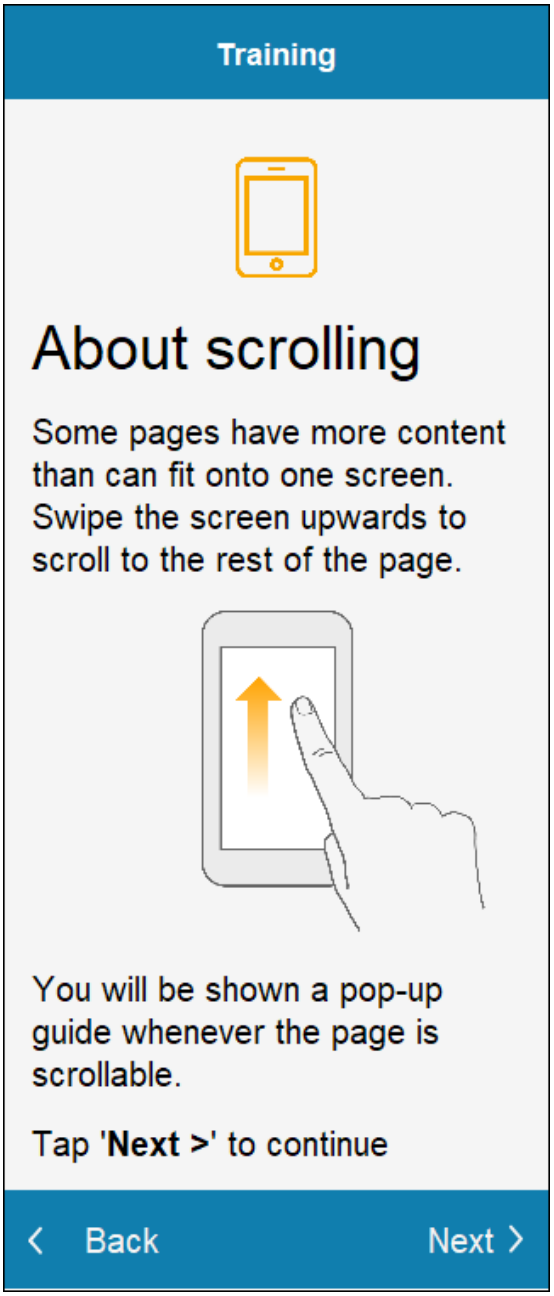


Screen 1

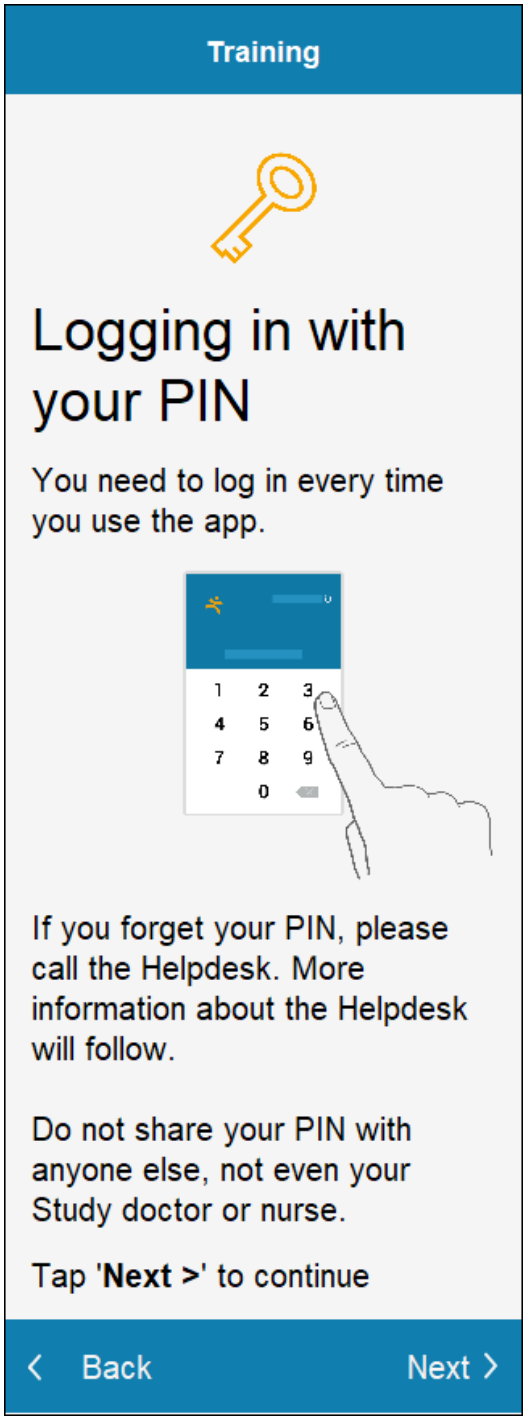


Message 1

090177e1a08e8b06\Approved\Approved On: 30-Apr-2024 04:32 (GMT)

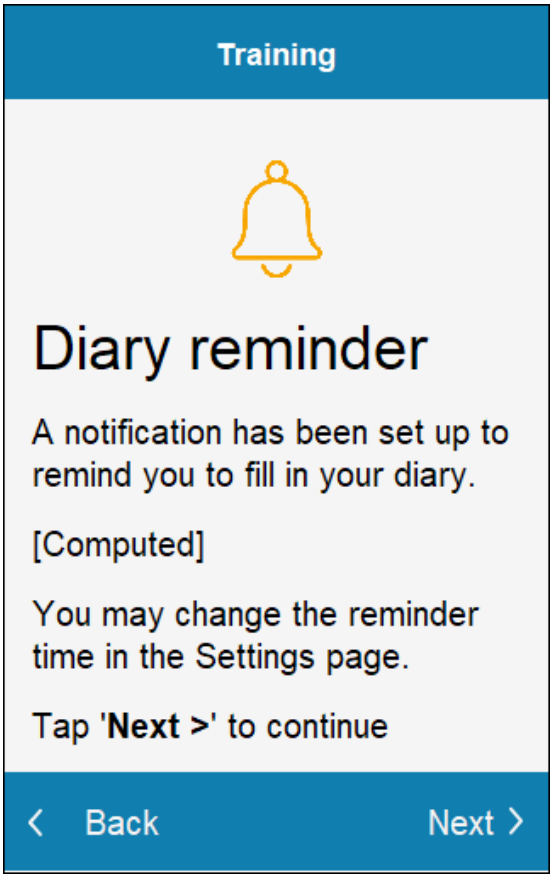


Screen 2

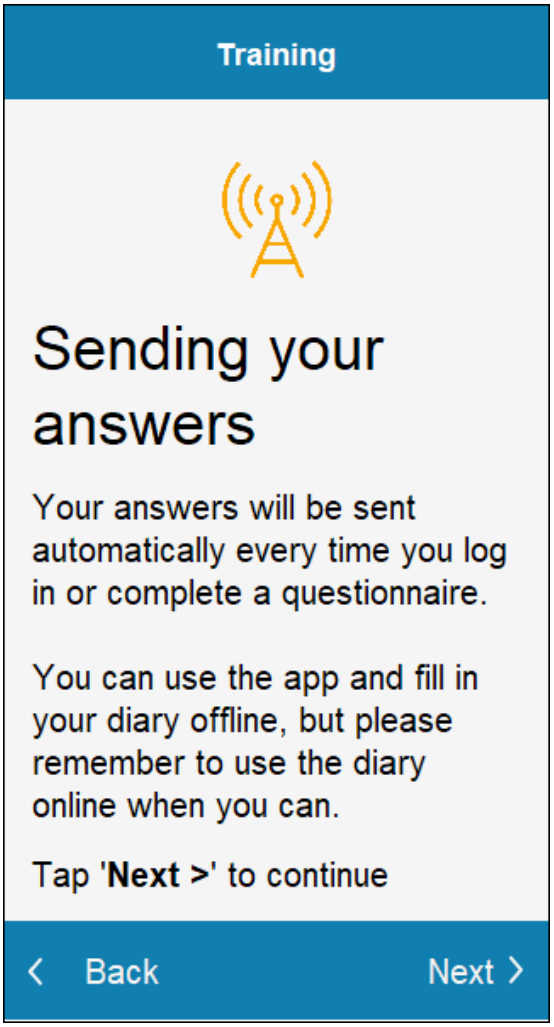


Screen 3

090177e1a08e8b06\Approved\Approved On: 30-Apr-2024 04:32 (GMT)

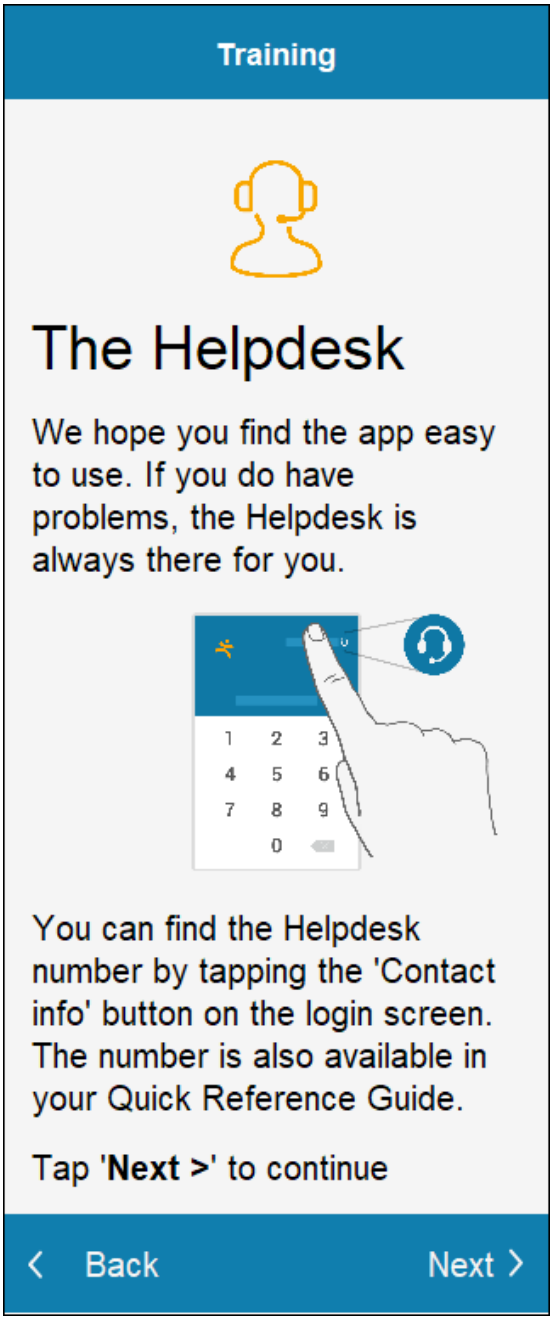


Screen 4

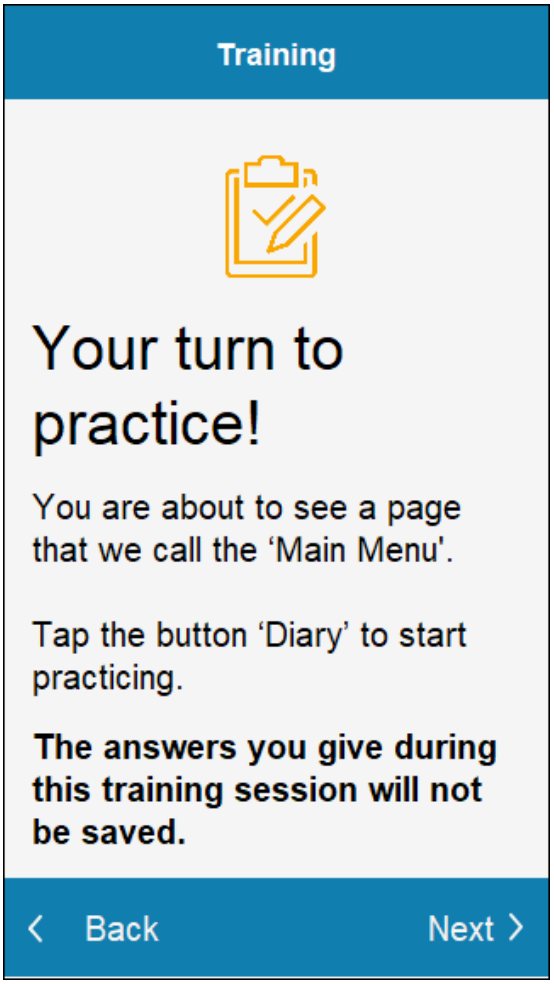


Screen 5

090177e1a08e8b06\Approved\Approved On: 30-Apr-2024 04:32 (GMT)



Screen 6



Screen 7

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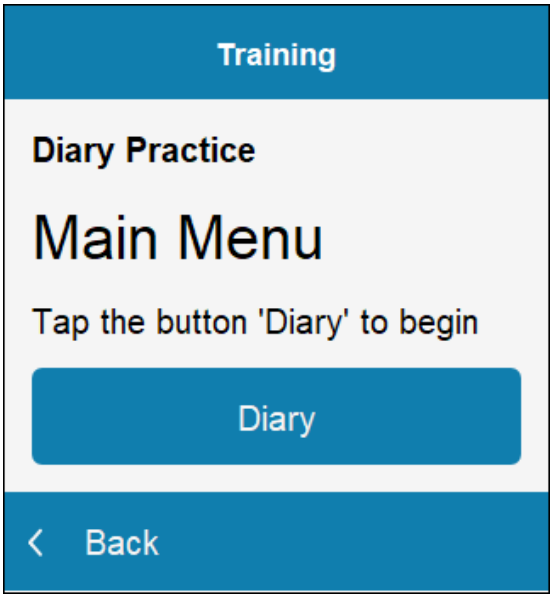
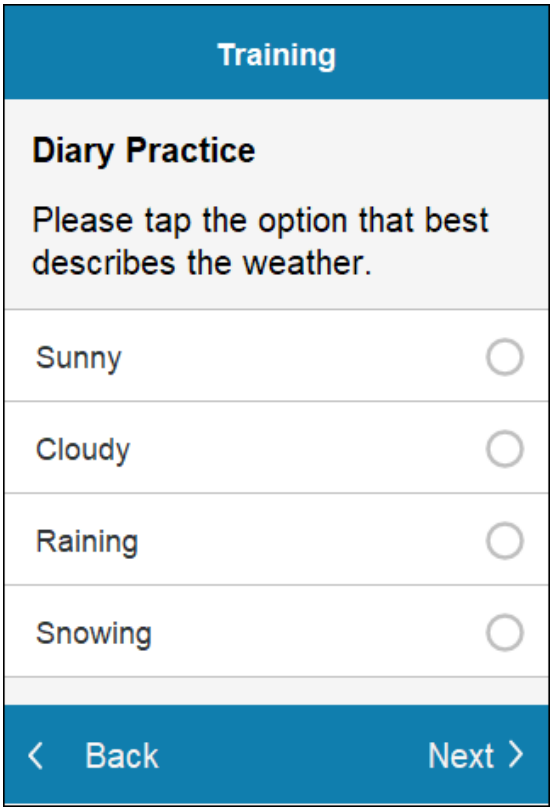
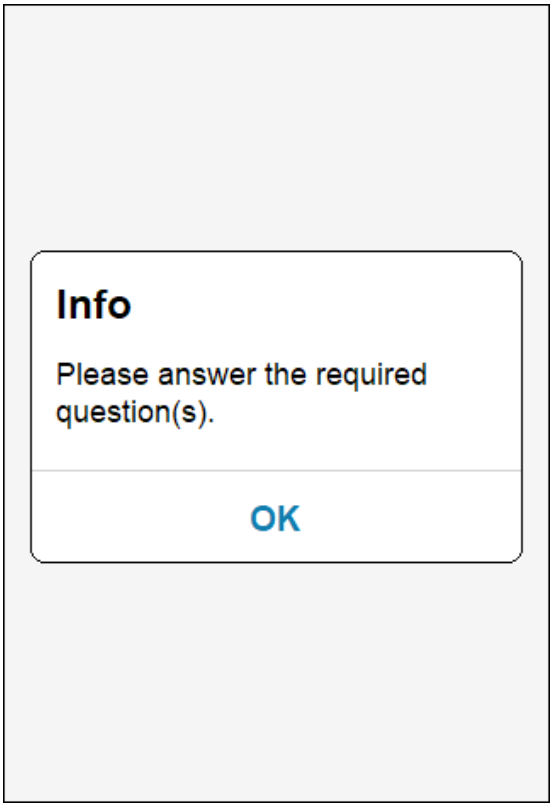


Screen 8

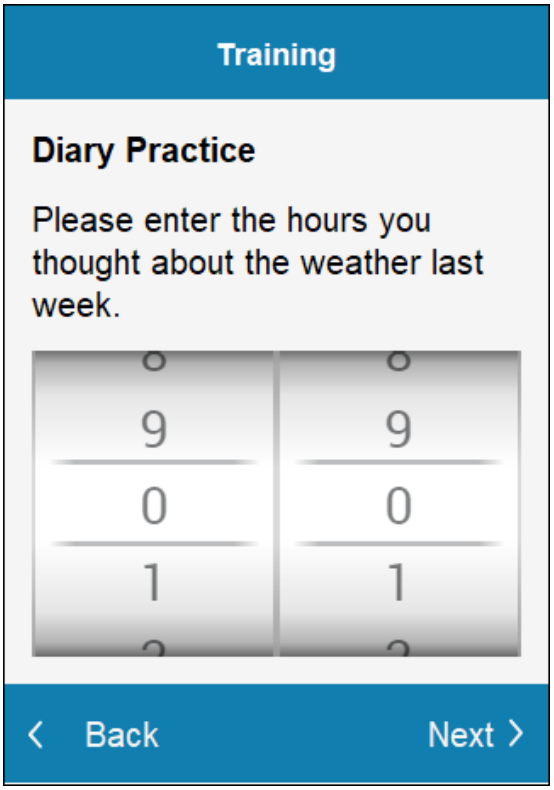


Screen 9

090177e1a08e8b06\Approved\Approved On: 30-Apr-2024 04:32 (GMT)



Message 1



Screen 10

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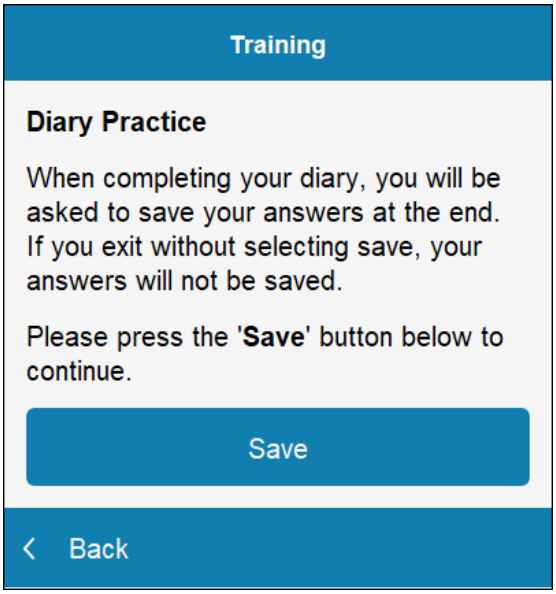
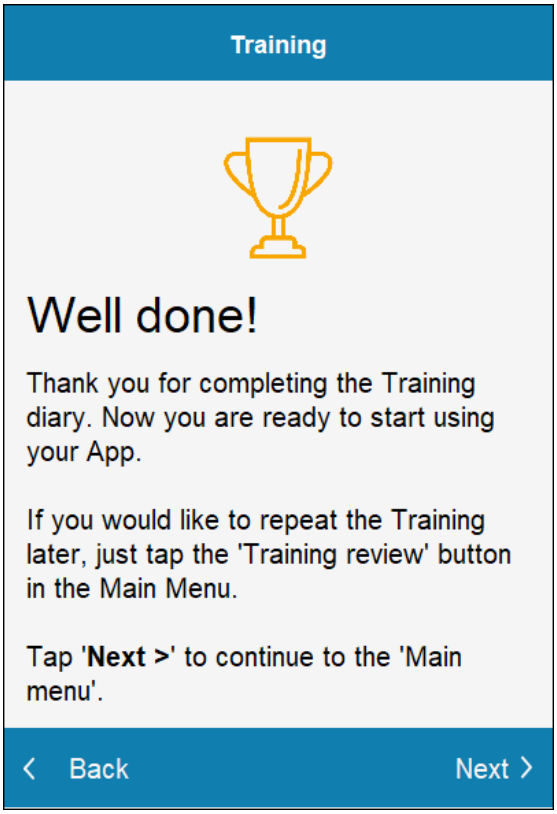


Screen 11



Screen 12

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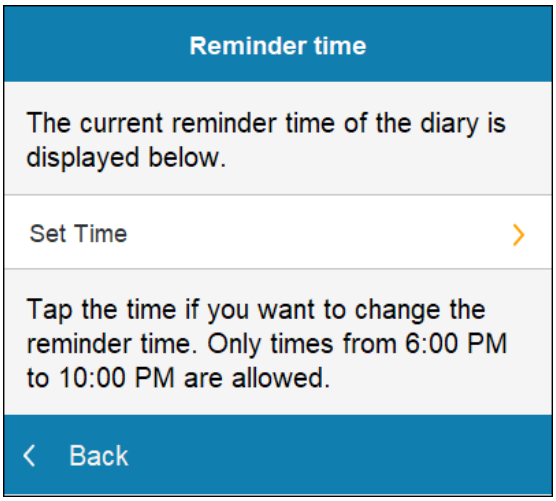
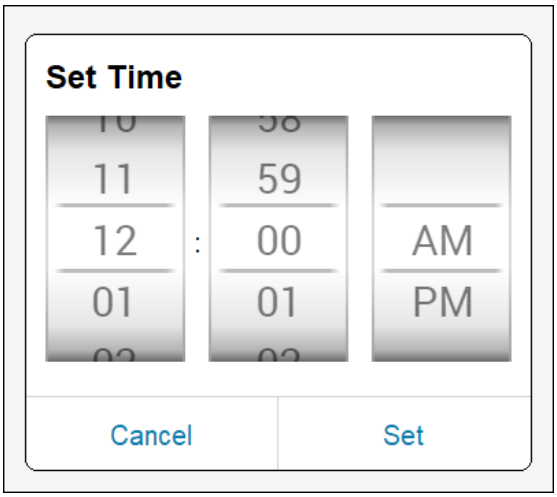
7 Form: Settings



Screen 1



Popup input 1

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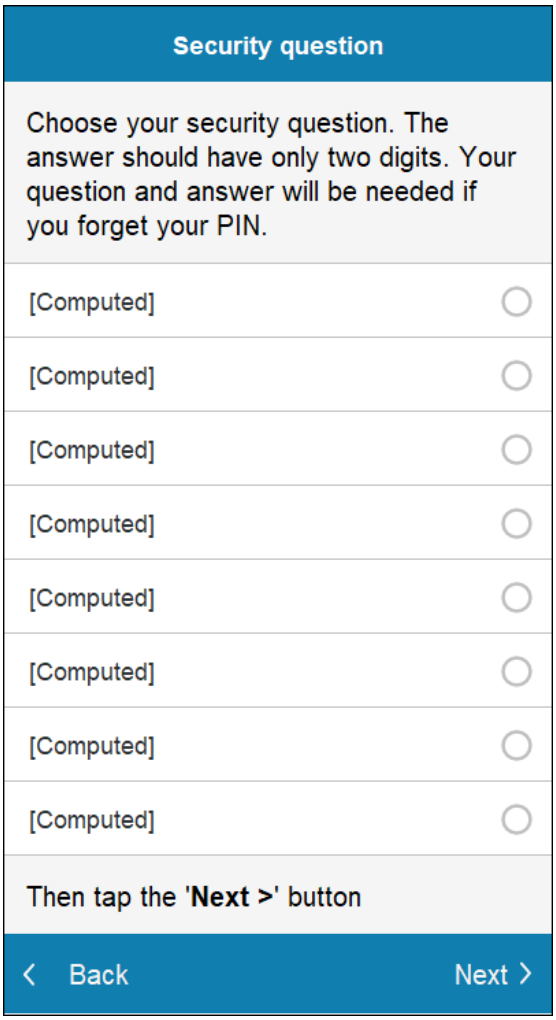
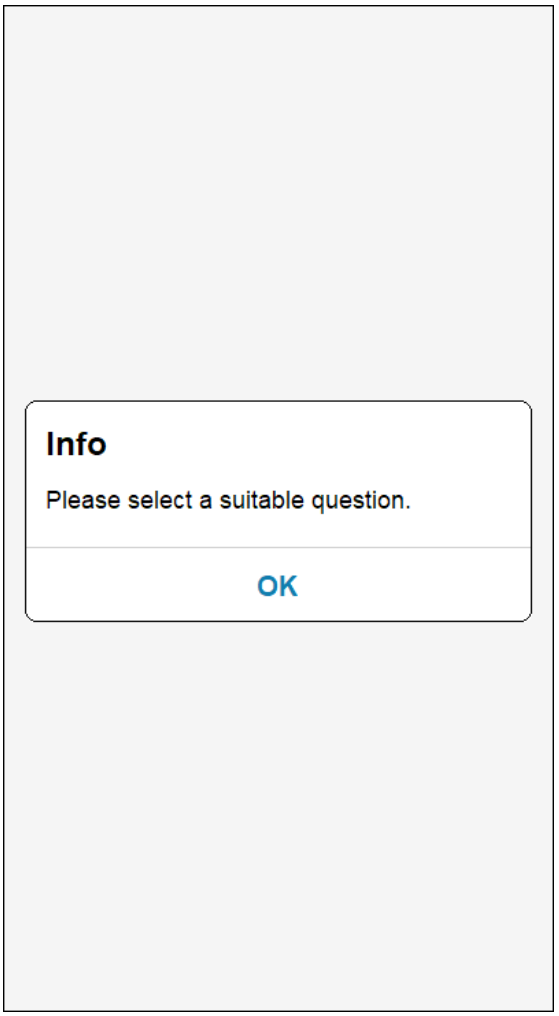
8 Form: Security question



Screen 1



Message 1

[Computed] will show one of the following:

'Your oldest sibling's birth year (YY)'
'Your mother's birth year (YY)'
'Last two digits of your childhood phone number'
'Day of the month of your father's birthday'
'Day of the month of your mother's birthday'
'Childhood home door number (2 digits only)'
'How old were you when you passed your driving test?'
'The year you got married (YY)'

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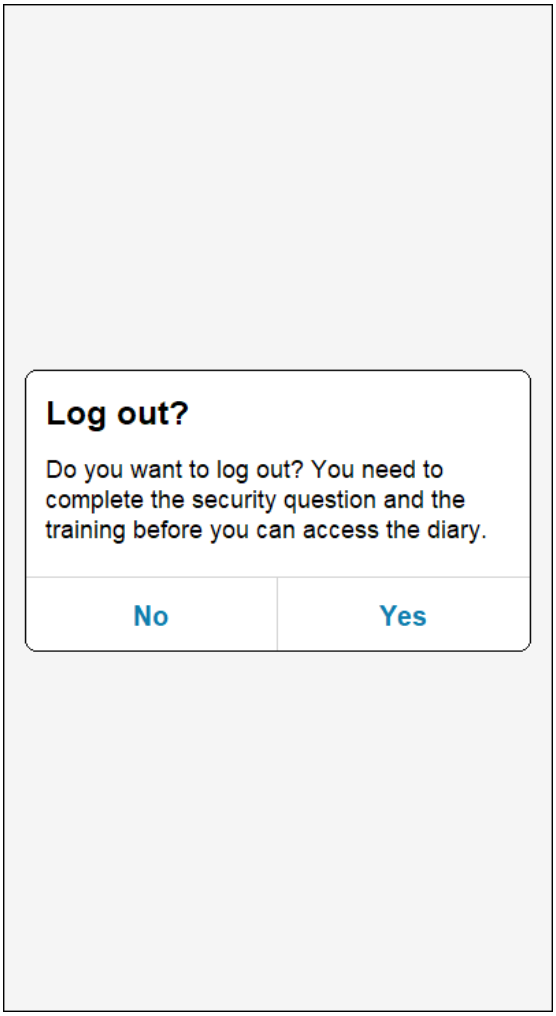
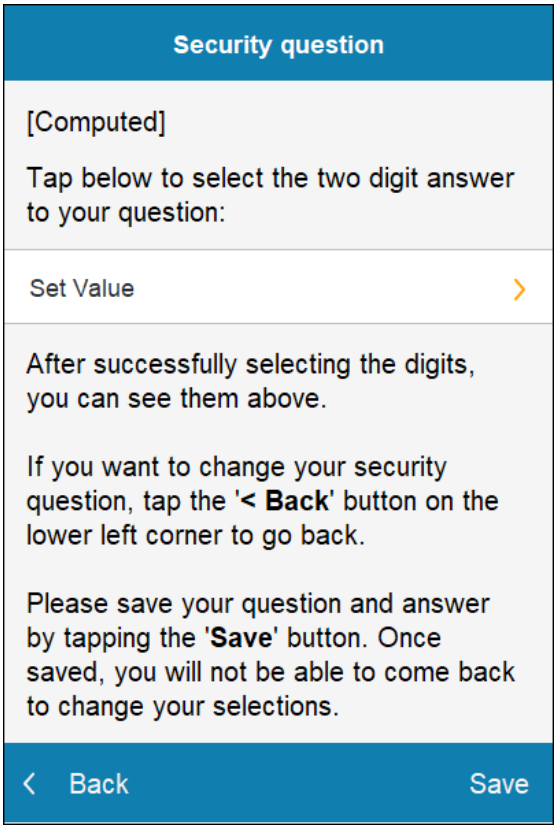


Message 2



Screen 2

[Computed] will display

'Your question:

{1}'

{1} will show the question selected on Screen 1

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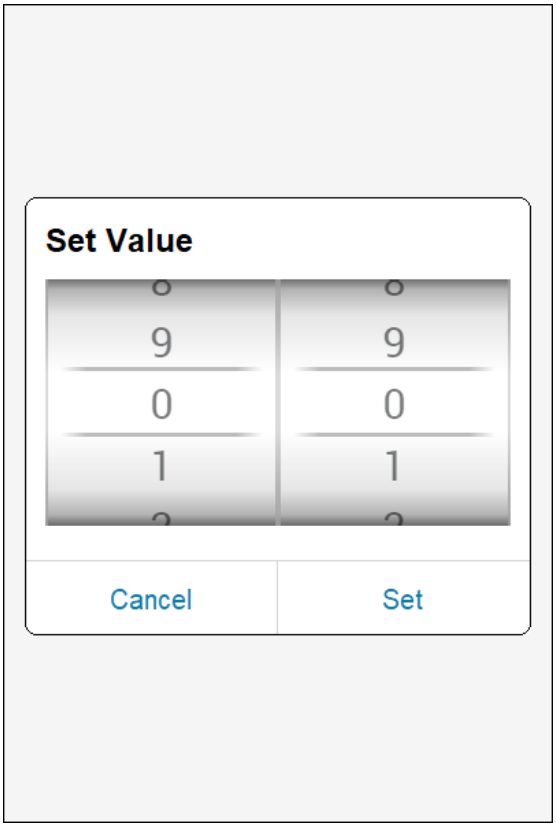
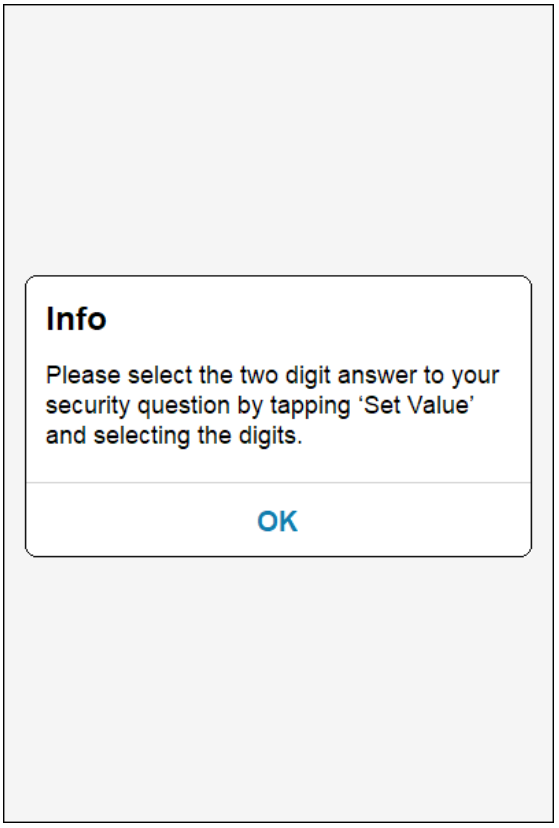


Popup input 1



Message 1

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16.1.3. INDEPENDENT ETHICS COMMITTEE (IEC) OR INSTITUTIONAL REVIEW BOARD (IRB) AND SAMPLE STANDARD SUBJECT INFORMATION SHEET AND INFORMED CONSENT DOCUMENT (ICD)

16.1.3.1 List of Independent Ethics Committee (IEC) or Institutional Review Board (IRB)

16.1.3.2 Sample Standard Subject Information Sheet and Informed Consent Document (ICD)

- C4591015 ICD Version 8.0_15 Nov 2021-Clean
- C4591015 Participant Guide to Using the [redacted]
- C4591015 [redacted] Activation Guidelines V1

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16.1.3.1 LIST OF INDEPENDENT ETHICS COMMITTEE (IEC) OR INSTITUTIONAL REVIEW BOARD (IRB)

BRAZIL

Study Site Number	Independent Ethics Committee or Institutional Review Board Address(es)
1019	[redacted] BRAZ L
	[redacted] BRAZIL
1142	[redacted] BRAZIL
	[redacted] BRAZIL
1151	[redacted] BRAZ L
	[redacted] BRAZIL

Study Site Number	Independent Ethics Committee or Institutional Review Board Address(es)
1194	[redacted] BRAZIL
	[redacted] BRAZ L
	[redacted] BRAZIL

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SOUTH AFRICA

Study Site Number	Independent Ethics Committee or Institutional Review Board Address(es)
1059	[redacted] SOUTH AFRICA
1071	[redacted] SOUTH AFRICA
1083	[redacted] SOUTH AFRICA
1104	[redacted] SOUTH AFR CA
1150	[redacted] SOUTH AFRICA
1152	[redacted] SOUTH AFRICA

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SPAIN

Study Site Number	Independent Ethics Committee or Institutional Review Board Address(es)
1076	[redacted] SPAIN
1077	[redacted] SPAIN
1127	[redacted] SPAIN
1219	[redacted] SPAIN
1226	[redacted] SPAIN
1251	[redacted] SPA N
1252	[redacted] SPAIN

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UNITED KINGDOM

Study Site Number	Independent Ethics Committee or Institutional Review Board Address(es)
1183	[redacted] UNITED KINGDOM
1184	[redacted] UNITED KINGDOM
1203	[redacted] UNITED KINGDOM
1204	[redacted] UNITED K NGDOM
1216	[redacted] UNITED KINGDOM
1233	[redacted] UNITED KINGDOM

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Study Site Number	Independent Ethics Committee or Institutional Review Board Address(es)
1234	[redacted] UNITED KINGDOM
1242	[redacted] UNITED K NGDOM
1244	[redacted] UNITED K NGDOM
1246	[redacted] UNITED KINGDOM
1254	[redacted] UNITED KINGDOM

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UNITED STATES

Study Site Number	Independent Ethics Committee or Institutional Review Board Address(es)
1004	[redacted] UNITED STATES
1006	[redacted] UNITED STATES
1007	[redacted] UNITED STATES
1009	[redacted] UNITED STATES
1010	[redacted] UNITED STATES
1011	[redacted] UNITED STATES
1013	[redacted] UNITED STATES

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Study Site Number	Independent Ethics Committee or Institutional Review Board Address(es)
1016	[redacted] UNITED STATES
1021	[redacted] UNITED STATES
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1025	[redacted] UNITED STATES
1026	[redacted] UNITED STATES
1028	[redacted] UNITED STATES
1030	[redacted] UNITED STATES

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Study Site Number	Independent Ethics Committee or Institutional Review Board Address(es)
1032	[redacted] UNITED STATES
1034	[redacted] UNITED STATES
1035	[redacted] UNITED STATES
1036	[redacted] UNITED STATES
1037	[redacted] UNITED STATES
1038	[redacted] UNITED STATES
1039	[redacted] UNITED STATES

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Study Site Number	Independent Ethics Committee or Institutional Review Board Address(es)
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1065	[redacted] UNITED STATES
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1069	[redacted] UNITED STATES

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Study Site Number	Independent Ethics Committee or Institutional Review Board Address(es)
1078	[redacted] UNITED STATES
1086	[redacted] UNITED STATES
1099	[redacted] UNITED STATES
1125	[redacted] UNITED STATES
1177	[redacted] UNITED STATES
1247	[redacted] UNITED STATES

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Protocol Number: C4591015		**ICD Version Date:** 15 Nov 2021	
☒ Study ☐ Country ☐ Site	**Language: English**	**Center ID:**	**Country:**
ICD Derived From: Study Level, Version 7.0 10 August 2021			

Dear Madam,

Thank you for taking the time to consider if you and your unborn baby would like to join this study. We understand that this may be a difficult decision. This consent document can help you make your decision by explaining **what you can expect to happen during this study**, also known as a clinical trial or a research study.

Taking part in this study is **completely voluntary (your choice)**. Take as long as you need to make your decision. You also can choose to take part in the study now, and then change your mind later at any time. Please keep in mind that even if you choose to take part, it may turn out that you do not meet the study's entry requirements.

We encourage you to **have conversations with your family, caregivers, doctors, and study team** about taking part in this study and whether it is right for you. The study team will work with you to answer any questions that you may have about the study. The study team includes the study doctor, nurses, and others who work with the study doctor.

If you choose to take part in this study, **you will be asked to sign this consent document** before you start the study to let the study team know your decision.

You will receive a signed copy of this consent document for your records. Please keep this consent document for your reference.
We appreciate that you are thinking of taking part in this study.

Sincerely,

_____
Study Doctor

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Table of Contents

This Table of Contents describes the different sections of this consent document. Be sure to read through all sections of this consent document before making your decision about whether or not to participate in this study.

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Privacy Supplement

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1. Key Study Information and Contact Information

The study team will address any questions, concerns or complaints you may have before, during and after you and you baby complete the study. The study team includes the study doctor, nurses, and others who work with the study doctor.

Phone numbers for the study team are listed below under "Study Site Contact Information." **You also will be given a card with important emergency contact information, including a 24-hour number.** Show this card to any doctor, nurse or other health care provider if you or your baby seek emergency care while you are taking part in this study. This card includes information about the study that will help them treat you or your baby.

If you have any general questions about your rights, or your baby's rights, as a study participant, or would like to obtain information from, offer suggestions to, or speak with someone not directly involved in the study, you may contact **[**For the site-level ICD, include as appropriate: the Institutional Review Board ***or*** the Independent Ethics Committee, patient rights advocate, and/or bioethicist**]** listed below.

Name of Study: A Phase 2/3, Placebo-Controlled, Randomized, Observer-Blind Study to Evaluate the Safety, Tolerability, and Immunogenicity of a SARS-CoV-2 RNA Vaccine Candidate (BNT162b2) against COVID-19 In Healthy Pregnant Women 18 years of Age and Older

Sponsor Consent Version Number (Study/Country/Site): 8.0 / /

[Institution] Study Number:

Sponsor Study Number: C4591015

Name of Company Sponsoring the Study: BioNTech. Study conducted by Pfizer

Name of Principal Investigator (Study Doctor):

Study Site Contact Information:

Contact Person:

Address:

Phone Number (Normal Business Hours):

Phone Number (Off-Hours or Emergency):

[Complete the following entries for the site-level ICD as appropriate.**]**

[Institutional Review Board *or* Independent Ethics Committee] Contact Information:

Contact Person:

Address:

Phone Number:

Patient Rights Advocate:

Contact Person:

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Address:

Phone Number:

Bioethicist:

Contact Person:

Address:

Phone Number:

2. Brief Summary of this Study

This is a research study involving both Pfizer and BioNTech. Pfizer and BioNTech are separate companies who are cooperating to perform this study. Pfizer is responsible for conducting this study. BioNTech is the regulatory sponsor of this study. Funding for this study is provided by BioNTech and Pfizer and [the study doctor/institution] will be paid to conduct this study.

A new respiratory disease appeared in Wuhan, China in December 2019 and has since rapidly spread to many other countries around the world. In January 2020, the cause of this disease was found to be a new Coronavirus; and the disease it causes was named COVID-19 (Coronavirus disease 2019). Since then, many companies around the World have quickly started to look for treatments and ways to prevent COVID-19. Since December 2020, many countries have approved the emergency or conditional use of several vaccines to prevent COVID-19, including the Pfizer-BioNTech COVID-19 vaccine (BNT162b2). [Language shown is specific to the United States, other countries edit as necessary per current Health Authority status: On August 23, 2021, the US Food and Drug Administration (FDA) approved the use of the Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19 in individuals 16 years of age and older.

Vaccines help your body to produce antibodies to help you to fight off a disease. This research study involves an investigational vaccine to prevent COVID-19, that will be given to healthy women who are 18 years of age or older and expecting a healthy baby. The study doctor will determine whether you and your unborn baby would be suitable for the study. If you decide to join the study and are found to be suitable, you will be given 2 doses of the study injection before your baby is born, which could be either the COVID-19 investigational vaccine or a placebo injection. After your baby is born you will be told if you were given the placebo injection or the COVID-19 investigational vaccine while you were pregnant. If you were given the placebo injection you will be given 2 doses of the COVID-19 investigational vaccine after your baby is born. This means that every woman in the study will be given the COVID-19 investigational vaccine either while they are pregnant or shortly after giving birth. It also means that some women will

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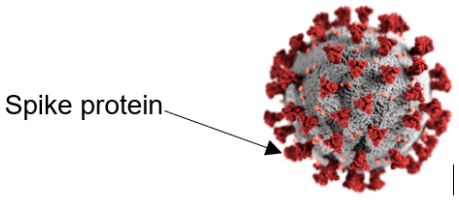
be given 2 injections and some women will have 4 injections (2 while pregnant and 2 after the baby is born).

The placebo injection in this study is saline (salt water) solution and does not contain any active ingredients.

The investigational vaccine is made up of part of the virus's genetic code, surrounded by fatty particles called lipids, it does not contain the whole virus, or the parts of the virus that could make you or your unborn baby ill. The part of the virus's genetic code contained in the investigational vaccine uses your own cells' protein making machinery to produce some, or all, of the spike protein seen on the outside of the virus. This spike protein, made by your own body, may help your body to produce antibodies to fight against COVID-19. We will check how many antibodies you make by taking blood samples and testing them. We also want to see if these antibodies are transferred to your baby and will take blood samples from your baby after he/she is born.

Coronavirus



Up until September 2021, the safety of BNT162b2 has been studied in clinical trials that have included about 52,100 people, aged 5 years and above, who have received at least one dose of the vaccine. In addition, since the vaccine has been approved for emergency use or received a full or conditional marketing authorization in many countries by the end of September 2021 about 1.7 billion doses have been distributed. Based on the available data, the following risks have been determined to be caused by BNT162b2 vaccine: Injection site pain, injection site swelling, fatigue (tiredness), increased body temperature (fever), chills, headache, diarrhea, joint aches, muscle aches, feeling sick (nausea), being sick (vomiting), injection site redness, enlarged lymph glands, allergic reaction (symptoms may include rash, itching, hives, and swelling of the face or lips), decreased appetite, lethargy, sweating and night sweats, pain in arm, feeling weak or unwell, and severe allergic reaction (anaphylaxis).

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received BNT162b2. Cases have mainly been reported in males under 30 years of age and following the second vaccination. Symptoms include: Chest pain, shortness of breath, or feelings of having a fast-beating, fluttering or pounding heart. As a precaution, you should seek

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medical attention right away if you have any of those symptoms after receiving the vaccine. The chance of having this occur is very low.

Although not seen to date, it cannot yet be ruled out that the study vaccine could make a later COVID-19 illness more severe.

This study is different from your and your baby's regular medical care. The purpose of regular medical care is to improve or otherwise manage your and your baby's health, but the purpose of research is to gather information to advance science and medicine and does not replace your or your baby's regular medical care. If you, or your baby, need medical care during your time in the study, you should contact your regular provider and inform the study team, as described later in this document.

Taking part in this study is voluntary (your choice). There is no penalty or change to your, or your baby's regular medical care if you decide not to take part. You can choose to take part in the study now, and then change your mind later at any time without losing any benefits or medical care to which you, or your baby, are entitled. We encourage you to have conversations with your family, caregivers, doctors, and study team about taking part in this study and whether it is right for you and your unborn baby. The study team will work with you to answer any questions that you may have about the study.

You will receive a signed copy of this consent document for your records. Please keep this consent document for your reference.

3. What is the purpose of this study?

The World Health Organization (WHO) has declared COVID-19 to be a pandemic (a disease that has spread all over the world and is affecting lots of people); finding a vaccine to prevent COVID-19 is an urgent need. Pregnant women might be at increased risk for severe illness from COVID-19 compared to non-pregnant women. There may also be an increased risk of adverse pregnancy outcomes, such as preterm birth, among pregnant women with COVID-19.

In this study we will see if the investigational vaccine is safe to give to pregnant women and their unborn baby and the amounts of antibodies they produce. We will also see if the investigational vaccine works to prevent COVID-19 in women given the vaccine while pregnant. After your baby is born you will be told if you were given the placebo injection or the investigational COVID-19 vaccine while you were pregnant. Every

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woman in the study will be given the COVID-19 investigational vaccine either while they are pregnant or shortly after giving birth.

4. How long will my baby and I be in the study?

The length of time you are in the study will depend if you are given the investigational COVID-19 vaccine while you are pregnant or shortly after your baby is born. You will be in the study for about 7-10 months, but the duration will depend on when your baby is born and whether you received placebo injection or the COVID-19 investigational vaccine at the beginning of the study.

Your baby will be in the study for up to approximately 6 months. Your baby will have a clinic visit at the study site when he/she is about 6 months old.

5. How many people will take part in this study?

There will be about approximately 700 healthy pregnant women and their unborn baby's taking part in this study.

This study will use competitive enrollment. This means that if enrollment ends before you are given the study vaccine, it is possible that you/your baby may not be allowed to continue in the study.

6. What will happen during this study?

All women who take part will need to visit the study site for 4 planned visits before their baby is born and then 2 more visits after the baby is born. Visits that occur before delivery of your baby include:

1. screening and your **first study injection visit** (these could take place on the same day),
2. your **second study injection visit**, which is about 3 weeks after the first injection,
3. **2-week follow-up** visit,
4. **1-month follow-up** visit,

A study visit should occur on the day of baby is born, or shortly after.
After your baby is born you will have:

- A phone call about a week after your baby is born to see how you and your baby are,
- A clinic visit about 1-month after you gave birth. At this visit you will be told if you were given the placebo injection while you were pregnant or the investigational COVID-19 vaccine.

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If you were given the investigational COVID-19 vaccine while you were pregnant you will only need to come back to the clinic for 1 more planned visit. This will be when your baby is around 6 months old.

If you were given the placebo injection while you were pregnant you will be given your first investigational COVID-19 vaccine injection about 1 month after your baby is born. You will need to come back to the clinic about 3 weeks later to receive your second investigational COVID-19 vaccine injection. You will have a follow-up telephone call about 1 month after your second vaccination. This follow-up call will be the end of the study for you. Your baby will continue to be followed up until they are 6 months old.

- Every baby will need to have a clinic visit when they are about 6 months old.

The study team will tell you when you and your baby need to come for your visits. Extra visits or contacts may also be necessary if you, or your baby develop any signs or symptom of COVID-19 illness during the study, or if you have any severe symptoms after your vaccinations that you are given while you are pregnant.

Before any study procedures begin, or before you begin preparing for the study, you will be asked to read and sign this consent document.

After signing this consent document, the study doctor will check if you, and your unborn baby, meet all the requirements to take part in this study. If you, or your baby, do not meet the requirements, you will not be able to take part in the study and the study doctor will explain why this is the case.

Study Vaccines – When you are pregnant

Once the study doctor has confirmed you, and your unborn baby, meet the study requirements, you will be randomly assigned (like flipping a coin) to receive the investigational COVID-19 vaccine (BNT162b2 30 micrograms) or placebo injection. The placebo injection contains salt-water and no active ingredients. For every 1 pregnant person who receives the investigational COVID-19 vaccine, 1 other pregnant person will receive the placebo injection. No one (including you, your personal doctor or the study team) can choose this assignment.

This part of the study is an 'observer-blind study', which means that you and the study doctor **will <u>not</u> know** whether you are receiving the investigational COVID-19 vaccine or placebo injection while you are pregnant. The person who gives you the injection will know which you are getting because the investigational COVID-19 vaccine and placebo injection do not look the same. However, the syringe will be covered with a label so the

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contents are not visible and the person that gives you the injection will not be able to talk about it with you. In case of urgent need, the study doctor can learn quickly whether you have received investigational vaccine or placebo injection.

The investigational COVID-19 vaccine or placebo injection will be given to you through an injection into the muscle in your upper arm. Everyone will receive 2 injections, approximately 3 weeks apart. On the days you receive the injection, you will be asked to wait at the study site for at least 30 minutes for observation.

Study Vaccines – After your baby is born

When you come for your visit about 1-month **after** your baby is born you will be told if you were given the investigational COVID-19 vaccine (BNT162b2 30 micrograms) or placebo injection while you are pregnant.

If you were given the investigational COVID-19 while you are pregnant you will not need any further injections in the study.

If you were given the placebo injection while you are pregnant you will be given your first dose of investigational COVID-19 vaccine as an injection into the muscle in your upper arm at this visit. You will be given your second injection of investigational COVID-19 vaccine about 3 weeks later. In this part of the study you and your study doctor **will know** that you are getting the investigational COVID-19 vaccine.

Overview of Study Procedures and Assessments

The tables below show the tests and procedures or assessments that you and your baby will have done in this research study. In addition to the visits listed, your study doctor may ask you to come in for extra visit(s) if necessary, to protect your well-being or if you or your baby have any COVID-19 like symptoms.

If you were given the COVID-19 investigational vaccine while pregnant you will need to attend a follow-up visit about 6 months after delivery in order to give a blood sample and provide information about your health, including HIV status (if applicable).

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Summary of Planned Study Visits and Procedures for EVERY Woman Taking Part

	Before your baby is born					After your baby is born	
Visit Description and Visit Timing	**Study Vaccine 1**	**Study Vaccine 2**	**2-Week Visit**	**1-Month Visit**	**Delivery**	**1-Week After Delivery (phone call)**	**1-Month After Delivery**
Review and sign informed consent document	✓						
Questions about your health	✓	✓	✓	✓	✓	✓	✓
Questions if you smoke or drink alcohol	✓						
Phase 3 only: For participants who are HIV-positive, record latest CD4 count and HIV viral load	✓		✓	✓	✓		✓
Take a swab from your nose	✓	✓					
Blood samples for antibody testing (~20 mL per blood sample)	✓ before the study injection	✓ Only if you are one of the first 200 women to take part	✓	✓	✓		
Oral temperature, blood pressure, and heart rate	✓	✓		✓			
Physical examination	✓	✓		✓			
Measure your height, weight and do an ultrasound	✓						
Obstetric examination (external only)	✓	✓		✓			
Study injection	✓	✓					
E-diary training	✓						
Give you an e-diary or help you download one	✓						
Vaccination e-diary completion for 7 days after each vaccination	✓	✓					
COVID-19 illness e-diary completion	✓	✓	✓	✓	✓	✓	✓
Discuss any vaccinations, medications or treatments you may be taking	✓	✓	✓	✓	✓	✓	✓
Tell you which vaccine you had							✓

NOTE:

If you were given the COVID-19 investigational vaccine while pregnant you will need to attend a follow-up visit about 6 months after delivery to give a blood sample and provide information about your health, including HIV status (if applicable). You will need to still fill out the illness diary.

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Summary of Additional Planned Study Visits and Procedures for Women who had placebo injection while pregnant

Visit Description and Visit Timing	First COVID-19 injection visit About 1 month after baby was born	Second COVID-19 injection visit About 3 weeks after the first COVID-19 injection visit	1-Month follow up Phone call About 1 month after the second COVID-19 injection visit
Tell you that you had placebo injection while pregnant	✔		
Questions about your health	✔	✔	✔
Phase 3 only: For participants who are HIV-positive, record latest CD4 count and HIV viral load	✔		✔
Take a swab from your nose	✔	✔	
Blood samples for antibody testing (~20 mL per blood sample)	✔		
Make sure you are ok to have the investigational COVID-19 injection	✔	✔	
Investigational COVID-19 injection	✔	✔	
Discuss any vaccinations, medications or treatments you may be taking	✔	✔	✔

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Summary of Planned Study Visits and Procedures for Your Baby

	Birth	1-Week Follow-up Phone call	6-Month Follow-up
Questions about your baby's health	✓	✓	✓
Collect information about feeding your baby		✓	✓
Cord blood collection for antibody assessment, or blood sample from baby if cord sample not available	✓		
Blood Sample (~5ml or 1 teaspoon of blood)			✓
Temperature, heart rate, oxygen saturation level and respiratory rate	✓		
Physical examination	✓		
Discuss any medications, treatments, or vaccinations	✓	✓	✓

Please note that if your baby's visit 1 assessments are not all completed on the day of your baby's birth, they should be done within 7 days.

Your blood samples for antibody testing

You will have to give a blood sample at most clinic visits. The exact number will depend if you are among the first 200 women who take part, if you are given the placebo injection when you are pregnant, and when you give birth. It is expected that most women will have to give between 5 or 6 blood samples. You will also need to give an extra blood sample each time you become ill with COVID-19 like symptoms.

Each blood sample will be about 20mL (about 4 teaspoons) and will be collected from your arm using a needle.

Your blood samples will be used to test if you already had antibodies against the coronavirus that causes COVID-19 when you enrolled in the study and may be used to test your antibody levels after vaccination, or after a COVID-19 like illness.

Your Baby's Blood samples for antibody testing

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The study team will collect about 10mL of blood (about 2 teaspoons) blood sample from your baby's cord at the time of delivery. If the study team are not able to collect a blood sample from your baby's cord at the time of delivery it is possible that your baby may have to give a blood sample that will be collected using a needle. If this happens the study team will weigh your baby and work out the amount of blood that they will collect. For a 3kg (7lb) baby a 2ml (half teaspoon) blood sample would be collected.

Your baby will have blood taken when they are 6 months old. This will be used to test if your baby has antibodies against the coronavirus that causes COVID-19. About 5mL of blood (about 1 teaspoon) will be collected from your baby using a needle.

Your baby may also need to give an extra blood sample each time he/she becomes ill with COVID-19 like symptoms. The study team will weigh your baby and work out the amount of blood that they will collect. Each blood sample will be collected using a needle and will be up to 5mL (up to about 1 teaspoon) depending on how much your baby weighs.

E-Diary

At Visit 1, the study team will explain what you need to do and show you how to fill in an electronic diary (or e-Diary). We will either give you a device (a bit like a mobile phone) or ask you to download an application ('app') to your smart phone if you have one. The device/app is secure, and your confidentiality will be maintained.

The e-Diary includes a **COVID-19 illness part** and a **vaccination part**.

You will need to complete the COVID-19 illness e-Diary once a week for the whole time you are in the study to say if you have any COVID-19 symptoms or not. You will also need to fill out the COVID-19 illness e-Diary if you have COVID-19 symptoms (the symptoms are listed in a later section of this document). Once your baby is born you will also need to say if your baby has any COVID-19 symptoms or not.

You may receive text messages to the device or your own smartphone, or emails (if you provide your email address) to remind you to complete the COVID-19 illness part of the e-Diary.

You will also need to complete the vaccination part of the e-Diary every evening for 7 days after both injections that you are given when you are pregnant. You will start on

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the evening of your injection and then complete the diary for 6 more days (7 days in total).

You will be given a thermometer and a measuring device to take home. You will use the thermometer to measure your temperature under your tongue and you will use the measuring device to measure any redness or swelling where the injection was given. You will need to record these measurements in the vaccination part of the e-Diary.

The vaccination part of the e-Diary will also ask other questions about potential side effects that you may have after your injection. If you have any severe symptoms after your injection, any redness or swelling that is bigger than 20 on the measuring device, or a temperature of 39.0°C or higher you must contact your study doctor and the study doctor or nurse may schedule an extra visit. It is very important that you complete the e-Diary every evening as instructed. If you do not, your study doctor or nurse may contact you to check how you are.

If You Get COVID-19 Symptoms

If you get any of the following, at any time while you are in the study, you must contact the study doctor straight away.

Note that this is not instead of your routine medical care. If you feel unwell enough that you would normally see a healthcare professional, please contact your usual provider, as well as the study doctor.

- **A diagnosis of COVID-19;**
- **Fever;**
- **New or increased cough;**
- **New or increased shortness of breath;**
- **Chills;**
- **New or increased muscle pain;**
- **New loss of taste/smell;**
- **Sore throat;**
- **Diarrhea;**
- **Vomiting.**

If you have any of these symptoms the study team will ask you to have a telephone conversation, video call or have an in-person visit to talk about how you are feeling and if you have needed any other medical care.

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If you have an in-person visit the site staff will take a swab from your nose, if you have a telephone or video call you will need to take a swab from your nose. The swab is to check for the coronavirus.

The study doctor will arrange an extra visit to the study site about a month after you became unwell and you will need to give a 20 mL (about 4 teaspoons) blood sample to test your antibody levels.

We will give you separate instructions about how to take a nose swab and how to ship the swab to the laboratory if needed. The result from this swab will be provided to the study doctor once it is available, but this will take some time, and cannot be used to diagnose if you have COVID-19. This is why it is important that you contact your usual provider if you have COVID-19 symptoms and think you need medical care.

If you are diagnosed with COVID-19, for the purposes of the study, the study doctor will contact your usual provider, and any facility where you are treated, to obtain details and collect medical records: **by signing this informed consent document, you agree to this**.

What happens if I have a positive nose swab test result?

Nose swabs at Visits 1 and 2, and at the time of a possible COVID-19 illness will be tested in a research laboratory.

Results from the Visit 1 and 2 swabs, and all results from the illness visit swabs, will be provided to your study doctor. This will take some time so you should not rely on these results for medical treatment.

If you have any potential COVID-19 symptoms with a positive nose swab test result before Visit 2, you will be given the second study injection as planned. At the visit 1 month after you give birth the study team will tell you if you had the placebo injection or the COVID-19 investigational vaccine. If you were given the placebo injection and had a positive nose swab test between Visit 1 and Visit 2 you WILL still be allowed to have the COVID-19 injection.

If you have positive nose swab test before Visit 2 but no potential COVID-19 related symptoms, you will be given the second study injection as planned.

If Your Baby Gets COVID-19 Symptoms

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The site staff will give you a list of symptoms and if your baby gets anything on that list at any time while your baby is in the study, you must contact the study doctor straight away.

Note that this is not instead of your baby's routine medical care. Please contact your usual provider, as well as the study doctor if you think your baby needs medical care.

If your baby has of the symptoms the study team will ask you to have a telephone conversation, video call or have an in-person visit to talk about your baby and see if he/she has needed any other medical care.

If your baby has an in-person visit the site staff will take a swab from baby's nose, if you have a telephone or video call you will need to take a swab from your baby's nose. The swab is to check for the coronavirus.

The study doctor will arrange an extra visit to the study site about a month after your baby became unwell and your baby will need to give a blood sample to test their antibody levels. The exact amount of blood will depend on how much your baby weighs, but it would not be more than 5mL (1 teaspoon full).

We will give you separate instructions about how to take a nose swab from your baby and how to ship the swab to the laboratory if needed. The result from this swab will be provided to the study doctor once it is available, but this will take some time, and cannot be used to diagnose if your baby had COVID-19. This is why it is important that you contact your usual provider if your baby has COVID-19 symptoms and think he/she may need medical care.

Leaving the Study Early

You, or your baby, may withdraw from the study at any time at your own request, or you/your baby may be withdrawn at any time at the discretion of the investigator for safety, behavioral, compliance, or administrative reasons. If you decide to leave the study, you will be asked why you would like to withdraw.

After the study [Country authors: *please edit section as necessary per health authority study vaccine status***]**

The study vaccine is available only during this study and not after the study is over.

7. Are there any special instructions to follow for this study?

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It is important you follow all the instructions given to you by the study nurse or doctor and tell them if:

- You don't understand anything about the study
- You are not able to comply with the study requirements
- There are changes in your or your baby's health
- Your e-diary device or APP is not working properly
- You or your baby take any new medications or receive any other vaccines
- You are going away for a long period
- You are going to move to a new house
- You wish to take part in another research study
- You previously took part in this study, have been in any other study in the past 28 days, or are currently involved in any other study.

It is important that you:

- Call the study doctor or study staff if you or your baby have any COVID-19 symptoms, even if they are mild
- Call the study doctor or study staff if you have a large reaction (redness/swelling) at the injection site, or any severe reaction or temperature of 39°C or higher after the injection you are given while you are pregnant
- Follow the instructions you are given by the study doctor and study team
- Do not take part in any other study without approval from the study doctor as taking part in more than one study at the same time could put you or your baby's safety at risk
- Take part in the study only at this location. Participating in this study at more than one study site could put your/your baby's safety at risk
- Tell other doctors, nurses, and health care providers about your/your baby's participation in this study by showing the information card provided to you by the study team.

8. What are the possible risks and discomforts of this study?

Any research has some risks, which may include negative effects that could make you unwell or uncomfortable and even potentially be serious or life-threatening. All research participants taking part in the study will be watched carefully for any negative effects; however, the study team does not know all the effects that the study vaccine may have on you or your unborn baby.

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If you take part in this study, the most likely risks or discomforts to happen to you are discussed below.

It is important that you report to the study team all symptoms and side effects as soon as they occur. Phone numbers for the study team are listed in [Section 1] of this consent document.

Study Vaccine Risks

Up until September 2021, the safety of BNT162b2 has been studied in clinical trials that have included more than 49,000 people aged over 12 years who have received at least one dose of the vaccine. Additionally, the safety of BNT162b2 has been studied in clinical trials including about 3100 children (ages 5 to <12 years) who have received at least one dose of the vaccine. Since the vaccine has been approved for emergency use or received a full or conditional marketing authorization in many countries across the world, by the end of September 2021 about 1.7 billion doses have been distributed and it is estimated that around 80% of those (around 1.3 billion doses) have been administered.

Based on the clinical trial results, and information gathered during general use, the following risks have been determined to be caused by the BNT162b2 vaccine:

Very common (occurring in more than 1 in 10 people): injection site pain, injection site swelling, fatigue (tiredness), increased body temperature (fever, more common after the second dose), chills, headache, diarrhea, joint aches and muscle aches.

Common (between 1 in 10 and 1 in 100 people): feeling sick (nausea), being sick (vomiting), and injection site redness.

Uncommon (between 1 in 100 and 1 in 1,000 people): enlarged lymph glands, allergic reactions (symptoms may include rash, itching [not reported in adolescents], hives), decreased appetite (not reported in adolescents), lethargy (not reported in children or adolescents), sweating and night sweats (not reported in children or adolescents), pain in arm, and feeling weak (not reported in children or adolescents) or unwell.

Rare (between 1 in 1,000 and 1 in 10,000 people): swelling of the face or lips (not reported in children or adolescents).

Frequency that cannot be estimated from available data: severe allergic reaction (anaphylaxis).

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The safety of an additional (third, booster) dose of BNT162b2 has also been studied in 306 people aged 18-55 years and the following risk (more frequent than listed above) has been determined to be caused by BNT162b2 vaccine following an additional third dose:

Common (between 1 in 10 and 1 in 100 people): enlarged lymph glands.

It was also determined that following an additional (third, booster) dose of BNT162b2 the following risks were not reported:

Hives, itching, lethargy, sweating and night sweats, feeling weak or unwell, swelling of the face or lips.

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received BNT162b2. Cases have mainly been reported in males under 30 years of age and following the second vaccination, however, there have been some cases reported in older males and females as well as following the first vaccination. The chance of having this occur is very low and in most of these people, symptoms began within a few days to a week following vaccination. As a precaution, you should seek medical attention right away if you have any of the following symptoms after receiving the vaccine:

- Chest pain
- Shortness of breath
- Feelings of having a fast-beating, fluttering, or pounding heart

Please also notify study staff, when appropriate, if you have any of these symptoms as you may be required to visit the study site for further assessments.

Whilst some severe cases have been reported, most cases have been associated with full resolution of symptoms in the short term, however, long-term follow-up is limited. It is not known whether the risk of myocarditis or pericarditis is increased following additional doses of the vaccine, e.g. following a booster dose.

If you have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart) previously, please tell your study doctor.

As in all research studies, the investigational COVID-19 vaccine may involve risks that might be expected based on results from studies of similar vaccines, as well as risks that are currently unknown.

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Therefore, it is important that you report all symptoms and side effects that you experience as soon as they occur, whether or not you think they are caused by the study vaccine.

Due to the way in which the study vaccines are made, they cannot cause COVID-19 disease.

If I catch COVID-19 disease, could the vaccine make it worse?
For some other vaccines tested in animals against similar viruses (but not the coronavirus that causes COVID-19), there have been reports of the illness being more severe in the animals that received the vaccine than in those that did not. So far this has not been seen with BNT162b2. It remains important for you to contact your study doctor if you develop symptoms that might be caused by COVID-19 (for example, fever, cough, shortness of breath).

Placebo Risks

As the placebo injection contains salt-water and no active ingredients, the chances of having the side effects mentioned above are less likely. In other studies, using the same placebo injection, some people who received the placebo injection reported pain, bruising, swelling and redness at the site of injection.

Risks from Study Procedures

Risks and possible discomforts you, or your baby, might have from the study procedures include:

- **Blood samples:** The risks and possible discomforts involved in taking blood include pain from inserting the needle, or less often, swelling, bruising, or infection around the vein where the blood is collected. You may feel dizzy or may faint. If you have a previous history of feeling dizzy or fainting during blood sample collection, you should talk to the study doctor.
- **Nose Swabs:** The risks and possible discomforts involved in taking nose swabs may include pain or general discomfort. Sometimes it may cause the nose to bleed.

What will happen to our blood and nose swab samples?

Your, and your baby's blood and nose swab samples will be used only for scientific research. Each sample will be labeled with a code so that the laboratory workers testing the samples will not know who you or your baby are. Some of the samples may be stored for future testing and may be kept for up to 15 years after the study ends, at

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which time they will be destroyed. In addition to testing for this study, any samples left over after the study is complete may be used for additional research related to the development of products. No testing of your, or your baby's DNA will be performed.

You may request that your, or your baby's, samples, if they can be identified, be destroyed at any time. Any data already collected from those samples will still be used for the study. The samples will remain the property of BioNTech/Pfizer and may be shared with other researchers as long as confidentiality is maintained and no testing of your, or your baby's, DNA will be performed. You will not be told of additional tests, nor will you receive results of any of these tests.

9. What are possible benefits of this study?

Vaccination with this investigational vaccine has been shown to be effective in preventing COVID-19 in the groups of people already studied, but not yet in pregnant women. Because of this, and the fact that you may receive the placebo injection, you still need to follow local recommendations about how to avoid COVID-19 (for example, social distancing and mask use).

10. What other choices do I have if my baby and I do not join this study?

This study is for research purposes only. Your alternative is to not take part in this study

11. What happens if my baby and I are injured during this study?

For mandatory research injury language, <**click here**> (retain this link in the study-level ICD). The country-specific research injury language must be included verbatim in the country-level ICD.

12. What if I join this study and then change my mind?

If you agree that you and your unborn baby will take part and then change your mind for any reason, you are free to stop at any time. Your decision will not affect your, or your baby's regular medical care or any benefits to which you or your baby are entitled. Tell the study doctor if you are thinking about stopping or decide to stop so that you can end participation in the study in the safest way.

While you are taking part, the study team will tell you in a timely manner if new information is learned during the study that could change your mind about continuing in this study. If you decide to withdraw from the study, or if you decide that you will withdraw your baby from the study you may be asked to continue to participate in the study procedures even though you would no longer receive the study vaccine.

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If you/your baby agree to continue with the study, information about your and your baby's health will continue to be collected as described in [Section 6].

If you decide that you, or your baby, will stop participating in this study, you must notify the study doctor. The study team will explain what other procedures or discussions would occur.

Sometimes the study doctor or BioNTech/Pfizer may decide to take you, or your baby, out of the study (even if you do not agree) if:

- You are unable or unwilling to follow the instructions of the study team;
- The study doctor decides that the study is not in your, or your baby's, best interest or that you/your baby are no longer eligible to participate; or
- The study is stopped by BioNTech/Pfizer, the institutional review board (IRB) or independent ethics committee (IEC) (a group of people who review the study to protect your rights), or by a government or regulatory agency.

The study team will give you a Privacy Supplement, which is considered part of this consent document. It describes what happens to your and your baby's personal information (including your biological samples) and how it may be used if you, or your baby, withdraw from the study.

13. What will I have to pay for taking part in this study?

You, or your baby will not need to pay for any of the study vaccines (investigational COVID-19 Vaccine or placebo injection), study-related procedures, or study visits.

14. Will I be paid for taking part in this study?

You will not receive any payment for taking part in this study. However, for each visit you/ your baby complete, you will be reimbursed by the study site to cover reasonable expenses (for example, parking, meals, travel) that you have as a result of taking part in this study.

You will be reimbursed $XX.XX by the research site for each visit you complete to cover your out-of-pocket expenses related to this study, such as travel and parking. In addition, you will be reimbursed $XX.XX by the research site for each visit completed for your baby, also to cover out-of-pocket expenses related to this study.

BioNTech/Pfizer may use information resulting from the study to develop products or processes from which they may make a profit. There are no plans to pay you or provide you with any products developed from this research. BioNTech/Pfizer will own all products or processes that are developed using information from the study.

15. What will happen to my baby or my personal information?

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<**Click here**> for language to be inserted into this section. This text must be inserted verbatim. Any requested changes must be approved by Clinical Development Legal. Note that the Privacy Supplement follows this consent document, after the signature section.

16. Where can I find additional information about this study or the study results?

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

The study results, when available, may also be found on www.pfizer.com and https://www.clinicaltrialsregister.eu/.

In addition, a plain summary of the study results will be made available in the EU database at [insert link to the database]. This information will be provided no matter what the study's outcome. To the extent possible, you will be able to access these summaries in the EU database soon after they become available using the following EU trial number for the study: [insert trial number].

These Web sites are in English only. If you need assistance understanding these Web sites, please ask a member of the study team.

BioNTech/Pfizer will provide the study doctor with information about the study results when all participants have completed the study. At that time, certain of your individual study results may be given to you or your doctor (if different from the study doctor) in accordance with applicable law, but will not be given to your family, your employer or any insurance company.

If any exploratory research is done, it may not be possible to link any results from that exploratory research to specific individuals, including you or your baby. BioNTech/Pfizer does not plan to return information from any exploratory research to you, the study doctor, or your doctor (if different from the study doctor).

17. Signatures

The column for subject initials in the table below may be removed if not required by the IRB/IEC, regulatory agencies, and/or other similar reviewers.

Agreement to Participate and to Process Data **1.1.1. MATERNAL AND INFANT PARTICIPANTS**	Participant Initials
1. I confirm I have read (or, if I cannot read, a study team member has read to me) and understand this consent document for the study described above and have had the opportunity to ask questions. I have had enough time to review this consent document. I also have had an opportunity to ask about the details of the study and to	

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decide whether or not to participate.	
2. I have read and understand the Privacy Supplement. I understand that taking part in the study will require the processing (including collection, use, transfer, storage, analysis and reporting) of my/my baby's personal information, as explained in the Privacy Supplement. I understand and agree to the processing of my/my baby's personal information within and outside my/my baby's country of residence for health care, medical research and/or regulatory purposes.	
3. I understand that taking part is voluntary and that I, or my baby, am free to stop taking part in this study or to withdraw my consent to the processing of my/my baby's personal information at any time. I do not need to give any reason and my/my baby's regular medical care and legal rights will not be affected. However, even if I withdraw my consent to processing, my/my baby's personal information held at that time may be kept to comply with laws and regulations and to maintain the integrity of the study. I also understand that my/my baby's biological samples may not be able to be destroyed because they may no longer be traceable to my/my baby's, may have already been used, or may have been given to a third party.	
4. I agree to the study team accessing my/my baby's medical history, including information from medical records and test results and any medical treatment I/my baby receive during the course of the study, and if necessary, contacting my/my baby's doctor or any other health care providers treating my/my baby's for access to such information.	
5. I understand that the Sponsor and/or others working with or on behalf of the Sponsor, institutional review boards (IRBs) or independent ethics committees (IECs), and regulatory agencies may need access to personal information about my/my baby's generated at the study site or collected by the study team for the study and any other research. I agree that they may have access to my/my baby's personal information.	
6. I do not give up any of my/my baby's legal rights by signing this consent document. I have been told that I will receive a signed and dated copy of this document.	
7. I agree that my baby and I will take part in the study described in this document.	

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_____
Printed name of participant

_____ _____
Signature of participant Date of signature§
(If no legally acceptable representative is used)

§Participant must personally date their signature.

Person Obtaining Consent:

_____
Printed Name of the Person Conducting the
Consent Discussion

_____ _____
Signature of the Person Conducting the Date of signature

Consent Discussion †

†The investigator, or an appropriately qualified and trained person designated by the investigator to conduct the informed consent process, must sign and date the consent document during the same discussion when the participant signs the consent document.

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PRIVACY SUPPLEMENT

For mandatory country-specific data privacy language to be inserted in this Privacy Supplement, <**click here**> (retain this link in the study-level ICD). The country-specific data privacy language must be included verbatim in the country-level ICD. Any requested changes must be approved by Clinical Development Legal.

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IRB Approved at the
Protocol Level
Feb 11, 2021

[redacted]

Participant Guide to Using the [redacted] App for Vaccination and COVID-19 Illness Diary

Pfizer

C4591015

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[redacted] App

Thank you for participating in the **C4591015** study.

This clinical study uses the [redacted] App to record important information during the study. The [redacted] App will be used on your personal device or on a provisioned device supplied by the site. This booklet explains how to use the [redacted] App on either device type.

Please note that pictures within this guide will not always appear exactly the same way on your personal device, as every device has different display settings.

Important: The [redacted] App whether on your personal or provisioned device is to gather information to advance science and medicine during this research study and does not replace your regular medical care. For urgent issues, please contact your study clinic staff on the contact number provided.

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App Guidelines

Please follow these points when using the [redacted] App for this clinical study.

1. Always keep your device **charged**.
2. Always download any updates to the [redacted] App.
3. Do **not** share your PIN code.
4. After entering your diary responses, please ensure they are sent by tapping the 'Save' button.
5. Your device will need a mobile network or Wi-Fi connection to send data. If your device is not connected to a mobile network or Wi-Fi connection, your data will automatically send once your device is connected again.
6. After entering your diary responses, please ensure they are sent by tapping the 'Save' button.

If you have installed the [redacted] App on your personal device, additional guidelines.

7. If prompted when installing or using the [redacted] App, always accept permissions for the [redacted] App to sync with your device's calendar. This will allow the reminder notifications for your diary to display.
8. Do not delete the [redacted] App unless instructed by the study clinic staff.
    - If you accidentally delete the [redacted] App or are planning to change your device, please call the helpdesk [redacted] as soon as possible.

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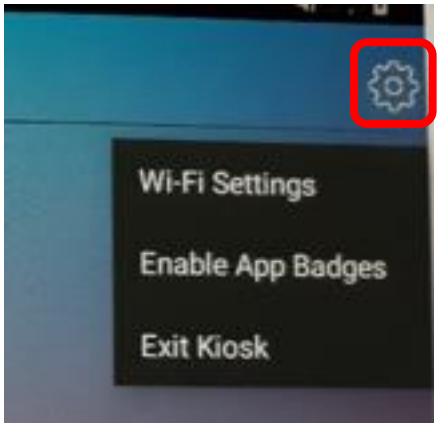
Setting up WiFi on a provisioned device

If you are using a device provided to you for the study, you can configure a WiFi connection by pressing the 'Gear/Setting' symbol in the top right-hand corner of the screen.



Gear/Setting symbol

Select 'Wi-Fi Settings'. Select the appropriate network and enter the password if required. Once the connection is authenticated, the Wi-Fi will connect. Once you return to the Home screen, the [redacted] App will automatically open.

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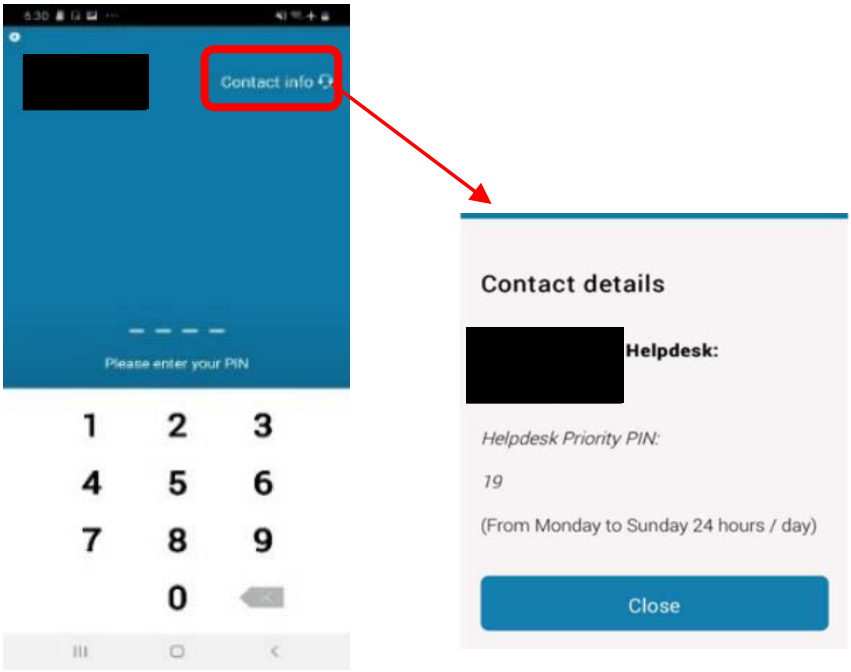
Using the [redacted] App

This Quick Reference Guide will walk you through various functions of the [redacted] App.

For any technical Issues with the [redacted] App, the helpdesk contact Information is displayed on the log-in screen of the [redacted] App.

Select ‘Contact info’ to view the helpdesk contact information



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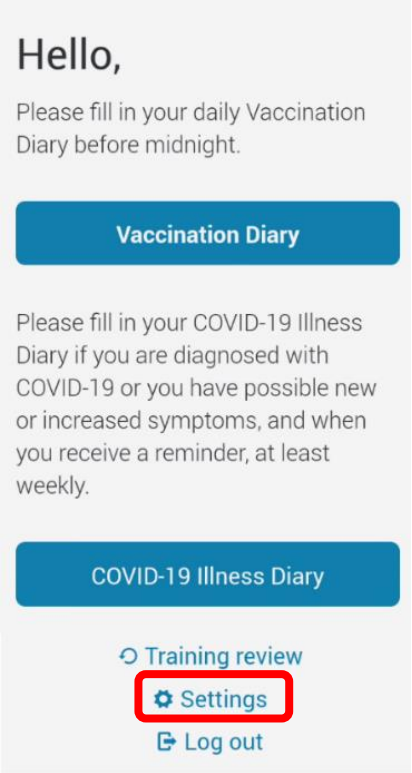
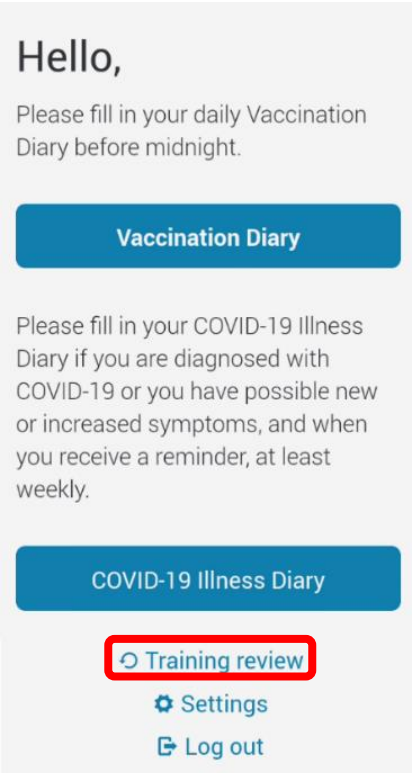


Once the Settings button is selected, you will be able to update your diary reminder notifications.



Training on how-to use the [redacted] App including a practice session. The practice session will allow you to practice using the different types of buttons and functions that will be available in the diary.

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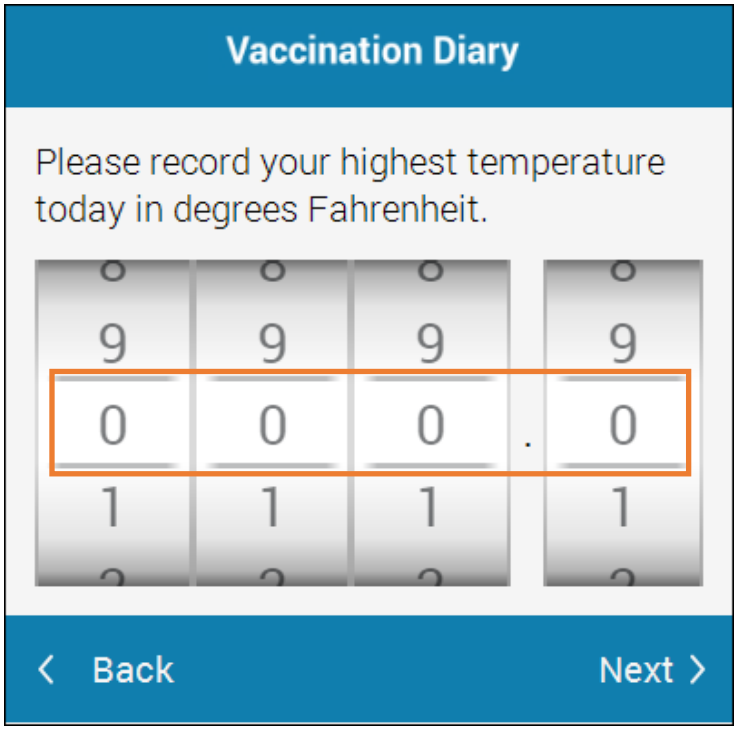
Types of Questions

The following provide examples of the screens in the study questionnaires on [redacted] App and how to use them.

Number Spinner Questions:

- To answer, scroll down or up on each column of numbers until you reach your desired answer.
- Tap your chosen numbers so that they appear within the orange lines.
- When you are ready to move to the next set of question, press ‘Next’.
- To go to the previous page, press ‘Back’ to review or modify your answer



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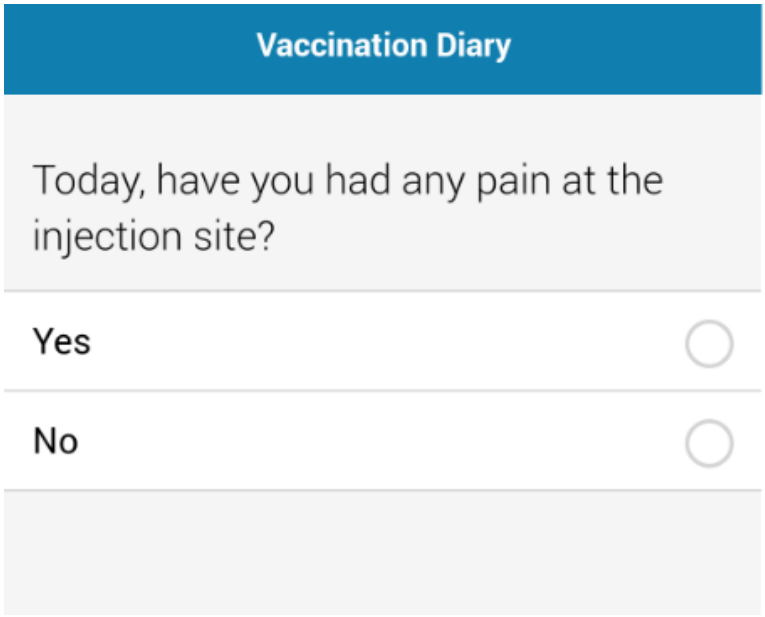
Multiple Choice Questions:

- Select the response that best describes your answer to each question, a black dot will appear in the circular button.
- When you are ready to move to the next set of questions, press ‘Next’.
- To go to the previous page, press ‘Back’ to review or modify your answer



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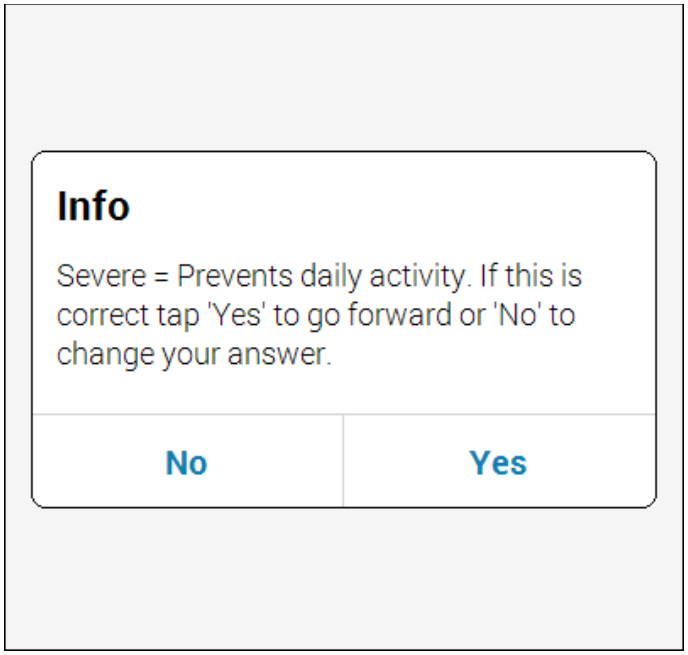
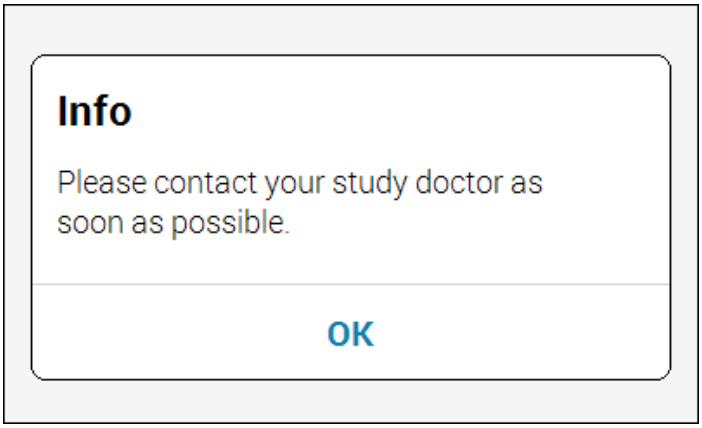
Information Pop-ups

These pop-ups display important information, such as confirming the severity of a symptom, confirming a temperature you have entered or, to contact your study doctor.





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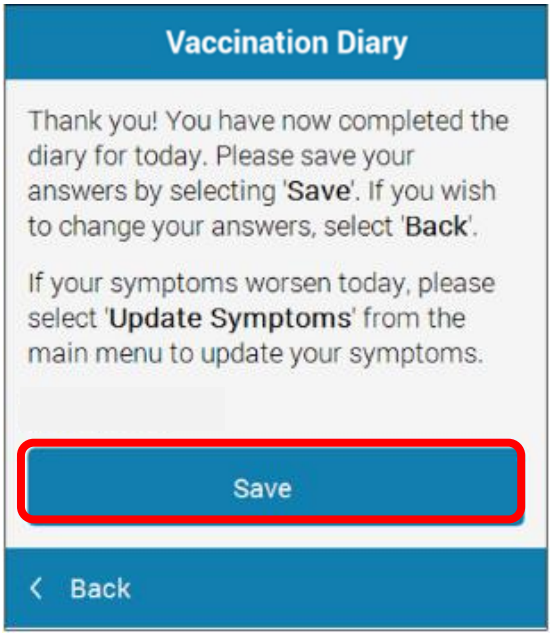
Saving Diary Data



For all entries in the [redacted] App:

- ensure you have completed all data requested.
- tap the 'Save' button.

Please note: If your device is left idle for longer than 10 minutes, your session will time out. You will be logged out of the [redacted] App and any unsaved responses will be lost.

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Traveling and Changing Time Zones with [redacted] App

Always take your personal or provisioned device with you when traveling in order to complete the [redacted] App away from home.

If traveling via airplane, turn off your device during the flight to avoid any interference.

If you are using a device provided by the site:

- The date and time will update automatically to the new time zone when you turn the device on.

If you are using your own device:

- Make sure your settings allow for automatic update of date and time.

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Sending Data

The [redacted] App sends data automatically each time you login or save a diary entry, provided the device is connected to a mobile network or Wi-Fi network.

The [redacted] App can be used offline temporarily; however, remember to log into the [redacted] App when the device is connected to a mobile network or Wi-Fi network as soon as possible to allow data sending to occur.

REMINDER - Keep your device charged

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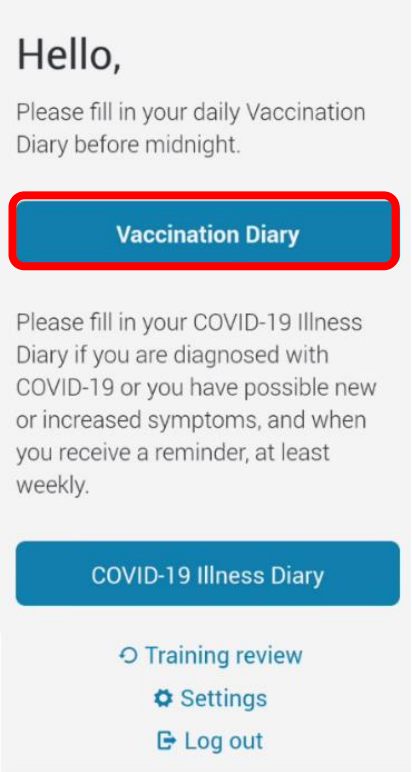
Vaccination Diary

Please note if you are using your own device, allow the [redacted] App to synchronise with your calendar in order to see notifications appropriately.



You should complete the Vaccination Diary every evening for a period of 7 days following vaccination, starting on the day you had your vaccination.

IMPORTANT: Please complete the diary every day between 06:00 PM and 11:59 PM. Answer all questions in one sitting.

Diary Entries started prior to midnight will be allowed to continue through to completion as long as you do not log out of the device.

Diary Entries started prior to midnight and saved after midnight will be counted for the day the questionnaire was started. If device is left for more than 10 minutes, the [redacted] App automatically will lock you out.

Example: Started diary 11:50 PM on 01 Jun 2020 and saved at 12:01 AM on 02 Jun 2020, will count for 01 Jun 2020.

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It’s important that you complete the “Vaccination Diary” as requested, because you can’t go back after midnight to fill in any missed entries.

Notifications are set up to help you remember to complete your diary. Site staff will set the notification alert time when they set-up your [redacted] App activation code. You can change the alert time as needed in the ‘Settings’ button.

Once you’ve selected the ‘Vaccination Diary’ button you will be able to record symptoms, their severity and if those symptoms resulted in a hospitalization/emergency room visit.

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General instructions

The study clinic staff will give you a digital thermometer and show you how to use it to measure your temperature under your tongue. Follow these instructions for all temperature measurements you record in the [redacted] App.

NOTE: The provisioned thermometer measures temperature in degrees Fahrenheit (°F). All entries made into the diary should be recorded in degrees Fahrenheit.

- You can record the temperature displayed on the thermometer into the [redacted] App.
- You can keep this thermometer at the end of the study.

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Thermometer use

How to take care of the thermometer:

- The thermometer is waterproof.
- To disinfect, you can put it completely in water or wipe it with a tissue dipped in a mild disinfectant.
- Do not put the thermometer in hot water or household bleach products.
- Do not leave the thermometer in direct sunlight or let it fall or be hit, as this could damage it.
- Do not try to open the thermometer.
- Please refer to the instructions in the thermometer box if you need further instructions for use, care, and maintenance instructions.

If you have any problems with measuring your temperature, if thermometer stops working, or if you lose or break the thermometer, please call the study doctor or study clinic staff.

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Instructions for taking and entering your temperature after study vaccination

- On the day you had your vaccination and for 6 more days (7 days in total), you will measure your temperature (under your tongue) every evening, and at any time you feel feverish.
- Enter your measured temperature in the [redacted] App between 6:00PM and 11:59PM.
- If your temperature is 102°F or higher, please call the study doctor or nurse to schedule an extra appointment so that they can assess the temperature.
- If you have a fever or a temperature of 102°F or higher on the last day you complete the [redacted] App (day 7), keep measuring your temperature daily until the temperature is below 102°F for at least one day. Make a note of the date and temperature as you will need to give this information to the study doctor or nurse.
- It is also important to let your study doctor or nurse know whether you have been hospitalised/or went to the ER for any of the ongoing symptoms.

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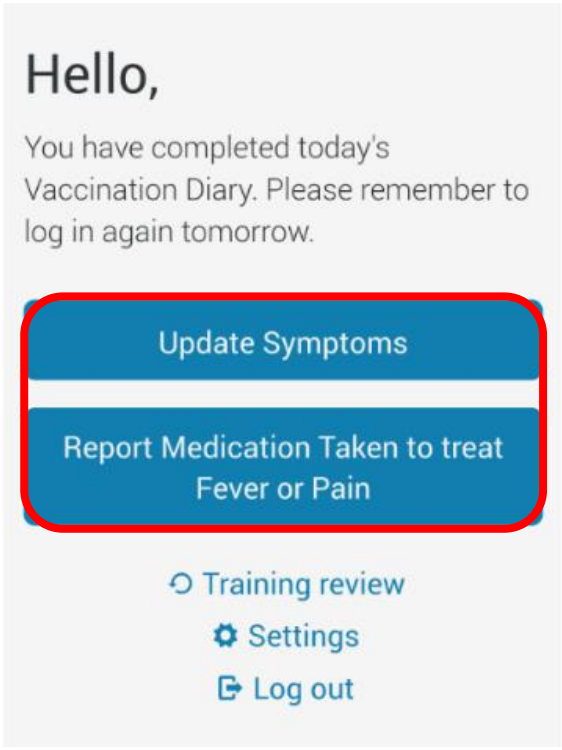
Updating symptoms and medication responses



If your temperature increases or symptoms worsen after the vaccination diary is completed for the day, please select 'Update Symptoms' from the main menu to record the increased temperature or worsened severity.

If you have taken medication to treat fever or pain since the vaccination, report this by selecting the 'Report Medication Taken to treat Fever or Pain' button.

These details can be updated until 11:59pm.

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Instructions for measuring any redness or swelling at the injection site:

Please note, that for any questions regarding the use of the measuring device you should contact your study clinic staff and not the [redacted] Helpdesk.

- On the day you had your vaccination and for 6 more days (7 days in total), you will need to examine the arm where you were given the injection (injection site) to see if there is any redness or swelling.
- Record this information in the [redacted] App each day between 6:00PM and 11:59PM.
- If you have any redness or swelling at the injection site on your arm, use the measuring device provided to measure the biggest part of the redness and/or swelling as shown by the study clinic staff.

For example:

Measure this Distance

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- The measuring device can be adjusted by sliding the two measuring pointers so that they are closer or further away from each other.
- Once the measuring device is the correct size to measure the biggest part of the redness/swelling, the size is displayed as a number. The number the arrow is pointing to in the window is the number that should be recorded in the [redacted] App.
- If the size is between two numbers, record the larger number in the [redacted] App.
  - For example, if the measurement is between 4 and 5, then 5 should be recorded in the [redacted] App.
- If the size of the redness or swelling is bigger than 21, then 21 should be recorded in the [redacted] App. Please call the study doctor or study clinic staff to discuss or schedule an extra appointment so that they can take a look at the redness/swelling.
  - Note: A pop-up in the [redacted] App will remind you to contact the study doctor if you have reported a value of 21.
- If the redness or swelling at the injection site is ongoing on the last day you complete the [redacted] App (Day 7), you will need to make a note of the date that this resolved. Give this information to the study doctor or study clinic staff.

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Instructions for assessing any pain at the injection site:

- On the day you had your vaccination and for 6 more days (7 days in total), you will need to examine the arm where you were given the injection (injection site) to see if there is any pain at the injection site.
- Information must be recorded in the [redacted] App each day between 6:00PM and 11:59PM.
- If you have pain at the injection site, you will need to assess if the pain was mild, moderate or severe, and record this information in the [redacted] App.
- Definitions of mild, moderate and severe pain will be displayed to you before this symptom is recorded.
- If the pain at the injection site is severe, please notify the study doctor or study clinic staff to discuss or schedule an extra appointment so that they can assess the pain at the injection site.
    - Note: A pop-up in the [redacted] App will remind you to contact the study doctor if you have reported a severe symptom.
- If the pain at the injection site is ongoing on the last day you complete the [redacted] App (Day 7), you will need to make a note of the date that this resolved. Give this information to the study doctor or study clinic staff.

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Instructions for assessing any fatigue (tiredness), headache, vomiting, diarrhea, chills, new and worsened muscle pain, new or worsened joint pain:

- On the day you had your study vaccination and for 6 more days (7 days in total), you will be asked whether you had experienced fatigue (tiredness), headache, vomiting, diarrhea, chills, new or worsened muscle pain and new or worsened joint pain since vaccination. This information must be recorded in the [redacted] App each day between 6:00PM and 11:59PM.
- If you experience any of these symptoms you will need to assess if they were mild, moderate or severe, and record this information in the [redacted] App.
- Definitions of mild, moderate and severe symptoms will be displayed to you before this is recorded.

- If a symptom you are experiencing is severe, please call the study doctor or study clinic staff to schedule an extra appointment so that they can investigate.
  - Note: A pop-up in the [redacted] App will remind you to contact the study doctor if you have reported a severe symptom.

- If you have symptom(s) that continue past the last day you completed the [redacted] App (Day 7), you will need to tell the study doctor or study clinic staff the date that the symptom(s) stopped. Please make a note of the date your symptoms stopped.

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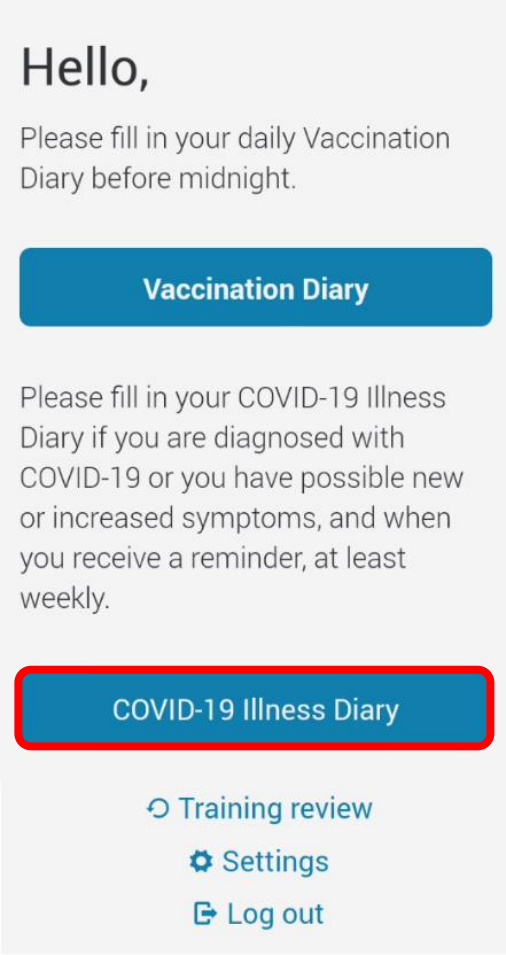
Illness Diary

Please note if you are using your own device, allow the [redacted] App to synchronise with your calendar in order to see notifications appropriately.



The Illness Diary will be available for you to complete at all times, starting on your first day of participation. The Illness Diary should be completed at least once every 7 days, if you are diagnosed with COVID-19, or if you have new or worsened symptoms.

IMPORTANT: Diary Entries started prior to midnight will be allowed to continue through to completion as long as you do not log out of the device.

Diary Entries started prior to midnight and saved after midnight will be counted for the day the questionnaire was started. If device is left for more than 10 minutes, the [redacted] App automatically will lock you out.

Example: Started diary 11:50 PM on 01 Jun 2020 and saved at 12:01 AM on 02 Jun 2020, will count for 01 Jun 2020.

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Notifications are set up to help you remember to complete your diary. Site staff will set the notification alert time when they set-up your [redacted] App activation code. You will get a reminder to complete the Illness Diary only weekly, if the Illness Diary is not completed before the scheduled notification alert time. You can change the alert time as needed in the 'Settings' button.

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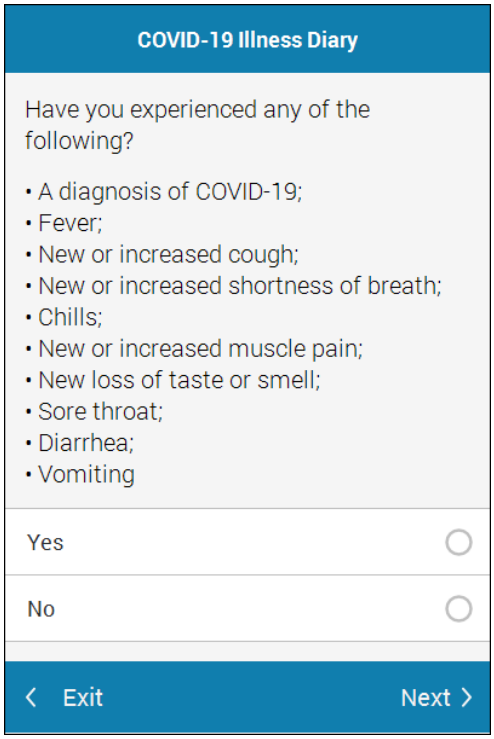
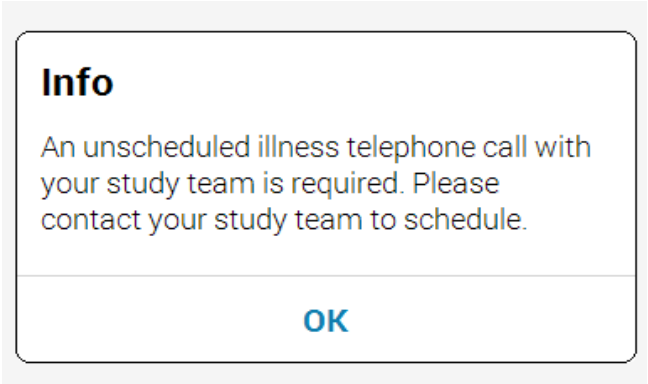
Instructions for assessing symptoms in the COIVID-19 Illness Diary

- Starting on the day your diary is activated you will be asked to note if you experience any of the following symptoms or events: A diagnosis of COVID-19, fever, new or increased cough, new or increased shortness of breath, chills, new or increased muscle pain, new loss of taste or smell, sore throat, diarrhea, or vomiting. This information can be recorded in the [redacted] App at any time.
- The Illness Diary must be completed a minimum of once every 7 days, even when there are no symptoms or events to report.



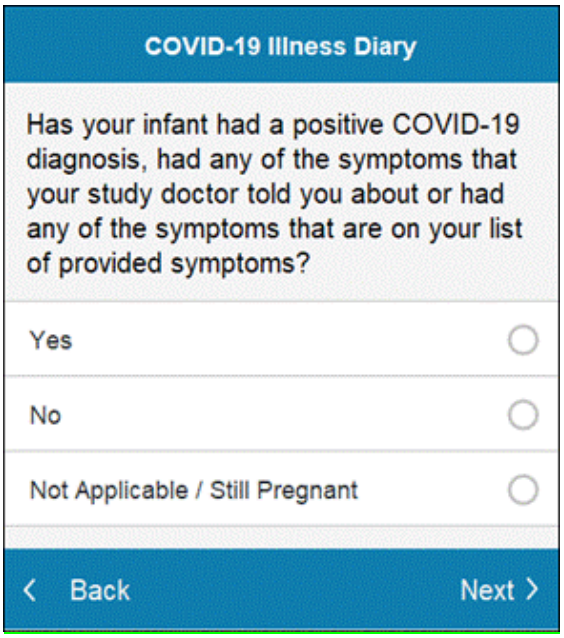
Carefully review the symptoms listed in the diary and select "yes" or "no" depending how you are feeling when completing the diary.

If you selected "Yes" to experiencing any of the listed symptoms a pop-up message will appear prompting you to contact your study clinic to schedule an illness check with the study team.



Instructions for Infant Diary

- Starting on the day your diary is activated you will be asked to record if your infant experienced any of the following symptoms or events: A diagnosis of COVID-19, fever, new/increased cough, new/increased shortness of breath, diarrhea, vomiting. This information can be recorded in the [redacted] App at any time.
- **If you are still pregnant or if the question is not applicable, please select the correct answer.**



Carefully review the options listed in the diary and select "yes" or "no" or "Not Applicable / Still Pregnant".

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Visits to the Study Clinic

IMPORTANT: Remember to take your personal or provisioned device to every study clinic visit (scheduled or unscheduled).

Speak to study clinic staff if:

- You have any questions about the App or the study
- Your device is lost, stolen or damaged
- You have questions about your health or participation in the study

If you are using your own device, please do not uninstall the [redacted] App during the duration of the study.

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Helpdesk

Telephone: [redacted]

Helpdesk Priority PIN: [redacted]

Available hours: 24 hours per day, 7 days per week.

For when you:

- Forget your PIN code or cannot log into [redacted]
- Need help with a technical issue
- Have any other questions about using the [redacted]

When calling the Helpdesk, you will be asked to enter a PIN. Enter the PIN code above to enter the priority queue. The Helpdesk will ask for the following information. This information can be found in this guide or on the sticker supplied by the clinic staff: **Study protocol, Study code, Site number and your Participant number.**

It is important not to provide any information about your health to the Helpdesk. Please contact your study doctor or study clinic staff for health concerns.

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[redacted] activation

Welcome to the C4591015 study. You will be using the [redacted] to record important study data throughout the duration of the study, you can use the app on either:

Your own **personal device** (e.g. your iPhone / Android phone)

or

A **provisioned device,** a device provided to you by the site which is limited to just the [redacted] functionality.

Note - if you have a **suitable** personal device, we recommend this option for ease of recording study data. The **suitable personal device** can be any smartphone which is able to install the [redacted]

Receiving your [redacted] Activation code:

Site personnel will ask you for either an email address or mobile phone number. This information is encrypted and can only be viewed by site personnel.

Your [redacted] activation code will be sent to by email or text/SMS message.

To opt-in to receive SMS activation code, send a text message with the word **SUBSCRIBE** to phone number [redacted]

If you do not receive the [redacted] activation code, your site staff will provide the [redacted] activation code directly to you.

Using a personal device:

The message containing your [redacted] activation code will include a link to the download the [redacted] from the App Store or Google Play store.

Alternatively, you can search the App Store or Google Play store for [redacted]

[redacted]

During installation, the [redacted] will perform a check to determine if your personal device meets the minimum system requirements.

- If installation is successful, select the [redacted] and enter the activation code.
- If installation is unsuccessful, please ask the site staff for a **provisioned device**.

Using a provisioned device:

Your site staff will provide you with a device which has the [redacted] pre-installed. After turning the device on, select the [redacted] and enter activation code.

Setting up a new PIN:

Whether using your own device or a provisioned device after launching the [redacted] for the first time, enter the default PIN of [redacted] and then set-up a new PIN code.

- Do not disclose this PIN to anyone else.

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16.1.4. LIST AND DESCRIPTION OF INVESTIGATORS AND OTHER SERVICE PROVIDERS

16.1.4.1 List of Investigators and Number of Sites and Subjects by Country

16.1.4.2 List of CROs, Vendors, and Service Providers for the Study

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16.1.4.1 LIST OF INVESTIGATORS AND NUMBER OF SITES AND SUBJECTS BY THE COUNTRY

Total Number of Sites (Per Study): 62
Total Number of Subjects Screened (Per Study): 726
Total Number of Subjects Randomized/Entered (Per Study): 683

BRAZIL

Number of Sites (Per Country): 4
Number of Subjects Screened (Per Country): 95
Number of Subjects Randomized/Entered (Per Country): 87
Coordinating Investigator:
<None Entered>

Study Site Number	Principal Investigator	Sub-Investigator	Study Conducted at Address(es)	Subjects Screened per Site	Subjects Randomized/ Entered per Site
1019	[redacted]	[redacted]	[redacted] BRAZIL	24	23
			[redacted] BRAZIL		
			[redacted] BRAZIL		

*Did not randomize subjects (for randomized study) or enter subjects (for open study)

†Did not screen subjects

Study Site Number	Principal Investigator	Sub-Investigator	Study Conducted at Address(es)	Subjects Screened per Site	Subjects Randomized/ Entered per Site
1142*†	[redacted]	[redacted]	[redacted] BRAZIL	0	0
			[redacted] BRAZIL		
1151	[redacted]	[redacted]	[redacted] BRAZIL	4	4
			[redacted] BRAZIL		
1194	[redacted]	[redacted]	[redacted] BRAZIL	67	60
			[redacted] BRAZIL		

*Did not randomize subjects (for randomized study) or enter subjects (for open study)

†Did not screen subjects

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SOUTH AFRICA

Number of Sites (Per Country): 6
Number of Subjects Screened (Per Country): 192
Number of Subjects Randomized/Entered (Per Country): 162
Coordinating Investigator:
<None Entered>

Study Site Number	Principal Investigator	Sub-Investigator	Study Conducted at Address(es)	Subjects Screened per Site	Subjects Randomized/ Entered per Site
1059	[redacted]	[redacted]	[redacted] SOUTH AFRICA	11	10
1071	[redacted]	[redacted]	[redacted] SOUTH AFRICA	24	22
1083*†	[redacted]	[redacted]	[redacted] SOUTH AFRICA	0	0

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*Did not randomize subjects (for randomized study) or enter subjects (for open study)

†Did not screen subjects

Study Site Number	Principal Investigator	Sub-Investigator	Study Conducted at Address(es)	Subjects Screened per Site	Subjects Randomized/ Entered per Site
1104	[redacted]	[redacted]	[redacted] SOUTH AFRICA	72	60
1150	[redacted]	[redacted]	[redacted] SOUTH AFRICA	68	54
1152	[redacted]	[redacted]	[redacted] SOUTH AFRICA [redacted] SOUTH AFRICA	17	16

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*Did not randomize subjects (for randomized study) or enter subjects (for open study)

†Did not screen subjects

SPAIN

Number of Sites (Per Country): 7
Number of Subjects Screened (Per Country): 75
Number of Subjects Randomized/Entered (Per Country): 75
Coordinating Investigator:
<None Entered>

Study Site Number	Principal Investigator	Sub-Investigator	Study Conducted at Address(es)	Subjects Screened per Site	Subjects Randomized/ Entered per Site
1076	[redacted]	[redacted]	[redacted] SPAIN	2	2
1077*†	[redacted]	[redacted]	[redacted] SPAIN	0	0

*Did not randomize subjects (for randomized study) or enter subjects (for open study)

†Did not screen subjects

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Study Site Number	Principal Investigator	Sub-Investigator	Study Conducted at Address(es)	Subjects Screened per Site	Subjects Randomized/ Entered per Site
1077*†					
1127			SPAIN	21	21
1219			SPAIN	14	14

*Did not randomize subjects (for randomized study) or enter subjects (for open study)

†Did not screen subjects

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Study Site Number	Principal Investigator	Sub-Investigator	Study Conducted at Address(es)	Subjects Screened per Site	Subjects Randomized/ Entered per Site
1226	[redacted]	[redacted]	[redacted] SPAIN	4	4
			[redacted] SPAIN		
			[redacted] SPAIN		
1251	[redacted]	[redacted]	[redacted] SPAIN	16	16
			[redacted] SPAIN		
			[redacted] SPAIN		
			[redacted] SPAIN		

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*Did not randomize subjects (for randomized study) or enter subjects (for open study)

†Did not screen subjects

Study Site Number	Principal Investigator	Sub-Investigator	Study Conducted at Address(es)	Subjects Screened per Site	Subjects Randomized/ Entered per Site
1251			[redacted] SPAIN		
1252	[redacted]	[redacted]	[redacted] SPA N [redacted] SPAIN [redacted] SPAIN	18	18

*Did not randomize subjects (for randomized study) or enter subjects (for open study)

†Did not screen subjects

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UNITED KINGDOM

Number of Sites (Per Country): 11
Number of Subjects Screened (Per Country): 28
Number of Subjects Randomized/Entered (Per Country): 28
Coordinating Investigator:
<None Entered>

Study Site Number	Principal Investigator	Sub-Investigator	Study Conducted at Address(es)	Subjects Screened per Site	Subjects Randomized/ Entered per Site
1183*†	[redacted]	[redacted]	[redacted] UNITED KINGDOM	0	0
			[redacted] UNITED KINGDOM		
1184*†	[redacted]	[redacted]	[redacted] UNITED KINGDOM	0	0
1203	[redacted]	[redacted]	[redacted] UNITED KINGDOM	4	4
			[redacted]		

*Did not randomize subjects (for randomized study) or enter subjects (for open study)

†Did not screen subjects

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Study Site Number	Principal Investigator	Sub-Investigator	Study Conducted at Address(es)	Subjects Screened per Site	Subjects Randomized/ Entered per Site
1203			[redacted] UNITED KINGDOM		
1204	[redacted]	[redacted]	[redacted] UNITED KINGDOM	4	4
1216*†	[redacted]	[redacted]	[redacted] UNITED KINGDOM	0	0
			[redacted] UNITED K NGDOM		
1233	[redacted]	[redacted]	[redacted] UNITED KINGDOM	4	4

*Did not randomize subjects (for randomized study) or enter subjects (for open study)

†Did not screen subjects

Study Site Number	Principal Investigator	Sub-Investigator	Study Conducted at Address(es)	Subjects Screened per Site	Subjects Randomized/ Entered per Site
1234	[redacted]	[redacted]	[redacted] UNITED K NGDOM	2	2
1242*†	[redacted]	[redacted]	[redacted] UNITED KINGDOM	0	0
1244*†	[redacted]	[redacted]	[redacted] UNITED KINGDOM	0	0
1246	[redacted]	[redacted]	[redacted] UNITED KINGDOM	2	2

*Did not randomize subjects (for randomized study) or enter subjects (for open study)

†Did not screen subjects

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Study Site Number	Principal Investigator	Sub-Investigator	Study Conducted at Address(es)	Subjects Screened per Site	Subjects Randomized/ Entered per Site
1254	[redacted]	[redacted]	[redacted] UNITED KINGDOM	12	12
			[redacted] UNITED KINGDOM		
			[redacted] UNITED KINGDOM		

*Did not randomize subjects (for randomized study) or enter subjects (for open study)

†Did not screen subjects

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UNITED STATES

Number of Sites (Per Country): 34
Number of Subjects Screened (Per Country): 336
Number of Subjects Randomized Entered (Per Country): 331
Coordinating Investigator: [redacted]

Study Site Number	Principal Investigator	Sub-Investigator	Study Conducted at Address(es)	Subjects Screened per Site	Subjects Randomized/ Entered per Site
1004	[redacted]	[redacted]	[redacted] UNITED STATES	2	2
1006	[redacted]	[redacted]	[redacted] UNITED STATES	4	4
1007*†	[redacted]	[redacted]	[redacted] UNITED STATES [redacted] UNITED STATES	0	0

*Did not randomize subjects (for randomized study) or enter subjects (for open study)

†Did not screen subjects

Study Site Number	Principal Investigator	Sub-Investigator	Study Conducted at Address(es)	Subjects Screened per Site	Subjects Randomized/ Entered per Site
1009*†	[redacted]	[redacted]	[redacted] UNITED STATES	0	0
1010*†	[redacted]	[redacted]	[redacted] UNITED STATES	0	0
1011	[redacted]	[redacted]	[redacted] UNITED STATES	12	12
1013	[redacted]	[redacted]	[redacted] UNITED STATES [redacted] UNITED STATES [redacted]	70	68

*Did not randomize subjects (for randomized study) or enter subjects (for open study)

†Did not screen subjects

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Study Site Number	Principal Investigator	Sub-Investigator	Study Conducted at Address(es)	Subjects Screened per Site	Subjects Randomized/ Entered per Site
1013			[redacted] UNITED STATES		
			[redacted] UNITED STATES		
			[redacted] UNITED STATES		
1016	[redacted]	[redacted]	[redacted] UNITED STATES	2	2
1021	[redacted]	[redacted]	[redacted] UNITED STATES	4	4
			[redacted] UNITED STATES		
			[redacted] UNITED STATES		
			[redacted]		

*Did not randomize subjects (for randomized study) or enter subjects (for open study)

†Did not screen subjects

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Study Site Number	Principal Investigator	Sub-Investigator	Study Conducted at Address(es)	Subjects Screened per Site	Subjects Randomized/ Entered per Site
1021			[redacted] UNITED STATES		
1024	[redacted]	[redacted]	[redacted] UNITED STATES	5	5
			[redacted] UNITED STATES		
			[redacted] UNITED STATES		
1025	[redacted]	[redacted]	[redacted] UNITED STATES	6	6
1026*†	[redacted]	[redacted]	[redacted] UNITED STATES	0	0
			[redacted]		

*Did not randomize subjects (for randomized study) or enter subjects (for open study)

†Did not screen subjects

Study Site Number	Principal Investigator	Sub-Investigator	Study Conducted at Address(es)	Subjects Screened per Site	Subjects Randomized/ Entered per Site
1026*†			[redacted] UNITED STATES		
			[redacted] UNITED STATES		
			[redacted] UNITED STATES		
			[redacted] UNITED STATES		
			[redacted] UNITED STATES		
			[redacted] UNITED STATES		
			[redacted] UNITED STATES		

*Did not randomize subjects (for randomized study) or enter subjects (for open study)

†Did not screen subjects

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Study Site Number	Principal Investigator	Sub-Investigator	Study Conducted at Address(es)	Subjects Screened per Site	Subjects Randomized/ Entered per Site
1028	[redacted]	[redacted]	[redacted] UNITED STATES	4	4
1030	[redacted]	[redacted]	[redacted] UNITED STATES	4	4
			[redacted] UNITED STATES		
			[redacted] UNITED STATES		
1032*†	[redacted]	[redacted]	[redacted] UNITED STATES	0	0
			[redacted] UNITED STATES		
			[redacted]		

*Did not randomize subjects (for randomized study) or enter subjects (for open study)

†Did not screen subjects

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Study Site Number	Principal Investigator	Sub-Investigator	Study Conducted at Address(es)	Subjects Screened per Site	Subjects Randomized/ Entered per Site
1032*†			[redacted] UNITED STATES		
			[redacted] UNITED STATES		
1034	[redacted]	[redacted]	[redacted] UNITED STATES	28	28
			[redacted] UNITED STATES		
			[redacted] UNITED STATES		
			[redacted] UNITED STATES		

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*Did not randomize subjects (for randomized study) or enter subjects (for open study)

†Did not screen subjects

Study Site Number	Principal Investigator	Sub-Investigator	Study Conducted at Address(es)	Subjects Screened per Site	Subjects Randomized/ Entered per Site
1035	[redacted]	[redacted]	[redacted] UNITED STATES	4	4
			[redacted] UNITED STATES		
1036	[redacted]	[redacted]	[redacted] UN TED STATES	2	2
			[redacted] UNITED STATES		
1037	[redacted]	[redacted]	[redacted] UNITED STATES	22	20
			[redacted] UNITED STATES		

*Did not randomize subjects (for randomized study) or enter subjects (for open study)

†Did not screen subjects

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Study Site Number	Principal Investigator	Sub-Investigator	Study Conducted at Address(es)	Subjects Screened per Site	Subjects Randomized/ Entered per Site
1038	[redacted]	[redacted]	[redacted] UNITED STATES	113	113
1039	[redacted]	[redacted]	[redacted] UNITED STATES	12	12
			[redacted] UNITED STATES		
			[redacted] UNITED STATES		
			[redacted] UNITED STATES		
			[redacted] UNITED STATES		
			[redacted] UNITED STATES		

*Did not randomize subjects (for randomized study) or enter subjects (for open study)

†Did not screen subjects

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Study Site Number	Principal Investigator	Sub-Investigator	Study Conducted at Address(es)	Subjects Screened per Site	Subjects Randomized/ Entered per Site
1039			[redacted] UNITED STATES		
			[redacted] UNITED STATES		
			[redacted] UNITED STATES		
			[redacted] UNITED STATES		
1040*†	[redacted]	[redacted]	[redacted] UNITED STATES	0	0
1046*†	[redacted]	[redacted]	[redacted] UNITED STATES	0	0
			[redacted] UNITED STA ES		

*Did not randomize subjects (for randomized study) or enter subjects (for open study)

†Did not screen subjects

Study Site Number	Principal Investigator	Sub-Investigator	Study Conducted at Address(es)	Subjects Screened per Site	Subjects Randomized/ Entered per Site
1046*†			[redacted] UNITED STATES		
			[redacted] UNITED STATES		
1048	[redacted]	[redacted]	[redacted] UNITED STATES	12	12
			[redacted] UNITED STATES		

*Did not randomize subjects (for randomized study) or enter subjects (for open study)

†Did not screen subjects

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Study Site Number	Principal Investigator	Sub-Investigator	Study Conducted at Address(es)	Subjects Screened per Site	Subjects Randomized/ Entered per Site
1048					
1057*†			UNITED STATES	0	0
			UNITED STATES		
			UNITED STATES		
			UNITED STATES		
1065			UNITED STATES	2	2
			UNITED STATES		

*Did not randomize subjects (for randomized study) or enter subjects (for open study)

†Did not screen subjects

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Study Site Number	Principal Investigator	Sub-Investigator	Study Conducted at Address(es)	Subjects Screened per Site	Subjects Randomized/ Entered per Site
1065			UNITED STATES		
			UNITED STATES		
1068*†			UNITED STATES	0	0
1069			UNITED STATES	6	6
1078*†			UNITED STATES	0	0
1086			UNITED STATES	2	2

*Did not randomize subjects (for randomized study) or enter subjects (for open study)

†Did not screen subjects

Study Site Number	Principal Investigator	Sub-Investigator	Study Conducted at Address(es)	Subjects Screened per Site	Subjects Randomized/ Entered per Site
1086			UNITED STATES		
1099*†			UNITED STATES	0	0
			UNITED STATES		
			UNITED STATES		
			UNITED STATES		
			UNITED STATES		

*Did not randomize subjects (for randomized study) or enter subjects (for open study)

†Did not screen subjects

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Study Site Number	Principal Investigator	Sub-Investigator	Study Conducted at Address(es)	Subjects Screened per Site	Subjects Randomized/ Entered per Site
1125*†	[redacted]	[redacted]	[redacted] UNITED STATES	0	0
			[redacted] UNITED STATES		
			[redacted] UNITED STATES		
			[redacted] UNITED STATES		
			[redacted] UNITED STATES		
			[redacted]		

*Did not randomize subjects (for randomized study) or enter subjects (for open study)

†Did not screen subjects

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Study Site Number	Principal Investigator	Sub-Investigator	Study Conducted at Address(es)	Subjects Screened per Site	Subjects Randomized/ Entered per Site
1125*†			UNITED STATES		
1177	[redacted]	[redacted]	[redacted] UNITED STATES	20	19
			[redacted] UNITED STATES		
			[redacted] UNITED STATES		
			[redacted] UNITED STATES		
1247*†	[redacted]	[redacted]	[redacted] UNITED STATES	0	0
			[redacted] UNITED STATES		

*Did not randomize subjects (for randomized study) or enter subjects (for open study)

†Did not screen subjects

Study Site Number	Principal Investigator	Sub-Investigator	Study Conducted at Address(es)	Subjects Screened per Site	Subjects Randomized/ Entered per Site
1247*†			[redacted] UNITED STATES		
			[redacted] UNITED STATES		

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*Did not randomize subjects (for randomized study) or enter subjects (for open study)

†Did not screen subjects

16.1.4.2. List of CROs and Vendors

List of Contract Research Organizations and Vendors

CRO or Vendor Name and Address(es)	Service Conducted
[redacted] USA	Statistical/Clinical Programming
[redacted] USA	Statistical/Clinical Programming
[redacted] USA	Study Management
[redacted] IRELAN	Clinical Study Agreement Contracting Services (Mozambique), Monitoring of Investigational Sites, Study Management
[redacted] USA	Study Management
[redacted] USA	Electronic Consent
[redacted] USA	Medical/Clinical Writing
[redacted] USA	Data Management, Dictionary Coding
[redacted] USA	Electronic Clinical Outcomes Assessment (eCOA)

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16.1.4.2. List of CROs and Vendors

CRO or Vendor Name and Address(es)	Service Conducted
[redacted] USA	Statistical Analysis
[redacted] USA	Study Coordination Support Services

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16.1.5.1 SPONSOR

CLINICAL STUDY REPORT APPROVAL FORM

PROTOCOL NUMBER: C4591015

REPORT TITLE: Final Report: A Phase 2/3, Placebo-Controlled, Randomized, Observer-Blind Study to Evaluate the Safety, Tolerability, and Immunogenicity of a SARS-CoV-2 RNA Vaccine Candidate (BNT162b2) Against COVID-19 in Healthy Pregnant Women 18 Years of Age and Older

AUTHOR: [redacted]

I have reviewed this clinical study report, which is from its definitive source and final in content. I confirm that it is a complete and accurate representation of the relevant data and statistical analyses for this report.

Known deviations in the study did not impact overall compliance with Good Clinical Practice and local regulations.

Organization/Institution: BioNTech SE

Name/Position: [redacted]

Signature: [redacted] Digitally signed by [redacted] Date: 2024.05.21 22:38:02 -04'00' **Date:** _____

[redacted]

090177e1a0c1faa6\Approved\Approved On: 23-May-2024 02:34 (GMT)

16.1.5.1 SPONSOR AGENT

CLINICAL STUDY REPORT APPROVAL FORM

PROTOCOL NUMBER: C4591015

REPORT TITLE: Final Report: A Phase 2/3, Placebo-Controlled, Randomized, Observer-Blind Study to Evaluate the Safety, Tolerability, and Immunogenicity of a SARS-CoV-2 RNA Vaccine Candidate (BNT162b2) Against COVID-19 in Healthy Pregnant Women 18 Years of Age and Older

AUTHOR: [redacted]

I have reviewed this clinical study report, which is from its definitive source and final in content. I confirm that it is a complete and accurate representation of the relevant data and statistical analyses for this report.

Known deviations in the study did not impact overall compliance with Good Clinical Practice and local regulations.

STATISTICS LINE HEAD: [redacted]

CLINICAL LEAD: [redacted]

090177e1a08bea7c\Approved\Approved On: 22-May-2024 21:58 (GMT)

Document Approval Record

Document Name:	16.1.5.1 Sponsor Agent
Document Title:	C4591015

Signed By:	Date(GMT)	Signing Capacity
[redacted]	22-May-2024 17:38:04	Final Approval
[redacted]	22-May-2024 21:58:58	Final Approval

090177e1a08bea7c\Approved\Approved On: 22-May-2024 21:58 (GMT)

[redacted]

INVESTIGATOR DECLARATION

Clinical Study Report

Protocol Number: C4591015

Report Title: Final Report: A Phase 2/3, Placebo-Controlled, Randomized, Observer- Blind Study to Evaluate the Safety, Tolerability, and Immunogenicity of a SARS-CoV-2 RNA Vaccine Candidate (BNT162b2) Against COVID-19 in Healthy Pregnant Women 18 Years of Age and Older

Clinical Lead: [redacted]

Date of the Report: 22 May 2024

I, [redacted] the undersigned, have read the above-referenced clinical study report for study C4591015 which I have undertaken with Pfizer.

I confirm that to the best of my knowledge, it accurately describes the conduct and results of the study.

Signed: [redacted]

Date: 28 May 2024

The above lead investigator is acting as coordinator and signing on behalf of all centers involved in the above study.

[redacted]

[redacted]

[redacted]

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C4591015 16.1.6 Study Drug Information

Data is presented by site and country

1019 BRAZIL

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
10191004	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
10191007	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
10191009	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
10191009	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
10191012	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
10191012	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
10191013	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
10191013	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
10191001	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10191004	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10191004	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10191006	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10191006	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10191007	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10191007	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10191008	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10191008	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10191009	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10191010	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10191010	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10191011	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10191011	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**

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C4591015 16.1.6 Study Drug Information

Data is presented by site and country

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
10191012	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10191013	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10191014	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10191014	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**

1142 BRAZIL

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
N/A	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
N/A	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**

1151 BRAZIL

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
N/A	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11511001	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11511002	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**

1194 BRAZIL

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
11941002	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**

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Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
11941002	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11941005	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11941005	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11941008	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11941011	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11941011	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11941013	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11941013	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11941015	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11941015	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11941018	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11941018	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11941019	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11941019	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11941025	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11941025	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11941026	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11941026	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11941029	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11941029	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11941031	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11941031	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11941032	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11941032	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**

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Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
11941036	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11941002	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11941002	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11941003	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11941003	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11941004	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11941004	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11941007	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11941007	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11941010	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11941010	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11941011	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11941011	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11941012	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11941012	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11941013	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11941015	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11941015	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11941016	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11941016	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11941017	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11941017	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11941018	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11941018	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**

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Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
11941019	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11941020	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11941021	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11941021	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11941022	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11941022	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11941025	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11941025	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11941026	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11941026	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11941028	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11941028	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11941029	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11941030	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11941030	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11941031	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11941032	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11941032	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11941033	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11941033	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11941034	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11941034	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11941035	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11941036	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**

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Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
11941037	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**

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1059 SOUTH AFRICA

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
10591004	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
10591005	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
10591006	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
10591002	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10591003	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10591004	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10591004	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10591005	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10591005	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10591006	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10591006	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**

1071 SOUTH AFRICA

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
10711001	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
10711002	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
10711006	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
10711006	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
10711010	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
10711010	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**

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Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
10711011	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
10711011	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
10711012	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
10711012	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
10711001	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10711002	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10711003	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10711004	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10711005	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10711008	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10711008	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10711010	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10711010	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10711011	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10711011	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10711012	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10711013	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10711013	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**

1083 SOUTH AFRICA

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
N/A	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**

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Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
N/A	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**

1104 SOUTH AFRICA

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
11041002	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11041008	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11041008	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11041011	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11041011	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11041013	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11041013	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11041015	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11041015	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11041019	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11041019	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11041020	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11041020	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11041021	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11041021	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11041027	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11041027	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11041028	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**

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Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
11041032	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11041032	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11041036	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11041036	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11041037	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11041037	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11041041	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11041041	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11041043	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11041043	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11041002	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11041003	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11041003	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11041006	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11041006	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11041008	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11041008	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11041010	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11041010	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11041011	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11041013	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11041013	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11041014	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11041014	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**

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Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
11041015	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11041015	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11041016	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11041016	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11041017	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11041017	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11041019	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11041020	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11041020	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11041021	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11041022	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11041022	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11041023	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11041023	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11041025	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11041025	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11041026	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11041026	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11041027	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11041028	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11041029	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11041029	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11041030	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11041030	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**

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Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
11041032	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11041032	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11041036	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11041036	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11041037	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11041038	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11041038	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11041041	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11041042	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11041042	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11041043	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11041043	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11041045	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**

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Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
11501003	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11501003	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11501005	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11501011	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11501011	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11501017	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**

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Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
11501017	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11501018	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11501018	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11501019	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11501019	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11501024	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11501024	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11501025	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11501025	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11501026	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11501026	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11501031	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11501031	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11501032	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11501032	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11501033	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11501033	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11501041	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11501044	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11501003	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11501003	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11501004	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11501005	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11501005	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**

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Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
11501006	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11501006	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11501008	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11501008	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11501010	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11501010	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11501011	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11501016	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11501016	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11501017	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11501017	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11501018	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11501018	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11501019	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11501021	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11501021	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11501022	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11501022	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11501024	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11501024	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11501025	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11501025	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11501026	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11501026	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**

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Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
11501029	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11501029	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11501030	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11501030	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11501033	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11501034	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11501034	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11501037	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11501037	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11501041	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11501042	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11501042	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11501043	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11501044	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11501044	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11501045	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**

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Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
11521003	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11521004	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11521005	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**

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Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
11521009	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11521009	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11521001	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11521002	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11521003	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11521003	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11521004	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11521005	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11521007	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11521007	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11521008	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11521008	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11521009	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**

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1076 SPAIN

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
N/A	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
10761001	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**

1077 SPAIN

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
N/A	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
N/A	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**

1127 SPAIN

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
11271001	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11271003	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11271006	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11271006	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11271008	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11271008	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11271010	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11271010	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**

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Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
11271001	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11271002	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11271004	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11271005	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11271006	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11271007	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11271007	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11271008	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11271009	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11271010	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11271011	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**

1219 SPAIN

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
12191001	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
12191002	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
12191004	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
12191005	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
12191005	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
12191001	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
12191001	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
12191002	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**

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Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
12191003	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
12191004	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
12191005	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
12191005	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
12191006	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
12191007	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**

1226 SPAIN

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
N/A	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
12261001	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
12261002	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**

1251 SPAIN

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
12511004	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
12511005	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
12511007	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
12511007	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
12511008	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**

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Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
12511001	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
12511002	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
12511003	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
12511003	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
12511004	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
12511005	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
12511005	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
12511006	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
12511007	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
12511007	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
12511008	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
12511008	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**

1252 SPAIN

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
12521003	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
12521003	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
12521004	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
12521005	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
12521005	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
12521006	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
12521006	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**

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Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
12521009	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
12521009	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
12521001	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
12521002	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
12521003	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
12521003	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
12521005	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
12521007	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
12521007	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
12521008	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
12521008	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
12521009	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
12521010	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
12521010	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**

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1183 UNITED KINGDOM

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
N/A	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
N/A	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**

1184 UNITED KINGDOM

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
N/A	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
N/A	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**

1203 UNITED KINGDOM

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
12031002	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
12031003	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
12031002	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
12031003	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**

1204 UNITED KINGDOM

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Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
N/A	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
12041001	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
12041002	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**

1216 UNITED KINGDOM

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
N/A	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
N/A	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**

1233 UNITED KINGDOM

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
12331001	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
12331002	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
12331001	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
12331002	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**

1234 UNITED KINGDOM

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
N/A	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**

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Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
12341001	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**

1242 UNITED KINGDOM

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
N/A	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
N/A	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**

1244 UNITED KINGDOM

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
N/A	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
N/A	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**

1246 UNITED KINGDOM

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
N/A	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
12461002	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**

1254 UNITED KINGDOM

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Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
12541001	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
12541002	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
12541004	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
12541006	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
12541006	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
12541001	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
12541003	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
12541004	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
12541004	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
12541005	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
12541006	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
12541007	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
12541007	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**

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1004 UNITED STATES

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
N/A	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10041001	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**

1006 UNITED STATES

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
10061001	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10061001	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10061002	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
N/A	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**

1007 UNITED STATES

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
N/A	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
N/A	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**

1009 UNITED STATES

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Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
N/A	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
N/A	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**

1010 UNITED STATES

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
N/A	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
N/A	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**

1011 UNITED STATES

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
10111001	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10111003	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10111003	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10111004	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10111005	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10111006	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10111002	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10111003	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10111006	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
N/A	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**

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Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
10111006	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**

1013 UNITED STATES

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
10131001	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131003	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131003	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131005	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131005	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131006	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131007	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131007	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131008	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131008	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131009	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131010	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131010	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131011	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131011	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131012	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131012	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131013	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**

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Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
10131013	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131014	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131014	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131015	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131016	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131018	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131018	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131019	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131019	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131020	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131020	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131021	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131021	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131022	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131023	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131023	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131024	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131024	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131025	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131026	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131027	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131028	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131028	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131029	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**

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Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
10131029	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131030	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131030	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131031	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131031	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131032	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131032	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131033	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131033	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131034	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131034	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131035	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131036	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131037	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131037	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10131002	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10131003	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10131003	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10131005	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10131005	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10131009	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10131009	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10131011	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10131011	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**

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Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
10131013	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10131013	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10131016	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10131016	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10131018	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10131018	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10131019	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10131019	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10131022	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10131022	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10131023	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10131023	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10131024	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10131024	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10131027	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10131027	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10131029	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10131029	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10131031	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10131031	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10131034	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10131036	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10131036	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
N/A	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**

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Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
10131006	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10131015	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10131025	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10131026	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**

1016 UNITED STATES

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
10161001	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
N/A	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**

1021 UNITED STATES

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
10211001	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10211002	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
N/A	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**

1024 UNITED STATES

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
10241001	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**

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Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
10241002	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10241002	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10241003	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
N/A	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**

1025 UNITED STATES

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
10251001	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10251002	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10251003	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10251003	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**

1026 UNITED STATES

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
N/A	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
N/A	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**

1028 UNITED STATES

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Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
10281001	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10281002	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10281001	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10281002	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
N/A	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**

1030 UNITED STATES

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
10301002	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10301001	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10301002	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**

1032 UNITED STATES

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
N/A	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
N/A	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**

1034 UNITED STATES

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Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
10341001	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10341002	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10341003	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10341003	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10341004	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10341004	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10341005	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10341006	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10341007	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10341007	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10341008	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10341009	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10341009	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10341010	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10341011	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10341011	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10341013	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10341003	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10341004	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10341005	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10341008	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10341008	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10341009	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**

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Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
10341012	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10341012	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10341013	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10341013	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10341014	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10341014	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10341012	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10341013	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10341014	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**

1035 UNITED STATES

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
10351001	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10351002	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10351001	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**

1036 UNITED STATES

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
10361001	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
N/A	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**

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1037 UNITED STATES

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
10371001	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10371002	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10371003	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10371003	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10371004	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10371004	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10371005	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10371006	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10371006	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10371007	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10371008	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10371009	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10371009	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10371011	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10371003	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10371004	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10371006	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10371006	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10371007	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10371011	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**

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Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
10371008	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10371009	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**

1038 UNITED STATES

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
10381001	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381002	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381002	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381003	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381004	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381005	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381006	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381006	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381007	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381008	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381008	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381009	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381009	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381010	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381010	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381011	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381012	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**

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Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
10381013	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381013	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381014	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381014	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381015	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381015	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381016	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381016	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381017	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381018	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381020	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381022	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381023	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381024	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381025	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381025	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381026	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381027	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381028	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381030	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381031	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381031	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381032	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381033	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**

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Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
10381034	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381035	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381037	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381037	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381039	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381039	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381040	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381041	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381042	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381042	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381043	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381045	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381045	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381047	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381049	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381049	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381051	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381052	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381052	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381053	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381053	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381054	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381054	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381055	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**

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10381055	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381058	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10381004	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381005	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381005	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381007	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381007	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381008	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381008	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381011	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381011	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381012	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381012	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381016	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381016	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381017	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381017	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381018	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381018	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381019	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381019	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381022	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381022	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381023	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**

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Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
10381023	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381025	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381025	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381027	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381027	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381029	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381029	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381031	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381031	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381035	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381035	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381036	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381036	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381038	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381038	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381039	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381039	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381042	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381042	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381044	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381048	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381048	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381049	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381049	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**

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Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
10381050	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381050	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381052	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381052	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381056	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381056	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381057	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10381059	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
N/A	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
10381004	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10381005	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10381007	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10381011	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10381012	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10381017	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10381018	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10381019	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10381021	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10381022	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10381024	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10381026	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10381028	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10381030	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10381032	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**

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10381033	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10381034	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10381040	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10381041	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10381043	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10381056	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10381057	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
10381059	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**

1039 UNITED STATES

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
10391001	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10391002	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10391002	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10391003	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10391004	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10391004	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10391005	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10391002	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10391004	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
N/A	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**

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1040 UNITED STATES

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
N/A	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
N/A	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**

1046 UNITED STATES

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
N/A	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
N/A	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**

1048 UNITED STATES

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
10481001	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10481002	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10481003	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10481003	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10481004	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10481005	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10481006	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**

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Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
10481002	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10481003	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10481006	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**

1057 UNITED STATES

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
N/A	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
N/A	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**

1065 UNITED STATES

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
10651001	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
N/A	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**

1068 UNITED STATES

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
N/A	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
N/A	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**

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1069 UNITED STATES

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
10691001	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10691002	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10691003	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10691002	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
10691003	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**

1078 UNITED STATES

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
N/A	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
N/A	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**

1086 UNITED STATES

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
10861001	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
10861001	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**

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1099 UNITED STATES

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
N/A	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
N/A	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**

1125 UNITED STATES

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
N/A	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
N/A	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**

1177 UNITED STATES

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
11771001	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
11771002	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
11771003	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
11771006	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
11771006	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
11771007	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
11771007	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
11771008	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**

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Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
11771008	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
11771009	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
11771009	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
11771010	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
11771010	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
11771011	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
11771002	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
11771006	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
11771007	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
11771011	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
11771011	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
11771012	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
11771012	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**
N/A	**Sodium Chloride Injection USP, 0.9% vial**	EE4253	PA2091593/P222676-0004L	0 ml	**SOLUTION**
11771011	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**
11771012	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	ER5832	PA2094601/P222676-0003L	0.5 mg/ml	**SOLUTION**

1247 UNITED STATES

Subject ID	Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
N/A	**BNT162b2 0.5 mg/ml 0.2 ml Vial**	EE3813	NC2075485/P222676-0001L	0.5 mg/ml	**SOLUTION**
N/A	**Sodium Chloride Injection USP, 0.9% vial**	DK2074;20-002221	PA2069407/P222676-0002L	0 ml	**SOLUTION**

Pfizer Regulatory Quality Assurance

Audit Certificate

I, the undersigned, confirm and certify that the following investigator site audit activities were performed.

Study: C4591015

Five (5) investigators site audits were performed between 16-Feb-21 and 30-Sep-2022 for Study C4591015.					
Investigator Name	**Center Number**	**Country**	**Dates of Audit**	**Type of Audit**	**Name of Auditor**
[redacted]	1038	UNITED STATES	25-Oct-2021 to 28-Oct-2021	Routine	[redacted]
[redacted]	1194	BRAZIL	16-Nov-2021 to 18-Nov-2021	Routine	[redacted]
[redacted]	1150	SOUTH AFRICA	08-Jun-2022 to 10-Jun-2022	Routine	[redacted]
[redacted]	1104	SOUTH AFRICA	13-Jun-2022 to 15-Jun-2022	Routine	[redacted]
[redacted]	1021	UNITED STATES	26-Sep-2022 to 28-Sep-2022	Non-Routine	[redacted]

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01 Feb 2023 16:01:006-0500	[redacted]	Started	[redacted]
01 Feb 2023 16:01:006-0500	[redacted]	RequestSent	Sign request sent to ePak recipient.
01 Feb 2023 16:12:026-0500	[redacted]	DocumentViewed	Document viewed by signer.
01 Feb 2023 16:12:047-0500	[redacted]	SignerTagFilled	The signer filled Time Stamp. Value: 01 Feb 2023 16:12:047-0500
01 Feb 2023 16:12:047-0500	[redacted]	Signed	The recipient signed the document with no comments. Comments: None Reason: None Consent: I understand that my Electronic Signature is Equivalent to my Handwritten Signature and is therefore legally binding. My Electronic Signature will remain unique to me, and under no circumstance I am allowed to disclose my password to any individual which may allow unauthorized access to system. I understand that I am accountable and responsible for all actions associated with my Electronic Signature.
01 Feb 2023 16:12:047-0500	[redacted]	Completed	The ePak is completed successfully.

Protocol C4591015

A PHASE 2/3, PLACEBO-CONTROLLED, RANDOMIZED, OBSERVER-BLIND STUDY TO EVALUATE THE SAFETY, TOLERABILITY, AND IMMUNOGENICITY OF A SARS-COV-2 RNA VACCINE CANDIDATE (BNT162b2) AGAINST COVID-19 IN HEALTHY PREGNANT WOMEN 18 YEARS OF AGE AND OLDER

Statistical Analysis Plan (SAP)

Version: 3

Date: 31 Mar 2022

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1. VERSION HISTORY

Table 1. Summary of Changes

Version/ Date	Associated Protocol Amendment	Summary and Rationale for Changes
1/ 24 Mar 2021	Protocol Amendment 2, 02 Mar 2021	N/A
2/ 07 Jun 2021	Protocol Amendment 3, 14 May 2021	1. Implemented the changes made in protocol amendment 3. 2. Deleted all content in Section 5.1.2 and the hypothesis test part in Section 6.2.1.1.1. 3. Added "chills" to the definition of confirmed COVID-19 in maternal participants in Appendix 2.
3/ 31 Mar 2022	Protocol Amendment 5, 08 Mar 2022	1. Implemented the changes made in protocol amendment 5. 2. Deleted content in Section 5 and revised to clarify that no hypothesis test will be done because of sample size reduction. 3. Removed model-based GMR and sensitivity analysis in Section 6.1.2. 4. Changed the selection of nonpregnant participants from Study C4591001 to 1:1 age matching to maternal participants in Section 3.1.2.

2. INTRODUCTION

This SAP provides the detailed methodology for summary and statistical analyses of the data collected in Study C4591015. This document may modify the plans outlined in the protocol; however, any major modifications of the primary endpoint definition or its analysis will also be reflected in a protocol amendment.

2.1. Study Objectives, Endpoints, and Estimands

The estimands corresponding to each primary, secondary, and exploratory objective are described in Table 2 below.

In the primary safety objective evaluations, missing AE start dates will be imputed according to Pfizer safety rules (Section 5.3). No other missing information (eg, missing e-diary data) will be imputed in the safety analysis.

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Table 2. List of Primary, Secondary, and Exploratory Objectives, Estimands, and Endpoints

Objectives[a]	Estimands	Endpoints
Primary Safety	**Primary Safety**	**Primary Safety**
To describe the safety and tolerability of prophylactic BNT162b2 when administered to maternal participants 18 years of age or older vaccinated at 24 to 34 weeks' gestation.	In maternal participants receiving at least 1 dose of study intervention from each vaccine group, the percentage of maternal participants reporting: • Local reactions for up to 7 days following each dose • Systemic events for up to 7 days following each dose • AEs from Dose 1 through 1 month after Dose 2 • SAEs from Dose 1 through 1 month after delivery	• Prompted local reactions (redness, swelling, and pain at the injection site) • Prompted systemic events (fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain) • AEs
[redacted]		

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Table 2. List of Primary, Secondary, and Exploratory Objectives, Estimands, and Endpoints

Objectives[a]	Estimands	Endpoints
Secondary	**Secondary**	**Secondary**
To describe the efficacy of prophylactic BNT162b2 against confirmed COVID-19 occurring from 7 days after Dose 2 through 1 month after delivery in maternal participants 18 years of age or older vaccinated at 24 to 34 weeks' gestation without evidence of prior SARS-CoV-2 infection.	In maternal participants complying with the key protocol criteria (evaluable participants) and no serological or virological evidence (prior to 7 days after receipt of Dose 2) of past SARS-CoV-2 infection: • 100 × (1 – IRR) [ratio of active vaccine to placebo]	• COVID-19 incidence per 1000 person-years of blinded follow-up based on central laboratory or locally confirmed NAAT
To describe the efficacy of prophylactic BNT162b2 against confirmed COVID-19 occurring from 7 days after Dose 2 through 1 month after delivery in maternal participants 18 years of age or older vaccinated at 24 to 34 weeks' gestation with and without evidence of prior SARS-CoV-2 infection.	In maternal participants complying with the key protocol criteria (evaluable participants): • 100 × (1 – IRR) [ratio of active vaccine to placebo]	• COVID-19 incidence per 1000 person-years of blinded follow-up based on central laboratory or locally confirmed NAAT
To describe the efficacy of prophylactic BNT162b2 against asymptomatic SARS-CoV-2 infection through 1 month after delivery in maternal participants 18 years of age or older vaccinated at 24 to 34 weeks' gestation without evidence of prior SARS C V 2 infection	In evaluable maternal participants without serological or virological evidence of prior SARS-CoV-2 infection: • 100 × (1 – IRR) [ratio of active vaccine to placebo]	• Incidence of asymptomatic infection of SARS-CoV-2 based on N-binding antibody seroconversion
[redacted]		

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Table 2. List of Primary, Secondary, and Exploratory Objectives, Estimands, and Endpoints

Objectives[a]	Estimands	Endpoints
To assess the safety of maternal immunization in infants born to maternal participants 18 years of age or older who were vaccinated with BNT162b2 during pregnancy.	In infants born to maternal participants receiving at least 1 dose of study intervention from each vaccine group, the percentage of infants with: • Specific birth outcomes • AEs from birth through 1 month of age • SAEs and AESIs (major congenital anomalies, developmental delay) through 6 nths of age	• Specific birth outcomes • AEs from birth through 1 month of age • SAEs and AESIs (major congenital anomalies, developmental delay) through 6 months of age
[redacted]		
Explora ory	**Exploratory**	**Exploratory**
To describe the incidence of confirmed COVID-19 among maternal participants who were vaccinated with BNT162b2.	In maternal participants who received BNT162b2 (at initial randomization): • Incidence per 1000 person-years of follow-up	• COVID-19 incidence per 1000 person-years of follow-up based on central laboratory or locally confirmed NAAT
To describe the incidence of asymptomatic SARS-CoV-2 infection through 6 months after delivery in maternal participants 18 years of age or older vaccinated at 24 to 34 weeks' gestation with BNT162b2 at initial randomization and without evidence of prior SARS-CoV-2 infection	In maternal participants who received BNT162b2 at initial randomization and without evidence of prior SARS-CoV-2 infection: • Incidence per 1000 person-years of follow-up	• Incidence of asymptomatic SARS-CoV-2 infection per 1000 person-years of follow-up based on N-binding antibody seroconversion
[redacted]		

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Table 2. List of Primary, Secondary, and Exploratory Objectives, Estimands, and Endpoints

Objectives[a]	Estimands	Endpoints
[redacted]		
To describe the safety of maternal immunization in infants born to breastfeeding maternal participants vaccinated with prophylactic BNT162b2 during pregnancy.	In infants born to maternal participants receiving at least 1 dose of study intervention from each vaccine group, based on the breastfeeding status, the percentage of infants with: • AEs from birth through 1 month of age • SAEs and AESIs (major congenital anomalies, developmental delay) through 6 months of age	AEs from birth through 1 month of age • SAEs and AESIs (major congenital anomalies, developmental delay) through 6 months of age
To describe the incidence of confirmed COVID-19 in infants born to maternal participants who were vaccinated with BNT162b2 during pregnancy.	In infants born to maternal participants from each vaccine group: • Incidence rate of infant participants with confirmed COVID-19	• COVID-19 incidence per 1000 person-years of follow-up based on central laboratory or locally confirmed NAAT
To describe MIS-C cases in infants born to maternal participants who were vaccinated with BNT162b2 during pregnancy.	In infants born to maternal participants from each vaccine group: • Incidence rate of MIS-C	• MIS-C incidence per 1000 person-years of follow-up

a. HIV-infected participants will not be included in analyses of the objectives, but in separate exploratory analyses. Analyses among HIV-infected women and their infants will be summarized separately.

2.2. Study Design

This will be a global Phase 2/3, randomized, placebo-controlled, observer-blind study evaluating the safety, tolerability, and immunogenicity of 30 µg of BNT162b2 or placebo administered in 2 doses, 21 days apart, in approximately 350 healthy pregnant women 18 years of age or older vaccinated at 24 to 34 weeks' gestation. Participants will be randomized 1:1 to receive BNT162b2 or placebo (saline).

The Phase 2 portion of the study will include approximately 200 pregnant women randomized 1:1 to receive BNT162b2 or placebo (saline) at 27 to 34 weeks' gestation. The IRC will review safety data through 7 days after the second dose for all Phase 2 participants.

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The Phase 3 portion of this study will include approximately 150 pregnant women at a 1:1 randomization ratio to assess the safety, tolerability, and immunogenicity of BNT162b2 among pregnant women enrolled at 24 to 34 weeks' gestation. Phase 3 will proceed after the first 200 maternal participants have been enrolled in Phase 2.

Maternal participants who originally received placebo will receive BNT162b2 at defined time points as part of the study.

Enrollment in this study was terminated on 25 Oct 2021 with approximately 350 participants enrolled. Enrollment was terminated because of enrollment challenges into a placebo-controlled study as a result of universal recommendations for COVID-19 vaccination of pregnant women and the increased global availability of COVID-19 vaccines. Enrollment numbers within this protocol have been modified accordingly.

The study is observer-blinded, as the physical appearance of the investigational vaccine and the placebo may differ. The participant, investigator, study coordinator, and other site staff will be blinded through the 1-month postdelivery visit for each maternal participant. At the study site, only the dispenser(s)/administrator(s) are unblinded.

3. ENDPOINTS AND BASELINE VARIABLES: DEFINITIONS AND CONVENTIONS

3.1. Primary Endpoints

3.1.1. Safety Endpoints (Maternal Participants)

- Prompted local reactions (redness, swelling, and pain at the injection site) for up to 7 days following each dose in each vaccine group
- Prompted systemic events (fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain) for up to 7 days following each dose in each vaccine group
- AEs from Dose 1 through 1 month after Dose 2
- SAEs from Dose 1 through 1 month after delivery

3.1.1.1. Local Reactions

The local reactions assessed and reported in the e-diary are redness, swelling, and pain at the injection site, from Day 1 through Day 7 after each dose, where Day 1 is the day of each dose. Maternal participants originally randomized to placebo who subsequently receive BNT162b2 1 month following delivery will not complete a reactogenicity e-diary after receiving BNT162b2.

This section describes derivations with details for the assessment of local reactions: presence, severity level, duration, and onset day.

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Presence or Absence

For each local reaction and any local reaction on any day, Table 3 explains the algorithm to derive the presence of a reaction (yes or no) during the interval from Day 1 through Day 7, where Day 1 is the day of each dose.

Table 3. Derived Variables for Presence of Each and Any Local Reaction Within 7 Days for Each Dose

Variable	Yes (1)	No (0)
Presence of each local reaction.	Participant reports the reaction as "yes" on any day (Day 1 through Day 7).	For each local reaction, participant reports the reaction as "no" on all 7 days (Day 1 through Day 7) or as a combination of "no" and missing on all 7 days (Day 1 through Day 7).
Presence of any local reaction.	Participant reports any local reaction as "yes" on any day (Day 1 through Day 7).	For all 3 local reactions, participant reports "no" on all 7 days (Day 1 through Day 7) or as a combination of "no" and missing on all 7 days (Day 1 through Day 7).

Note: Missing e-diary data will not be imputed. Participants with no e-diary data reported will not be included in the e-diary summaries.

Severity and Maximum Severity

Redness and swelling will be measured and recorded in measuring device units (range: 1 to 21) and then categorized during analysis as absent, mild, moderate, or severe based on the grading scale in Table 4. Measuring device units can be converted to centimeters according to the following formula: 1 measuring device unit = 0.5 cm. Pain at the injection site will be assessed by the participant as absent, mild, moderate, or severe according to the grading scale in Table 4.

Table 4. Local Reaction Grading Scale

	Mild (Grade 1)	Moderate (Grade 2)	Severe (Grade 3)	Potentially Life Threatening (Grade 4)
Pain at the injection site	Does not interfere with activity.	Interferes with activity.	Prevents daily activity.	Emergency room visit or hospitalization for severe pain.
Redness	>2.0 cm to 5.0 cm (5 to 10 measuring device units).	>5.0 cm to 10.0 cm (11 to 20 measuring device units).	>10 cm (≥21 measuring device units).	Necrosis or exfoliative dermatitis.
Swelling	>2.0 cm to 5.0 cm (5 to 10 measuring device units).	>5.0 cm to 10.0 cm (11 to 20 measuring device units).	>10 cm (≥21 measuring device units).	Necrosis.

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For each local reaction reported for each dose, the maximum severity grade will be derived for the e-diary collection period (Day 1 through Day 7, where Day 1 is the day of each dose) as follows:

> maximum severity grade = highest grade (maximum severity) within 7 days after vaccination (Day 1 through Day 7) among severity grades where the answers are neither "no" nor missing for at least 1 day during the interval from Day 1 through Day 7.

Duration (First to Last Day Reported)

For participants experiencing any local reactions (or those with a derived reaction as described in Table 4), the maximum duration (last day of reaction – first day of reaction + 1) will be derived for each study vaccination. Resolution of the reaction is the last day on which the reaction is recorded in the e-diary or the date the reaction ends if it is unresolved during the participant e-diary recording period (end date collected on the CRF), unless chronicity is established. If there is no known end date, the duration will be considered unknown and set to missing. However, if a reaction is ongoing at the time of a subsequent vaccination, the end date/day for the ongoing reaction would be the date/day that the next vaccine is administered, which will be used for the duration computation. Participants with no reported reaction have no duration.

Onset Day

The onset day of each local reaction will be derived. Onset day is defined as the first day after vaccination that a reaction is reported of any severity.

For the onset day of each local reaction, if participants report a change in severity of the local reaction, only the first day of reporting that specific local reaction will be counted.

3.1.1.2. Systemic Events (Systemic Event Symptoms and Fever)

The systemic events assessed and recorded in the e-diary are fever, vomiting, diarrhea, headache, fatigue/tiredness, chills, new or worsened muscle pain, and new or worsened joint pain from Day 1 through Day 7, where Day 1 is the day of each dose. The derivations for systemic events will be handled in a way similar to the handling of local reactions with respect to presence of event, severity level, duration, and onset day (see Section 3.1.1.1).

The symptoms will be assessed by the participant as absent, mild, moderate, or severe according to the grading scale in Table 5.

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Table 5. Systemic Event Grading Scale

	Mild (Grade 1)	Moderate (Grade 2)	Severe (Grade 3)	Potentially Life Threatening (Grade 4)
Vomiting	1-2 times in 24 hours.	>2 times in 24 hours.	Requires IV hydration.	Emergency room visit or hospitalization for hypotensive shock.
Diarrhea	2 to 3 loose stools in 24 hours.	4 to 5 loose stools in 24 hours.	6 or more loose stools in 24 hours.	Emergency room visit or hospitalization for severe diarrhea.
Headache	Does not interfere with activity.	Some interference with activity.	Prevents daily routine activity.	Emergency room visit or hospitalization for severe headache.
Fatigue/tiredness	Does not interfere with activity.	Some interference with activity.	Prevents daily routine activity.	Emergency room visit or hospitalization for severe fatigue.
Chills	Does not interfere with activity.	Some interference with activity.	Prevents daily routine activity.	Emergency room visit or hospitalization for severe chills.
New or worsened muscle pain	Does not interfere with activity.	Some interference with activity.	Prevents daily routine activity.	Emergency room visit or hospitalization for severe new or worsened muscle pain.
New or worsened joint pain	Does not interfere with activity.	Some interference with activity.	Prevents daily routine activity.	Emergency room visit or hospitalization for severe new or worsened joint pain.

Abbreviation: IV = intravenous.

Oral temperature will be collected in the evening, daily, for 7 days following each dose (Days 1 through 7, where Day 1 is the day of each dose) and at any time during the 7 days that fever is suspected. Fever is defined as an oral temperature of ≥38.0°C (100.4°F). The highest temperature for each day will be recorded in the e-diary.

Temperature will be measured and recorded to 1 decimal place. Temperatures recorded in degrees Fahrenheit will be programmatically converted to degrees Celsius for reporting. Temperatures <35.0°C and >42.0°C will be excluded from the analysis. Fever will be grouped into ranges for the analysis according to Table 6 below.

Table 6. Scale for Fever

≥38.0°C to 38.4°C (100.4°F to 101.1°F)
>38.4°C to 38.9°C (101.2°F to 102.0°F)
>38.9°C to 40.0°C (102.1°F to 104.0°F)
>40.0°C (>104.0°F)

Note: Fever is defined as temperature ≥38.0°C (≥100.4°F).

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3.1.1.3. Use of Antipyretic Medication

The use of antipyretic medication is also recorded in the e-diary from Day 1 through Day 7, where Day 1 is the day of each dose. For the use of antipyretic medication from Day 1 through Day 7 after each dose, the following endpoints and variables will be derived for analysis following the same rules as for local reactions (see Section 3.1.1.1), where applicable.

- Presence (yes or no) of use of antipyretic medication on each day (Day 1 through Day 7)
- Presence (yes or no) of use of antipyretic medication on any day (Day 1 through Day 7)
- Duration (first to last day reported) of use of antipyretic medication
- Onset day of use of antipyretic medication

The use of antipyretic medication will be summarized and included in the systemic event summary tables but will not be considered a systemic event.

3.1.1.4. Adverse Events

For maternal participants, AEs will be assessed from the time of informed consent through 1 month after Dose 2. Additionally, for those maternal participants who originally received placebo and subsequently receive BNT162b2, AEs will be collected from the first dose through 1 month after the second dose of BNT162b2. AEs will be categorized according to MedDRA terms.

The primary safety endpoint "AEs from Dose 1 through 1 month after Dose 2" and other AE endpoints will be summarized by SOC and PT at the participant level.

This primary safety endpoint will be supported by summaries and listings of related AEs, severe AEs, and immediate AEs (within the first 30 minutes after each dose). AE reporting will be based on the specific reporting period. Missing AE start dates will be imputed following the Pfizer data standard rules as described in Section 5.3.

3.1.1.5. Serious Adverse Events

SAEs will be collected from the time the participant provides informed consent to 6 months after delivery for maternal participants originally randomized to BNT162b2 or through 1 month after the second dose of BNT162b2 for maternal participants who originally received placebo and subsequently receive BNT162b2. SAEs will be categorized according to MedDRA terms.

The primary safety endpoint "SAEs from Dose 1 through 1 month after delivery" will be summarized by SOC and PT at the participant level.

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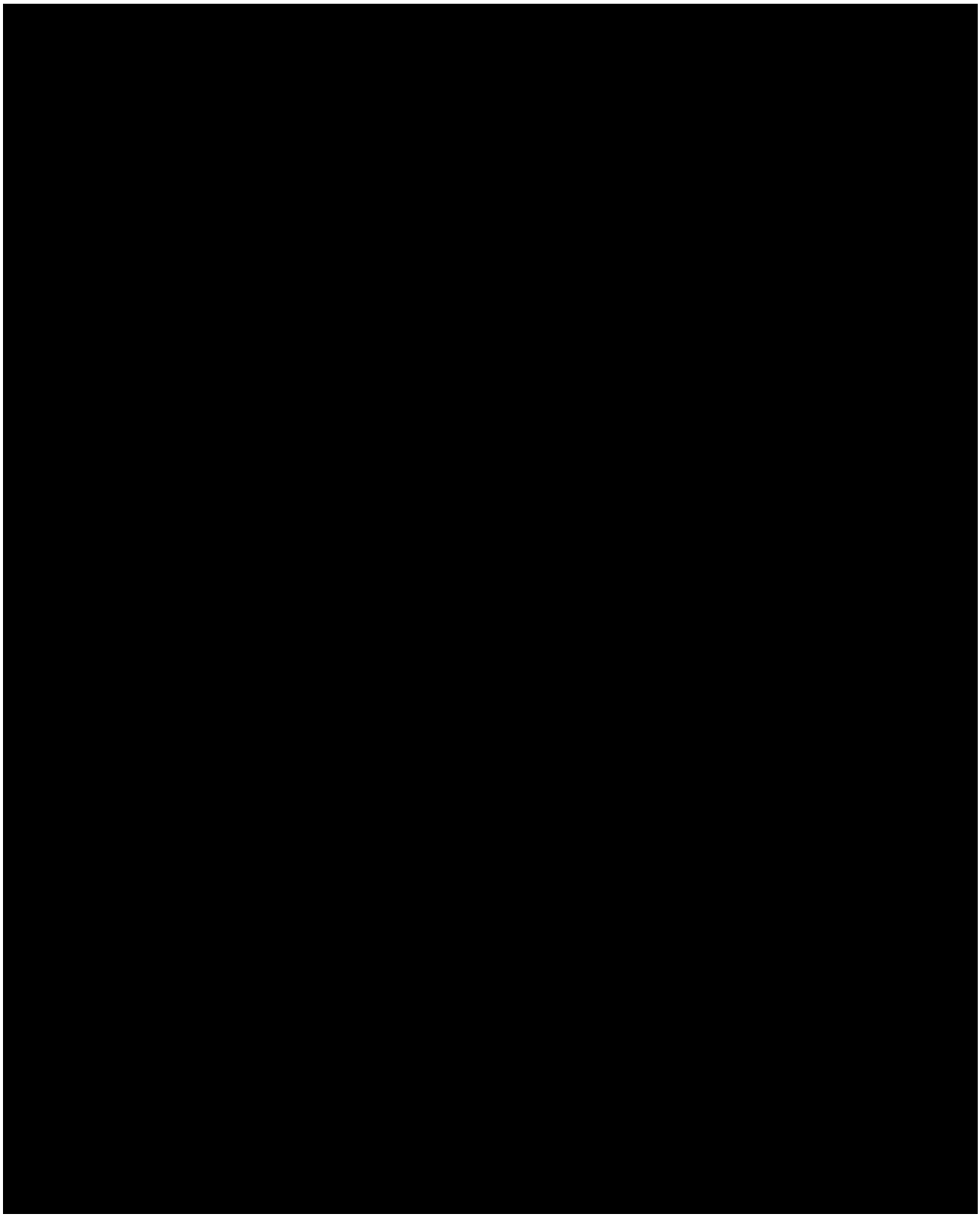

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3.2.3. Safety Endpoints (Infant Participants)

- Specific birth outcomes
- AEs from birth through 1 month of age
- SAEs and AESIs (major congenital anomalies, developmental delay) through 6 months of age

[redacted]

3.3. Exploratory Endpoints

3.3.1. COVID-19 Incidence Rate (Maternal Participants)

- COVID-19 incidence per 1000 person-years of follow-up based on central laboratory or locally confirmed NAAT from 7 days after the second dose of BNT162b2 in participants who received BNT162b2 at initial randomization

3.3.2. Asymptomatic SARS-CoV-2 Infection (Maternal Participants)

- Incidence of asymptomatic SARS-CoV-2 infection per 1000 person-years of follow-up based on N-binding antibody seroconversion in maternal participants who received BNT162b2 at initial randomization and without evidence of prior SARS-CoV-2 infection

[redacted]

These endpoints will be summarized by COVID-19 and SARS-CoV-2 infection status:

- Confirmed COVID-19
- Confirmed severe COVID-19
- SARS-CoV-2 infection but no confirmed COVID-19

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3.3.6. Safety Endpoints by Breastfeeding Status (Infant Participants)

- AEs from birth through 1 month of age by breastfeeding status
- SAEs and AESIs (major congenital anomalies, developmental delay) through 6 months of age by breastfeeding status

3.3.7. COVID-19 Incidence Rate (Infant Participants)

- COVID-19 incidence per 1000 person-years of follow-up based on central laboratory or locally confirmed NAAT

3.3.8. MIS-C Cases (Infant Participants)

- MIS-C incidence per 1000 person-years of follow-up

3.4. Other Endpoints

All safety, immunogenicity, and efficacy endpoints described above will be summarized separately for participants with confirmed stable HIV infection.

3.5. Baseline and Other Variables

For maternal participants, measurements or samples collected prior to Dose 1 are considered the baseline data for the assessments. For infant participants, measurements or samples collected at birth are considered the starting time points for the assessments.

3.5.1. Demographics, Medical History, and Physical Examination

For both maternal and infant participants, the demographic variables are date of birth, sex (male or female, for infant participants only), race (black/African American, American Indian or Alaskan native, Asian, Native Hawaiian or other Pacific Islander, white), and ethnicity (Hispanic/Latino, non-Hispanic/non-Latino, not reported). In cases where more than 1 category is selected for race, the category "multiracial" will be created and used for analysis.

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The maternal participants also have the demographic variable age at Dose 1 (in years), which is derived based on the maternal participant's birthday. For example, if the vaccination day is 1 day before the maternal participant's 19th birthday, the maternal participant is considered to be 18 years old. For maternal participants who were randomized but not vaccinated, the randomization date will be used in place of the date of vaccination at Dose 1 for the age calculation. If the randomization date is also missing, then the informed consent date will be used for the age calculation. The infant participants also have the demographic variable gestational age at birth (in weeks).

Medical history for maternal participants will be categorized according to MedDRA. Comorbidities that increase the risk for severe COVID-19 illness will be categorized based on medical history terms.

If the clinical assessment indicates that a physical examination is necessary to comprehensively evaluate the maternal participant at Visit 1 and the infant participant at birth, a physical examination will be performed and any findings recorded in the source documents and, if clinically significant, it will be recorded on the medical history CRF for maternal participants and on the AE CRF for infant participants.

[redacted]

3.5.3. Prior/Concomitant Vaccines and Concomitant Medications

The following concomitant medications and vaccinations will be recorded in the CRF for maternal participants:

- All vaccinations received from 14 days prior to study enrollment until the 6-month follow-up visit for participants originally randomized to receive BNT162b2.
- Any medication taken to treat AEs from the signing of the ICD through the final study visit will be recorded in the CRF.
- Prohibited medications listed in the protocol, Section 6.5.1, will be recorded in the CRF to include start and stop dates, name of the medication, dose, unit, route, and frequency from the signing of the ICD through the final study visit.

The following concomitant medications will be recorded in the CRF for infant participants:

- Any medications taken to treat AEs and/or SAEs from birth (Visit 1) through the final study visit.

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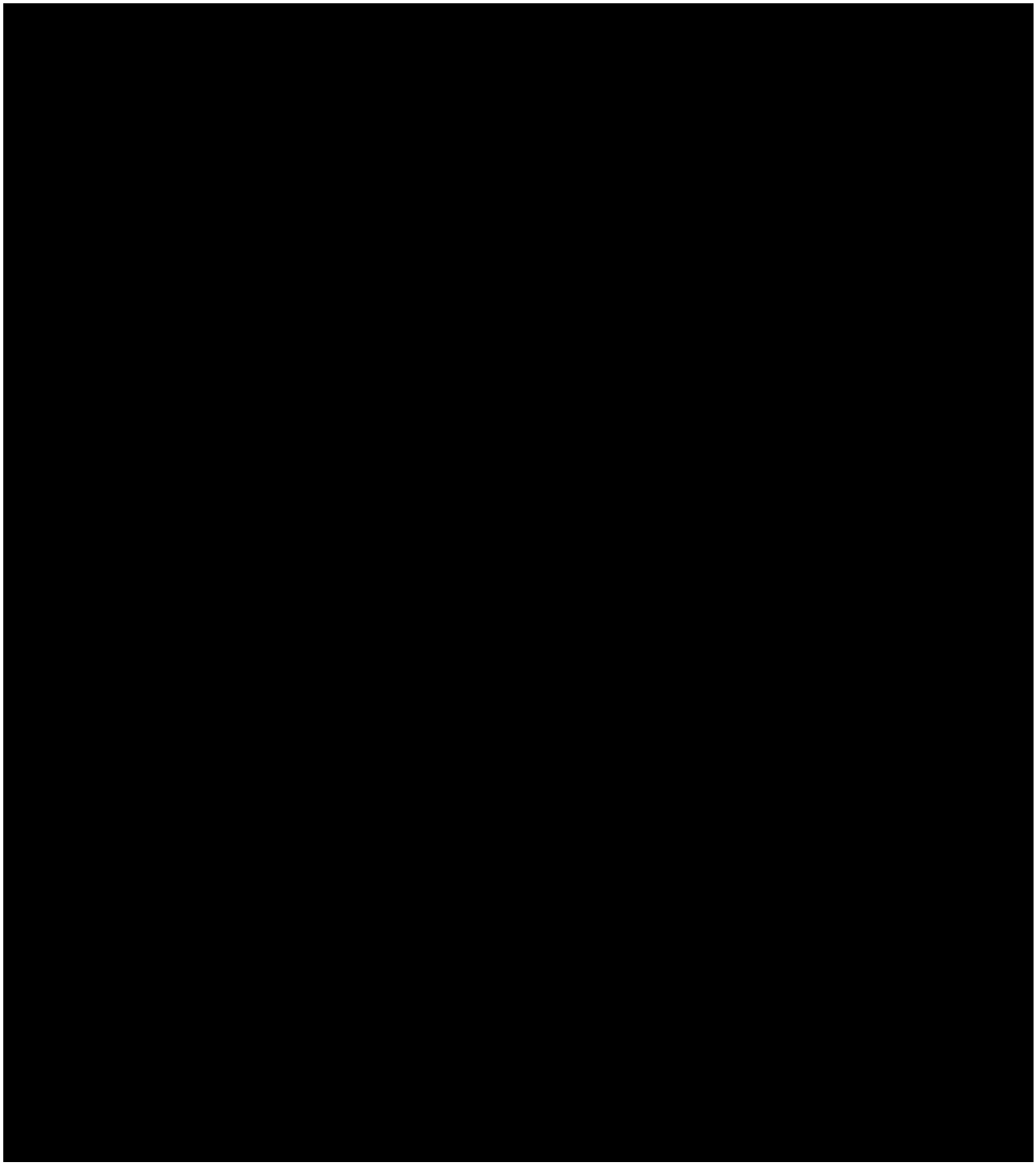
Prior and concomitant vaccines and concomitant medications will be coded using the WHO Drug Dictionary.

3.6. Safety Endpoints

Local reactions, systemic events, AEs, and SAEs have been described above in the primary safety endpoints. Specific birth outcomes and AESIs (major congenital anomalies, developmental delay) have been described above in the secondary safety endpoints.



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The important protocol deviations will be determined by the medical monitor. An important protocol deviation is a protocol deviation that, in the opinion of the sponsor's clinician, would materially affect assessment of immunogenicity/efficacy, eg, participant receipt of a prohibited vaccine or medication that might affect immune response or a medication error with suspected decrease in potency of the vaccine. The sponsor's clinician will identify those participants with important protocol deviations that result in exclusion from analysis populations before any unblinded analysis is carried out.

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The safety analyses will be based on the safety population. Participants will be summarized by vaccine group according to the study interventions the maternal participants actually received.

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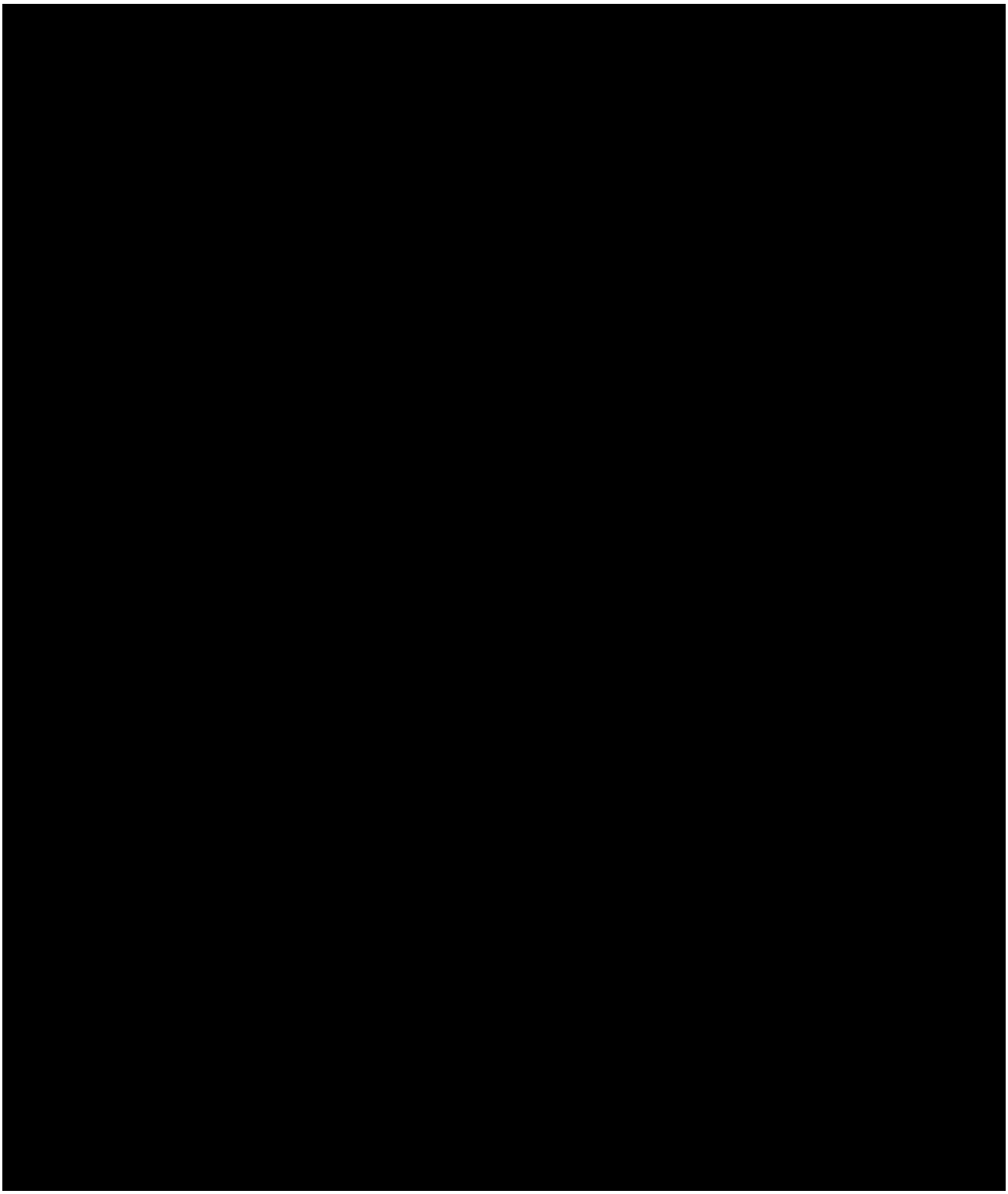

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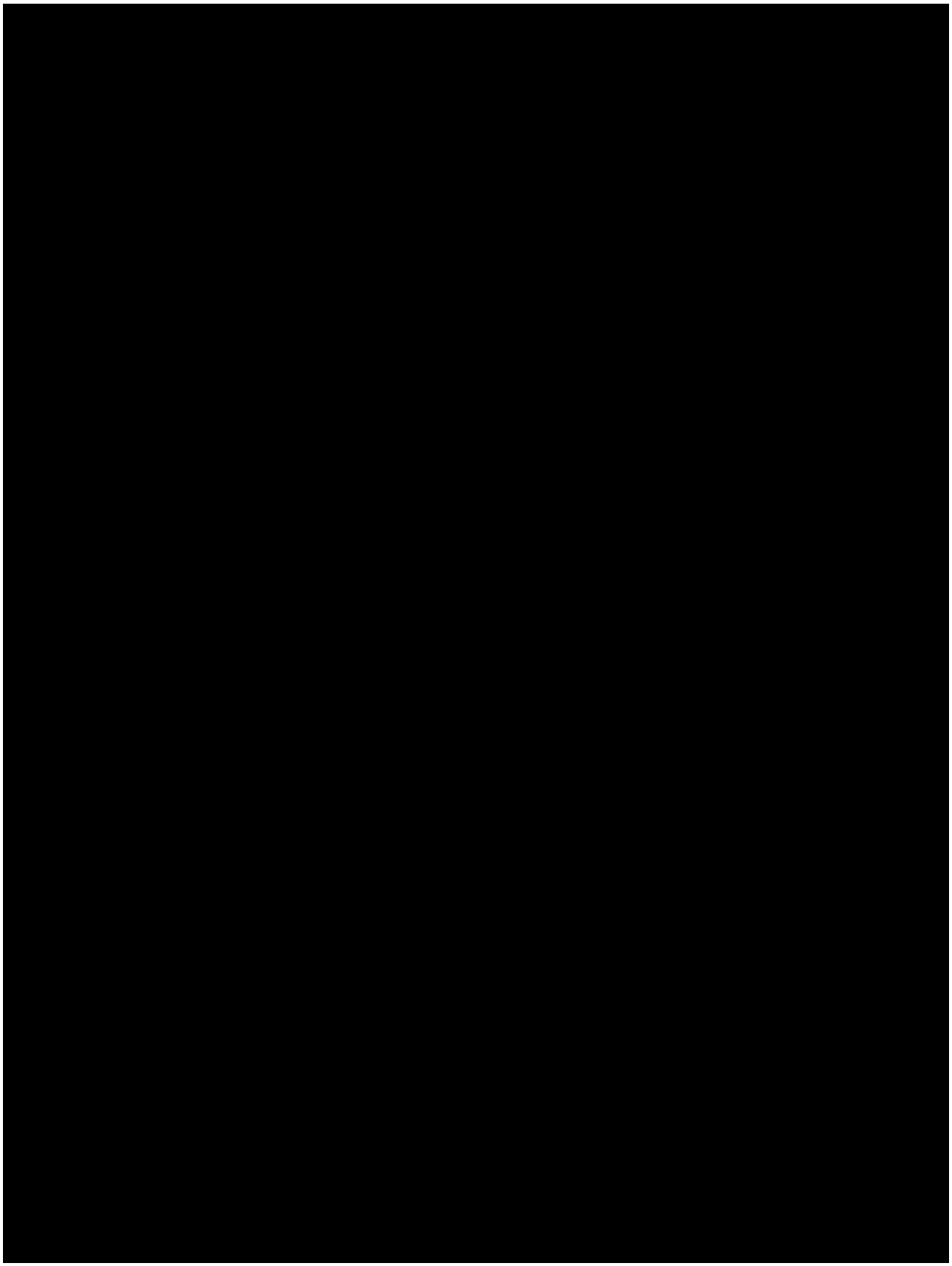

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6. ANALYSES AND SUMMARIES

6.1. Primary Endpoints

6.1.1. Safety Endpoints (Maternal Participants)

6.1.1.1. Local Reactions

6.1.1.1.1. Main Analysis

- Estimand: The percentage of maternal participants reporting local reactions (redness, swelling, and pain at the injection site) within 7 days after each dose (Section 2.1).
- Analysis set: Safety population (maternal) (Section 4).
- Analysis time point: Within 7 days after each dose.
- Analysis methodology: Descriptive statistics (Section 5.2.1).
- Intercurrent events and missing data: The participants without any e-diary data throughout the 7 days after vaccination will be excluded from the analysis at that particular vaccination; missing values will not be imputed.
- Reporting results: Descriptive statistics for each and any local reaction after each dose in each vaccine group will be presented by maximum severity and cumulatively across severity levels. Confirmed e-diary errors will be excluded from the analysis. Descriptive summary statistics will include counts and percentages of participants with the indicated endpoint and the associated 2-sided Clopper-Pearson 95% CIs.

6.1.1.1.2. Supplementary Analyses

To support the assessment of local reactions, the following endpoints (as defined in Section 3.1.1.1) will be summarized with the same analysis time point and analysis population as above, and appropriate analysis methodology and reporting results. Confirmed e-diary errors will be excluded from these analyses.

- Duration (days) of each local reaction after each dose.
- Onset day of each local reaction after each dose.

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These continuous endpoints will be summarized by displaying n, mean, median, standard deviation, minimum, and maximum for each vaccine group.

In addition, the proportions of participants reporting each prompted local reaction after any dose will be summarized by maximum severity level.

Figures:

Bar charts with the proportions of participants for each local reaction throughout 7 days will be plotted for each vaccine group. The bars will be divided into severity categories to highlight the proportions of participants by maximum severity.

6.1.1.2. Systemic Events

6.1.1.2.1. Main Analysis

- Estimand: The percentage of maternal participants reporting systemic events (fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain) within 7 days after each dose (Section 2.1).
- Analysis set: Safety population (maternal) (Section 4).
- Analysis time point: Within 7 days after each dose.
- Analysis methodology: Descriptive statistics (Section 5.2.1).
- Intercurrent events and missing data: The participants without any e-diary data throughout the 7 days after vaccination will be excluded from the analysis at that particular vaccination; missing values will not be imputed.
- Reporting results: Descriptive statistics for each systemic event after each dose in each vaccine group will be presented by maximum severity and cumulatively across severity levels. Descriptive summary statistics will include counts and percentages of participants with the indicated endpoint and the associated 2-sided Clopper-Pearson 95% CIs.

6.1.1.2.2. Supplementary Analyses

The following endpoints for assessment of systemic events will be summarized similarly to the assessment of local reactions:

- Duration of each systemic event after each dose.
- Onset day of each systemic event after each dose.

These continuous endpoints will be summarized by displaying n, mean, median, standard deviation, minimum, and maximum for each vaccine group.

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The use of antipyretic medication (see Section 3.1.1.3) will be summarized similarly to systemic events, except that there is no severity level associated with the use of antipyretic medication.

In addition, the proportions of participants reporting each prompted systemic event after any dose will be summarized by maximum severity level.

Figures:

Bar charts with the proportions of participants for each systemic event throughout 7 days after each dose will be plotted for each vaccine group. The bars will be divided into severity categories to highlight the proportions of participants by severity.

6.1.1.3. Adverse Events

6.1.1.3.1. Main Analysis

- Estimand: The percentage of maternal participants reporting AEs from Dose 1 through 1 month after Dose 2 (Section 2.1).
- Analysis set: Safety population (maternal) (Section 4).
- Analysis time point: Dose 1 through 1 month after Dose 2.
- Analysis methodology: Descriptive statistics and 3-tiered approach (Section 5.2.1).
- Intercurrent events and missing data: Missing data will not be imputed except for partial AE start dates (Section 5.3).
- Reporting results: Counts, percentages, and the associated Clopper-Pearson 95% CIs of AEs from Dose 1 through 1 month after Dose 2 will be provided for each vaccine group. For both Tier 1 (if any) and Tier 2 events, the between-group difference in proportions and the associated 95% CI based on the Miettinen and Nurminen[2] method will be provided. For Tier 1 events (if any), the asymptotic p-values for the difference in proportions will be provided. For Tier 3 events, counts and percentages will be provided for each vaccine group.

6.1.1.3.2. Supplementary Analyses

Related AEs, severe AEs, and immediate AEs (within the first 30 minutes after each dose) will also be summarized for each vaccine group. Immediate AEs (within the first 30 minutes after each dose) will also be summarized for each vaccine group if the number of immediate AEs is sufficiently large; otherwise, they will be listed only.

All AEs after informed consent and prior to the first vaccination will not be included in the analyses but will be listed.

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6.1.1.4. Serious Adverse Events

6.1.1.4.1. Main Analyses

- Estimand: The percentage of maternal participants reporting SAEs from Dose 1 through 1 month after delivery (Section 2.1).
- Analysis set: Safety population (maternal) (Section 4).
- Analysis time point: Dose 1 through 1 month after delivery.
- Analysis methodology: Descriptive statistics (Section 5.2.1).
- Intercurrent events and missing data: Missing data will not be imputed except for partial SAE start dates (Section 5.3).
- Reporting results: Counts, percentages, and the associated Clopper-Pearson 95% CIs of SAEs from Dose 1 through 1 month after delivery will be provided for each vaccine group.

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6.2. Secondary Endpo nts

6.2.1. Vaccine Efficacy Endpoints

6.2.1.1. COVID-19 Incidence per 1000 Person-Years of Blinded Follow-Up Based on Central Laboratory or Locally Confirmed NAAT

6.2.1.1.1. Main Analyses

- Estimands:
  - 100 × (1 – IRR) [ratio of confirmed COVID-19 illness from 7 days after Dose 2 through 1 month after delivery per 1000 person-years of blinded follow-up in maternal participants without evidence of prior SARS-CoV-2 infection (prior to 7 days after receipt of Dose 2) for the active vaccine group to the placebo group (Section 2.1)].
  - 100 × (1 – IRR) [ratio of confirmed COVID-19 illness from 7 days after Dose 2 through 1 month after delivery per 1000 person-years of blinded follow-up in maternal participants with and without evidence of prior SARS-CoV-2 infection (prior to 7 days after receipt of Dose 2) for the active vaccine group to the placebo group (Section 2.1)].
- Analysis set: Evaluable efficacy population (maternal), all-available efficacy population (maternal) (Section 4).
- Analysis time point: End of the surveillance period (blinded follow-up).

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- Analysis methodology: Assessment of VE will be performed for confirmed COVID-19 illness (using the first definition in Appendix 2) from 7 days after Dose 2 through 1 month after delivery, and will be estimated by 100 × (1 – IRR), where IRR is the calculated ratio of confirmed COVID-19 illness per 1000 person-years of blinded follow-up in the active vaccine group to the corresponding illness rate in the placebo group (see Appendix 2 for details on the derivation of IRR and VE).

- Intercurrent events and missing data: Missing data (symptom is present without laboratory testing data) will not be imputed.

- Reporting results: VE and the associated 2-sided 95% CI derived using the Clopper-Pearson method adjusted for surveillance time will be provided.

6.2.1.1.2. Supplemental Analyses

The same assessment of VE and the associated 2-sided 95% CI derived using the Clopper-Pearson method adjusted for surveillance time will be performed for confirmed COVID-19 illness based on CDC-defined symptoms (using the second definition in Appendix 2).

All COVID-19 cases after Dose 1 may be analyzed using the Dose 1 all-available efficacy population. Kaplan-Meier cumulative incidence curves may be provided.

6.2.1.2. Incidence of Asymptomatic Infection of SARS-CoV-2 Based on N-Binding Antibody Seroconversion

6.2.1.2.1. Main Analyses

- Estimand:

  - 100 × (1 – IRR) [ratio of incidence of asymptomatic infection of SARS-CoV-2 through 1 month after delivery in evaluable maternal participants without evidence of prior SARS-CoV-2 infection for the active vaccine group to the placebo group (Section 2.1)].

- Analysis set: Evaluable efficacy population (maternal), all-available efficacy population (maternal) (Section 4).

- Analysis time point: End of the surveillance period.

- Analysis methodology: Assessment of VE will be performed for the incidence of asymptomatic infection of SARS-CoV-2 through 1 month after delivery, and will be estimated by 100 × (1 - IRR), where IRR is the calculated ratio of incidence of asymptomatic infection per 1000 person-years of follow-up in the active vaccine group to the corresponding infection rate in the placebo group through 1 month after delivery (see Appendix 2 for details on the definition of asymptomatic infection and the derivation of IRR and VE).

- Intercurrent events and missing data: Missing N-binding data will not be imputed.

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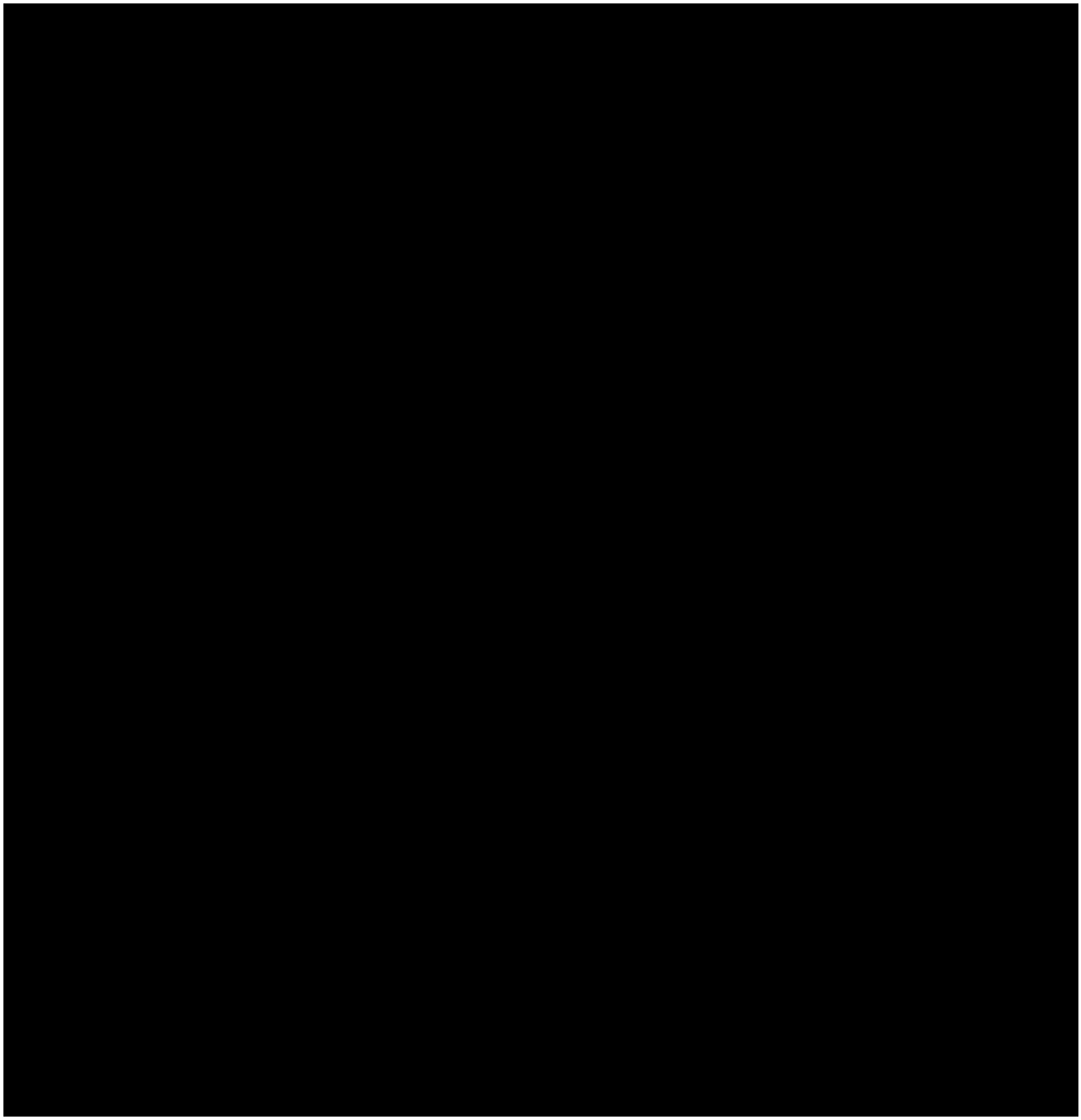
- Reporting results: VE and the associated 2-sided 95% CI derived using the Clopper-Pearson method adjusted for surveillance time will be provided.



6.2.3. Safety Endpoints (Infant Participants)

6.2.3.1. Specific Birth Outcomes

6.2.3.1.1. Main Analyses

- Estimand: The percentage of infant participants reporting specific birth outcomes (Section 2.1).

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- Analysis set: Safety population (infant) (Section 4).
- Analysis time point: Birth.
- Analysis methodology: Descriptive statistics (Section 5.2.1).
- Intercurrent events and missing data: Missing data will not be imputed.
- Reporting results: Counts, percentages, and the associated Clopper-Pearson 95% CIs for infant participants with specific birth outcomes will be provided for each vaccine group (according to the study intervention the maternal participants received).

6.2.3.2. Adverse Events

6.2.3.2.1. Main Analyses

- Estimand: The percentage of infant participants reporting AEs from birth through 1 month of age (Section 2.1).
- Analysis set: Safety population (infant) (Section 4).
- Analysis time point: Birth through 1 month of age.
- Analysis methodology: Descriptive statistics and 3-tiered approach (Section 5.2.1).
- Intercurrent events and missing data: Missing data will not be imputed except for partial AE start dates (Section 5.3).
- Reporting results: Counts, percentages, and the associated Clopper-Pearson 95% CIs for infant participants with AEs from birth through 1 month of age will be provided for each vaccine group (according to the study intervention the maternal participants received). For both Tier 1 (if any) and Tier 2 events, the between-group difference in proportions and the associated 95% CI based on the Miettinen and Nurminen[2] method will be provided. For Tier 1 events (if any), the asymptotic p-values for the difference in proportions will be provided. For Tier 3 events, counts and percentages will be provided for each vaccine group (according to the study intervention the maternal participants received).

6.2.3.3. Serious Adverse Events and AESIs

6.2.3.3.1. Main Analyses

- Estimand: The percentage of infant participants reporting SAEs and AESIs (major congenital anomalies, developmental delay) from birth through 6 months of age (Section 2.1).
- Analysis set: Safety population (infant) (Section 4).
- Analysis time point: Birth through 6 months of age.

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- Analysis methodology: Descriptive statistics (Section 5.2.1).
- Intercurrent events and missing data: Missing data will not be imputed except for partial SAE start dates (Section 5.3).
- Reporting results: Counts, percentages, and the associated Clopper-Pearson 95% CIs for infant participants with SAEs and AESIs from birth through 6 months of age will be provided for each vaccine group (according to the study intervention the maternal participants received).

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6.3. Exploratory Endpoints

6.3.1. COVID-19 Incidence Rate (Maternal Participants)

6.3.1.1. COVID-19 Incidence per 1000 Person-Years of Follow-Up Based on Central Laboratory or Locally Confirmed NAAT

6.3.1.1.1. Main Analyses

- Estimands:
  - COVID-19 incidence based on central laboratory or locally confirmed NAAT from 7 days after the second dose of BNT162b2 per 1000 person-years of follow-up in maternal participants who received BNT162b2 at initial randomization (Section 2.1).
- Analysis set: Evaluable efficacy population (maternal), all-available efficacy population (maternal) (Section 4).
- Analysis time point: End of the surveillance period.
- Analysis methodology: Incidence rate (per 1000 person-years of follow-up) and 2-sided 95% CI for confirmed COVID-19 illness (using the first definition in Appendix 2) from 7 days after the second dose of BNT162b2 for participants who received BNT162b2 at initial randomization.
- Intercurrent events and missing data: Missing data will not be imputed.
- Reporting results: Incidence rates and the associated 2-sided 95% CIs will be provided.

6.3.1.1.2. Supplemental Analyses

The same analyses will be performed for confirmed COVID-19 illness based on CDC-defined symptoms (using the second definition in Appendix 2).

6.3.2. Asymptomatic SARS-CoV-2 Infection (Maternal Participants)

6.3.2.1. Incidence of Asymptomatic SARS-CoV-2 Infection per 1000 Person-Years of Follow-Up Based on N-Binding Antibody Seroconversion

6.3.2.1.1. Main Analyses

- Estimand:
  - Incidence of asymptomatic SARS-CoV-2 infection based on the N-binding antibody seroconversion through 6 months after delivery per 1000 person-years of follow-up in maternal participants who received BNT162b2 at initial randomization and without evidence of prior SARS-CoV-2 infection (Section 2.1).
- Analysis set: Evaluable efficacy population (maternal), all-available efficacy population (maternal) (Section 4).

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- Analysis time point: End of the surveillance period.
- Analysis methodology: Incidence rate (per 1000 person-years of follow-up) and 2-sided 95% CI for asymptomatic SARS-CoV-2 infection based on the N-binding antibody seroconversion (see Appendix 2 for the definition) through 6 months after delivery for participants who received BNT162b2 at initial randomization and without evidence of prior SARS-CoV-2 infection.
- Intercurrent events and missing data: Missing data will not be imputed.
- Reporting results: Incidence rate and the associated 2-sided 95% CI will be provided.

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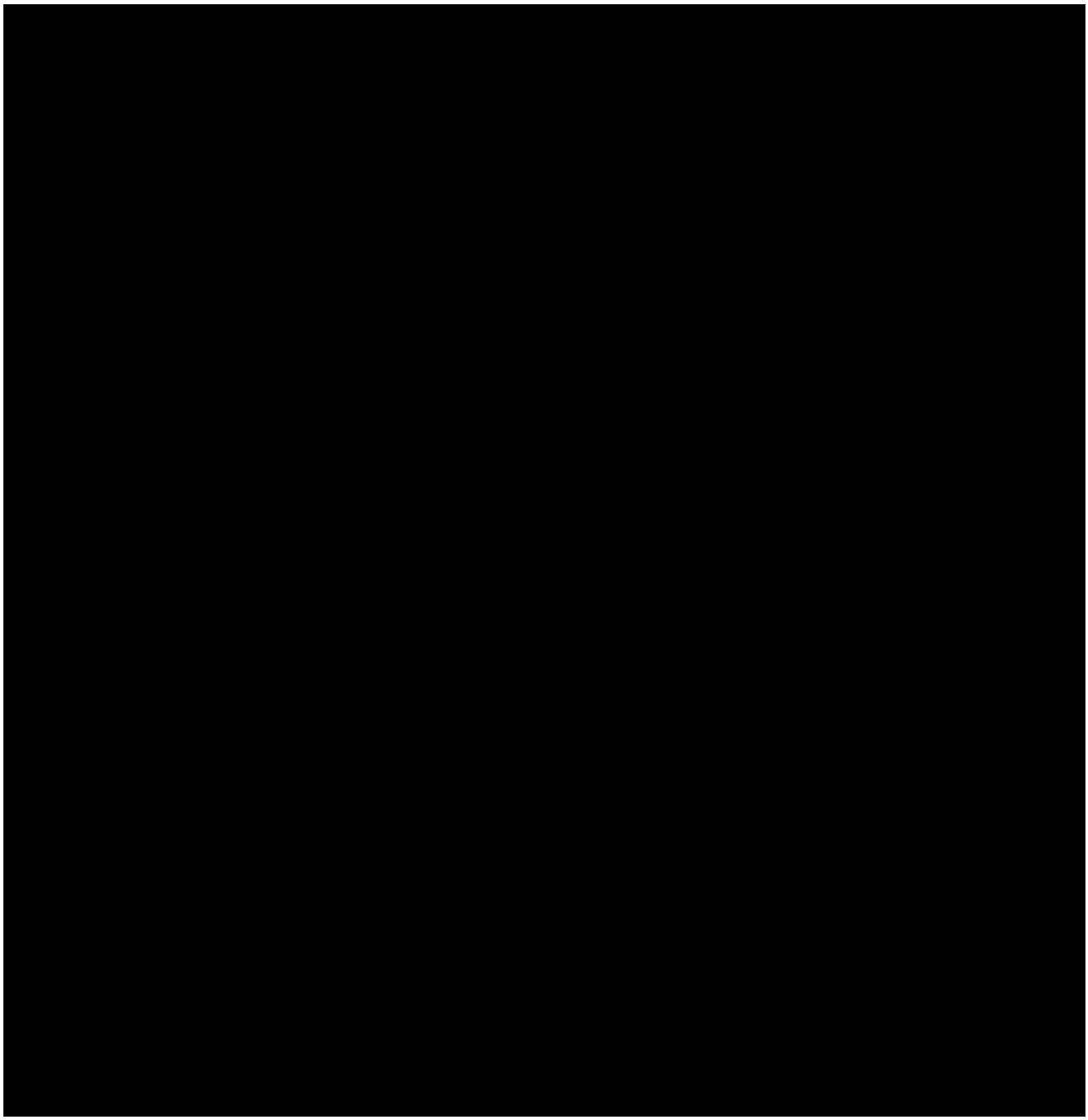
6.3.3.1.2. Supplemental Analyses

The same analyses will be performed in each subset of maternal participants with confirmed COVID-19 (using the second definition in Appendix 2), confirmed severe COVID-19 (using the second definition in Appendix 2), and SARS-CoV-2 infection without confirmed COVID-19 (using the second definition in Appendix 2).



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6.3.6. Safety Endpoints by Breastfeeding Status (Infant Participants)

6.3.6.1. Adverse Events

6.3.6.1.1. Main Analyses

- Estimand: The percentage of infant participants reporting AEs from birth through 1 month of age (Section 2.1).
- Analysis set: Safety population (infant) (Section 4) by breastfeeding status.
- Analysis time point: Birth through 1 month of age.
- Analysis methodology: Descriptive statistics (Section 5.2.1).
- Intercurrent events and missing data: Missing data will not be imputed except for partial AE start dates (Section 5.3).

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- Reporting results: Counts, percentages, and the associated Clopper-Pearson 95% CIs for infant participants with AEs from birth through 1 month of age will be provided for each vaccine group (according to the study intervention the maternal participants received).

6.3.6.2. Serious Adverse Events and AESIs

6.3.6.2.1. Main Analyses

- Estimand: The percentage of infant participants reporting SAEs and AESIs (major congenital anomalies, developmental delay) from birth through 6 months of age (Section 2.1).
- Analysis set: Safety population (infant) (Section 4) by breastfeeding status.
- Analysis time point: Birth through 6 months of age.
- Analysis methodology: Descriptive statistics (Section 5.2.1).
- Intercurrent events and missing data: Missing data will not be imputed except for partial SAE start dates (Section 5.3).
- Reporting results: Counts, percentages, and the associated Clopper-Pearson 95% CIs for infant participants with SAEs and AESIs from birth through 6 months of age will be provided for each vaccine group (according to the study intervention the maternal participants received).

6.3.7. COVID-19 Incidence Rate (Infant Participants)

6.3.7.1. COVID-19 Incidence per 1000 Person-Years of Follow-Up Based on Central Laboratory or Locally Confirmed NAAT

6.3.7.1.1. Main Analyses

- Estimand:
  - COVID-19 incidence based on central laboratory or locally confirmed NAAT per 1000 person-years of follow-up in infants born to maternal participants from each vaccine group (Section 2.1).
- Analysis set: All-available efficacy population (infant) (Section 4).
- Analysis time point: End of the surveillance period.
- Analysis methodology: Incidence rate (per 1000 person-years of follow-up) and 2-sided 95% CI for confirmed COVID-19 illness (using the first definition in Appendix 2) for infants born to maternal participants from each vaccine group.
- Intercurrent events and missing data: Missing data will not be imputed.

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- Reporting results: Counts, incidence of COVID-19 per 1000 person-years of follow-up, and the associated 2-sided 95% CIs will be provided for each vaccine group (according to the study intervention the maternal participants randomized).

6.3.7.1.2. Supplemental Analyses

The same analyses will be performed for confirmed COVID-19 illness (using the second definition in Appendix 2).

6.3.8. MIS-C Cases (Infant Participants)

6.3.8.1. MIS-C Incidence per 1000 Person-Years of Follow-Up

6.3.8.1.1. Main Analyses

- Estimand:
  - MIS-C incidence per 1000 person-years of follow-up in infants born to maternal participants from each vaccine group (Section 2.1).
- Analysis set: All-available efficacy population (infant) (Section 4).
- Analysis time point: End of the surveillance period.
- Analysis methodology: Incidence rate (per 1000 person-years of follow-up) and 2-sided 95% CI for confirmed MIS-C cases (see Appendix 2 for the definition) for infants born to maternal participants from each vaccine group.
- Intercurrent events and missing data: Missing data will not be imputed.
- Reporting results: Counts, incidence of MIS-C per 1000 person-years of follow-up, and the associated 2-sided 95% CIs will be provided for each vaccine group (according to the study intervention the maternal participants randomized).

6.4. Other Endpoints

The safety data and immunogenicity results for individuals with confirmed stable HIV disease will be summarized descriptively. Furthermore, VE may be assessed if there is a sufficient number of COVID-19 cases in this group of participants.

For maternal participants, the AEs, including SAEs, reported in the open-label follow-up period will be summarized separately from those reported during the blinded follow-up period.

6.5. Subset Analysis

Subgroup analyses based on race and ethnicity will be performed on all primary safety and immunogenicity endpoints (as supplemental analyses).

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6.6. Baseline and Other Summaries and Analyses

6.6.1. Baseline Summaries

6.6.1.1. Demographic Characteristics

For maternal participants, demographic characteristics, including age at Dose 1, race, ethnicity, and classification of BMI, will be summarized for the safety population (maternal) for each vaccine group and overall.

For infant participants, demographic characteristics, including sex, race, ethnicity, and gestational age at birth, will be summarized for the safety population (infant) for each vaccine group and overall.

6.6.1.2. Medical History

For maternal participants, each reported medical history term will be mapped to a SOC and PT according to MedDRA. The number and percentage of vaccinated maternal participants having at least 1 diagnosis, overall and at each SOC and PT level, will be summarized by vaccine group for the safety population (maternal).

The number and proportion of maternal participants with comorbidities that increase the risk for severe COVID-19 illness will be summarized by each vaccine group.

6.6.2. Study Conduct and Participant Disposition

6.6.2.1. Participant Disposition

The number and percentage of randomized maternal participants and their infant participants will be included in the maternal and infant participant disposition summary, respectively.

For maternal participants, the numbers and percentages of participants who received vaccinations (Doses 1 and 2 for both vaccine groups, Doses 3 and 4 for the original placebo group), who completed the follow-up visits (1 month after Dose 2, at delivery, 1 month after delivery, 6 months after delivery for the original active group, 1 month after Dose 4 for the original placebo group), and who withdrew before each follow-up visit, along with the reasons for withdrawal, will be tabulated by vaccine group (according to randomized group assignment). The reasons for withdrawal will be those as specified in the database.

For infant participants, the number of participants who completed the study (6 months after birth) and who withdrew from the study, along with the reasons for withdrawal, will be tabulated by vaccine group (according to the study intervention the maternal participants randomized). The reasons for withdrawal will be those as specified in the database.

Participants excluded from each analysis population will also be summarized separately, along with the reasons for exclusion, by vaccine group.

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[redacted]

6.6.3 S udy Vaccination Exposure

6.6.3.1. Vaccination Timing and Administration

For each dose, the number and percentage of maternal participants randomized and receiving each study intervention within the protocol-specified time frame, as well as before and after the specified time frame, will be tabulated for each vaccine group and overall for all randomized maternal participants. The denominator for the percentages is the total number of randomized maternal participants in the given vaccine group or overall.

In addition, the relation of randomized vaccine to vaccine actually received will be presented as a cross tabulation of the vaccine actually received versus the randomized vaccine.

A listing of maternal participants showing the randomized vaccine and the vaccine actually received at each dose will be presented.

[redacted]

6.7. Safety Summaries and Analyses

Local reaction, systemic event, AE, and SAE summaries and analyses are described under Primary Safety Endpoints (Section 6.1.1).

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7. INTERIM ANALYSES

No formal interim analysis will be conducted for this study. Statistical analyses will be carried out when the final data for specified objectives are available while the study is ongoing. The timing of these planned analysis and reporting events is described in the section below.

7.1. Analysis Timing

Statistical analyses will be carried out when the following data are available:

- Immunogenicity data through 1 month after Dose 2 from all randomized maternal participants for assessment of SARS-CoV-2 neutralizing titers.
- Complete safety, immunogenicity, and efficacy analysis after complete data are available or at the end of the study.

Additional analyses may be conducted if required for regulatory purposes. All analyses conducted while the study is ongoing will be performed by an unblinded statistical team.

7.2. Data Monitoring Committee

This study will use an IRC, a DMC, and a group of internal case reviewers. The IRC is independent of the study team and includes only internal members. The DMC is independent of the study team and includes only external members. The IRC and DMC charters describe the roles of the IRC and DMC in more detail.

The DMC will be responsible for ongoing monitoring of the safety of participants in the study according to the charter. The recommendations made by the DMC to alter the conduct of the study will be forwarded to the appropriate Pfizer personnel for final decision. Pfizer will forward such decisions, which may include summaries of aggregate analyses of safety data, to regulatory authorities, as appropriate.

8. REFERENCES

1. Agresti A. Introduction: distributions and inference for categorical data. In: Agresti A, ed. Categorical data analysis. 2nd ed. Hoboken, NJ: John Wiley & Sons; 2002:1-35.

2. Miettinen O, Nurminen M. Comparative analysis of two rates. Stat Med. 1985;4(2):213-26.

3. Goldstein B, Giroir B, Randolph A; International Consensus Conference on Pediatric Sepsis. International pediatric sepsis consensus conference: definitions for sepsis and organ dysfunction in pediatrics. Pediatr Crit Care Med. 2005;6(1):2-8. DOI: 10.1097/01.PCC.0000149131.72248.E6.

4. Godfred-Cato S, Bryant B, Leung J, et al. COVID-19–associated multisystem inflammatory syndrome in children—United States, March–July 2020. MMWR Morb Mortal Wkly Rep. 2020;69(32):1074-80.

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9. APPENDICES

Appendix 1. List of Abbreviations

Abbreviation	Term
AE	adverse event
AESI	adverse event of special interest
ALT	alanine aminotransferase
ARDS	adult respiratory distress syndrome
ATC	Anatomic Therapeutic Chemical
BiPaP	bilevel positive airway pressure
BLQ	below the limit of quantitation
BMI	body mass index
BNP	brain natriuretic peptide
BP	blood pressure
CDC	Centers for Disease Control and Prevention (United States)
CI	confidence interval
COVID-19	coronavirus disease 2019
CPaP	continuous positive airway pressure
CRF	case report form
CRP	C-reactive protein
CVA	cerebrovascular accident
DBP	diastolic blood pressure
DMC	data monitoring committee
ECMO	extracorporeal membrane oxygenation
e-diary	electronic diary
ESR	erythrocyte sedimentation rate
FiO_2	fraction of inspired oxygen
GI	gastrointestinal
GM	geometric mean
GMC	geometric mean concentration
GMFR	geometric mean fold rise
GMR	geometric mean ratio
GMT	geometric mean titer
HIV	human immunodeficiency virus
HR	heart rate
ICD	informed consent document
ICU	intensive care unit
IgG	immunoglobulin G
IL-6	interleukin 6
IRC	internal review committee
IRR	illness rate ratio
IWR	interactive Web-based response
LDH	lactate dehydrogenase
LLOQ	lower limit of quantitation
LS	least squares
MedDRA	Medical Dictionary for Regulatory Activities
MIS-C	multisystem inflammatory syndrome in children

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Abbreviation	Term
mITT	modified intent-to-treat
N	SARS-CoV-2 nucleoprotein
N/A	not applicable
NAAT	nucleic acid amplification test
PaO_2	partial pressure of oxygen, arterial
PT	preferred term
RCDC	reverse cumulative distribution curve
RNA	ribonucleic acid
RR	respiratory rate
RT-PCR	reverse transcription–polymerase chain reaction
S	spike protein
SAE	serious adverse event
SAP	statistical analysis plan
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
SBP	systolic blood pressure
SOC	system organ class
SpO_2	oxygen saturation as measured by pulse oximetry
ULN	upper limit of normal
VE	vaccine efficacy
WHO	World Health Organization

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Appendix 2. IRR and VE Derivation

COVID-19 Case Definition

Maternal Participants

Two definitions of SARS-CoV-2–related cases, and SARS-CoV-2–related severe cases, will be considered (for both, the onset date of the case will be the date that symptoms were first experienced by the maternal participant; if new symptoms are reported within 4 days after resolution of all previous symptoms, they will be considered as part of a single illness):

Confirmed COVID-19, first definition: presence of at least 1 of the following symptoms and SARS-CoV-2 NAAT-positive during, or within 4 days before or after, the symptomatic period, either at the central laboratory or at a local testing facility (using an acceptable test):

- Fever;
- New or increased cough;
- New or increased shortness of breath;
- Chills;
- New or increased muscle pain;
- New loss of taste or smell;
- Sore throat;
- Diarrhea;
- Vomiting.

The second definition, which may be updated as more is learned about COVID-19, will include the following additional symptoms defined by the CDC (listed at https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html):

- Fatigue;
- Headache;
- Nasal congestion or runny nose;
- Nausea.

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Confirmed Severe COVID-19, first definition: confirmed COVID-19 and presence of at least 1 of the following:

- Clinical signs at rest indicative of severe systemic illness (RR ≥30 breaths/min, HR ≥125 beats/min, SpO_2 ≤93% on room air at sea level, or PaO_2/FiO_2 <300 mm Hg);
- Respiratory failure (defined as needing high-flow oxygen, noninvasive ventilation, mechanical ventilation, or ECMO);
- Evidence of shock (SBP <90 mm Hg, DBP <60 mm Hg, or requiring vasopressors);
- Significant acute renal, hepatic, or neurologic dysfunction*;
- Admission to an ICU;
- Death.

The second definition, which may be updated as more is learned about COVID-19, will include the following additional outcomes defined by the CDC (listed at https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html):

- Hospitalization;
- Admission to the ICU;
- Intubation or mechanical ventilation;
- Death.

Infant Participants

Two definitions of SARS-CoV-2–related cases, and SARS-CoV-2–related severe cases, will be considered (for both, the onset date of the case will be the date that symptoms were first experienced by the infant participant; if new symptoms are reported within 4 days after resolution of all previous symptoms, they will be considered as part of a single illness). Signs and symptoms of an acute respiratory illness will not be considered a potential COVID-19–related illness if they occur within the first 72 hours after birth.

Confirmed COVID-19, first definition: presence of at least 1 of the following symptoms and SARS-CoV-2 NAAT-positive during, or within 4 days before or after, the symptomatic period, either at the central laboratory or at a local testing facility (using an acceptable test):

- Fever;
- New or increased cough;
- New or increased shortness of breath;

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- Diarrhea;
- Vomiting.

The second definition, which may be updated as more is learned about COVID-19, will include the following additional symptoms defined by the CDC (listed at https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html) but does not trigger a potential COVID-19 illness visit unless, in the opinion of the principal investigator, it is deemed necessary:

- Nasal congestion or runny nose;
- Poor appetite or poor feeding;
- Abdominal pain (colic).

Confirmed Severe Infant COVID-19 definition: confirmed COVID-19 and presence of at least 1 of the following:

- Clinical signs at rest indicative of severe systemic illness:
  - RR (breaths/min): >50 from birth to 1 week of age, ≥40 from 1 week to 1 month of age, ≥34 from 1 month to 6 months of age;
  - HR (beats/min): >180;
  - SpO_2 ≤92% on room air or >50% FiO_2 to maintain ≥92%, or PaO_2/FiO_2 <300 mm Hg[3];
- Respiratory failure (defined as needing high-flow oxygen, including nasal CPaP/BiPaP, noninvasive ventilation, mechanical ventilation, or ECMO);
- Evidence of shock or cardiac failure:
  - SBP (mm Hg) (<5th percentile for age):
    - <65 from birth to 1 week of age, <75 from 1 week to 1 month of age, <100 from 1 month to 6 months of age;

OR

  - Requiring vasoactive drugs to maintain BP in the normal range;
- Significant acute renal failure: serum creatinine >2 times ULN for age or 2-fold increase in baseline creatinine;
- Significant GI/hepatic failure: total bilirubin >4 mg/dL or ALT 2 times ULN for age;

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- Significant neurologic dysfunction: Glasgow Coma Scale score <11 or acute change in mental status with a decrease in Glasgow Coma Scale score ≥3 points from abnormal baseline;
- Admission to an ICU;
- Death.

Confirmed Multisystem Inflammatory Syndrome in Children (MIS-C) definition[4]:
as per the CDC MIS-C case definition:

- An infant presenting with fever (≥38.0°C for ≥24 hours or report of subjective fever lasting ≥24 hours); AND
- Laboratory evidence of inflammation (based on local laboratory ranges) including, but not limited to, 1 or more of the following: an elevated CRP, ESR, fibrinogen, procalcitonin, D-dimer, ferritin, LDH, or IL-6, elevated neutrophils, reduced lymphocytes, and low albumin; AND
- Evidence of clinically severe illness requiring hospitalization (definition as noted above for severe disease), with multisystem (≥2) organ involvement:
    - Cardiac (eg, shock, elevated troponin, elevated BNP, abnormal echocardiogram, arrhythmia);
    - Renal (eg, acute kidney injury or renal failure);
    - Respiratory (eg, pneumonia, ARDS, pulmonary embolism);
    - Hematologic (eg, elevated D-dimers, thrombophilia, or thrombocytopenia);
    - GI/hepatic (eg, elevated bilirubin, elevated liver enzymes, or diarrhea);
    - Dermatologic (eg, rash, mucocutaneous lesions);
    - Neurological (eg, CVA, aseptic meningitis, encephalopathy); AND
- No alternative plausible diagnoses; AND
- Positive for current or recent SARS-CoV-2 infection by RT-PCR, serology, or antigen test; OR
- COVID-19 exposure within the 4 weeks prior to the onset of symptoms.

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The following are applicable for both maternal and infant participants:

The DMC may recommend modification of the definition of severe disease according to emerging information.

* A small group of blinded case reviewers (medically qualified Pfizer staff members) will review all potential COVID-19 illness events. If a NAAT-confirmed case in Phase 2/3 may be considered severe, or not, solely on the basis of these criteria, the blinded data will be reviewed by the case reviewers to assess whether the criterion is met; the majority opinion will prevail.

In addition, a serological definition will be used for participants without clinical presentation of COVID-19:

- Confirmed seroconversion to SARS-CoV-2 without confirmed COVID-19: a positive N-binding antibody result in a participant with a prior negative N-binding antibody result.

Surveillance Times

Fundamental to VE assessment is the surveillance, for each participant, for cases satisfying various endpoints that may occur during the trial. Endpoint and participant combinations where surveillance is applicable require identification of the start and the end of the surveillance period in order to determine the participant-level endpoint surveillance time. For all COVID-19 VE-related endpoints in this study, the start-of-surveillance times are summarized as follows:

Endpoint's Associated Participant-Level Population	Start-of-Surveillance Time
Evaluable efficacy (maternal)	Dose 2 + 7 days
Dose 2 all-available efficacy (maternal)	Dose 2 + 7 days
Dose 1 all-available efficacy (mITT) (maternal)	Dose 1

For all COVID-19 VE-related endpoints in this study, the end of a surveillance period for each participant is the earliest of the following events:

- When the first COVID-19 case occurs.
- When the participant's end of the study occurs (eg, because of withdrawal, death, or trial completion).
- When the participant has his or her first important protocol violation.
- When the participant is unblinded at 1 month after delivery.

For descriptive assessment of exploratory endpoints of COVID-19 incidence rate (maternal and infant), the surveillance period is defined the same way except that unblinding at 1 month after delivery will not be considered as the end of the surveillance period.

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Specific information regarding VE-related endpoint surveillance start and end times by endpoint will be provided in Analysis and Reporting Plan specification documents.

Once the COVID-19 cases and surveillance period have been identified, VE can be calculated as 100 × (1 – IRR), where IRR is the ratio of confirmed COVID-19 illness per 1000 person-years of follow-up for the active vaccine group to the placebo group.

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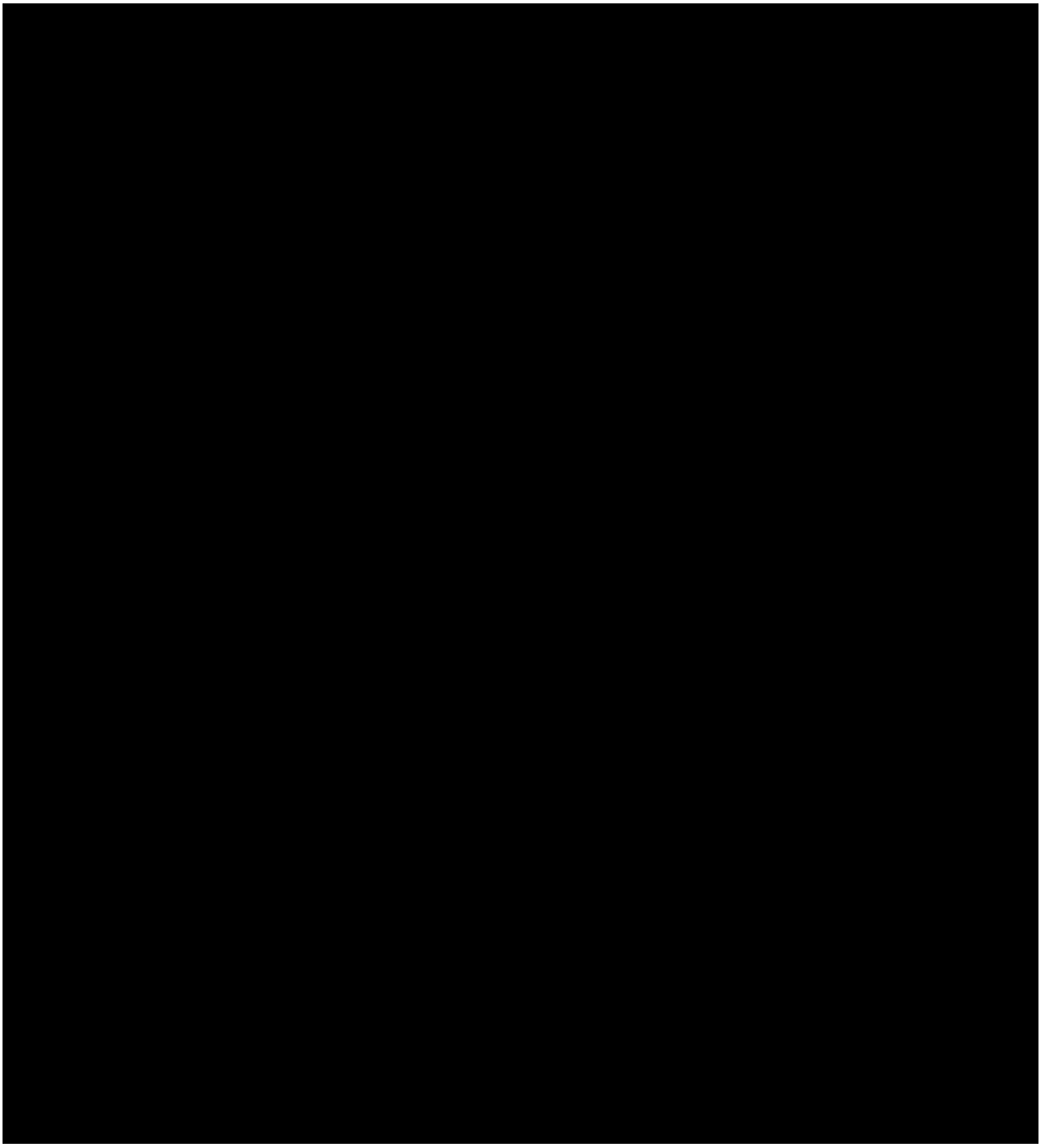

Asymptomatic Case Definition

An asymptomatic case is defined as positive N-binding antibody at a post–Dose 2 visit (eg, Visit 4, 1 month after Dose 2) in participants without serological or virological evidence of infection prior to that visit, determined by negative N-binding antibody at Visit 1 and negative NAAT at Visit 1 and Visit 2 and at the time of a potential COVID-19 illness. A secondary definition will be applied without the requirement for a negative NAAT at Visit 2.

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Surveillance Times

For the asymptomatic cases based on N-binding antibody seroconversion, the start-of-surveillance times are summarized as follows:

Endpoint's Associated Participant-Level Population	Start-of-Surveillance Time
Evaluable efficacy (maternal)	Dose 2
Dose 2 all-available efficacy (maternal)	Dose 2
Dose 1 all-available efficacy (mITT) (maternal)	Dose 1

The end of a surveillance period for each participant is the earliest of the following:

- Date of the first positive N-binding antibody result after Dose 2.
- Date of the participant's last post–Dose 2 N-binding antibody test that is prior to a COVID-19 symptom associated with a nonnegative NAAT result.
- Date of the participant's last post–Dose 2 N-binding antibody test that is prior to an important protocol violation (for analysis based on the evaluable efficacy population).

Once the asymptomatic cases and surveillance periods have been identified, VE can be calculated as 100 × (1 – IRR), where IRR is the ratio of incidence of asymptomatic infection per 1000 person-years of follow-up for the active vaccine group to the placebo group.

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16.1.10 List of Laboratories Under Vaccine Research & Development Oversight

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EXTERNAL DATA MONITORING COMMITTEE

C459

Investigational BNT162 Vaccine Program

PF-07302048

Version: 14

Date: 20-Jan-2022

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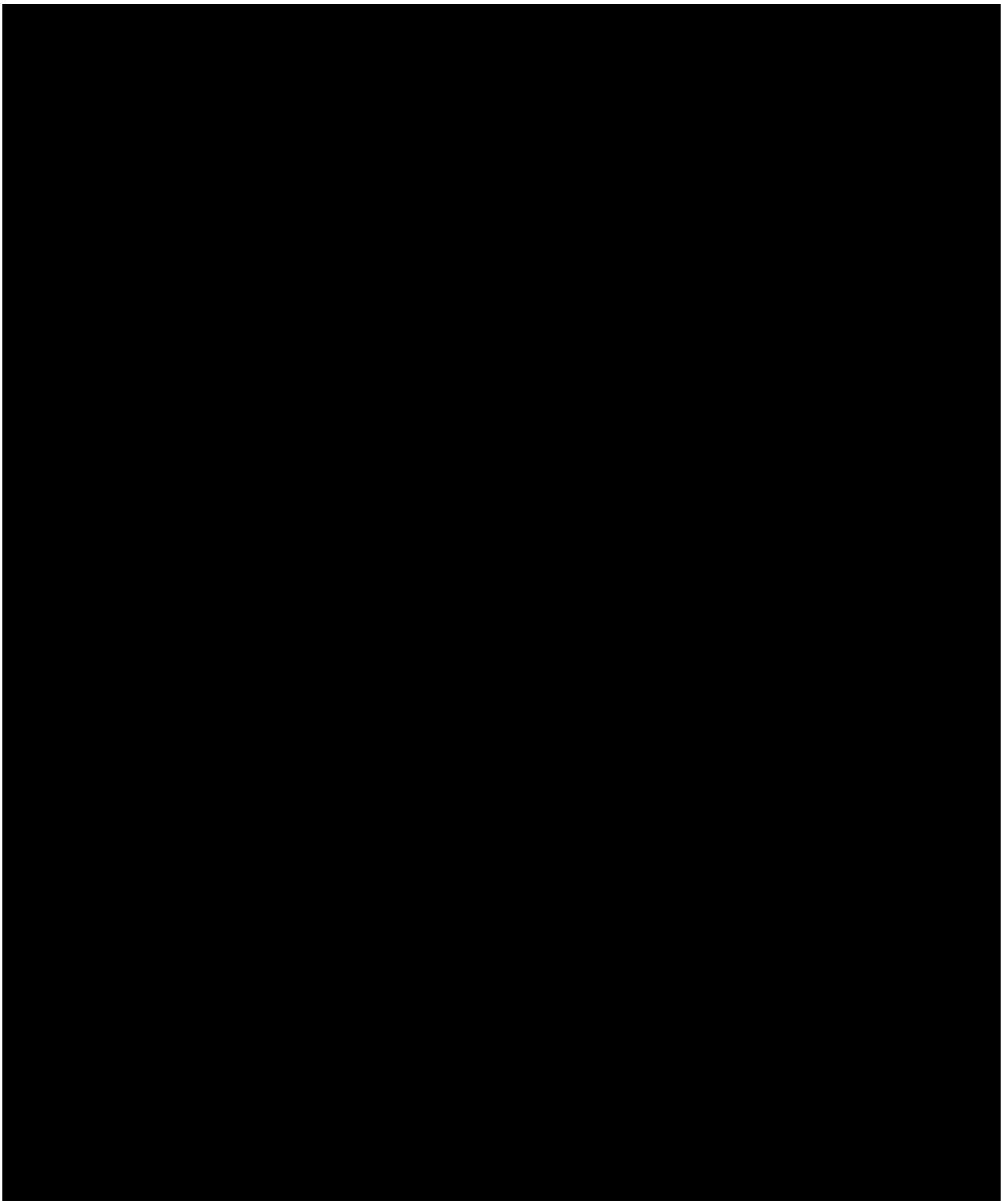

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1. INTRODUCTION

This External Data Monitoring Committee (E-DMC) (hereafter referred to as "the committee") is a single, external, independent, expert advisory group established to oversee safety and efficacy data from the BNT162 Vaccine Program. The primary rationale for establishing the committee is to make certain that appropriate external safeguards are in place to help ensure the safety of subjects and to maintain scientific rigor and study integrity while the trial is on-going.

Pfizer is responsible for conducting this study. BioNTech is the regulatory sponsor of this study.

1.1. Study Design

The COVID-19 program is being developed to address the pandemic crisis which has spread globally at high speed. There are currently no vaccines to prevent infection with SARS-CoV-2 or antiviral drugs to treat COVID-19.

Given the rapid transmission of COVID-19 and incidence of disease in the United States and elsewhere, the rapid development of a safe and effective vaccine is of utmost importance. In the COVID-19 vaccine program, the safety and tolerability of the BNT162 vaccine candidates will be evaluated by assessing prompted local injection-site reactions and systemic events, as well as adverse events and serious adverse events. Predefined stopping rules may be used to ensure safety of study subjects and guide dose escalation and participants may also undergo hematological and chemistry evaluation as defined per protocol. These procedures are described in detail in each study protocol where relevant. The background of the COVID-19 vaccine candidates and pre-clinical development is described in the BNT162 COVID-19 Investigator Brochure (IB). The updated IB will be provided to the committee when available.

Please refer to the current study protocols for details of the study design.

1.2. Purpose of the Committee

The committee will review accumulating safety data across all studies, as well as efficacy data in those studies that include an efficacy assessment which requires or warrants review by the committee. The committee will advise Pfizer regarding the safety of current participants and those yet to be recruited, as well as the continuing scientific validity of the trial. In addition to safety review by the committee, qualified Pfizer personnel will review safety data as specified in the safety surveillance review plan and will inform the committee of significant findings. Efficacy data from relevant studies will be available to the committee when there is a planned interim analysis of efficacy or if this is considered necessary to conduct a risk-benefit assessment.

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1.3. Committee Close-Out

The committee will have completed its work and been dissolved when it has reviewed final safety data from the last study within the scope of this charter.

2. COMMITTEE MEMBERSHIP

The committee consists of a chairperson and 2-4 additional members, as indicated in the list of members in [redacted] including at least one with medical qualifications and at least one other who is a statistician.

During the conduct of the study, membership of the committee may change based on expertise needed, availability, and new conflicts of interest that warrant a change. A dated log must be maintained in Appendix 1 reflecting any changes in membership. Committee membership is to be for the duration specified in each member's contract. If any member leaves the committee, Pfizer will promptly appoint a replacement in consultation with the committee chairperson, if needed.

2.1. Conflicts of Interest

The committee members will complete a CT22-GSOP-RF01 *Independent Oversight Committee Member Conflict of Interest Form*. Committee members should be free of apparent significant conflicts of interest. Any potential conflict of interest that develops during a member's tenure on the committee must be disclosed by the committee member. Pfizer will determine if any potential conflict requires termination of committee membership.

Each time the committee meets, the study team will ask the committee members to consider whether or not any changes in their conflict of interest status have emerged. Status must be recorded in the committee open meeting minutes and any potential conflicts must be reported using CT22-GSOP-RF01.

2.2. Confidentiality Agreement/Contract

A written agreement (i.e., contract, including confidentiality agreement) must be in place for each external committee member before any services are rendered. No communication, either written or verbal, concerning the deliberations or recommendations of the committee will be made outside of the committee without approval of Pfizer, except as prov ded for in this charter [redacted]

2.3. Authorship

A committee member must not be an author of a publication emanating from any study on the BNT162 vaccine program for which they are a member.

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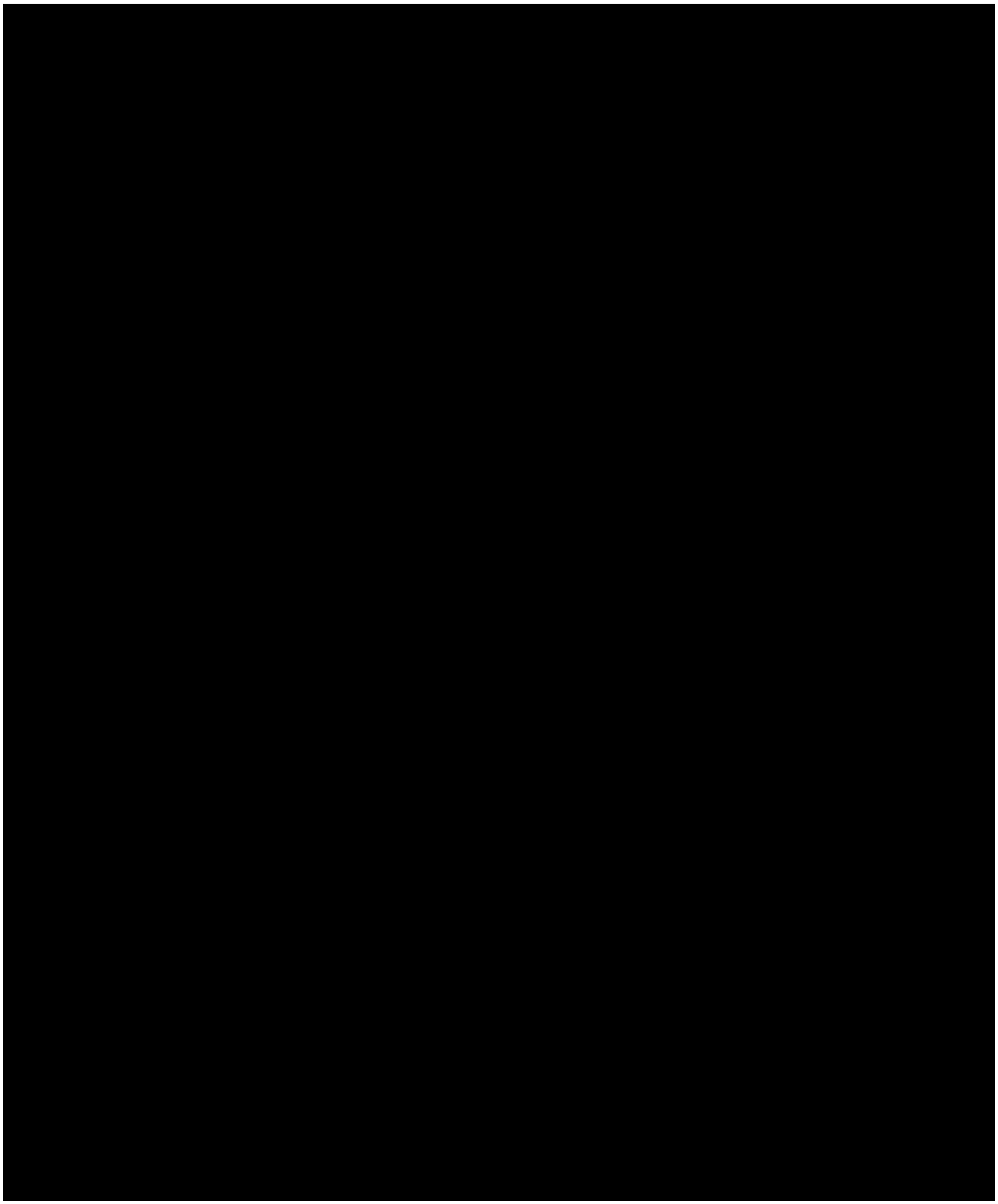

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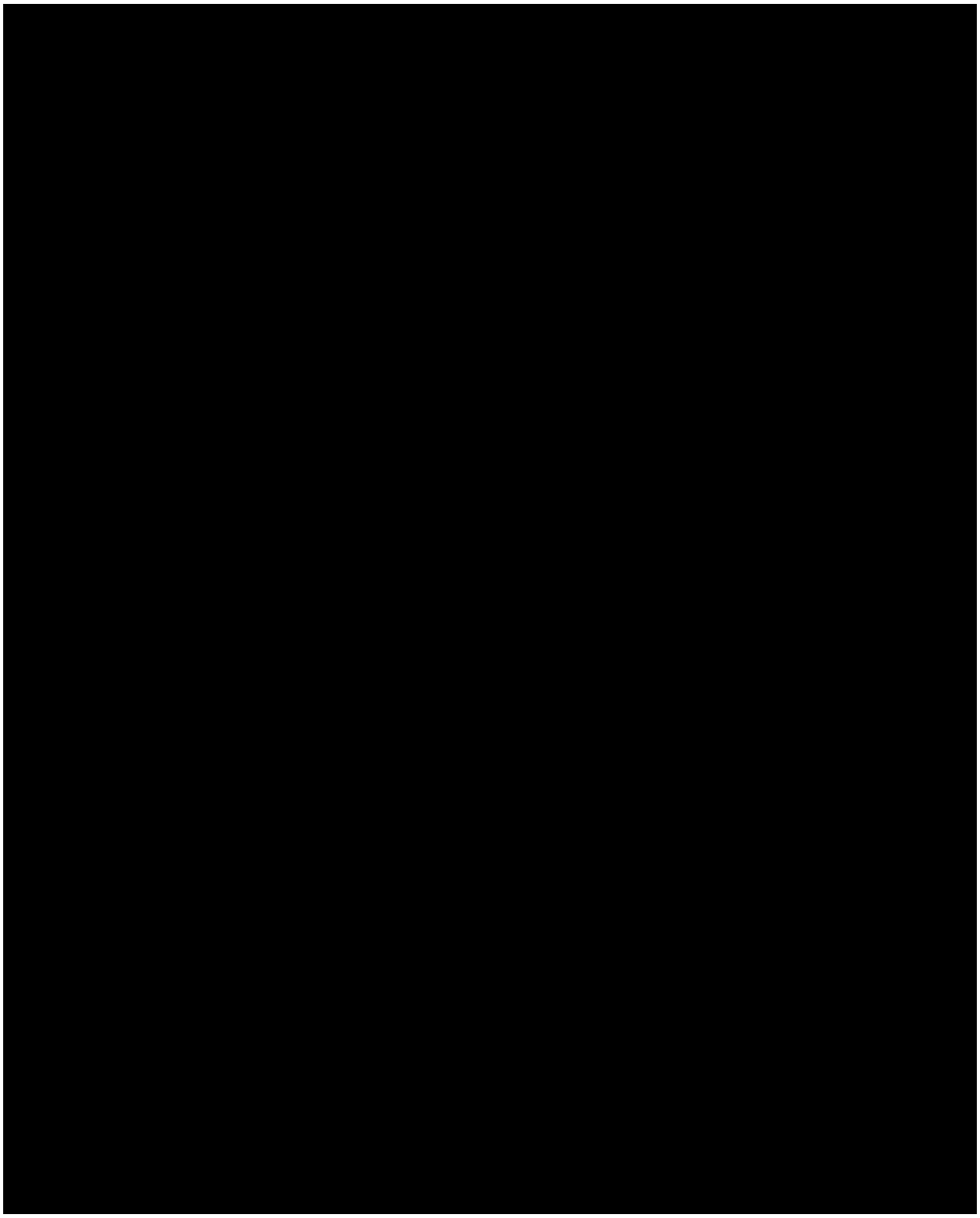

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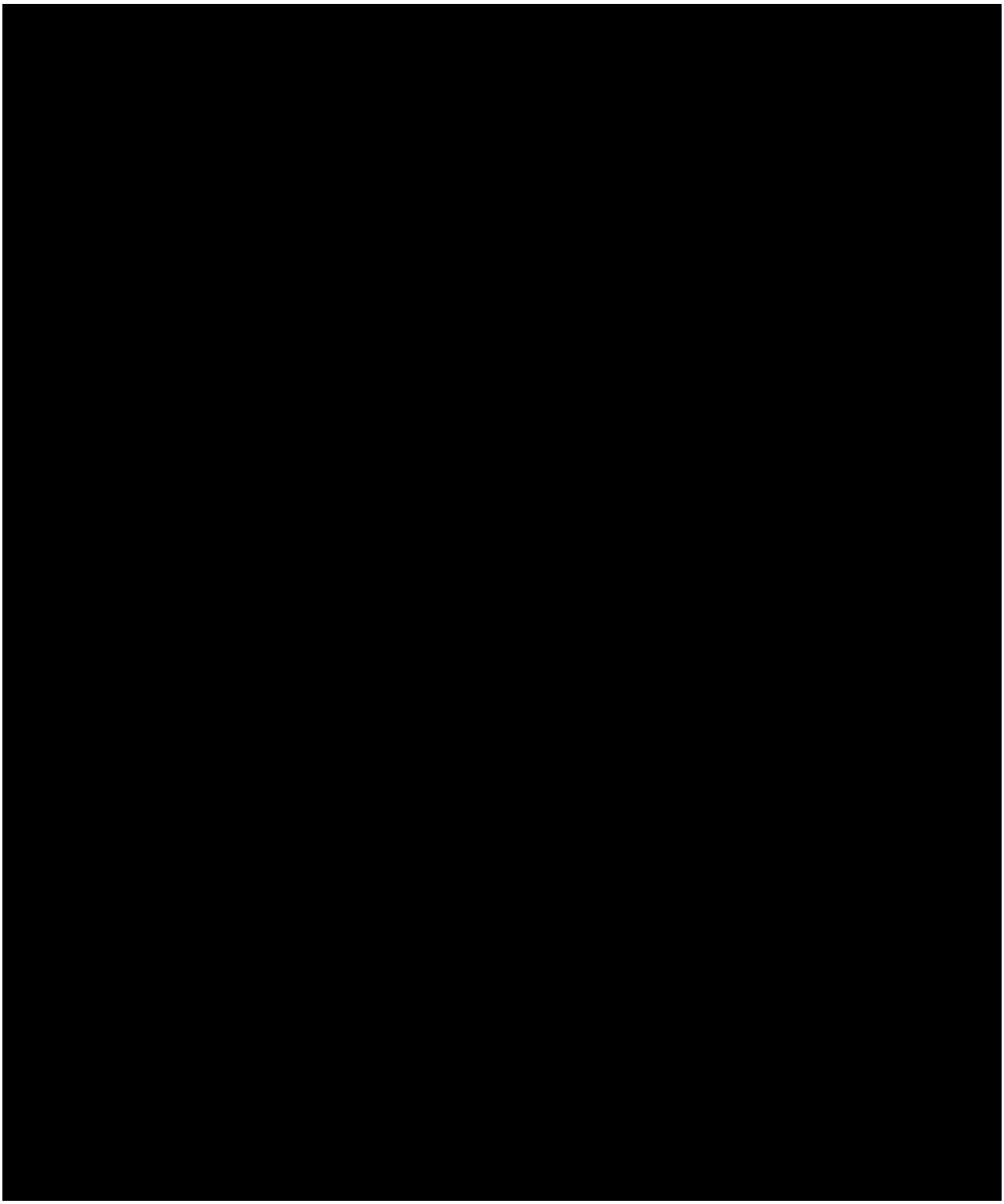

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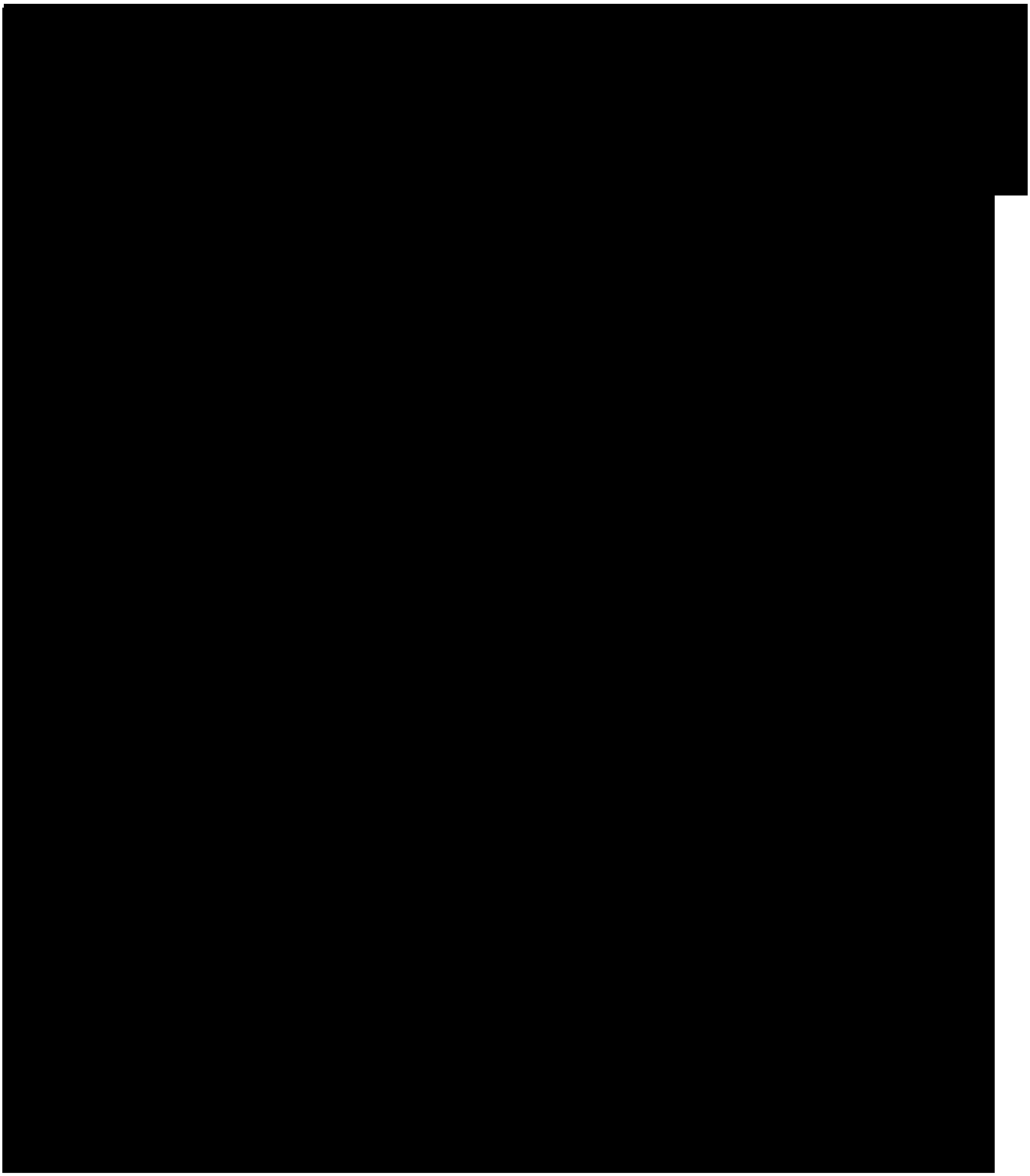

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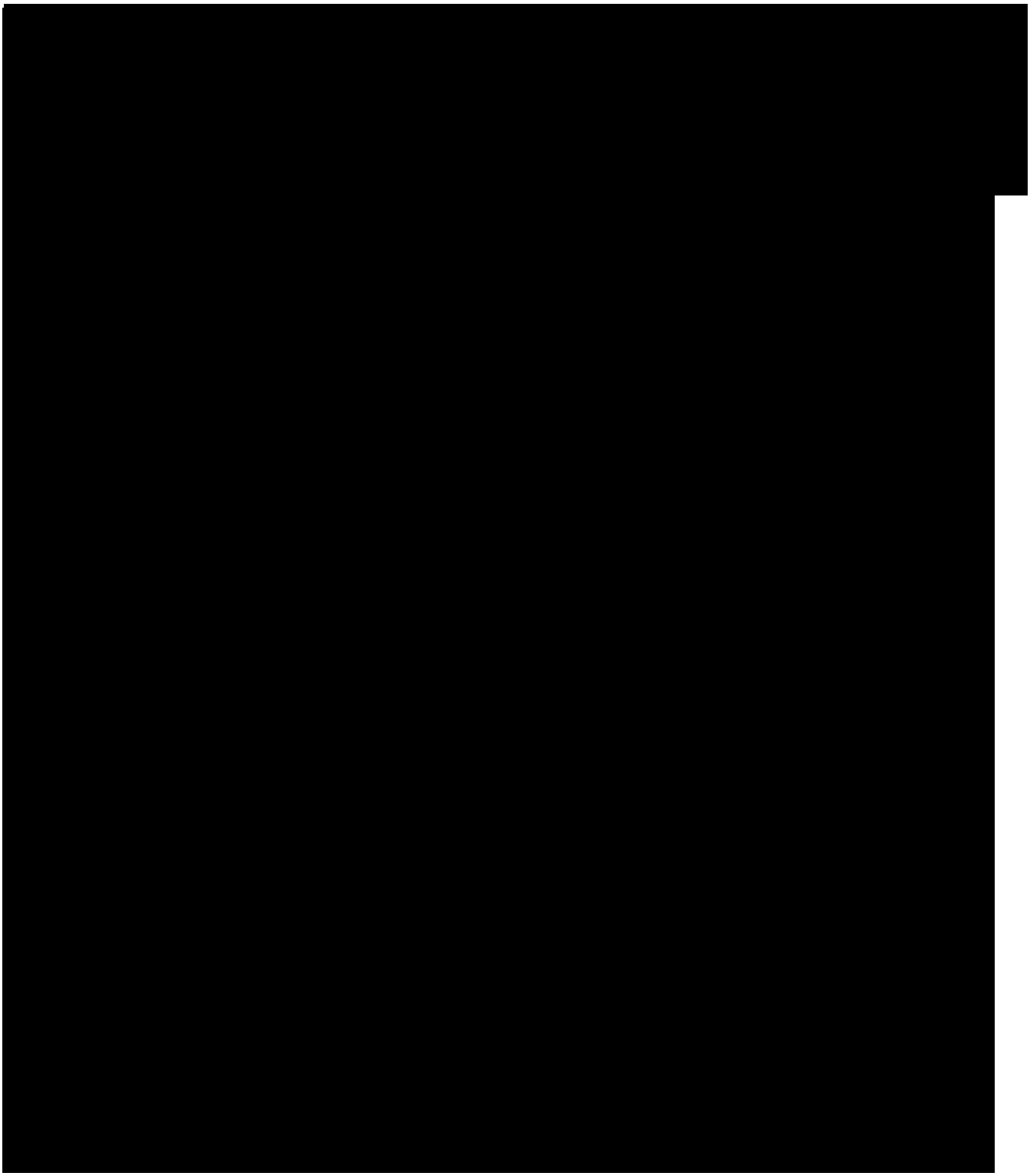

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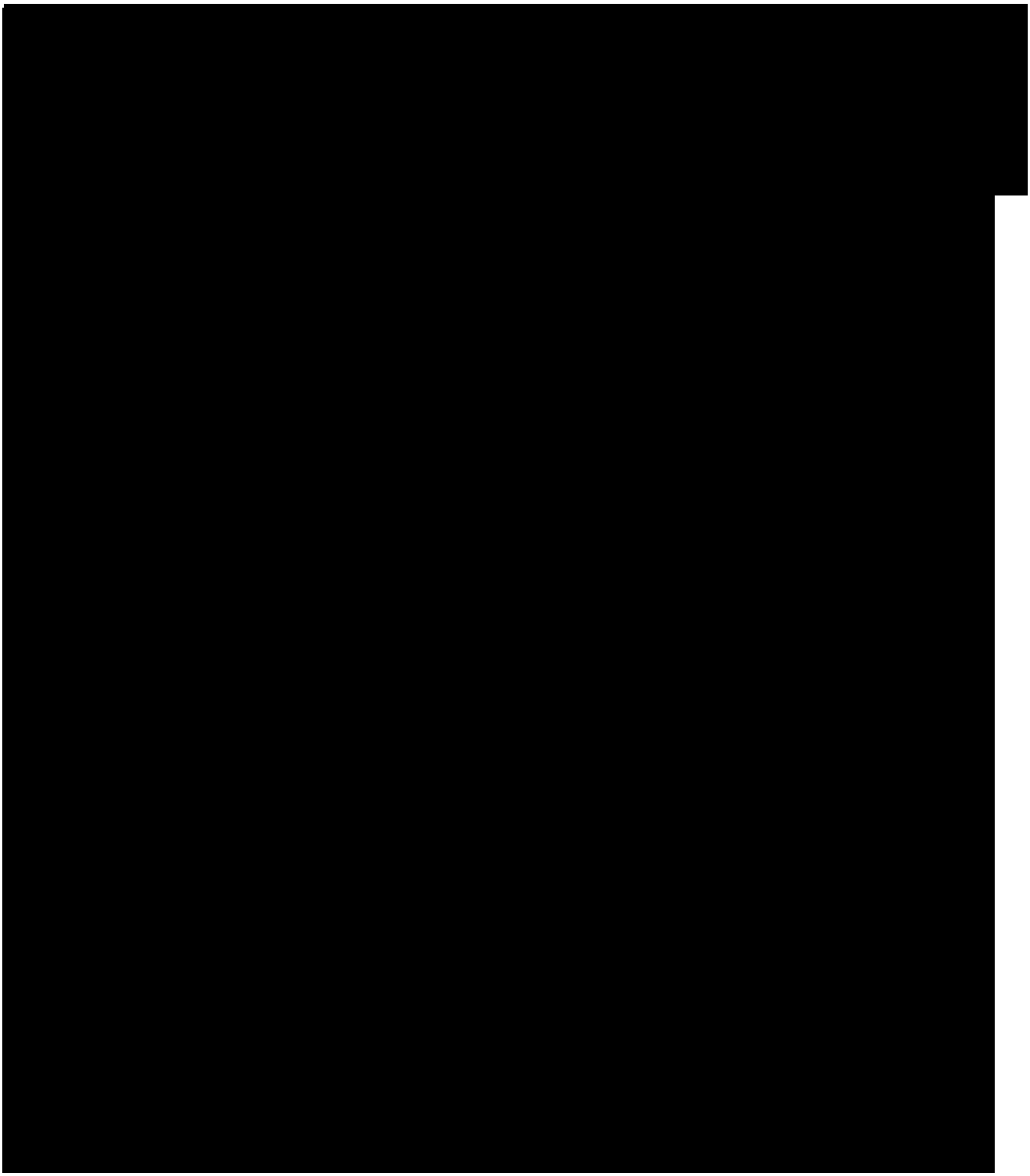

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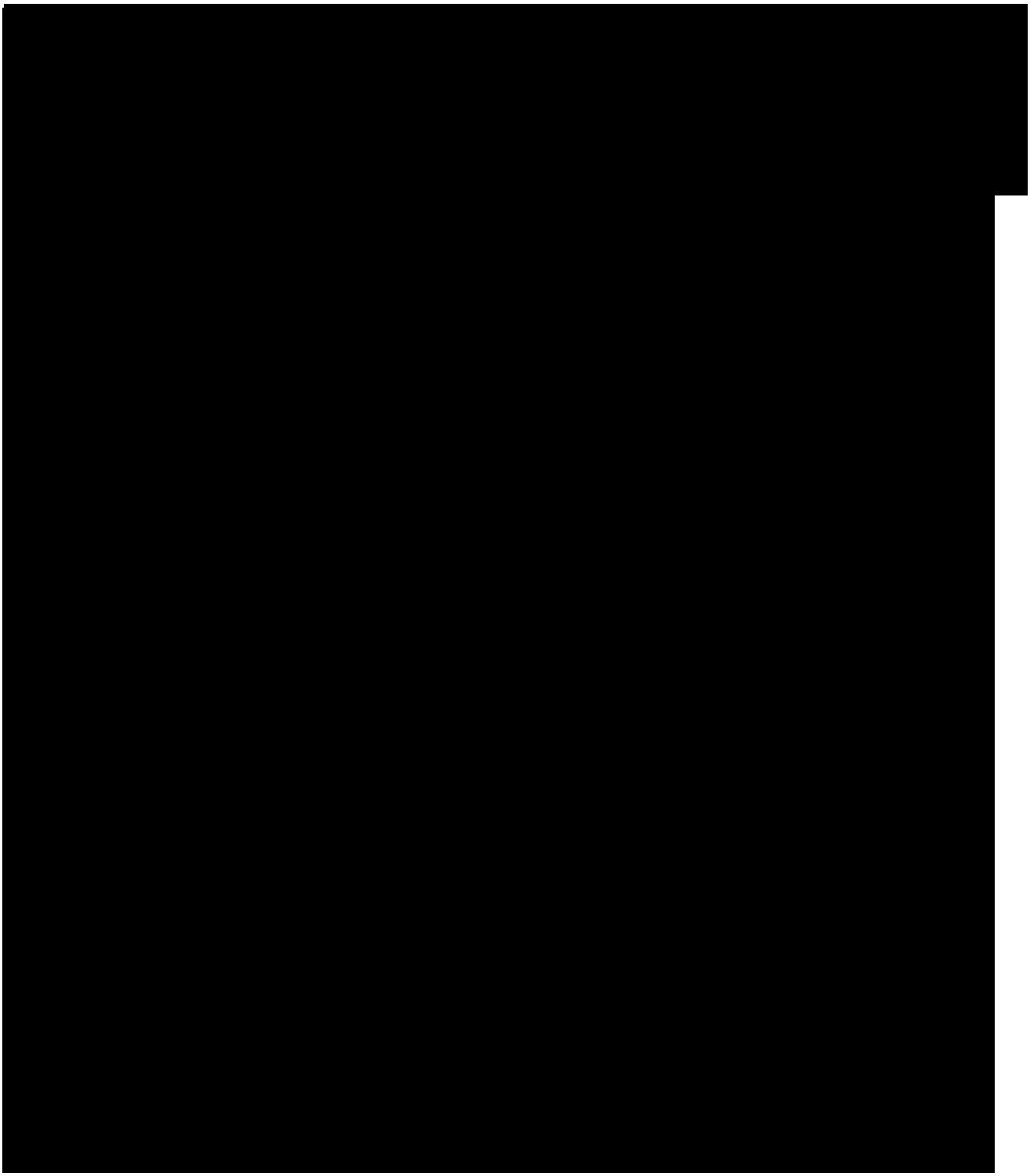

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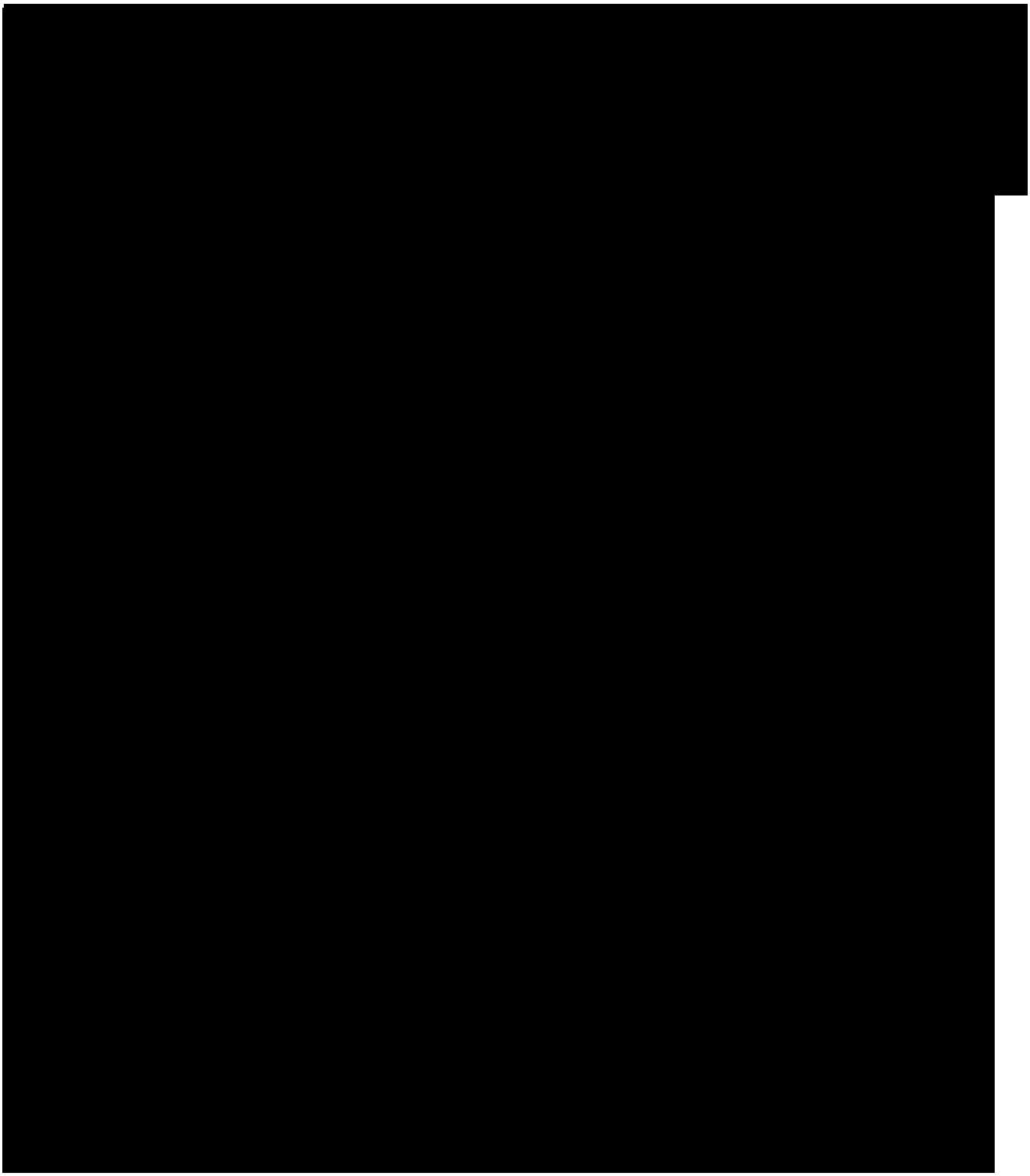

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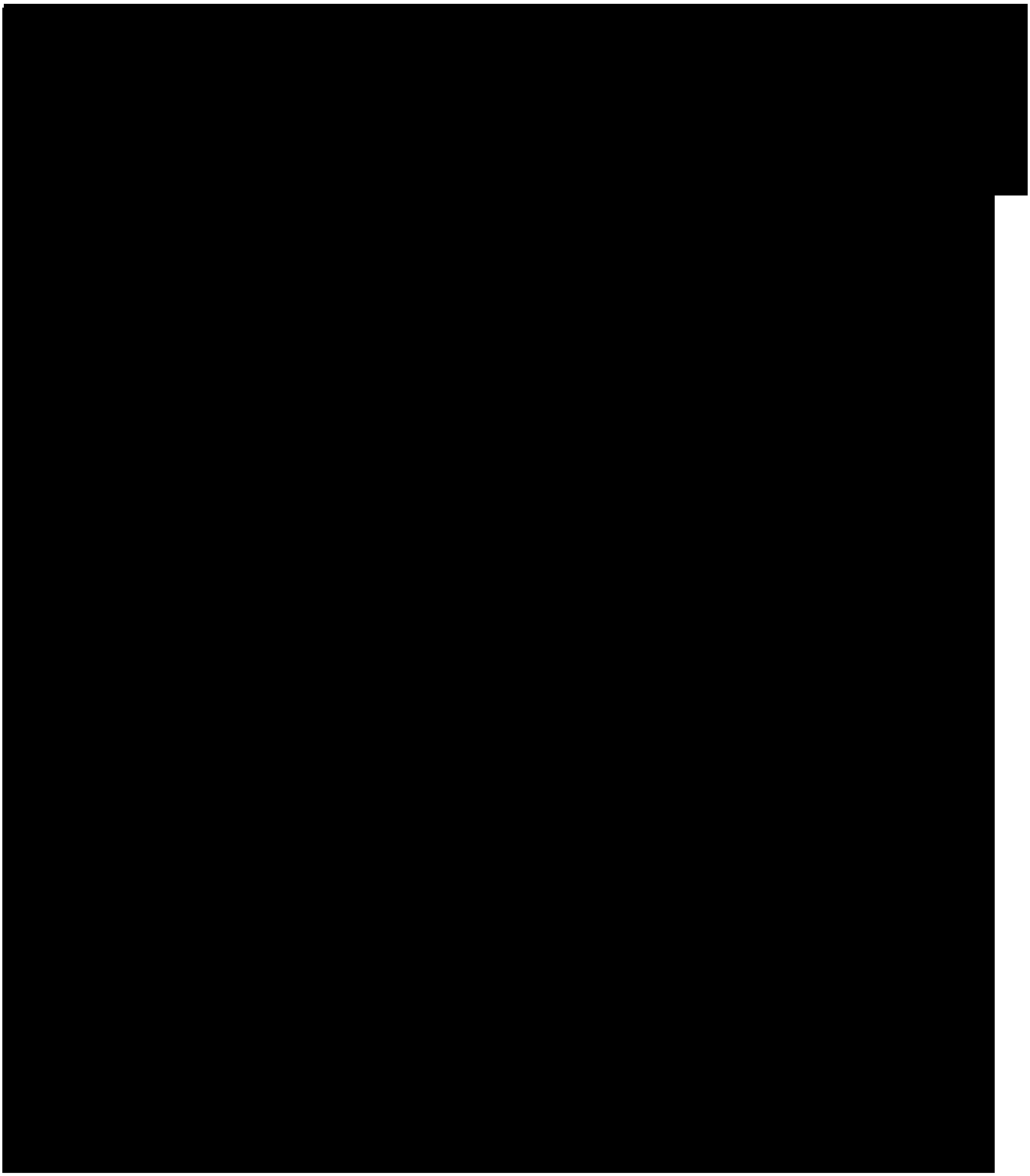

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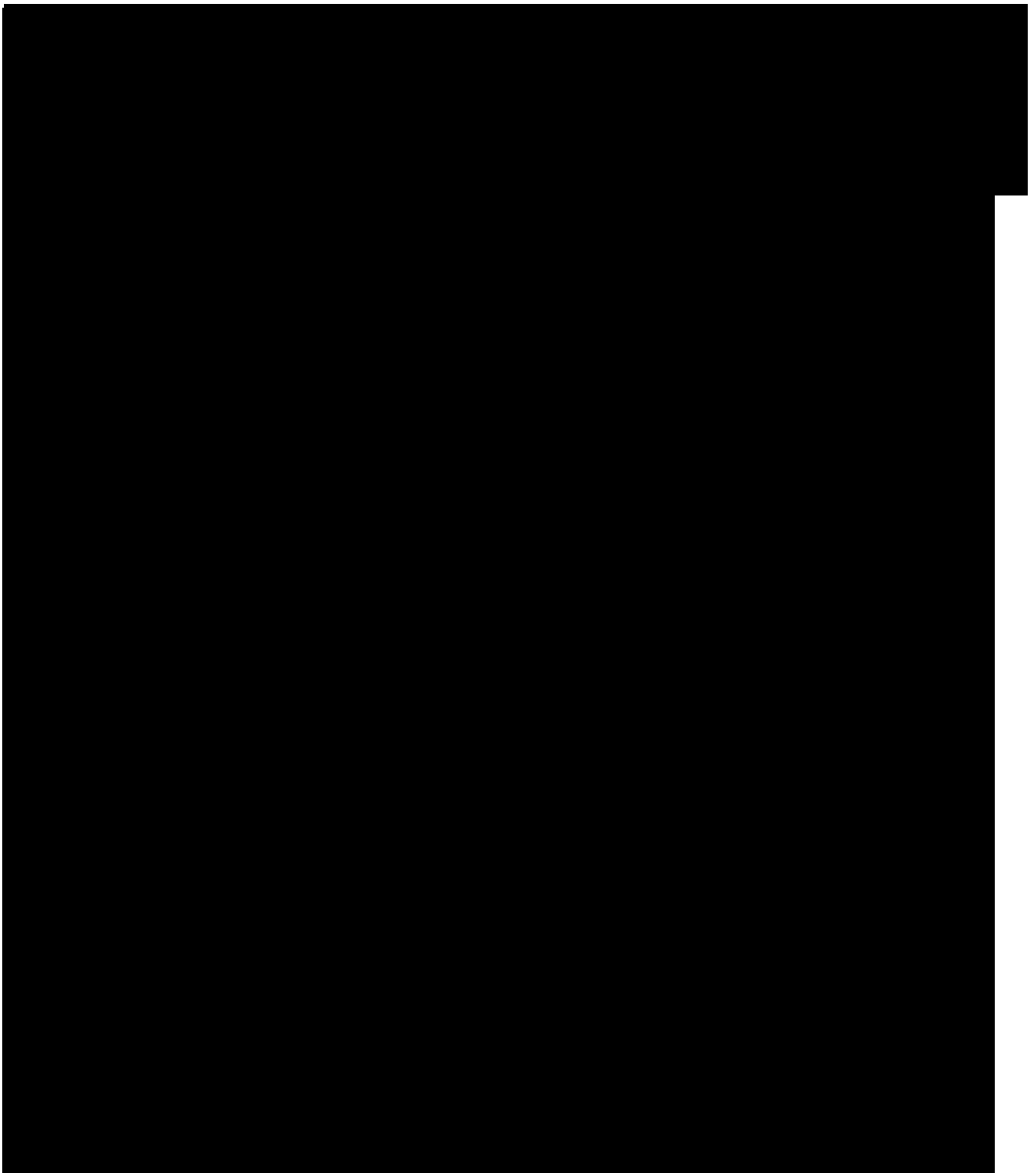

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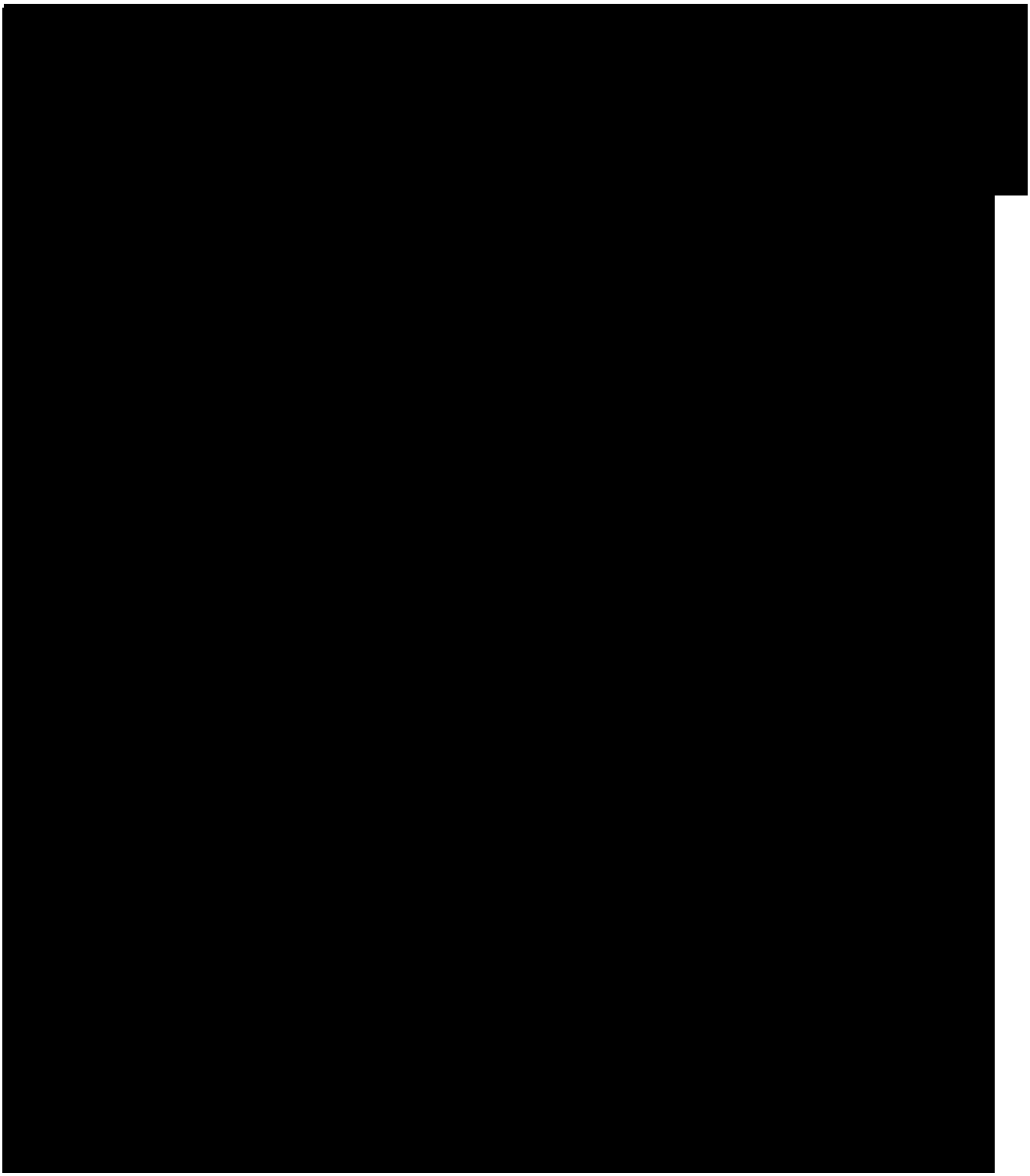

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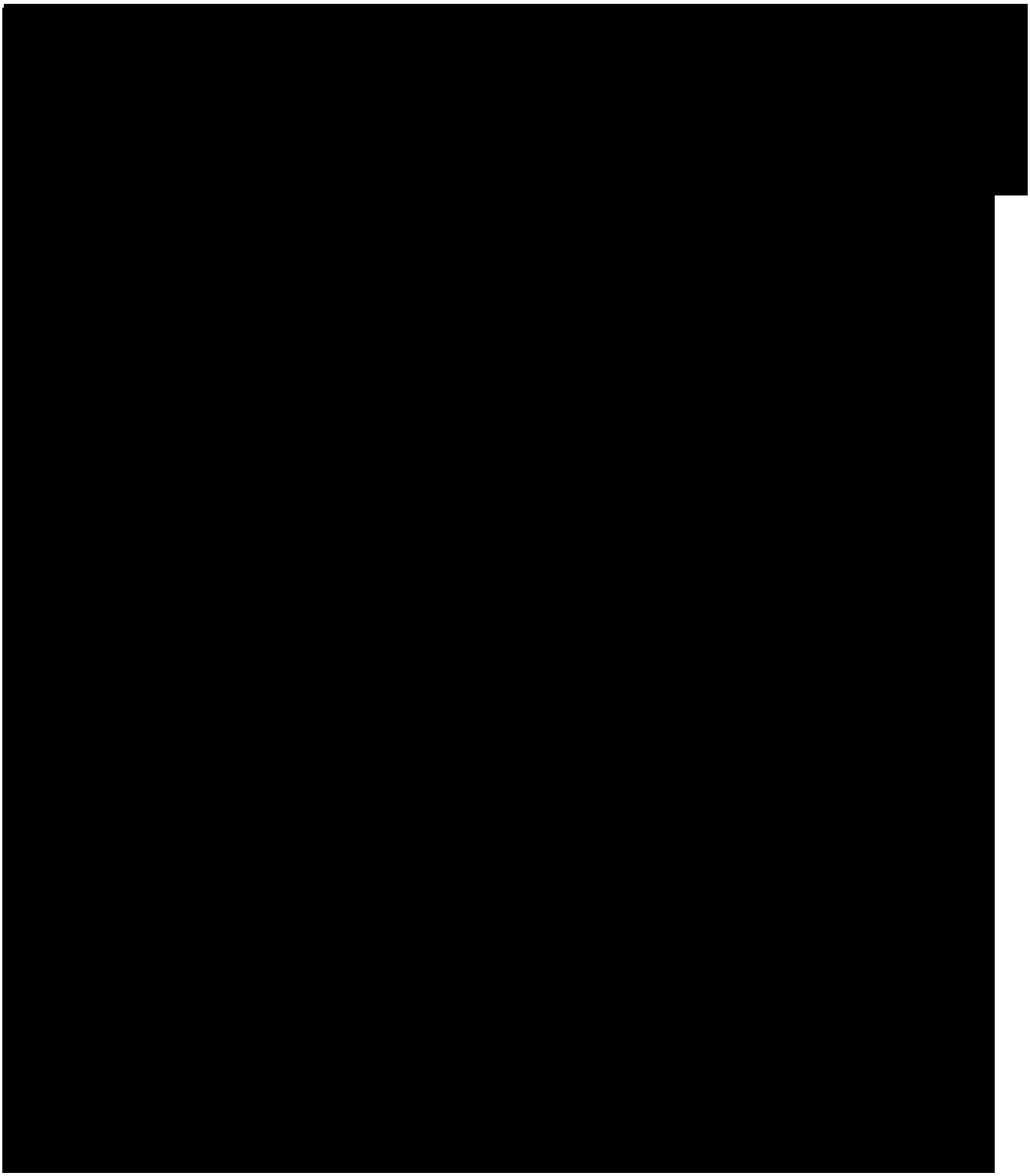

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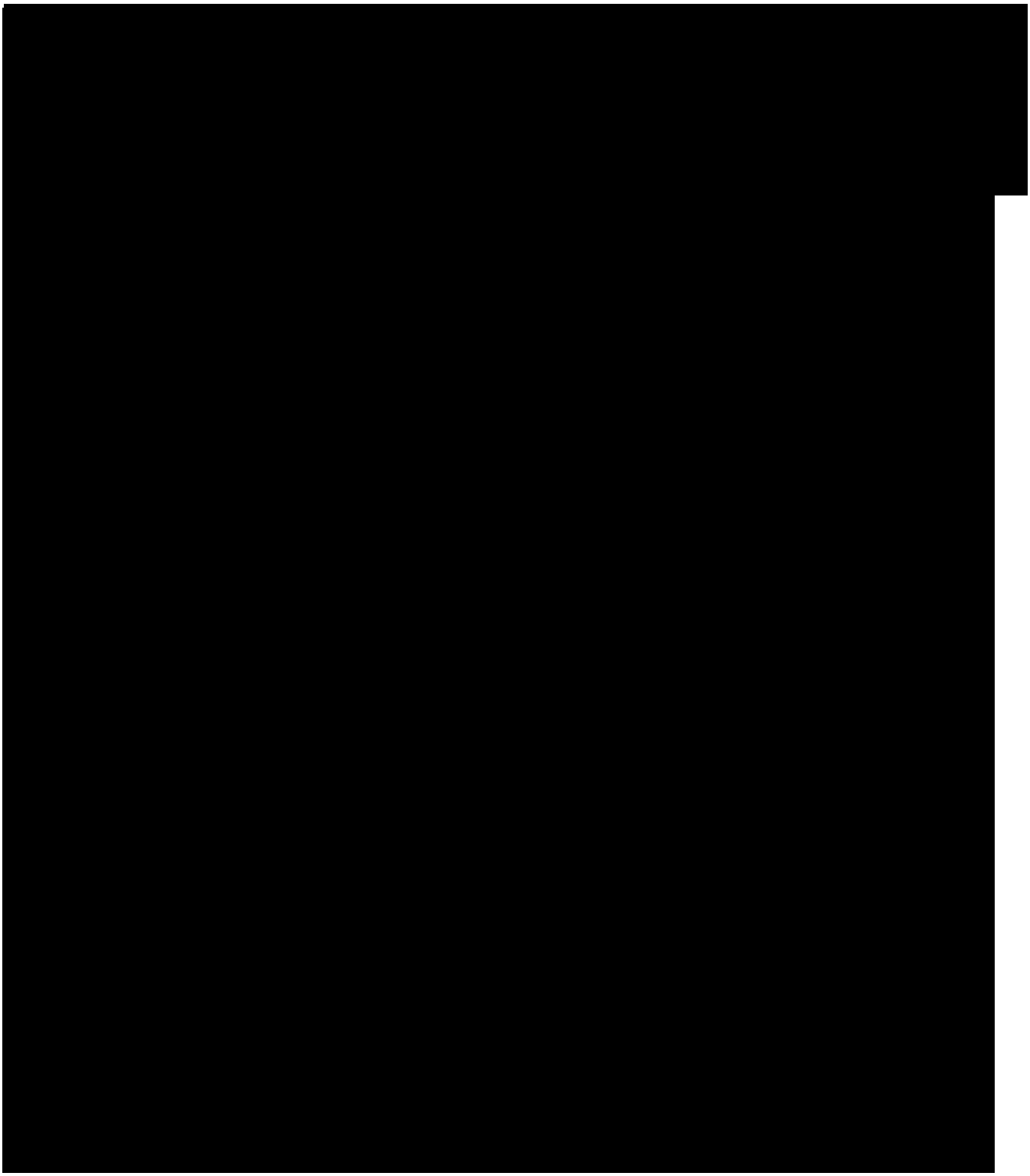

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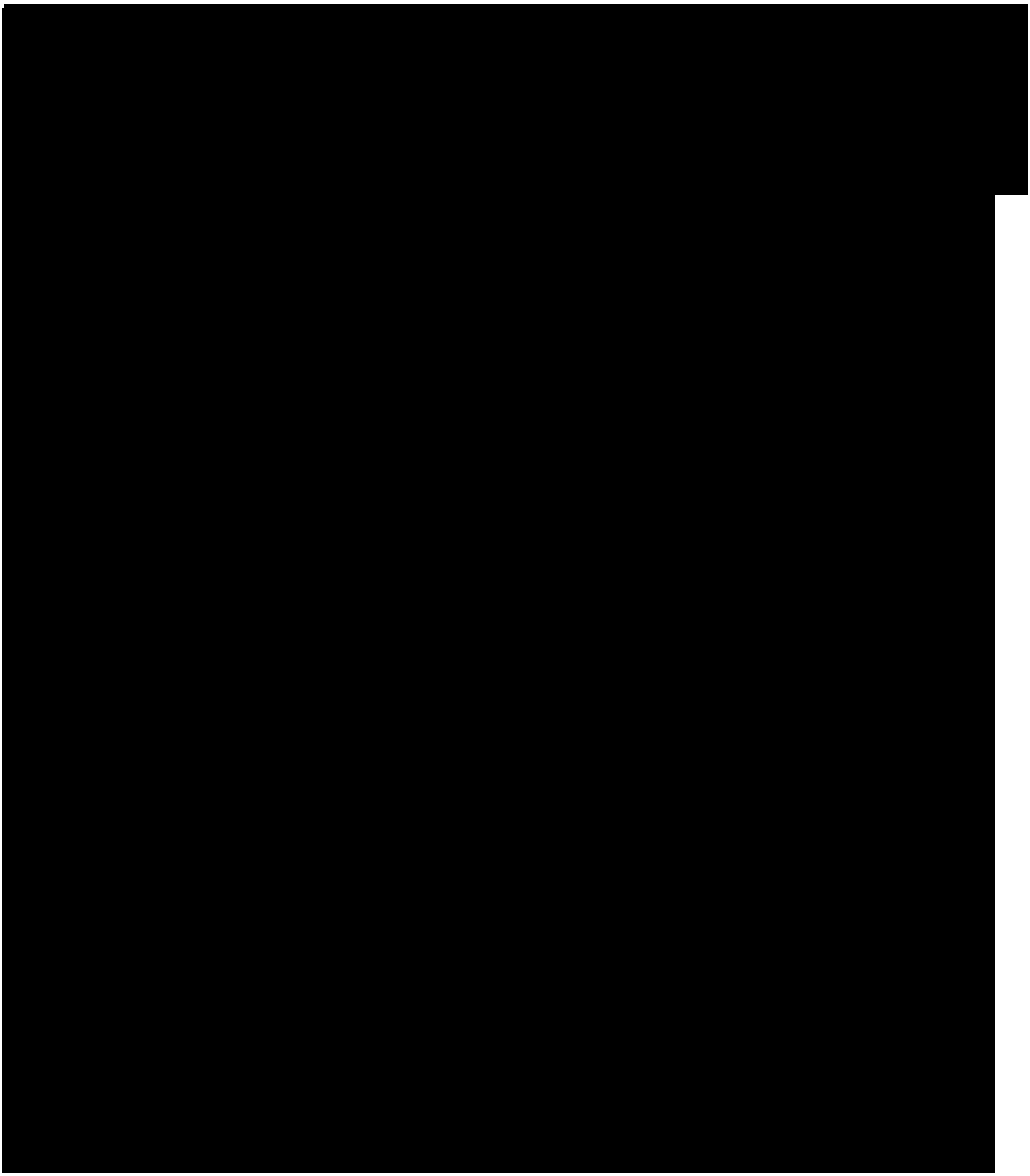

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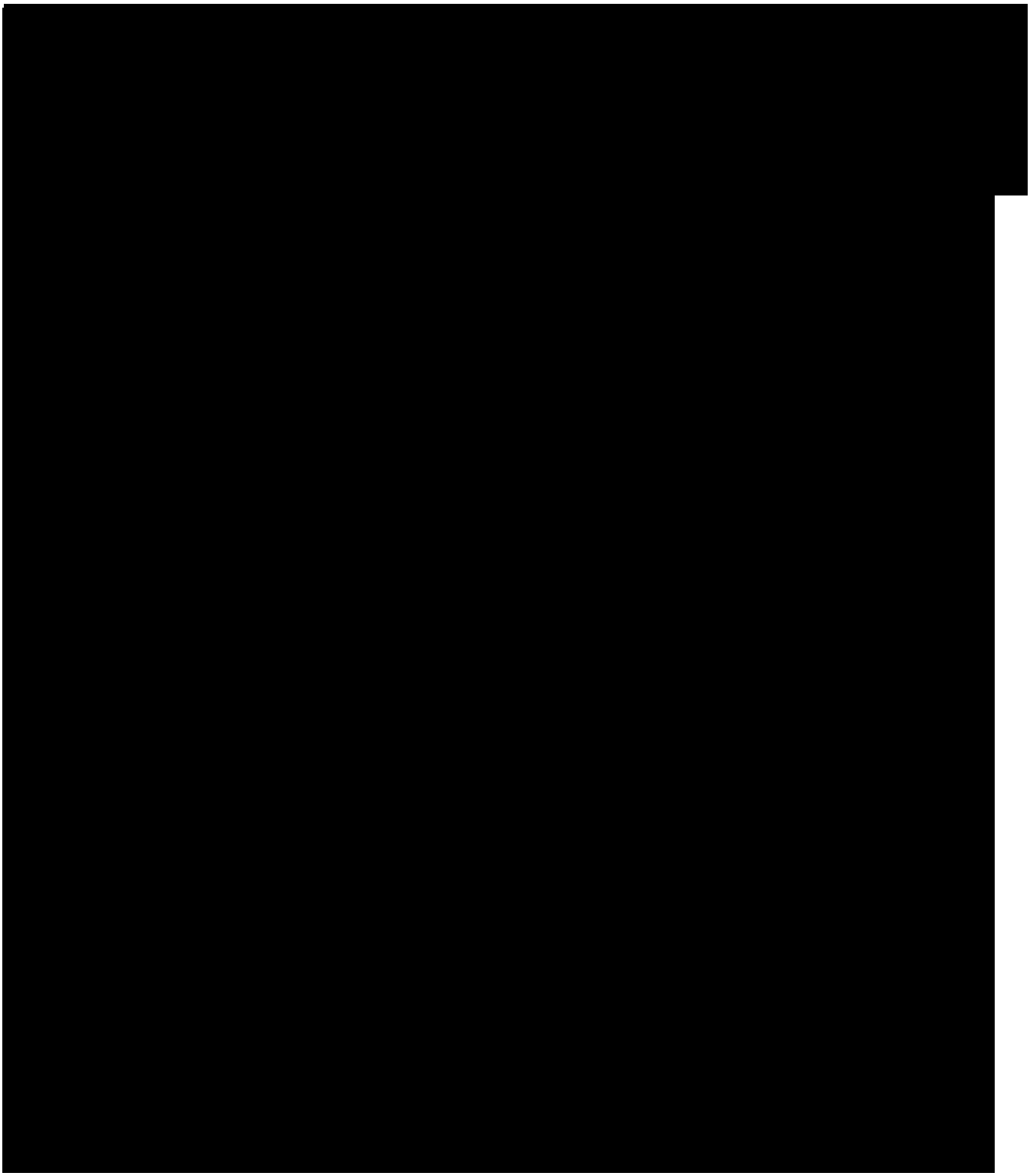

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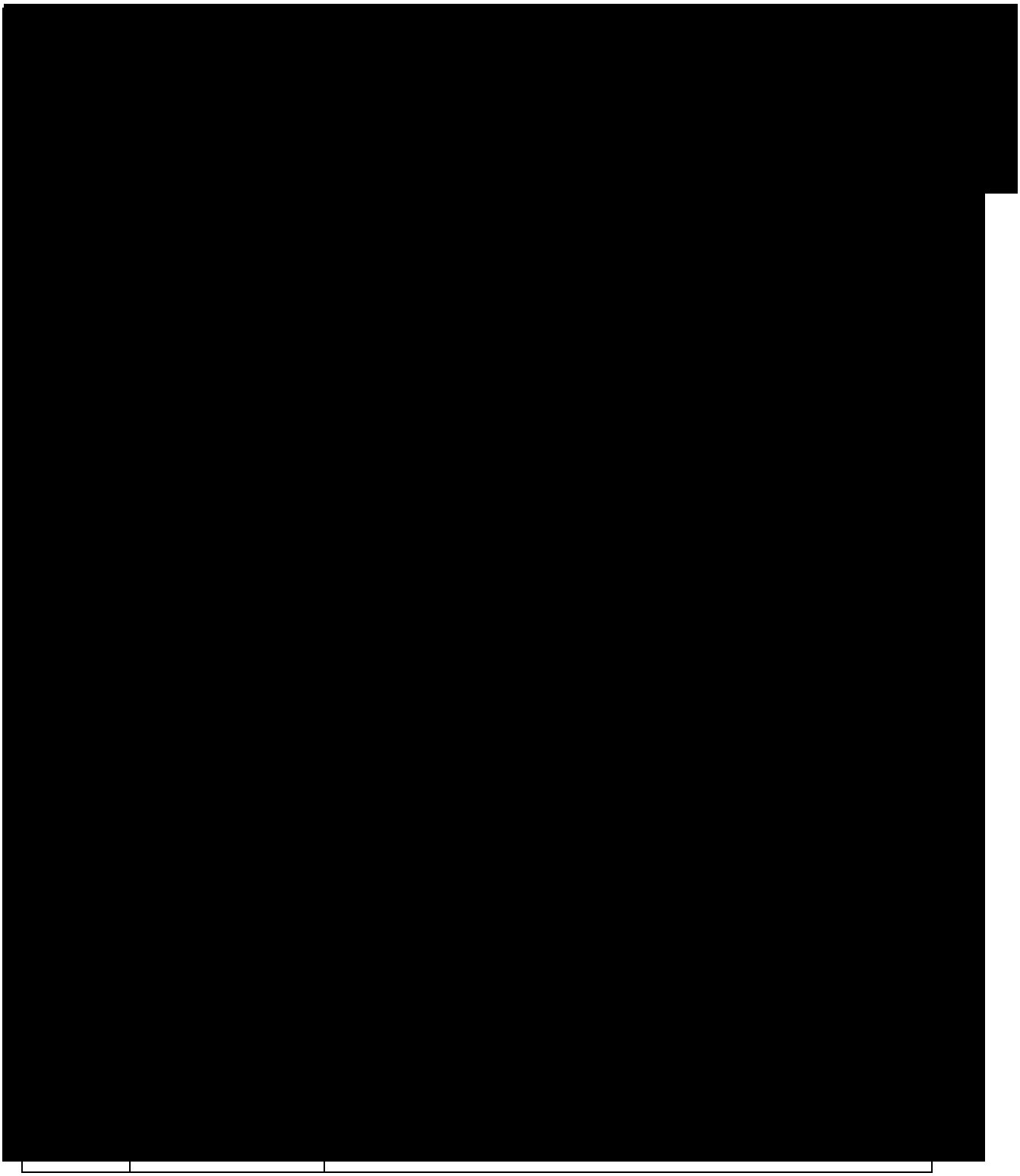

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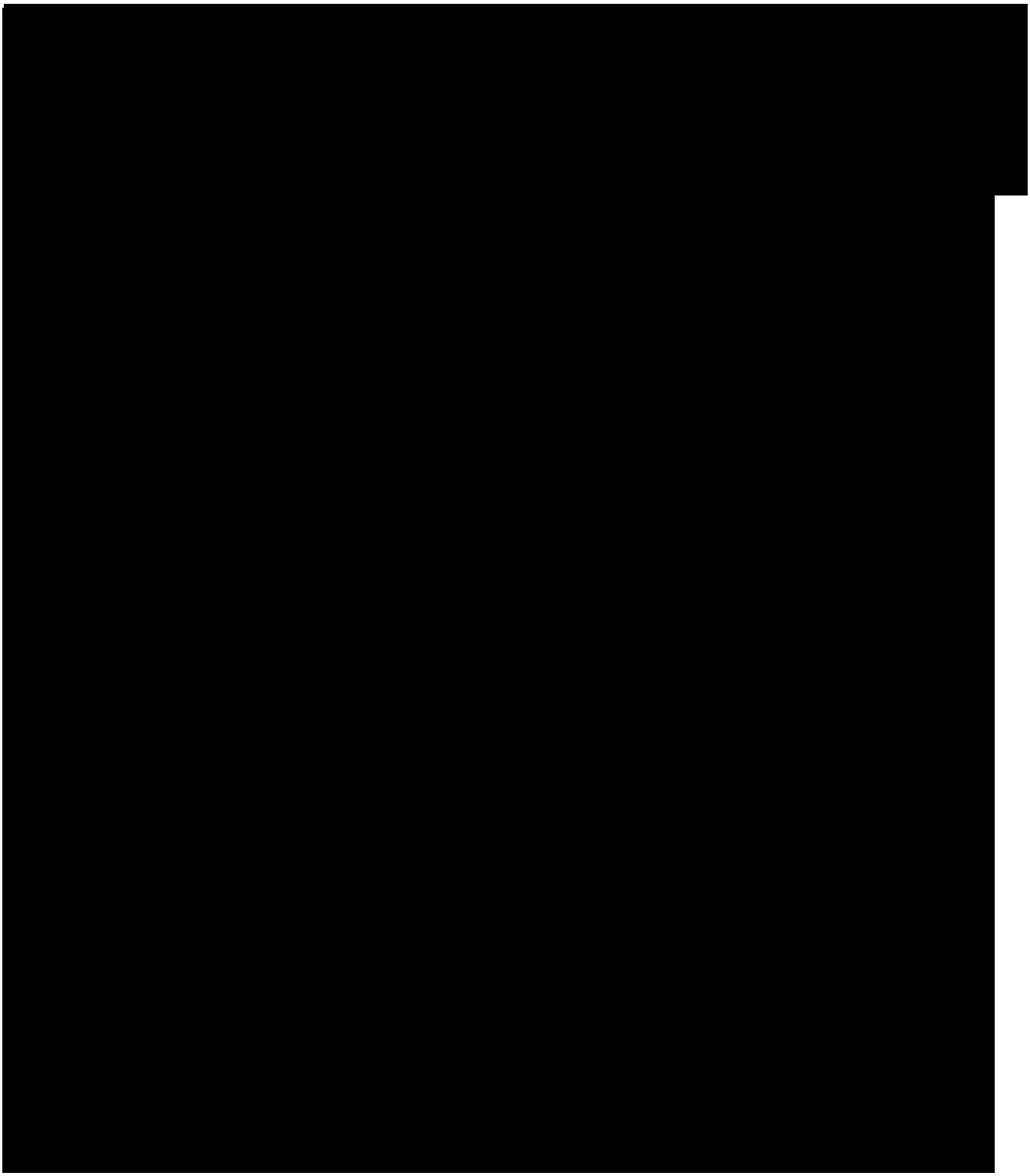

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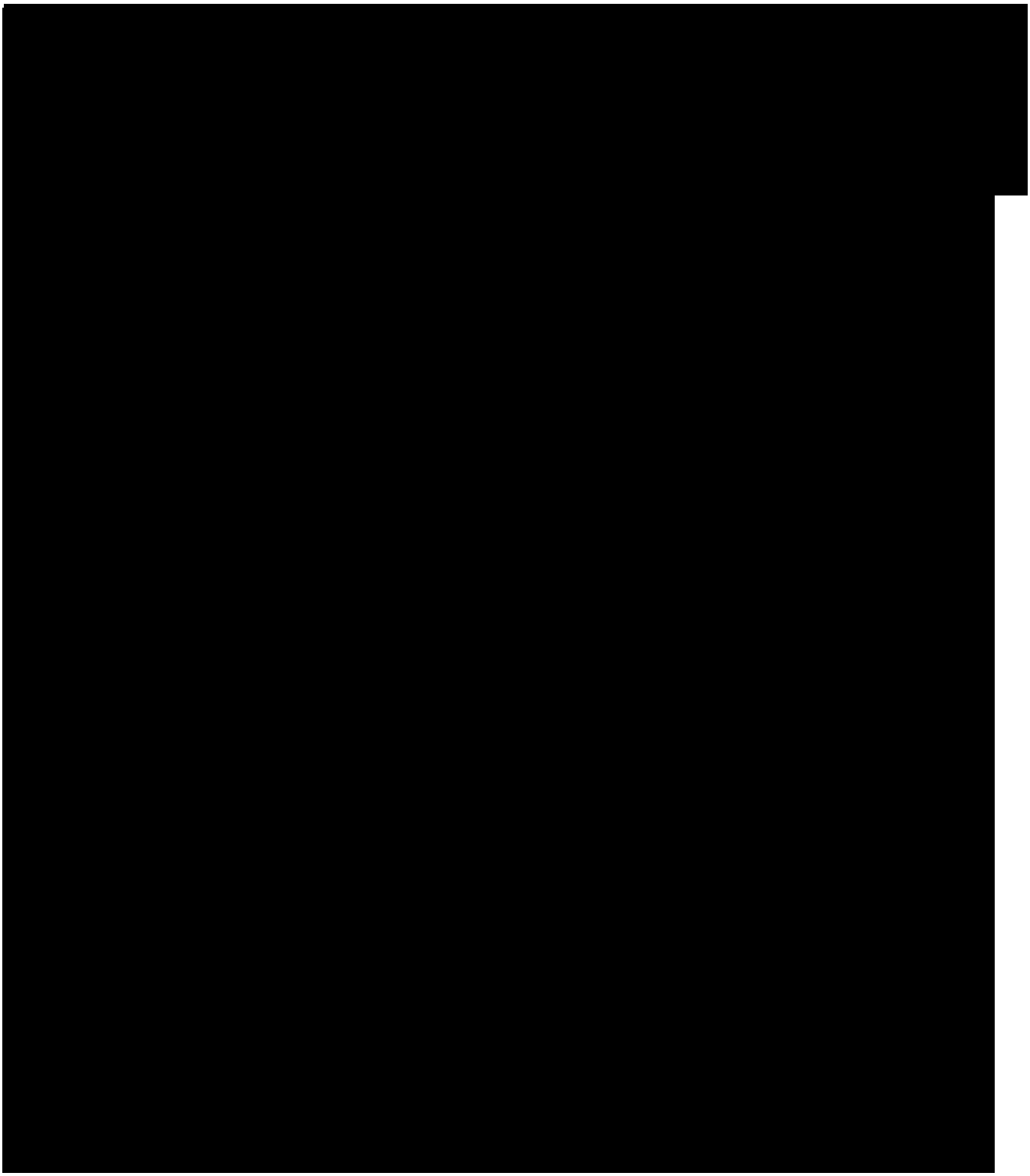

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Member	Affiliation/Address	Role	*Dates of Membership	Biography
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
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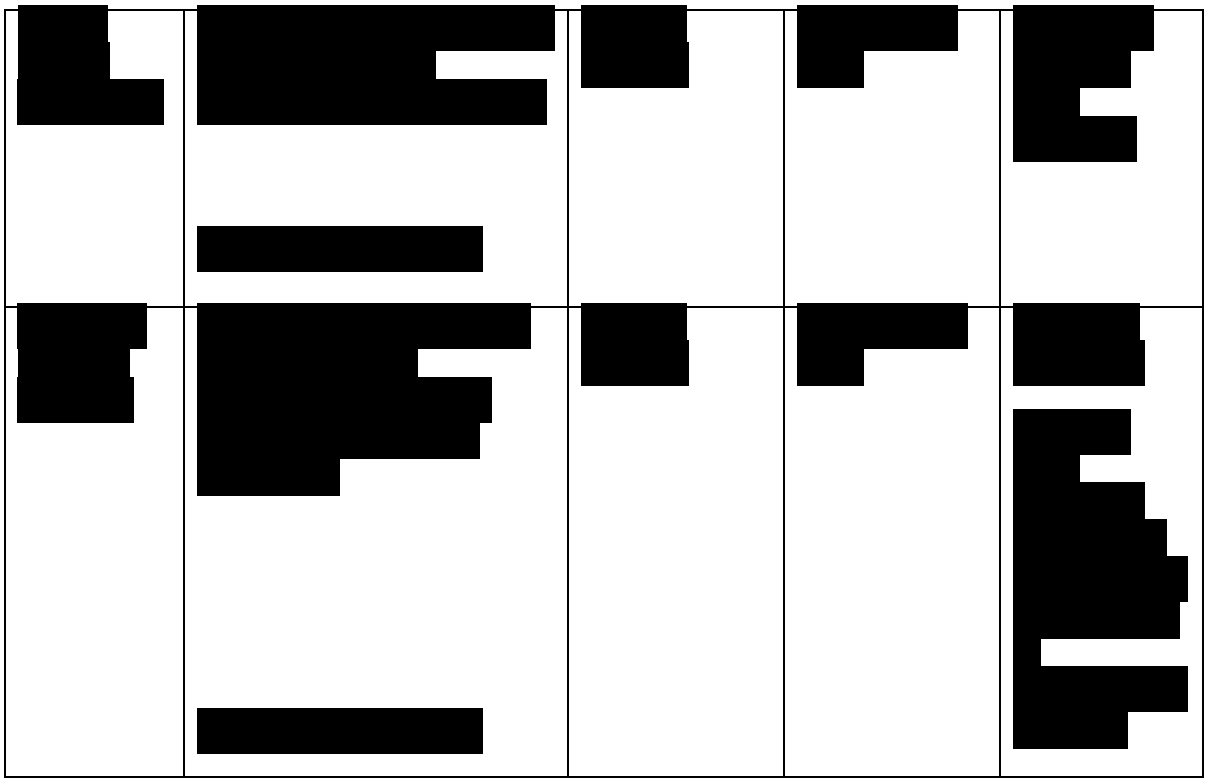

* Initial date of membership is the date the effective date of the contract signed by the committee member.

Note: Curriculum vitae are on-file at Pfizer and may be accessed by contacting the Study Team.

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[redacted]

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Appendix 3. Key Contacts

Vaccine Research & Development Clinical and Statistical Heads	
Name*	***Contact Information***
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

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[redacted]	[redacted]

Committee Liaison	
Name*	***Contact Information***
[redacted]	[redacted]
[redacted]	[redacted]

Reporting Team Members (Unblinded)*		
Name*	***Contact Information***	***Role***

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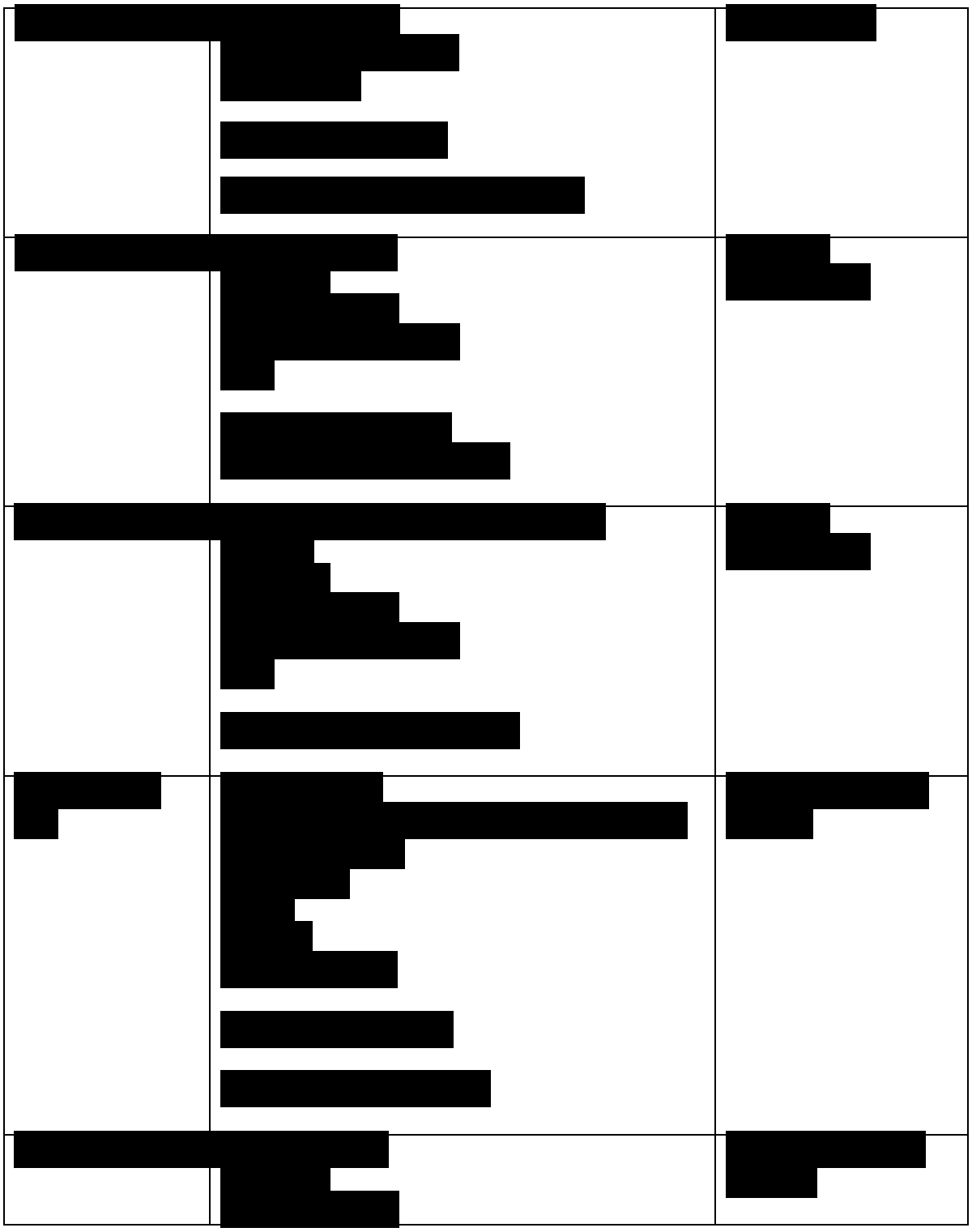

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	[redacted]	

[redacted]

Study Team Members		
Name*	***Contact Information***	***Role***
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

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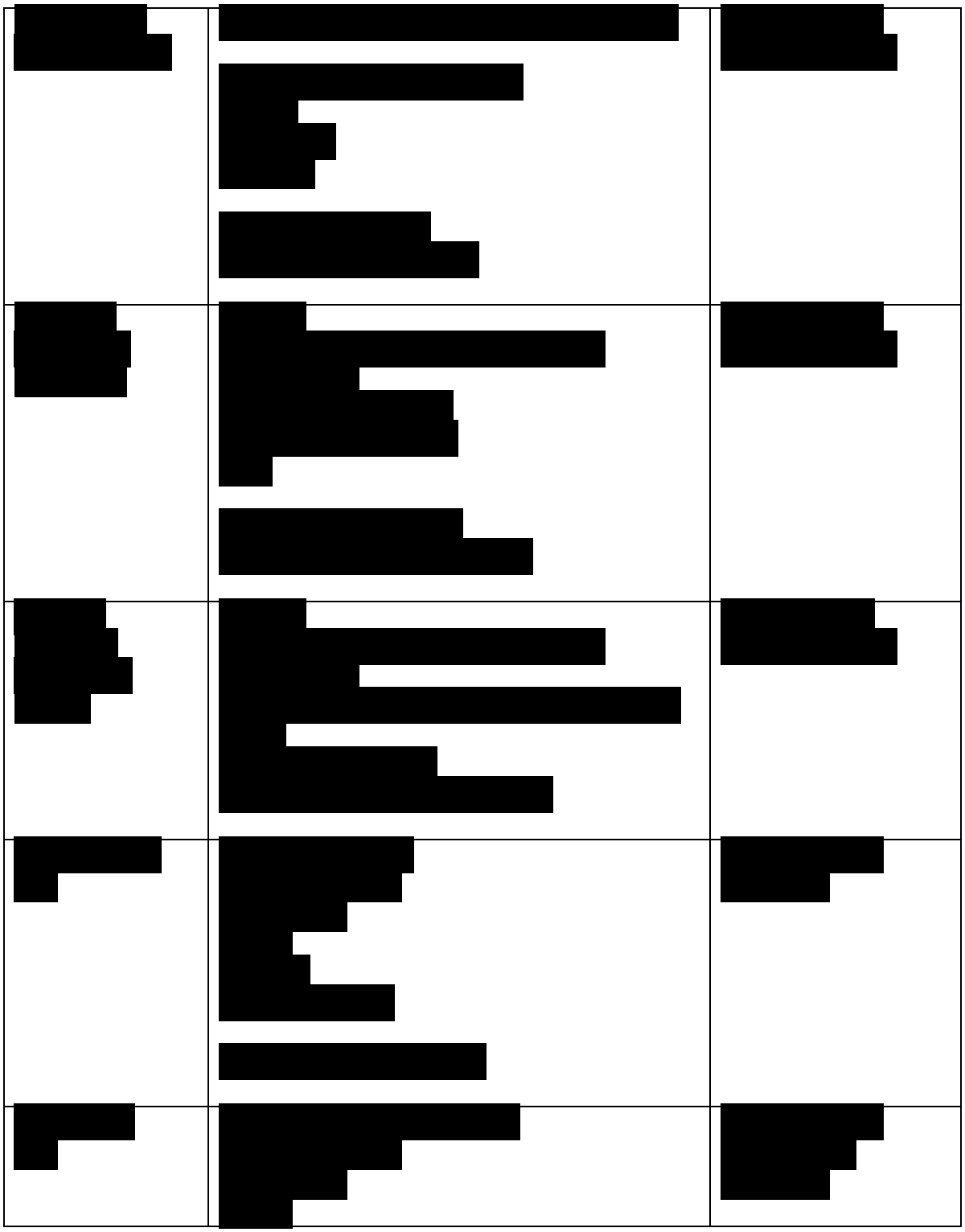

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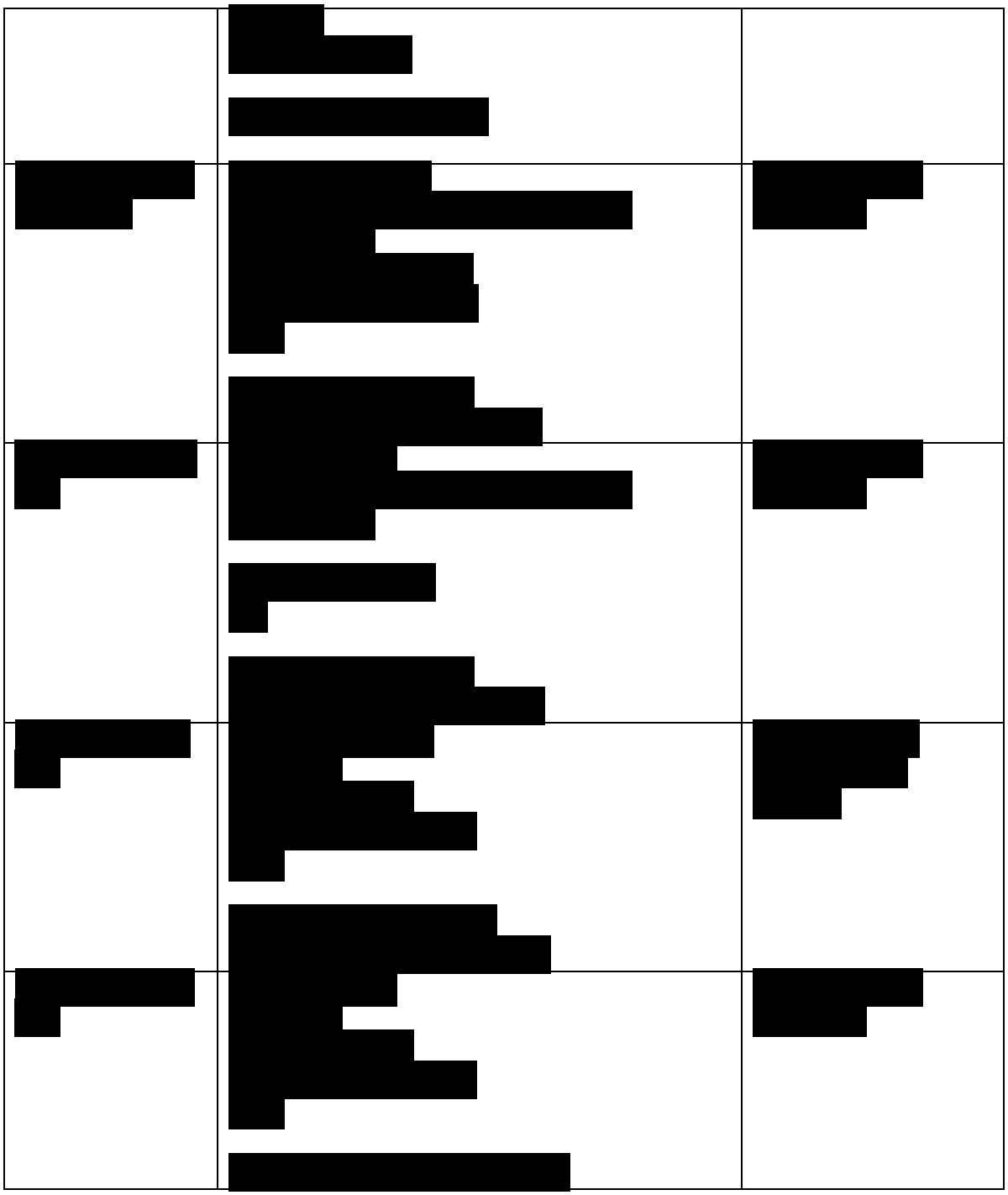

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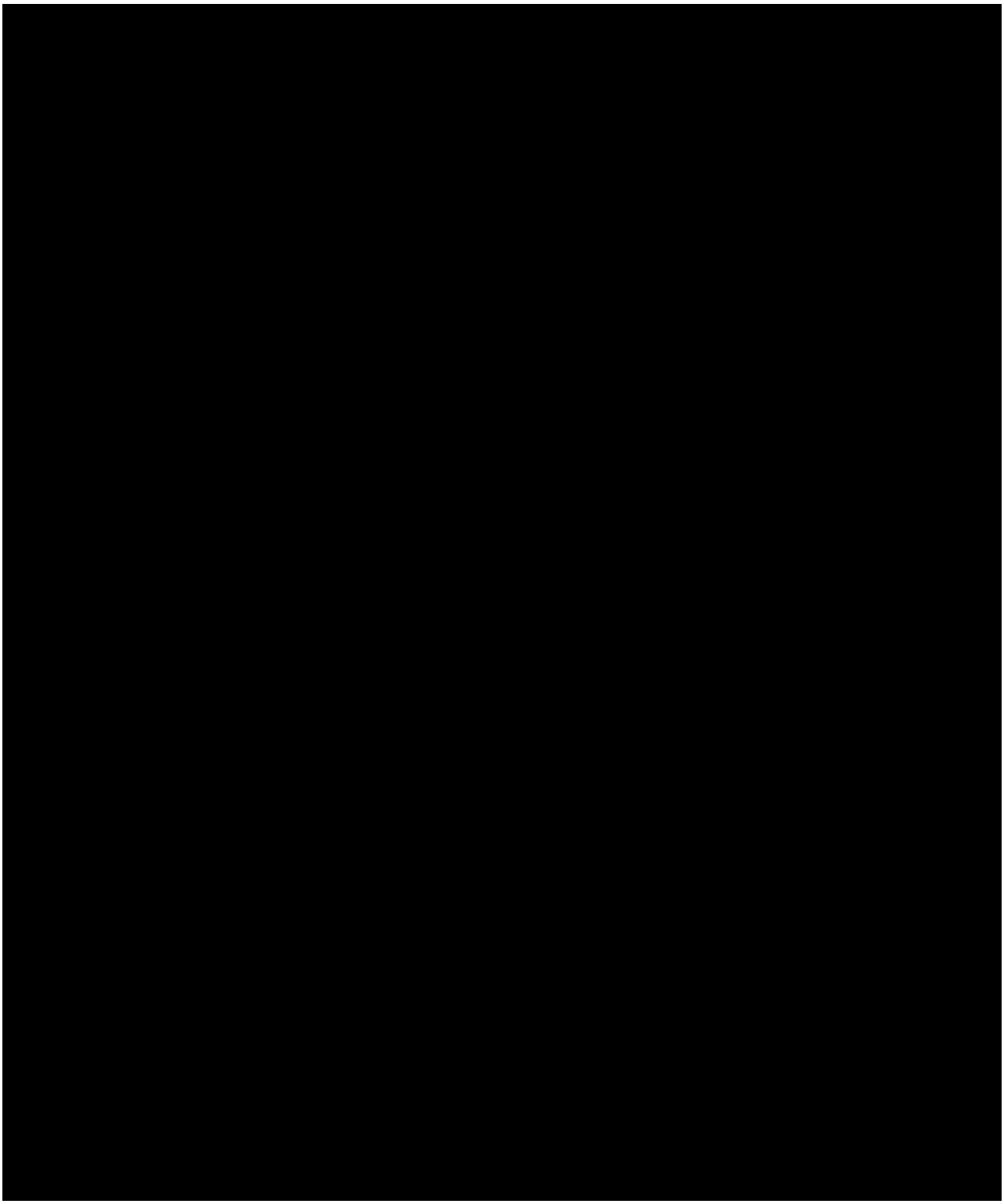

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INTERNAL REVIEW COMMITTEE CHARTER

C4591007 AND C4591015

Investigational BNT162b2 Vaccine Program
PF-07302048

Version: 4.0

Date: 26-May-2021

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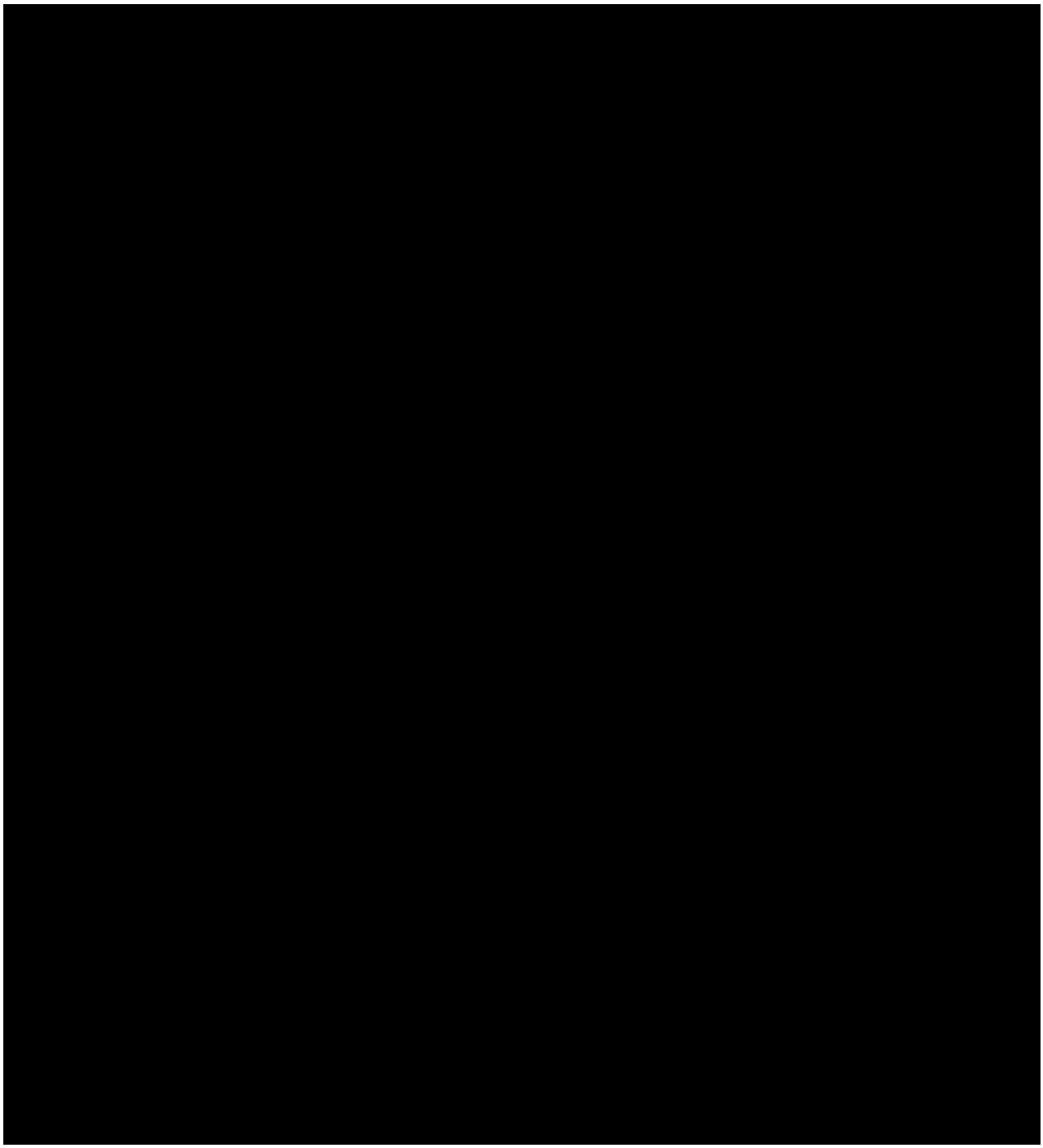

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1. INTRODUCTION

This internal review committee (IRC) (hereafter referred to as "the committee") is a single, expert advisory group including one or more Pfizer colleagues (who are not closely/directly involved in the conduct of this study) established to oversee Pfizer-managed trials. The primary rationale for establishing the committee is to make certain that appropriate safeguards are in place to help ensure the safety of participants. The IRC will be responsible for reviewing safety and immunogenicity data at multiple planned study specific timepoints in the C4591007 and C4591015 studies, as well as in the event a stopping rule is met.

Pfizer is responsible for conducting this study. BioNTech is the regulatory sponsor of this study.

[redacted]

1.2. Purpose of the Committee

The committee will review accumulating safety and immunogenicity data from the above-mentioned studies during Phase 1 for the C4591007 study and Phase 2 for the C4591015 study. The committee will advise the study teams and senior management regarding the safety of current participants, as well as the continuing scientific validity of these trials.

The committee will review safety data which may contribute to stopping rules at *ad hoc* meetings and all available safety data at regular meetings (Refer to Section 5 for details).

In addition to safety review by the committee, qualified Pfizer personnel will review safety data as specified in each studies Safety Surveillance Review Plan and will inform the committee of significant findings.

1.3. Committee Close-Out

The committee will have completed its work and been dissolved when final data from the studies under the scope of the IRC Charter have been reviewed.

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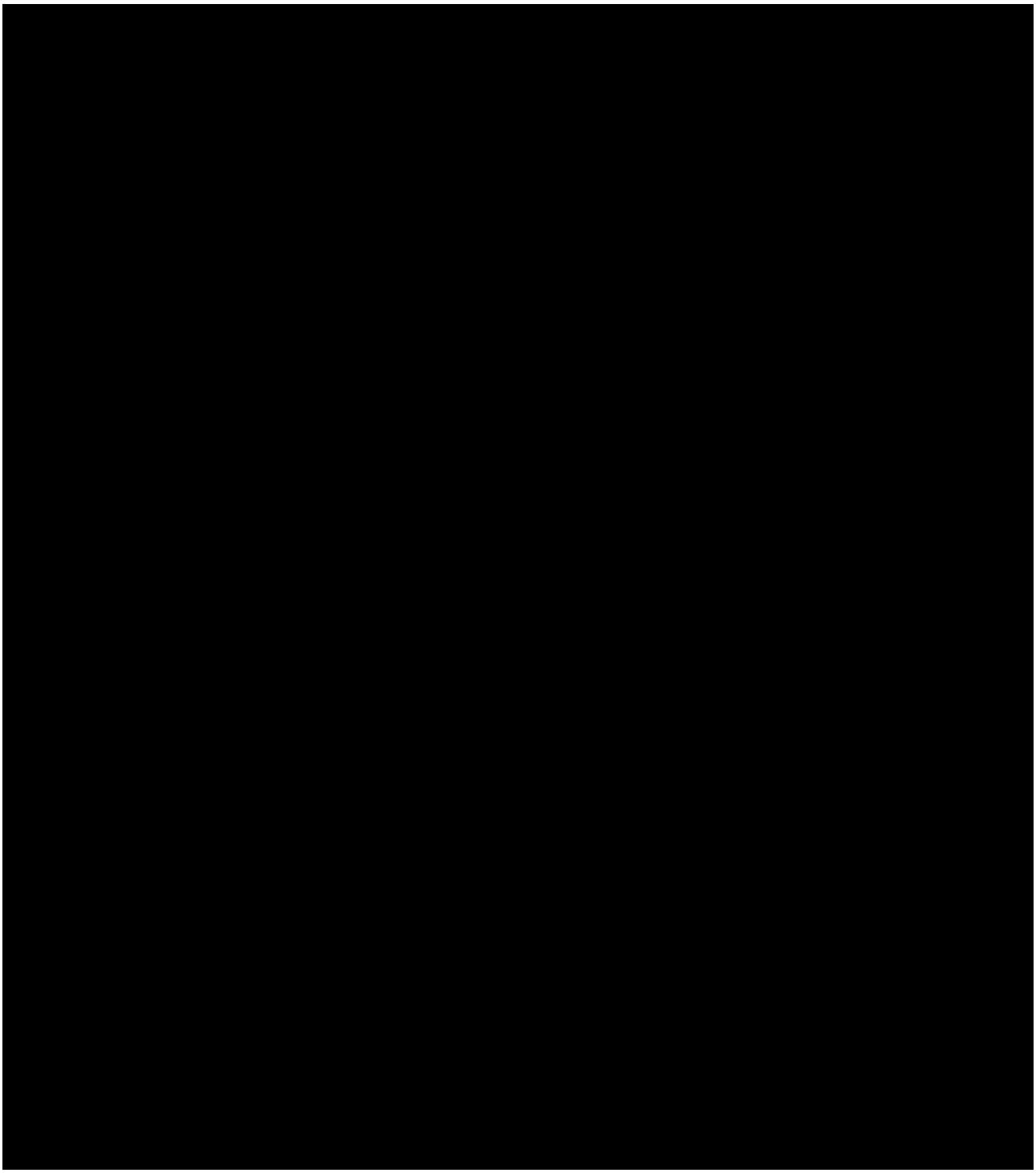

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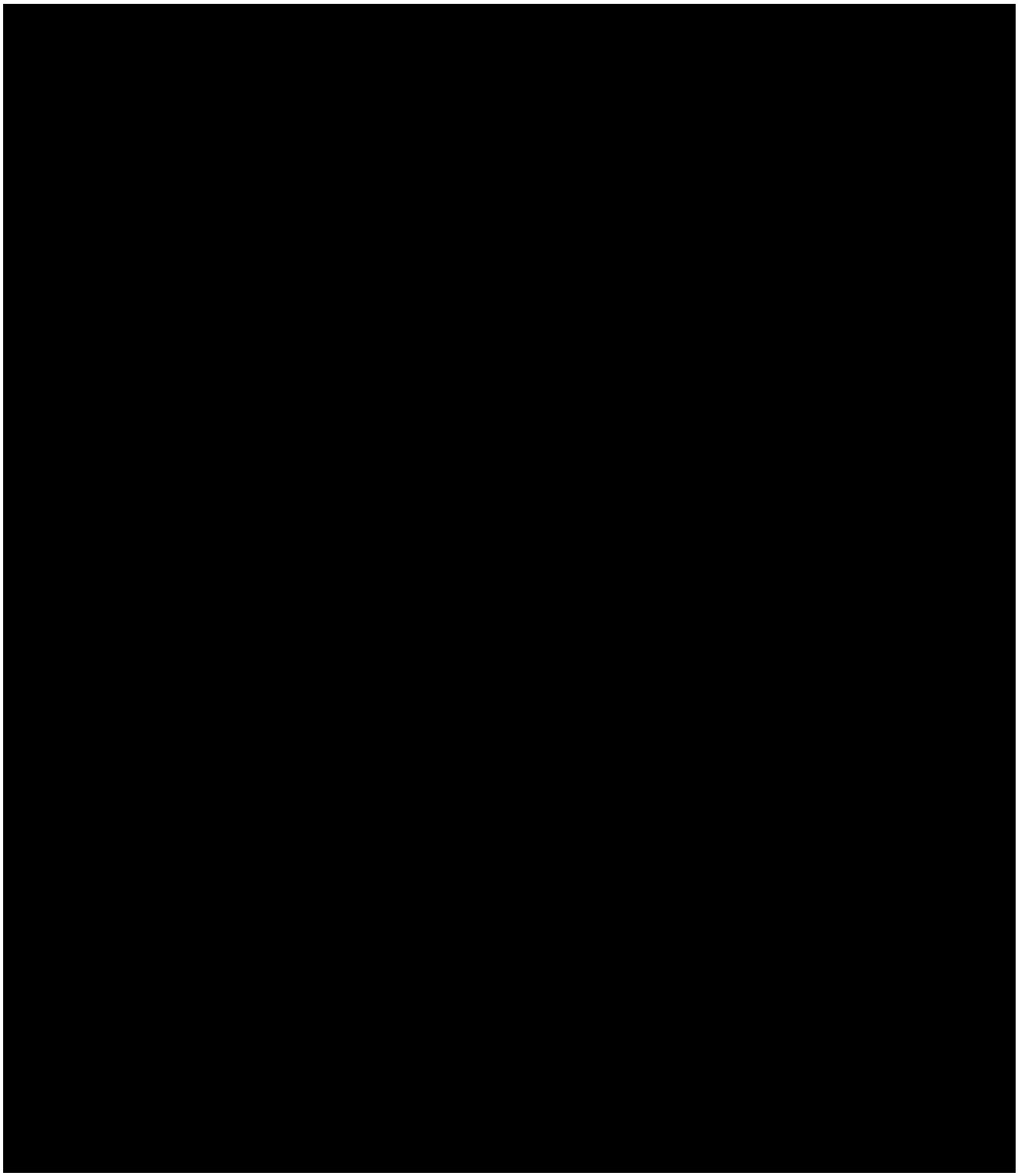

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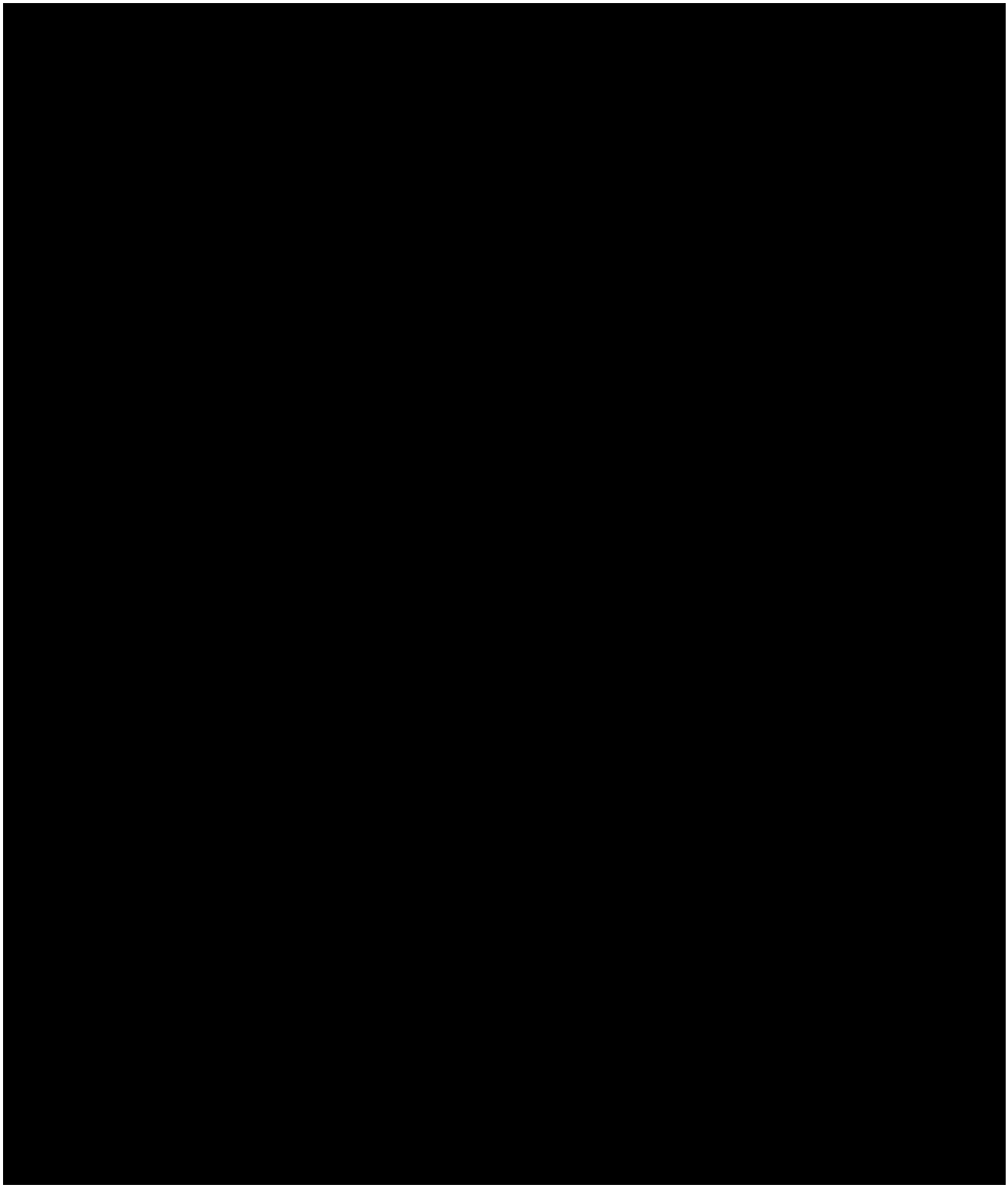

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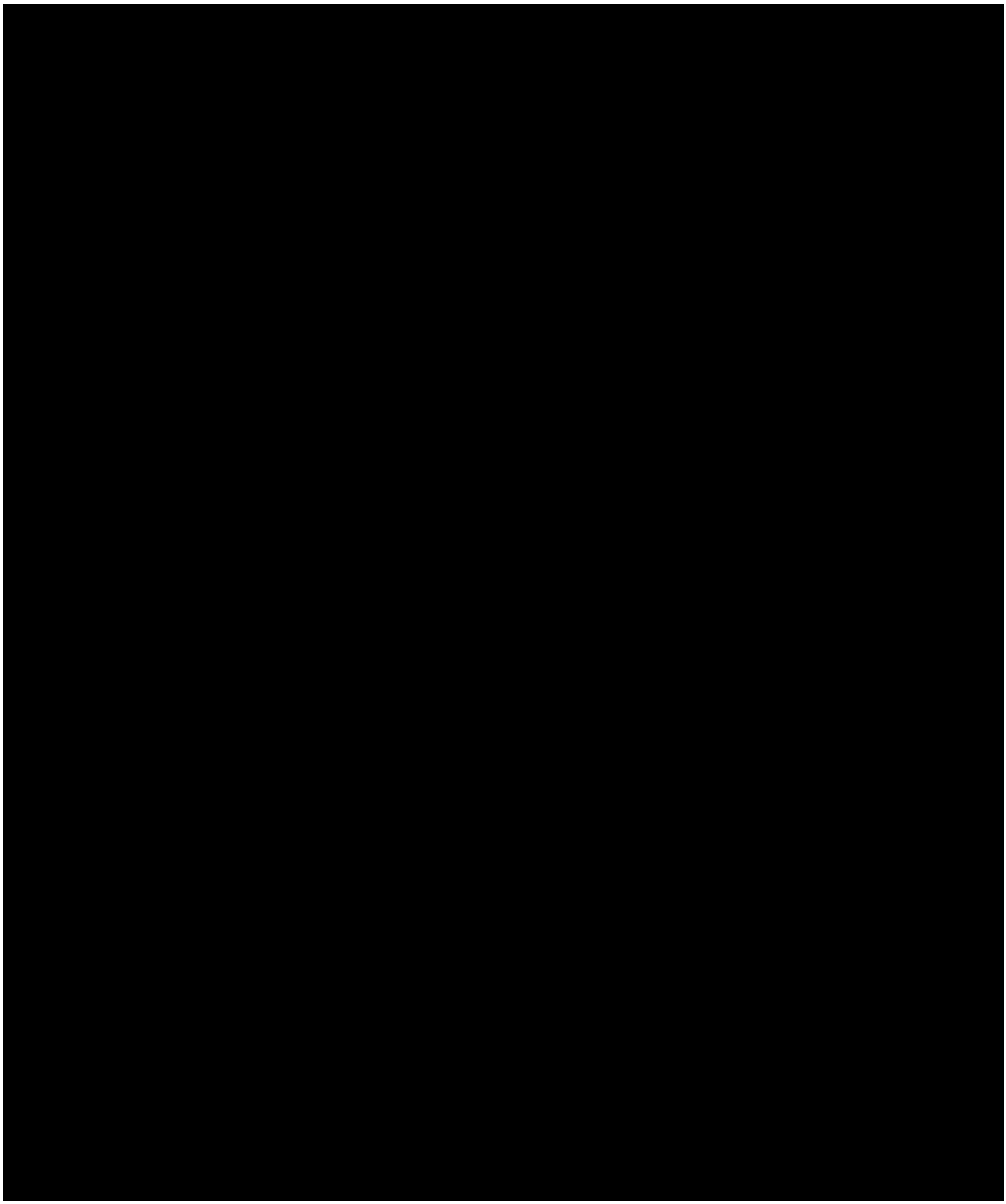

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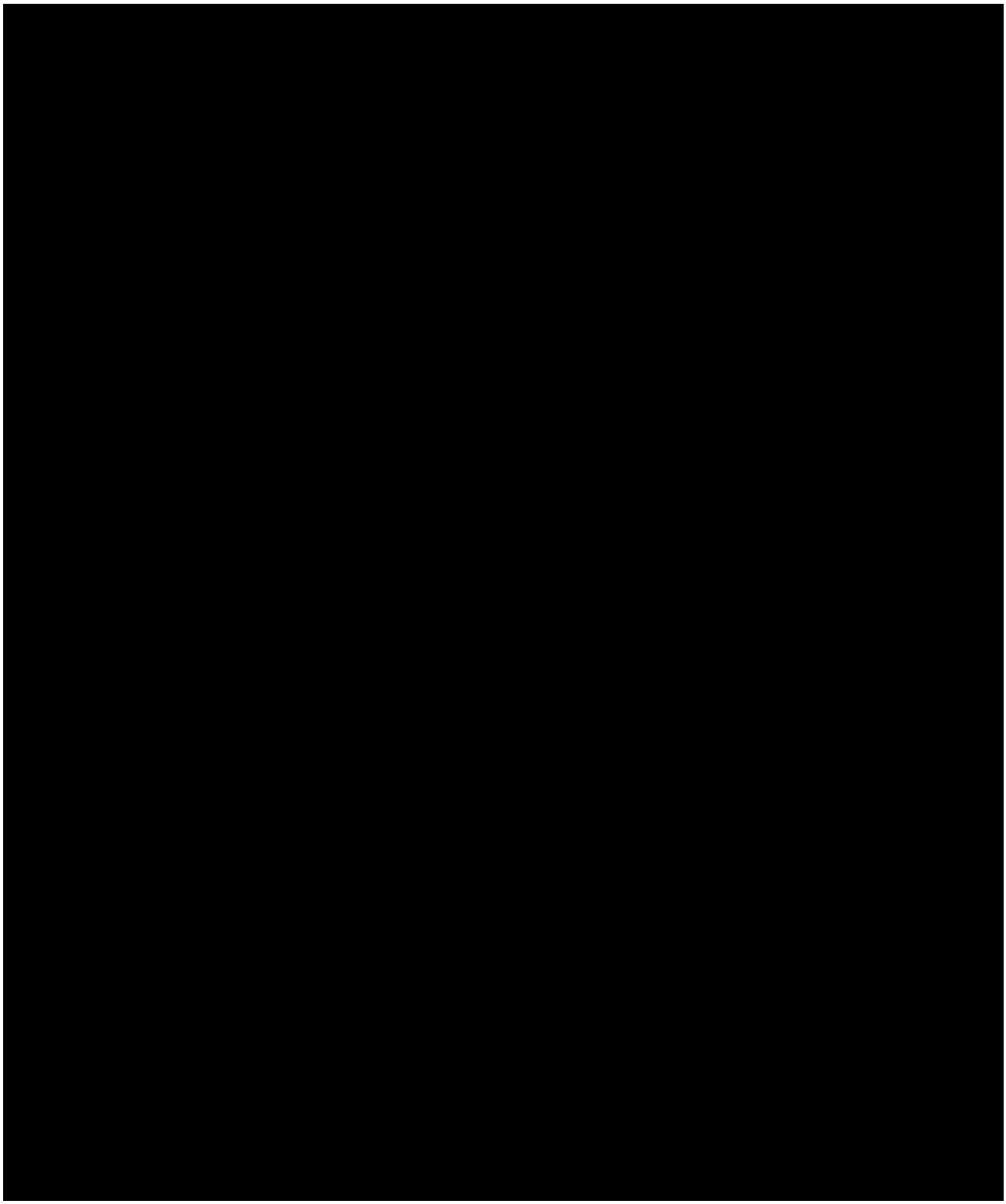

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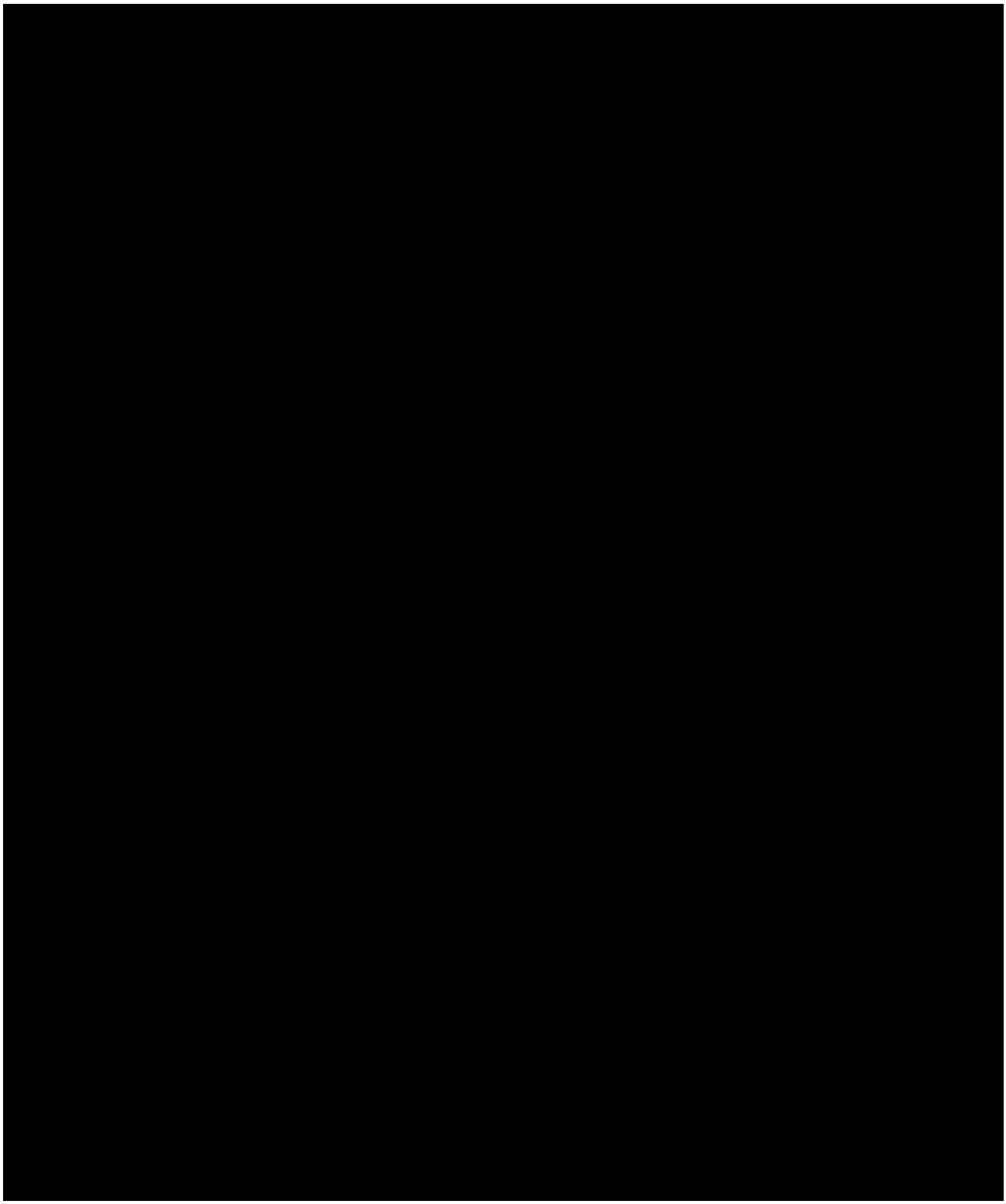

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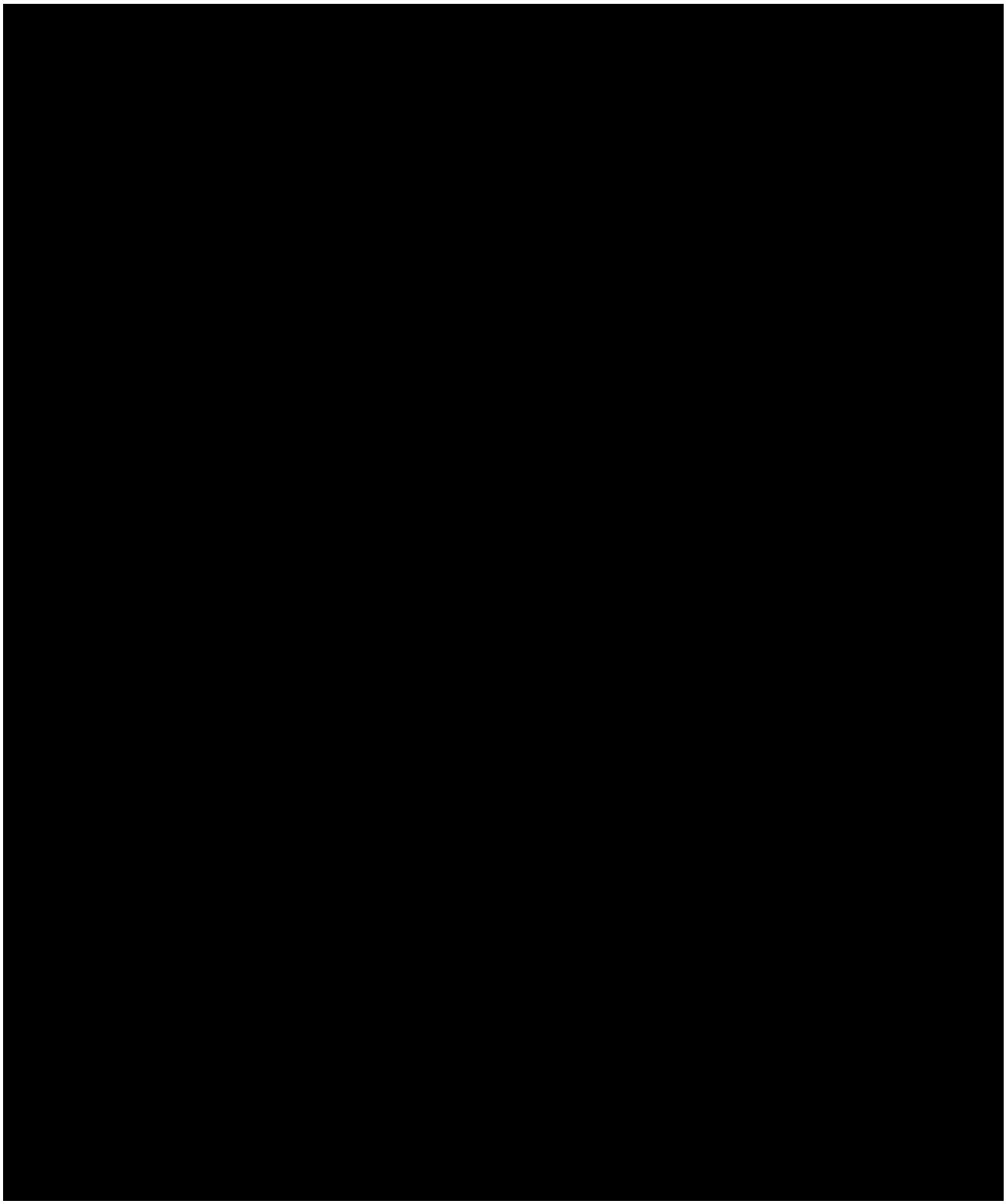

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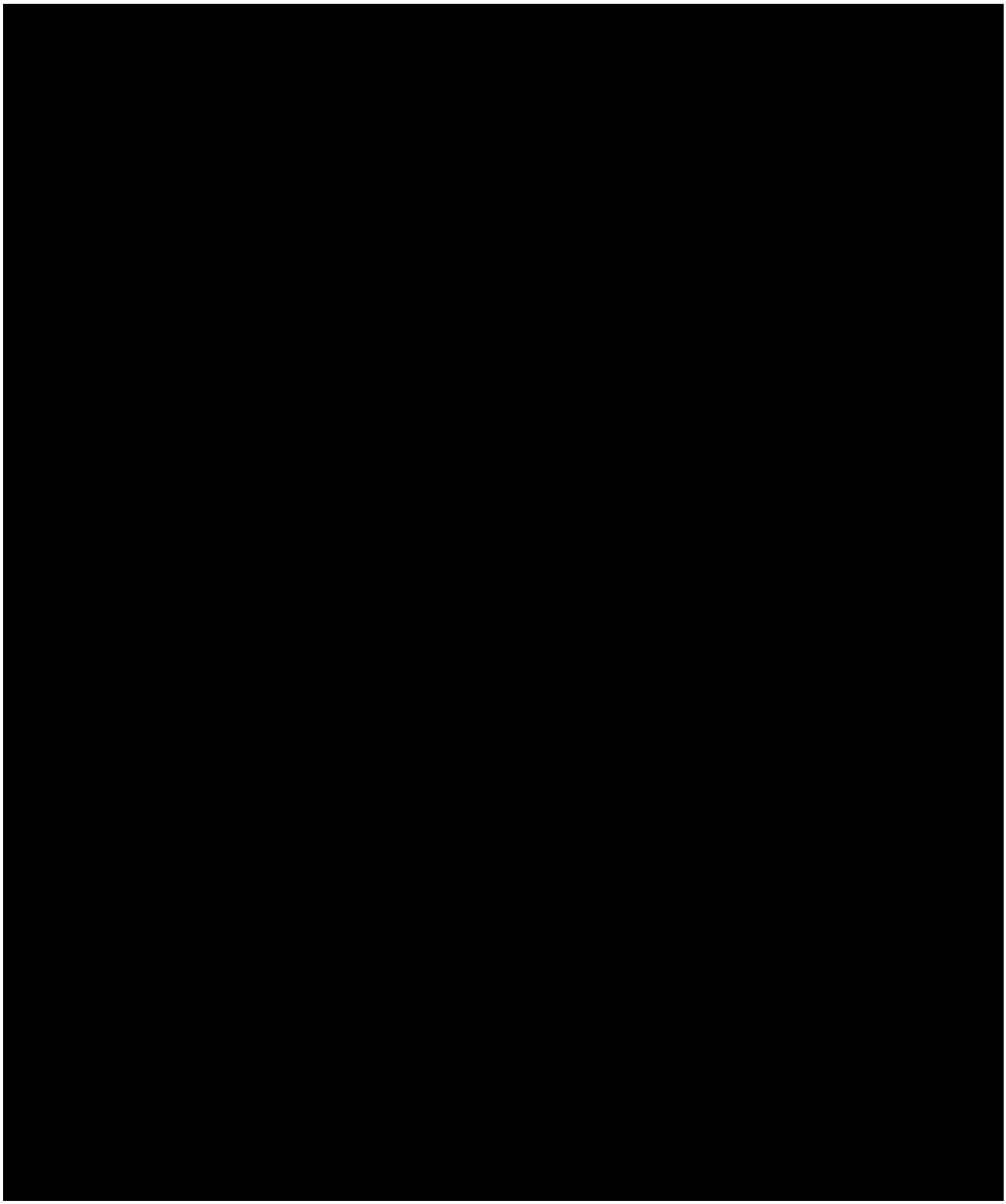

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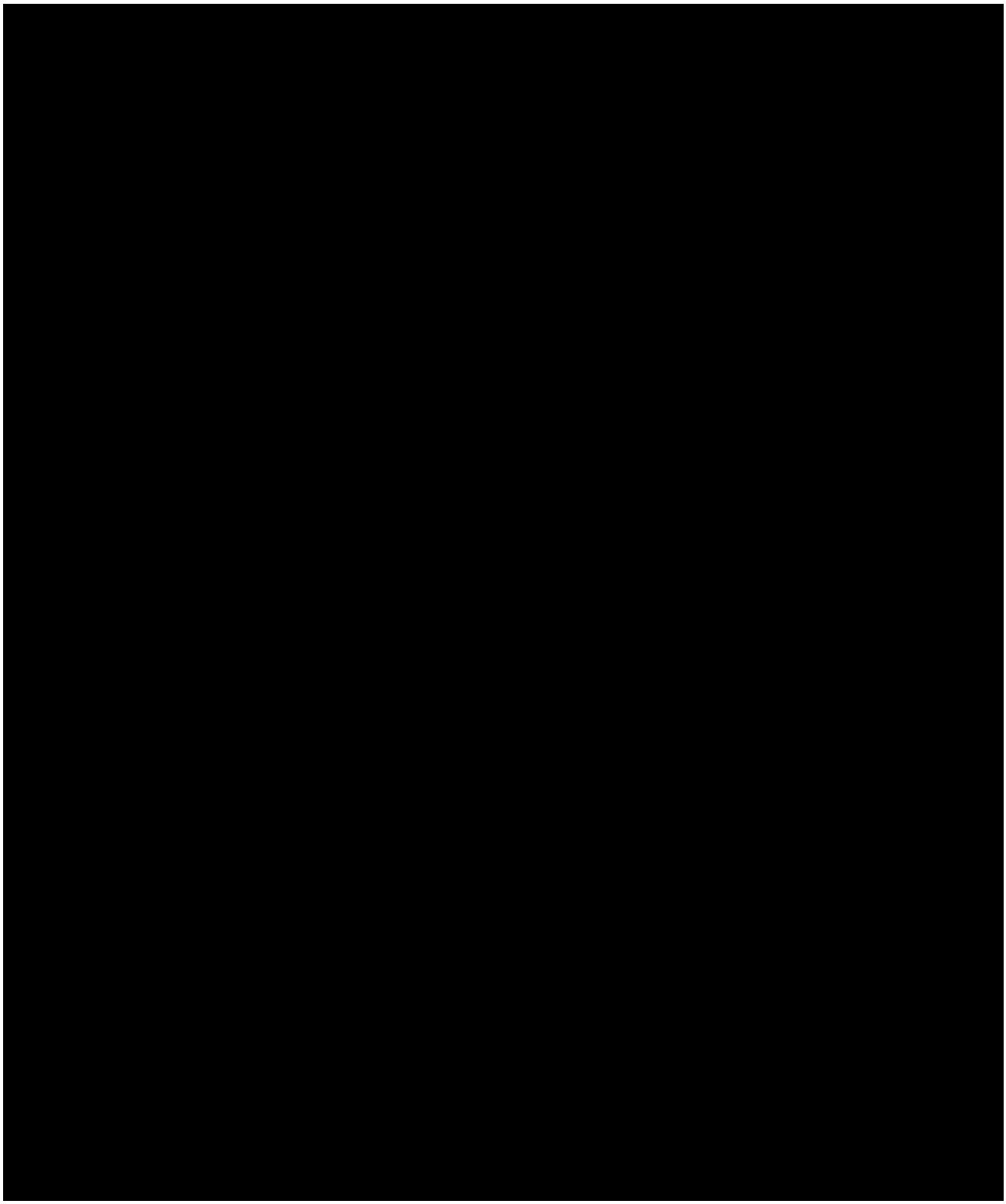

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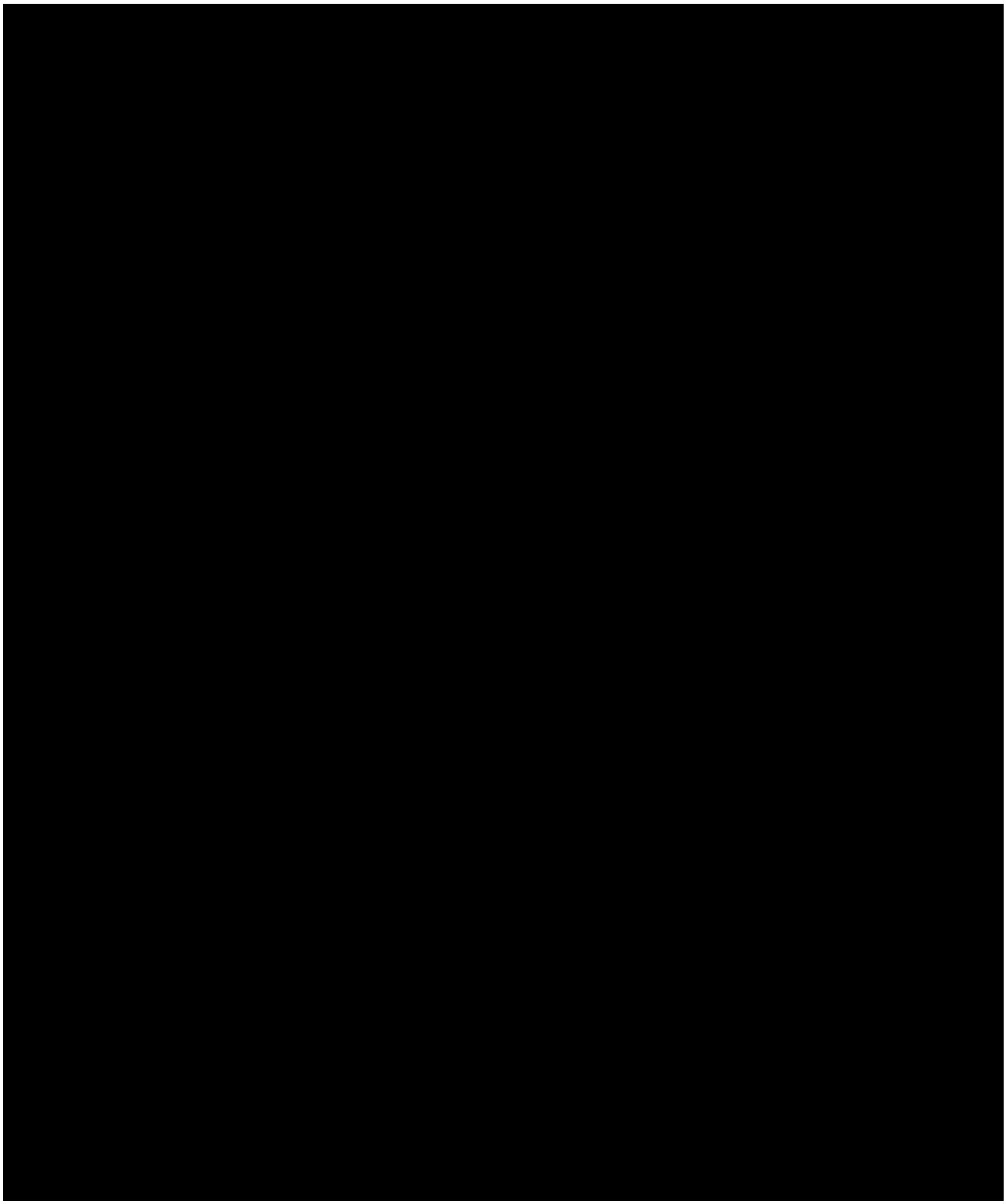

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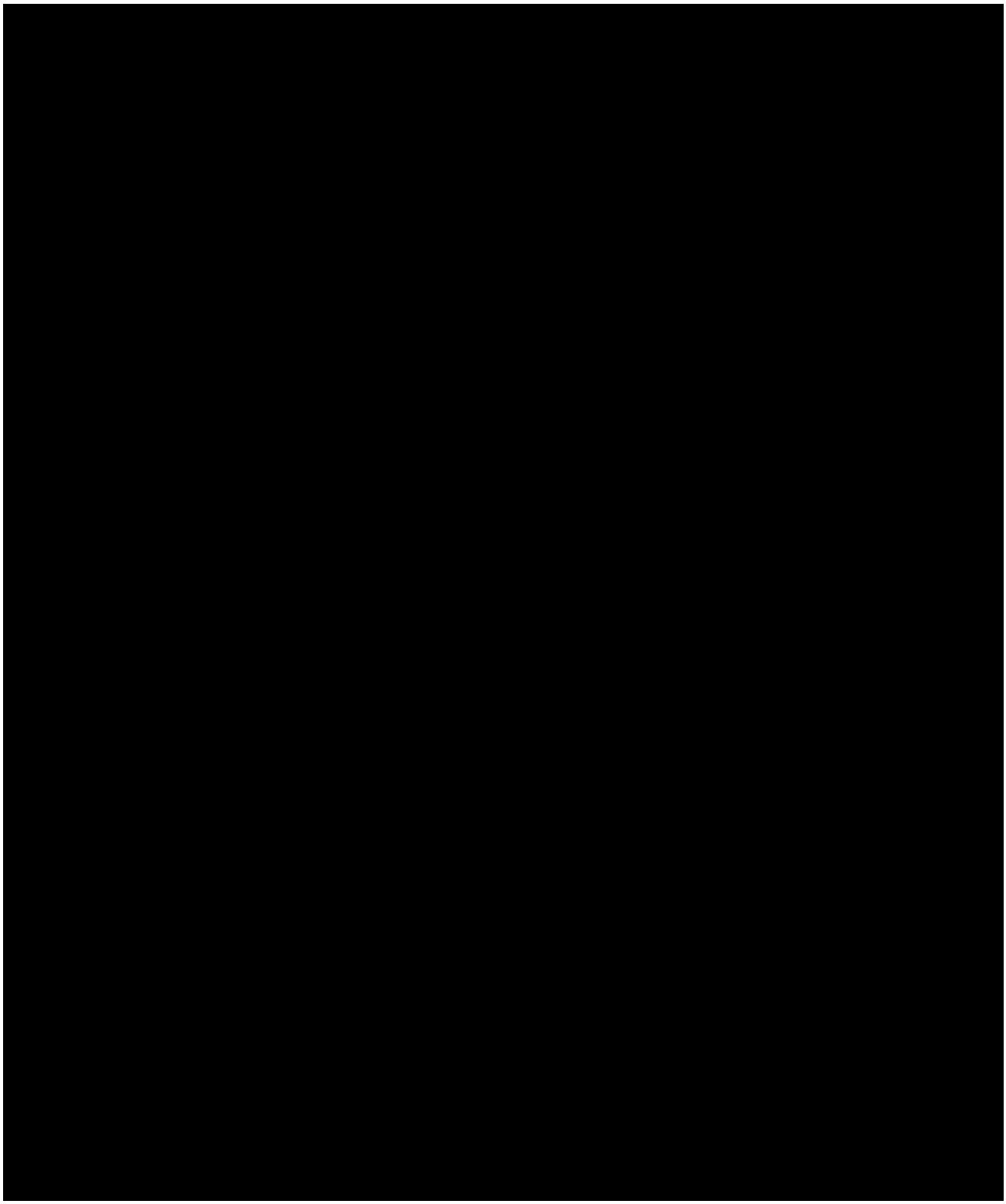

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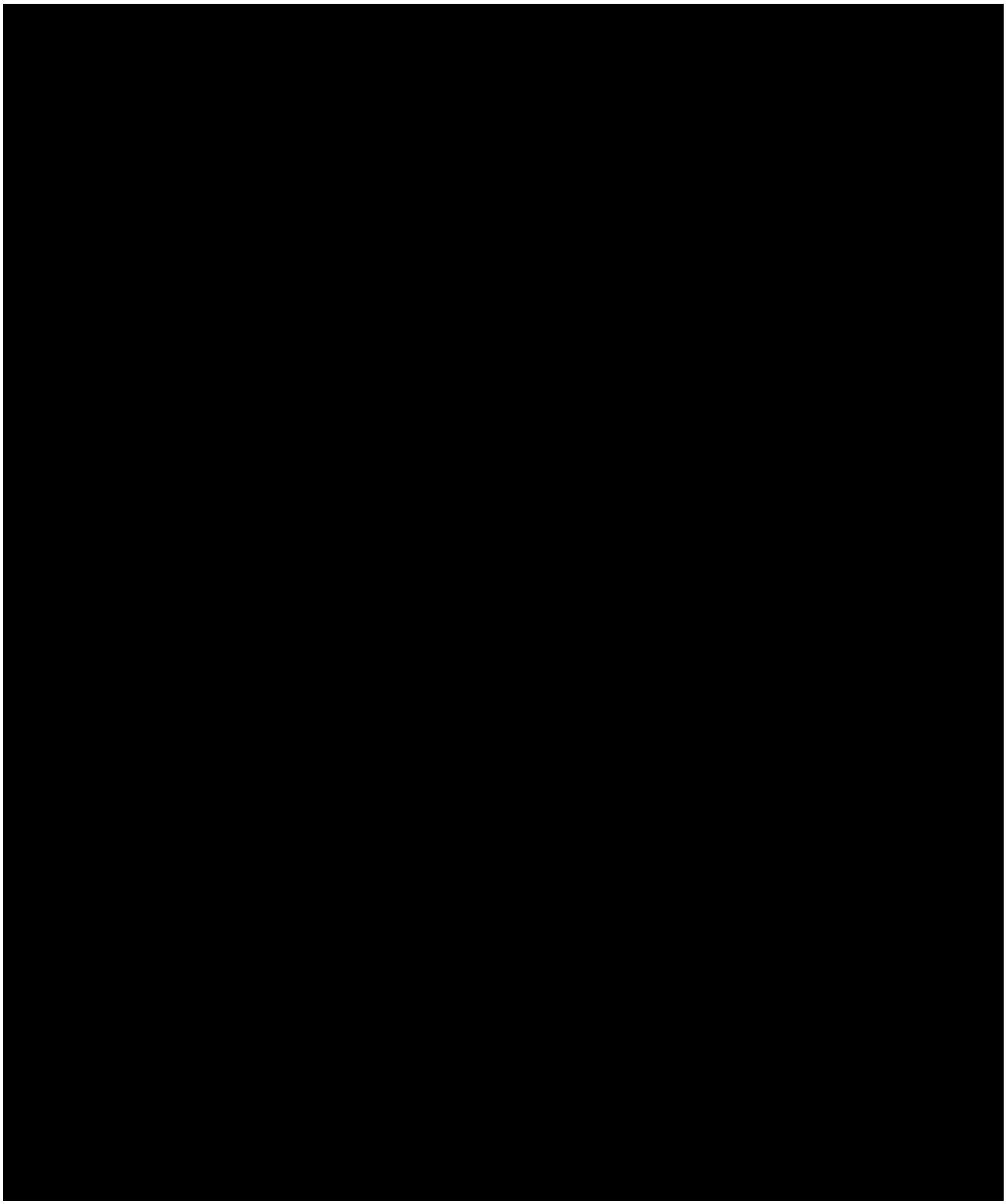

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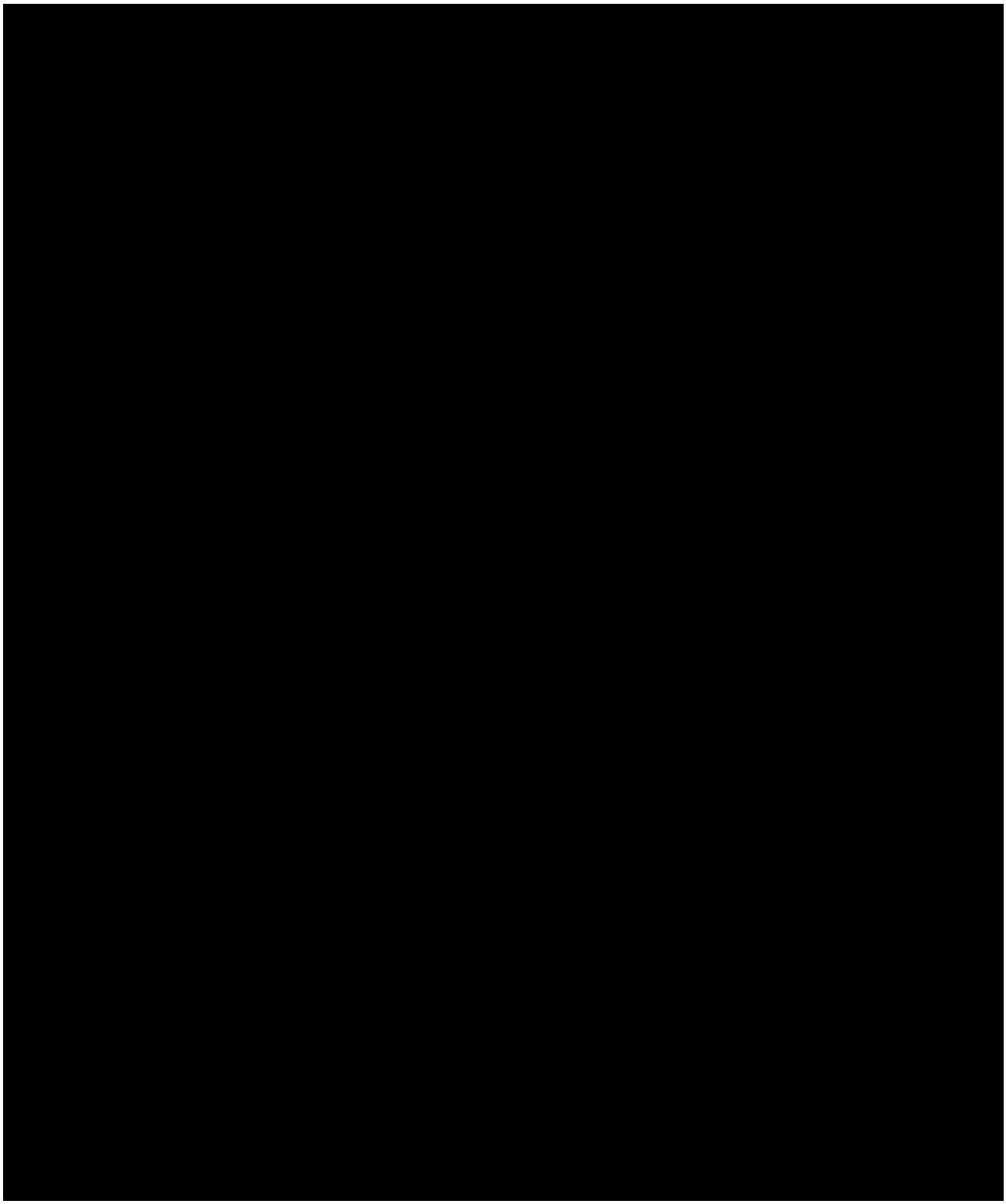

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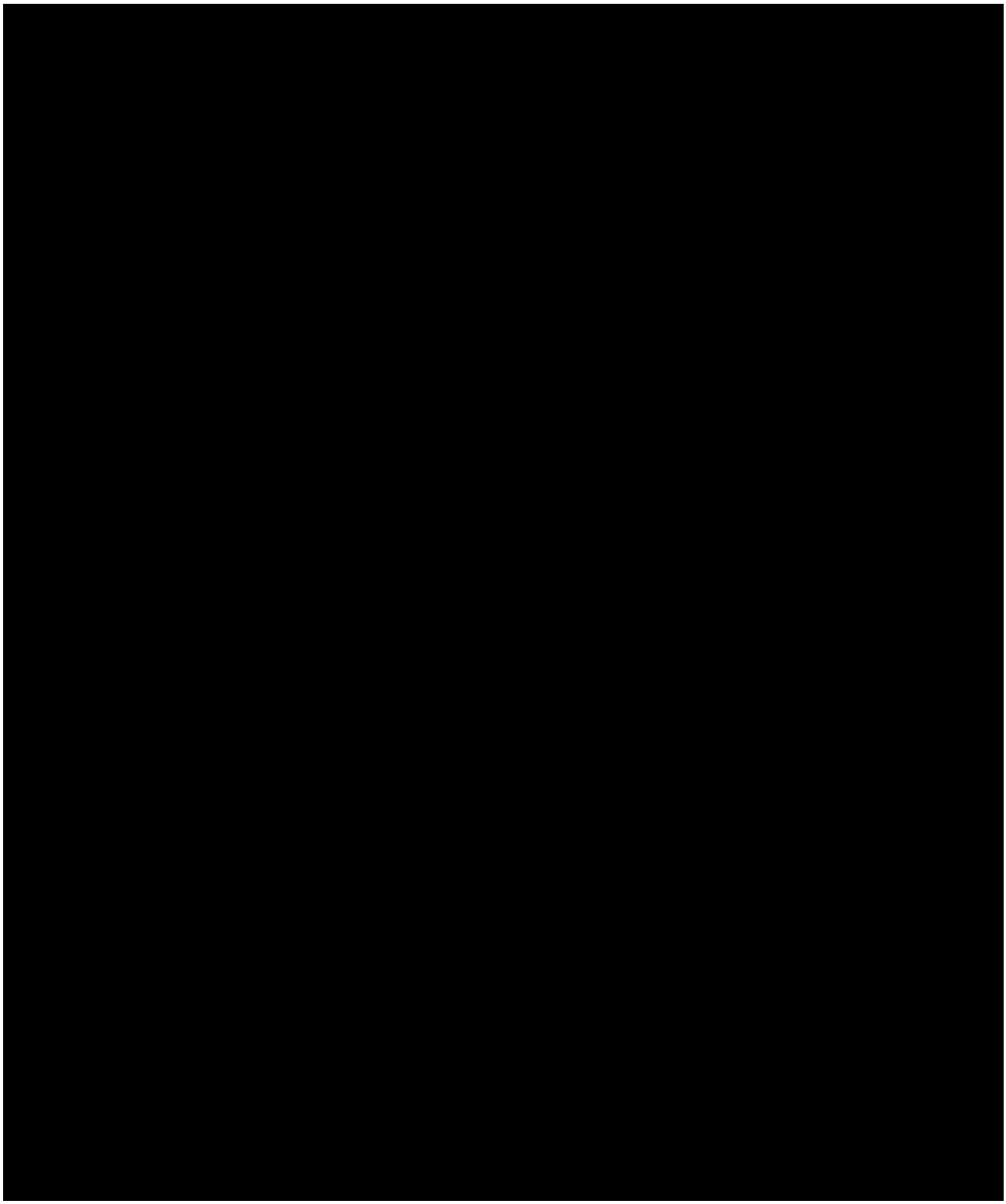

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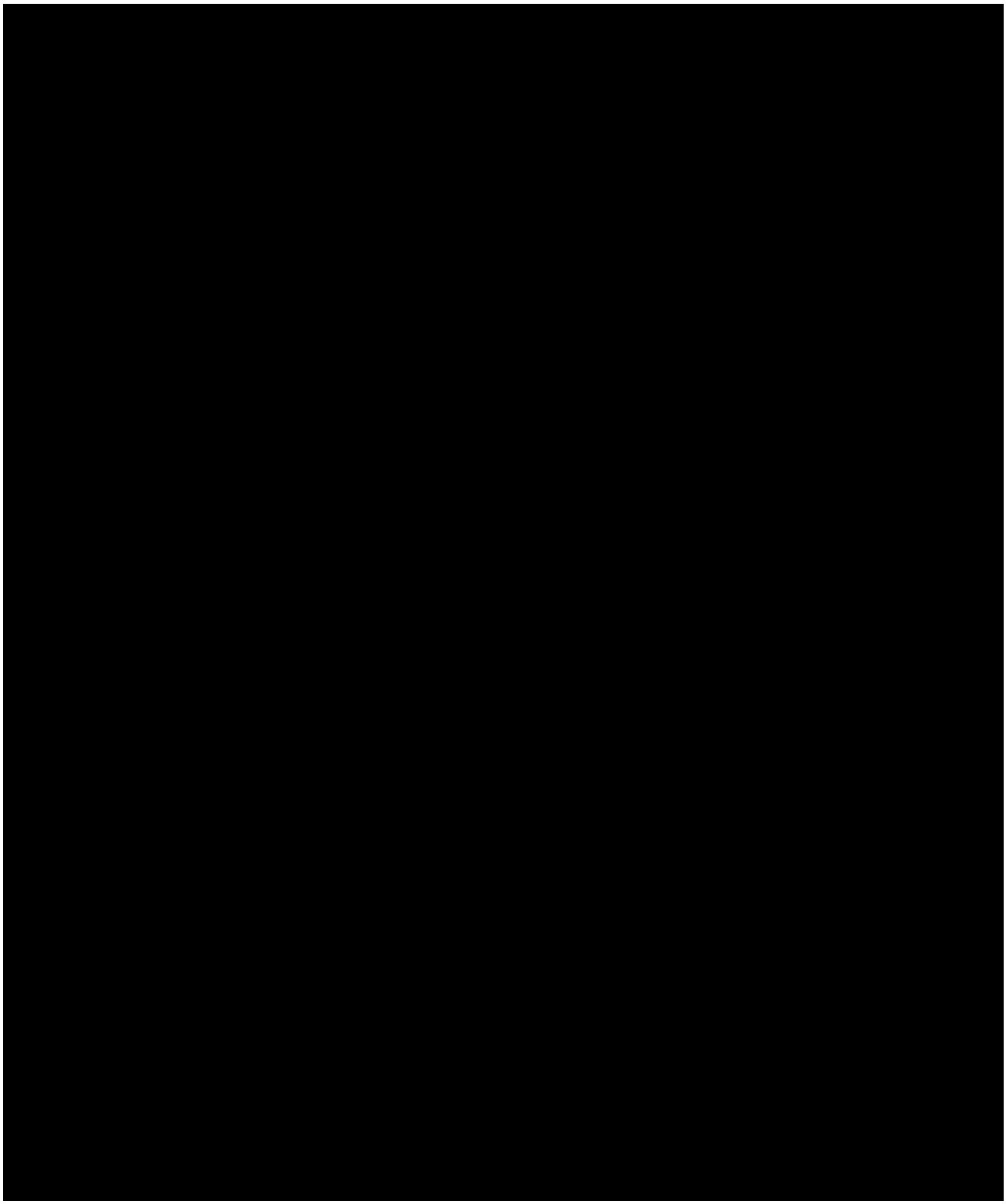

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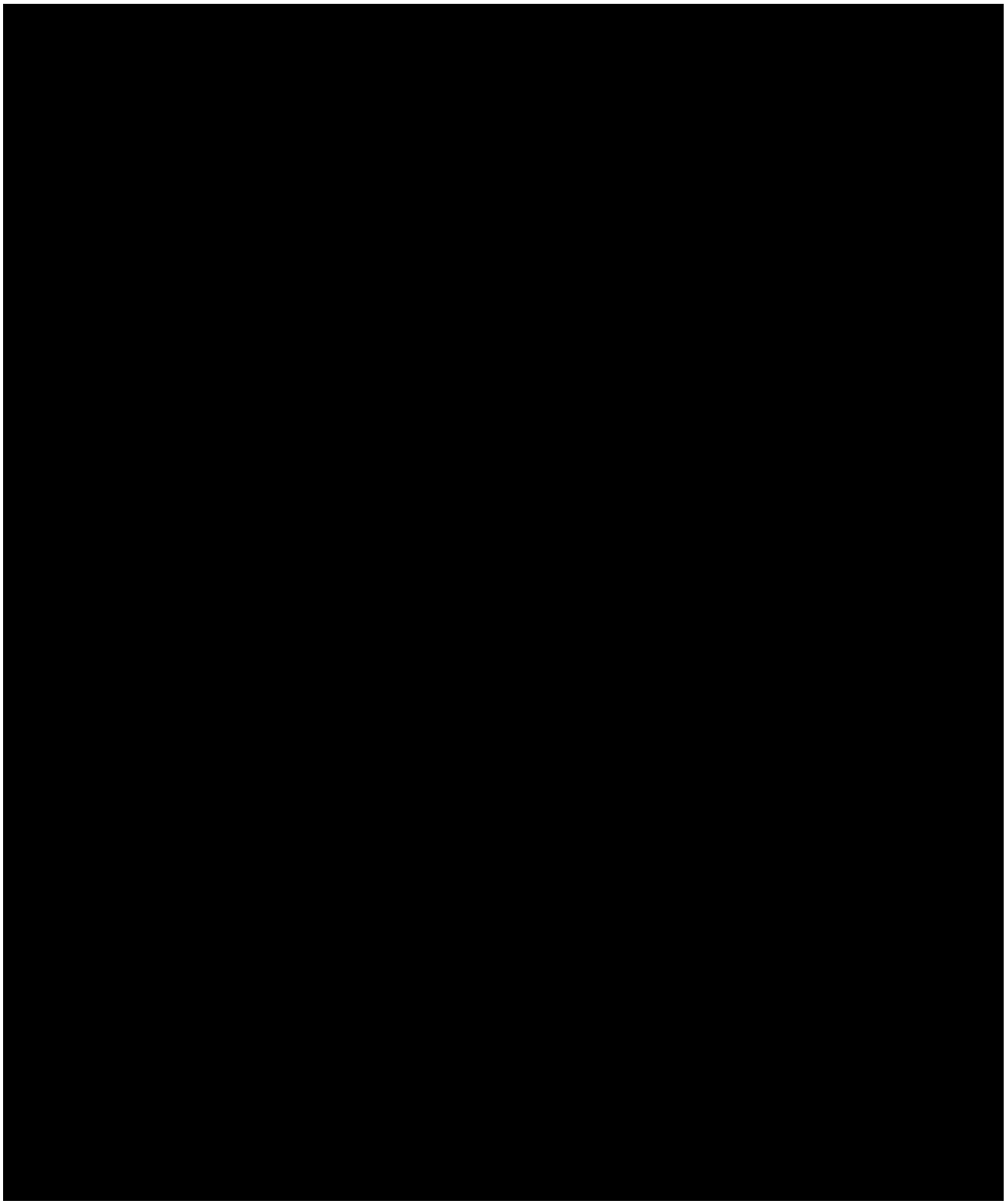

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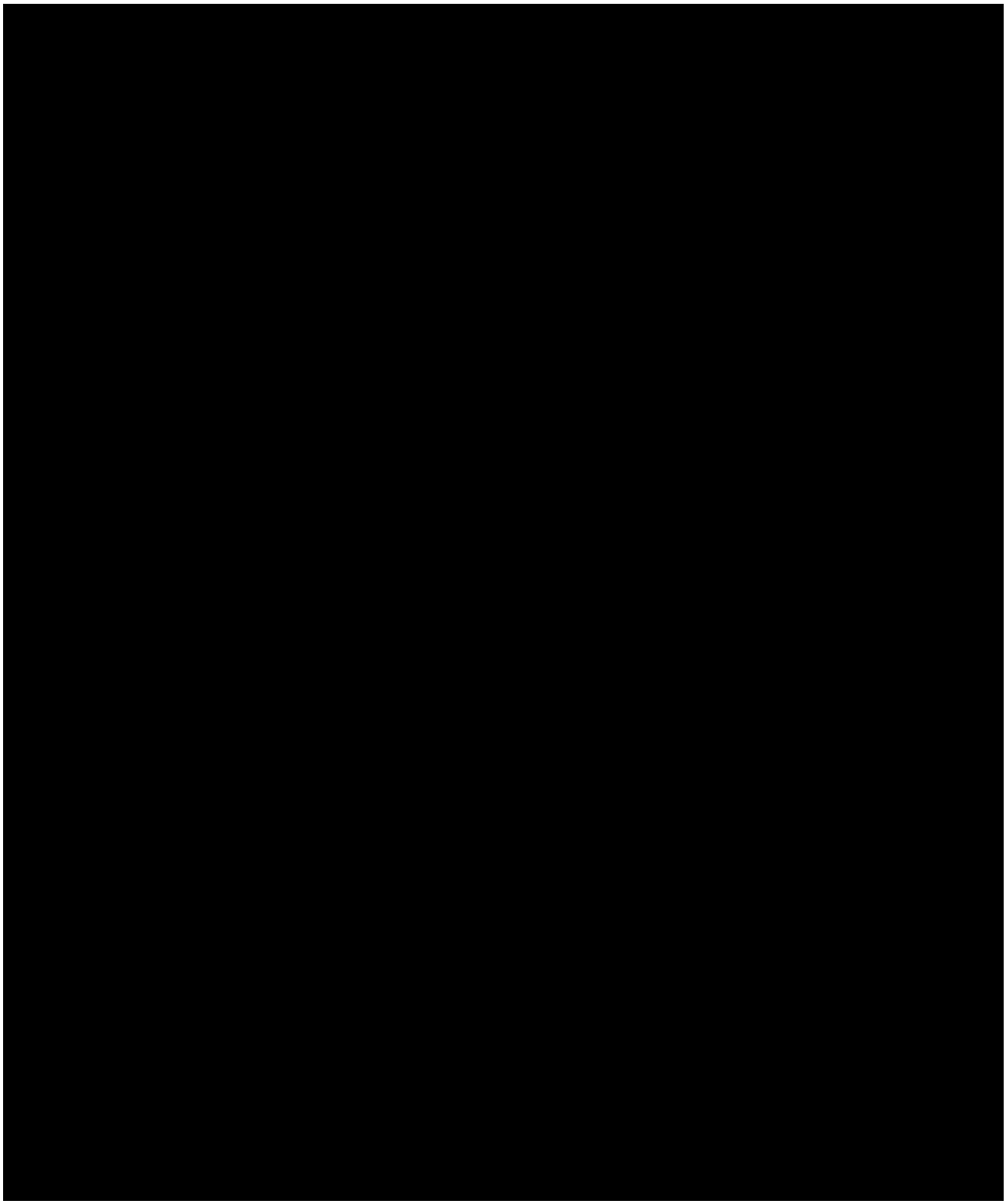

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Appendix 1. Committee Membership Log

The committee consists of the following members (past and present).

Member	Affiliation/Address	Role	Dates of Membership
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
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[redacted]	[redacted]	[redacted]	[redacted]

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Member	Affiliation/Address	Role	Dates of Membership
* [redacted]	[redacted]	[redacted]	[redacted]

*Attendance only required when IRC convenes to discuss the C4591015 study

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Appendix 2. Plan to Control Dissemination of Results (C4591015 only)

This is an observer-blinded study as the physical appearance of the BNT162b2 vaccine candidates and placebo differ.

Study Site:
The participant, investigator, study coordinator, and other site staff will be blinded. The dispenser(s)/administrator(s) and those study site team members who are involved in ensuring that protocol requirements for investigational product handling, allocation, and administration are fulfilled at the site (e.g. study manager, clinical research associates) will be unblinded for the duration of the study.

Blinding codes should be broken by the investigator only when knowledge of the actual treatment code is absolutely essential for further management of the participant. The method will be an electronic process via Impala.

Pfizer:
The study team members are blinded to the vaccine assigned/received by all participants during Phase 2 and 3 of the study.

Randomization codes will be released to the reporting team (**C4591015 only**) who need access to the codes to generate the summaries and participant data listings for the review by the unblinded committee members during Phase 2 of the study. Randomization codes will be available to the committee via the reporting team.

Release of the randomization codes to designated personnel will only be performed upon completion of the Randomization Code Release Request Form in GRAABS. Randomization codes and unblinded data will be maintained in a secure location.

Laboratory personnel performing the immunologic assays will remain blinded to vaccine assigned/received throughout the study.

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Appendix 3. Key Contacts

Name/Study	*Contact Information*	*Role*
[redacted]	[redacted]	[redacted]

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Name/Study	*Contact Information*	*Role*
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
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Name/Study	*Contact Information*	*Role*
[redacted]	[redacted]	[redacted]

Reporting Team Members C4591015		
Name	*Contact Information*	*Expertise*
[redacted]	[redacted]	[redacted]
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16.2.1.1 Listing of Participants Discontinued From Vaccination and/or From the Study (Maternal)

Vaccine Group (as Randomized)	Participant	Last Dose	Rel Day[a]	Withdrawal Date	Study Phase	Withdrawal Reason	Comment[b]
BNT162b2 (30 µg)	[redacted]	2	108	08SEP2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Patient no longer wishes to participate in the trial
	[redacted]	2	169	26OCT2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject moved out of state
	[redacted]	2	203	29DEC2021	FOLLOW-UP	OTHER	Subject moved to another state and not able to travel and no site in state that she lives in
	[redacted]	2	224	27JAN2022	FOLLOW-UP	WITHDRAWAL BY SUBJECT	WITHDRAWAL BY SUBJECT
	[redacted]	2	111	02NOV2021	FOLLOW-UP	OTHER	Relocation
	[redacted]	2	230	09FEB2022	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Patient decided to withdraw from the study for personal reasons
	[redacted]	2	254	09FEB2022	FOLLOW-UP	LOST TO FOLLOW-UP	Subject did not arrive for the 6 month visit. Certified Letter sent for eDiary non compliance.
	[redacted]	1	24	03JUN2021	VACCINATION	WITHDRAWAL BY SUBJECT	The patient withdrew consent.
		1	24	03JUN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent from participating in study
	[redacted]	2	66	10SEP2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject was no longer interested in participating in study
	[redacted]			30SEP2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject walked out of clinic after signing ICF. Site unable to reach subject
	[redacted]	2	246	13DEC2021	FOLLOW-UP	LOST TO FOLLOW-UP	Subject did not return calls or respond to certified letter
	[redacted]	2	249	03JUN2022	FOLLOW-UP	LOST TO FOLLOW-UP	Participant not rechargeable, she was contacted several times
	[redacted]	2	280	21JUN2022	FOLLOW-UP	OTHER	Subject unblinded per CEC request 12/14/21 and agreed to 6 mon fup visit to collect safety only.

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16.2.1.1 Listing of Participants Discontinued From Vaccination and/or From the Study (Maternal)

Vaccine Group (as Randomized)	Participant	Last Dose	Rel Day[a]	Withdrawal Date	Study Phase	Withdrawal Reason	Comment[b]
	[redacted]	2	177	01MAR2022	FOLLOW-UP	WITHDRAWAL BY SUBJECT	participant leaving for Mozambique, unsure of when she will return to South Africa. Withdrawing
	[redacted]	2	190	03JUN2022	FOLLOW-UP	LOST TO FOLLOW-UP	Withdrawal from study by sub-investigator.9 attempts were made,4 home visits done still no contact
	[redacted]	2	27	25JUL2021	VACCINATION	PROTOCOL DEVIATION	Sponsor Approved Blind Break
		2	27	25JUL2021	FOLLOW-UP	PROTOCOL DEVIATION	Unblinding was performed before V7
	[redacted]	2	35	06JUL2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject requested to be unblinded prior to delivery, subject was unblinded.
	[redacted]	1	24	25JUN2021	VACCINATION	PROTOCOL DEVIATION	The patient received a dose of the vaccine for COVID-19 outside of the study.
		1	85	25AUG2021	FOLLOW-UP	PROTOCOL DEVIATION	The patient received a dosee of the vaccine for COVID-19 outside of the study.
	[redacted]	2	337	25MAY2022	FOLLOW-UP	LOST TO FOLLOW-UP	The subject was contacted by phone and whatsapp more than three times.
	[redacted]	2	314	11MAY2022	FOLLOW-UP	LOST TO FOLLOW-UP	Subject didn't answer the phone calls and didn't contact site after mail with reception confirmation
	[redacted]	2	210	17JAN2022	FOLLOW-UP	PROTOCOL DEVIATION	Discontinued. Subject received 3r dose of covid-19 vaccine outside of study.
	[redacted]	2	2	06JUL2021	VACCINATION	WITHDRAWAL BY SUBJECT	participant wanting a covid vaccine that has become more readily accessible nowdays
		2	2	06JUL2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the participant decided to drop out the study and the follow up
	[redacted]	1	7	06SEP2021	VACCINATION	WITHDRAWAL BY SUBJECT	Consent withdrawn for any further follow up

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16.2.1.1 Listing of Participants Discontinued From Vaccination and/or From the Study (Maternal)

Vaccine Group (as Randomized)	Participant	Last Dose	Rel Day[a]	Withdrawal Date	Study Phase	Withdrawal Reason	Comment[b]
		1	7	06SEP2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	refused further follow ups
Placebo	[redacted]	2	87	08JUL2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject reports she no longer had the time to commit to the study.
	[redacted]	2	145	02NOV2021	FOLLOW-UP	LOST TO FOLLOW-UP	02,07,AND10SEP2021 VM; 13SEP20 CERT LETTER,16,22,28SEP2021 AND 05OCT2021 LEFT VM 11OCT2021 CERT LETT
	[redacted]	1	28	03JUN2021	VACCINATION	WITHDRAWAL BY SUBJECT	Participant declined second vax, but agreed to routine study visits and cord blood collection
		1	221	13DEC2021	FOLLOW-UP	LOST TO FOLLOW-UP	Maternal pt didn't responded to many contact attempts since 10/8/21. Final attempt made on 12/10/21.
	[redacted]	2	148	20SEP2021	FOLLOW-UP	LOST TO FOLLOW-UP	Last contact was made on 10 Aug 2021. Certified letter was sent. Still no contact.
	[redacted]			28MAY2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject randomized in error
	[redacted]	1	25	01JUL2021	VACCINATION	WITHDRAWAL BY SUBJECT	subject withdrew consent after vax1
		1	25	01JUL2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent after vax1
	[redacted]	2	65	29JUN2021	FOLLOW-UP	PROTOCOL DEVIATION	d/t time constraints,subject opted to receive COVID vaccine outside of study,but agrees to safety fu
	[redacted]	x1	1	28JUN2021	OPEN LABEL TREATMENT	WITHDRAWAL BY SUBJECT	Maternal subject withdrew consent
		x1	1	28JUN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject no longer wishes to be in study
	[redacted]	x1	12	13SEP2021	OPEN LABEL TREATMENT	WITHDRAWAL BY SUBJECT	Maternal Subject withdrew consent

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16.2.1.1 Listing of Participants Discontinued From Vaccination and/or From the Study (Maternal)

Vaccine Group (as Randomized)	Participant	Last Dose	Rel Day[a]	Withdrawal Date	Study Phase	Withdrawal Reason	Comment[b]
		x1	12	13SEP2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Moved out of state due to work
	[redacted]	2	71	18AUG2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject no longer wants to participate in study
	[redacted]	2	84	07SEP2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject no longer wished to participate in study.
	[redacted]	2	82	13SEP2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent to participate in this study
	[redacted]	2	58	02SEP2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent
	[redacted]	2	106	16NOV2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent
	[redacted]	2	96	12NOV2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject no longer wanted to participate in Study
	[redacted]	2	45	01DEC2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Mom and baby in KZN not planning to return to Johannesburg anytime soon,requested to be offstudy.
	[redacted]	x1	32	30JUN2022	OPEN LABEL TREATMENT	PROTOCOL DEVIATION	Subject out of window and IP expired
		x1	32	30JUN2022	FOLLOW-UP	PROTOCOL DEVIATION	Subject out of window and IP expired
	[redacted]	2	30	27JUL2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	change of residence.
	[redacted]†	2	64	22DEC2021	FOLLOW-UP	LOST TO FOLLOW-UP	Participant non-compliant. Does not answer phone, multiple unsuccessful home visits.
	[redacted]†	2	10	20OCT2021	VACCINATION	WITHDRAWAL BY SUBJECT	subject confirmed her exclusion from study

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16.2.1.1 Listing of Participants Discontinued From Vaccination and/or From the Study (Maternal)

Vaccine Group (as Randomized)	Participant	Last Dose	Rel Day[a]	Withdrawal Date	Study Phase	Withdrawal Reason	Comment[b]
		2	10	20OCT2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	participant was reluctant to come to site for review of the severe reaction & ended up withdrawing
	[redacted]	2	46	02AUG2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	After the blind was broken, the participant chose to leave the study.
	[redacted]	1	21	16JUN2021	VACCINATION	PROTOCOL DEVIATION	As per sponsor request, patient had been unblinded as received Pfizer vaccine outside study
		1	72	06AUG2021	FOLLOW-UP	PROTOCOL DEVIATION	Patient received COVID-19 vaccine outside of the study.
	[redacted]	x1	77	02MAY2022	OPEN LABEL TREATMENT	WITHDRAWAL BY SUBJECT	Patient discontinued
		x1	77	02MAY2022	FOLLOW-UP	WITHDRAWAL BY SUBJECT	PATIENT REQUESTS WITHDRAWAL FROM THE STUDY FOR PERSONAL REASONS
	[redacted]	x2	31	04DEC2021	OPEN LABEL TREATMENT	PROTOCOL DEVIATION	Visit was not performed by error
		x2	31	04DEC2021	FOLLOW-UP	PROTOCOL DEVIATION	Protocol deviation because V103 was not performed.
	[redacted]	2	49	10AUG2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the patient rejected to continue with the study follow up
	[redacted]	2	24	22JUL2021	VACCINATION	PROTOCOL DEVIATION	She decided to be vaccinated against covid in health service and that supposed to abandon the study
		2	24	22JUL2021	FOLLOW-UP	PROTOCOL DEVIATION	She decided to be vaccinated against covid in health service and that supposed to abandon the study
	[redacted]	2	15	16JUL2021	VACCINATION	WITHDRAWAL BY SUBJECT	participant refused further follow-ups
		2	15	16JUL2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Refused further follow-ups

Note: x1 = First dose of BNT162b2 (30 µg); x2 = Second dose of BNT162b2 (30 µg).
Note: † = Human immunodeficiency virus (HIV)-positive participant.

16.2.1.1 Listing of Participants Discontinued From Vaccination and/or From the Study (Maternal)

Vaccine Group (as Randomized)	Participant	Last Dose	Rel Day[a]	Withdrawal Date	Study Phase	Withdrawal Reason	Comment[b]

a. Relative day (Rel Day) = date of withdrawal - date of last vaccination + 1. For a withdrawal that occurred before the date of the first study vaccination, relative day was not calculated.
b. MedDRA (v25.1) coding dictionary applied.
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16.2.1.2 Listing of Participants Discontinued From the Study (Infant)

Maternal Vaccine Group (as Randomized)	Participant	Withdrawal Date	Study Phase	Withdrawal Reason	Comment[a]
BNT162b2 (30 µg)	[redacted]	08SEP2021	FOLLOW-UP	WITHDRAWAL BY PARENT/GUARDIAN	Maternal participant withdrew consent for mother and infant participants.
	[redacted]	26OCT2021	FOLLOW-UP	WITHDRAWAL BY PARENT/GUARDIAN	Consent withdrawn
	[redacted]	29DEC2021	FOLLOW-UP	WITHDRAWAL BY PARENT/GUARDIAN	Subject unable to continue with appointments.
	[redacted]	27JAN2022	FOLLOW-UP	WITHDRAWAL BY PARENT/GUARDIAN	Subject withdrew consent
	[redacted]	02NOV2021	FOLLOW-UP	WITHDRAWAL BY PARENT/GUARDIAN	Family moving out of state and withdrew infant consent
	[redacted]	10SEP2021	FOLLOW-UP	WITHDRAWAL BY PARENT/GUARDIAN	The patient's mother, patient number 10191011, decided that she would no longer like to participate
	[redacted]	09FEB2022	FOLLOW-UP	LOST TO FOLLOW-UP	The site has been unable to reach subject
	[redacted]	13DEC2021	FOLLOW-UP	LOST TO FOLLOW-UP	subject did not return calls for visit 8
	[redacted]	03JUN2022	FOLLOW-UP	LOST TO FOLLOW-UP	Maternal participant not rechargeable
	[redacted]	01MAR2022	FOLLOW-UP	WITHDRAWAL BY PARENT/GUARDIAN	Participant leaving for Mozambique, unsure of when will return to South Africa. Withdrawing
	[redacted]†	17MAY2022	FOLLOW-UP	DEATH	DEATH/PNEUMONIA
	[redacted]†	03JUN2022	FOLLOW-UP	OTHER	mother withdrawn from study by sub-investigator
	[redacted]	25JUL2021	FOLLOW-UP	WITHDRAWAL BY PARENT/GUARDIAN	Mother requested the unblinding because she would get the Pfizer covid-19 vaccine outside study

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16.2.1.2 Listing of Participants Discontinued From the Study (Infant)

Maternal Vaccine Group (as Randomized)	Participant	Withdrawal Date	Study Phase	Withdrawal Reason	Comment[a]
	[redacted]	02MAY2022	FOLLOW-UP	OTHER	The patient (mother) received a dosee of the vaccine for COVID-19 outside of the study.
	[redacted]	25MAY2022	FOLLOW-UP	WITHDRAWAL BY PARENT/GUARDIAN	The mother didn't come to visits after all the efforts to schedule the visit.
	[redacted]	11MAY2022	FOLLOW-UP	LOST TO FOLLOW-UP	The attempts were by phone, whatsapp and mail.
Placebo	[redacted]	08JUL2021	FOLLOW-UP	WITHDRAWAL BY PARENT/GUARDIAN	Mother withdrew consent for herself and infant subject. No longer able to commit the time for visits
	[redacted]	02NOV2021	FOLLOW-UP	LOST TO FOLLOW-UP	attempts to contact subject via phone on: 16,22,28 SEP2021 and 05OCT2021, Certified letter 11OCT2021
	[redacted]	13DEC2021	FOLLOW-UP	LOST TO FOLLOW-UP	Maternal pt didn't responded to many contact attempts since 10/8/21. Final attempt made on 12/10/21.
	[redacted]	20SEP2021	FOLLOW-UP	LOST TO FOLLOW-UP	several attempts were made, 10Aug2021,24Aug2021,26Aug2021,31Aug,2021, Certified letter 01Sep2021
	[redacted]	24JAN2022	FOLLOW-UP	LOST TO FOLLOW-UP	Several attempts were made to contact the gurdian (incl. certified letter) without response.
	[redacted]	07OCT2021	FOLLOW-UP	WITHDRAWAL BY PARENT/GUARDIAN	Subject withdrew consent
	[redacted]	18JAN2022	FOLLOW-UP	LOST TO FOLLOW-UP	Several attempts to contact with no response
	[redacted]	22NOV2021	FOLLOW-UP	WITHDRAWAL BY PARENT/GUARDIAN	Parent withdrew consent
	[redacted]	21APR2022	FOLLOW-UP	LOST TO FOLLOW-UP	Subject did not answer after so many attempts, Certified letter was sent, Per PI: lost to Follow U
	[redacted]	21APR2022	FOLLOW-UP	LOST TO FOLLOW-UP	Certified letter sent with no respond back. Per PI subject id lost to follow up

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16.2.1.2 Listing of Participants Discontinued From the Study (Infant)

Maternal Vaccine Group (as Randomized)	Participant	Withdrawal Date	Study Phase	Withdrawal Reason	Comment[a]
	[redacted]	28JUN2021	FOLLOW-UP	WITHDRAWAL BY PARENT/GUARDIAN	Maternal subject withdrew consent
	[redacted]	13SEP2021	FOLLOW-UP	WITHDRAWAL BY PARENT/GUARDIAN	Maternal Participant withdrew consent
	[redacted]	18AUG2021	FOLLOW-UP	WITHDRAWAL BY PARENT/GUARDIAN	Maternal participant withdrew consent
	[redacted]	07SEP2021	FOLLOW-UP	WITHDRAWAL BY PARENT/GUARDIAN	MAternal subject withdrew consent.
	[redacted]	13SEP2021	FOLLOW-UP	WITHDRAWAL BY PARENT/GUARDIAN	Maternal participant withdrew consent
	[redacted]	02SEP2021	FOLLOW-UP	WITHDRAWAL BY PARENT/GUARDIAN	Maternal Subject withdrew consent.
	[redacted]	16NOV2021	FOLLOW-UP	WITHDRAWAL BY PARENT/GUARDIAN	Maternal subject withdrew due to difficulty with being complaint to ediary
	[redacted]	12NOV2021	FOLLOW-UP	WITHDRAWAL BY PARENT/GUARDIAN	Maternal participant could not be complaint to the edairy hassle.
	[redacted]	04JUL2022	FOLLOW-UP	LOST TO FOLLOW-UP	after several attempts, unable to get subject back to site for visit 8
	[redacted]	01DEC2021	FOLLOW-UP	WITHDRAWAL BY PARENT/GUARDIAN	Maternal participant withdrew from the study verbally as she has relocated to KZN
	[redacted]	01FEB2022	FOLLOW-UP	WITHDRAWAL BY PARENT/GUARDIAN	WITHDRAWAL BY PARENTS
	[redacted]†	26MAY2022	FOLLOW-UP	WITHDRAWAL BY PARENT/GUARDIAN	PARTICIPANT WITHDREW FROM THE STUDY DUE TO RELOCATION
	[redacted]†	22DEC2021	FOLLOW-UP	LOST TO FOLLOW-UP	Mother non-compliant. Does not answer phone, multiple unsuccessful home visits.

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16.2.1.2 Listing of Participants Discontinued From the Study (Infant)

Maternal Vaccine Group (as Randomized)	Participant	Withdrawal Date	Study Phase	Withdrawal Reason	Comment[a]
	[redacted]	22NOV2021	FOLLOW-UP	DEATH	neonatal pneumonia/NEONATAL PNEUMONIA
	[redacted]	02AUG2021	FOLLOW-UP	WITHDRAWAL BY PARENT/GUARDIAN	PARTICIPANT AND CHILD'S PARENT WITHDRAWN CONSENT
	[redacted]	06AUG2021	FOLLOW-UP	OTHER	Patient (mother) received COVID-19 vaccine outside of the study.
	[redacted]	11MAY2022	FOLLOW-UP	LOST TO FOLLOW-UP	The mother didn't come to site and didn't answer contacts.
	[redacted]	02MAY2022	FOLLOW-UP	WITHDRAWAL BY PARENT/GUARDIAN	The mother didn't want to complete the study. On 02May2022 they finished the study by discontinuatio
	[redacted]	10AUG2021	FOLLOW-UP	WITHDRAWAL BY PARENT/GUARDIAN	ICD was removed by mother for her and Infant participation including for Safety FUP upon unblinding

Note: † = Infant born to human immunodeficiency virus (HIV)-positive participant.
a. MedDRA (v25.1) coding dictionary applied.
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16.2.2.1 Listing of Important Protocol Deviations (Maternal)

Vaccine Group (as Randomized)	Participant	Site	Protocol Deviation Category	Protocol Deviation Subcategory	Protocol Deviation Start Date
BNT162b2 (30 µg)	[redacted]	1011	Inclusion/Exclusion	IC 10 M Pts: Pre-pregnancy BMI of <= 40 kg/m2 at enrollment. If pre-pregnancy BMI is not available the BMI at the time of the first obstetric visit during the current pregnancy may be used.	08JUN2021
	[redacted]	1019	Inclusion/Exclusion	IC 1 M Pts: Women >=18 yrs old and btwn 27 (P2) or 24 (P3) and 34 wks gestation the day of planned vax, with an uncomplicated, singleton pregnancy, at no known increased risk for complication.	31MAY2021
	[redacted]	1019	Investigational Product	*Participant was vaccinated despite meeting temporary delay (Maternal: Receipt of any seasonal or pandemic influenza vaccine in the previous 14 days).	03JUN2021
	[redacted]	1038	Inclusion/Exclusion	Participant did not meet inclusion criteria 2 (Maternal: Willing and able to comply with scheduled visits, treatment plan, laboratory tests, and other study procedures).	30SEP2021
	[redacted]	1071	Inclusion/Exclusion	EC 8 M Pts: Ph.3 Current major illness of maternal pt or condition of fetus that will increase risk with maternal pts participation in/completion of study or preclude evaluation of pts response.	09SEP2021
	[redacted]	1104	Inclusion/Exclusion	IC 6 M Pts: Documented negative HIV antibody test (Ph. 2 only), syphilis test, and hepatitis B virus (HBV) surface antigen test during this pregnancy and prior to randomization (Visit 1).	13AUG2021
	[redacted]	1150	Investigational Product	*Pt vaccinated despite meeting temporary delay (Maternal: Anticipated receipt of a tetanus-, diphtheria-, and/or pertussis-containing vaccine in the 7 days after study intervention administration).	28SEP2021
	[redacted]	1151	Inclusion/Exclusion	EC 6 M Pts: Ph.2 Prior or current major illness of mother/fetus that increase the risk associated with participation in/completion of the study or could preclude the evaluation of the pts response.	10JUN2021
			Concomitant Medications	*Participant received vaccines other than IP within 14 days before or 7 days after each study vaccination, including seasonal and pandemic influenza vaccines.	29JUN2021

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16.2.2.1 Listing of Important Protocol Deviations (Maternal)

Vaccine Group (as Randomized)	Participant	Site	Protocol Deviation Category	Protocol Deviation Subcategory	Protocol Deviation Start Date
	[redacted]	1194	Concomitant Medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	08JUL2021
	[redacted]	1204	Inclusion/Exclusion	IC 6 M Pts: Documented negative HIV antibody test (Ph. 2 only), syphilis test, and hepatitis B virus (HBV) surface antigen test during this pregnancy and prior to randomization (Visit 1).	08JUN2021
	[redacted]	1234	Concomitant Medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	21DEC2021
	[redacted]	1251	Concomitant Medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	17JAN2022
	[redacted]	1252	Investigational Product	* Participant was vaccinated despite meeting temporary delay (Maternal: Receipt of a tetanus-, diphtheria-, and/or pertussis-containing vaccine in the previous 14 days).	31MAY2021
			Concomitant Medications	*Subject received chronic systemic treatment with known immunosuppressant medication, within 60 days before enrollment through conclusion of the study.	16NOV2021
	[redacted]	1252	Investigational Product	* Participant was vaccinated despite meeting temporary delay (Maternal: Receipt of a tetanus-, diphtheria-, and/or pertussis-containing vaccine in the previous 14 days).	14JUN2021
Placebo	[redacted]	1013	Investigational Product	*Pt vaccinated despite meeting temporary delay (Maternal: Anticipated receipt of a tetanus-, diphtheria-, and/or pertussis-containing vaccine in the 7 days after study intervention administration).	26MAY2021
	[redacted]	1019	Inclusion/Exclusion	Participant did not meet inclusion criteria 7 (Maternal: Intention to deliver at a hospital or birthing facility where study procedures can be obtained).	08AUG2021
	[redacted]	1030	Concomitant Medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	29JUN2021

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16.2.2.1 Listing of Important Protocol Deviations (Maternal)

Vaccine Group (as Randomized)	Participant	Site	Protocol Deviation Category	Protocol Deviation Subcategory	Protocol Deviation Start Date
	[redacted]	1034	Investigational Product	* Participant was vaccinated despite meeting temporary delay (Maternal: Receipt of a tetanus-, diphtheria-, and/or pertussis-containing vaccine in the previous 14 days).	02JUN2021
	[redacted]	1048	Investigational Product	*Participant was vaccinated despite meeting temporary delay (Maternal: Anticipated receipt of any seasonal or pandemic influenza vaccine in the 7 days after study intervention administration.	01SEP2021
	[redacted]	1071	Investigational Product	*Pt vaccinated despite meeting temporary delay (Maternal: Anticipated receipt of a tetanus-, diphtheria-, and/or pertussis-containing vaccine in the 7 days after study intervention administration).	20AUG2021
	[redacted]	1104	Inclusion/Exclusion	IC 6 M Pts: Documented negative HIV antibody test (Ph. 2 only), syphilis test, and hepatitis B virus (HBV) surface antigen test during this pregnancy and prior to randomization (Visit 1).	13AUG2021
	[redacted]	1127	Inclusion/Exclusion	IC 1 M Pts: Women >=18 yrs old and btwn 27 (P2) or 24 (P3) and 34 wks gestation the day of planned vax, with an uncomplicated, singleton pregnancy, at no known increased risk for complication.	14JUL2021
	[redacted]	1127	Inclusion/Exclusion	IC 1 M Pts: Women >=18 yrs old and btwn 27 (P2) or 24 (P3) and 34 wks gestation the day of planned vax, with an uncomplicated, singleton pregnancy, at no known increased risk for complication.	14JUL2021
	[redacted]	1177	Investigational Product	*Pt vaccinated despite meeting temporary delay (Maternal: Anticipated receipt of a tetanus-, diphtheria-, and/or pertussis-containing vaccine in the 7 days after study intervention administration).	11OCT2021
	[redacted]	1194	Concomitant Medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	14JUN2021
	[redacted]	1252	Investigational Product	* Participant was vaccinated despite meeting temporary delay (Maternal: Receipt of a tetanus-, diphtheria-, and/or pertussis-containing vaccine in the previous 14 days).	07JUN2021
			Concomitant Medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	02JUL2021

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16.2.2.1 Listing of Important Protocol Deviations (Maternal)

Vaccine Group (as Randomized)	Participant	Site	Protocol Deviation Category	Protocol Deviation Subcategory	Protocol Deviation Start Date

Note: † = Human immunodeficiency virus (HIV)-positive participant.
Note: * = Protocol deviation subcategory related to violation of temporary delay criteria and prohibited medications.
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16.2.2.2 Listing of Important Protocol Deviations (Infant)

Maternal Vaccine Group (as Randomized)	Participant	Site	Protocol Deviation Category	Protocol Deviation Subcategory	Protocol Deviation Start Date
Placebo	[redacted]	1034	Concomitant Medications	Receipt of blood/plasma products or immunoglobulins within 60 days before enrollment through conclusion of the study.	28APR2021

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16.2.3.1.1 Listing of Participants Excluded From Immunogenicity Populations (Maternal)

Population From Which Excluded	Vaccine Group (as Randomized)	Participant	Reason for Exclusion
Dose 1 Evaluable	BNT162b2 (30 µg)	[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 19-23 days after Dose 1.
Evaluable			Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]	Not eligible for the study at randomization; had other protocol deviation(s) as determined by the clinician.
Evaluable			Not eligible for the study at randomization; did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2; had other protocol deviation(s) as determined by the clinician.
Dose 1 Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 19-23 days after Dose 1.
Evaluable			Did not receive Dose 2 within 19-42 days after Dose 1.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 19-23 days after Dose 1.
Evaluable			Did not receive Dose 2 within 19-42 days after Dose 1; did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 19-23 days after Dose 1.
Evaluable			Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.

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16.2.3.1.1 Listing of Participants Excluded From Immunogenicity Populations (Maternal)

Population From Which Excluded	Vaccine Group (as Randomized)	Participant	Reason for Exclusion
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]	Not eligible for the study at randomization; had other protocol deviation(s) as determined by the clinician.
Evaluable			Not eligible for the study at randomization; did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2; had other protocol deviation(s) as determined by the clinician.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 19-23 days after Dose 1.

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16.2.3.1.1 Listing of Participants Excluded From Immunogenicity Populations (Maternal)

Population From Which Excluded	Vaccine Group (as Randomized)	Participant	Reason for Exclusion
Evaluable			Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 19-23 days after Dose 1.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
All-available		[redacted]	Did not have at least 1 valid and determinate immunogenicity result after vaccination.
Dose 1 Evaluable			Did not have at least 1 valid and determinate immunogenicity result within 19-23 days after Dose 1.
Evaluable			Did not receive 2 doses of the vaccine to which they were randomized; did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.

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16.2.3.1.1 Listing of Participants Excluded From Immunogenicity Populations (Maternal)

Population From Which Excluded	Vaccine Group (as Randomized)	Participant	Reason for Exclusion
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Evaluable			Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Evaluable			Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Evaluable			Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
All-available		[redacted]	Did not receive at least 1 dose of the study intervention.
Dose 1 Evaluable			Not applicable for Phase 3 participants.
Evaluable			Not eligible for the study at randomization; did not receive 2 doses of the vaccine to which they were randomized; did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2; had other protocol deviation(s) as determined by the clinician.

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16.2.3.1.1 Listing of Participants Excluded From Immunogenicity Populations (Maternal)

Population From Which Excluded	Vaccine Group (as Randomized)	Participant	Reason for Exclusion
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Evaluable		[redacted]	Not eligible for the study at randomization; had other protocol deviation(s) as determined by the clinician.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Evaluable		[redacted]	Not eligible for the study at randomization; had other protocol deviation(s) as determined by the clinician.

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16.2.3.1.1 Listing of Participants Excluded From Immunogenicity Populations (Maternal)

Population From Which Excluded	Vaccine Group (as Randomized)	Participant	Reason for Exclusion
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Evaluable			Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Evaluable			Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.

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16.2.3.1.1 Listing of Participants Excluded From Immunogenicity Populations (Maternal)

Population From Which Excluded	Vaccine Group (as Randomized)	Participant	Reason for Exclusion
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Evaluable			Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]†	Not applicable for Phase 3 participants.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Evaluable			Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]†	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]†	Not applicable for Phase 3 participants.
Evaluable			Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.

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16.2.3.1.1 Listing of Participants Excluded From Immunogenicity Populations (Maternal)

Population From Which Excluded	Vaccine Group (as Randomized)	Participant	Reason for Exclusion
Dose 1 Evaluable		[redacted]†	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]†	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]†	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]†	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]†	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]†	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]†	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]†	Not applicable for Phase 3 participants.
Evaluable			Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]	Not eligible for the study at randomization; had other protocol deviation(s) as determined by the clinician.
Evaluable			Not eligible for the study at randomization; had other protocol deviation(s) as determined by the clinician.
Dose 1 Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 19-23 days after Dose 1.
Evaluable			Did not receive Dose 2 within 19-42 days after Dose 1; did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.

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16.2.3.1.1 Listing of Participants Excluded From Immunogenicity Populations (Maternal)

Population From Which Excluded	Vaccine Group (as Randomized)	Participant	Reason for Exclusion
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.

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16.2.3.1.1 Listing of Participants Excluded From Immunogenicity Populations (Maternal)

Population From Which Excluded	Vaccine Group (as Randomized)	Participant	Reason for Exclusion
Evaluable		[redacted]	Did not receive 2 doses of the vaccine to which they were randomized; did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2; had other protocol deviation(s) as determined by the clinician.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Evaluable			Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not eligible for the study at randomization; had other protocol deviation(s) as determined by the clinician.
Evaluable			Not eligible for the study at randomization; did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2; had other protocol deviation(s) as determined by the clinician.
Dose 1 Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 19-23 days after Dose 1.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.

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16.2.3.1.1 Listing of Participants Excluded From Immunogenicity Populations (Maternal)

Population From Which Excluded	Vaccine Group (as Randomized)	Participant	Reason for Exclusion
Evaluable			Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
All-available		[redacted]	Did not have at least 1 valid and determinate immunogenicity result after vaccination.
Dose 1 Evaluable			Not applicable for Phase 3 participants.
Evaluable			Did not receive 2 doses of the vaccine to which they were randomized; did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Evaluable	Placebo	[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 19-23 days after Dose 1.
Dose 1 Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 19-23 days after Dose 1.

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16.2.3.1.1 Listing of Participants Excluded From Immunogenicity Populations (Maternal)

Population From Which Excluded	Vaccine Group (as Randomized)	Participant	Reason for Exclusion
Evaluable			Did not receive 2 doses of the vaccine to which they were randomized; did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 19-23 days after Dose 1.
Evaluable			Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 19-23 days after Dose 1.
Dose 1 Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 19-23 days after Dose 1.
Evaluable			Did not receive Dose 2 within 19-42 days after Dose 1; did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
All-available		[redacted]	Did not receive at least 1 dose of the study intervention.
Dose 1 Evaluable			Not eligible for the study at randomization; did not receive Dose 1 of the vaccine to which they were randomized; did not have at least 1 valid and determinate immunogenicity result within 19-23 days after Dose 1.

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16.2.3.1.1 Listing of Participants Excluded From Immunogenicity Populations (Maternal)

Population From Which Excluded	Vaccine Group (as Randomized)	Participant	Reason for Exclusion
Evaluable			Not eligible for the study at randomization; did not receive 2 doses of the vaccine to which they were randomized; did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
All-available		[redacted]	Did not have at least 1 valid and determinate immunogenicity result after vaccination.
Dose 1 Evaluable			Did not have at least 1 valid and determinate immunogenicity result within 19-23 days after Dose 1.
Evaluable			Did not receive 2 doses of the vaccine to which they were randomized; did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Evaluable			Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 19-23 days after Dose 1.

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16.2.3.1.1 Listing of Participants Excluded From Immunogenicity Populations (Maternal)

Population From Which Excluded	Vaccine Group (as Randomized)	Participant	Reason for Exclusion
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Evaluable			Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Evaluable			Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.

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16.2.3.1.1 Listing of Participants Excluded From Immunogenicity Populations (Maternal)

Population From Which Excluded	Vaccine Group (as Randomized)	Participant	Reason for Exclusion
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Evaluable			Did not receive Dose 2 within 19-42 days after Dose 1.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Evaluable			Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Evaluable			Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.

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16.2.3.1.1 Listing of Participants Excluded From Immunogenicity Populations (Maternal)

Population From Which Excluded	Vaccine Group (as Randomized)	Participant	Reason for Exclusion
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Evaluable			Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Evaluable			Not eligible for the study at randomization; had other protocol deviation(s) as determined by the clinician.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Evaluable			Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Evaluable			Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.

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16.2.3.1.1 Listing of Participants Excluded From Immunogenicity Populations (Maternal)

Population From Which Excluded	Vaccine Group (as Randomized)	Participant	Reason for Exclusion
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Evaluable			Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Evaluable			Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Evaluable			Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.

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16.2.3.1.1 Listing of Participants Excluded From Immunogenicity Populations (Maternal)

Population From Which Excluded	Vaccine Group (as Randomized)	Participant	Reason for Exclusion
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Evaluable			Not eligible for the study at randomization; did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2; had other protocol deviation(s) as determined by the clinician.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Evaluable			Not eligible for the study at randomization; did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2; had other protocol deviation(s) as determined by the clinician.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]†	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]†	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]†	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]†	Not applicable for Phase 3 participants.

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16.2.3.1.1 Listing of Participants Excluded From Immunogenicity Populations (Maternal)

Population From Which Excluded	Vaccine Group (as Randomized)	Participant	Reason for Exclusion
Dose 1 Evaluable		[redacted]†	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]†	Not applicable for Phase 3 participants.
All-available		[redacted]†	Did not have at least 1 valid and determinate immunogenicity result after vaccination.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]†	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.

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16.2.3.1.1 Listing of Participants Excluded From Immunogenicity Populations (Maternal)

Population From Which Excluded	Vaccine Group (as Randomized)	Participant	Reason for Exclusion
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Evaluable			Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 19-23 days after Dose 1.
Evaluable			Did not receive Dose 2 within 19-42 days after Dose 1; did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
All-available		[redacted]	Did not have at least 1 valid and determinate immunogenicity result after vaccination.
Dose 1 Evaluable			Did not have at least 1 valid and determinate immunogenicity result within 19-23 days after Dose 1; had other protocol deviation(s) as determined by the clinician.
Evaluable			Did not receive 2 doses of the vaccine to which they were randomized; did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2; had other protocol deviation(s) as determined by the clinician.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.

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16.2.3.1.1 Listing of Participants Excluded From Immunogenicity Populations (Maternal)

Population From Which Excluded	Vaccine Group (as Randomized)	Participant	Reason for Exclusion
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 19-23 days after Dose 1.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 19-23 days after Dose 1.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.

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16.2.3.1.1 Listing of Participants Excluded From Immunogenicity Populations (Maternal)

Population From Which Excluded	Vaccine Group (as Randomized)	Participant	Reason for Exclusion
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2; had other protocol deviation(s) as determined by the clinician.
Dose 1 Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 19-23 days after Dose 1.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.
Dose 1 Evaluable		[redacted]	Not applicable for Phase 3 participants.

Note: † = Human immunodeficiency virus (HIV)-positive participant.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (08:47) Source Data: adsl Table Generation: 19FEB2024 (07:17)
(Database snapshot date: Safety [29Mar2023], Immunogenicity [09Jan2024]) Output File: ./nda3/C4591015_CSR/adsl_l001_excl_eval

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16.2.3.1.2 Listing of Participants Excluded From Immunogenicity Populations (Infant)

Population From Which Excluded	Maternal Vaccine Group (as Randomized)	Participant	Reason for Exclusion
All-available	BNT162b2 (30 μg)	[redacted]	Did not have at least 1 valid and determinate immunogenicity result.
Evaluable			Were born to maternal participants who were not evaluable immunogenicity maternal participants; did not have at least 1 valid and determinate immunogenicity result.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
All-available		[redacted]	Did not have at least 1 valid and determinate immunogenicity result.
Evaluable			Were born to maternal participants who were not evaluable immunogenicity maternal participants; did not have at least 1 valid and determinate immunogenicity result.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.

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16.2.3.1.2 Listing of Participants Excluded From Immunogenicity Populations (Infant)

Population From Which Excluded	Maternal Vaccine Group (as Randomized)	Participant	Reason for Exclusion
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.

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16.2.3.1.2 Listing of Participants Excluded From Immunogenicity Populations (Infant)

Population From Which Excluded	Maternal Vaccine Group (as Randomized)	Participant	Reason for Exclusion
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.

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16.2.3.1.2 Listing of Participants Excluded From Immunogenicity Populations (Infant)

Population From Which Excluded	Maternal Vaccine Group (as Randomized)	Participant	Reason for Exclusion
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]†	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
All-available		[redacted]	Did not have at least 1 valid and determinate immunogenicity result.
Evaluable			Were born to maternal participants who were not evaluable immunogenicity maternal participants; did not have at least 1 valid and determinate immunogenicity result.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.

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16.2.3.1.2 Listing of Participants Excluded From Immunogenicity Populations (Infant)

Population From Which Excluded	Maternal Vaccine Group (as Randomized)	Participant	Reason for Exclusion
All-available		[redacted]	Did not have at least 1 valid and determinate immunogenicity result.
Evaluable			Were born to maternal participants who were not evaluable immunogenicity maternal participants; did not have at least 1 valid and determinate immunogenicity result.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
All-available	Placebo	[redacted]	Did not have at least 1 valid and determinate immunogenicity result.
Evaluable			Did not have at least 1 valid and determinate immunogenicity result.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.

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16.2.3.1.2 Listing of Participants Excluded From Immunogenicity Populations (Infant)

Population From Which Excluded	Maternal Vaccine Group (as Randomized)	Participant	Reason for Exclusion
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants; had other protocol deviation(s) as determined by the clinician.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.

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16.2.3.1.2 Listing of Participants Excluded From Immunogenicity Populations (Infant)

Population From Which Excluded	Maternal Vaccine Group (as Randomized)	Participant	Reason for Exclusion
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
All-available		[redacted]	Did not have at least 1 valid and determinate immunogenicity result.
Evaluable			Did not have at least 1 valid and determinate immunogenicity result.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
All-available		[redacted]	Did not have at least 1 valid and determinate immunogenicity result.
Evaluable			Did not have at least 1 valid and determinate immunogenicity result.
All-available		[redacted]	Did not have at least 1 valid and determinate immunogenicity result.
Evaluable			Did not have at least 1 valid and determinate immunogenicity result.
All-available		[redacted]	Did not have at least 1 valid and determinate immunogenicity result.
Evaluable			Did not have at least 1 valid and determinate immunogenicity result.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
All-available		[redacted]	Did not have at least 1 valid and determinate immunogenicity result.

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16.2.3.1.2 Listing of Participants Excluded From Immunogenicity Populations (Infant)

Population From Which Excluded	Maternal Vaccine Group (as Randomized)	Participant	Reason for Exclusion
Evaluable			Did not have at least 1 valid and determinate immunogenicity result.
All-available			Did not have at least 1 valid and determinate immunogenicity result.
Evaluable			Did not have at least 1 valid and determinate immunogenicity result.
Evaluable			Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable			Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable			Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable			Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable			Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable			Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable			Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable			Were born to maternal participants who were not evaluable immunogenicity maternal participants.
All-available			Did not have at least 1 valid and determinate immunogenicity result.
Evaluable			Were born to maternal participants who were not evaluable immunogenicity maternal participants; did not have at least 1 valid and determinate immunogenicity result.
Evaluable			Were born to maternal participants who were not evaluable immunogenicity maternal participants.

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16.2.3.1.2 Listing of Participants Excluded From Immunogenicity Populations (Infant)

Population From Which Excluded	Maternal Vaccine Group (as Randomized)	Participant	Reason for Exclusion
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
All-available		[redacted]	Were born to maternal participants who were not all-available immunogenicity maternal participants; did not have at least 1 valid and determinate immunogenicity result.
Evaluable			Were born to maternal participants who were not evaluable immunogenicity maternal participants; did not have at least 1 valid and determinate immunogenicity result.

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16.2.3.1.2 Listing of Participants Excluded From Immunogenicity Populations (Infant)

Population From Which Excluded	Maternal Vaccine Group (as Randomized)	Participant	Reason for Exclusion
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
All-available		[redacted]	Did not have at least 1 valid and determinate immunogenicity result.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants; did not have at least 1 valid and determinate immunogenicity result.
All-available		[redacted]	Did not have at least 1 valid and determinate immunogenicity result.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result.
All-available		[redacted]	Did not have at least 1 valid and determinate immunogenicity result.
Evaluable		[redacted]	Did not have at least 1 valid and determinate immunogenicity result.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.

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16.2.3.1.2 Listing of Participants Excluded From Immunogenicity Populations (Infant)

Population From Which Excluded	Maternal Vaccine Group (as Randomized)	Participant	Reason for Exclusion
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.
Evaluable		[redacted]	Were born to maternal participants who were not evaluable immunogenicity maternal participants.

Note: † = Infant born to Human immunodeficiency virus (HIV)-positive participant.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (08:47) Source Data: adsl Table Generation: 19FEB2024 (07:15)
(Database snapshot date: Safety [29Mar2023], Immunogenicity [09Jan2024]) Output File: ./nda3/C4591015_CSR/adsl_l001_excl_eval_inf

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16.2.3.1.3 Listing of Participants Excluded From the Immunogenicity Populations – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Population From Which Excluded	Vaccine Group (as Randomized)	Study	Participant	Reason for Exclusion
All-available	BNT162b2 (30 µg)	C4591001	[redacted]	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
Evaluable				Did not receive 2 doses of the vaccine to which they were randomized; did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
All-available			[redacted]	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
Evaluable				Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not receive Dose 2 within 19-42 days after Dose 1.
All-available			[redacted]	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
Evaluable				Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not receive Dose 2 within 19-42 days after Dose 1.
Evaluable			[redacted]	Did not receive Dose 2 within 19-42 days after Dose 1.

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16.2.3.1.3 Listing of Participants Excluded From the Immunogenicity Populations – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Population From Which Excluded	Vaccine Group (as Randomized)	Study	Participant	Reason for Exclusion
Evaluable		C4591015	[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Not eligible for the study at randomization; did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2; had other protocol deviation(s) as determined by the clinician.
Evaluable			[redacted]	Did not receive Dose 2 within 19-42 days after Dose 1.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not receive Dose 2 within 19-42 days after Dose 1; did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.

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16.2.3.1.3 Listing of Participants Excluded From the Immunogenicity Populations – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Population From Which Excluded	Vaccine Group (as Randomized)	Study	Participant	Reason for Exclusion
Evaluable			[redacted]	Not eligible for the study at randomization; did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2; had other protocol deviation(s) as determined by the clinician.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
All-available			[redacted]	Did not have at least 1 valid and determinate immunogenicity result after vaccination.
Evaluable				Did not receive 2 doses of the vaccine to which they were randomized; did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.

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16.2.3.1.3 Listing of Participants Excluded From the Immunogenicity Populations – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Population From Which Excluded	Vaccine Group (as Randomized)	Study	Participant	Reason for Exclusion
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
All-available			[redacted]	Did not receive at least 1 dose of the study intervention.
Evaluable				Not eligible for the study at randomization; did not receive 2 doses of the vaccine to which they were randomized; did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2; had other protocol deviation(s) as determined by the clinician.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.

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16.2.3.1.3 Listing of Participants Excluded From the Immunogenicity Populations – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Population From Which Excluded	Vaccine Group (as Randomized)	Study	Participant	Reason for Exclusion
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Not eligible for the study at randomization; had other protocol deviation(s) as determined by the clinician.
Evaluable			[redacted]	Not eligible for the study at randomization; had other protocol deviation(s) as determined by the clinician.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]†	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]†	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Not eligible for the study at randomization; had other protocol deviation(s) as determined by the clinician.
Evaluable			[redacted]	Did not receive Dose 2 within 19-42 days after Dose 1; did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.

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16.2.3.1.3 Listing of Participants Excluded From the Immunogenicity Populations – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Population From Which Excluded	Vaccine Group (as Randomized)	Study	Participant	Reason for Exclusion
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not receive 2 doses of the vaccine to which they were randomized; did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2; had other protocol deviation(s) as determined by the clinician.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.

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16.2.3.1.3 Listing of Participants Excluded From the Immunogenicity Populations – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Population From Which Excluded	Vaccine Group (as Randomized)	Study	Participant	Reason for Exclusion
Evaluable			[redacted]	Not eligible for the study at randomization; did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2; had other protocol deviation(s) as determined by the clinician.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
All-available			[redacted]	Did not have at least 1 valid and determinate immunogenicity result after vaccination.
Evaluable				Did not receive 2 doses of the vaccine to which they were randomized; did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
All-available	Placebo	C4591001	[redacted]	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
Evaluable				Did not receive 2 doses of the vaccine to which they were randomized; did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
All-available			[redacted]	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
Evaluable				Did not receive 2 doses of the vaccine to which they were randomized; did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.

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16.2.3.1.3 Listing of Participants Excluded From the Immunogenicity Populations – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Population From Which Excluded	Vaccine Group (as Randomized)	Study	Participant	Reason for Exclusion
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not receive Dose 2 within 19-42 days after Dose 1.
All-available			[redacted]	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
Evaluable			[redacted]	Did not receive 2 doses of the vaccine to which they were randomized; did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
All-available			[redacted]	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
Evaluable			[redacted]	Did not receive 2 doses of the vaccine to which they were randomized; did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable		C4591015	[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not receive 2 doses of the vaccine to which they were randomized; did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.

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16.2.3.1.3 Listing of Participants Excluded From the Immunogenicity Populations – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Population From Which Excluded	Vaccine Group (as Randomized)	Study	Participant	Reason for Exclusion
Evaluable			[redacted]	Did not receive Dose 2 within 19-42 days after Dose 1; did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
All-available			[redacted]	Did not receive at least 1 dose of the study intervention.
Evaluable				Not eligible for the study at randomization; did not receive 2 doses of the vaccine to which they were randomized; did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
All-available			[redacted]	Did not have at least 1 valid and determinate immunogenicity result after vaccination.
Evaluable				Did not receive 2 doses of the vaccine to which they were randomized; did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.

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16.2.3.1.3 Listing of Participants Excluded From the Immunogenicity Populations – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Population From Which Excluded	Vaccine Group (as Randomized)	Study	Participant	Reason for Exclusion
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.

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16.2.3.1.3 Listing of Participants Excluded From the Immunogenicity Populations – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Population From Which Excluded	Vaccine Group (as Randomized)	Study	Participant	Reason for Exclusion
Evaluable			[redacted]	Did not receive Dose 2 within 19-42 days after Dose 1.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Not eligible for the study at randomization; had other protocol deviation(s) as determined by the clinician.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Not eligible for the study at randomization; did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2; had other protocol deviation(s) as determined by the clinician.

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16.2.3.1.3 Listing of Participants Excluded From the Immunogenicity Populations – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Population From Which Excluded	Vaccine Group (as Randomized)	Study	Participant	Reason for Exclusion
Evaluable			[redacted]	Not eligible for the study at randomization; did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2; had other protocol deviation(s) as determined by the clinician.
All-available			[redacted]†	Did not have at least 1 valid and determinate immunogenicity result after vaccination.
Evaluable				Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not receive Dose 2 within 19-42 days after Dose 1; did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
All-available			[redacted]	Did not have at least 1 valid and determinate immunogenicity result after vaccination.
Evaluable				Did not receive 2 doses of the vaccine to which they were randomized; did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2; had other protocol deviation(s) as determined by the clinician.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.

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16.2.3.1.3 Listing of Participants Excluded From the Immunogenicity Populations – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Population From Which Excluded	Vaccine Group (as Randomized)	Study	Participant	Reason for Exclusion
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2; had other protocol deviation(s) as determined by the clinician.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.
Evaluable			[redacted]	Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after Dose 2.

16.2.3.1.3 Listing of Participants Excluded From the Immunogenicity Populations – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Population From Which Excluded	Vaccine Group (as Randomized)	Study	Participant	Reason for Exclusion

Note: Participants from C4591001 are a selected subset of age matched nonpregnant female Phase 3 participants.
Note: † = Human immunodeficiency virus (HIV)-positive participant.
PFIZER CONFIDENTIAL Source Data: adsl Table Generation: 01MAR2024 (02:40)
(Data cutoff date : C4591001 [31Aug2021]) Output File: ./nda3/C4591015_Bridging/adsl_l001_excl_eval_brdg

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16.2.3.2.1 Listing of Participants Excluded From Safety Population (Maternal)

Vaccine Group (as Randomized)	Participant	Reason for Exclusion
BNT162b2 (30 µg)	[redacted]	Did not receive study vaccine.
Placebo	[redacted]	Did not receive study vaccine.

PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (09:47) Source Data: adsl Table Generation: 09MAY2023 (14:02) Output File: ./nda3/C4591015_BR/adsl_l001_excl_saf

16.2.3.2.2 Listing of Participants Excluded From Safety Population (Infant)

Maternal Vaccine Group (as Randomized)	Participant	Reason for Exclusion
No participant meets the reporting criteria.		

PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (09:47) Source Data: adsl Table Generation: 09MAY2023 (14:02) Output File: ./nda3/C4591015_BR/adsl_l001_excl_saf_inf

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16.2.3.3.1 Listing of Participants Excluded From the Efficacy Populations (Maternal)

Population From Which Excluded	Vaccine Group (as Randomized)	Participant	Reason for Exclusion
Dose 1 All-available	BNT162b2 (30 µg)	[redacted]	Did not receive at least 1 dose of the study intervention.
	Placebo	[redacted]	Did not receive at least 1 dose of the study intervention.
Dose 2 All-available	BNT162b2 (30 µg)	[redacted]	Did not receive 2 doses of the vaccine.
		[redacted]	Did not receive 2 doses of the vaccine.
		[redacted]	Did not receive 2 doses of the vaccine.
		[redacted]	Did not receive 2 doses of the vaccine.
	Placebo	[redacted]	Did not receive 2 doses of the vaccine.
		[redacted]	Did not receive 2 doses of the vaccine.
		[redacted]	Did not receive 2 doses of the vaccine.
		[redacted]	Did not receive 2 doses of the vaccine.
Evaluable	BNT162b2 (30 µg)	[redacted]	Not eligible for the study at randomization; had other protocol deviation(s) as determined by the clinician.
		[redacted]	Did not receive Dose 2 within 19-42 days after Dose 1.
		[redacted]	Did not receive Dose 2 within 19-42 days after Dose 1.

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16.2.3.3.1 Listing of Participants Excluded From the Efficacy Populations (Maternal)

Population From Which Excluded	Vaccine Group (as Randomized)	Participant	Reason for Exclusion
		[redacted]	Not eligible for the study at randomization; had other protocol deviation(s) as determined by the clinician.
		[redacted]	Did not receive 2 doses of the vaccine to which they were randomized.
		[redacted]	Not eligible for the study at randomization; had other protocol deviation(s) as determined by the clinician.
		[redacted]	Not eligible for the study at randomization; had other protocol deviation(s) as determined by the clinician.
		[redacted]	Not eligible for the study at randomization; had other protocol deviation(s) as determined by the clinician.
		[redacted]	Not eligible for the study at randomization; had other protocol deviation(s) as determined by the clinician.
		[redacted]	Did not receive Dose 2 within 19-42 days after Dose 1.
		[redacted]	Did not receive 2 doses of the vaccine to which they were randomized; had other protocol deviation(s) as determined by the clinician.
		[redacted]	Not eligible for the study at randomization; had other protocol deviation(s) as determined by the clinician.
		[redacted]	Did not receive 2 doses of the vaccine to which they were randomized.
	Placebo	[redacted]	Did not receive 2 doses of the vaccine to which they were randomized.
		[redacted]	Did not receive Dose 2 within 19-42 days after Dose 1.
		[redacted]	Not eligible for the study at randomization.

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16.2.3.3.1 Listing of Participants Excluded From the Efficacy Populations (Maternal)

Population From Which Excluded	Vaccine Group (as Randomized)	Participant	Reason for Exclusion
		[redacted]	Did not receive 2 doses of the vaccine to which they were randomized.
		[redacted]	Did not receive Dose 2 within 19-42 days after Dose 1.
		[redacted]	Not eligible for the study at randomization; had other protocol deviation(s) as determined by the clinician.
		[redacted]	Not eligible for the study at randomization; had other protocol deviation(s) as determined by the clinician.
		[redacted]	Not eligible for the study at randomization; had other protocol deviation(s) as determined by the clinician.
		[redacted]	Did not receive Dose 2 within 19-42 days after Dose 1.
		[redacted]	Did not receive 2 doses of the vaccine to which they were randomized; had other protocol deviation(s) as determined by the clinician.
		[redacted]	Had other protocol deviation(s) as determined by the clinician.

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16.2.3.3.2 Listing of Participants Excluded From the Efficacy Populations (Infant)

Population From Which Excluded	Maternal Vaccine Group (as Randomized)	Participant	Reason for Exclusion
No participant meets the reporting criteria.			

PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (08:47) Source Data: adsl Table Generation: 12DEC2023 (23:13) Output File: ./nda3/C4591015_EFF/adsl_l001_excl_eff_inf

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16.2.4.1 Listing of Demographic Characteristics (Maternal)

Vaccine Group (as Administered)	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Race	Ethnicity
BNT162b2 (30 µg)	[redacted]						

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16.2.4.1 Listing of Demographic Characteristics (Maternal)

Vaccine Group (as Administered)	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Race	Ethnicity
[redacted]							

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16.2.4.1 Listing of Demographic Characteristics (Maternal)

Vaccine Group (as Administered)	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Race	Ethnicity
[redacted]							

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16.2.4.1 Listing of Demographic Characteristics (Maternal)

Vaccine Group (as Administered)	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Race	Ethnicity
[redacted]							

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16.2.4.1 Listing of Demographic Characteristics (Maternal)

Vaccine Group (as Administered)	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Race	Ethnicity
[redacted]							

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16.2.4.1 Listing of Demographic Characteristics (Maternal)

Vaccine Group (as Administered)	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Race	Ethnicity
[redacted]							

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16.2.4.1 Listing of Demographic Characteristics (Maternal)

Vaccine Group (as Administered)	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Race	Ethnicity
[redacted]							

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16.2.4.1 Listing of Demographic Characteristics (Maternal)

Vaccine Group (as Administered)	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Race	Ethnicity
[redacted]							

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16.2.4.1 Listing of Demographic Characteristics (Maternal)

Vaccine Group (as Administered)	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Race	Ethnicity
[redacted]							

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16.2.4.1 Listing of Demographic Characteristics (Maternal)

Vaccine Group (as Administered)	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Race	Ethnicity
[redacted]							

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16.2.4.1 Listing of Demographic Characteristics (Maternal)

Vaccine Group (as Administered)	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Race	Ethnicity
[redacted]							

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16.2.4.1 Listing of Demographic Characteristics (Maternal)

Vaccine Group (as Administered)	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Race	Ethnicity
[redacted]							

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16.2.4.1 Listing of Demographic Characteristics (Maternal)

Vaccine Group (as Administered)	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Race	Ethnicity
[redacted]							

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16.2.4.1 Listing of Demographic Characteristics (Maternal)

Vaccine Group (as Administered)	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Race	Ethnicity
[redacted]							

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16.2.4.1 Listing of Demographic Characteristics (Maternal)

Vaccine Group (as Administered)	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Race	Ethnicity
[redacted]							

Note: † = Human immunodeficiency virus (HIV)-positive participant.
a. Maternal age at first vaccination.
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16.2.4.2 Listing of Demographic Characteristics (Infant)

Maternal Vaccine Group (as Administered)	Participant	Gestational Age at Birth	Body Length (cm)	Weight (kg)	Race	Ethnicity
BNT162b2 (30 µg)	[redacted]					

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16.2.4.2 Listing of Demographic Characteristics (Infant)

Maternal Vaccine Group (as Administered)	Participant	Gestational Age at Birth	Body Length (cm)	Weight (kg)	Race	Ethnicity
[redacted]						

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16.2.4.2 Listing of Demographic Characteristics (Infant)

Maternal Vaccine Group (as Administered)	Participant	Gestational Age at Birth	Body Length (cm)	Weight (kg)	Race	Ethnicity
[redacted]						

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16.2.4.2 Listing of Demographic Characteristics (Infant)

Maternal Vaccine Group (as Administered)	Participant	Gestational Age at Birth	Body Length (cm)	Weight (kg)	Race	Ethnicity
[redacted]						

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16.2.4.2 Listing of Demographic Characteristics (Infant)

Maternal Vaccine Group (as Administered)	Participant	Gestational Age at Birth	Body Length (cm)	Weight (kg)	Race	Ethnicity
[redacted]						

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16.2.4.2 Listing of Demographic Characteristics (Infant)

Maternal Vaccine Group (as Administered)	Participant	Gestational Age at Birth	Body Length (cm)	Weight (kg)	Race	Ethnicity
[redacted]						

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16.2.4.2 Listing of Demographic Characteristics (Infant)

Maternal Vaccine Group (as Administered)	Participant	Gestational Age at Birth	Body Length (cm)	Weight (kg)	Race	Ethnicity
[redacted]						

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16.2.4.2 Listing of Demographic Characteristics (Infant)

Maternal Vaccine Group (as Administered)	Participant	Gestational Age at Birth	Body Length (cm)	Weight (kg)	Race	Ethnicity
[redacted]						

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16.2.4.2 Listing of Demographic Characteristics (Infant)

Maternal Vaccine Group (as Administered)	Participant	Gestational Age at Birth	Body Length (cm)	Weight (kg)	Race	Ethnicity
[redacted]						

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16.2.4.2 Listing of Demographic Characteristics (Infant)

Maternal Vaccine Group (as Administered)	Participant	Gestational Age at Birth	Body Length (cm)	Weight (kg)	Race	Ethnicity
[redacted]						

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16.2.4.2 Listing of Demographic Characteristics (Infant)

Maternal Vaccine Group (as Administered)	Participant	Gestational Age at Birth	Body Length (cm)	Weight (kg)	Race	Ethnicity
[redacted]						

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16.2.4.2 Listing of Demographic Characteristics (Infant)

Maternal Vaccine Group (as Administered)	Participant	Gestational Age at Birth	Body Length (cm)	Weight (kg)	Race	Ethnicity
[redacted]						

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16.2.4.2 Listing of Demographic Characteristics (Infant)

Maternal Vaccine Group (as Administered)	Participant	Gestational Age at Birth	Body Length (cm)	Weight (kg)	Race	Ethnicity
[redacted]						

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16.2.4.2 Listing of Demographic Characteristics (Infant)

Maternal Vaccine Group (as Administered)	Participant	Gestational Age at Birth	Body Length (cm)	Weight (kg)	Race	Ethnicity
[redacted]						

16.2.4.2 Listing of Demographic Characteristics (Infant)

Maternal Vaccine Group (as Administered)	Participant	Gestational Age at Birth	Body Length (cm)	Weight (kg)	Race	Ethnicity

Abbreviations: D = day(s); W = weeks.
Note: † = Infant born to human immunodeficiency virus (HIV)-positive participant.
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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
BNT162b2 (30 µg)	C4591001	[redacted]	[redacted]							

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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
[redacted]										

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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
[redacted]										

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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
[redacted]										

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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
[redacted]										

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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
[redacted]										

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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
[redacted]										

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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
[redacted]										

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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
[redacted]										

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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
[redacted]										

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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
[redacted]	C4591015	[redacted]	[redacted]						[redacted]	[redacted]

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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
[redacted]										

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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
[redacted]										

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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
[redacted]										

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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
[redacted]										

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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
[redacted]										

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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
[redacted]										

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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
[redacted]										

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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
[redacted]										

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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
[redacted]										

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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
[redacted]										

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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
[redacted]										

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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
[redacted]										

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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
[redacted]										
Placebo	C4591001	[redacted]								

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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
[redacted]										

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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
[redacted]										

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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
[redacted]										

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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
[redacted]										

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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
[redacted]										

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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
[redacted]										

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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
[redacted]										

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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
[redacted]										

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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
[redacted]										

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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
[redacted]										

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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
[redacted]	C4591015	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
[redacted]										

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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
[redacted]										

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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
[redacted]										

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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
[redacted]										

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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
[redacted]										

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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
[redacted]										

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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
[redacted]										

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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
[redacted]										

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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
[redacted]										

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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
[redacted]										

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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
[redacted]										

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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
[redacted]										

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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
[redacted]										

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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
[redacted]										

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16.2.4.3 Listing of Demographic Characteristics – Maternal Participants (Study C4591015) and Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Study	Participant	Age (Years)[a]	Height (cm)	Weight (kg)	Body Mass Index (BMI) (kg/m^2)	Gestational Age at Dose 1	Gestational Age at Dose 2	Race	Ethnicity
[redacted]										

Abbreviation: N/A = not applicable.
Note: Participants from C4591001 are a selected subset of age matched nonpregnant female Phase 3 participants.
Note: As per inclusion criteria 10 for weight in C4591015 protocol, the BMI included is pre-pregnancy and if unavailable, the BMI recorded from the first obstetric visit was used. The weight categories included in the table were created as per these records.
Note: † = Human immunodeficiency virus (HIV)-positive participant.
a. Age at first vaccination.
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(Data cutoff date : C4591001 [31Aug2021]) Output File: ./nda3/C4591015_Bridging/adsl_l001_mat1

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16.2.5.1 Listing of Medical History (Maternal)

Vaccine Group (as Randomized)	Participant	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
BNT162b2 (30 µg)	[redacted]	Gastrointestinal disorders	Nausea	01DEC2020		Y
		Psychiatric disorders	Bipolar I disorder	01MAR2012		Y
	[redacted]	Blood and lymphatic system disorders	Anaemia of pregnancy	01APR2021		Y
	[redacted]	Metabolism and nutrition disorders	Obesity	04JAN2021		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2021		Y
		Surgical and medical procedures	Adenotonsillectomy	01JAN2003	31DEC2003	N
	[redacted]	Congenital, familial and genetic disorders	Thalassaemia	01JAN1982		Y
	[redacted]	Blood and lymphatic system disorders	Anaemia	01JUN2014		Y
	[redacted]	Psychiatric disorders	Anxiety	01NOV2020		Y
			Depression	01NOV2020		Y
	[redacted]	Surgical and medical procedures	Bunion operation	01JAN2020	31JAN2020	N
			Wisdom teeth removal	01JUL2015	31JUL2015	N
	[redacted]	Psychiatric disorders	Anxiety	01SEP2020		Y
		Surgical and medical procedures	Uterine dilation and curettage	01MAY2020	31MAY2020	N
			Wisdom teeth removal	01JUN2016	30JUN2016	N
	[redacted]	Infections and infestations	Appendicitis	01JAN2011	31DEC2011	N

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16.2.5.1 Listing of Medical History (Maternal)

Vaccine Group (as Randomized)	Participant	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	[redacted]	Reproductive system and breast disorders	Polycystic ovaries	01JAN2015		Y
	[redacted]	Psychiatric disorders	Anxiety	01SEP2017		Y
			Bipolar disorder	01JAN2020		Y
	[redacted]	Hepatobiliary disorders	Cholecystitis	01JAN2014	31DEC2014	N
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2014	31DEC2014	N
	[redacted]	Nervous system disorders	Migraine	01MAY2019		Y
		Psychiatric disorders	Depression	01JAN2020		Y
		Reproductive system and breast disorders	Adnexa uteri pain	09DEC2020	09DEC2020	N
		Surgical and medical procedures	Oophorectomy	09DEC2020	09DEC2020	N
	[redacted]	Gastrointestinal disorders	Eosinophilic oesophagitis	01FEB2016		Y
	[redacted]	Gastrointestinal disorders	Gastrooesophageal reflux disease	01APR2021		Y
	[redacted]	Psychiatric disorders	Anxiety	01JUN2015		Y
			Depression	01JUN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	17MAY2021	17MAY2021	N
		Surgical and medical procedures	Uterine dilation and curettage	22JAN2020	22JAN2020	N

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16.2.5.1 Listing of Medical History (Maternal)

Vaccine Group (as Randomized)	Participant	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	[redacted]	Reproductive system and breast disorders	Endometriosis	01JAN2016		Y
	[redacted]	Pregnancy, puerperium and perinatal conditions	Gestational diabetes	01MAY2021		Y
	[redacted]	Nervous system disorders	Migraine	01JAN2000		Y
	[redacted]	Surgical and medical procedures	Gastric stapling	01JAN2011	31DEC2011	N
	[redacted]	Metabolism and nutrition disorders	Diabetes mellitus	01JAN2021		Y
	[redacted]	Surgical and medical procedures	Myopia correction	01JAN2015	31DEC2015	N
			Temporomandibular joint surgery	01JAN2016	31DEC2016	N
	[redacted]	Injury, poisoning and procedural complications	Road traffic accident	01JAN2007	31DEC2007	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2004		Y
	[redacted]	General disorders and administration site conditions	Fatigue	01DEC2020	23MAY2021	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ovarian germ cell teratoma benign	07JAN2021	13MAY2021	N
		Nervous system disorders	Migraine	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
	[redacted]	Investigations	Human papilloma virus test positive	01JUL2015	31JUL2015	N
		Surgical and medical procedures	Gastric banding	01JUN2007	01JUN2007	N

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16.2.5.1 Listing of Medical History (Maternal)

Vaccine Group (as Randomized)	Participant	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Loop electrosurgical excision procedure	01JUL2015	01JUL2015	N
			Rhinoplasty	01JAN1999	01JAN1999	N
	[redacted]	Infections and infestations	Chlamydial infection	01JAN2011	31DEC2011	N
			Varicella	01JAN1996	31DEC1996	N
		Musculoskeletal and connective tissue disorders	Symphysiolysis	17FEB2021		Y
		Nervous system disorders	Migraine	01DEC2020		Y
		Psychiatric disorders	Anxiety	01AUG2010		Y
			Depression	01AUG2010		Y
	[redacted]	Gastrointestinal disorders	Abdominal pain	01OCT2020		Y
		Infections and infestations	Chlamydial infection	01JAN2008	31DEC2008	N
			Papilloma viral infection	01JAN2012	31DEC2012	N
			Varicella	01JAN1995	31DEC1995	N
		Nervous system disorders	Headache	01OCT2020	31DEC2020	N
	[redacted]	Infections and infestations	Tonsillitis	01JAN1993	31DEC1993	N
			Varicella	01JAN1991	31DEC1991	N
		Injury, poisoning and procedural complications	Cartilage injury	01JAN2010	31DEC2010	N
		Investigations	Arthroscopy	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Tonsillectomy	01JAN1993	31DEC1993	N
	[redacted]	Gastrointestinal disorders	Bowel movement irregularity	01JAN2010		Y
			Gastrooesophageal reflux disease	01SEP2020		Y

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16.2.5.1 Listing of Medical History (Maternal)

Vaccine Group (as Randomized)	Participant	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Tonsillitis	01JAN2010	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Nasal polyps	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Sinuplasty	01JAN2014	31DEC2014	N
	[redacted]	Blood and lymphatic system disorders	Anaemia	01JAN2010		Y
		Cardiac disorders	Ventricular extrasystoles	01FEB2021		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01NOV2020		Y
			Irritable bowel syndrome	01JAN2010		Y
			Nausea	01NOV2020		Y
		General disorders and administration site conditions	Fatigue	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2014		Y
		Nervous system disorders	Migraine	01JAN2018		Y
			Sinus headache	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN1999		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2014		Y
	[redacted]	Gastrointestinal disorders	Nausea	05NOV2020		Y
			Vomiting	01DEC2020		Y
		Immune system disorders	Food allergy	01DEC2018		Y
			Seasonal allergy	01FEB2021		Y
		Nervous system disorders	Headache	01NOV2020		Y

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16.2.5.1 Listing of Medical History (Maternal)

Vaccine Group (as Randomized)	Participant	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Dyspnoea	01FEB2021		Y
	[redacted]	Immune system disorders	Drug hypersensitivity	01JAN1996		Y
	[redacted]	Musculoskeletal and connective tissue disorders	Back pain	01JAN2008		Y
			Intervertebral disc protrusion	01JAN2008		Y
			Pain in extremity	01DEC2020		Y
	[redacted]	Blood and lymphatic system disorders	Anaemia	01NOV2017		Y
		Cardiac disorders	Ventricular extrasystoles	01SEP2015		Y
	[redacted]	Reproductive system and breast disorders	Abnormal uterine bleeding	01MAR2012	31JUL2012	N
			Dysmenorrhoea	01MAR2012	31JUL2012	N
		Surgical and medical procedures	Ligament operation	01JAN2010	31DEC2010	N
	[redacted]	Endocrine disorders	Thyroid mass	23JAN2013		Y
			Toxic nodular goitre	06DEC2017	08FEB2018	N
		Investigations	Biopsy cervix	05AUG2016	05AUG2016	N
				09FEB2012	09FEB2012	N
			Biopsy thyroid gland	01AUG2013	31AUG2013	N
				01JUN2014	30JUN2014	N
			Human papilloma virus test positive	16DEC2011	17NOV2017	N
		Reproductive system and breast disorders	Cervical dysplasia	13MAY2016	05AUG2016	N
		Surgical and medical procedures	Debridement	01JAN2011	31DEC2011	N

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16.2.5.1 Listing of Medical History (Maternal)

Vaccine Group (as Randomized)	Participant	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Ligament operation	01JAN2010	31DEC2010	N
			Thyroidectomy	08FEB2018	08FEB2018	N
	[redacted]	Cardiac disorders	Pulmonary valve stenosis	01JAN1992		Y
		Congenital, familial and genetic disorders	Congenital pulmonary artery anomaly	01JAN1992		Y
		Infections and infestations	Appendicitis	01MAY2009	31MAY2009	N
		Psychiatric disorders	Depression	19FEB2021		Y
		Surgical and medical procedures	Appendicectomy	01MAY2009	31MAY2009	N
			Valvuloplasty cardiac	28FEB2007	28FEB2007	N
	[redacted]	Psychiatric disorders	Perinatal depression	04DEC2020	28FEB2021	N
		Reproductive system and breast disorders	Pelvic pain	14MAR2021		Y
	[redacted]	Metabolism and nutrition disorders	Type 1 diabetes mellitus	16FEB2021		Y
	[redacted]	Investigations	Chlamydia test positive	04AUG2021		Y
	[redacted]	Infections and infestations	Appendicitis	01JAN1992	01DEC1992	N
		Injury, poisoning and procedural complications	Fibula fracture	01JUL2006	01SEP2006	N
		Surgical and medical procedures	Appendicectomy	01DEC1992	01DEC1992	N
			Fracture treatment	01SEP2006	01SEP2006	N
	[redacted]	General disorders and administration site conditions	Chest pain	01APR2021	08JUN2021	N
				05SEP2018	01NOV2018	N

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16.2.5.1 Listing of Medical History (Maternal)

Vaccine Group (as Randomized)	Participant	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Tonsillitis	17NOV2003	01DEC2003	N
		Surgical and medical procedures	Tonsillectomy	01DEC2003	01DEC2003	N
	[redacted]	Blood and lymphatic system disorders	Anaemia	01DEC2020		Y
		Immune system disorders	Food allergy	01MAR2019		Y
			Rubber sensitivity	01FEB2017		Y
		Skin and subcutaneous tissue disorders	Sensitive skin	01FEB2017		Y
	[redacted]	Immune system disorders	Seasonal allergy	01MAR2021		Y
		Infections and infestations	Appendicitis	01MAR2017	31MAR2017	N
		Psychiatric disorders	Anxiety	01DEC2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01MAR2021		Y
		Surgical and medical procedures	Appendicectomy	01MAR2017	31MAR2017	N
	[redacted]	Metabolism and nutrition disorders	Vitamin D deficiency	05NOV2020		Y
	[redacted]	Nervous system disorders	Migraine	01JAN2007		Y
	[redacted]	Immune system disorders	Seasonal allergy	01JAN2010		Y
	[redacted]	Gastrointestinal disorders	Gastrooesophageal reflux disease	27JAN2021	11MAY2021	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2012	31DEC2012	N
	[redacted]	Endocrine disorders	Hyperthyroidism	22DEC2020	16FEB2021	N
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y

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16.2.5.1 Listing of Medical History (Maternal)

Vaccine Group (as Randomized)	Participant	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	[redacted]	Blood and lymphatic system disorders	Anaemia	06JUL2021	24AUG2021	N
				25AUG2021		Y
		Reproductive system and breast disorders	Vaginal discharge	01JUL2021		Y
	[redacted]	Pregnancy, puerperium and perinatal conditions	Gestational hypertension	16JUN2018	17JUN2021	N
	[redacted]	Infections and infestations	Vulvovaginal candidiasis	12MAY2021	12JUN2021	N
	[redacted]	Surgical and medical procedures	Abortion induced	01JUN2020	30JUN2020	N
	[redacted]†	Investigations	HIV test positive	01AUG2012		Y
	[redacted]†	Investigations	HIV test positive	01JAN2010		Y
	[redacted]	Gastrointestinal disorders	Gastrooesophageal reflux disease	15FEB2021		Y
			Hiatus hernia			Y
		Immune system disorders	Food allergy			Y
		Pregnancy, puerperium and perinatal conditions	Morning sickness	25MAR2021		Y
		Psychiatric disorders	Mixed anxiety and depressive disorder	01JAN2019		Y
	[redacted]	Gastrointestinal disorders	Gastrooesophageal reflux disease	01OCT2018	31OCT2018	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JUL2017	31JUL2017	N

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16.2.5.1 Listing of Medical History (Maternal)

Vaccine Group (as Randomized)	Participant	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Oesophagogastric fundoplasty	01OCT2018	31OCT2018	N
			Thyroidectomy	01JUL2017	31JUL2017	N
	[redacted]	Endocrine disorders	Hypothyroidism	01JAN2010		Y
	[redacted]	Endocrine disorders	Hypothyroidism	15OCT2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN2019	31DEC2019	N
		Reproductive system and breast disorders	Cervical dysplasia	01APR2019	10APR2019	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2019		Y
		Surgical and medical procedures	Cervical conisation	10APR2019	10APR2019	N
			Lipoma excision	01JAN2019	31DEC2019	N
	[redacted]†	Investigations	HIV test positive	01AUG2015		Y
	[redacted]†	Investigations	HIV test positive	01MAR2017		Y
	[redacted]†	Infections and infestations	HIV infection	01APR2020		Y
			Tuberculosis	01APR2020	31OCT2020	N
	[redacted]†	Infections and infestations	Pulmonary tuberculosis	01MAY2012	31MAY2012	N
		Investigations	HIV test positive	01NOV2012		Y
	[redacted]†	Investigations	HIV test positive	01JAN2014		Y

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16.2.5.1 Listing of Medical History (Maternal)

Vaccine Group (as Randomized)	Participant	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	[redacted]†	Investigations	HIV test positive	01JAN2017		Y
	[redacted]†	Investigations	HIV test positive	01DEC2016		Y
	[redacted]†	Investigations	HIV test positive	01JUN2019		Y
	[redacted]	Infections and infestations	Echinococciasis	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Liver operation	01JAN2014	31DEC2014	N
	[redacted]†	Investigations	HIV test positive	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	16SEP2021		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	02OCT2021		Y
	[redacted]†	Investigations	HIV test positive	16JAN2020		Y
	[redacted]	Infections and infestations	Herpes simplex	03FEB2021	15FEB2021	N
		Reproductive system and breast disorders	Cervical dysplasia	23MAR2021		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2020		Y
	[redacted]	Infections and infestations	Candida infection	21MAY2021	21MAY2021	N
			Influenza	21JAN2021	26JAN2021	N
			Urinary tract infection	18JAN2021	31JAN2021	N

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16.2.5.1 Listing of Medical History (Maternal)

Vaccine Group (as Randomized)	Participant	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	[redacted]	Pregnancy, puerperium and perinatal conditions	Gestational hypertension	01MAR2021		Y
	[redacted]	Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2014		Y
	[redacted]	Endocrine disorders	Thyroid dysfunction in pregnancy	18DEC2020		Y
	[redacted]	Immune system disorders	Drug hypersensitivity			Y
		Psychiatric disorders	Anxiety			Y
	[redacted]	Psychiatric disorders	Anxiety disorder			Y
	[redacted]	Injury, poisoning and procedural complications	Femur fracture	01APR2009	01APR2009	N
		Surgical and medical procedures	Abdominoplasty	01AUG2018	31AUG2018	N
			Internal fixation of fracture	01APR2009	01APR2009	N
	[redacted]	Cardiac disorders	Cardiac disorder			Y
		Immune system disorders	Drug hypersensitivity			Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis			Y
			Rheumatic fever			Y
		Psychiatric disorders	Anxiety			Y
			Bipolar disorder			Y
			Depression			Y
			Panic disorder			Y
		Surgical and medical procedures	Joint arthroplasty	16JUN2019	16JUN2019	N

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16.2.5.1 Listing of Medical History (Maternal)

Vaccine Group (as Randomized)	Participant	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	[redacted]	Surgical and medical procedures	Abdominoplasty	08AUG2018	08AUG2018	N
			Liposuction	08AUG2018	08AUG2018	N
			Mammoplasty	08AUG2018	08AUG2018	N
	[redacted]	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2021		Y
		Surgical and medical procedures	Rhinoplasty	01JAN2006	31DEC2006	N
			Varicose vein operation	01DEC2014	31DEC2014	N
		Vascular disorders	Varicose vein	01JAN2012	31DEC2014	N
	[redacted]	Infections and infestations	Tonsillitis	01JAN1992	31DEC1992	N
		Surgical and medical procedures	Tonsillectomy	01JAN1992	31DEC1992	N
	[redacted]	Endocrine disorders	Thyroid dysfunction in pregnancy	26FEB2021		Y
		Hepatobiliary disorders	Primary biliary cholangitis	01JAN2020		Y
	[redacted]	Infections and infestations	Urinary tract infection	01JUL2021	02JUL2021	N
	[redacted]	Immune system disorders	Anaphylactic reaction	14APR1990		Y
		Surgical and medical procedures	Knee operation	14APR2007	14APR2007	N
	[redacted]	Metabolism and nutrition disorders	Vitamin D deficiency	01NOV2020		Y
	[redacted]	Eye disorders	Myopia	01JAN1987		Y
		Surgical and medical procedures	Nasal septal operation	01NOV2014	01NOV2014	N
	[redacted]	Nervous system disorders	Migraine	01JAN2016		Y

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16.2.5.1 Listing of Medical History (Maternal)

Vaccine Group (as Randomized)	Participant	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y
		Surgical and medical procedures	Rhinoplasty	01AUG2013	31AUG2013	N
	[redacted]	Psychiatric disorders	Anxiety	01DEC2020		Y
	[redacted]	Cardiac disorders	Sinus tachycardia	08JAN2021	08JAN2021	N
		Congenital, familial and genetic disorders	Kidney duplex	01JAN1988		Y
		Nervous system disorders	Relapsing-remitting multiple sclerosis	01JAN2009		Y
	[redacted]	Infections and infestations	Ear infection	11DEC2018	20DEC2018	N
		Psychiatric disorders	Anxiety	01JAN1985		Y
			Obsessive-compulsive disorder	01JAN1985		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
		Skin and subcutaneous tissue disorders	Dermatitis allergic	27SEP2018	27SEP2018	N
	[redacted]	Psychiatric disorders	Anxiety	01JAN2008		Y
Placebo	[redacted]	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN2000		Y
	[redacted]	Infections and infestations	Genital herpes simplex	01JAN2019	31DEC2020	N
	[redacted]	Blood and lymphatic system disorders	Anaemia of pregnancy	05MAR2021		Y

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16.2.5.1 Listing of Medical History (Maternal)

Vaccine Group (as Randomized)	Participant	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	[redacted]	Congenital, familial and genetic disorders	Heart disease congenital	01JAN2003	31DEC2003	N
		Investigations	Biopsy breast normal	01JAN2019	31DEC2019	N
	[redacted]	Hepatobiliary disorders	Cholelithiasis	01JAN2007	31DEC2007	N
		Psychiatric disorders	Anxiety	01OCT2020		Y
			Depression	01OCT2020		Y
			Post-traumatic stress disorder	01OCT2020		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2007	31DEC2007	N
			Gastrectomy	01JAN2013	31DEC2013	N
	[redacted]	Blood and lymphatic system disorders	Anaemia	03MAR2021		Y
		Infections and infestations	Tonsillitis	01MAR1998	31MAR1998	N
		Reproductive system and breast disorders	Polycystic ovaries	01OCT2014		Y
		Surgical and medical procedures	Adenoidectomy	01MAR1998	31MAR1998	N
	[redacted]	Hepatobiliary disorders	Cholelithiasis	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Cholecystectomy	01JAN2008	31DEC2008	N
	[redacted]	Investigations	Cystoscopy	01JAN2003	31DEC2003	N
			Oesophagogastroduodenoscopy	01JAN2012	31DEC2012	N
	[redacted]	Surgical and medical procedures	Wisdom teeth removal	01APR2016	30APR2016	N
	[redacted]	Psychiatric disorders	Anxiety	01JAN2015		Y

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16.2.5.1 Listing of Medical History (Maternal)

Vaccine Group (as Randomized)	Participant	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Attention deficit hyperactivity disorder	01JAN2015		Y
			Depression	01JAN2015		Y
	[redacted]	Hepatobiliary disorders	Cholelithiasis	01JAN2020	31DEC2020	N
		Infections and infestations	Chronic tonsillitis	01JAN2001		Y
		Investigations	Biopsy	01JAN1996	31DEC1996	N
		Surgical and medical procedures	Adenoidectomy	01JAN2001	31DEC2001	N
			Cyst removal	01JAN1996	31DEC1996	N
			Tonsillectomy	01JAN2001	31DEC2001	N
	[redacted]	Reproductive system and breast disorders	Polycystic ovaries	01MAR2007		Y
		Surgical and medical procedures	Uterine dilation and curettage	01SEP2018	30SEP2018	N
	[redacted]	Psychiatric disorders	Attention deficit hyperactivity disorder	01APR2019		Y
	[redacted]	Infections and infestations	Pharyngitis	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Fracture treatment	01JAN2014	31DEC2014	N
	[redacted]	Endocrine disorders	Hypothyroidism	01JAN2014		Y
	[redacted]	Endocrine disorders	Hypothyroidism	11NOV2020		Y
	[redacted]	Infections and infestations	Appendicitis	01JAN1996	31DEC1996	N
	[redacted]	Reproductive system and breast disorders	Cervical dysplasia	04FEB2019		Y

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16.2.5.1 Listing of Medical History (Maternal)

Vaccine Group (as Randomized)	Participant	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Loop electrosurgical excision procedure	01MAR2020	31MAR2020	N
	[redacted]	Hepatobiliary disorders	Cholelithiasis	01NOV2019	30NOV2019	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01OCT2020	31OCT2020	N
		Psychiatric disorders	Anxiety	01JAN2015	31DEC2019	N
		Surgical and medical procedures	Cholecystectomy	01NOV2019	30NOV2019	N
			Myomectomy	01OCT2020	31OCT2020	N
	[redacted]	Endocrine disorders	Hypothyroidism	01JUL2020		Y
	[redacted]	Psychiatric disorders	Anxiety	23DEC2020		Y
	[redacted]	Immune system disorders	Seasonal allergy	01JAN2021		Y
		Psychiatric disorders	Depression	01JAN2021		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2001	31DEC2011	N
	[redacted]	Blood and lymphatic system disorders	Anaemia	01JAN2013	31DEC2013	N
		Immune system disorders	Rubber sensitivity	01JAN2006		Y
		Nervous system disorders	Migraine	01JAN2013		Y
		Pregnancy, puerperium and perinatal conditions	Morning sickness	01SEP2020	30NOV2020	N
	[redacted]	Gastrointestinal disorders	Gastrooesophageal reflux disease	01FEB2021		Y

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16.2.5.1 Listing of Medical History (Maternal)

Vaccine Group (as Randomized)	Participant	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		General disorders and administration site conditions	Fatigue	01OCT2020		Y
		Injury, poisoning and procedural complications	Facial bones fracture	01OCT2012	31OCT2012	N
		Psychiatric disorders	Insomnia	24SEP2020		Y
		Skin and subcutaneous tissue disorders	Night sweats	01FEB2020		Y
		Surgical and medical procedures	Rhinoplasty	01MAR2013	31MAR2013	N
				01OCT2012	31OCT2012	N
	[redacted]	Blood and lymphatic system disorders	Anaemia	01NOV2020		Y
		Gastrointestinal disorders	Dyspepsia	08MAR2021		Y
			Nausea	01OCT2020	31JAN2021	N
		Skin and subcutaneous tissue disorders	Dermatitis contact	17APR2017		Y
	[redacted]	Blood and lymphatic system disorders	Anaemia	06OCT2017	30APR2018	N
				21APR2021		Y
		Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Gastrointestinal disorders	Abdominal pain lower	18APR2018	30JUN2018	N
			Nausea	01NOV2020		Y
		Infections and infestations	Bacterial vulvovaginitis	30APR2018	07MAY2018	N
			Gastrointestinal infection	18APR2018	30JUN2018	N
			Herpes simplex	03AUG2017	10AUG2017	N
			Oral herpes	03AUG2017	10AUG2017	N
			Trichomoniasis	19APR2019	26APR2019	N
			Vaginal infection	06OCT2017	10OCT2017	N
			Varicella	01JAN2005	31DEC2005	N

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16.2.5.1 Listing of Medical History (Maternal)

Vaccine Group (as Randomized)	Participant	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Cardiac murmur	01AUG1990		Y
		Metabolism and nutrition disorders	Vitamin B12 deficiency	25JUL2017	31JAN2018	N
		Nervous system disorders	Disturbance in attention	24DEC2018		Y
		Psychiatric disorders	Bipolar disorder	01JAN2018		Y
			Depression	28NOV2018	31JAN2019	N
		Reproductive system and breast disorders	Intermenstrual bleeding	06OCT2017	30APR2018	N
			Ovarian cyst	06OCT2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01SEP2004		Y
	[redacted]	Endocrine disorders	Hypothyroidism	21JAN2021		Y
		Metabolism and nutrition disorders	Obesity	01MAY2014		Y
	[redacted]	Ear and labyrinth disorders	Ear congestion	01FEB2021		Y
		Eye disorders	Glaucoma	01JAN2004		Y
		Immune system disorders	Allergy to animal	01JAN1982		Y
			Seasonal allergy	01APR2021		Y
	[redacted]	Immune system disorders	Seasonal allergy	01JAN2002		Y
		Infections and infestations	Fungal infection	23FEB2021	26FEB2021	N
		Pregnancy, puerperium and perinatal conditions	Placenta praevia haemorrhage	25OCT2019	27OCT2019	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2002		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y

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16.2.5.1 Listing of Medical History (Maternal)

Vaccine Group (as Randomized)	Participant	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Acne	01JAN2010	31DEC2012	N
	[redacted]	Gastrointestinal disorders	Nausea	02FEB2021	16FEB2021	N
		General disorders and administration site conditions	Fatigue	02FEB2021	28FEB2021	N
		Reproductive system and breast disorders	Breast tenderness	01JAN2021	02FEB2021	N
			Uterine spasm	01JAN2021	02FEB2021	N
	[redacted]	Injury, poisoning and procedural complications	Lower limb fracture	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Bone operation	01JAN2008	31DEC2008	N
	[redacted]	Eye disorders	Visual impairment	10MAR2020	11NOV2020	N
		General disorders and administration site conditions	Fatigue	10MAR2020	11NOV2020	N
		Investigations	Rhesus antigen negative	11NOV2020		Y
			Smear cervix abnormal	28SEP2015	28DEC2015	N
		Nervous system disorders	Migraine with aura	01JAN1993		Y
		Pregnancy, puerperium and perinatal conditions	Morning sickness	11NOV2020		Y
	[redacted]	Blood and lymphatic system disorders	Iron deficiency anaemia	19FEB2021		Y
			Thrombocytopenia	26MAR2021		Y
	[redacted]	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2011		Y
		Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Gastrointestinal disorders	Umbilical hernia	05FEB2021		Y

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16.2.5.1 Listing of Medical History (Maternal)

Vaccine Group (as Randomized)	Participant	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Food allergy	01JAN2019		Y
			Seasonal allergy	01JAN2010		Y
		Infections and infestations	Endometritis	01APR2018	13APR2018	N
			Pelvic inflammatory disease	01JAN2017	30APR2017	N
			Sinusitis	01JAN2009	31DEC2010	N
				01JAN2015	31DEC2016	N
			Tonsillitis	01JAN2005	31DEC2005	N
		Nervous system disorders	Migraine	01JAN1998		Y
		Pregnancy, puerperium and perinatal conditions	Morning sickness	01JAN2017	13DEC2017	N
		Psychiatric disorders	Anxiety	01JAN2006		Y
			Depression	01JAN2006		Y
		Surgical and medical procedures	Adenotonsillectomy	01DEC2005	31DEC2005	N
			Sinus operation	01JAN2010	31DEC2010	N
				01JAN2016	31DEC2016	N
	[redacted]	Blood and lymphatic system disorders	Thrombocytopenia	21APR2021		Y
		Injury, poisoning and procedural complications	Lip injury	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Keratomileusis	01JAN2017	31DEC2017	N
			Lip operation	01JAN2000	31DEC2000	N
			Wisdom teeth removal	01JAN2005	31DEC2005	N
	[redacted]	Endocrine disorders	Hypothyroidism	01JAN2005	28OCT2020	N
				28OCT2020		Y

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16.2.5.1 Listing of Medical History (Maternal)

Vaccine Group (as Randomized)	Participant	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Facial bones fracture	31MAY2015	31MAY2015	N
			Road traffic accident	01FEB2007	28FEB2007	N
		Surgical and medical procedures	Intestinal operation	01FEB2007	28FEB2007	N
			Wisdom teeth removal	01JAN2013	31DEC2013	N
	[redacted]	Infections and infestations	Herpes simplex	01JAN2019	31DEC2019	N
	[redacted]	Pregnancy, puerperium and perinatal conditions	Gestational diabetes	08MAY2021		Y
	[redacted]	Pregnancy, puerperium and perinatal conditions	Gestational diabetes	08JUN2021		Y
	[redacted]	Cardiac disorders	Supraventricular tachycardia	01OCT2017		Y
		Immune system disorders	Allergy to arthropod sting	01AUG1994		Y
		Infections and infestations	Bronchitis	17APR2016	31OCT2017	N
			Herpes virus infection	01JAN1995		Y
		Psychiatric disorders	Anxiety	10MAR2020	01SEP2020	N
			Depression	10MAR2020	01SEP2020	N
	[redacted]	Gastrointestinal disorders	Dyspepsia	10SEP2020		Y
			Irritable bowel syndrome	01OCT2018		Y
		Immune system disorders	Allergy to arthropod sting	01AUG2002		Y
			Seasonal allergy	01MAR2015		Y
		Investigations	Endoscopy	01NOV2018	01NOV2018	N
		Surgical and medical procedures	Wisdom teeth removal	01JUN2002	01JUN2002	N
	[redacted]	Endocrine disorders	Hypothyroidism	01APR2021		Y

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16.2.5.1 Listing of Medical History (Maternal)

Vaccine Group (as Randomized)	Participant	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN2011		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pituitary tumour benign	01JAN2018		Y
	[redacted]	Metabolism and nutrition disorders	Vitamin D deficiency	08FEB2021		Y
	[redacted]	Infections and infestations	Appendicitis	01MAR2007	31MAR2007	N
	[redacted]	Gastrointestinal disorders	Diarrhoea	11AUG2021	13AUG2021	N
			Gastrooesophageal reflux disease	01AUG2021		Y
		Infections and infestations	Tinea cruris	10AUG2021	16SEP2021	N
			Urinary tract infection	22JUN2021	24JUN2021	N
			Vaginal infection	22JUN2021	24JUN2021	N
		Metabolism and nutrition disorders	Insulin resistance	01JAN2019		Y
	[redacted]	Immune system disorders	Drug hypersensitivity	01JAN1993		Y
				01JAN2007		Y
			Seasonal allergy	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01OCT2016		Y
			Intervertebral disc protrusion	01OCT2016		Y
	[redacted]	Infections and infestations	Asymptomatic bacteriuria	07JAN2021	15FEB2021	N
		Psychiatric disorders	Anxiety	01JAN2011		Y
			Depression	01JAN2011		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2004		Y

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16.2.5.1 Listing of Medical History (Maternal)

Vaccine Group (as Randomized)	Participant	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	[redacted]	Renal and urinary disorders	Leukocyturia	22SEP2021	28SEP2021	N
	[redacted]	Infections and infestations	Urinary tract infection	21SEP2021	28SEP2021	N
	[redacted]†	Infections and infestations	HIV infection	01JAN2018		Y
	[redacted]	Reproductive system and breast disorders	Vaginal haemorrhage	01MAR2021	31MAR2021	N
	[redacted]	Infections and infestations	Appendicitis	01JAN2011	31DEC2011	N
		Investigations	Human papilloma virus test positive	22MAY2019	01FEB2021	N
		Nervous system disorders	Migraine	01JAN2011		Y
		Reproductive system and breast disorders	Cervical dysplasia	01JAN2019	01FEB2021	N
		Surgical and medical procedures	Appendicectomy	01JAN2011	31DEC2011	N
	[redacted]†	Investigations	HIV test positive	01AUG2016		Y
	[redacted]	General disorders and administration site conditions	Drug intolerance	01JAN1985		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	24NOV2020		Y
	[redacted]	Surgical and medical procedures	Cholecystectomy	01JAN2013	31DEC2013	N
			Wisdom teeth removal	01JAN2013	31DEC2013	N
	[redacted]	Infections and infestations	Folliculitis	04APR2018		Y

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16.2.5.1 Listing of Medical History (Maternal)

Vaccine Group (as Randomized)	Participant	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	[redacted]†	Investigations	HIV test positive	01JAN2015		Y
	[redacted]†	Investigations	HIV test positive	01JAN2020		Y
	[redacted]	Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	12JUN2019	12JUN2019	N
		Surgical and medical procedures	Laparotomy	12JUN2019	12JUN2019	N
	[redacted]†	Infections and infestations	HIV infection	13NOV2020		Y
	[redacted]†	Investigations	HIV test positive	01JUN2018		Y
	[redacted]†	Investigations	HIV test positive	01AUG2017		Y
	[redacted]†	Investigations	HIV test positive	01JAN2011		Y
	[redacted]†	Investigations	HIV test positive	01JAN2016		Y
	[redacted]†	Investigations	HIV test positive	27MAY2015		Y
	[redacted]	Surgical and medical procedures	Appendicectomy	01SEP2007	30SEP2007	N
	[redacted]	Endocrine disorders	Hypothyroidism	01JAN2014		Y
	[redacted]	Endocrine disorders	Hypothyroidism	01FEB2020		Y
	[redacted]	Investigations	Chlamydia test positive	17MAY2021	26AUG2021	N

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16.2.5.1 Listing of Medical History (Maternal)

Vaccine Group (as Randomized)	Participant	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	[redacted]	Nervous system disorders	Headache	01JAN2020		Y
	[redacted]	Immune system disorders	Drug hypersensitivity	01JAN1992		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	14OCT2020		Y
	[redacted]	Surgical and medical procedures	Mammoplasty	26DEC2016	26DEC2016	N
	[redacted]	Surgical and medical procedures	Abdominoplasty	01JAN2013	31DEC2013	N
			Liposuction	01JAN2013	31DEC2013	N
	[redacted]	Nervous system disorders	Migraine	01JAN2000		Y
	[redacted]	Immune system disorders	Drug hypersensitivity	01JAN2017		Y
				01JAN2019		Y
				01JAN2021		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2009		Y
	[redacted]	Congenital, familial and genetic disorders	Accessory kidney	23DEC1993		Y
	[redacted]	Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
	[redacted]	Hepatobiliary disorders	Cholecystitis	01JAN2009	31DEC2009	N
		Infections and infestations	Meningitis viral	01JAN1999	31DEC1999	N

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16.2.5.1 Listing of Medical History (Maternal)

Vaccine Group (as Randomized)	Participant	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillitis	01JAN1985	31DEC1985	N
		Surgical and medical procedures	Cholecystectomy	01JAN2009	31DEC2009	N
			Tonsillectomy	01JAN1985	31DEC1985	N
	[redacted]	Endocrine disorders	Thyroiditis	01JAN2020		Y
	[redacted]	Gastrointestinal disorders	Gastric disorder	01JAN1987	31DEC1987	N
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN2019	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Trigger finger	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Fracture treatment	01JAN2019	31DEC2019	N
			Pyloroplasty	22OCT1987	22OCT1987	N
			Tendon sheath incision	01JAN2008	31DEC2008	N
	[redacted]	Gastrointestinal disorders	Irritable bowel syndrome	01JAN1993		Y
		Investigations	Human papilloma virus test positive	01DEC2020		Y
	[redacted]	Musculoskeletal and connective tissue disorders	Scoliosis	01AUG2004		Y
	[redacted]	Infections and infestations	Appendicitis	01APR2009	30APR2009	N
		Surgical and medical procedures	Appendicectomy	01APR2009	30APR2009	N
	[redacted]	Injury, poisoning and procedural complications	Joint injury	25DEC2020	25DEC2020	N
	[redacted]	Injury, poisoning and procedural complications	Ligament sprain	09MAY2021	09MAY2021	N

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16.2.5.1 Listing of Medical History (Maternal)

Vaccine Group (as Randomized)	Participant	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	02FEB2021	16FEB2021	N
	[redacted]	Nervous system disorders	Headache	26JUN2015		Y
	[redacted]	Immune system disorders	Seasonal allergy	15APR2021		Y
		Reproductive system and breast disorders	Uterine polyp	01JUN2020	01JUL2020	N

Note: MedDRA (v25.1) coding dictionary applied.
Note: † = Human immunodeficiency virus (HIV)-positive participant.
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16.2.5.2 Listing of Nonstudy Vaccines Received (Maternal)

Vaccine Group (as Administered)	Participant	Date of Nonstudy Vaccination	Dose No.	Rel Day[a]	Investigator Term	Preferred Term[b]
BNT162b2 (30 µg)	[redacted]	28MAY2021		-6	Influenza vaccine	INFLUENZA VACCINE
	[redacted]	08JUN2021	2	58	TDAP - TETANUS, DIPTHERIA, ACELLULAR PERTUSSIS (BOOSTRIX)	DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR 3-COMPONENT;TETANUS VACCINE TOXOID
		01OCT2021	2	173	Influenza Vaccine	INFLUENZA VACCINE
	[redacted]	26JUN2021	2	54	MEASLES, MUMPS, & RUBELLA VACCINE (M-M-R II)	MEASLES VACCINE LIVE (ENDERS-EDMONSTON);MUMPS VACCINE LIVE (JERYL LYNN);RUBELLA VACCINE LIVE (WISTAR RA 27/3)
	[redacted]	24JUN2021	2	24	TDAP VACCINE	DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID
	[redacted]	25OCT2021	2	211	influenza	INFLUENZA VACCINE
	[redacted]	18MAY2021	2	16	TDAP	DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID
		24NOV2021	2	206	influenza	INFLUENZA VACCINE
	[redacted]	20SEP2021	2	102	influenza	INFLUENZA VACCINE
	[redacted]	05JUN2021	2	54	Measles Mumps Rubella Vaccine	MEASLES VACCINE;MUMPS VACCINE;RUBELLA VACCINE
		05JUN2021	2	54	Tetanus/ Diphtheria/ Pertussis Vaccine (Tdap)	DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID

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16.2.5.2 Listing of Nonstudy Vaccines Received (Maternal)

Vaccine Group (as Administered)	Participant	Date of Nonstudy Vaccination	Dose No.	Rel Day[a]	Investigator Term	Preferred Term[b]
	[redacted]	25MAY2021	2	26	Tetanus/Diphtheria/Pertussis Vaccine (Tdap)	DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID
	[redacted]	03NOV2021	2	80	Influenza Virus Vaccine, Inactivated	INFLUENZA VACCINE
		03NOV2021	2	80	TETANUS/DIPHTHERIA/PERTUSSIS(TDAP) ADULT VACCINE.	DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID
	[redacted]	25OCT2021	2	27	Influenza Virus Vaccine, inactivated	INFLUENZA VACCINE
		25OCT2021	2	27	TETANUS/DIPHTHERIA/PERTUSSIS(TDAP) ADULT VACCINE.	DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID
	[redacted]	01OCT2021	2	128	Influenza vaccine	INFLUENZA VACCINE
	[redacted]	09JUN2021	2	28	TDAP (Diphtheria, Tetanus, Pertussis)	DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID
	[redacted]	06JUL2021	2	34	Tdap Vaccine	DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID
	[redacted]	08JUL2021	2	16	DTP VACCINE(BOOSTRIX)/1 VIAL/INTRAMUSCULAR/PROPHYLAXIS	DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR 3-COMPONENT;TETANUS VACCINE TOXOID
	[redacted]	14JUL2021	2	15	DTP VACCINE(BOOSTRIX)/1 VIAL/INTRAMUSCULAR/PROPHYLAXIS	DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR 3-COMPONENT;TETANUS VACCINE TOXOID

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16.2.5.2 Listing of Nonstudy Vaccines Received (Maternal)

Vaccine Group (as Administered)	Participant	Date of Nonstudy Vaccination	Dose No.	Rel Day[a]	Investigator Term	Preferred Term[b]
		15NOV2021	2	139	INFLUENZA VACCINE/PROPHYLAXIS/I.M.	INFLUENZA VACCINE
		09DEC2021	2	163	HBV VACCINE/PROPHYLAXIS/I.M.	HEPATITIS B VACCINE
	[redacted]	15NOV2021	2	62	TDAP/I.M./PROPHYLAXIS	DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID
	[redacted]	28SEP2021	1	8	TETANUS TOXOID	TETANUS VACCINE TOXOID
	[redacted]	28JUN2021	1	19	hepatitis b vaccine (intramuscular)	HEPATITIS B VACCINE
	[redacted]	16SEP2021	1	14	Influenza Vaccine	INFLUENZA VACCINE
		16SEP2021	1	14	Tdap	DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID
	[redacted]	03JUL2021	1	32	CORONAVAC Vaccine	COVID-19 VACCINE INACT (VERO) CZ02
	[redacted]	20AUG2021	2	19	whooping cough vaccine	PERTUSSIS VACCINE
	[redacted]	20AUG2021	2	9	boostrix	DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR 3-COMPONENT;TETANUS VACCINE TOXOID
	[redacted]	21DEC2021	2	133	MODERNA COVID-19 VACCINATION	ELASOMERAN

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16.2.5.2 Listing of Nonstudy Vaccines Received (Maternal)

Vaccine Group (as Administered)	Participant	Date of Nonstudy Vaccination	Dose No.	Rel Day[a]	Investigator Term	Preferred Term[b]
	[redacted]	06JUL2021	2	15	dTpa vaccine	DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID
		17JAN2022	2	210	Moderna covid-19 vaccine	ELASOMERAN
	[redacted]	20MAY2021		-12	Vaccine for pertussis, diphteria, tetanus / Brand: Triaxis	DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR 5-COMPONENT;TETANUS VACCINE TOXOID
		12NOV2021	2	143	hepatitis A and B	HEPATITIS A VACCINE;HEPATITIS B VACCINE
		12NOV2021	2	143	meningococcal vaccine	MENINGOCOCCAL VACCINE
	[redacted]	29JUL2021	2	29	PERTUSSIS VACCINE	PERTUSSIS VACCINE
	[redacted]	10JUN2021		-4	Pertussis Vaccine	PERTUSSIS VACCINE
	[redacted]	21OCT2021	2	10	diphtheria/tetanus/pertussis/poliomyelitis vaccine (BOOSTRIX-IPV)	DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR 3-COMPONENT;POLIO VACCINE INACT 3V (VERO);TETANUS VACCINE TOXOID
Placebo	[redacted]	26MAY2021	1	7	Tdap	DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID
	[redacted]	15JUL2021	2	10	Tdap	DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID
	[redacted]	29JUN2021	2	65	Pfizer COVID-19 vaccine,intramuscular	TOZINAMERAN

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16.2.5.2 Listing of Nonstudy Vaccines Received (Maternal)

Vaccine Group (as Administered)	Participant	Date of Nonstudy Vaccination	Dose No.	Rel Day[a]	Investigator Term	Preferred Term[b]
	[redacted]	30APR2021	2	19	MEASLES, MUMPS, AND RUBELLA (M-M-R II)	MEASLES VACCINE LIVE (ENDERS-EDMONSTON);MUMPS VACCINE LIVE (JERYL LYNN);RUBELLA VACCINE LIVE (WISTAR RA 27/3)
		30APR2021	2	19	TDAP-DIPHTHERIA/TETANUS/ACELLULLAR PERTUSSIS (BOOSTRIX)	DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR 3-COMPONENT;TETANUS VACCINE TOXOID
	[redacted]	28APR2021	2	17	TDAP TETANUS DIPTHERIA PERTUSSIS	DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID
	[redacted]	04MAY2021	2	23	TDAP - TETANUS, DIPHTHERIA, PERTUSSIS	DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID
	[redacted]	02JUN2021	2	22	TDAP TETNUS DIPTHERIA PERTUSSIS	DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID
	[redacted]	12JUL2021	2	50	MEASLES, MUMPS & RUBELLA VACCINE (M-M-R II)	MEASLES VACCINE LIVE (ENDERS-EDMONSTON);MUMPS VACCINE LIVE (JERYL LYNN);RUBELLA VACCINE LIVE (WISTAR RA 27/3)
	[redacted]	01JUL2021	2	24	TDAP VACCINE	DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID
	[redacted]	19MAY2021		-14	TDAP VACCINE	DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID
	[redacted]	07JUL2021	2	15	TDAP VACCINE	DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID

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16.2.5.2 Listing of Nonstudy Vaccines Received (Maternal)

Vaccine Group (as Administered)	Participant	Date of Nonstudy Vaccination	Dose No.	Rel Day[a]	Investigator Term	Preferred Term[b]
	[redacted]	27MAY2021	2	66	Measles Mumps Rubella Vaccine	MEASLES VACCINE;MUMPS VACCINE;RUBELLA VACCINE
	[redacted]	17JUN2021	2	85	Tetanus/Diphtheria/Pertussis Vaccine (Tdap)	DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID
	[redacted]	30MAY2021	2	41	Tetanus/Diphtheria/Pertussis (Boostrix Tdap)	DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR 3-COMPONENT;TETANUS VACCINE TOXOID
	[redacted]	27MAY2021	2	29	Measles/Mumps/Rubella Virus Vaccine	MEASLES VACCINE;MUMPS VACCINE;RUBELLA VACCINE
		27MAY2021	2	29	Tetanus/Diphtheria/Pertussis Vaccine (Tdap)	DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID
	[redacted]	13JAN2022	2	93	Influenza Virus Vaccine, inactivated	INFLUENZA VACCINE
		13JAN2022	2	93	TETANUS/DIPHTHERIA/PERTUSSIS(TDAP) ADULT VACCINE.	DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID
	[redacted]	01SEP2021	x1	3	Influenza Vaccine	INFLUENZA VACCINE
	[redacted]	07JUL2021	2	36	TDAP (Diphtheria, Tetanus, Pertussis)	DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID
	[redacted]	28JUL2021	2	48	TDAP (Diphtheria, Tetanus, Pertussis)	DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID

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16.2.5.2 Listing of Nonstudy Vaccines Received (Maternal)

Vaccine Group (as Administered)	Participant	Date of Nonstudy Vaccination	Dose No.	Rel Day[a]	Investigator Term	Preferred Term[b]
	[redacted]	27AUG2021	1	8	Tetanus Toxoid IM,Prophylaxis,Injectable	TETANUS VACCINE TOXOID
	[redacted]	06OCT2021	2	24	Tetanus Toxoid IM,Prophylaxis,Injectable	TETANUS VACCINE TOXOID
	[redacted]	26NOV2021	2	24	Tetanus toxoid	TETANUS VACCINE TOXOID
	[redacted]	06JUL2021	2	9	BOOSTRIX (Diphtheria, tetanus and pertussis vaccines)/1 VIAL/PROPHYLAXIS/INTRAMUCULAR	DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR 3-COMPONENT;TETANUS VACCINE TOXOID
	[redacted]	16SEP2021	1	16	Tetanus Toxoid	TETANUS VACCINE TOXOID
	[redacted]	28SEP2021	2	47	Influenza Vaccine	INFLUENZA VACCINE
		28SEP2021	2	47	TDap Vaccine	DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID
	[redacted]	11OCT2021	1	7	Flu Vaccine	INFLUENZA VACCINE
		11OCT2021	1	7	TDAP	DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID
	[redacted]	14JUN2021	1	19	Comirnaty	TOZINAMERAN

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16.2.5.2 Listing of Nonstudy Vaccines Received (Maternal)

Vaccine Group (as Administered)	Participant	Date of Nonstudy Vaccination	Dose No.	Rel Day[a]	Investigator Term	Preferred Term[b]
	[redacted]	12JUL2021	2	25	HEPATITIS B VACCINE	HEPATITIS B VACCINE
		12JUL2021	2	25	Triple bacterial - DTPA	PENTETIC ACID
	[redacted]	30SEP2021	2	16	Triple Bacterial (DTPA)	DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID
	[redacted]	21OCT2021	x2	29	Quadrivalent Influenza Vaccine - 0.5ml IM injection	INFLUENZA VACCINE INACT SPLIT 4V
	[redacted]	23JUL2021	2	19	diphtheria	DIPHTHERIA VACCINE TOXOID
		23JUL2021	2	19	tetanus vaccine	TETANUS VACCINE
		23JUL2021	2	19	whooping cough vaccine	PERTUSSIS VACCINE
	[redacted]	20JUL2021	2	16	BOOSTRIX	DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR 3-COMPONENT;TETANUS VACCINE TOXOID
	[redacted]	12AUG2021	2	11	whooping cough vaccine	PERTUSSIS VACCINE
	[redacted]	03JUN2021		-4	Pertussis vaccine	PERTUSSIS VACCINE
		02JUL2021	2	4	BNT162b2 vaccine - Pfizer	TOZINAMERAN
	[redacted]	12OCT2021	x2	15	Influenza vaccine	INFLUENZA VACCINE

Note: x1 = First dose of BNT162b2 (30 µg); x2 = Second dose of BNT162b2 (30 µg).
Note: † = Human immunodeficiency virus (HIV)-positive participant.

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16.2.5.2 Listing of Nonstudy Vaccines Received (Maternal)

Vaccine Group (as Administered)	Participant	Date of Nonstudy Vaccination	Dose No.	Rel Day[a]	Investigator Term	Preferred Term[b]

Note: Listing includes all nonstudy vaccines received within 14 days before Dose 1.

a. Relative day (Rel Day) = start date of nonstudy vaccination – date of last vaccination + 1. For a nonstudy vaccine received prior to first vaccination, +1 was not added to compute relative day.

b. WHODDG B3 v202203 coding dictionary applied.

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16.2.5.3.1 Listing of Concomitant Medications Used After Dose 1 (Maternal)

Vaccine Group (as Administered)	Participant	Preferred Term[a]/Investigator Term	Route	Start Date	End Date	Dose No.	Rel Day[b]	Treat Adverse Event
BNT162b2 (30 µg)	[redacted]	AZITHROMYCIN/Azithromycin	ORAL	09AUG2021	13AUG2021	2	42	
		CALCIUM CARBONATE/Calcium Carbonate	ORAL	26JUN2021	26JUN2021	1	19	Yes
		PARACETAMOL/Acetaminophen	ORAL	26JUN2021	26JUN2021	1	19	Yes
		POTASSIUM CHLORIDE/Potassium Chloride	ORAL	26JUN2021	26JUN2021	1	19	Yes
	[redacted]	CAFFEINE;PARACETAMOL/Acetaminophen-Caffeine	ORAL	15JUN2021	18JUN2021	2	2	
		PARACETAMOL/Tylenol	ORAL	27MAY2021	01JUN2021	1	2	
	[redacted]	PARACETAMOL/Paracetamol	ORAL	23JUN2021	23JUN2021	2	2	Yes
	[redacted]	LORATADINE/Loratadine	ORAL	05OCT2021	30NOV2021	2	96	
		PARACETAMOL/Paracetamol	ORAL	04NOV2021	10NOV2021	2	126	
	[redacted]	BETAMETHASONE ACETATE;BETAMETHASONE SODIUM PHOSPHATE/Betamethasone Acetate-Betamethasone Sodium Phosphate (Celestone)	INTRAMUSCULAR	08APR2021	09APR2021	2	9	Yes
		DIPHENHYDRAMINE HYDROCHLORIDE/Diphenhydramine (Benadryl)	ORAL	08APR2021	09APR2021	2	9	Yes
		HYDROCODONE BITARTRATE;PARACETAMOL/Hydrocodone-Acetaminophen(Norco)	ORAL	09APR2021	09APR2021	2	10	Yes
		HYDROXYZINE HYDROCHLORIDE/Hydroxyzine (Atarax)	ORAL	09APR2021	06OCT2021	2	10	Yes
		PARACETAMOL/Acetaminophen	ORAL	09APR2021	06OCT2021	2	10	Yes
		URSODEOXYCHOLIC ACID/Ursodiol (Actigall)	ORAL	08APR2021	12APR2021	2	9	Yes

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16.2.5.3.1 Listing of Concomitant Medications Used After Dose 1 (Maternal)

Vaccine Group (as Administered)	Participant	Preferred Term[a]/Investigator Term	Route	Start Date	End Date	Dose No.	Rel Day[b]	Treat Adverse Event
	[redacted]	FAMOTIDINE/Famotidine (Pf) (Pepcid)	INTRAVENOUS	15MAY2021	16MAY2021	2	34	
		FUROSEMIDE/Furosemide	INTRAVENOUS	15MAY2021	16MAY2021	2	34	Yes
		HYDRALAZINE HYDROCHLORIDE/Hydralazine (Apresoline)	INTRAVENOUS	14MAY2021	14MAY2021	2	33	Yes
		HYDROCODONE BITARTRATE;PARACETAMOL/Hydrocodone-Acetaminophen (Norco 10-325 Mg)	ORAL	14MAY2021	15MAY2021	2	33	
		HYDROCODONE BITARTRATE;PARACETAMOL/Hydrocodone-Acetaminophen (Norco) 5-325 Mg	ORAL	07MAY2021	08MAY2021	2	26	Yes
		MAGNESIUM SULFATE/Magnesium Sulfate In Water 20 Gram/500 Ml (4%) Infusion	INTRAVENOUS	14MAY2021	15MAY2021	2	33	Yes
		MAGNESIUM SULFATE/Magnesium Sulfate In Water 4 Gram/100ml (4%) Ivpb	INTRAVENOUS	14MAY2021	14MAY2021	2	33	Yes
		ONDANSETRON/Ondansetron (Zofran-Odt)	ORAL	15MAY2021	15MAY2021	2	34	
		POTASSIUM CHLORIDE/Potassium Chloride (K-Dur) Cr	ORAL	15MAY2021	15MAY2021	2	34	Yes
		PROMETHAZINE/Promethazine (Phenergan) Injection	INTRAVENOUS	15MAY2021	15MAY2021	2	34	
	[redacted]	ANTI-D IMMUNOGLOBULIN/Rho (D) Immune Globulin	INTRAMUSCULAR	25JUN2021	25JUN2021	2	53	
	[redacted]	FAMOTIDINE/Pepcid (Famotidine)	ORAL	20JUN2021	04AUG2021	2	24	Yes
	[redacted]	DIPHENHYDRAMINE HYDROCHLORIDE/Diphenhydramine Hcl	ORAL	11JUN2021	11JUN2021	2	2	Yes
		IBUPROFEN/Ibuprofen	ORAL	09AUG2021	09AUG2021	2	61	Yes
	[redacted]	OMEPRAZOLE/Omeprazole	ORAL	22APR2021	14JUN2021	2	22	Yes

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16.2.5.3.1 Listing of Concomitant Medications Used After Dose 1 (Maternal)

Vaccine Group (as Administered)	Participant	Preferred Term[a]/Investigator Term	Route	Start Date	End Date	Dose No.	Rel Day[b]	Treat Adverse Event
	[redacted]	LABETALOL/Labetalol	INTRAVENOUS	24JUN2021	25JUN2021	2	53	Yes
			ORAL	27JUN2021	13JUL2021	2	56	Yes
		MAGNESIUM SULFATE/Magnesium Sulfate	INTRAVENOUS	24JUN2021	24JUN2021	2	53	Yes
					25JUN2021	2	53	Yes
		NIFEDIPINE/Nifedipine	ORAL	24JUN2021	25JUN2021	2	53	Yes
				25JUN2021	27JUN2021	2	54	Yes
				27JUN2021	27JUN2021	2	56	Yes
	[redacted]	LABETALOL/Labetalol	INTRAVENOUS	27JUL2021	27JUL2021	2	54	Yes
	[redacted]	AMOXICILLIN/Amoxicillin	ORAL	21JUN2021	29JUN2021	2	11	Yes
		PARACETAMOL/Tylenol	ORAL	21JUN2021	23JUN2021	2	11	Yes
	[redacted]	SERTRALINE HYDROCHLORIDE/Zoloft 25mg 1 Tab Po Qd - Associated With Ae1	ORAL	03JUL2021		2	32	Yes
	[redacted]	AMYLMETACRESOL;DICHLOROBENZYL ALCOHOL/Strepsils	ORAL	06DEC2021	08DEC2021	2	106	
		ASCORBIC ACID;CYANOCOBALAMIN;FOLIC ACID;IRON/Ferrous Forte	ORAL	25OCT2021		2	64	Yes
		PARACETAMOL/Panado	ORAL	27AUG2021	05SEP2021	2	5	Yes
	[redacted]	CINCHOCAINE HYDROCHLORIDE;PREDNISOLONE CAPROATE/Scheriproct (Synthetic Corticosteroids, Prednisolone Hexanoate And Cinchocaine Hydrochloride)	RECTAL	01SEP2021	01OCT2021	2	3	Yes

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16.2.5.3.1 Listing of Concomitant Medications Used After Dose 1 (Maternal)

Vaccine Group (as Administered)	Participant	Preferred Term[a]/Investigator Term	Route	Start Date	End Date	Dose No.	Rel Day[b]	Treat Adverse Event
	[redacted]	CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE/Lactated Ringers	INTRAVENOUS	19JUL2021	19JUL2021	2	47	Yes
		CEFTRIAXONE/Ceftriaxone	INTRAVENOUS	18JUL2021	19JUL2021	2	46	Yes
		NITROFURANTOIN/Macrobid (Nitrofurantoin)	ORAL	20JUL2021	31JUL2021	2	48	Yes
	[redacted]	CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE/Ringers Lactate	INTRAVENOUS	27JAN2022	02MAY2022	2	94	Yes
		COUGH AND COLD PREPARATIONS/Cough Mixture	ORAL	20APR2022	02MAY2022	2	177	
	[redacted]	ASCORBIC ACID/Vitamin C	ORAL	04OCT2021	08OCT2021	1	22	
		PARACETAMOL/Paracetamol	ORAL	04OCT2021	08OCT2021	1	22	
	[redacted]	CEFAZOLIN SODIUM/Kefzol	INTRAVENOUS	14NOV2021	14NOV2021	2	27	Yes
		METOCLOPRAMIDE/Metoclopramide	INTRAVENOUS	14NOV2021	14NOV2021	2	27	Yes
	[redacted]	BROMHEXINE HYDROCHLORIDE;ORCIPRENALINE SULFATE/Adco-Linctopent (Bromhexine Hydrochloride Orciprenaline Sulphate)	ORAL	29APR2022	10MAY2022	2	164	
		CEFAZOLIN SODIUM/Kefzol	INTRAVENOUS	14JAN2022	14JAN2022	2	59	Yes
		METOCLOPRAMIDE/Metoclopramide	INTRAVENOUS	14JAN2022	14JAN2022	2	59	Yes
	[redacted]	AZITHROMYCIN/Azithromycin	ORAL	21OCT2021	23OCT2021	1	8	Yes
		PARACETAMOL/Paracetamol	ORAL	21OCT2021	23OCT2021	1	8	Yes
	[redacted]	AMOXICILLIN;CLAVULANIC ACID/Amoxicillin-Clavulanic Acid	ORAL	12SEP2021	18SEP2021	2	39	Yes

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16.2.5.3.1 Listing of Concomitant Medications Used After Dose 1 (Maternal)

Vaccine Group (as Administered)	Participant	Preferred Term[a]/Investigator Term	Route	Start Date	End Date	Dose No.	Rel Day[b]	Treat Adverse Event
		CLINDAMYCIN/Clindamycin	INTRAVENOUS	09SEP2021	11SEP2021	2	36	Yes
		DEXKETOPROFEN/Dexketoprofen	ORAL	13SEP2021	30SEP2021	2	40	Yes
		GENTAMICIN/Gentamycin	INTRAVENOUS	09SEP2021	11SEP2021	2	36	Yes
		METHYLERGOMETRINE MALEATE/Methergin	INTRAVENOUS	09SEP2021	10SEP2021	2	36	Yes
			ORAL	10SEP2021	11SEP2021	2	37	Yes
		PARACETAMOL/Paracetamol	INTRAVENOUS	09SEP2021	10SEP2021	2	36	Yes
			ORAL	10SEP2021	11SEP2021	2	37	Yes
		TRANEXAMIC ACID/Amchafibrin	INTRAVENOUS	09SEP2021	10SEP2021	2	36	Yes
	[redacted]	AMPICILLIN/Ampicillin	INTRAVENOUS	15SEP2021	15SEP2021	2	15	Yes
		CEFAZOLIN SODIUM/Kefzol	INTRAVENOUS	15SEP2021	15SEP2021	2	15	Yes
		ENOXAPARIN SODIUM/Clexane	CUTANEOUS	16SEP2021	16SEP2021	2	16	Yes
		METOCLOPRAMIDE HYDROCHLORIDE/Maxolon	INTRAMUSCULAR	15SEP2021	15SEP2021	2	15	Yes
		METRONIDAZOLE/Flagyl	ORAL	15SEP2021	15SEP2021	2	15	Yes
		PETHIDINE/Pethidine	INTRAMUSCULAR	15SEP2021	15SEP2021	2	15	Yes
	[redacted]†	AMLODIPINE/Amlodipine	ORAL	19OCT2021	25OCT2021	2	30	Yes
		AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM/Augmentin	ORAL	19OCT2021	20OCT2021	2	30	Yes
		CABERGOLINE/Cabergoline	ORAL	20OCT2021	27OCT2021	2	31	Yes
		FERROUS SULFATE/Ferrous Sulfate	ORAL	20OCT2021	29OCT2021	2	31	Yes
		PARACETAMOL/Panado	ORAL	19OCT2021	25OCT2021	2	30	Yes
	[redacted]†	AMMONIUM CHLORIDE;POLYSORBATE 20/Expigen Cough Syrup	ORAL	04NOV2021	08NOV2021	2	22	
		PARACETAMOL/Paracetamol	ORAL	04NOV2021	08NOV2021	2	22	

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16.2.5.3.1 Listing of Concomitant Medications Used After Dose 1 (Maternal)

Vaccine Group (as Administered)	Participant	Preferred Term[a]/Investigator Term	Route	Start Date	End Date	Dose No.	Rel Day[b]	Treat Adverse Event
		SODIUM CHLORIDE/Salex Nasal Spray	NASAL	04NOV2021	08NOV2021	2	22	
	[redacted]†	AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM/Augmentin	ORAL	27OCT2021	01NOV2021	2	3	Yes
		AZITHROMYCIN/Azithromycin	ORAL	14OCT2021	14OCT2021	1	10	Yes
		CEFTRIAXONE/Ceftriaxone	INTRAMUSCULAR	14OCT2021	14OCT2021	1	10	Yes
		METOCLOPRAMIDE HYDROCHLORIDE/Maxolon	ORAL	27OCT2021	01NOV2021	2	3	Yes
		METRONIDAZOLE/Metronidazole	ORAL	14OCT2021	14OCT2021	1	10	Yes
		PROBIOTICS NOS/Probiotic	ORAL	27OCT2021	01NOV2021	2	3	Yes
	[redacted]	PARACETAMOL/Paracetamol	ORAL	03NOV2021	06NOV2021	2	8	Yes
	[redacted]†	PARACETAMOL/Paracetamol	ORAL	26NOV2021	29NOV2021	2	1	Yes
	[redacted]	LORATADINE/Loratadine	ORAL	18DEC2021		2	173	
	[redacted]	METHYLERGOMETRINE/Methylergometrine	INTRAVENOUS	25JUL2021	25JUL2021	2	27	Yes
		OXYTOCIN/Oxytocin	INTRAVENOUS	25JUL2021	25JUL2021	2	27	Yes
		TRANEXAMIC ACID/Transamine	INTRAVENOUS	25JUL2021	25JUL2021	2	27	Yes
	[redacted]	CEFALEXIN/Cephalexin	ORAL	01JUL2021	07JUL2021	2	11	Yes
	[redacted]	CODEINE/Codeine	ORAL	25AUG2021		1	85	Yes

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16.2.5.3.1 Listing of Concomitant Medications Used After Dose 1 (Maternal)

Vaccine Group (as Administered)	Participant	Preferred Term[a]/Investigator Term	Route	Start Date	End Date	Dose No.	Rel Day[b]	Treat Adverse Event
		METAMIZOLE SODIUM/Dipyrone	ORAL	25AUG2021		1	85	Yes
		PARACETAMOL/Paracetamol	ORAL	25AUG2021		1	85	Yes
		PREDNISONE/Prednisone	ORAL	12AUG2021	25AUG2021	1	72	Yes
		TRAMADOL/Tramadol	INTRAVENOUS	13AUG2021	17AUG2021	1	73	Yes
	[redacted]	OXYTOCIN/Oxytocin	INTRAMUSCULAR	26AUG2021	26AUG2021	2	59	Yes
	[redacted]	CEFALEXIN/Cephalexin	ORAL	02AUG2021	09AUG2021	2	32	Yes
	[redacted]	CLINDAMYCIN/Clindamycin	INTRAVENOUS	02AUG2021	03AUG2021	2	35	Yes
			ORAL	03AUG2021	07AUG2021	2	36	Yes
		DIHYDROCODEINE/Dihydrocodeine	ORAL	01AUG2021	01SEP2021	2	34	Yes
		ENOXAPARIN SODIUM/Enoxaparin Sodium Injection	SUBCUTANEOUS	02AUG2021	02AUG2021	2	35	Yes
				03AUG2021	30OCT2021	2	36	Yes
		GENTAMICIN/Gentamicin	INTRAVENOUS	02AUG2021	02AUG2021	2	35	Yes
				03AUG2021	03AUG2021	2	36	Yes
		IBUPROFEN/Ibuprofen	ORAL	02AUG2021	03AUG2021	2	35	Yes
		PARACETAMOL/Paracetamol	ORAL	01AUG2021	03AUG2021	2	34	Yes
		WARFARIN/Warfarin	ORAL	13SEP2021	01DEC2021	2	77	Yes
	[redacted]	IBUPROFEN/Ibuprofen	ORAL	20AUG2021	23AUG2021	2	46	Yes
		PARACETAMOL/Paracetamol	ORAL	20AUG2021	23AUG2021	2	46	Yes

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16.2.5.3.1 Listing of Concomitant Medications Used After Dose 1 (Maternal)

Vaccine Group (as Administered)	Participant	Preferred Term[a]/Investigator Term	Route	Start Date	End Date	Dose No.	Rel Day[b]	Treat Adverse Event
	[redacted]	AMOXICILLIN/Amoxicilline	ORAL	16OCT2021	23OCT2021	2	76	Yes
		ANTHOXANTHUM ODORATUM;DACTYLIS GLOMERATA;LOLIUM PERENNE;PHLEUM PRATENSE;POA PRATENSIS/Oralair	ORAL	02APR2022		2	244	Yes
		BETAMETHASONE DIPROPIONATE/Betametasone	INTRAMUSCULAR	23JUL2021	23JUL2021	1	12	Yes
		BUDESONIDE/Budesonide	RESPIRATORY (INHALATION)	13AUG2021	15AUG2021	2	12	
				30MAR2022	01APR2022	2	241	
		CINITAPRIDE/Cinitapride	ORAL	09OCT2021		2	69	Yes
		CLAVULANIC ACID/Clavulanic Acid	ORAL	16OCT2021	23OCT2021	2	76	Yes
		COLECALCIFEROL/Cholecalciferol (Vit D)	ORAL	04NOV2021		2	95	Yes
		GLUCOSE/Glucose Solution 5%	INTRAVENOUS	30JUL2021	30JUL2021	1	19	Yes
		HALOPERIDOL/Haloperidol	INTRAMUSCULAR	18SEP2021	18SEP2021	2	48	Yes
		HYOSCINE BUTYLBROMIDE/Scopolamine Butylbromide	INTRAVENOUS	18SEP2021	18SEP2021	2	48	Yes
		IBUPROFEN/Ibuprofen	ORAL	16OCT2021	21OCT2021	2	76	Yes
		IRON/Liposomal Iron	ORAL	01OCT2021		2	61	Yes
		METOCLOPRAMIDE/Metoclopramide	ORAL	01SEP2021	01OCT2021	2	31	Yes
		NITROFURANTOIN/Nitrofurantoin	ORAL	27AUG2021	01SEP2021	2	26	Yes
		PANCREATIN/Pancreatine	ORAL	09OCT2021		2	69	Yes
		PARACETAMOL/Paracetamol	ORAL	23JUL2021	25JUL2021	1	12	Yes
				12AUG2021	15AUG2021	2	11	Yes
				22AUG2021	21SEP2021	2	21	Yes
		PETHIDINE HYDROCHLORIDE/Pethidine Hydrochloride	SUBCUTANEOUS	18SEP2021	18SEP2021	2	48	Yes
		SIMETICONE/Simeticone	ORAL	09OCT2021		2	69	Yes

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16.2.5.3.1 Listing of Concomitant Medications Used After Dose 1 (Maternal)

Vaccine Group (as Administered)	Participant	Preferred Term[a]/Investigator Term	Route	Start Date	End Date	Dose No.	Rel Day[b]	Treat Adverse Event
	[redacted]	DEXKETOPROFEN/Dexketoprofen	ORAL	19SEP2021	26SEP2021	2	39	Yes
		PARACETAMOL/Paracetamol	ORAL	13AUG2021	13AUG2021	2	2	Yes
				19SEP2021	26SEP2021	2	39	Yes
	[redacted]	ANTI-D IMMUNOGLOBULIN/Rhogam	INTRAMUSCULAR	12SEP2021	12SEP2021	2	32	
		PARACETAMOL/Paracetamol	ORAL	12AUG2021	12AUG2021	2	1	Yes
	[redacted]	ANTI-D IMMUNOGLOBULIN/Anti D Gamma Globulin	INTRAMUSCULAR	05AUG2021	05AUG2021	1	15	
		DEXKETOPROFEN TROMETAMOL/Enantyum 25 Mg	ORAL	21OCT2021	01NOV2021	2	71	Yes
		METAMIZOLE MAGNESIUM/Nolotil 575 Mg	ORAL	21OCT2021	01NOV2021	2	71	Yes
		PARACETAMOL/Paracetamol	ORAL	10AUG2021	12AUG2021	1	20	
	[redacted]	CEFUROXIME/Cefuroxima	ORAL	02SEP2021	11SEP2021	2	10	Yes
		DIAZEPAM/Valium 5 Mg	ORAL	22AUG2021	24AUG2021	1	19	Yes
		FOSFOMYCIN TROMETAMOL/Monurol 3 G	ORAL	23AUG2021	24AUG2021	1	20	Yes
		METAMIZOLE MAGNESIUM/Nolotil	INTRAMUSCULAR	26AUG2021	26AUG2021	2	3	Yes
		METAMIZOLE MAGNESIUM/Nolotil (Metamizole)	INTRAVENOUS	22AUG2021	22AUG2021	1	19	Yes
		PARACETAMOL/Paracetamol	ORAL	26AUG2021	03SEP2021	2	3	Yes
	[redacted]	PARACETAMOL/Paracetamol	ORAL	25OCT2021	02NOV2021	2	76	
	[redacted]	CEFALEXIN/Cefalexin	ORAL	29SEP2021	03OCT2021	2	76	

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16.2.5.3.1 Listing of Concomitant Medications Used After Dose 1 (Maternal)

Vaccine Group (as Administered)	Participant	Preferred Term[a]/Investigator Term	Route	Start Date	End Date	Dose No.	Rel Day[b]	Treat Adverse Event
	[redacted]	AMOXICILLIN;CLAVULANIC ACID/Amoxicillin And Clavulanic Acid	ORAL	19NOV2021	19NOV2021	2	151	
		IBUPROFEN/Ibuprofeno	ORAL	19NOV2021	19NOV2021	2	151	
	[redacted]	NATALIZUMAB/Natalizumab	INTRAVENOUS	16NOV2021		2	147	
	[redacted]	PARACETAMOL/Paracetamol	ORAL	01FEB2022	01FEB2022	2	218	
	[redacted]	FERRIC CARBOXYMALTOSE/Ferric Carboxymaltose (Ferinject)	INTRAVENOUS	06OCT2021	13OCT2021	1	16	Yes
Placebo	[redacted]	AMOXICILLIN;CLAVULANIC ACID/Amoxicillin/Clavulanate	ORAL	18MAY2021	21MAY2021	1	19	
		CEFPROZIL/Cefprozil	ORAL	24MAY2021	31JUL2021	1	25	
		FEXOFENADINE/Fexofenadine	ORAL	17MAY2021	27MAY2021	1	18	
		PSEUDOEPHEDRINE/Pseudoephedrine	ORAL	17MAY2021	27MAY2021	1	18	
	[redacted]	AZITHROMYCIN/Azithromycin	ORAL	16AUG2021	16AUG2021	2	67	Yes
				17AUG2021	22AUG2021	2	68	Yes
	[redacted]	FAMOTIDINE/Pepcid	ORAL	06JUL2021	19AUG2021	2	1	Yes
	[redacted]	ANTIBIOTICS/Antibiotic	ORAL	06AUG2021	13AUG2021	2	45	Yes

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16.2.5.3.1 Listing of Concomitant Medications Used After Dose 1 (Maternal)

Vaccine Group (as Administered)	Participant	Preferred Term[a]/Investigator Term	Route	Start Date	End Date	Dose No.	Rel Day[b]	Treat Adverse Event
		CAFFEINE;PARACETAMOL/Acetaminophen + Caffeine	ORAL	26AUG2021	26AUG2021	x1	1	Yes
	[redacted]	AMOXICILLIN/Amoxicillin	ORAL	15JUN2021	29JUN2021	1	9	
	[redacted]	FAMOTIDINE/Famotidine	ORAL	21APR2021	28APR2021	2	10	Yes
	[redacted]	NIFEDIPINE/Nifedipine Er	ORAL	02JUN2021	23JUN2021	2	22	Yes
		SULFAMETHOXAZOLE/Sulfamethoxazole	ORAL	30SEP2021		x2	32	Yes
	[redacted]	ANTI-D IMMUNOGLOBULIN/Rho D Immune Globulin	INTRAMUSCULAR	12JUL2021	12JUL2021	2	50	
	[redacted]	BENZYLPENICILLIN POTASSIUM/Penicillin G Potassium 3 Million Units	INTRAVENOUS	04AUG2021	04AUG2021	2	58	Yes
		BENZYLPENICILLIN POTASSIUM/Penicillin G Potassium 5 Million Units In Sodium Chloride 0.9%	INTRAVENOUS	04AUG2021	04AUG2021	2	58	Yes
		DOCUSATE SODIUM/Stool Softener	ORAL	02JUL2021	06AUG2021	2	25	Yes
		HYDROCORTISONE ACETATE/Hydrocortisone (Anusol-Hc) 2.5% Rectal Cream	RECTAL	05AUG2021	06AUG2021	2	59	Yes
	[redacted]	BENZYLPENICILLIN POTASSIUM/Penicillin G Potassium 3 Million Units/50 Ml Ivpb	INTRAVENOUS	27JUL2021	27JUL2021	2	35	Yes
		BENZYLPENICILLIN POTASSIUM/Penicillin G Potassium In Sodium Chloride	INTRAVENOUS	26JUL2021	26JUL2021	2	34	Yes
		CEFDINIR/Cefdinir	ORAL	16JUN2021	25JUN2021	1	15	

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16.2.5.3.1 Listing of Concomitant Medications Used After Dose 1 (Maternal)

Vaccine Group (as Administered)	Participant	Preferred Term[a]/Investigator Term	Route	Start Date	End Date	Dose No.	Rel Day[b]	Treat Adverse Event
		HYDROCODONE BITARTRATE;PARACETAMOL/Hydrocodone/Acetaminophen (Norco) 5-325 Mg	ORAL	28JUL2021	03AUG2021	2	36	Yes
	[redacted]	HYDROCORTISONE/Hydrocortisone 2% Cream	TOPICAL	01JUN2021	05JUN2021	2	35	Yes
		TERBUTALINE/Terbutaline	SUBCUTANEOUS	29MAY2021	29MAY2021	2	32	Yes
	[redacted]	DOCUSATE SODIUM/Docusate Sodium	ORAL	20JUN2021	25JUN2021	2	12	Yes
		FERROUS SULFATE/Ferrous Sulfate	ORAL	22JUN2021	25JUN2021	2	14	Yes
		MAGNESIUM OXIDE/Magnesium Oxide	ORAL	01JUN2021	25JUN2021	1	15	Yes
		OMEPRAZOLE/Omeprazole	ORAL	28MAY2021	27JUN2021	1	11	Yes
		PARACETAMOL/Tylenol	ORAL	19JUL2021	19JUL2021	x1	1	Yes
	[redacted]	PARACETAMOL/Tylenol	ORAL	16AUG2021	18AUG2021	x1	1	Yes
	[redacted]	FERROUS SULFATE/Ferrous Sulfate	ORAL	15JUN2021	13JUL2021	2	15	Yes
	[redacted]	PARACETAMOL/Acetaminophen	ORAL	11JUN2021		x2	2	Yes
	[redacted]	FLUCONAZOLE/Fluconazole	ORAL	12SEP2021	12SEP2021	x1	14	Yes
		METRONIDAZOLE/Metronidazole	ORAL	12SEP2021	13SEP2021	x1	14	Yes

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16.2.5.3.1 Listing of Concomitant Medications Used After Dose 1 (Maternal)

Vaccine Group (as Administered)	Participant	Preferred Term[a]/Investigator Term	Route	Start Date	End Date	Dose No.	Rel Day[b]	Treat Adverse Event
	[redacted]	CLINDAMYCIN/Clindamycin	INTRAVENOUS	03AUG2021	03AUG2021	2	54	Yes
		GENTAMICIN/Gentamicin	INTRAVENOUS	03AUG2021	03AUG2021	2	54	Yes
		IRON/Iron Supplement	ORAL	13AUG2021	18OCT2021	2	64	Yes
	[redacted]	PETHIDINE/Pethidine	INTRAMUSCULAR	01DEC2021	01DEC2021	2	27	Yes
		PROMETHAZINE/Phenergan	INTRAMUSCULAR	01DEC2021	01DEC2021	2	27	Yes
	[redacted]	ASCORBIC ACID/Vitamin C	ORAL	13DEC2021	20DEC2021	2	32	
		AZITHROMYCIN/Azithromycin	ORAL	13DEC2021	15DEC2021	2	32	
		CAFFEINE;CHLORPHENAMINE MALEATE;EPHEDRINE HYDROCHLORIDE;PARACETAMOL/Sinucon (Ephedrine Hcl 6mg, Caffeine 20mg, Paracetamol 200mg,chlorpheniramine Maleate 2mg)	ORAL	13DEC2021	15DEC2021	2	32	
		CLOTRIMAZOLE/Clotrimazole Cream	TOPICAL	02FEB2022	05FEB2022	x1	17	Yes
		PARACETAMOL/Paracetamol	ORAL	13DEC2021	17DEC2021	2	32	
	[redacted]	PARACETAMOL/Paracetamol	ORAL	15NOV2021	18NOV2021	2	13	
	[redacted]	CEFAZOLIN SODIUM/Kefzol	INTRAVENOUS	17OCT2021	17OCT2021	2	47	Yes
		METOCLOPRAMIDE/Metoclopramide	INTRAVENOUS	17OCT2021	17OCT2021	2	47	Yes
	[redacted]	CEFAZOLIN SODIUM/Kefzol	INTRAVENOUS	25OCT2021	25OCT2021	2	28	Yes
		METOCLOPRAMIDE/Metoclopramide	INTRAVENOUS	25OCT2021	25OCT2021	2	28	Yes

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16.2.5.3.1 Listing of Concomitant Medications Used After Dose 1 (Maternal)

Vaccine Group (as Administered)	Participant	Preferred Term[a]/Investigator Term	Route	Start Date	End Date	Dose No.	Rel Day[b]	Treat Adverse Event
		PARACETAMOL/Paracetamol	ORAL	15SEP2021	15SEP2021	1	9	Yes
		ZINC/Zinc	ORAL	10DEC2021	16DEC2021	x2	4	Yes
	[redacted]	AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM/Augmentin	ORAL	05OCT2021	09OCT2021	2	1	Yes
		AMOXICILLIN/Amoxycillin	ORAL	03OCT2021	05OCT2021	1	20	Yes
		ERYTHROMYCIN/Erythromycin	ORAL	05OCT2021	09OCT2021	2	1	Yes
		PARACETAMOL/Paracetamol	ORAL	05OCT2021	09OCT2021	2	1	Yes
	[redacted]	CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE/Ringer's Lactate	INTRAVENOUS	05OCT2021	06OCT2021	1	16	Yes
		CEFAZOLIN/Cefazolin	INTRAVENOUS	05OCT2021	05OCT2021	1	16	Yes
		DEXAMETHASONE/Dexamethasone	INTRAMUSCULAR	04OCT2021	04OCT2021	1	15	Yes
		MAGNESIUM SULFATE/Magnesium Sulphate	INTRAVENOUS	26SEP2021	26SEP2021	1	7	Yes
		METHYLDOPA/Methyldopa	ORAL	26SEP2021	03OCT2021	1	7	Yes
				04OCT2021	07OCT2021	1	15	Yes
		METOCLOPRAMIDE/Metoclopramide	INTRAVENOUS	05OCT2021	05OCT2021	1	16	Yes
		NIFEDIPINE/Nifedipine	ORAL	25SEP2021	25SEP2021	1	6	Yes
		PROMETHAZINE/Promethazine	ORAL	26SEP2021	26SEP2021	1	7	Yes
		SODIUM CHLORIDE/Normal Saline Solution	INTRAVENOUS	26SEP2021	26SEP2021	1	7	Yes
	[redacted]	ASCORBIC ACID/Vitamin C	ORAL	10DEC2021	15DEC2021	x2	4	Yes
		BROMHEXINE HYDROCHLORIDE;ORCIPRENALINE SULFATE/Bromhexine Hcl,orciprenaline Sulphate	ORAL	10DEC2021	15DEC2021	x2	4	Yes
		VITAMIN D NOS/Vitamin D	ORAL	10DEC2021	15DEC2021	x2	4	Yes
		ZINC/Zinc	ORAL	10DEC2021	15DEC2021	x2	4	Yes

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16.2.5.3.1 Listing of Concomitant Medications Used After Dose 1 (Maternal)

Vaccine Group (as Administered)	Participant	Preferred Term[a]/Investigator Term	Route	Start Date	End Date	Dose No.	Rel Day[b]	Treat Adverse Event
	[redacted]	ASCORBIC ACID/Vitamin C	ORAL	12OCT2021	20OCT2021	1	8	
		PARACETAMOL/Paracetamol	ORAL	12OCT2021	20OCT2021	1	8	
	[redacted]†	ASCORBIC ACID/Vitamin C	ORAL	24NOV2021	28NOV2021	2	10	
	[redacted]	CEFAZOLIN SODIUM/Kefzol	INTRAVENOUS	05JAN2022	05JAN2022	2	50	Yes
		METRONIDAZOLE/Metronidazole	INTRAVENOUS	05JAN2022	05JAN2022	2	50	Yes
	[redacted]	AMOXICILLIN/Amoxicillin	ORAL	01JUL2021	06JUL2021	2	9	Yes
		FOSFOMYCIN/Fosfomycin	ORAL	29JUN2021	29JUN2021	2	7	Yes
	[redacted]†	CLOTRIMAZOLE/Clotrimazole	TOPICAL	15SEP2021	19SEP2021	2	1	Yes
	[redacted]†	PARACETAMOL/Panado	ORAL	06OCT2021	09OCT2021	2	36	
		SODIUM CHLORIDE/Salex Nasal Spray	RESPIRATORY (INHALATION)	06OCT2021	09OCT2021	2	36	
	[redacted]	CEFAZOLIN SODIUM/Kefzol	INTRAVENOUS	25NOV2021	27NOV2021	2	71	Yes
		ENOXAPARIN SODIUM/Clexane	SUBCUTANEOUS	25NOV2021	27NOV2021	2	71	Yes
		IBUPROFEN/Brufen	ORAL	25NOV2021	04DEC2021	2	71	Yes
		METOCLOPRAMIDE HYDROCHLORIDE/Maxolon	INTRAMUSCULAR	25NOV2021	27NOV2021	2	71	Yes

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16.2.5.3.1 Listing of Concomitant Medications Used After Dose 1 (Maternal)

Vaccine Group (as Administered)	Participant	Preferred Term[a]/Investigator Term	Route	Start Date	End Date	Dose No.	Rel Day[b]	Treat Adverse Event
		PARACETAMOL/Paracetamol	ORAL	25NOV2021	04DEC2021	2	71	Yes
		PETHIDINE/Pethidine	INTRAMUSCULAR	25NOV2021	27NOV2021	2	71	Yes
	[redacted]†	ALGINIC ACID;ALUMINIUM HYDROXIDE/Gaviscon(Alginic Acid/Aluminium Hydroxide)	ORAL	26OCT2021	29OCT2021	2	29	Yes
		PARACETAMOL/Paracetamol	ORAL	04NOV2021	07NOV2021	2	38	
	[redacted]†	CHLORPHENOXAMINE HYDROCHLORIDE/Allergex Ointment	TOPICAL	27SEP2021	30SEP2021	1	21	Yes
		HYDROCORTISONE ACETATE/Biocort	TOPICAL	30SEP2021	02OCT2021	2	1	Yes
				21OCT2021	26OCT2021	2	22	Yes
		PARACETAMOL/Paracetamol	ORAL	21OCT2021	26OCT2021	2	22	
	[redacted]	AMPICILLIN/Ampicillin	INTRAVENOUS	14NOV2021	14NOV2021	2	32	Yes
		BETAMETHASONE/Betamethasone	INTRAMUSCULAR	14NOV2021	15NOV2021	2	32	Yes
		METOCLOPRAMIDE HYDROCHLORIDE/Maxolon	ORAL	18OCT2021	21OCT2021	2	5	Yes
		METRONIDAZOLE/Flagyl	ORAL	18OCT2021	21OCT2021	2	5	Yes
		METRONIDAZOLE/Metronidazole	ORAL	14NOV2021	30NOV2021	2	32	Yes
		MISOPROSTOL/Misoprostol	VAGINAL	16NOV2021	16NOV2021	2	34	Yes
		NIFEDIPINE/Nifedipine	ORAL	14NOV2021	14NOV2021	2	32	Yes
		NITROFURANTOIN/Nitrofurantoin	ORAL	18OCT2021	21OCT2021	2	5	Yes
		PARACETAMOL/Paracetamol	ORAL	17DEC2021	22DEC2021	x1	11	Yes
		PHYTOMENADIONE/Konakion	INTRAMUSCULAR	16NOV2021	16NOV2021	2	34	Yes
	[redacted]	PARACETAMOL/Paracetamol	ORAL	14DEC2021	14DEC2021	x2	2	Yes

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16.2.5.3.1 Listing of Concomitant Medications Used After Dose 1 (Maternal)

Vaccine Group (as Administered)	Participant	Preferred Term[a]/Investigator Term	Route	Start Date	End Date	Dose No.	Rel Day[b]	Treat Adverse Event
	[redacted]	FERRIC CARBOXYMALTOSE/Ferric Carboxymaltose (Ferinject)	INTRAVENOUS	14SEP2021	14SEP2021	2	1	Yes
		PARACETAMOL/Paracetamol	ORAL	14SEP2021	15SEP2021	2	1	Yes
	[redacted]	NITROFURANTOIN/Nitrofurantoin	ORAL	17JUL2021	31JUL2021	2	6	Yes
	[redacted]	FOSFOMYCIN/Fosfomycin	ORAL	10SEP2021	10SEP2021	x1	17	Yes
	[redacted]	NITROFURANTOIN/Nitrofurantoin	ORAL	14JUN2021	21JUN2021	1	14	Yes
	[redacted]	METAMIZOLE SODIUM/Dipyrone	ORAL	18AUG2021		x2	1	Yes
	[redacted]	CAPTOPRIL/Captopril	ORAL	29AUG2021	30AUG2021	2	61	Yes
		METHYLDOPA/Methyldopa	ORAL	29AUG2021	29AUG2021	2	61	Yes
	[redacted]	PARACETAMOL/Paracetamol	ORAL	05JUL2021	05JUL2021	2	1	
	[redacted]	IBUPROFEN/Ibuprofen	ORAL	11SEP2021	13SEP2021	2	41	Yes
	[redacted]	ERYTHROMYCIN/Erythromycin	ORAL	04DEC2021	06DEC2021	2	79	Yes

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16.2.5.3.1 Listing of Concomitant Medications Used After Dose 1 (Maternal)

Vaccine Group (as Administered)	Participant	Preferred Term[a]/Investigator Term	Route	Start Date	End Date	Dose No.	Rel Day[b]	Treat Adverse Event
	[redacted]	LIDOCAINE HYDROCHLORIDE;PENTOSAN POLYSULFATE SODIUM;TRIAMCINOLONE ACETONIDE/Anso(Triamcinolone Acetonide, Lidocaine And Pentosan Polysulfate Sodium).	RECTAL	01JUL2021		2	9	Yes
	[redacted]	PARACETAMOL/Paracetamol	ORAL	17SEP2021	17SEP2021	x2	1	Yes
	[redacted]	PARACETAMOL/Paracetamol	ORAL	09SEP2021	10SEP2021	x2	1	Yes
	[redacted]	CEFADROXIL/Cefadroxilo	ORAL	28OCT2021	05NOV2021	x2	15	Yes
	[redacted]	AMOXICILLIN/Amoxicilina	ORAL	02JUL2021	06JUL2021	1	19	Yes
		ENOXAPARIN SODIUM/Enoxaparina	SUBCUTANEOUS	01JUL2021	06JUL2021	1	18	
		PARACETAMOL/Paracetamol	ORAL	01JUL2021	06JUL2021	1	18	Yes
	[redacted]	DINOPROSTONE/Dinoprostone	VAGINAL	15JUL2021	16JUL2021	2	18	Yes
		ERGOMETRINE;OXYTOCIN/Syntometrine (Ergometrine/Oxytocin)	INTRAMUSCULAR	18JUL2021	18JUL2021	2	21	Yes
		IRON/Iron Tablets	ORAL	20JUL2021	16AUG2021	2	23	Yes
		OXYTOCIN/Oxytocin 10 Units In Sodium Chloride 0.9% 500 Ml	INTRAVENOUS	18JUL2021	18JUL2021	2	21	Yes
		OXYTOCIN/Oxytocin 40 Units In Sodium Chloride 0.9% In 500ml	INTRAVENOUS	18JUL2021	18JUL2021	2	21	Yes
		TRANEXAMIC ACID/Tranexamic Acid	INTRAVENOUS	18JUL2021	18JUL2021	2	21	Yes
	[redacted]	SODIUM PHOSPHATE;SODIUM PHOSPHATE MONOBASIC (ANHYDROUS)/Phosphate Enema (Sodium Dihydrogen Phosphate 18.1% And Sodium Phosphate 8% Enema)	RECTAL	06AUG2021	06AUG2021	2	31	Yes

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16.2.5.3.1 Listing of Concomitant Medications Used After Dose 1 (Maternal)

Vaccine Group (as Administered)	Participant	Preferred Term[a]/Investigator Term	Route	Start Date	End Date	Dose No.	Rel Day[b]	Treat Adverse Event

Note: x1 = First dose of BNT162b2 (30 µg); x2 = Second dose of BNT162b2 (30 µg).
Note: † = Human immunodeficiency virus (HIV)-positive participant.
a. WHODDG B3 v202203 coding dictionary applied.
b. Relative day (Rel Day) = start date of concomitant medication – date of last vaccination + 1.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: ADCM Table Generation: 12MAY2023 (14:30) Output File: ./nda3/C4591015_BR/adcm_l001_cm_trt

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16.2.5.3.2 Listing of Concomitant Medications Received After Birth (Infant)

Maternal Vaccine Group (as Administered)	Participant	Preferred Term[a]/Investigator Term	Route	Start Date	End Date	Treat Adverse Event
BNT162b2 (30 µg)	[redacted]	PARACETAMOL/Tylenol	ORAL	27JAN2022	01FEB2022	
	[redacted]	NYSTATIN/Nystatin	TOPICAL	26SEP2021	01JAN2022	Yes
	[redacted]	ACICLOVIR/Acyclovir	INTRAVENOUS	26JUL2021	29JUL2021	Yes
		AMPICILLIN/Ampicillin/Sterile H2o	INTRAVENOUS	26JUL2021	30JUL2021	Yes
		CLOBAZAM/Clobazam	ORAL	15DEC2021		Yes
		GENTAMICIN/Gentamicin	INTRAVENOUS	26JUL2021	30JUL2021	Yes
		LEVETIRACETAM/Keppra	ORAL	08OCT2021	08OCT2021	Yes
		LEVETIRACETAM/Keppra (Levetiracetam)	ORAL	09DEC2021		Yes
		MELATONIN/Melatonin	ORAL	18NOV2021		Yes
		OFLOXACIN/Ofloxacin	OPHTHALMIC	24AUG2021	09SEP2021	Yes
		PREDNISOLONE/Prednisolone	OPHTHALMIC	24AUG2021	23SEP2021	Yes
		VALGANCICLOVIR/Valganciclovir	ORAL	31JUL2021	05AUG2021	Yes
	[redacted]	HEDERA HELIX LEAF/Prospan Cough Syrup	ORAL	31MAR2022		
		OXYMETAZOLINE/Oxymetazoline	NASAL	05APR2022		
	[redacted]	OXYMETAZOLINE/Oxymetazoline	NASAL	29MAR2022		
		PARACETAMOL/Paracetamol	ORAL	29MAR2022		
		SODIUM CHLORIDE/Normal Saline	NASAL	29MAR2022	02APR2022	

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16.2.5.3.2 Listing of Concomitant Medications Received After Birth (Infant)

Maternal Vaccine Group (as Administered)	Participant	Preferred Term[a]/Investigator Term	Route	Start Date	End Date	Treat Adverse Event
	[redacted]	AMPICILLIN/Ampicillin	INTRAVENOUS	28JAN2022	30JAN2022	Yes
		COUGH AND COLD PREPARATIONS/Cough Mixture	ORAL	20APR2022	19MAY2022	
		GENTAMICIN/Gentamycin	INTRAVENOUS	28JAN2022	30JAN2022	Yes
		OXYGEN/Supplemental Oxygen	RESPIRATORY (INHALATION)	27JAN2022	29JAN2022	Yes
		OXYMETAZOLINE/Oxymetazoline Drops	NASAL	19MAY2022		
		PARACETAMOL/Paracetamol	ORAL	29APR2022	19MAY2022	
				19MAY2022		
		SODIUM CHLORIDE/Normal Saline Nose Drops	NASAL	29APR2022	04MAY2022	
	[redacted]	PARACETAMOL/Paracetamol	ORAL	15FEB2022	23FEB2022	
		ZINC/Zinc Syrup	ORAL	15FEB2022	23FEB2022	
	[redacted]	AMIKACIN/Amikacin	INTRAVENOUS	11DEC2021	13DEC2021	Yes
		AMPICILLIN/Ampicillin	INTRAVENOUS	11DEC2021	13DEC2021	Yes
	[redacted]	DRIMIA MARITIMA;MYROXYLON BALSAMUM;PSYCHOTRIA IPECACUANHA/Linctus Tussi Infans Syrup	ORAL	17FEB2022		
		PARACETAMOL/Paracetamol	ORAL	17FEB2022		
		ZINC/Zinc Syrup	ORAL	17FEB2022		
	[redacted]	BROMHEXINE HYDROCHLORIDE;ORCIPRENALINE SULFATE/Adco-Linctopent(Bromhexine Hydrochloride Orciprenaline Sulfate)	ORAL	29APR2022	04MAY2022	
		PSEUDOEPHEDRINE HYDROCHLORIDE;TRIPROLIDINE HYDROCHLORIDE/Betafed (Pseudoephedrine Triprolidine Hydrochloride)	ORAL	29APR2022	04MAY2022	

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16.2.5.3.2 Listing of Concomitant Medications Received After Birth (Infant)

Maternal Vaccine Group (as Administered)	Participant	Preferred Term[a]/Investigator Term	Route	Start Date	End Date	Treat Adverse Event
	[redacted]	BROMHEXINE HYDROCHLORIDE;ORCIPRENALINE SULFATE/Adco-Linctopent Cough Syrup	ORAL	01JUL2022		
		DEXTROMETHORPHAN HYDROBROMIDE;PSEUDOEPHEDRINE HYDROCHLORIDE;TRIPROLIDINE HYDROCHLORIDE MONOHYDRATE/Sinuclear Cough Syrup	ORAL	01JUL2022		
		MICONAZOLE/Daktarin Nappy Ointment	INTRADERMAL	01JUN2022		
		SODIUM CHLORIDE/Go Baby Saline Nasal Spray	ORAL	01JUL2022		
	[redacted]	AMIKACIN/Amikacin	INTRAVENOUS	23DEC2021		Yes
		AMPICILLIN/Ampicillin	INTRAVENOUS	23DEC2021		Yes
	[redacted]†	AMOXICILLIN/Amoxicillin Syrup	ORAL	14FEB2022		
		PARACETAMOL/Paracetamol	ORAL	14FEB2022		
	[redacted]†	SODIUM CHLORIDE/Saline Drops	NASAL	01DEC2021	08DEC2021	
	[redacted]	SALBUTAMOL/Salbutamol	RESPIRATORY (INHALATION)	14JAN2022		Yes
	[redacted]	PHYTOMENADIONE/Kanakion	INTRAMUSCULAR	20JUL2021	20JUL2021	Yes
		SILVER NITRATE/Silver Nitrate 1%	OPHTHALMIC	20JUL2021	20JUL2021	Yes
	[redacted]	OXYGEN/Oxygen	RESPIRATORY (INHALATION)	23AUG2021	23AUG2021	Yes

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16.2.5.3.2 Listing of Concomitant Medications Received After Birth (Infant)

Maternal Vaccine Group (as Administered)	Participant	Preferred Term[a]/Investigator Term	Route	Start Date	End Date	Treat Adverse Event
	[redacted]	DEXAMETHASONE SODIUM PHOSPHATE;GENTAMICIN SULFATE;TETRYZOLINE HYDROCHLORIDE/Colicursi Gentadexa	OPHTHALMIC	04NOV2021	09NOV2021	Yes
	[redacted]	PARACETAMOL/Apiretal	ORAL	29OCT2021	29OCT2021	Yes
	[redacted]	AMINO ACIDS NOS;FATS NOS;MALTODEXTRIN;MINERALS NOS;VITAMINS NOS/Neocate Formula	ORAL	24OCT2021		Yes
		CERATONIA SILIQUA EXTRACT/Carobel Thickener	ORAL	24OCT2021		Yes
		OMEPRAZOLE/Omeprazole	ORAL	24OCT2021	20DEC2021	Yes
	[redacted]	PARACETAMOL/Paracetamol	ORAL	21DEC2021	23DEC2021	
	[redacted]	AMOXICILLIN;CLAVULANIC ACID/Amoxicilin-Clavulanic	INTRAVENOUS	27JUL2021	28JUL2021	Yes
		AMPICILLIN/Ampiciline	INTRAVENOUS	23JUL2021	26JUL2021	Yes
				23AUG2021	25AUG2021	Yes
		AMPICILLIN/Ampicillin	INTRAVENOUS	23DEC2021		Yes
		CEFOTAXIME/Cefotaxime	INTRAVENOUS	23JUL2021	26JUL2021	Yes
		CEFUROXIME/Cefuroxime	INTRAVENOUS	23AUG2021	25AUG2021	Yes
		CEFUROXIME/Cefuroxime.	INTRAVENOUS	23DEC2021		Yes
		GENTAMICIN/Gentamicine	INTRAVENOUS	25AUG2021	27AUG2021	Yes
		SULFAMETHOXAZOLE;TRIMETHOPRIM/Trimetoprim-Sulfametoxazol	ORAL	27AUG2021		Yes
	[redacted]	PARACETAMOL/Paracetamol	ORAL	08DEC2021	11DEC2021	Yes

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16.2.5.3.2 Listing of Concomitant Medications Received After Birth (Infant)

Maternal Vaccine Group (as Administered)	Participant	Preferred Term[a]/Investigator Term	Route	Start Date	End Date	Treat Adverse Event
Placebo	[redacted]	AMOXICILLIN/Amoxicillin	ORAL	09SEP2021	18SEP2021	
		NYSTATIN/Nystatin	ORAL	09SEP2021	18SEP2021	
		PARACETAMOL/Acetaminophen	ORAL	04SEP2021		
	[redacted]	CEFTRIAXONE SODIUM/Rocephin	INTRAVENOUS	26SEP2021	29SEP2021	Yes
		OXYGEN/Oxygen	NASAL	26SEP2021	29SEP2021	Yes
	[redacted]	OXYGEN/Oxygen	RESPIRATORY (INHALATION)	13AUG2021	13AUG2021	Yes
	[redacted]	ACICLOVIR/Acyclovir		13MAY2021	16MAY2021	Yes
		AMPICILLIN/Ampicillin	INTRAVENOUS	28APR2021	29APR2021	Yes
		CEFEPIME/Cefepime		13MAY2021	16MAY2021	Yes
		DEXMEDETOMIDINE/Dexmedetomidine	INTRAVENOUS	28APR2021	04MAY2021	Yes
		GENTAMICIN/Gentamicin		13MAY2021	16MAY2021	Yes
			INTRAVENOUS	28APR2021	29APR2021	Yes
		HYDRALAZINE/Hydralazine		17MAY2021	24MAY2021	Yes
		HYDROCORTISONE/Hydrocortisone	INTRAVENOUS	28APR2021	06MAY2021	Yes
		LEVETIRACETAM/Levetiracetam		03MAY2021	15MAY2021	Yes
		LIPIDS NOS/Lipid Emulsion Mixed Oil	INTRAVENOUS	29APR2021	25MAY2021	Yes
		PHENOBARBITAL/Phenobarbital		03MAY2021	03MAY2021	Yes
		PROPRANOLOL/Propanolol	ORAL	10MAY2021		Yes
		RED BLOOD CELLS, CONCENTRATED/Packed Red Blood Cells	INTRAVENOUS	28APR2021	28APR2021	Yes
		SODIUM ACETATE/Nicu Sodium Acetate	INTRAVENOUS	28APR2021	04MAY2021	Yes

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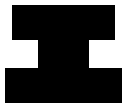
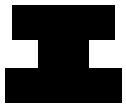
16.2.5.3.2 Listing of Concomitant Medications Received After Birth (Infant)

Maternal Vaccine Group (as Administered)	Participant	Preferred Term[a]/Investigator Term	Route	Start Date	End Date	Treat Adverse Event
		SODIUM CHLORIDE/1/2 Saline 12 Ml/Iv Fluids	INTRAVENOUS	28APR2021	04MAY2021	Yes
		TOTAL PARENTERAL NUTRITION/Neonatal Renal Tpn	INTRAVENOUS	29APR2021	25MAY2021	Yes
		GLUCOSE/Dextrose (Glucose) 40% Gel	ORAL	24MAY2021	24MAY2021	Yes
		NYSTATIN/Nystatin	ORAL	03AUG2021	06AUG2021	Yes
		AMPICILLIN SODIUM/Ampicilin	INTRAVENOUS	29MAY2021	31MAY2021	Yes
		FENTANYL/Fentanyl	INTRAVENOUS	29MAY2021	29MAY2021	Yes
		GENTAMICIN/Gentamicin	INTRAVENOUS	29MAY2021	31MAY2021	Yes
		SUCROSE/Sucrose	ORAL	30MAY2021	30MAY2021	Yes
		CHLORAMPHENICOL SODIUM SUCCINATE/Chloromax Eye Ointment	TOPICAL	15NOV2021		Yes
		OXYMETAZOLINE HYDROCHLORIDE/Iliadin Nose Drops	NASAL	21FEB2022		
		PARACETAMOL/Panado Syrup	NASAL	21FEB2022		
		SODIUM CHLORIDE/Normal Saline Drop	NASAL	21FEB2022		
		AMPICILLIN/Ampicillin	INTRAVENOUS	24NOV2021	27NOV2021	Yes
	†	AMIKACIN/Amikacin	INTRAVENOUS	10MAR2022	13MAR2022	Yes
		CEFOTAXIME/Cefotaxime	INTRAVENOUS	09FEB2022		Yes
		CEFTRIAXONE/Ceftriaxone	INTRAVENOUS	10MAR2022	10MAR2022	Yes
		ENOXAPARIN SODIUM/Clexane	SUBCUTANEOUS	14FEB2022	15FEB2022	Yes

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16.2.5.3.2 Listing of Concomitant Medications Received After Birth (Infant)

Maternal Vaccine Group (as Administered)	Participant	Preferred Term[a]/Investigator Term	Route	Start Date	End Date	Treat Adverse Event
				16FEB2022	18FEB2022	Yes
				19FEB2022	22FEB2022	Yes
				22FEB2022		Yes
		I.V. SOLUTIONS/Intravenous Fluid	INTRAVENOUS	09FEB2022		Yes
		NEVIRAPINE/Nevirapine	ORAL	28DEC2021		Yes
		PIPERACILLIN SODIUM;TAZOBACTAM SODIUM/Tazocin	INTRAVENOUS	10MAR2022	13MAR2022	Yes
		POTASSIUM CHLORIDE/Potassium Chloride	INTRAVENOUS	09FEB2022	28FEB2022	Yes
		SODIUM CHLORIDE/Normal Saline	INTRAVENOUS	09FEB2022	09FEB2022	Yes
		ZINC/Zinc	ORAL	09FEB2022	28FEB2022	Yes
				09MAR2022		Yes
	[redacted]	OXYMETAZOLINE/Oxymetazoline	NASAL	09FEB2022	23FEB2022	
		PARACETAMOL/Paracetamol	ORAL	09FEB2022	14FEB2022	
	[redacted]	PARACETAMOL/Paracetamol	ORAL	17FEB2022		
		PSEUDOEPHEDRINE;TRIPROLIDINE/Pseudoephedrine Triprolidine Syrup	ORAL	17FEB2022		
	[redacted]	ASCORBIC ACID;PSEUDOEPHEDRINE HYDROCHLORIDE;TRIPROLIDINE HYDROCHLORIDE/Coryx Syrup	ORAL	08FEB2022	13FEB2022	
		GUAIFENESIN;PSEUDOEPHEDRINE HYDROCHLORIDE/Tussin Pediatric(Gauifenesin Pseudoephedrine)	ORAL	08FEB2022	13FEB2022	
		PARACETAMOL/Paracetamol	ORAL	08FEB2022	13FEB2022	
		ZINC/Zinc Syrup	ORAL	08FEB2022	13FEB2022	
		ZINC/Zincsyrup	ORAL	10DEC2021	17DEC2021	

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16.2.5.3.2 Listing of Concomitant Medications Received After Birth (Infant)

Maternal Vaccine Group (as Administered)	Participant	Preferred Term[a]/Investigator Term	Route	Start Date	End Date	Treat Adverse Event
	[redacted]	DRIMIA MARITIMA;MYROXYLON BALSAMUM;PSYCHOTRIA IPECACUANHA/Linctus Tussi Infans	ORAL	07JAN2022	12JAN2022	
		GLUCOSE;SODIUM CHLORIDE/Dextrose Sodium Chloride	ORAL	10DEC2021	18DEC2021	
		ZINC/Zincsyrup	ORAL	10DEC2021	18DEC2021	
	[redacted]	PARACETAMOL/Paracetamol	ORAL	07APR2022		
		PSEUDOEPHEDRINE HYDROCHLORIDE;TRIPROLIDINE HYDROCHLORIDE/Betafed (Pseudoephedrine Hydrochloride Triprolidine Hydrochloride)	ORAL	08APR2022		
		ZINC/Zinc Syrup	ORAL	08APR2022		
	[redacted]†	GUAIFENESIN;PSEUDOEPHEDRINE HYDROCHLORIDE/Tussin Pediatric (Guaifensin,pseudoephedrine)infant Syrup	ORAL	17FEB2022		
		PARACETAMOL/Paracetamol	ORAL	17FEB2022		
		ZINC/Zinc Syrup	ORAL	17FEB2022		
	[redacted]†	SODIUM CHLORIDE/Salex Nasal Spray	NASAL	05DEC2021	10DEC2021	
	[redacted]	AMPICILLIN/Ampicillin	INTRAVENOUS	04DEC2021	31DEC2021	Yes
		GENTAMICIN/Gentamycin	INTRAVENOUS	04DEC2021	31DEC2021	Yes
	[redacted]	AMPICILLIN/Ampicillin	INTRAVENOUS	30NOV2021	07DEC2021	Yes
		GENTAMICIN/Gentamicin	INTRAVENOUS	30NOV2021	07DEC2021	Yes

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16.2.5.3.2 Listing of Concomitant Medications Received After Birth (Infant)

Maternal Vaccine Group (as Administered)	Participant	Preferred Term[a]/Investigator Term	Route	Start Date	End Date	Treat Adverse Event
	[redacted]†	AMPICILLIN SODIUM/Ampicilin	INTRAVENOUS	05DEC2021	06DEC2021	Yes
		GENTAMICIN/Gentamicin	INTRAVENOUS	05DEC2021	06DEC2021	Yes
	[redacted]	AMPICILLIN/Ampicillin	INTRAVENOUS	16NOV2021	16NOV2021	Yes
		CALCIUM GLUCONATE/Calcium Gluconate	INTRAVENOUS	22NOV2021	22NOV2021	Yes
		EPINEPHRINE/Adrenaline	INTRAVENOUS	22NOV2021	22NOV2021	Yes
		GENTAMICIN/Gentamicin	INTRAVENOUS	16NOV2021	16NOV2021	Yes
		NEVIRAPINE/Nevirapine	ORAL	16NOV2021	17NOV2021	Yes
		OXYGEN/Oxygen	NASAL	16NOV2021	31DEC2021	Yes
		SODIUM BICARBONATE/Sodium Bicarbonate	INTRAVENOUS	22NOV2021	22NOV2021	Yes
		ZIDOVUDINE/Azt (Zidovudine)	ORAL	16NOV2021	17NOV2021	Yes
	[redacted]†	CLOTRIMAZOLE/Clotrimazole	TOPICAL	02FEB2022		Yes
	[redacted]	SIMETICONE/Simethicone	ORAL	17NOV2021		Yes
	[redacted]	SALBUTAMOL/Salbutamol	RESPIRATORY (INHALATION)	11AUG2021	11AUG2021	Yes
		SODIUM CHLORIDE/Saline Solution 0,9%	NASAL	10AUG2021		Yes
	[redacted]	PARACETAMOL/Paracetamol	ORAL	10DEC2021	13DEC2021	

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16.2.5.3.2 Listing of Concomitant Medications Received After Birth (Infant)

Maternal Vaccine Group (as Administered)	Participant	Preferred Term[a]/Investigator Term	Route	Start Date	End Date	Treat Adverse Event
	[redacted]	AMPICILLIN/Ampicillin	INTRAVENOUS	31JUL2021		Yes
		GENTAMICIN/Gentamicin	INTRAVENOUS	31JUL2021		Yes
	[redacted]	DEXAMETHASONE/Dexamethasone	INTRAVENOUS	27JAN2022	27JAN2022	
		PREDNISOLONE/Prednisolone	ORAL	27JAN2022	30JAN2022	
	[redacted]	AMIKACIN/Amikacin	INTRAVENOUS	18JUL2021	23JUL2021	Yes
		BENZYLPENICILLIN/Benzylpenicillin	INTRAVENOUS	18JUL2021	23JUL2021	Yes
		GLUCOSE/Glucose 10% Infusion	INTRAVENOUS	18JUL2021	20JUL2021	Yes
		OXYGEN/Oxygen	RESPIRATORY (INHALATION)	18JUL2021	18JUL2021	Yes

Note: † = Infant born to human immunodeficiency virus (HIV)-positive participant.
a. WHODDG B3 v202203 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: ADCM Table Generation: 09MAY2023 (18:35) Output File: ./nda3/C4591015_BR/adcm_l001_cm_aeinf

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16.2.5.4 Listing of Participants Who Received Vaccine Not as Randomized (Maternal)

Vaccine Group (as Randomized)	Participant	Randomization Date	Vaccination Date	Dose No.	Vaccine Received
No participant meets the reporting criteria.					

PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (09:47) Source Data: adsl Table Generation: 04MAY2023 (09:44) Output File: ./nda3/C4591015_BR/adsl_l001_p3_rand_notvax

16.2.5.5 Listing of Study Vaccination Errors (Maternal)

Vaccine Group (as Administered)	Participant	System Organ Class	Preferred Term/ Investigator Text	Dose No.[a]	Rel Day[b]	Action Taken[c]	Associated AE (Yes/No)
No participant meets the reporting criteria.							

Note: MedDRA (Version 25.1) coding dictionary applied.
a. Dose No. = the vaccination visit at which the vaccination error occurred.
b. Relative day (Rel Day) = start date – date of vaccination + 1.
c. Action taken with investigational product, treatment given for the event, or other action taken (specify).
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 04MAY2023 (09:44) Output File: ./nda3/C4591015_BR/adae_l002_me_all_p3

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
BNT162b2 (30 µg)	[redacted]			1/Prevax	30APR2021	1	10	2.41
				2/Prevax	24MAY2021	25	94	2108.22
	[redacted]			1/Prevax	20MAY2021	1	10	2.97
				2/Prevax	08JUN2021	20	33	1733.04
				6-Month postdelivery	14DEC2021	190	102	781.43
	[redacted]	SARS-CoV-2 Infection	08JUN2021	1/Prevax	08JUN2021	1	41	99.72
				2/Prevax	29JUN2021	22	13327	32681.11
				2/2 Weeks	12JUL2021	14	27442	42730.54
				Delivery	20JUL2021	22	43974	43155.65
				6-Month postdelivery	10JAN2022	196	12026	11666.54
	[redacted]			1/Prevax	19FEB2021	1	10	40.49
				2/Prevax	12MAR2021	22	48	1045.34
				2/2 Weeks	07APR2021	27	4179	10223.3
				Delivery	09APR2021	29	3131	3520.04
				6-Month postdelivery	17SEP2021	190	560	1922.82

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
	[redacted]	SARS-CoV-2 Infection	27DEC2021	1/Prevax	14MAY2021	2	10	9.37
				2/Prevax	01JUN2021	20	45	1077.08
				2/2 Weeks	15JUN2021	15	632	8763.88
				Delivery	30JUN2021	30	880	6125.85
				6-Month postdelivery	27DEC2021	210	5039	8383.36
	[redacted]	Confirmed COVID-19	19SEP2021	1/Prevax	20APR2021	1	10	BLQ
				2/Prevax	11MAY2021	22	232	1063.43
				2/2 Weeks	26MAY2021	16	1086	3714.16
				2/1 Month	10JUN2021	31	1821	2715.39
				Delivery	03JUL2021	54	504	1619.68
	[redacted]	Confirmed COVID-19	15JAN2022	1/Prevax	23APR2021	1	10	BLQ
				2/Prevax	12MAY2021	20	326	2537.58
				2/2 Weeks	26MAY2021	15	1142	9172.68
				2/1 Month	09JUN2021	29	1503	5459.39
				Delivery	22JUL2021	72	541	2505.77
				6-Month postdelivery	08MAR2022	301	15542	24004.24
	[redacted]			1/Prevax	26APR2021	1	10	1.15

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
				2/Prevax	10JUN2021	46	23	408.91
				2/2 Weeks	24JUN2021	15	6353	20625.88
				2/1 Month	08JUL2021	29	8175	10745.23
				Delivery	14JUL2021	35	534	4927.37
	[redacted]			1/Prevax	29APR2021	1	10	2.76
				2/Prevax	18MAY2021	20	66	1098.03
				Delivery	01JUN2021	15	5309	27970.68
				6-Month postdelivery	12NOV2021	179	857	2205.23
	[redacted]	Confirmed COVID-19	25OCT2021	1/Prevax	05MAY2021	1	10	5.98
				2/Prevax	26MAY2021	22	161	2050.78
				2/2 Weeks	09JUN2021	15	2403	6219.23
				2/1 Month	25JUN2021	31	1345	9826.59
				Delivery	18JUL2021	54	789	3916.44
				6-Month postdelivery	07JAN2022	227	23570	10591.54
	[redacted]	SARS-CoV-2 Infection	10MAY2021	1/Prevax	10MAY2021	1	92	197.07
				2/Prevax	01JUN2021	23	12982	25563.16
				2/2 Weeks	15JUN2021	15	16340	27557.3
				2/1 Month	29JUN2021	29	15824	27173.89

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
				Delivery	27JUL2021	57	8338	14183.73
				6-Month postdelivery	04JAN2022	218	2786	3719.4
	[redacted]			1/Prevax	17MAY2021	1	10	1.14
				2/Prevax	07JUN2021	22	147	1303.33
				2/2 Weeks	18JUN2021	12	2392	5629.96
				Delivery	26JUN2021	20	1671	3982.56
				6-Month postdelivery	06DEC2021	183	385	1178.87
	[redacted]	Confirmed COVID-19	16JAN2022	1/Prevax	20MAY2021	1	10	5.42
				2/Prevax	09JUN2021	21	78	2648.2
				2/2 Weeks	22JUN2021	14	1235	9443.32
				2/1 Month	07JUL2021	29	1769	4941.15
				Delivery	09AUG2021	62	459	1955.68
				6-Month postdelivery	24FEB2022	261	7638	14325.39
	[redacted]			1/Prevax	26MAY2021	1	10	BLQ
				2/Prevax	14JUN2021	20	46	635.16
				2/2 Weeks	25JUN2021	12	1214	9984.68
				Delivery	26JUN2021	13	947	6410.2

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
				6-Month postdelivery	16DEC2021	186	151	945.88
	[redacted]			1/Prevax	27MAY2021	1	10	BLQ
				2/Prevax	18JUN2021	23	133	3159.22
				2/2 Weeks	29JUN2021	12	2649	13438.76
				2/1 Month	22JUL2021	35	8538	6829.34
				Delivery	14AUG2021	58	718	2411.86
	[redacted]	SARS-CoV-2 Infection	03JUN2021	1/Prevax	03JUN2021	1	670	344.58
				2/Prevax	20JUL2021	48	13241	10107.91
				2/2 Weeks	03AUG2021	15	14294	20496.13
				Delivery	16AUG2021	28	18170	17712.88
				6-Month postdelivery	04MAR2022	228	5963	5302.97
	[redacted]	Confirmed COVID-19	19JAN2022	1/Prevax	07JUN2021	1	10	BLQ
				2/Prevax	30JUN2021	24	331	3449.24
				2/2 Weeks	12JUL2021	13	10851	29850.54
				2/1 Month	29JUL2021	30	5175	19954.75
				Delivery	18AUG2021	50	1206	9856.33
				6-Month postdelivery	01MAR2022	245	14407	18769.51

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Full-Length S-Binding IgG Level Assay (U/mL)
	[redacted]	Confirmed COVID-19	17OCT2021	1/Prevax	10JUN2021	1	10	1.96
				2/Prevax	15JUL2021	36	654	3524.59
				2/2 Weeks	29JUL2021	15	2884	7297.08
				Delivery	04AUG2021	21	1668	5759.73
	[redacted]			1/Prevax	11JUN2021	1	10	1.79
				2/Prevax	02JUL2021	22	114	6356.29
				2/2 Weeks	16JUL2021	15	7124	12777.96
				2/1 Month	02AUG2021	32	3755	7584.05
				Delivery	27AUG2021	57	1274	3725.75
				6-Month postdelivery	11FEB2022	225	74	2050.8
	[redacted]	SARS-CoV-2 Infection	18JUN2021	1/Prevax	18JUN2021	1	670	1060.61
				2/2 Weeks	23JUL2021	15	57889	63738.66
				2/1 Month	06AUG2021	29	27615	45600.52
				Delivery	19AUG2021	42	41512	31848.16
				6-Month postdelivery	01APR2022	267	6445	5913.3
	[redacted]	SARS-CoV-2 Infection	24JUN2021	1/Prevax	24JUN2021	1	74	136.71
				2/2 Weeks	30JUL2021	17	40674	33851.37

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
				2/1 Month	11AUG2021	29	17619	26693.66
				Delivery	13AUG2021	31	19151	26532.59
				6-Month postdelivery	25JAN2022	196	3623	4232.53
	[redacted]			1/Prevax	26APR2021	1	10	2.88
				2/Prevax	17MAY2021	22	72	4795.61
				2/2 Weeks	01JUN2021	16	7044	16924.23
	[redacted]			1/Prevax	24MAY2021	1	10	2.77
				2/Prevax	14JUN2021	22	10	50.42
				Delivery	25JUN2021	12	148	854.33
				6-Month postdelivery	23DEC2021	193	25	252.82
	[redacted]	SARS-CoV-2 Infection	21FEB2022	1/Prevax	31MAY2021	1	10	2.01
				2/Prevax	21JUN2021	22	132	1363.94
				2/2 Weeks	05JUL2021	15	2438	14185.19
				2/1 Month	06AUG2021	47	591	2237.73
				Delivery	03SEP2021	75	464	1917.13
				6-Month postdelivery	21FEB2022	246	23827	29703.16

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
	[redacted]			1/Prevax	01JUN2021	1	10	2.59
				2/Prevax	22JUN2021	22	611	3445.52
				2/2 Weeks	06JUL2021	15	3957	20797.39
				2/1 Month	09AUG2021	49	2522	7781.79
				Delivery	30AUG2021	70	1616	6356.17
				6-Month postdelivery	11FEB2022	235	26526	37582.46
	[redacted]			1/Prevax	03JUN2021	1	10	6.04
				2/Prevax	24JUN2021	22	24	643.82
				2/2 Weeks	07JUL2021	14	787	4638.81
				Delivery	15JUL2021	22	1716	4775.03
				6-Month postdelivery	31JAN2022	222	178	735.94
	[redacted]			1/Prevax	03JUN2021	1	10	BLQ
				2/Prevax	25JUN2021	23	29	1670.45
				2/2 Weeks	07JUL2021	13	1430	9294.64
				Delivery	02SEP2021	70	129	2025.85
	[redacted]	SARS-CoV-2 Infection	11FEB2022	1/Prevax	10JUN2021	1	10	1.34
				2/Prevax	02JUL2021	23	14	199.44

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Full-Length S-Binding IgG Level Assay (U/mL)
				2/2 Weeks	16JUL2021	15	190	2101.05
				Delivery	11AUG2021	41	103	979.82
				6-Month postdelivery	11FEB2022	225	12160	28167.89
	[redacted]	SARS-CoV-2 Infection	21MAY2021	1/Prevax	21MAY2021	1	228	291.54
				2/Prevax	11JUN2021	22	227	260.35
				2/2 Weeks	23JUN2021	13	21700	55743.62
				2/1 Month	14JUL2021	34	15403	27387.35
				Delivery	29JUL2021	49	5075	15790.24
				6-Month postdelivery	07JAN2022	211	20688	17509.83
	[redacted]			1/Prevax	16JUN2021	1	10	BLQ
				2/Prevax	06JUL2021	21	QNS	QNS
				2/2 Weeks	27JUL2021	22	1269	6249.47
				2/1 Month	10AUG2021	36	642	3171.53
				Delivery	10SEP2021	67	641	2474.31
	[redacted]			1/Prevax	23MAR2021	1	10	BLQ
				2/Prevax	14APR2021	23	40	863.33
				2/2 Weeks	23APR2021	10	12744	22882.39
				2/1 Month	10MAY2021	27	2320	15980.97

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
				Delivery	11MAY2021	28	8879	14894.79
				6-Month postdelivery	11NOV2021	212	1544	4410.1
	[redacted]	SARS-CoV-2 Infection	25MAR2021	1/Prevax	25MAR2021	1	1255	765.11
				2/Prevax	16APR2021	23	92	1118.89
				2/2 Weeks	30APR2021	15	1295	5453.76
				2/1 Month	18MAY2021	33	977	3759.3
				Delivery	22JUN2021	68	487	1694.5
				6-Month postdelivery	16DEC2021	245	139	496.88
	[redacted]	SARS-CoV-2 Infection	30JUN2021	1/Prevax	14APR2021	1	10	3.51
				2/Prevax	05MAY2021	22	136	1442.2
				2/2 Weeks	24MAY2021	20	2624	10652.29
				2/1 Month	03JUN2021	30	2647	7093.65
				Delivery	30JUN2021	57	3897	13267.03
				6-Month postdelivery	04JAN2022	245	1288	5845.35
	[redacted]			1/Prevax	11MAR2021	1	10	2.06
				2/Prevax	31MAR2021	21	99	1559.16
				2/2 Weeks	15APR2021	16	903	4038.56

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
				Delivery	25APR2021	26	571	4535.79
				6-Month postdelivery	06OCT2021	190	322	930.58
	[redacted]			1/Prevax	17MAR2021	1	10	4.25
				2/Prevax	12APR2021	27	1815	4266.22
				2/2 Weeks	27APR2021	16	13461	35068
				Delivery	07MAY2021	26	3815	29141.31
				6-Month postdelivery	01NOV2021	204	417	780.82
	[redacted]	SARS-CoV-2 Infection	08MAR2022	1/Prevax	24MAR2021	1	10	3.79
				2/Prevax	12APR2021	20	248	2251.78
				2/2 Weeks	26APR2021	15	2711	6129.82
				2/1 Month	17MAY2021	36	1188	2812.35
				Delivery	07JUN2021	57	654	1924.71
				6-Month postdelivery	08MAR2022	331	47092	57749.17
	[redacted]			1/Prevax	12APR2021	1	10	4.12
				2/Prevax	04MAY2021	23	99	850.54
				2/2 Weeks	20MAY2021	17	1672	5985.2
				2/1 Month	08JUN2021	36	834	2602.74

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Full-Length S-Binding IgG Level Assay (U/mL)
				Delivery	24JUN2021	52	417	1879.93
				6-Month postdelivery	10JAN2022	252	124	481.16
	[redacted]			1/Prevax	06MAY2021	1	10	1.79
				2/Prevax	28MAY2021	23	558	2865.66
				2/2 Weeks	11JUN2021	15	6483	18306.6
				2/1 Month	25JUN2021	29	3189	5017.41
				Delivery	04AUG2021	69	1332	4001.5
				6-Month postdelivery	07FEB2022	256	5779	21097.41
	[redacted]			1/Prevax	11MAY2021	1	10	1.06
				2/Prevax	01JUN2021	22	318	2046.79
				2/2 Weeks	17JUN2021	17	2979	7872.97
				2/1 Month	29JUN2021	29	1439	4430.71
				Delivery	15AUG2021	76	399	1324.17
	[redacted]	Confirmed COVID-19	14SEP2021	1/Prevax	17JUN2021	1	10	BLQ
				2/2 Weeks	21JUL2021	14	3507	12286.09
				2/1 Month	05AUG2021	29	1831	5287.49
				Delivery	17AUG2021	41	828	3789.06

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
				6-Month postdelivery	25JAN2022	202	3698	5262.1
	[redacted]			1/Prevax	20MAY2021	1	10	4.27
				2/Prevax	10JUN2021	22	102	1670.01
				2/2 Weeks	22JUN2021	13	6171	10697.5
				2/1 Month	13JUL2021	34	2204	5961.01
				Delivery	05AUG2021	57	969	2664.47
				6-Month postdelivery	13JAN2022	218	308	1236.48
	[redacted]			1/Prevax	10MAR2021	1	10	2.45
				2/Prevax	29MAR2021	20	68	983.83
				2/2 Weeks	12APR2021	15	2150	8094.88
				2/1 Month	26APR2021	29	1094	3817.92
				Delivery	03MAY2021	36	2480	2750.59
				6-Month postdelivery	15NOV2021	232	91	439.82
	[redacted]			1/Prevax	11MAR2021	1	10	BLQ
				2/Prevax	01APR2021	22	406	2011.22
				2/2 Weeks	13APR2021	13	3101	9357.77
				2/1 Month	06MAY2021	36	2696	3302.11

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
				Delivery	13JUN2021	74	930	1594.16
				6-Month postdelivery	22DEC2021	266	26179	18935.38
	[redacted]			1/Prevax	13APR2021	1	10	8.36
				2/Prevax	03MAY2021	21	143	2564.68
				2/2 Weeks	18MAY2021	16	1066	8260.44
				2/1 Month	04JUN2021	33	866	5179.6
				Delivery	22JUN2021	51	483	2621.87
				6-Month postdelivery	08DEC2021	220	133	547.08
	[redacted]			1/Prevax	14MAY2021	1	10	6.34
				2/Prevax	04JUN2021	22	119	2171.15
				2/2 Weeks	18JUN2021	15	2698	23090.6
				2/1 Month	02JUL2021	29	3901	10599.72
				Delivery	26JUL2021	53	484	5981.21
				6-Month postdelivery	03JAN2022	214	76	805.62
	[redacted]			1/Prevax	14MAY2021	1	10	1.27
				2/Prevax	11JUN2021	29	514	3095.54
				2/2 Weeks	25JUN2021	15	10557	23822.84

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
				2/1 Month	09JUL2021	29	4124	15011.66
				Delivery	14JUL2021	34	4678	13132.59
				6-Month postdelivery	21DEC2021	194	428	1120.98
	[redacted]	SARS-CoV-2 Infection	04OCT2021	1/Prevax	16FEB2021	1	10	BLQ
				2/Prevax	08MAR2021	21	454	3747.72
				2/2 Weeks	22MAR2021	15	828	3820.37
				2/1 Month	08APR2021	32	584	3872.48
				Delivery	17APR2021	41	3621	4740.66
				6-Month postdelivery	04OCT2021	211	4286	5623.48
	[redacted]	SARS-CoV-2 Infection	09MAR2021	1/Prevax	09MAR2021	1	421	98.22
				2/Prevax	30MAR2021	22	19652	14144.64
				2/2 Weeks	13APR2021	15	8621	11357.64
				2/1 Month	27APR2021	29	7581	4632.85
				Delivery	16JUN2021	79	2309	2487.94
				6-Month postdelivery	29NOV2021	245	1284	680.27
	[redacted]	SARS-CoV-2 Infection	18FEB2021	1/Prevax	18FEB2021	1	1932	346.93
				2/Prevax	09MAR2021	20	15074	31809.18

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
				2/2 Weeks	22MAR2021	14	5724	15001.79
				2/1 Month	06APR2021	29	17811	25359.85
				Delivery	09APR2021	32	16069	31543.22
				6-Month postdelivery	23SEP2021	199	4167	2639.14
	[redacted]	SARS-CoV-2 Infection	18OCT2021	1/Prevax	04MAR2021	1	291	110.65
				2/Prevax	24MAR2021	21	32686	38446.49
				2/2 Weeks	08APR2021	16	39597	65756.42
				Delivery	11APR2021	19	5395	6303.03
				6-Month postdelivery	18OCT2021	209	2680	8927
	[redacted]			1/Prevax	12MAR2021	1	10	BLQ
				2/Prevax	31MAR2021	20	1131	5687.07
				Delivery	04APR2021	5	9976	22496.24
				6-Month postdelivery	20SEP2021	174	750	784.28
	[redacted]	SARS-CoV-2 Infection	16NOV2021	1/Prevax	16MAR2021	1	10	2.32
				2/Prevax	05APR2021	21	388	11820.82
				2/2 Weeks	20APR2021	16	1384	3568.78
				2/1 Month	06MAY2021	32	822	9544.57

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Full-Length S-Binding IgG Level Assay (U/mL)
				Delivery	14MAY2021	40	2469	10211.95
				6-Month postdelivery	16NOV2021	226	2906	11397.58
	[redacted]			1/Prevax	23MAR2021	1	10	BLQ
				2/Prevax	13APR2021	22	96	716.25
				2/2 Weeks	29APR2021	17	1697	3229.87
				2/1 Month	13MAY2021	31	280	1973.54
				Delivery	15MAY2021	33	1241	3733.93
				6-Month postdelivery	18NOV2021	220	131	187.91
	[redacted]			1/Prevax	08APR2021	1	10	1.49
				2/Prevax	27APR2021	20	300	1039.02
				2/2 Weeks	11MAY2021	15	1515	6069.26
				2/1 Month	25MAY2021	29	10	223.91
				Delivery	23JUN2021	58	542	1795.47
				6-Month postdelivery	30NOV2021	218	893	330.73
	[redacted]	SARS-CoV-2 Infection	25MAR2021	1/Prevax	25MAR2021	1	36	44.48
				2/Prevax	13APR2021	20	4145	20648.31
				2/2 Weeks	27APR2021	15	3663	8223.62

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
				2/1 Month	11MAY2021	29	1276	8002.28
				Delivery	04JUN2021	53	82	788.96
				6-Month postdelivery	20DEC2021	252	2627	4883.61
	[redacted]			1/Prevax	09APR2021	1	10	BLQ
				2/Prevax	30APR2021	22	39	532.89
				2/2 Weeks	13MAY2021	14	583	3439.16
				Delivery	25MAY2021	26	10	1.11
				6-Month postdelivery	19NOV2021	204	33	88.3
	[redacted]	SARS-CoV-2 Infection	11MAY2021	1/Prevax	11MAY2021	1	10	178.77
	[redacted]	SARS-CoV-2 Infection	28APR2021	1/Prevax	28APR2021	1	397	435.69
				2/Prevax	18MAY2021	21	8917	19098.39
				2/2 Weeks	01JUN2021	15	32392	19484.17
				2/1 Month	17JUN2021	31	11616	6333.99
				Delivery	21JUN2021	35	1906	2128
				6-Month postdelivery	29NOV2021	196	3314	1757.74
	[redacted]	SARS-CoV-2 Infection	11MAY2021	1/Prevax	11MAY2021	1	157	465.17

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
				2/Prevax	02JUN2021	23	969	5997.54
				2/2 Weeks	14JUN2021	13	9510	20127.34
				2/1 Month	28JUN2021	27	2768	2818.54
				Delivery	02JUL2021	31	7750	11696.42
				6-Month postdelivery	13DEC2021	195	2826	3571.82
	[redacted]	SARS-CoV-2 Infection	16DEC2021	1/Prevax	13MAY2021	1	10	1.09
				2/Prevax	02JUN2021	21	10	3.96
				Delivery	09JUN2021	8	1100	9604.4
				6-Month postdelivery	16DEC2021	198	34426	45841.09
	[redacted]			1/Prevax	18MAY2021	1	10	BLQ
				2/Prevax	09JUN2021	23	77	366.25
				2/2 Weeks	21JUN2021	13	400	2771.16
				2/1 Month	07JUL2021	29	369	2053.48
				6-Month postdelivery	11JAN2022	217	10	438.99
	[redacted]	SARS-CoV-2 Infection	10JUN2021	1/Prevax	18MAY2021	1	10	2.93
				2/Prevax	10JUN2021	24	20	2068.19
				2/2 Weeks	22JUN2021	13	10	1.21

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Full-Length S-Binding IgG Level Assay (U/mL)
				2/1 Month	12JUL2021	33	INDETERMINATE	310.09
				6-Month postdelivery	03FEB2022	239	33064	29923.08
	[redacted]			1/Prevax	20MAY2021	1	10	BLQ
				2/Prevax	08JUN2021	20	245	292.97
				2/2 Weeks	23JUN2021	16	10	0.98
				Delivery	03JUL2021	26	10	5.4
				6-Month postdelivery	19JAN2022	226	4256	4529.1
	[redacted]	SARS-CoV-2 Infection	20MAY2021	1/Prevax	20MAY2021	1	267	317.19
				2/Prevax	08JUN2021	20	260	486.82
				2/2 Weeks	23JUN2021	16	10	1.95
				Delivery	06JUL2021	29	50	375.39
				6-Month postdelivery	21JAN2022	228	130	97.63
	[redacted]	SARS-CoV-2 Infection	14JUN2021	1/Prevax	26MAY2021	1	2291	5889.89
				2/Prevax	14JUN2021	20	20693	40498.22
				2/2 Weeks	25JUN2021	12	22678	29968.11
				Delivery	26JUN2021	13	10	1.03

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
				6-Month postdelivery	12JAN2022	213	15	25.75
	[redacted]	SARS-CoV-2 Infection	08JUN2021	1/Prevax	08JUN2021	1	105	445.27
				2/Prevax	28JUN2021	21	29898	37797.17
				2/2 Weeks	12JUL2021	15	34979	30618.55
				2/1 Month	26JUL2021	29	29322	25671.87
				6-Month postdelivery	24JAN2022	211	1352	3116.77
	[redacted]	SARS-CoV-2 Infection	05AUG2021	1/Prevax	14JUN2021	1	10	BLQ
				2/2 Weeks	19JUL2021	14	1470	9861.71
				2/1 Month	05AUG2021	31	569	1199.95
				Delivery	24SEP2021	81	85989	46693.81
				6-Month postdelivery	07MAR2022	245	12448	11885.78
	[redacted]	SARS-CoV-2 Infection	05AUG2021	1/Prevax	18JUN2021	1	10	3.41
				2/2 Weeks	19JUL2021	13	10	2.93
				2/1 Month	05AUG2021	30	17971	30935.4
	[redacted]	SARS-CoV-2 Infection	24JAN2022	1/Prevax	18JUN2021	1	10	1.7
				2/2 Weeks	28JUL2021	16	44	184.92

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
				6-Month postdelivery	24JAN2022	196	1791	4151.92
	[redacted]			1/Prevax	13JUL2021	1	10	7.54
				2/2 Weeks	16AUG2021	15	262	4268.85
				Delivery	25SEP2021	55	66	2066.9
				6-Month postdelivery	04MAR2022	215	12781	149.77
	[redacted]	SARS-CoV-2 Infection	09MAY2022	1/Prevax	27JUL2021	1	10	1.13
				2/2 Weeks	30AUG2021	15	2528	16683.64
				2/1 Month	13SEP2021	29	570	9090.85
				Delivery	03NOV2021	80	551	4319.02
				6-Month postdelivery	09MAY2022	267	10119	12058.72
	[redacted]	SARS-CoV-2 Infection	20OCT2021	1/Prevax	30AUG2021	1	10	1.03
				2/2 Weeks	05OCT2021	14	8752	30838.84
				2/1 Month	20OCT2021	29	388	447.58
				Delivery	25NOV2021	65	23957	53551.15
				6-Month postdelivery	05MAY2022	226	13131	16520.35

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
	[redacted]	SARS-CoV-2 Infection	08SEP2021	1/Prevax	08SEP2021	1	1015	2018.93
				2/2 Weeks	16OCT2021	18	3390	10479.31
				Delivery	25OCT2021	27	188	1099.08
				6-Month postdelivery	26APR2022	210	25561	12466.7
	[redacted]	SARS-CoV-2 Infection	08SEP2021	1/Prevax	08SEP2021	1	1463	3756.3
				2/2 Weeks	15OCT2021	17	5801	5830.48
				2/1 Month	03NOV2021	36	1840	5772.8
				Delivery	14DEC2021	77	311	1320.42
				6-Month postdelivery	02JUN2022	247	16757	11372.44
	[redacted]			1/Prevax	24FEB2021	1	10	2.43
				2/Prevax	17MAR2021	22	130	978.74
				2/2 Weeks	30MAR2021	14	2864	6058.4
				2/1 Month	16APR2021	31	1457	2278.77
				Delivery	12MAY2021	57	619	820.94
				6-Month postdelivery	10NOV2021	239	64	432.39
	[redacted]			1/Prevax	15APR2021	1	10	1.2

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
				2/Prevax	06MAY2021	22	256	8872.85
				2/2 Weeks	21MAY2021	16	2480	10343.56
				Delivery	08JUN2021	34	1134	6238.01
				6-Month postdelivery	09DEC2021	218	315	1088.14
	[redacted]			1/Prevax	06MAY2021	1	10	1.23
				2/Prevax	27MAY2021	22	208	3687.28
				2/2 Weeks	10JUN2021	15	2684	9136.22
				2/1 Month	29JUN2021	34	1894	5112.15
				Delivery	04AUG2021	70	817	2806.25
				6-Month postdelivery	17JAN2022	236	488	492.88
	[redacted]	Confirmed COVID-19	03JAN2022	1/Prevax	21APR2021	1	10	9.57
				2/Prevax	13MAY2021	23	38	3747.83
				2/2 Weeks	27MAY2021	15	2322	8515.47
				2/1 Month	16JUN2021	35	1347	5241.66
				Delivery	10JUL2021	59	259	2825.13
				6-Month postdelivery	13JAN2022	246	25902	11027.99
	[redacted]			1/Prevax	12MAY2021	1	10	BLQ

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
				2/Prevax	02JUN2021	22	173	1085.7
				2/2 Weeks	16JUN2021	15	3474	14352.6
				Delivery	28JUN2021	27	1673	9675.09
				6-Month postdelivery	16DEC2021	198	293	2445.58
	[redacted]	SARS-CoV-2 Infection	20MAY2021	1/Prevax	20MAY2021	1	325	1069.51
				2/Prevax	10JUN2021	22	12601	21596.08
				2/2 Weeks	24JUN2021	15	17995	18138.68
				2/1 Month	07JUL2021	28	24633	13708.27
				Delivery	09JUL2021	30	7759	13916.3
				6-Month postdelivery	16DEC2021	190	2029	2785.96
	[redacted]	Confirmed COVID-19	02MAR2022	1/Prevax	03AUG2021	-1	10	0.89
				2/2 Weeks	06SEP2021	15	960	5784.32
				2/1 Month	20SEP2021	29	427	3091.05
				Delivery	23SEP2021	32	475	2671.04
				6-Month postdelivery	25MAR2022	215	7995	11253.28
	[redacted]	SARS-CoV-2 Infection	04AUG2021	1/Prevax	04AUG2021	-6	141	622.66
				2/2 Weeks	14SEP2021	16	13557	32721.26

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
				Delivery	22SEP2021	24	10367	23548.59
				6-Month postdelivery	22MAR2022	205	5797	6000.84
	[redacted]			1/Prevax	22MAR2021	-2	10	0.97
				2/Prevax	12APR2021	20	391	1694.96
				2/2 Weeks	27APR2021	16	3216	16536.08
				Delivery	11MAY2021	30	1903	9327.79
	[redacted]	Confirmed COVID-19	09JAN2022	1/Prevax	11MAY2021	1	10	2.52
				2/Prevax	03JUN2021	24	498	5794.55
				2/2 Weeks	17JUN2021	15	14676	23005.39
				2/1 Month	06JUL2021	34	4028	13790.58
				Delivery	07AUG2021	66	3799	5526.74
				6-Month postdelivery	10FEB2022	253	5009	12458.46
	[redacted]	SARS-CoV-2 Infection	05APR2022	1/Prevax	26AUG2021	1	10	14.11
				Delivery	30SEP2021	17	5813	15600.35
				6-Month postdelivery	05APR2022	204	7648	6274.69
	[redacted]	SARS-CoV-2 Infection	09SEP2021	1/Prevax	09SEP2021	1	110	341.37

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
	[redacted]	SARS-CoV-2 Infection	17SEP2021	2/2 Weeks	11OCT2021	14	42247	78232.24
				2/1 Month	27OCT2021	30	39605	63189.78
				Delivery	15NOV2021	49	5645	10762.35
				1/Prevax	17SEP2021	1	1013	1025.47
				2/2 Weeks	18OCT2021	13	10722	20354.11
				2/1 Month	03NOV2021	29	18373	18473.93
				Delivery	22NOV2021	48	4288	14919.64
				6-Month postdelivery	23MAY2022	230	10048	9119.97
	[redacted]	SARS-CoV-2 Infection	07OCT2021	1/Prevax	07OCT2021	1	415	1518.42
				2/2 Weeks	08NOV2021	14	42860	61156.45
				2/1 Month	06DEC2021	42	17957	37855.3
				Delivery	27JAN2022	94	3699	25294.25
				6-Month postdelivery	06JUL2022	254	9827	15444.15
	[redacted]			1/Prevax	21JUL2021	1	10	BLQ
				2/2 Weeks	26AUG2021	17	1613	10047.59
				Delivery	15SEP2021	37	868	5278.44
				6-Month postdelivery	23FEB2022	198	151	1389.59

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
	[redacted]	SARS-CoV-2 Infection	13AUG2021	1/Prevax	13AUG2021	1	635	2442.64
				2/2 Weeks	17SEP2021	15	18810	43501.04
				2/1 Month	01OCT2021	29	12146	26931.08
				Delivery	21OCT2021	49	10170	22132.8
				6-Month postdelivery	03MAY2022	243	12529	10722.54
	[redacted]	SARS-CoV-2 Infection	26AUG2021	1/Prevax	26AUG2021	-2	394	1047.92
				2/2 Weeks	28SEP2021	12	7517	14327.47
				Delivery	19OCT2021	33	2616	7024.93
				6-Month postdelivery	04APR2022	200	561	1481.34
	[redacted]	SARS-CoV-2 Infection	02SEP2021	1/Prevax	02SEP2021	-5	10	97.62
				2/2 Weeks	14OCT2021	16	7039	15610.42
				2/1 Month	17NOV2021	50	4574	5472.93
				Delivery	12DEC2021	75	948	5835.33
				6-Month postdelivery	01JUN2022	246	2922	3417.71
	[redacted]	SARS-CoV-2 Infection	13SEP2021	1/Prevax	13SEP2021	1	245	446.58
				2/2 Weeks	27OCT2021	14	32959	30891

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
				2/1 Month	15NOV2021	33	20251	23712.51
				Delivery	17DEC2021	65	7524	11116.08
				6-Month postdelivery	06JUN2022	236	5796	5441.25
	[redacted]	SARS-CoV-2 Infection	13SEP2021	1/Prevax	13SEP2021	1	90	176.18
				2/2 Weeks	20OCT2021	16	6862	12978.84
				2/1 Month	02NOV2021	29	3915	9013.83
				6-Month postdelivery	15JUN2022	254	10629	2518.12
	[redacted]	SARS-CoV-2 Infection	10SEP2021	1/Prevax	10SEP2021	-4	10	103.46
				2/2 Weeks	19OCT2021	13	34835	24995.24
				2/1 Month	09NOV2021	34	23510	17359.26
				Delivery	09JAN2022	95	13317	11609.65
				6-Month postdelivery	22JUN2022	259	6766	5010.11
	[redacted]	SARS-CoV-2 Infection	27SEP2021	1/Prevax	27SEP2021	-1	29	137.17
				2/2 Weeks	04NOV2021	15	8623	22774.6
				2/1 Month	25NOV2021	36	4189	13091.15
				Delivery	30DEC2021	71	1954	6089.75

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
				6-Month postdelivery	08JUN2022	231	4065	10169.11
	[redacted]	SARS-CoV-2 Infection	29SEP2021	1/Prevax	29SEP2021	1	318	488.46
				2/2 Weeks	02NOV2021	15	7170	15710.97
				Delivery	14NOV2021	27	3889	5998.57
				6-Month postdelivery	27MAY2022	221	6742	2080.92
	[redacted]	SARS-CoV-2 Infection	30SEP2021	1/Prevax	30SEP2021	-7	44	601.57
				2/2 Weeks	11NOV2021	15	8861	30138.15
				2/1 Month	30NOV2021	34	14254	18991.51
				Delivery	26DEC2021	60	2113	12956.24
				6-Month postdelivery	29JUN2022	245	2159	4859.63
	[redacted]	SARS-CoV-2 Infection	05OCT2021	1/Prevax	05OCT2021	-21	88	160.66
				2/2 Weeks	30NOV2021	14	24555	32881.86
				2/1 Month	21DEC2021	35	20443	21340.3
				Delivery	15JAN2022	60	7936	16061.32
				6-Month postdelivery	29JUN2022	225	5971	4798.8

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
	[redacted]	SARS-CoV-2 Infection	07OCT2021	1/Prevax	07OCT2021	-12	273	460.74
				2/2 Weeks	24NOV2021	16	11627	17535.21
				2/1 Month	07DEC2021	29	7311	11922.3
				Delivery	16DEC2021	38	6694	9682.76
				6-Month postdelivery	01JUL2022	235	1073	1964.59
	[redacted]	SARS-CoV-2 Infection	07OCT2021	1/Prevax	07OCT2021	-7	1864	1935.38
				2/2 Weeks	17NOV2021	16	57878	59157.07
				2/1 Month	30NOV2021	29	35191	42019.95
				Delivery	11JAN2022	71	23013	22991.51
				6-Month postdelivery	22JUN2022	233	7739	5998.14
	[redacted]	SARS-CoV-2 Infection	21OCT2021	1/Prevax	21OCT2021	1	24	233.65
				2/2 Weeks	24NOV2021	16	5998	26289.66
				2/1 Month	07DEC2021	29	6946	15002.59
				Delivery	23DEC2021	45	3649	6156.82
				6-Month postdelivery	01JUN2022	205	1685	53.79
	[redacted]	SARS-CoV-2 Infection	28OCT2021	1/Prevax	28OCT2021	1	96	258.58

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
				2/2 Weeks	30NOV2021	14	4485	18649.39
				Delivery	11DEC2021	25	6284	13212.95
				6-Month postdelivery	01JUN2022	197	1092	2655.54
	[redacted]			1/Prevax	02JUN2021	1	10	BLQ
				2/Prevax	23JUN2021	22	50	973.14
				2/2 Weeks	07JUL2021	15	1077	2977.87
				2/1 Month	21JUL2021	29	818	1971.03
				Delivery	16AUG2021	55	177	422.32
				6-Month postdelivery	26JAN2022	218	29	283.55
	[redacted]			1/Prevax	10JUN2021	1	10	14.93
				2/Prevax	30JUN2021	21	10	923.19
				2/2 Weeks	12JUL2021	13	1248	15182.07
				2/1 Month	02AUG2021	34	454	11357.99
				Delivery	11SEP2021	74	98	4747.56
				6-Month postdelivery	28FEB2022	244	15	1668.6
	[redacted]	SARS-CoV-2 Infection	19JAN2022	1/Prevax	10JUN2021	1	10	1.65
				2/Prevax	30JUN2021	21	10	1430.16

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
				2/2 Weeks	14JUL2021	15	888	10245.37
				Delivery	23JUL2021	24	1160	6093.56
				6-Month postdelivery	19JAN2022	204	4459	3406.43
	[redacted]	Confirmed COVID-19	12JAN2022	1/Prevax	14JUL2021	1	10	4.83
				2/2 Weeks	18AUG2021	14	976	5399.78
				Delivery	03SEP2021	30	274	2921.65
				6-Month postdelivery	16FEB2022	196	14280	17627.97
	[redacted]			1/Prevax	19JUL2021	1	10	5.21
				2/2 Weeks	25AUG2021	17	1962	5258.94
				Delivery	07SEP2021	30	1412	3593.28
				6-Month postdelivery	28FEB2022	204	866	1080.51
	[redacted]			1/Prevax	25AUG2021	1	10	BLQ
				2/2 Weeks	29SEP2021	15	1587	4308.41
				2/1 Month	13OCT2021	29	528	2889.8
				Delivery	12DEC2021	89	186	1117.1
	[redacted]	SARS-CoV-2 Infection	11AUG2021	1/Prevax	11AUG2021	1	601	729.17

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
				2/2 Weeks	13SEP2021	13	10510	16238.81
				Delivery	16SEP2021	16	11254	17473.66
				6-Month postdelivery	22FEB2022	175	2353	1870.3
	[redacted]	SARS-CoV-2 Infection	18AUG2021	1/Prevax	18AUG2021	1	121	476.12
				2/2 Weeks	17SEP2021	12	36485	38719.86
				2/1 Month	04OCT2021	29	23521	28417.36
				Delivery	25OCT2021	50	17461	20617.82
	[redacted]	SARS-CoV-2 Infection	20AUG2021	1/Prevax	20AUG2021	1	37	208.59
				2/2 Weeks	22SEP2021	15	8938	19191.96
				2/1 Month	06OCT2021	29	7240	11491.62
				Delivery	08OCT2021	31	4470	5139.74
				6-Month postdelivery	17MAR2022	191	684	996.62
	[redacted]	SARS-CoV-2 Infection	06OCT2021	1/Prevax	06OCT2021	1	789	1262.02
				2/2 Weeks	10NOV2021	15	32834	62847.3
				2/1 Month	24NOV2021	29	27780	49862.7
				Delivery	22DEC2021	57	20602	29037.28
				6-Month postdelivery	30MAY2022	216	36799	32493.95

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Full-Length S-Binding IgG Level Assay (U/mL)
	[redacted]			1/Prevax	10JUN2021	1	10	1.26
				2/Prevax	29JUN2021	20	14	169.62
				2/2 Weeks	15JUL2021	17	483	1238.85
				Delivery	30JUL2021	32	101	676.43
				6-Month postdelivery	14JAN2022	200	61	424.97
	[redacted]			1/Prevax	11JUN2021	1	10	11.74
				2/Prevax	29JUN2021	19	50	553.6
				2/2 Weeks	13JUL2021	15	306	4219.19
	[redacted]	SARS-CoV-2 Infection	04JUN2021	1/Prevax	04JUN2021	1	88	448.22
				2/Prevax	25JUN2021	22	6683	25446.21
				2/2 Weeks	07JUL2021	13	11828	25981.22
				Delivery	22JUL2021	28	18465	19844.21
				6-Month postdelivery	14JAN2022	204	2446	3408.46
	[redacted]	SARS-CoV-2 Infection	17JAN2022	1/Prevax	04JUN2021	1	10	12.77
				2/Prevax	25JUN2021	22	108	8579.54
				2/2 Weeks	07JUL2021	13	3217	11548.55
				Delivery	14JUL2021	20	1775	12797.21

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
				6-Month postdelivery	17JAN2022	207	4648	3507.92
	[redacted]	Confirmed COVID-19	02JAN2022	1/Prevax	12AUG2021	1	10	1.78
				2/2 Weeks	16SEP2021	15	3367	11027.08
				2/1 Month	05OCT2021	34	2793	4850.04
				Delivery	27OCT2021	56	642	3057.31
				6-Month postdelivery	28APR2022	239	9040	10038.77
	[redacted]	SARS-CoV-2 Infection	20AUG2021	1/Prevax	20AUG2021	1	142	178.73
				2/2 Weeks	29SEP2021	21	16984	9248.14
				Delivery	30SEP2021	22	10658	13750.96
	[redacted]			1/Prevax	14MAY2021	1	10	2.59
				2/Prevax	02JUN2021	20	72	2068.03
				2/2 Weeks	17JUN2021	16	1109	6429.24
				2/1 Month	30JUN2021	29	1525	4876.73
	[redacted]			1/Prevax	26MAY2021	1	10	0.93
				2/Prevax	17JUN2021	23	318	4165.27
				2/2 Weeks	02JUL2021	16	10640	21833.33
				2/1 Month	19JUL2021	33	4027	12856.29

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
				Delivery	05AUG2021	50	1311	6921.44
				6-Month postdelivery	07FEB2022	236	13312	9944.26
	[redacted]	SARS-CoV-2 Infection	03MAY2022	1/Prevax	31AUG2021	1	10	1.67
				2/2 Weeks	19OCT2021	28	1298	7591.33
				6-Month postdelivery	03MAY2022	224	2560	4658.39
	[redacted]	SARS-CoV-2 Infection	01SEP2021	1/Prevax	01SEP2021	1	66	543.46
				2/2 Weeks	06OCT2021	15	26724	53302.21
				2/1 Month	05NOV2021	45	21370	39798.63
				Delivery	20NOV2021	60	18515	17077.43
				6-Month postdelivery	26MAY2022	247	5473	4350.09
	[redacted]	SARS-CoV-2 Infection	03SEP2021	1/Prevax	03SEP2021	1	95	346.33
				2/2 Weeks	21OCT2021	15	17308	34320.27
				6-Month postdelivery	25APR2022	201	6250	3513.58
	[redacted]	SARS-CoV-2 Infection	26MAY2021	1/Prevax	26MAY2021	1	83	110.09
				2/Prevax	14JUN2021	20	24640	41059.46

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
				2/2 Weeks	30JUN2021	17	20788	40989.88
				2/1 Month	12JUL2021	29	27209	31283.23
				Delivery	28JUL2021	45	21570	19437.5
				6-Month postdelivery	12JAN2022	213	13572	15808.67
	[redacted]	SARS-CoV-2 Infection	25JAN2022	1/Prevax	27MAY2021	1	10	5.46
				2/Prevax	15JUN2021	20	33	599.53
				2/2 Weeks	01JUL2021	17	1200	6082.77
				2/1 Month	16JUL2021	32	646	2890.75
				Delivery	25JUL2021	41	279	1599.25
				6-Month postdelivery	25JAN2022	225	18096	24139.09
	[redacted]	SARS-CoV-2 Infection	27MAY2021	1/Prevax	27MAY2021	1	65	28.35
				2/Prevax	15JUN2021	20	24625	38669.21
				2/2 Weeks	05JUL2021	21	32283	29536.37
				2/1 Month	20JUL2021	36	24576	21621.07
				6-Month postdelivery	25APR2022	315	3484	3305.87
	[redacted]			1/Prevax	28MAY2021	1	10	17.84
				2/Prevax	18JUN2021	22	52	2056.41

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
				2/2 Weeks	05JUL2021	18	6432	15466.69
				Delivery	12JUL2021	25	1386	13719.11
				6-Month postdelivery	10JAN2022	207	1122	1872.49
	[redacted]	SARS-CoV-2 Infection	28MAY2021	1/Prevax	28MAY2021	1	30	62.72
				2/Prevax	18JUN2021	22	5639	20795.09
				2/2 Weeks	02JUL2021	15	31919	17168.21
				Delivery	20JUL2021	33	9342	7036.56
				6-Month postdelivery	24JAN2022	221	5729	1477.93
	[redacted]	Confirmed COVID-19	03JUL2021	1/Prevax	31MAY2021	1	10	7.79
				2/Prevax	21JUN2021	22	40	701.52
				2/2 Weeks	05JUL2021	15	2273	9415.94
				6-Month postdelivery	25MAY2022	339	773	636.85
	[redacted]	SARS-CoV-2 Infection	31MAY2021	1/Prevax	31MAY2021	1	28	132.18
				2/Prevax	21JUN2021	22	20849	25520.64
				2/2 Weeks	06JUL2021	16	28320	38778.67
				Delivery	13JUL2021	23	21652	24501.79

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
				6-Month postdelivery	21DEC2021	184	6332	6058.01
	[redacted]			2/Prevax	25JUN2021	24	19490	33271.9
				Delivery	23AUG2021	83	QNS	QNS
	[redacted]	SARS-CoV-2 Infection	02JUN2021	1/Prevax	02JUN2021	1	315	584.2
				2/Prevax	23JUN2021	22	49419	53073.83
				2/2 Weeks	14JUL2021	22	32480	29991.53
				2/1 Month	29JUL2021	37	9856	19645.99
				Delivery	23AUG2021	62	6286	8978.6
				6-Month postdelivery	02FEB2022	225	3513	1681.36
	[redacted]			1/Prevax	02JUN2021	1	10	1.06
				2/Prevax	23JUN2021	22	10	132.3
				2/2 Weeks	07JUL2021	15	485	1899.75
				2/1 Month	21JUL2021	29	519	1701.52
				Delivery	04AUG2021	43	198	937.12
	[redacted]	SARS-CoV-2 Infection	08JUN2021	1/Prevax	08JUN2021	1	93	343.23
				2/Prevax	29JUN2021	22	3904	14606.89
				2/2 Weeks	13JUL2021	15	11535	21738.23

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
				2/1 Month	27JUL2021	29	7374	12167.88
				Delivery	06AUG2021	39	1981	5377.3
				6-Month postdelivery	26JAN2022	212	1149	2304.11
	[redacted]	SARS-CoV-2 Infection	08JUN2021	1/Prevax	08JUN2021	1	367	157.24
				2/Prevax	29JUN2021	22	17448	44886.35
				2/2 Weeks	13JUL2021	15	19857	40893.79
				2/1 Month	27JUL2021	29	16941	1198.52
				Delivery	26AUG2021	59	8820	24413.39
				6-Month postdelivery	15FEB2022	232	4559	11806.15
	[redacted]			1/Prevax	11JUN2021	1	10	1.13
				2/Prevax	02JUL2021	22	61	555.8
				2/2 Weeks	20JUL2021	19	2653	11930.83
				2/1 Month	13AUG2021	43	2959	4092.24
				Delivery	25AUG2021	55	419	2083.03
				6-Month postdelivery	14FEB2022	228	32	278.98
	[redacted]	SARS-CoV-2 Infection	11JUN2021	1/Prevax	11JUN2021	1	1027	1528.99
				2/Prevax	02JUL2021	22	19877	25559.69

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
	[redacted]	SARS-CoV-2 Infection	06AUG2021	Delivery	01SEP2021	62	6583	5957.48
				1/Prevax	06AUG2021	1	1099	1747.81
				2/2 Weeks	14SEP2021	16	3068	7994.84
				Delivery	14SEP2021	16	6162	8764.82
				6-Month postdelivery	02MAY2022	246	1336	1753.86
	[redacted]	SARS-CoV-2 Infection	24SEP2021	1/Prevax	24SEP2021	1	10	106.36
				2/2 Weeks	29OCT2021	15	2272	10102.77
				2/1 Month	16NOV2021	33	1410	5551.27
				Delivery	19DEC2021	66	764	2598.52
	[redacted]	SARS-CoV-2 Infection	04FEB2022	1/Prevax	08JUN2021	1	10	3.18
				2/Prevax	29JUN2021	22	74	674.47
				2/2 Weeks	13JUL2021	15	1244	7423.07
				Delivery	17JUL2021	19	1982	12240.37
				6-Month postdelivery	04FEB2022	221	7449	13092.16
	[redacted]			1/Prevax	11JUN2021	1	10	1.81
				2/Prevax	06JUL2021	26	10	276.01
				2/2 Weeks	20JUL2021	15	441	4290.25

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
				2/1 Month	03AUG2021	29	311	1487.63
				Delivery	20AUG2021	46	272	1381.27
				6-Month postdelivery	28JAN2022	207	7029	10819.83
	[redacted]			1/Prevax	12JUL2021	1	10	28.03
				2/2 Weeks	17AUG2021	16	3278	6151.29
				2/1 Month	02SEP2021	32	601	5378.23
				Delivery	01OCT2021	61	758	2577.59
				6-Month postdelivery	07APR2022	249	141	434.07
	[redacted]			1/Prevax	23JUL2021	1	10	9.49
				2/2 Weeks	26AUG2021	15	968	3612.13
				2/1 Month	09SEP2021	29	287	3639.86
				Delivery	15SEP2021	35	637	2955.19
	[redacted]	SARS-CoV-2 Infection	08APR2022	1/Prevax	22JUL2021	1	10	30.66
				2/2 Weeks	25AUG2021	14	3175	15353.5
				2/1 Month	09SEP2021	29	2442	14521.68
				Delivery	11SEP2021	31	686	13458.16
				6-Month postdelivery	08APR2022	240	14208	23071.97

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Full-Length S-Binding IgG Level Assay (U/mL)
	[redacted]			1/Prevax	22JUL2021	1	10	1.02
				2/2 Weeks	24AUG2021	13	564	3589.6
				2/1 Month	09SEP2021	29	219	2140.99
				Delivery	21OCT2021	71	53	556.42
				6-Month postdelivery	30MAR2022	231	38	221.3
	[redacted]			1/Prevax	04AUG2021	1	10	2.15
				2/2 Weeks	08SEP2021	16	1036	6150.11
				Delivery	19SEP2021	27	1354	5114.56
				6-Month postdelivery	10MAR2022	199	236	559.56
	[redacted]			1/Prevax	22JUL2021	1	10	1.58
				2/2 Weeks	27AUG2021	17	678	4276.18
				2/1 Month	10SEP2021	31	744	2597.15
				Delivery	27SEP2021	48	372	1664.09
	[redacted]			1/Prevax	24JUN2021	1	10	1.49
				2/2 Weeks	28JUL2021	13	5830	12824.12
				2/1 Month	13AUG2021	29	3631	8790.1
				Delivery	21SEP2021	68	854	2905.72

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
				6-Month postdelivery	17MAR2022	245	810	1376.23
	[redacted]			1/Prevax	01JUN2021	1	10	1.89
				2/Prevax	22JUN2021	22	10	113.16
				2/2 Weeks	06JUL2021	15	188	1522.12
				2/1 Month	21JUL2021	30	154	983.93
				Delivery	29AUG2021	69	65	424.09
	[redacted]			1/Prevax	01JUN2021	1	10	3.34
				2/Prevax	22JUN2021	22	15	478.29
				2/2 Weeks	06JUL2021	15	464	3182.97
				Delivery	20JUL2021	29	336	1697.15
				6-Month postdelivery	29DEC2021	191	4213	9493.21
	[redacted]	Confirmed COVID-19	19DEC2021	1/Prevax	17JUN2021	1	10	157
				2/Prevax	07JUL2021	21	112	6190.35
				2/2 Weeks	19JUL2021	13	844	19362.83
				Delivery	03AUG2021	28	263	10484.31
				6-Month postdelivery	03FEB2022	212	9869	13915.6

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Full-Length S-Binding IgG Level Assay (U/mL)
	[redacted]			1/Prevax	08JUN2021	1	10	BLQ
				2/Prevax	28JUN2021	21	138	640.74
				2/2 Weeks	12JUL2021	15	639	5025.32
				Delivery	15JUL2021	18	349	3930.94
				6-Month postdelivery	07JAN2022	194	69	418.43
	[redacted]	Confirmed COVID-19	05JAN2022	1/Prevax	01JUN2021	1	10	2.47
				2/Prevax	21JUN2021	21	178	2669.8
				2/2 Weeks	12JUL2021	22	1490	13211.99
				2/1 Month	27JUL2021	37	1793	5340.94
				Delivery	16AUG2021	57	530	3325.89
				6-Month postdelivery	09FEB2022	234	6576	15682.69
	[redacted]			1/Prevax	01JUN2021	1	10	38.42
				2/Prevax	23JUN2021	23	8098	8104.27
				2/2 Weeks	13JUL2021	21	16823	9544.25
				Delivery	21JUL2021	29	4676	7176.03
				6-Month postdelivery	02FEB2022	225	16972	14818.3

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Full-Length S-Binding IgG Level Assay (U/mL)
	[redacted]	SARS-CoV-2 Infection	16FEB2022	1/Prevax	08JUN2021	1	10	0.92
				2/Prevax	29JUN2021	22	77	372.94
				2/2 Weeks	16JUL2021	18	376	7484.58
				2/1 Month	30JUL2021	32	1211	4249.96
				Delivery	02AUG2021	35	1411	4678.1
				6-Month postdelivery	16FEB2022	233	21993	29028.75
	[redacted]			1/Prevax	09JUN2021	1	10	BLQ
				2/Prevax	01JUL2021	23	102	570.46
				2/2 Weeks	13JUL2021	13	977	5707.96
				2/1 Month	29JUL2021	29	595	3562.75
				Delivery	05SEP2021	67	276	1332.69
				6-Month postdelivery	16FEB2022	231	12494	31912.39
	[redacted]			1/Prevax	14JUN2021	1	15	1.63
				2/Prevax	05JUL2021	22	10	499.56
	[redacted]			1/Prevax	11JUN2021	1	10	26.45
				2/Prevax	01JUL2021	21	INDETERMINATE	7535.14
				2/2 Weeks	12JUL2021	12	1467	14974.57

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Full-Length S-Binding IgG Level Assay (U/mL)
				2/1 Month	29JUL2021	29	1302	4889.66
				Delivery	18AUG2021	49	242	2554.47
				6-Month postdelivery	26JAN2022	210	2960	5272.19
	[redacted]			1/Prevax	31AUG2021	1	10	4.09
	[redacted]	Confirmed COVID-19	24FEB2022	1/Prevax	21SEP2021	1	10	16.72
				2/2 Weeks	27OCT2021	16	253	2250.1
				2/1 Month	11NOV2021	31	180	1388.66
				6-Month postdelivery	01JUL2022	263	3623	1814.99
Placebo	[redacted]			1/Prevax	23MAR2021	1	10	BLQ
				2/Prevax	13APR2021	22	10	BLQ
				2/2 Weeks	26APR2021	14	10	BLQ
				2/1 Month	11MAY2021	29	10	BLQ
	[redacted]			1/Prevax	01APR2021	1	10	BLQ
				2/Prevax	22APR2021	22	10	1.06
				2/2 Weeks	03MAY2021	12	10	1.25
				Delivery	16MAY2021	25	10	BLQ

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Full-Length S-Binding IgG Level Assay (U/mL)
	[redacted]			1/Prevax	30APR2021	1	10	BLQ
				2/Prevax	11JUN2021	43	10	BLQ
				2/2 Weeks	22JUN2021	12	10	BLQ
				2/1 Month	12JUL2021	32	10	0.95
				Delivery	27JUL2021	47	10	BLQ
	[redacted]			1/Prevax	07MAY2021	1	10	4.89
				2/Prevax	03JUN2021	28	10	2.92
				2/2 Weeks	18JUN2021	43	10	2.13
				2/1 Month	12JUL2021	67	10	2.9
				Delivery	26JUL2021	81	10	2.2
	[redacted]	SARS-CoV-2 Infection	20MAY2021	1/Prevax	20MAY2021	1	105	275.6
				2/Prevax	11JUN2021	23	59	326.8
				2/2 Weeks	24JUN2021	14	59	256.61
				2/1 Month	14JUL2021	34	57	212.02
				Delivery	09AUG2021	60	57	174.98
	[redacted]			1/Prevax	18JUN2021	1	10	BLQ
				2/2 Weeks	23JUL2021	16	10	BLQ
				2/1 Month	09AUG2021	33	10	BLQ
				Delivery	01OCT2021	86	10	BLQ

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
	[redacted]	SARS-CoV-2 Infection	05APR2021	1/Prevax	05APR2021	1	154	28.2
				2/Prevax	26APR2021	22	95	36.82
				2/2 Weeks	10MAY2021	15	166	47.32
				2/1 Month	24MAY2021	29	766	44.11
				Delivery	25MAY2021	30	772	41.24
	[redacted]			1/Prevax	05APR2021	1	10	1.01
				2/Prevax	30APR2021	26	10	2.7
				2/2 Weeks	14MAY2021	15	10	2.24
				Delivery	25MAY2021	26	10	2.78
	[redacted]	SARS-CoV-2 Infection	28APR2021	1/Prevax	28APR2021	1	232	916.28
				2/Prevax	17MAY2021	20	203	942.55
				2/2 Weeks	01JUN2021	16	437	790.41
				2/1 Month	14JUN2021	29	234	611.96
				Delivery	27JUN2021	42	325	514.17
	[redacted]			1/Prevax	23APR2021	1	10	10.28
				2/Prevax	12MAY2021	20	10	4.96
				2/2 Weeks	28MAY2021	17	10	8.62
				2/1 Month	09JUN2021	29	10	6.7
				Delivery	11JUL2021	61	10	6.58

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
	[redacted]			1/Prevax	29APR2021	1	10	56.77
				2/Prevax	20MAY2021	22	10	76.67
				2/2 Weeks	03JUN2021	15	10	87.77
				2/1 Month	17JUN2021	29	10	77.88
				Delivery	14JUL2021	56	10	63.29
	[redacted]	SARS-CoV-2 Infection	30APR2021	1/Prevax	30APR2021	1	521	1968.67
				2/Prevax	21MAY2021	22	87	1610.25
				2/2 Weeks	07JUN2021	18	319	1116.13
				2/1 Month	18JUN2021	29	311	1143.19
				Delivery	05JUL2021	46	106	653.36
	[redacted]	SARS-CoV-2 Infection	10MAY2021	1/Prevax	10MAY2021	1	120	795.32
				2/Prevax	01JUN2021	23	380	899.98
				2/2 Weeks	16JUN2021	16	202	941.39
				2/1 Month	30JUN2021	30	132	425.44
				Delivery	07JUL2021	37	293	985.29
	[redacted]	SARS-CoV-2 Infection	11MAY2021	1/Prevax	11MAY2021	1	196	551.28
				2/Prevax	01JUN2021	22	307	800.32
				2/2 Weeks	14JUN2021	14	280	665.97
				2/1 Month	29JUN2021	29	367	576.83

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
				Delivery	01AUG2021	62	121	383.83
	[redacted]			1/Prevax	18MAY2021	1	10	4.47
				2/Prevax	09JUN2021	23	10	1.41
				2/2 Weeks	21JUN2021	13	10	1.39
				2/1 Month	07JUL2021	29	10	1.22
				Delivery	11JUL2021	33	10	BLQ
	[redacted]			1/Prevax	20MAY2021	1	19	4.1
				2/Prevax	10JUN2021	22	10	2.68
				2/2 Weeks	24JUN2021	15	10	4.34
				2/1 Month	08JUL2021	29	10	3.34
				Delivery	09AUG2021	61	10	BLQ
	[redacted]	SARS-CoV-2 Infection	21MAY2021	1/Prevax	21MAY2021	1	93	375.55
				2/Prevax	11JUN2021	22	178	442.43
				2/2 Weeks	25JUN2021	15	85	346.79
				2/1 Month	09JUL2021	29	319	327.7
				Delivery	24JUL2021	44	34	185.84
	[redacted]			1/Prevax	25MAY2021	1	10	30.4
				2/Prevax	15JUN2021	22	10	28.77
				2/2 Weeks	28JUN2021	14	10	28.09

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
	[redacted]			Delivery	10JUL2021	26	10	23.54
				1/Prevax	02JUN2021	1	10	2.2
				2/Prevax	24JUN2021	23	10	2.16
				2/2 Weeks	07JUL2021	14	10	1.78
				2/1 Month	22JUL2021	29	10	2.02
				Delivery	02SEP2021	71	10	2.54
	[redacted]			1/Prevax	04JUN2021	1	10	BLQ
				2/Prevax	09JUL2021	36	10	BLQ
				2/2 Weeks	23JUL2021	15	10	BLQ
				2/1 Month	09AUG2021	32	10	BLQ
				Delivery	13AUG2021	36	10	BLQ
	[redacted]			1/Prevax	07JUN2021	1	10	12.36
				2/Prevax	27JUL2021	51	10	14.36
				Delivery	09JUL2021	33	10	12.74
	[redacted]			1/Prevax	17JUN2021	1	10	1.66
				2/Prevax	06JUL2021	20	QNS	QNS
				2/2 Weeks	19JUL2021	14	10	1.1
				2/1 Month	09AUG2021	35	10	1.29
				Delivery	19AUG2021	45	10	1.27

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Full-Length S-Binding IgG Level Assay (U/mL)
	[redacted]	Confirmed COVID-19	28JUL2021	1/Prevax	22JUN2021	1	10	2.6
				2/2 Weeks	02AUG2021	21	22	2.13
				2/1 Month	11AUG2021	30	34	267.09
				Delivery	14SEP2021	64	INDETERMINATE	210.9
	[redacted]			1/Prevax	28MAY2021	1	10	3.94
				2/Prevax	18JUN2021	22	10	2.38
				2/2 Weeks	01JUL2021	14	10	2.32
				Delivery	26JUL2021	39	10	2.29
	[redacted]			1/Prevax	01JUN2021	1	10	1.42
				2/Prevax	23JUN2021	23	10	2.52
				2/2 Weeks	07JUL2021	15	10	1.95
				Delivery	18JUL2021	26	10	1.79
	[redacted]			1/Prevax	02JUN2021	1	10	2.55
				2/Prevax	23JUN2021	22	10	2.32
				2/2 Weeks	08JUL2021	16	10	2.54
				Delivery	28JUL2021	36	10	2.43
	[redacted]	SARS-CoV-2 Infection	07JUN2021	1/Prevax	07JUN2021	1	16	538.09
				2/Prevax	28JUN2021	22	96	624.03

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
				2/2 Weeks	12JUL2021	15	19	840.71
				2/1 Month	05AUG2021	39	170	1043.32
	[redacted]			1/Prevax	08JUN2021	1	10	0.95
				2/Prevax	29JUN2021	22	31	BLQ
				2/2 Weeks	13JUL2021	15	10	BLQ
				Delivery	04AUG2021	37	10	BLQ
	[redacted]			1/Prevax	01APR2021	1	10	43.43
				2/Prevax	20APR2021	20	10	31.29
				2/2 Weeks	04MAY2021	15	10	29.36
				2/1 Month	03JUN2021	45	10	35.61
				Delivery	12JUN2021	54	10	29.23
	[redacted]			1/Prevax	07JUN2021	1	10	BLQ
	[redacted]			1/Prevax	12MAY2021	1	10	1.15
				2/Prevax	01JUN2021	21	10	1.09
				2/2 Weeks	14JUN2021	14	10	1.43
				2/1 Month	28JUN2021	28	20	1.08
				Delivery	03JUL2021	33	10	BLQ
	[redacted]			1/Prevax	06APR2021	1	10	16.24

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
				2/Prevax	27APR2021	22	40	15.41
				2/2 Weeks	10MAY2021	14	10	13.37
				2/1 Month	27MAY2021	31	10	14.9
				Delivery	02JUN2021	37	10	5.62
	[redacted]			1/Prevax	06MAY2021	1	10	2.1
				2/Prevax	25MAY2021	20	10	1.74
				2/2 Weeks	08JUN2021	15	10	1.46
				Delivery	16JUN2021	23	10	1.54
	[redacted]			1/Prevax	05APR2021	1	10	BLQ
				2/Prevax	26APR2021	22	10	1.04
				2/2 Weeks	10MAY2021	15	10	BLQ
				2/1 Month	24MAY2021	29	10	BLQ
				Delivery	04JUN2021	40	10	BLQ
	[redacted]			1/Prevax	15JUN2021	1	10	0.88
				2/2 Weeks	21JUL2021	14	10	1.15
				Delivery	22JUL2021	15	10	1.36
	[redacted]			1/Prevax	22MAR2021	1	10	1.68
				2/Prevax	12APR2021	22	10	1.71
				2/2 Weeks	26APR2021	15	10	1.44

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
				Delivery	28APR2021	17	10	BLQ
	[redacted]			1/Prevax	22MAR2021	1	10	1.27
				2/Prevax	12APR2021	22	10	1.21
				2/2 Weeks	27APR2021	16	10	1.03
				2/1 Month	11MAY2021	30	10	BLQ
				Delivery	24MAY2021	43	10	BLQ
	[redacted]			1/Prevax	24MAR2021	1	10	BLQ
				2/Prevax	12APR2021	20	10	BLQ
				2/2 Weeks	27APR2021	16	10	BLQ
				2/1 Month	14MAY2021	33	10	BLQ
				Delivery	06JUN2021	56	10	BLQ
	[redacted]			1/Prevax	23APR2021	1	10	0.95
				2/Prevax	12MAY2021	20	10	1.02
				2/2 Weeks	26MAY2021	15	10	BLQ
				2/1 Month	16JUN2021	36	10	0.97
				Delivery	09JUL2021	59	10	1.35
	[redacted]			1/Prevax	04MAY2021	1	10	2.99
				2/Prevax	24MAY2021	21	10	1.28
				2/2 Weeks	07JUN2021	15	10	1.95

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Full-Length S-Binding IgG Level Assay (U/mL)
				2/1 Month	06JUL2021	44	10	1.51
				Delivery	11JUL2021	49	10	2.22
	[redacted]			1/Prevax	11MAY2021	1	10	1.19
				2/Prevax	08JUN2021	29	10	2.08
				2/2 Weeks	24JUN2021	17	10	1.61
				2/1 Month	08JUL2021	31	10	1.28
				Delivery	04AUG2021	58	10	BLQ
	[redacted]			1/Prevax	02JUN2021	1	10	BLQ
				2/Prevax	23JUN2021	22	10	BLQ
				2/2 Weeks	08JUL2021	16	10	BLQ
				2/1 Month	21JUL2021	29	10	BLQ
				Delivery	27JUL2021	35	10	BLQ
	[redacted]			1/Prevax	04JUN2021	1	10	BLQ
				2/Prevax	23JUN2021	20	10	BLQ
				2/2 Weeks	07JUL2021	15	10	1.54
				2/1 Month	22JUL2021	30	10	1.29
				Delivery	14AUG2021	53	10	1.72
	[redacted]			1/Prevax	16MAR2021	1	10	1.07
				2/Prevax	06APR2021	22	10	0.91

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
				2/2 Weeks	21APR2021	16	10	0.9
				Delivery	28APR2021	23	10	1.29
	[redacted]			1/Prevax	20APR2021	1	10	1.25
				2/Prevax	11MAY2021	22	10	BLQ
				2/2 Weeks	25MAY2021	15	10	BLQ
				Delivery	05JUN2021	26	10	BLQ
	[redacted]			1/Prevax	06APR2021	-2	10	14.23
				2/Prevax	28APR2021	21	10	8.61
				2/2 Weeks	13MAY2021	16	10	8.33
				2/1 Month	27MAY2021	30	10	6.48
				Delivery	29MAY2021	32	10	7.1
	[redacted]			1/Prevax	26APR2021	1	10	2.55
				2/Prevax	17MAY2021	22	10	2.63
				2/2 Weeks	01JUN2021	16	10	2.49
				Delivery	11JUN2021	26	10	2.75
	[redacted]			1/Prevax	26APR2021	-1	10	BLQ
				2/Prevax	17MAY2021	21	10	BLQ
				2/2 Weeks	02JUN2021	17	10	BLQ
				2/1 Month	14JUN2021	29	10	BLQ

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
	[redacted]			Delivery	12JUL2021	57	10	1.26
				1/Prevax	18MAY2021	1	10	29.42
				2/Prevax	09JUN2021	23	10	44.51
				2/2 Weeks	23JUN2021	15	10	39.26
				Delivery	27JUN2021	19	10	39.87
	[redacted]	SARS-CoV-2 Infection	01APR2021	1/Prevax	22FEB2021	1	18	BLQ
				2/Prevax	16MAR2021	23	10	BLQ
				2/2 Weeks	01APR2021	17	53	327.78
				2/1 Month	13APR2021	29	10	BLQ
				Delivery	15APR2021	31	10	BLQ
	[redacted]	SARS-CoV-2 Infection	02MAR2021	1/Prevax	02MAR2021	1	46	59.03
				2/Prevax	23MAR2021	22	96	178.31
				2/2 Weeks	09APR2021	18	70	244.59
				2/1 Month	23APR2021	32	38	239.32
				Delivery	26MAY2021	65	10	51.43
	[redacted]	SARS-CoV-2 Infection	04MAR2021	1/Prevax	04MAR2021	1	357	132.18
				2/Prevax	25MAR2021	22	190	393.31
				2/2 Weeks	08APR2021	15	26	96.36
				2/1 Month	29APR2021	36	330	315.19

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
	[redacted]	SARS-CoV-2 Infection	09MAR2021	1/Prevax	09MAR2021	1	484	31.96
				2/Prevax	30MAR2021	22	34	91.09
				2/2 Weeks	15APR2021	17	25	60.67
				Delivery	26APR2021	28	63	112.99
	[redacted]	SARS-CoV-2 Infection	17MAR2021	1/Prevax	17MAR2021	1	28	467.49
				2/Prevax	05APR2021	20	134	3106.6
				2/2 Weeks	20APR2021	16	162	1691.12
				2/1 Month	05MAY2021	31	10	1598.19
				Delivery	14MAY2021	40	48	1680.31
	[redacted]			1/Prevax	19MAR2021	1	10	25.78
				2/Prevax	09APR2021	22	10	46.7
				2/2 Weeks	22APR2021	14	10	34.6
				Delivery	10MAY2021	32	10	20.85
	[redacted]	SARS-CoV-2 Infection	21APR2021	1/Prevax	21APR2021	1	59	234.33
				2/Prevax	11MAY2021	21	97	275.41
				2/2 Weeks	25MAY2021	15	86	407.86
				2/1 Month	08JUN2021	29	10	107.25
				Delivery	18JUL2021	69	63	52.72

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Full-Length S-Binding IgG Level Assay (U/mL)
	[redacted]	SARS-CoV-2 Infection	31MAR2021	1/Prevax	31MAR2021	1	571	248.65
				2/Prevax	20APR2021	21	441	518.83
				2/2 Weeks	05MAY2021	16	439	324.6
				2/1 Month	20MAY2021	31	49	78.04
				Delivery	30MAY2021	41	404	352.07
	[redacted]	SARS-CoV-2 Infection	02APR2021	1/Prevax	02APR2021	1	335	1048.7
				2/Prevax	22APR2021	21	322	729.83
				2/2 Weeks	05MAY2021	14	326	1264.83
				Delivery	17MAY2021	26	16	155.12
	[redacted]	SARS-CoV-2 Infection	28JUN2021	1/Prevax	08APR2021	1	10	1.16
				2/Prevax	29APR2021	22	10	BLQ
				2/2 Weeks	13MAY2021	15	10	BLQ
				Delivery	27MAY2021	29	10	1.19
	[redacted]			1/Prevax	13APR2021	1	10	5.19
				2/Prevax	04MAY2021	22	15	2.99
				2/2 Weeks	18MAY2021	15	10	2.08
				2/1 Month	02JUN2021	30	10	1.23
				Delivery	11JUN2021	39	10	BLQ

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Full-Length S-Binding IgG Level Assay (U/mL)
	[redacted]	SARS-CoV-2 Infection	02SEP2021	1/Prevax	12MAY2021	1	10	BLQ
				2/Prevax	01JUN2021	21	10	BLQ
				2/2 Weeks	15JUN2021	15	10	BLQ
				2/1 Month	29JUN2021	29	10	BLQ
				Delivery	29JUL2021	59	10	BLQ
	[redacted]			1/Prevax	03MAY2021	1	17	BLQ
				2/Prevax	24MAY2021	22	10	BLQ
				2/2 Weeks	08JUN2021	16	10	BLQ
				2/1 Month	28JUN2021	36	10	BLQ
	[redacted]	SARS-CoV-2 Infection	13JUL2021	1/Prevax	13MAY2021	1	10	4.8
				2/Prevax	01JUN2021	20	10	12.08
				2/2 Weeks	14JUN2021	14	10	14.61
				Delivery	15JUN2021	15	10	10.4
	[redacted]			1/Prevax	18MAY2021	1	10	BLQ
				2/Prevax	09JUN2021	23	10	BLQ
				2/2 Weeks	22JUN2021	14	10	BLQ
				2/1 Month	08JUL2021	30	10	1.12
	[redacted]			1/Prevax	18MAY2021	1	10	1.67

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Full-Length S-Binding IgG Level Assay (U/mL)
				2/Prevax	09JUN2021	23	10	1.3
				2/2 Weeks	22JUN2021	14	146	24.79
				2/1 Month	13JUL2021	35	10	3.78
	[redacted]	SARS-CoV-2 Infection	26MAY2021	1/Prevax	26MAY2021	1	447	1060.19
				2/Prevax	16JUN2021	22	222	521.15
				2/2 Weeks	01JUL2021	16	651	1129.35
				2/1 Month	21JUL2021	36	1262	1226.84
				Delivery	23JUL2021	38	377	2334.52
	[redacted]	SARS-CoV-2 Infection	26MAY2021	1/Prevax	26MAY2021	1	28	844.01
				2/Prevax	16JUN2021	22	15	222.3
				2/2 Weeks	28JUN2021	13	65	778.26
				2/1 Month	21JUL2021	36	712	910.77
	[redacted]	SARS-CoV-2 Infection	02JUN2021	1/Prevax	02JUN2021	1	10	173.23
				2/Prevax	24JUN2021	23	1963	3706.86
				2/2 Weeks	09JUL2021	16	10	10.07
				2/1 Month	22JUL2021	29	295	370.27
	[redacted]	SARS-CoV-2 Infection	08JUN2021	1/Prevax	08JUN2021	1	255	374.99
				2/Prevax	28JUN2021	21	57	226.92
				2/2 Weeks	13JUL2021	16	225	343.67

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
	[redacted]	SARS-CoV-2 Infection	12AUG2021	2/1 Month	27JUL2021	30	116	385.06
				1/Prevax	18JUN2021	1	10	28.69
				Delivery	21JUL2021	13	10	4.42
	[redacted]	SARS-CoV-2 Infection	18JUN2021	1/Prevax	18JUN2021	1	256	503.62
				2/2 Weeks	19JUL2021	13	198	250
				2/1 Month	06AUG2021	31	84	273.08
	[redacted]	SARS-CoV-2 Infection	07SEP2021	1/Prevax	13JUL2021	1	10	2.48
				2/2 Weeks	19AUG2021	17	10	BLQ
				2/1 Month	07SEP2021	36	432	0.96
	[redacted]	SARS-CoV-2 Infection	16SEP2021	1/Prevax	13JUL2021	1	10	BLQ
				2/2 Weeks	17AUG2021	15	10	BLQ
				Delivery	21AUG2021	19	QNS	0.94
	[redacted]	SARS-CoV-2 Infection	20JUL2021	1/Prevax	20JUL2021	1	90	1361.05
				2/2 Weeks	24AUG2021	16	36	2346.98
				2/1 Month	07SEP2021	30	28	1614.18
				Delivery	12OCT2021	65	154	1859.33
	[redacted]	SARS-CoV-2 Infection	27JUL2021	1/Prevax	27JUL2021	1	143	228.45

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
				2/2 Weeks	01SEP2021	16	44	142.89
				2/1 Month	15SEP2021	30	42	208.98
				Delivery	24SEP2021	39	53	153.58
	[redacted]	SARS-CoV-2 Infection	22SEP2021	1/Prevax	22SEP2021	1	3369	6134.49
				2/2 Weeks	29OCT2021	17	2712	8357.68
				2/1 Month	17NOV2021	36	5625	9662.95
				Delivery	13JAN2022	93	40689	50185.04
	[redacted]	SARS-CoV-2 Infection	28OCT2021	1/Prevax	22SEP2021	1	242	298.26
				2/2 Weeks	28OCT2021	18	3878	4845.86
				2/1 Month	15NOV2021	36	7257	5212.66
				Delivery	20DEC2021	71	10	BLQ
	[redacted]	SARS-CoV-2 Infection	13OCT2021	1/Prevax	13OCT2021	1	261	492.21
				2/2 Weeks	15NOV2021	14	267	393.6
				2/1 Month	30NOV2021	29	193	332.38
				Delivery	03DEC2021	32	407	453.5
	[redacted]			1/Prevax	17MAR2021	1	10	1.65
				2/Prevax	06APR2021	21	10	1.11
				2/2 Weeks	21APR2021	16	10	1.27
				Delivery	24APR2021	19	10	1.06

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Full-Length S-Binding IgG Level Assay (U/mL)
	[redacted]			1/Prevax	21APR2021	1	10	BLQ
				2/Prevax	12MAY2021	22	10	BLQ
				2/2 Weeks	26MAY2021	15	10	BLQ
				Delivery	28MAY2021	17	16	BLQ
	[redacted]			1/Prevax	11MAY2021	1	10	5.73
				2/Prevax	01JUN2021	22	10	5.12
				2/2 Weeks	14JUN2021	14	10	6.06
				2/1 Month	28JUN2021	28	10	5.41
				Delivery	08AUG2021	69	10	2.85
	[redacted]			1/Prevax	12MAY2021	1	10	2.24
				2/Prevax	02JUN2021	22	10	2.83
				2/2 Weeks	16JUN2021	15	10	1.69
				2/1 Month	30JUN2021	29	10	2.07
				Delivery	21JUL2021	50	10	2.44
	[redacted]			1/Prevax	21MAY2021	1	10	BLQ
				2/Prevax	11JUN2021	22	10	BLQ
				2/2 Weeks	23JUN2021	13	10	BLQ
				2/1 Month	14JUL2021	34	10	1.16
				Delivery	03AUG2021	54	10	BLQ

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Full-Length S-Binding IgG Level Assay (U/mL)
	[redacted]			1/Prevax	30SEP2021	1	10	1.64
				2/2 Weeks	28OCT2021	15	10	0.91
				2/1 Month	15NOV2021	33	10	1.01
				Delivery	24NOV2021	42	10	3.05
	[redacted]	SARS-CoV-2 Infection	15OCT2021	1/Prevax	15OCT2021	1	17	249.3
				2/2 Weeks	19NOV2021	15	55	232.43
				Delivery	01DEC2021	27	1140	2569.84
	[redacted]	SARS-CoV-2 Infection	20DEC2021	1/Prevax	22OCT2021	1	10	1.18
				2/2 Weeks	26NOV2021	15	10	1.79
				2/1 Month	09DEC2021	28	10	1.1
				Delivery	20DEC2021	39	10	44.73
	[redacted]			1/Prevax	13MAY2021	1	10	2.28
				2/Prevax	03JUN2021	22	10	1.27
				2/2 Weeks	14JUN2021	12	10	1.75
				Delivery	27JUN2021	25	10	1.94
	[redacted]			1/Prevax	24JUN2021	1	10	3.77
				2/2 Weeks	29JUL2021	15	10	5.34
				2/1 Month	12AUG2021	29	10	4.02

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
				Delivery	18AUG2021	35	10	3.74
	[redacted]	SARS-CoV-2 Infection	20AUG2021	1/Prevax	20AUG2021	1	519	1188.37
				2/2 Weeks	23SEP2021	13	477	849.19
				2/1 Month	12OCT2021	32	385	555.92
				Delivery	25OCT2021	45	584	398.01
	[redacted]	SARS-CoV-2 Infection	25AUG2021	1/Prevax	25AUG2021	1	4653	3201.97
				2/2 Weeks	27SEP2021	15	2866	3534.15
				2/1 Month	11OCT2021	29	3422	4669.28
				Delivery	21OCT2021	39	1828	2076.56
	[redacted]			1/Prevax	28SEP2021	1	68	87.88
				2/2 Weeks	29OCT2021	12	39	48.81
	[redacted]	SARS-CoV-2 Infection	11OCT2021	1/Prevax	11OCT2021	1	392	999.38
				2/2 Weeks	15NOV2021	13	301	487.1
				2/1 Month	02DEC2021	30	740	810.37
				Delivery	10DEC2021	38	352	565.73
	[redacted]	SARS-CoV-2 Infection	22OCT2021	1/Prevax	22OCT2021	1	155	280.19
				2/2 Weeks	22NOV2021	13	74	220.04
				2/1 Month	08DEC2021	29	2252	1200.14

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
	[redacted]			Delivery	20DEC2021	41	2546	1691.05
				1/Prevax	20MAY2021	1	10	14.17
				2/Prevax	08JUN2021	20	10	12.73
				2/2 Weeks	22JUN2021	15	10	12.15
				2/1 Month	06JUL2021	29	10	12.01
				Delivery	05AUG2021	59	10	16.97
	[redacted]	SARS-CoV-2 Infection	13AUG2021	1/Prevax	13AUG2021	1	10	39.54
				2/2 Weeks	17SEP2021	17	10	45.9
				2/1 Month	29SEP2021	29	10	39.87
				Delivery	17OCT2021	47	10	34.35
	[redacted]	SARS-CoV-2 Infection	30AUG2021	1/Prevax	30AUG2021	-4	71	562.94
				2/2 Weeks	05OCT2021	13	29459	48314.09
				Delivery	20OCT2021	28	35470	39521.29
	[redacted]	SARS-CoV-2 Infection	10JAN2022	1/Prevax	08SEP2021	1	10	0.9
				2/2 Weeks	15OCT2021	18	10	1.38
				2/1 Month	26OCT2021	29	10	BLQ
				Delivery	23NOV2021	57	10	1.85
	[redacted]	SARS-CoV-2 Infection	06SEP2021	1/Prevax	06SEP2021	-1	121	270.67

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
				2/2 Weeks	11OCT2021	14	192	264.75
				Delivery	25OCT2021	28	133	249.01
	[redacted]	SARS-CoV-2 Infection	10SEP2021	1/Prevax	10SEP2021	-4	457	1152.64
				2/2 Weeks	20OCT2021	16	640	829.94
				2/1 Month	05NOV2021	32	235	370.54
				Delivery	27DEC2021	84	279	841.15
	[redacted]	SARS-CoV-2 Infection	10SEP2021	1/Prevax	10SEP2021	-10	10	113.64
				Delivery	05OCT2021	16	10	70.61
	[redacted]	SARS-CoV-2 Infection	23SEP2021	1/Prevax	23SEP2021	1	10	101.21
				Delivery	23OCT2021	10	10	126.52
	[redacted]	SARS-CoV-2 Infection	22SEP2021	1/Prevax	22SEP2021	-13	47	421.49
				2/2 Weeks	09NOV2021	15	15	258.69
				2/1 Month	25NOV2021	31	42	572.12
				Delivery	13JAN2022	80	1555	788.63
	[redacted]	SARS-CoV-2 Infection	05OCT2021	1/Prevax	05OCT2021	-2	10	125.97
				2/2 Weeks	12NOV2021	18	57	208.01
				2/1 Month	30NOV2021	36	59	190.63

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
	[redacted]	SARS-CoV-2 Infection	14OCT2021	1/Prevax	14OCT2021	1	52	370.97
				2/2 Weeks	17NOV2021	16	276	445.08
				2/1 Month	07DEC2021	36	2774	6306.81
				Delivery	15JAN2022	75	1337	2142.88
	[redacted]	SARS-CoV-2 Infection	19OCT2021	1/Prevax	19OCT2021	1	49	162.91
				2/2 Weeks	24NOV2021	16	35	142.73
				2/1 Month	07DEC2021	29	1622	1607.98
				Delivery	17DEC2021	39	1172	1342.42
	[redacted]	SARS-CoV-2 Infection	23OCT2021	1/Prevax	23OCT2021	1	15	161.61
				2/2 Weeks	24NOV2021	10	27	141.36
				2/1 Month	20DEC2021	36	30	137.87
				Delivery	21DEC2021	37	42	170.54
	[redacted]	SARS-CoV-2 Infection	28OCT2021	1/Prevax	28OCT2021	1	5417	6213.96
				2/2 Weeks	30NOV2021	14	2304	9810.28
				2/1 Month	20DEC2021	34	4635	11174.32
				Delivery	05JAN2022	50	2320	13836.64
	[redacted]	SARS-CoV-2 Infection	05NOV2021	1/Prevax	05NOV2021	1	214	1631.76
				2/2 Weeks	06DEC2021	12	93	1348.26

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Full-Length S-Binding IgG Level Assay (U/mL)
	[redacted]			1/Prevax	02JUN2021	1	10	4
				2/Prevax	23JUN2021	22	10	2.97
				2/2 Weeks	07JUL2021	15	10	2.85
				2/1 Month	22JUL2021	30	10	2.06
				Delivery	11AUG2021	50	10	1.48
	[redacted]			1/Prevax	07JUN2021	1	10	0.96
				2/Prevax	28JUN2021	22	10	BLQ
				2/2 Weeks	12JUL2021	15	10	0.96
				2/1 Month	26JUL2021	29	10	BLQ
	[redacted]			1/Prevax	14JUL2021	1	10	BLQ
				Delivery	25AUG2021	21	10	BLQ
	[redacted]			1/Prevax	14JUL2021	1	10	BLQ
				2/2 Weeks	18AUG2021	17	10	BLQ
				Delivery	24AUG2021	23	10	BLQ
	[redacted]			1/Prevax	26JUL2021	1	10	1.34
				2/2 Weeks	01SEP2021	17	10	BLQ
				2/1 Month	15SEP2021	31	10	1.33
				Delivery	02OCT2021	48	10	2.13

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
	[redacted]	SARS-CoV-2 Infection	20AUG2021	1/Prevax	20AUG2021	1	62	205.09
				2/2 Weeks	21SEP2021	14	185	231.71
				2/1 Month	06OCT2021	29	63	230
				Delivery	04DEC2021	88	59	176.46
	[redacted]	SARS-CoV-2 Infection	22DEC2021	1/Prevax	27AUG2021	1	10	1.92
				2/2 Weeks	08OCT2021	16	10	1.94
				2/1 Month	21OCT2021	29	10	1.76
				Delivery	23NOV2021	62	10	0.94
	[redacted]	SARS-CoV-2 Infection	27AUG2021	1/Prevax	27AUG2021	1	62	155.01
				2/2 Weeks	01OCT2021	16	161	313.04
				2/1 Month	18OCT2021	33	167	196.01
				Delivery	25NOV2021	71	109	148.82
	[redacted]	SARS-CoV-2 Infection	01SEP2021	1/Prevax	01SEP2021	1	256	554.01
				2/2 Weeks	15OCT2021	15	332	549.7
				2/1 Month	29OCT2021	29	17575	13003.18
				Delivery	18NOV2021	49	129	366.81
	[redacted]	SARS-CoV-2 Infection	20SEP2021	1/Prevax	20SEP2021	1	294	245.96
				2/2 Weeks	28OCT2021	15	92	260.83

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
				2/1 Month	11NOV2021	29	162	192.55
				Delivery	16NOV2021	34	175	357.45
	[redacted]	Confirmed COVID-19	04DEC2021	1/Prevax	14OCT2021	1	74	178.57
				2/2 Weeks	16NOV2021	12	95	135.58
				2/1 Month	03DEC2021	29	8573	21190.29
				Delivery	31DEC2021	57	2508	2075.31
	[redacted]	SARS-CoV-2 Infection	09JUN2021	1/Prevax	09JUN2021	1	15	124.32
				2/Prevax	30JUN2021	22	33	102.72
				2/2 Weeks	12JUL2021	13	30	91.02
				2/1 Month	28JUL2021	29	26	96.97
				Delivery	02AUG2021	34	32	85.32
	[redacted]	SARS-CoV-2 Infection	09JUN2021	1/Prevax	09JUN2021	1	40	140.16
				2/Prevax	30JUN2021	22	52	196.47
				2/2 Weeks	17JUL2021	18	29	180.71
				2/1 Month	28JUL2021	29	181	153.1
				Delivery	01SEP2021	64	167	186.55
	[redacted]			1/Prevax	05AUG2021	1	10	1.18
				2/2 Weeks	09SEP2021	15	10	1.68
				2/1 Month	29SEP2021	35	10	1

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
	[redacted]			Delivery	18OCT2021	54	10	1.09
				1/Prevax	26AUG2021	1	10	1.06
				2/2 Weeks	01OCT2021	18	10	BLQ
				2/1 Month	18OCT2021	35	10	1.1
				Delivery	24NOV2021	72	10	1.13
	[redacted]	SARS-CoV-2 Infection	19MAY2021	1/Prevax	19MAY2021	1	3818	3607.77
				2/Prevax	10JUN2021	23	1375	2661.34
				2/1 Month	01JUL2021	22	1576	2090.46
				Delivery	19JUL2021	40	1616	1867.26
	[redacted]			1/Prevax	23JUL2021	1	10	BLQ
				2/2 Weeks	27AUG2021	15	10	0.94
				2/1 Month	24SEP2021	43	10	BLQ
				Delivery	26SEP2021	45	10	BLQ
	[redacted]			1/Prevax	17AUG2021	1	10	6.4
				2/2 Weeks	27SEP2021	15	10	4.89
				2/1 Month	12OCT2021	30	10	5.34
				Delivery	17OCT2021	35	10	4.58
	[redacted]			1/Prevax	20OCT2021	1	10	BLQ

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
				Delivery	18NOV2021	10	10	BLQ
	[redacted]	SARS-CoV-2 Infection	05OCT2021	1/Prevax	05OCT2021	1	219	472.67
				2/2 Weeks	09NOV2021	15	310	450.95
				2/1 Month	07DEC2021	43	443	424.82
				Delivery	08DEC2021	44	169	289.52
	[redacted]	Confirmed COVID-19	30MAY2021	1/Prevax	26MAY2021	1	10	3.97
				Delivery	17JUL2021	6	98	531.18
	[redacted]			1/Prevax	27MAY2021	1	10	1.58
				2/Prevax	18JUN2021	23	10	BLQ
				Delivery	12JUL2021	25	10	2.67
	[redacted]			1/Prevax	27MAY2021	1	10	1.07
	[redacted]			1/Prevax	28MAY2021	1	10	BLQ
				2/Prevax	18JUN2021	22	10	2.16
				2/2 Weeks	02JUL2021	15	10	BLQ
				2/1 Month	20JUL2021	33	10	0.9
				Delivery	26JUL2021	39	10	BLQ
	[redacted]	SARS-CoV-2 Infection	28MAY2021	1/Prevax	28MAY2021	1	179	688.57

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
				2/Prevax	18JUN2021	22	34	975.76
				Delivery	10JUL2021	23	70	914.69
	[redacted]	SARS-CoV-2 Infection	28MAY2021	1/Prevax	28MAY2021	1	391	3089.89
				2/Prevax	18JUN2021	22	290	3549.2
				Delivery	01AUG2021	45	195	2620.82
	[redacted]			1/Prevax	01JUN2021	1	10	6.38
				2/Prevax	22JUN2021	22	10	3.72
				2/2 Weeks	06JUL2021	15	10	2.05
				2/1 Month	20JUL2021	29	10	1.83
				Delivery	29JUL2021	38	10	1.17
	[redacted]			1/Prevax	01JUN2021	1	10	BLQ
				2/Prevax	22JUN2021	22	10	BLQ
				Delivery	30JUN2021	9	10	BLQ
	[redacted]	SARS-CoV-2 Infection	07JUN2021	1/Prevax	07JUN2021	1	254	360.58
				2/Prevax	28JUN2021	22	297	324.85
				2/2 Weeks	14JUL2021	17	603	461.77
				2/1 Month	26JUL2021	29	280	514.5
				Delivery	20AUG2021	54	275	529.81

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
	[redacted]	SARS-CoV-2 Infection	07JUN2021	1/Prevax	07JUN2021	1	43	135.19
				2/Prevax	28JUN2021	22	73	174.41
				Delivery	17JUL2021	20	91	149.9
	[redacted]	SARS-CoV-2 Infection	08JUN2021	1/Prevax	08JUN2021	1	10	72.81
				2/Prevax	30JUN2021	23	75	67.94
				2/2 Weeks	14JUL2021	15	28	75.65
				2/1 Month	29JUL2021	30	10	48.65
				Delivery	26AUG2021	58	141	66.26
	[redacted]	SARS-CoV-2 Infection	09JUN2021	1/Prevax	09JUN2021	1	1908	1466.91
				2/Prevax	30JUN2021	22	1048	1083.9
	[redacted]			1/Prevax	10JUN2021	1	10	1.96
				2/Prevax	01JUL2021	22	10	4.16
				2/2 Weeks	15JUL2021	15	10	3.43
				2/1 Month	29JUL2021	29	10	3.26
	[redacted]	Confirmed COVID-19	09JAN2022	1/Prevax	25AUG2021	1	15	41.88
				2/2 Weeks	06OCT2021	22	10	20.05
				2/1 Month	13OCT2021	29	10	14.66

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Full-Length S-Binding IgG Level Assay (U/mL)
	[redacted]			1/Prevax	15JUN2021	1	10	2.59
				2/2 Weeks	21JUL2021	14	10	2.43
				Delivery	04AUG2021	28	10	2.33
	[redacted]			1/Prevax	17JUN2021	1	10	33.54
				2/2 Weeks	21JUL2021	14	10	19.77
				Delivery	03AUG2021	27	26	24.71
	[redacted]			1/Prevax	10JUN2021	1	10	1.06
				2/Prevax	05JUL2021	26	10	BLQ
				2/2 Weeks	20JUL2021	16	10	BLQ
				Delivery	24AUG2021	51	10	BLQ
	[redacted]			1/Prevax	10JUN2021	1	10	2.13
				2/Prevax	05JUL2021	26	10	2.48
				2/2 Weeks	20JUL2021	16	10	2.31
				2/1 Month	02AUG2021	29	10	1.64
				Delivery	16AUG2021	43	10	2.21
	[redacted]			1/Prevax	12JUL2021	1	10	19.09
				2/2 Weeks	17AUG2021	16	10	31.57
				2/1 Month	07SEP2021	37	10	12.21

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Full-Length S-Binding IgG Level Assay (U/mL)
	[redacted]			Delivery	10SEP2021	40	10	14.46
				1/Prevax	12JUL2021	1	10	1.18
				2/2 Weeks	17AUG2021	16	10	1.8
				Delivery	19AUG2021	18	10	3.08
	[redacted]			1/Prevax	22JUN2021	1	10	BLQ
				2/2 Weeks	27JUL2021	15	10	0.89
				2/1 Month	16AUG2021	35	10	0.93
				Delivery	02SEP2021	52	10	0.96
	[redacted]	Confirmed COVID-19	26AUG2021	1/Prevax	24AUG2021	1	10	0.96
				2/2 Weeks	28SEP2021	12	15	171.23
				2/1 Month	20OCT2021	34	63	180.44
				Delivery	06DEC2021	81	15	46.74
	[redacted]			1/Prevax	04JUN2021	1	10	BLQ
				2/Prevax	23JUN2021	20	10	BLQ
				2/2 Weeks	05JUL2021	13	10	BLQ
				Delivery	14JUL2021	22	10	BLQ
	[redacted]			1/Prevax	04JUN2021	1	10	44.25
				2/Prevax	23JUN2021	20	638	2428.42

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Full-Length S-Binding IgG Level Assay (U/mL)
				2/2 Weeks	05JUL2021	13	29	36.95
				2/1 Month	27JUL2021	35	10	33.86
				Delivery	30JUL2021	38	10	29.42
	[redacted]			1/Prevax	21JUN2021	1	10	1.62
				2/Prevax	12JUL2021	22	10	1.32
				2/2 Weeks	27JUL2021	16	10	1.1
				Delivery	09AUG2021	29	10	0.97
	[redacted]			1/Prevax	11JUN2021	1	10	1.15
				2/Prevax	02JUL2021	22	10	1.29
				2/2 Weeks	14JUL2021	13	10	1.03
				Delivery	29JUL2021	28	10	BLQ
	[redacted]			1/Prevax	07JUN2021	1	15	1.37
				2/Prevax	28JUN2021	22	10	1.18
				2/2 Weeks	12JUL2021	15	10	1.45
				2/1 Month	26JUL2021	29	10	1.39
				Delivery	06AUG2021	40	10	3.28
	[redacted]			1/Prevax	04JUN2021	1	10	BLQ
				2/Prevax	23JUN2021	20	10	BLQ
				2/2 Weeks	16JUL2021	24	10	BLQ

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
	[redacted]			Delivery	26JUL2021	34	10	0.99
				1/Prevax	04JUN2021	1	10	2.37
				2/Prevax	23JUN2021	20	10	2.44
				2/2 Weeks	16JUL2021	24	10	1.77
				2/1 Month	04AUG2021	43	10	1.74
				Delivery	21AUG2021	60	10	1.65
	[redacted]			1/Prevax	07JUN2021	1	10	0.89
				2/Prevax	29JUN2021	23	10	435.45
				2/2 Weeks	13JUL2021	15	QNS	QNS
	[redacted]	SARS-CoV-2 Infection	26JUL2021	1/Prevax	14JUN2021	1	10	4.21
				2/Prevax	26JUL2021	43	1487	12382.73
				2/2 Weeks	12AUG2021	18	336	4872.4
				Delivery	28AUG2021	34	207	4736.21
	[redacted]			1/Prevax	07JUN2021	1	10	1.06
				2/Prevax	28JUN2021	22	10	0.94
				2/2 Weeks	12JUL2021	15	10	1.51
	[redacted]			1/Prevax	11JUN2021	1	10	1.46
				2/Prevax	02JUL2021	22	10	1.68

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16.2.6.1.1 Listing of Assay Data (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay Full-Length S-Binding IgG Level Assay (U/mL)
	[redacted]			2/2 Weeks	16JUL2021	15	10	1.12
				1/Prevax	16JUN2021	1	10	2.24
				2/2 Weeks	21JUL2021	15	10	1.36
				Delivery	05AUG2021	30	10	3.02
	[redacted]			1/Prevax	14SEP2021	1	10	BLQ
				2/2 Weeks	20OCT2021	16	10	BLQ
				2/1 Month	03NOV2021	30	10	BLQ
				Delivery	15NOV2021	42	10	BLQ

Abbreviations: BLQ = below the limit of quantitation; IgG = immunoglobulin G; NT50 = 50% neutralizing titer; QNS = quantity not sufficient for analysis; S = spike protein; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Human immunodeficiency virus (HIV)-positive participants are not included in this listing.
a. SARS-CoV-2 infection without confirmed COVID-19.
b. Relative day (Rel Day) = date of blood draw - date of last vaccination + 1. For a blood draw that occurred before the date of the last vaccination, + 1 was not added to compute relative day.
PFIZER CONFIDENTIAL SDTM Creation: 12JAN2024 (03:07) Source Data: adva Table Generation: 19FEB2024 (03:16)
(Database snapshot date: Safety [29Mar2023], Immunogenicity [09Jan2024]) Output File: ./nda3/C4591015_CSR/adva_l001

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16.2.6.1.2 Listing of Assay Data – HIV Positive Participants (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay: SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay: Full-Length S-Binding IgG Level Assay (U/mL)
BNT162b2 (30 µg)	[redacted]	SARS-CoV-2 Infection	27OCT2021	1/Prevax	27OCT2021	1	120	218.47
				2/2 Weeks	30NOV2021	15	8309	12346.75
				2/1 Month	14DEC2021	29	2081	5577.62
				Delivery	02JAN2022	48	5547	6206.37
				6-Month postdelivery	13JUN2022	210	1577	1773.31
	[redacted]	SARS-CoV-2 Infection	05NOV2021	1/Prevax	05NOV2021	1	10	117.21
				2/2 Weeks	06DEC2021	12	27142	72828.24
				2/1 Month	23DEC2021	29	13257	38799.36
				Delivery	25DEC2021	31	4183	41510.55
				6-Month postdelivery	08JUN2022	196	4039	10508.6
	[redacted]			1/Prevax	19AUG2021	1	72	209.02
				2/2 Weeks	20SEP2021	14	41146	40035.6
				2/1 Month	05OCT2021	29	22941	32785.68
				Delivery	25NOV2021	80	9229	15267.75
				6-Month postdelivery	06MAY2022	242	9020	10282.85
	[redacted]			1/Prevax	01SEP2021	1	10	1.25

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16.2.6.1.2 Listing of Assay Data – HIV Positive Participants (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay: SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay: Full-Length S-Binding IgG Level Assay (U/mL)
				2/2 Weeks	01OCT2021	12	846	4962.08
				Delivery	16OCT2021	27	374	1515.87
				6-Month postdelivery	14APR2022	207	47	773.29
	[redacted]	SARS-CoV-2 Infection	03SEP2021	1/Prevax	03SEP2021	1	3079	1776.56
				2/2 Weeks	06OCT2021	15	14216	14482.41
				2/1 Month	20OCT2021	29	6509	12585.82
				Delivery	31OCT2021	40	3509	4459.66
				6-Month postdelivery	19APR2022	210	1399	2102.07
	[redacted]	SARS-CoV-2 Infection	06SEP2021	1/Prevax	06SEP2021	1	98	349.38
				2/2 Weeks	11OCT2021	15	13379	24684.56
				2/1 Month	25OCT2021	29	6158	17247.19
				Delivery	13DEC2021	78	1829	3479.61
				6-Month postdelivery	20MAY2022	236	555	1384.77
	[redacted]	SARS-CoV-2 Infection	29OCT2021	1/Prevax	20SEP2021	1	10	54.84
				2/2 Weeks	29OCT2021	16	199	452.78
				2/1 Month	11NOV2021	29	24700	13009.24
				Delivery	14NOV2021	32	11598	11896.56

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16.2.6.1.2 Listing of Assay Data – HIV Positive Participants (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay: SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay: Full-Length S-Binding IgG Level Assay (U/mL)
				6-Month postdelivery	25APR2022	194	4676	2577.85
	[redacted]	SARS-CoV-2 Infection	17SEP2021	1/Prevax	17SEP2021	1	504	649.29
				2/2 Weeks	19OCT2021	12	23819	37899.83
				2/1 Month	05NOV2021	29	11164	18555.86
				Delivery	08DEC2021	62	11626	9814.61
				6-Month postdelivery	22JUN2022	258	3772	2615.57
	[redacted]	SARS-CoV-2 Infection	21SEP2021	1/Prevax	21SEP2021	1	623	1562.3
				2/2 Weeks	28OCT2021	15	16759	37980.33
				2/1 Month	11NOV2021	29	8684	25059.72
				Delivery	28NOV2021	46	6763	13532.51
				6-Month postdelivery	02JUN2022	232	5872	6061.12
	[redacted]	SARS-CoV-2 Infection	05OCT2021	1/Prevax	05OCT2021	1	7372	1438.82
				2/2 Weeks	08NOV2021	15	33717	10955.43
				2/1 Month	22NOV2021	29	13246	5669.03
				Delivery	14JAN2022	82	11040	4067.16
				6-Month postdelivery	23JUN2022	242	6897	1396.59

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16.2.6.1.2 Listing of Assay Data – HIV Positive Participants (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay: SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay: Full-Length S-Binding IgG Level Assay (U/mL)
	[redacted]	SARS-CoV-2 Infection	12OCT2021	1/Prevax	12OCT2021	-2	86	421.12
				2/2 Weeks	18NOV2021	15	32968	20034.44
				2/1 Month	02DEC2021	29	19345	18448.35
				Delivery	25JAN2022	83	10765	13341.35
				6-Month postdelivery	15JUL2022	254	8344	3899.16
	[redacted]	Confirmed COVID-19	22DEC2021	1/Prevax	05NOV2021	1	10	20.36
				Delivery	15NOV2021	11	9568	31666.6
Placebo	[redacted]	SARS-CoV-2 Infection	12OCT2021	1/Prevax	12OCT2021	1	80	351.19
				2/2 Weeks	15NOV2021	14	68	239.9
				2/1 Month	30NOV2021	29	158	536.07
				Delivery	28DEC2021	57	872	1367.1
	[redacted]	SARS-CoV-2 Infection	23OCT2021	1/Prevax	23OCT2021	1	1309	694.53
				2/2 Weeks	24NOV2021	10	641	837.06
				2/1 Month	21DEC2021	37	471	479.23
				Delivery	24JAN2022	71	177	374.3
	[redacted]	SARS-CoV-2 Infection	11AUG2021	1/Prevax	11AUG2021	1	4129	4179.13
				2/2 Weeks	27SEP2021	13	902	2071.24

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16.2.6.1.2 Listing of Assay Data – HIV Positive Participants (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay: SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay: Full-Length S-Binding IgG Level Assay (U/mL)
				2/1 Month	13OCT2021	29	1057	1619.84
				Delivery	18NOV2021	65	415	898.3
	[redacted]	SARS-CoV-2 Infection	13AUG2021	1/Prevax	13AUG2021	1	92	151.81
				2/2 Weeks	14SEP2021	14	23	186.89
				2/1 Month	29SEP2021	29	38	151.21
				Delivery	18NOV2021	79	63	152.56
	[redacted]	SARS-CoV-2 Infection	05DEC2021	1/Prevax	07SEP2021	1	122	128.63
				2/2 Weeks	11OCT2021	14	47	117.14
				2/1 Month	26OCT2021	29	29	96.68
				Delivery	05DEC2021	69	780	1199.93
	[redacted]	SARS-CoV-2 Infection	22DEC2021	1/Prevax	07SEP2021	1	171	479.96
				2/2 Weeks	11OCT2021	12	238	325.09
				2/1 Month	28OCT2021	29	84	337.62
				Delivery	01DEC2021	63	90	261.37
	[redacted]			1/Prevax	21SEP2021	1	10	5.81
				2/2 Weeks	26OCT2021	15	10	4.59
				2/1 Month	09NOV2021	29	10	3.3
				Delivery	20NOV2021	40	10	3.06

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16.2.6.1.2 Listing of Assay Data – HIV Positive Participants (Maternal)

Vaccine Group (as Randomized)	Participant	SARS-CoV-2 Infection[a] / Confirmed COVID-19	Onset Date	Dose/Sampling Time Point	Date of Sample	Rel Day[b]	Assay: SARS-CoV-2 Neutralization Assay - NT50 (Titer)	Assay: Full-Length S-Binding IgG Level Assay (U/mL)
	[redacted]	SARS-CoV-2 Infection	29SEP2021	1/Prevax	29SEP2021	1	10	226.15
				2/2 Weeks	03NOV2021	15	10	148.26
				2/1 Month	17NOV2021	29	16	180.71
				Delivery	07DEC2021	49	140	1263.26
	[redacted]	SARS-CoV-2 Infection	20SEP2021	1/Prevax	20SEP2021	1	10	205.3
	[redacted]	SARS-CoV-2 Infection	29DEC2021	1/Prevax	15OCT2021	1	10	270.14
				2/2 Weeks	17NOV2021	14	10	240.52
				2/1 Month	02DEC2021	29	10	375.36
				Delivery	29DEC2021	56	10	526.65

Abbreviations: IgG = immunoglobulin G; NT50 = 50% neutralizing titer; S = spike protein; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

a. SARS-CoV-2 infection without confirmed COVID-19.

b. Relative day (Rel Day) = date of blood draw - date of last vaccination + 1. For a blood draw that occurred before the date of the last vaccination, + 1 was not added to compute relative day.

PFIZER CONFIDENTIAL SDTM Creation: 12JAN2024 (03:07) Source Data: adva Table Generation: 19FEB2024 (03:16)
(Database snapshot date: Safety [29Mar2023], Immunogenicity [09Jan2024]) Output File: ./nda3/C4591015_CSR/adva_l001_hiv

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16.2.6.2.1 Listing of Assay Data (Infant)

Maternal Vaccine Group (as Randomized)	Participant	Sampling Time Point	Date of Sample	Assay Full-Length S-Binding IgG Level Assay (U/mL)
BNT162b2 (30 µg)	[redacted]	Birth	15JUN2021	1260.05
		6 Months of age	14DEC2021	20.51
	[redacted]	Birth	20JUL2021	39962.8
	[redacted]	Birth	09APR2021	9981.28
		6 Months of age	17SEP2021	116.83
	[redacted]	Birth	30JUN2021	6321.29
		6 Months of age	27DEC2021	226.86
	[redacted]	Birth	03JUL2021	3460.08
	[redacted]	Birth	22JUL2021	2076.79
		6 Months of age	08MAR2022	419.95
	[redacted]	Birth	14JUL2021	9535.46
	[redacted]	Birth	01JUN2021	5.47
		6 Months of age	12NOV2021	297.51
	[redacted]	Birth	18JUL2021	3310.15
		6 Months of age	07JAN2022	649.64
	[redacted]	Birth	27JUL2021	23926.05
		6 Months of age	04JAN2022	423.24
	[redacted]	Birth	26JUN2021	1077.91
		6 Months of age	06DEC2021	197.57
	[redacted]	Birth	09AUG2021	4041.54
		6 Months of age	24FEB2022	48.9
	[redacted]	Birth	26JUN2021	1216.78
		6 Months of age	16DEC2021	22.18
	[redacted]	Birth	14AUG2021	4443.71

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16.2.6.2.1 Listing of Assay Data (Infant)

Maternal Vaccine Group (as Randomized)	Participant	Sampling Time Point	Date of Sample	Assay Full-Length S-Binding IgG Level Assay (U/mL)
	[redacted]	Birth	16AUG2021	18313.65
		6 Months of age	04MAR2022	409.67
	[redacted]	Birth	18AUG2021	15251.28
		6 Months of age	01MAR2022	320.71
	[redacted]	Birth	04AUG2021	5470.49
	[redacted]	Birth	27AUG2021	10772.56
		6 Months of age	11FEB2022	324
	[redacted]	Birth	19AUG2021	27416.18
		6 Months of age	01APR2022	294.07
	[redacted]	Birth	13AUG2021	11580.24
		6 Months of age	25JAN2022	1740.7
	[redacted]	Birth	25JUN2021	188.15
		6 Months of age	23DEC2021	3.44
	[redacted]	Birth	03SEP2021	4013.56
		6 Months of age	21FEB2022	289.71
	[redacted]	Birth	30AUG2021	6229.48
		6 Months of age	11FEB2022	435.35
	[redacted]	Birth	15JUL2021	1406.57
		6 Months of age	31JAN2022	25.35
	[redacted]	Birth	02SEP2021	4658.48
	[redacted]	Birth	11AUG2021	1416.41
		6 Months of age	11FEB2022	235.78
	[redacted]	Birth	29JUL2021	17599.8
		6 Months of age	07JAN2022	1346.71

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16.2.6.2.1 Listing of Assay Data (Infant)

Maternal Vaccine Group (as Randomized)	Participant	Sampling Time Point	Date of Sample	Assay Full-Length S-Binding IgG Level Assay (U/mL)
	[redacted]	Birth	10SEP2021	4561.59
	[redacted]	Birth	13MAY2021	11777.59
	[redacted]	Birth	22JUN2021	5414.63
	[redacted]	Birth	30JUN2021	5994.09
	[redacted]	Birth	25APR2021	4715.21
		6 Months of age	06OCT2021	151.51
	[redacted]	Birth	07MAY2021	16510.83
	[redacted]	Birth	07JUN2021	3337.04
	[redacted]	Birth	24JUN2021	3211.29
	[redacted]	Birth	04AUG2021	5579.58
		6 Months of age	07FEB2022	362.27
	[redacted]	Birth	15AUG2021	3518.72
	[redacted]	Birth	17AUG2021	4420.35
		6 Months of age	25JAN2022	444.25
	[redacted]	Birth	05AUG2021	3934.93
		6 Months of age	13JAN2022	243.76
	[redacted]	Birth	04MAY2021	3149.56
		6 Months of age	15NOV2021	42.33
	[redacted]	Birth	14JUN2021	2562.53
		6 Months of age	22DEC2021	67.82
	[redacted]	Birth	22JUN2021	3518.14
		6 Months of age	08DEC2021	134.13
	[redacted]	Birth	27JUL2021	10067.96
		6 Months of age	03JAN2022	551.41

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16.2.6.2.1 Listing of Assay Data (Infant)

Maternal Vaccine Group (as Randomized)	Participant	Sampling Time Point	Date of Sample	Assay Full-Length S-Binding IgG Level Assay (U/mL)
	[redacted]	Birth	14JUL2021	11738.34
		6 Months of age	21DEC2021	772.51
	[redacted]	6 Months of age	04OCT2021	1147.85
	[redacted]	Birth	16JUN2021	627.82
		6 Months of age	29NOV2021	214.54
	[redacted]	Birth	09APR2021	2793.6
		6 Months of age	23SEP2021	3171.86
	[redacted]	Birth	11APR2021	60561.92
	[redacted]	Birth	04APR2021	8088.4
		6 Months of age	20SEP2021	48.34
	[redacted]	Birth	14MAY2021	1321.48
	[redacted]	Birth	15MAY2021	468.76
		6 Months of age	18NOV2021	4712.61
	[redacted]	Birth	23JUN2021	970.17
		6 Months of age	30NOV2021	97.19
	[redacted]	Birth	04JUN2021	1087.06
		6 Months of age	20DEC2021	200.7
	[redacted]	Birth	25MAY2021	449.35
		6 Months of age	19NOV2021	123.44
	[redacted]	Birth	21JUN2021	36733.34
		6 Months of age	29NOV2021	1435.57
	[redacted]	Birth	02JUL2021	3797.4
		6 Months of age	13DEC2021	872.91
	[redacted]	Birth	09JUN2021	891.13

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16.2.6.2.1 Listing of Assay Data (Infant)

Maternal Vaccine Group (as Randomized)	Participant	Sampling Time Point	Date of Sample	Assay Full-Length S-Binding IgG Level Assay (U/mL)
		6 Months of age	16DEC2021	21.97
	[redacted]	6 Months of age	11JAN2022	29.04
	[redacted]	6 Months of age	03FEB2022	2583.77
	[redacted]	Birth	03JUL2021	BLQ
		6 Months of age	19JAN2022	24.74
	[redacted]	Birth	06JUL2021	3497.2
		6 Months of age	21JAN2022	4961.62
	[redacted]	Birth	26JUN2021	BLQ
		6 Months of age	12JAN2022	5066.73
	[redacted]	6 Months of age	24JAN2022	4957.58
	[redacted]	Birth	24SEP2021	21.85
		6 Months of age	07MAR2022	205.66
	[redacted]	6 Months of age	24JAN2022	229.4
	[redacted]	Birth	25SEP2021	1389.28
		6 Months of age	04MAR2022	1338.84
	[redacted]	Birth	03NOV2021	9921.99
		6 Months of age	09MAY2022	21.49
	[redacted]	Birth	25NOV2021	32.63
		6 Months of age	05MAY2022	9.6
	[redacted]	Birth	25OCT2021	1638.59
		6 Months of age	26APR2022	1816.03
	[redacted]	Birth	14DEC2021	1027.83
		6 Months of age	02JUN2022	1500.01
	[redacted]	Birth	13MAY2021	4423.04

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16.2.6.2.1 Listing of Assay Data (Infant)

Maternal Vaccine Group (as Randomized)	Participant	Sampling Time Point	Date of Sample	Assay Full-Length S-Binding IgG Level Assay (U/mL)
		6 Months of age	10NOV2021	170.39
	[redacted]	Birth	08JUN2021	7623.12
		6 Months of age	09DEC2021	386.27
	[redacted]	6 Months of age	17JAN2022	293.24
	[redacted]	Birth	11JUL2021	7413.87
		6 Months of age	13JAN2022	394.48
	[redacted]	Birth	28JUN2021	4677.17
		6 Months of age	16DEC2021	201.68
	[redacted]	Birth	09JUL2021	14841.15
		6 Months of age	16DEC2021	1055.95
	[redacted]	Birth	23SEP2021	4057.8
		6 Months of age	25MAR2022	QNS
	[redacted]	Birth	22SEP2021	35247.89
		6 Months of age	22MAR2022	1286.3
	[redacted]	Birth	11MAY2021	12878.82
	[redacted]	Birth	07AUG2021	10963.46
		6 Months of age	10FEB2022	470.48
	[redacted]	Birth	30SEP2021	826.45
		6 Months of age	05APR2022	338.09
	[redacted]	Birth	15NOV2021	33865.82
	[redacted]	Birth	22NOV2021	19546.84
		6 Months of age	23MAY2022	410.19
	[redacted]	Birth	28JAN2022	51383.09
		6 Months of age	06JUL2022	1186.41

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16.2.6.2.1 Listing of Assay Data (Infant)

Maternal Vaccine Group (as Randomized)	Participant	Sampling Time Point	Date of Sample	Assay Full-Length S-Binding IgG Level Assay (U/mL)
	[redacted]	Birth	15SEP2021	6344.69
		6 Months of age	23FEB2022	182.09
	[redacted]	Birth	21OCT2021	31236.2
		6 Months of age	03MAY2022	384.43
	[redacted]	Birth	19OCT2021	12716.24
		6 Months of age	04APR2022	127.19
	[redacted]	Birth	12DEC2021	12946.71
		6 Months of age	01JUN2022	235.81
	[redacted]	Birth	17DEC2021	13756.11
		6 Months of age	06JUN2022	764.32
	[redacted]	6 Months of age	15JUN2022	89.82
	[redacted]	Birth	10JAN2022	15708.95
		6 Months of age	22JUN2022	625.58
	[redacted]	Birth	30DEC2021	13529.02
		6 Months of age	08JUN2022	746.28
	[redacted]	Birth	14NOV2021	13122.59
		6 Months of age	27MAY2022	498.42
	[redacted]	Birth	26DEC2021	15484.73
		6 Months of age	29JUN2022	491.57
	[redacted]	Birth	15JAN2022	28409.86
		6 Months of age	29JUN2022	718.86
	[redacted]	Birth	16DEC2021	12045.75
		6 Months of age	01JUL2022	142.49
	[redacted]	Birth	11JAN2022	34466.33

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16.2.6.2.1 Listing of Assay Data (Infant)

Maternal Vaccine Group (as Randomized)	Participant	Sampling Time Point	Date of Sample	Assay Full-Length S-Binding IgG Level Assay (U/mL)
		6 Months of age	22JUN2022	589.04
	[redacted]	Birth	23DEC2021	11103.08
		6 Months of age	01JUN2022	287.79
	[redacted]	Birth	11DEC2021	15517.36
		6 Months of age	01JUN2022	327.19
	[redacted]	Birth	16AUG2021	2272.73
		6 Months of age	26JAN2022	103.09
	[redacted]	Birth	11SEP2021	10019.05
		6 Months of age	28FEB2022	347.02
	[redacted]	Birth	22JUL2021	4871.06
		6 Months of age	19JAN2022	92.14
	[redacted]	Birth	03SEP2021	3330.6
		6 Months of age	16FEB2022	433.09
	[redacted]	Birth	06SEP2021	6022.78
		6 Months of age	28FEB2022	213.95
	[redacted]	Birth	12DEC2021	2409.17
	[redacted]	Birth	15SEP2021	14413.56
		6 Months of age	22FEB2022	358.33
	[redacted]	Birth	25OCT2021	18454.38
	[redacted]	Birth	08OCT2021	16099.3
		6 Months of age	17MAR2022	338.95
	[redacted]	Birth	22DEC2021	71414.98
		6 Months of age	30MAY2022	1123.56
	[redacted]	Birth	29JUL2021	1069.99

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16.2.6.2.1 Listing of Assay Data (Infant)

Maternal Vaccine Group (as Randomized)	Participant	Sampling Time Point	Date of Sample	Assay Full-Length S-Binding IgG Level Assay (U/mL)
		6 Months of age	14JAN2022	14.95
	[redacted]	Birth	22JUL2021	32165.78
	[redacted]	Birth	14JUL2021	9105.11
		6 Months of age	11JAN2022	208.25
	[redacted]	Birth	27OCT2021	4756.23
	[redacted]	Birth	30SEP2021	18636.45
	[redacted]	Birth	05AUG2021	19656.05
		6 Months of age	07FEB2022	378.89
	[redacted]	6 Months of age	03MAY2022	338.82
	[redacted]	Birth	20NOV2021	40646.32
	[redacted]	6 Months of age	25APR2022	1485.97
	[redacted]	Birth	28JUL2021	54306.98
		6 Months of age	12JAN2022	1621.46
	[redacted]	Birth	25JUL2021	3064.74
		6 Months of age	25JAN2022	127.22
	[redacted]	6 Months of age	25APR2022	137.83
	[redacted]	Birth	12JUL2021	22241.22
		6 Months of age	10JAN2022	222.5
	[redacted]	Birth	20JUL2021	20757.74
		6 Months of age	24JAN2022	416.61
	[redacted]	Birth	13JUL2021	39901.05
		6 Months of age	21DEC2021	760.44
	[redacted]	Birth	23AUG2021	30159.51
	[redacted]	Birth	23AUG2021	QNS

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16.2.6.2.1 Listing of Assay Data (Infant)

Maternal Vaccine Group (as Randomized)	Participant	Sampling Time Point	Date of Sample	Assay Full-Length S-Binding IgG Level Assay (U/mL)
		6 Months of age	02FEB2022	1737.19
	[redacted]	Birth	04AUG2021	2153.18
	[redacted]	Birth	06AUG2021	40082.98
		6 Months of age	26JAN2022	584.51
	[redacted]	Birth	26AUG2021	22525.24
		6 Months of age	15FEB2022	1803.88
	[redacted]	Birth	25AUG2021	6350.19
		6 Months of age	14FEB2022	704.27
	[redacted]	Birth	01SEP2021	39024.39
	[redacted]	Birth	14SEP2021	5703.54
		6 Months of age	02MAY2022	QNS
	[redacted]	Birth	19DEC2021	4327.9
		6 Months of age	06JUN2022	147.26
	[redacted]	Birth	17JUL2021	5947.59
		6 Months of age	04FEB2022	87.09
	[redacted]	Birth	20AUG2021	2828.98
		6 Months of age	28JAN2022	49.82
	[redacted]	Birth	01OCT2021	3633.72
		6 Months of age	13MAR2022	87.11
	[redacted]	Birth	16SEP2021	5311.02
		6 Months of age	13MAR2022	54.72
	[redacted]	Birth	11SEP2021	10161.38
	[redacted]	Birth	21OCT2021	1411.98
		6 Months of age	30MAR2022	58.83

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16.2.6.2.1 Listing of Assay Data (Infant)

Maternal Vaccine Group (as Randomized)	Participant	Sampling Time Point	Date of Sample	Assay Full-Length S-Binding IgG Level Assay (U/mL)
	[redacted]	Birth	19SEP2021	10379.46
		6 Months of age	10MAR2022	153.56
	[redacted]	Birth	28SEP2021	4720.44
		6 Months of age	15MAR2022	932.04
	[redacted]	Birth	21SEP2021	5591.47
		6 Months of age	17MAR2022	131.7
	[redacted]	Birth	29AUG2021	1359.91
		6 Months of age	08MAR2022	26.41
	[redacted]	Birth	20JUL2021	2155.61
		6 Months of age	29DEC2021	236.72
	[redacted]	Birth	03AUG2021	14137.63
		6 Months of age	03FEB2022	577.58
	[redacted]	Birth	15JUL2021	4253.24
		6 Months of age	07JAN2022	101.14
	[redacted]	Birth	16AUG2021	9278.42
		6 Months of age	09FEB2022	371.27
	[redacted]	Birth	21JUL2021	11822.53
		6 Months of age	02FEB2022	267.45
	[redacted]	Birth	02AUG2021	8509.16
		6 Months of age	16FEB2022	207.65
	[redacted]	Birth	05SEP2021	2200.29
		6 Months of age	16FEB2022	102.78
	[redacted]	Birth	17AUG2021	9484.25
		6 Months of age	26JAN2022	274.84

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16.2.6.2.1 Listing of Assay Data (Infant)

Maternal Vaccine Group (as Randomized)	Participant	Sampling Time Point	Date of Sample	Assay Full-Length S-Binding IgG Level Assay (U/mL)
	[redacted]	Birth	04JAN2022	1549.84
		6 Months of age	14JUN2022	55.86
Placebo	[redacted]	Birth	16MAY2021	1
	[redacted]	Birth	27JUL2021	1.09
	[redacted]	Birth	24JUL2021	4.04
	[redacted]	Birth	08AUG2021	443
		6 Months of age	28JAN2022	14095.51
	[redacted]	Birth	02OCT2021	BLQ
		6 Months of age	04MAR2022	24992.78
	[redacted]	Birth	25MAY2021	25.85
	[redacted]	Birth	25MAY2021	1.17
		6 Months of age	06DEC2021	BLQ
	[redacted]	Birth	27JUN2021	362.77
		6 Months of age	10DEC2021	47.69
	[redacted]	Birth	11JUL2021	1.88
	[redacted]	Birth	14JUL2021	25.04
	[redacted]	Birth	05JUL2021	339.68
		6 Months of age	15DEC2021	24.63
	[redacted]	Birth	07JUL2021	425.81
	[redacted]	Birth	01AUG2021	502.81
		6 Months of age	10JAN2022	22.36
	[redacted]	Birth	11JUL2021	BLQ
		6 Months of age	04JAN2022	BLQ
	[redacted]	Birth	09AUG2021	2.27

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16.2.6.2.1 Listing of Assay Data (Infant)

Maternal Vaccine Group (as Randomized)	Participant	Sampling Time Point	Date of Sample	Assay Full-Length S-Binding IgG Level Assay (U/mL)
		6 Months of age	17JAN2022	18.01
	[redacted]	Birth	23JUL2021	138.19
		6 Months of age	07JAN2022	23.17
	[redacted]	Birth	10JUL2021	11.5
		6 Months of age	04JAN2022	556.18
	[redacted]	Birth	02SEP2021	3.23
		6 Months of age	09FEB2022	654.44
	[redacted]	Birth	13AUG2021	BLQ
	[redacted]	Birth	09JUL2021	3.76
		6 Months of age	11JAN2022	4.35
	[redacted]	Birth	19AUG2021	0.91
		6 Months of age	22FEB2022	93.94
	[redacted]	Birth	13SEP2021	320.66
		6 Months of age	24MAR2022	4.49
	[redacted]	Birth	26JUL2021	4.43
		6 Months of age	31JAN2022	5.99
	[redacted]	Birth	18JUL2021	1.64
		6 Months of age	31JAN2022	2.51
	[redacted]	Birth	28JUL2021	3.26
		6 Months of age	31JAN2022	BLQ
	[redacted]	Birth	08AUG2021	1073.64
	[redacted]	Birth	04AUG2021	1.09
		6 Months of age	10FEB2022	28.99
	[redacted]	Birth	12JUN2021	12.16

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16.2.6.2.1 Listing of Assay Data (Infant)

Maternal Vaccine Group (as Randomized)	Participant	Sampling Time Point	Date of Sample	Assay Full-Length S-Binding IgG Level Assay (U/mL)
		6 Months of age	09DEC2021	1.73
	[redacted]	Birth	03JUL2021	1.13
		6 Months of age	14JAN2022	2337.93
	[redacted]	Birth	03JUN2021	7.9
	[redacted]	Birth	17JUN2021	2.01
	[redacted]	Birth	04JUN2021	BLQ
	[redacted]	Birth	22JUL2021	BLQ
		6 Months of age	18JAN2022	BLQ
	[redacted]	Birth	28APR2021	BLQ
	[redacted]	Birth	24MAY2021	BLQ
		6 Months of age	13DEC2021	1.04
	[redacted]	Birth	06JUN2021	BLQ
		6 Months of age	15DEC2021	BLQ
	[redacted]	Birth	09JUL2021	BLQ
	[redacted]	Birth	11JUL2021	1.76
	[redacted]	Birth	04AUG2021	1.07
	[redacted]	Birth	27JUL2021	1.7
	[redacted]	Birth	14AUG2021	1.06
	[redacted]	Birth	29APR2021	BLQ
	[redacted]	Birth	06JUN2021	BLQ
		6 Months of age	19NOV2021	BLQ
	[redacted]	Birth	29MAY2021	7.16
		6 Months of age	08DEC2021	528.03
	[redacted]	Birth	11JUN2021	2.17

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16.2.6.2.1 Listing of Assay Data (Infant)

Maternal Vaccine Group (as Randomized)	Participant	Sampling Time Point	Date of Sample	Assay Full-Length S-Binding IgG Level Assay (U/mL)
		6 Months of age	19NOV2021	1.25
	[redacted]	Birth	13JUL2021	1.42
		6 Months of age	21JAN2022	0.95
	[redacted]	Birth	27JUN2021	44.13
		6 Months of age	10DEC2021	616.35
	[redacted]	Birth	15APR2021	BLQ
		6 Months of age	28OCT2021	BLQ
	[redacted]	Birth	26MAY2021	160.9
		6 Months of age	10DEC2021	246.47
	[redacted]	6 Months of age	17DEC2021	4722.62
	[redacted]	Birth	26APR2021	32.63
	[redacted]	Birth	14MAY2021	641.75
		6 Months of age	04NOV2021	12.8
	[redacted]	Birth	10MAY2021	17.2
		6 Months of age	14NOV2021	2.17
	[redacted]	Birth	18JUL2021	186.4
		6 Months of age	27DEC2021	21.02
	[redacted]	Birth	30MAY2021	60.98
		6 Months of age	08NOV2021	13.12
	[redacted]	Birth	17MAY2021	121.39
		6 Months of age	04NOV2021	19.51
	[redacted]	Birth	27MAY2021	BLQ
	[redacted]	Birth	11JUN2021	BLQ
		6 Months of age	24NOV2021	1.67

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16.2.6.2.1 Listing of Assay Data (Infant)

Maternal Vaccine Group (as Randomized)	Participant	Sampling Time Point	Date of Sample	Assay Full-Length S-Binding IgG Level Assay (U/mL)
	[redacted]	Birth	29JUL2021	BLQ
	[redacted]	Birth	15JUN2021	1.37
		6 Months of age	27DEC2021	237.84
	[redacted]	6 Months of age	24JAN2022	4685.5
	[redacted]	Birth	23JUL2021	1331.41
		6 Months of age	20JAN2022	619.22
	[redacted]	6 Months of age	24JAN2022	269.09
	[redacted]	Birth	21JUL2021	3.88
		6 Months of age	20JAN2022	563.27
	[redacted]	Birth	21AUG2021	BLQ
		6 Months of age	10FEB2022	159.63
	[redacted]	Birth	12OCT2021	2408.54
	[redacted]	Birth	24SEP2021	216.66
		6 Months of age	03MAR2022	13.13
	[redacted]	Birth	13JAN2022	628.29
		6 Months of age	22JUN2022	3.08
	[redacted]	Birth	20DEC2021	BLQ
		6 Months of age	02JUN2022	255.57
	[redacted]	Birth	03DEC2021	645.82
		6 Months of age	07JUN2022	21.27
	[redacted]	Birth	24APR2021	1.59
	[redacted]	Birth	28MAY2021	0.88
		6 Months of age	17NOV2021	BLQ
	[redacted]	Birth	08AUG2021	3.83

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16.2.6.2.1 Listing of Assay Data (Infant)

Maternal Vaccine Group (as Randomized)	Participant	Sampling Time Point	Date of Sample	Assay Full-Length S-Binding IgG Level Assay (U/mL)
		6 Months of age	24JAN2022	4.11
	[redacted]	Birth	21JUL2021	1.94
		6 Months of age	26JAN2022	30.61
	[redacted]	Birth	03AUG2021	BLQ
	[redacted]	Birth	24NOV2021	1.1
	[redacted]	Birth	01DEC2021	329.1
		6 Months of age	01JUN2022	2.77
	[redacted]	Birth	20DEC2021	6
		6 Months of age	04JUL2022	2.11
	[redacted]	Birth	28JUN2021	1.87
		6 Months of age	06JAN2022	0.97
	[redacted]	Birth	19AUG2021	4.85
		6 Months of age	25JAN2022	BLQ
	[redacted]	Birth	25OCT2021	671.05
		6 Months of age	28APR2022	20.3
	[redacted]	Birth	21OCT2021	2888.49
		6 Months of age	26APR2022	142.27
	[redacted]	Birth	10DEC2021	942.24
		6 Months of age	19MAY2022	36.01
	[redacted]	Birth	20DEC2021	1386.4
		6 Months of age	30MAY2022	5.57
	[redacted]	Birth	05AUG2021	6.74
		6 Months of age	08FEB2022	0.92
	[redacted]	Birth	17OCT2021	49.67

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16.2.6.2.1 Listing of Assay Data (Infant)

Maternal Vaccine Group (as Randomized)	Participant	Sampling Time Point	Date of Sample	Assay Full-Length S-Binding IgG Level Assay (U/mL)
		6 Months of age	03MAY2022	30.88
	[redacted]	Birth	19OCT2021	36248.22
		6 Months of age	06MAY2022	14.07
	[redacted]	Birth	23NOV2021	1.07
		6 Months of age	03MAY2022	3.65
	[redacted]	Birth	27OCT2021	258.64
		6 Months of age	03MAY2022	5.47
	[redacted]	Birth	28DEC2021	433.31
		6 Months of age	08JUN2022	11.85
	[redacted]	Birth	05OCT2021	40
		6 Months of age	14APR2022	71.42
	[redacted]	Birth	23OCT2021	84.9
		6 Months of age	06MAY2022	160.27
	[redacted]	Birth	13JAN2022	3946.33
		6 Months of age	22JUN2022	307.5
	[redacted]	6 Months of age	30MAY2022	10.62
	[redacted]	Birth	15JAN2022	2918.06
		6 Months of age	29JUN2022	90.12
	[redacted]	Birth	17DEC2021	1044.35
		6 Months of age	08JUN2022	355.65
	[redacted]	Birth	21DEC2021	95.89
		6 Months of age	08JUN2022	2.82
	[redacted]	Birth	05JAN2022	12636.85
		6 Months of age	22JUN2022	342.71

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16.2.6.2.1 Listing of Assay Data (Infant)

Maternal Vaccine Group (as Randomized)	Participant	Sampling Time Point	Date of Sample	Assay Full-Length S-Binding IgG Level Assay (U/mL)
	[redacted]	6 Months of age	01JUL2022	29.16
	[redacted]	Birth	10AUG2021	1.55
	[redacted]	Birth	24AUG2021	0.9
	[redacted]	Birth	24AUG2021	BLQ
		6 Months of age	16FEB2022	BLQ
	[redacted]	Birth	02OCT2021	1.03
		6 Months of age	06APR2022	BLQ
	[redacted]	Birth	04DEC2021	275.22
		6 Months of age	18MAY2022	8.45
	[redacted]	Birth	23NOV2021	1.2
		6 Months of age	03MAY2022	2754.68
	[redacted]	Birth	25NOV2021	404.37
		6 Months of age	24MAY2022	91.6
	[redacted]	Birth	18NOV2021	467.97
		6 Months of age	06MAY2022	445.45
	[redacted]	Birth	16NOV2021	121.94
	[redacted]	Birth	31DEC2021	3064.82
		6 Months of age	24JUN2022	23.5
	[redacted]	Birth	02AUG2021	76.53
	[redacted]	Birth	01SEP2021	181.13
		6 Months of age	11MAR2022	6.02
	[redacted]	Birth	18OCT2021	3.95
	[redacted]	Birth	24NOV2021	BLQ
	[redacted]	Birth	20JUL2021	1819.53

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16.2.6.2.1 Listing of Assay Data (Infant)

Maternal Vaccine Group (as Randomized)	Participant	Sampling Time Point	Date of Sample	Assay Full-Length S-Binding IgG Level Assay (U/mL)
	[redacted]	Birth	26SEP2021	1.49
		6 Months of age	30MAR2022	130.31
	[redacted]	Birth	17OCT2021	7.84
	[redacted]	Birth	18NOV2021	BLQ
	[redacted]	Birth	08DEC2021	549.57
		6 Months of age	17MAY2022	20.92
	[redacted]	Birth	17JUL2021	536.14
		6 Months of age	18JAN2022	9.36
	[redacted]	Birth	12JUL2021	BLQ
	[redacted]	Birth	26JUL2021	2.91
		6 Months of age	11JAN2022	4.77
	[redacted]	Birth	10JUL2021	1179.65
	[redacted]	Birth	01AUG2021	6105.91
	[redacted]	Birth	29JUL2021	2.62
		6 Months of age	24JAN2022	24.64
	[redacted]	Birth	30JUN2021	BLQ
	[redacted]	Birth	20AUG2021	859.97
	[redacted]	Birth	17JUL2021	176.66
	[redacted]	Birth	26AUG2021	126.5
		6 Months of age	04APR2022	290.76
	[redacted]	Birth	04AUG2021	4.49
		6 Months of age	13JAN2022	1.02
	[redacted]	Birth	03AUG2021	25.93
		6 Months of age	13JAN2022	5.32

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16.2.6.2.1 Listing of Assay Data (Infant)

Maternal Vaccine Group (as Randomized)	Participant	Sampling Time Point	Date of Sample	Assay Full-Length S-Binding IgG Level Assay (U/mL)
	[redacted]	Birth	24AUG2021	BLQ
		6 Months of age	19FEB2022	29.51
	[redacted]	Birth	16AUG2021	2.66
		6 Months of age	19FEB2022	BLQ
	[redacted]	Birth	09SEP2021	22.79
		6 Months of age	26FEB2022	122.06
	[redacted]	Birth	19AUG2021	1.58
		6 Months of age	21MAR2022	BLQ
	[redacted]	Birth	02SEP2021	1.44
		6 Months of age	21FEB2022	BLQ
	[redacted]	Birth	06DEC2021	165.17
	[redacted]	Birth	14JUL2021	BLQ
		6 Months of age	10JAN2022	BLQ
	[redacted]	Birth	01AUG2021	17.77
		6 Months of age	09FEB2022	BLQ
	[redacted]	Birth	06AUG2021	BLQ
		6 Months of age	09FEB2022	2.75
	[redacted]	Birth	31JUL2021	10
		6 Months of age	14FEB2022	228.98
	[redacted]	Birth	06AUG2021	2.55
	[redacted]	Birth	25JUL2021	0.94
	[redacted]	Birth	21AUG2021	1.38
		6 Months of age	22FEB2022	BLQ
	[redacted]	Birth	28AUG2021	4651.52

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16.2.6.2.1 Listing of Assay Data (Infant)

Maternal Vaccine Group (as Randomized)	Participant	Sampling Time Point	Date of Sample	Assay Full-Length S-Binding IgG Level Assay (U/mL)
		6 Months of age	16FEB2022	341.28
	[redacted]	Birth	18JUL2021	1.41
		6 Months of age	26JAN2022	BLQ
	[redacted]	Birth	04AUG2021	2.79
		6 Months of age	26JAN2022	1.48
	[redacted]	Birth	15NOV2021	1.02
		6 Months of age	17MAY2022	48.31

Abbreviations: BLQ = below the limit of quantitation; IgG = immunoglobulin G; QNS = quantity not sufficient for analysis; S = spike protein.
Note: Infants born to human immunodeficiency virus (HIV)-positive participants are not included in this listing.
PFIZER CONFIDENTIAL SDTM Creation: 12JAN2024 (03:07) Source Data: adva Table Generation: 19FEB2024 (03:16)
(Database snapshot date: Safety [29Mar2023], Immunogenicity [09Jan2024]) Output File: ./nda3/C4591015_CSR/adva_l001_inf

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16.2.6.2.2 Listing of Assay Data – Born to HIV Positive Maternal Participants (Infant)

Maternal Vaccine Group (as Randomized)	Participant	Sampling Time Point	Date of Sample	Assay Full-Length S-Binding IgG Level Assay (U/mL)
BNT162b2 (30 µg)	[redacted]	Birth	02JAN2022	10669.47
		6 Months of age	13JUN2022	473.64
	[redacted]	Birth	25DEC2021	26971.42
		6 Months of age	08JUN2022	548.83
	[redacted]	Birth	25NOV2021	406.32
		6 Months of age	06MAY2022	600.55
	[redacted]	Birth	31OCT2021	8960.45
		6 Months of age	19APR2022	471.44
	[redacted]	Birth	13DEC2021	5018.82
		6 Months of age	20MAY2022	361.61
	[redacted]	Birth	14NOV2021	1551.72
		6 Months of age	25APR2022	169.12
	[redacted]	Birth	08DEC2021	28257.87
		6 Months of age	22JUN2022	326.25
	[redacted]	Birth	28NOV2021	39970
		6 Months of age	02JUN2022	723.29
	[redacted]	Birth	15JAN2022	3431.9
	[redacted]	Birth	25JAN2022	15750.44
		6 Months of age	15JUL2022	5029.4
	[redacted]	Birth	15NOV2021	4998.95
Placebo	[redacted]	Birth	28DEC2021	1561.33
		6 Months of age	06JUN2022	61.78
	[redacted]	Birth	24JAN2022	366.02
		6 Months of age	01JUL2022	425.67

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16.2.6.2.2 Listing of Assay Data – Born to HIV Positive Maternal Participants (Infant)

Maternal Vaccine Group (as Randomized)	Participant	Sampling Time Point	Date of Sample	Assay Full-Length S-Binding IgG Level Assay (U/mL)
	[redacted]	Birth	18NOV2021	1084.89
	[redacted]	Birth	18NOV2021	169.34
		6 Months of age	28APR2022	7.01
	[redacted]	Birth	04DEC2021	311.44
		6 Months of age	19MAY2022	60.55
	[redacted]	Birth	01DEC2021	444.77
		6 Months of age	18MAY2022	65.66
	[redacted]	Birth	20NOV2021	4.92
		6 Months of age	19MAY2022	43.4
	[redacted]	Birth	07DEC2021	572.41
	[redacted]	Birth	29DEC2021	174.87
		6 Months of age	24JUN2022	653.18

Abbreviations: IgG = immunoglobulin G; S = spike protein.
PFIZER CONFIDENTIAL SDTM Creation: 12JAN2024 (03:07) Source Data: adva Table Generation: 01MAR2024 (02:03)
(Database snapshot date: Safety [29Mar2023], Immunogenicity [09Jan2024]) Output File: ./nda3/C4591015_CSR/adva_l001_inf_hiv

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16.2.6.3 Listing of Assay Data – Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Participant	Dose/Sampling Time Point	Date of Sample	Rel Day[a]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)
BNT162b2 (30 µg)	[redacted]	1/Prevax	21SEP2020	1	10
		2/1 Month	09NOV2020	29	2829
	[redacted]	1/Prevax	11AUG2020	1	10
		2/1 Month	28SEP2020	29	840
	[redacted]	1/Prevax	29AUG2020	1	10
		2/1 Month	16OCT2020	29	6626
	[redacted]	1/Prevax	10AUG2020	1	10
		2/1 Month	29SEP2020	30	2009
	[redacted]	1/Prevax	19AUG2020	1	10
		2/1 Month	13OCT2020	33	2165
	[redacted]	1/Prevax	02OCT2020	1	10
		2/1 Month	20NOV2020	29	1618
	[redacted]	1/Prevax	03AUG2020	1	10
		2/1 Month	22SEP2020	30	3581
	[redacted]	1/Prevax	27OCT2020	1	10
		2/1 Month	17DEC2020	29	4114
	[redacted]	1/Prevax	01SEP2020	1	10
		2/1 Month	21OCT2020	29	2260
	[redacted]	1/Prevax	23AUG2020	1	10
		2/1 Month	12OCT2020	30	3194
	[redacted]	1/Prevax	11SEP2020	1	10
		2/1 Month	02NOV2020	32	4199
	[redacted]	1/Prevax	25AUG2020	1	10
		2/1 Month	13OCT2020	29	600

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16.2.6.3 Listing of Assay Data – Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Participant	Dose/Sampling Time Point	Date of Sample	Rel Day[a]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)
	[redacted]	1/Prevax	09SEP2020	1	10
		2/1 Month	28OCT2020	31	1425
	[redacted]	1/Prevax	25SEP2020	1	10
		2/1 Month	11NOV2020	29	1122
	[redacted]	1/Prevax	19OCT2020	1	10
		2/1 Month	07DEC2020	50	166
	[redacted]	1/Prevax	28OCT2020	1	10
		2/1 Month	15DEC2020	29	2943
	[redacted]	1/Prevax	14AUG2020	1	10
		2/1 Month	05OCT2020	33	750
	[redacted]	1/Prevax	04SEP2020	1	10
		2/1 Month	21OCT2020	29	420
	[redacted]	1/Prevax	12AUG2020	1	10
		2/1 Month	30SEP2020	29	4310
	[redacted]	1/Prevax	17AUG2020	1	10
		2/1 Month	07OCT2020	29	3032
	[redacted]	1/Prevax	14AUG2020	1	10
		2/1 Month	07OCT2020	35	968
	[redacted]	1/Prevax	28AUG2020	1	10
		2/1 Month	16OCT2020	29	4844
	[redacted]	1/Prevax	08SEP2020	1	10
		2/1 Month	26OCT2020	28	2963
	[redacted]	1/Prevax	28AUG2020	1	10
		2/1 Month	16OCT2020	29	2227

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16.2.6.3 Listing of Assay Data – Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Participant	Dose/Sampling Time Point	Date of Sample	Rel Day[a]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)
	[redacted]	1/Prevax	07AUG2020	1	10
		2/1 Month	25SEP2020	29	786
	[redacted]	1/Prevax	02SEP2020	1	10
		2/1 Month	21OCT2020	29	1432
	[redacted]	1/Prevax	06AUG2020	1	10
		2/1 Month	22SEP2020	29	3114
	[redacted]	1/Prevax	13AUG2020	1	10
		2/1 Month	30SEP2020	29	5621
	[redacted]	1/Prevax	09SEP2020	1	10
		2/1 Month	02NOV2020	36	1261
	[redacted]	1/Prevax	23OCT2020	1	10
		2/1 Month	17DEC2020	36	1058
	[redacted]	1/Prevax	31JUL2020	1	10
		2/1 Month	18SEP2020	29	3409
	[redacted]	1/Prevax	06AUG2020	1	10
		2/1 Month	30SEP2020	34	4887
	[redacted]	1/Prevax	18AUG2020	1	10
		2/1 Month	08OCT2020	30	2888
	[redacted]	1/Prevax	03AUG2020	1	10
		2/1 Month	22SEP2020	29	2611
	[redacted]	1/Prevax	13AUG2020	1	10
		2/1 Month	02OCT2020	31	1645
	[redacted]	1/Prevax	16SEP2020	1	10
		2/1 Month	06NOV2020	31	321

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16.2.6.3 Listing of Assay Data – Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Participant	Dose/Sampling Time Point	Date of Sample	Rel Day[a]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)
	[redacted]	1/Prevax	03SEP2020	1	10
		2/1 Month	22OCT2020	29	397
	[redacted]	1/Prevax	25AUG2020	1	10
		2/1 Month	13OCT2020	30	7261
	[redacted]	1/Prevax	26OCT2020	1	10
		2/1 Month	23DEC2020	36	786
	[redacted]	1/Prevax	28OCT2020	1	10
		2/1 Month	21DEC2020	33	2315
	[redacted]	1/Prevax	18SEP2020	1	10
		2/1 Month	05NOV2020	29	4302
	[redacted]	1/Prevax	08SEP2020	1	10
		2/1 Month	26OCT2020	29	3240
	[redacted]	1/Prevax	24SEP2020	1	10
		2/1 Month	13NOV2020	32	2581
	[redacted]	1/Prevax	13AUG2020	1	10
		2/1 Month	06OCT2020	33	724
	[redacted]	1/Prevax	14AUG2020	1	10
		2/1 Month	06OCT2020	33	439
	[redacted]	1/Prevax	04AUG2020	1	10
		2/1 Month	23SEP2020	29	3427
	[redacted]	1/Prevax	25AUG2020	1	10
		2/1 Month	14OCT2020	30	2410
	[redacted]	1/Prevax	28AUG2020	1	10
		2/1 Month	22OCT2020	35	525

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16.2.6.3 Listing of Assay Data – Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Participant	Dose/Sampling Time Point	Date of Sample	Rel Day[a]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)
	[redacted]	1/Prevax	10SEP2020	1	10
		2/1 Month	28OCT2020	30	3230
	[redacted]	1/Prevax	01SEP2020	1	10
		2/1 Month	20OCT2020	29	1592
	[redacted]	1/Prevax	02SEP2020	1	10
		2/1 Month	21OCT2020	29	244
	[redacted]	1/Prevax	11SEP2020	1	10
		2/1 Month	30OCT2020	29	579
	[redacted]	1/Prevax	15SEP2020	1	10
		2/1 Month	04NOV2020	30	1113
	[redacted]	1/Prevax	02SEP2020	1	10
		2/1 Month	21OCT2020	29	1747
	[redacted]	1/Prevax	11SEP2020	1	10
		2/1 Month	30OCT2020	29	1597
	[redacted]	1/Prevax	05OCT2020	1	10
		2/1 Month	23NOV2020	27	1368
	[redacted]	1/Prevax	04SEP2020	1	10
		2/1 Month	23OCT2020	29	3427
	[redacted]	1/Prevax	29OCT2020	1	10
		2/1 Month	17DEC2020	29	4787
	[redacted]	1/Prevax	15OCT2020	1	10
		2/1 Month	03DEC2020	29	942
	[redacted]	1/Prevax	16OCT2020	1	10
		2/1 Month	10DEC2020	34	667

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16.2.6.3 Listing of Assay Data – Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Participant	Dose/Sampling Time Point	Date of Sample	Rel Day[a]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)
	[redacted]	1/Prevax	15OCT2020	1	10
		2/1 Month	01DEC2020	29	3872
	[redacted]	1/Prevax	18OCT2020	1	10
		2/1 Month	05DEC2020	29	241
	[redacted]	1/Prevax	10SEP2020	1	10
		2/1 Month	29OCT2020	30	920
	[redacted]	1/Prevax	08OCT2020	1	10
		2/1 Month	01DEC2020	35	1015
	[redacted]	1/Prevax	09OCT2020	1	10
		2/1 Month	30NOV2020	33	1364
	[redacted]	1/Prevax	15OCT2020	1	10
		2/1 Month	10DEC2020	36	454
	[redacted]	1/Prevax	04NOV2020	1	10
		2/1 Month	29DEC2020	35	2593
	[redacted]	1/Prevax	30OCT2020	1	10
		2/1 Month	18DEC2020	29	3640
	[redacted]	1/Prevax	07DEC2020	1	10
		2/1 Month	27JAN2021	31	3341
	[redacted]	1/Prevax	02SEP2020	1	10
		2/1 Month	29OCT2020	36	1786
	[redacted]	1/Prevax	09SEP2020	1	10
		2/1 Month	03NOV2020	35	4127
	[redacted]	1/Prevax	07AUG2020	1	10
		2/1 Month	14OCT2020	41	1951

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16.2.6.3 Listing of Assay Data – Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Participant	Dose/Sampling Time Point	Date of Sample	Rel Day[a]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)
	[redacted]	1/Prevax	27AUG2020	1	10
		2/1 Month	22OCT2020	34	1431
	[redacted]	1/Prevax	28AUG2020	1	10
		2/1 Month	19OCT2020	31	2168
	[redacted]	1/Prevax	16SEP2020	1	10
		2/1 Month	04NOV2020	30	462
	[redacted]	1/Prevax	29SEP2020	1	10
		2/1 Month	23NOV2020	35	3849
	[redacted]	1/Prevax	01OCT2020	1	10
		2/1 Month	27NOV2020	36	2488
	[redacted]	1/Prevax	23SEP2020	1	10
		2/1 Month	11NOV2020	29	3559
	[redacted]	1/Prevax	23SEP2020	1	10
		2/1 Month	11NOV2020	28	772
	[redacted]	1/Prevax	09OCT2020	1	300
		2/1 Month	30NOV2020	32	11578
	[redacted]	1/Prevax	12AUG2020	1	10
		2/1 Month	01OCT2020	30	822
	[redacted]	1/Prevax	16AUG2020	1	10
		2/1 Month	07OCT2020	30	2443
	[redacted]	1/Prevax	18AUG2020	1	10
		2/1 Month	12OCT2020	34	1882
	[redacted]	1/Prevax	19AUG2020	1	10
		2/1 Month	07OCT2020	29	791

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16.2.6.3 Listing of Assay Data – Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Participant	Dose/Sampling Time Point	Date of Sample	Rel Day[a]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)
	[redacted]	1/Prevax	21AUG2020	1	10
		2/1 Month	12OCT2020	30	2599
	[redacted]	1/Prevax	21AUG2020	1	10
		2/1 Month	12OCT2020	34	799
	[redacted]	1/Prevax	22AUG2020	1	10
		2/1 Month	09OCT2020	30	4255
	[redacted]	1/Prevax	22AUG2020	1	10
		2/1 Month	11NOV2020	37	1891
	[redacted]	1/Prevax	23AUG2020	1	10
		2/1 Month	16OCT2020	34	2481
	[redacted]	1/Prevax	25AUG2020	1	10
		2/1 Month	14OCT2020	32	871
	[redacted]	1/Prevax	26AUG2020	1	10
		2/1 Month	13OCT2020	30	1509
	[redacted]	1/Prevax	27AUG2020	1	10
		2/1 Month	15OCT2020	31	836
	[redacted]	1/Prevax	27AUG2020	1	10
		2/1 Month	19OCT2020	35	2806
	[redacted]	1/Prevax	28AUG2020	1	10
		2/1 Month	19OCT2020	34	449
	[redacted]	1/Prevax	28AUG2020	1	10
		2/1 Month	22OCT2020	37	613
	[redacted]	1/Prevax	28AUG2020	1	10
		2/1 Month	20OCT2020	34	INDETERMINATE

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16.2.6.3 Listing of Assay Data – Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Participant	Dose/Sampling Time Point	Date of Sample	Rel Day[a]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)
	[redacted]	1/Prevax	28AUG2020	1	10
		2/1 Month	19OCT2020	34	10641
	[redacted]	1/Prevax	29AUG2020	1	10
		2/1 Month	22OCT2020	35	1031
	[redacted]	1/Prevax	30AUG2020	1	10
		2/1 Month	23OCT2020	32	2393
	[redacted]	1/Prevax	30AUG2020	1	10
		2/1 Month	23OCT2020	35	208
	[redacted]	1/Prevax	31AUG2020	1	10
		2/1 Month	23OCT2020	35	4466
	[redacted]	1/Prevax	23SEP2020	1	10
		2/1 Month	09NOV2020	29	1508
	[redacted]	2/1 Month	30NOV2020	29	518
	[redacted]	1/Prevax	10SEP2020	1	10
		2/1 Month	28OCT2020	30	6310
	[redacted]	1/Prevax	07AUG2020	1	10
		2/1 Month	25SEP2020	31	2686
	[redacted]	1/Prevax	11AUG2020	1	10
		2/1 Month	05OCT2020	35	442
	[redacted]	1/Prevax	12AUG2020	1	10
		2/1 Month	02OCT2020	31	4459
	[redacted]	1/Prevax	12AUG2020	1	159
		2/1 Month	01OCT2020	30	9361
	[redacted]	1/Prevax	12AUG2020	1	10

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16.2.6.3 Listing of Assay Data – Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Participant	Dose/Sampling Time Point	Date of Sample	Rel Day[a]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)
		2/1 Month	02OCT2020	31	1117
	[redacted]	1/Prevax	13AUG2020	1	10
		2/1 Month	30SEP2020	30	1253
	[redacted]	1/Prevax	19AUG2020	1	10
		2/1 Month	08OCT2020	29	2812
	[redacted]	1/Prevax	25AUG2020	1	192
		2/1 Month	15OCT2020	32	8162
	[redacted]	1/Prevax	01SEP2020	1	10
		2/1 Month	21OCT2020	31	891
	[redacted]	1/Prevax	16OCT2020	1	10
		2/1 Month	04DEC2020	30	6013
	[redacted]	1/Prevax	02SEP2020	1	10
		2/1 Month	21OCT2020	29	1402
	[redacted]	1/Prevax	21SEP2020	1	10
		2/1 Month	18NOV2020	38	2442
	[redacted]	1/Prevax	25SEP2020	1	10
		2/1 Month	13NOV2020	29	255
	[redacted]	1/Prevax	25SEP2020	1	10
		2/1 Month	12NOV2020	30	1371
	[redacted]	1/Prevax	25SEP2020	1	10
		2/1 Month	13NOV2020	30	1526
	[redacted]	1/Prevax	25SEP2020	1	10
		2/1 Month	11NOV2020	29	1715
	[redacted]	1/Prevax	27SEP2020	1	10

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16.2.6.3 Listing of Assay Data – Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Participant	Dose/Sampling Time Point	Date of Sample	Rel Day[a]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)
		2/1 Month	13NOV2020	30	464
	[redacted]	1/Prevax	27SEP2020	1	10
		2/1 Month	13NOV2020	30	1682
Placebo	[redacted]	1/Prevax	28OCT2020	1	10
		2/1 Month	15DEC2020	29	10
	[redacted]	1/Prevax	04AUG2020	1	10
		2/1 Month	25SEP2020	32	10
	[redacted]	1/Prevax	17SEP2020	1	10
		2/1 Month	05NOV2020	29	10
	[redacted]	1/Prevax	10SEP2020	1	10
		2/1 Month	29OCT2020	29	10
	[redacted]	1/Prevax	12OCT2020	1	10
		2/1 Month	02DEC2020	31	10
	[redacted]	1/Prevax	20OCT2020	1	10
		2/1 Month	16DEC2020	36	61
	[redacted]	1/Prevax	18AUG2020	1	10
		2/1 Month	07OCT2020	29	10
	[redacted]	1/Prevax	27AUG2020	1	10
		2/1 Month	22OCT2020	36	10
	[redacted]	1/Prevax	24AUG2020	1	21
		2/1 Month	14OCT2020	31	10
	[redacted]	1/Prevax	03SEP2020	1	10
		2/1 Month	26OCT2020	29	10
	[redacted]	1/Prevax	27AUG2020	1	10

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16.2.6.3 Listing of Assay Data – Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Participant	Dose/Sampling Time Point	Date of Sample	Rel Day[a]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)
		2/1 Month	13OCT2020	29	10
	[redacted]	1/Prevax	21OCT2020	1	10
		2/1 Month	10DEC2020	29	10
	[redacted]	1/Prevax	31JUL2020	1	10
		2/1 Month	22SEP2020	33	10
	[redacted]	1/Prevax	27AUG2020	1	10
		2/1 Month	22OCT2020	32	10
	[redacted]	1/Prevax	05AUG2020	1	10
		2/1 Month	23SEP2020	29	10
	[redacted]	1/Prevax	21AUG2020	1	10
		2/1 Month	09OCT2020	50	10
	[redacted]	1/Prevax	23SEP2020	1	10
		2/1 Month	16NOV2020	29	10
	[redacted]	1/Prevax	14OCT2020	1	10
		2/1 Month	08DEC2020	33	10
	[redacted]	1/Prevax	17AUG2020	1	10
		2/1 Month	06OCT2020	29	10
	[redacted]	1/Prevax	04SEP2020	1	10
		2/1 Month	23OCT2020	29	10
	[redacted]	1/Prevax	19AUG2020	1	10
		2/1 Month	17NOV2020	91	44
	[redacted]	1/Prevax	20AUG2020	1	10
		2/1 Month	08OCT2020	29	10
	[redacted]	1/Prevax	17AUG2020	1	10

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16.2.6.3 Listing of Assay Data – Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Participant	Dose/Sampling Time Point	Date of Sample	Rel Day[a]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)
		2/1 Month	29OCT2020	51	10
	[redacted]	1/Prevax	24AUG2020	1	10
		2/1 Month	16OCT2020	31	10
	[redacted]	1/Prevax	09SEP2020	1	10
		2/1 Month	06NOV2020	36	10
	[redacted]	1/Prevax	10SEP2020	1	10
		2/1 Month	29OCT2020	29	10
	[redacted]	1/Prevax	31JUL2020	1	10
		2/1 Month	18SEP2020	29	10
	[redacted]	1/Prevax	28AUG2020	1	10
		2/1 Month	16OCT2020	29	10
	[redacted]	1/Prevax	25AUG2020	1	10
		2/1 Month	12OCT2020	29	10
	[redacted]	1/Prevax	01SEP2020	1	10
		2/1 Month	23OCT2020	32	10
	[redacted]	1/Prevax	03SEP2020	1	10
		2/1 Month	22OCT2020	29	10
	[redacted]	1/Prevax	10SEP2020	1	10
		2/1 Month	30OCT2020	29	10
	[redacted]	1/Prevax	11SEP2020	1	10
		2/1 Month	06NOV2020	36	10
	[redacted]	1/Prevax	08AUG2020	1	10
		2/1 Month	25SEP2020	29	10
	[redacted]	1/Prevax	21AUG2020	1	10

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16.2.6.3 Listing of Assay Data – Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Participant	Dose/Sampling Time Point	Date of Sample	Rel Day[a]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)
		2/1 Month	08OCT2020	29	10
	[redacted]	1/Prevax	25AUG2020	1	10
		2/1 Month	30OCT2020	47	124
	[redacted]	1/Prevax	01SEP2020	1	10
		2/1 Month	20OCT2020	29	10
	[redacted]	1/Prevax	19SEP2020	1	10
		2/1 Month	06NOV2020	30	10
	[redacted]	1/Prevax	23OCT2020	1	10
		2/1 Month	09DEC2020	29	10
	[redacted]	1/Prevax	26OCT2020	1	10
		2/1 Month	18DEC2020	33	10
	[redacted]	1/Prevax	27OCT2020	1	10
		2/1 Month	16DEC2020	27	10
	[redacted]	1/Prevax	16OCT2020	1	10
		2/1 Month	04DEC2020	29	10
	[redacted]	1/Prevax	30JUL2020	1	10
		2/1 Month	22SEP2020	35	10
	[redacted]	1/Prevax	19AUG2020	1	10
		2/1 Month	13OCT2020	36	10
	[redacted]	1/Prevax	24AUG2020	1	10
		2/1 Month	12OCT2020	29	10
	[redacted]	1/Prevax	07AUG2020	1	10
		2/1 Month	25SEP2020	29	10
	[redacted]	1/Prevax	26OCT2020	1	10

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16.2.6.3 Listing of Assay Data – Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Participant	Dose/Sampling Time Point	Date of Sample	Rel Day[a]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)
		2/1 Month	14DEC2020	29	10
	[redacted]	1/Prevax	26AUG2020	1	10
		2/1 Month	14OCT2020	29	10
	[redacted]	1/Prevax	24AUG2020	1	23
		2/1 Month	19OCT2020	36	10
	[redacted]	1/Prevax	13AUG2020	1	10
		2/1 Month	01OCT2020	30	10
	[redacted]	1/Prevax	09SEP2020	1	10
		2/1 Month	27OCT2020	29	10
	[redacted]	1/Prevax	21AUG2020	1	10
		2/1 Month	08OCT2020	30	10
	[redacted]	1/Prevax	17AUG2020	1	10
		2/1 Month	07OCT2020	29	10
	[redacted]	1/Prevax	08SEP2020	1	10
		2/1 Month	28OCT2020	30	10
	[redacted]	1/Prevax	10SEP2020	1	10
		2/1 Month	30OCT2020	30	10
	[redacted]	1/Prevax	11SEP2020	1	10
		2/1 Month	30OCT2020	29	10
	[redacted]	1/Prevax	17SEP2020	1	10
		2/1 Month	09NOV2020	33	10
	[redacted]	1/Prevax	27OCT2020	1	10
		2/1 Month	17DEC2020	31	10
	[redacted]	1/Prevax	12AUG2020	1	10

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16.2.6.3 Listing of Assay Data – Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Participant	Dose/Sampling Time Point	Date of Sample	Rel Day[a]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)
		2/1 Month	28SEP2020	29	10
	[redacted]	1/Prevax	14AUG2020	1	10
		2/1 Month	08OCT2020	35	10
	[redacted]	1/Prevax	19AUG2020	1	10
		2/1 Month	08OCT2020	29	10
	[redacted]	1/Prevax	25AUG2020	1	10
		2/1 Month	13OCT2020	29	10
	[redacted]	1/Prevax	10SEP2020	1	10
		2/1 Month	26OCT2020	29	10
	[redacted]	1/Prevax	28SEP2020	1	10
		2/1 Month	16NOV2020	29	10
	[redacted]	1/Prevax	04SEP2020	1	10
		2/1 Month	23OCT2020	29	10
	[redacted]	1/Prevax	09SEP2020	1	10
		2/1 Month	28OCT2020	29	10
	[redacted]	1/Prevax	10SEP2020	1	10
		2/1 Month	29OCT2020	29	10
	[redacted]	1/Prevax	10SEP2020	1	10
		2/1 Month	29OCT2020	29	10
	[redacted]	1/Prevax	24SEP2020	1	10
		2/1 Month	12NOV2020	29	10
	[redacted]	1/Prevax	06OCT2020	1	10
		2/1 Month	30NOV2020	36	10
	[redacted]	1/Prevax	12OCT2020	1	10

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16.2.6.3 Listing of Assay Data – Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Participant	Dose/Sampling Time Point	Date of Sample	Rel Day[a]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)
		2/1 Month	01DEC2020	29	10
	[redacted]	1/Prevax	21OCT2020	1	10
		2/1 Month	09DEC2020	29	10
	[redacted]	1/Prevax	27OCT2020	1	10
		2/1 Month	15DEC2020	30	10
	[redacted]	1/Prevax	29OCT2020	1	10
		2/1 Month	16DEC2020	29	10
	[redacted]	1/Prevax	16OCT2020	1	10
		2/1 Month	02DEC2020	29	10
	[redacted]	1/Prevax	18OCT2020	1	10
		2/1 Month	12DEC2020	35	10
	[redacted]	1/Prevax	16OCT2020	1	10
		2/1 Month	04DEC2020	29	10
	[redacted]	1/Prevax	04NOV2020	1	10
		2/1 Month	24DEC2020	30	10
	[redacted]	1/Prevax	16NOV2020	1	10
		2/1 Month	07JAN2021	32	10
	[redacted]	1/Prevax	23NOV2020	1	10
		2/1 Month	12JAN2021	29	10
	[redacted]	1/Prevax	24NOV2020	1	60
		2/1 Month	12JAN2021	30	71
	[redacted]	1/Prevax	22OCT2020	1	10
		2/1 Month	16DEC2020	35	10
	[redacted]	1/Prevax	27AUG2020	1	10

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16.2.6.3 Listing of Assay Data – Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Participant	Dose/Sampling Time Point	Date of Sample	Rel Day[a]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)
		2/1 Month	15OCT2020	29	10
	[redacted]	1/Prevax	17SEP2020	1	10
		2/1 Month	05NOV2020	30	10
	[redacted]	1/Prevax	17SEP2020	1	10
		2/1 Month	07NOV2020	32	10
	[redacted]	1/Prevax	17SEP2020	1	10
		2/1 Month	12NOV2020	37	10
	[redacted]	1/Prevax	16OCT2020	1	10
		2/1 Month	07DEC2020	33	10
	[redacted]	1/Prevax	16OCT2020	1	10
		2/1 Month	03DEC2020	30	10
	[redacted]	1/Prevax	19OCT2020	1	10
		2/1 Month	15DEC2020	35	10
	[redacted]	1/Prevax	08OCT2020	1	10
		2/1 Month	27NOV2020	30	10
	[redacted]	1/Prevax	10AUG2020	1	10
		2/1 Month	19OCT2020	71	10
	[redacted]	1/Prevax	13AUG2020	1	10
		2/1 Month	02OCT2020	30	10
	[redacted]	1/Prevax	16AUG2020	1	10
		2/1 Month	07OCT2020	30	10
	[redacted]	1/Prevax	18AUG2020	1	10
		2/1 Month	06OCT2020	30	10
	[redacted]	1/Prevax	18AUG2020	1	10

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16.2.6.3 Listing of Assay Data – Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Participant	Dose/Sampling Time Point	Date of Sample	Rel Day[a]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)
		2/1 Month	12OCT2020	34	10
	[redacted]	1/Prevax	18AUG2020	1	10
		2/1 Month	07OCT2020	29	10
	[redacted]	1/Prevax	19AUG2020	1	10
		2/1 Month	06OCT2020	29	10
	[redacted]	1/Prevax	20AUG2020	1	10
		2/1 Month	09OCT2020	29	10
	[redacted]	1/Prevax	21AUG2020	1	10
		2/1 Month	12OCT2020	30	10
	[redacted]	1/Prevax	21AUG2020	1	10
		2/1 Month	07OCT2020	29	10
	[redacted]	1/Prevax	21AUG2020	1	10
		2/1 Month	12OCT2020	33	10
	[redacted]	1/Prevax	23AUG2020	1	10
		2/1 Month	12NOV2020	82	101
	[redacted]	1/Prevax	24AUG2020	1	10
		2/1 Month	14OCT2020	32	10
	[redacted]	1/Prevax	24AUG2020	1	435
		2/1 Month	15OCT2020	33	257
	[redacted]	1/Prevax	25AUG2020	1	10
		2/1 Month	15OCT2020	32	10
	[redacted]	1/Prevax	26AUG2020	1	10
		2/1 Month	16OCT2020	33	10
	[redacted]	1/Prevax	26AUG2020	1	10

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16.2.6.3 Listing of Assay Data – Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Participant	Dose/Sampling Time Point	Date of Sample	Rel Day[a]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)
		2/1 Month	20OCT2020	34	10
	[redacted]	1/Prevax	27AUG2020	1	10
		2/1 Month	16OCT2020	32	10
	[redacted]	1/Prevax	27AUG2020	1	10
		2/1 Month	19OCT2020	35	10
	[redacted]	1/Prevax	28AUG2020	1	10
		2/1 Month	20OCT2020	35	10
	[redacted]	1/Prevax	28AUG2020	1	10
		2/1 Month	20OCT2020	35	10
	[redacted]	1/Prevax	29AUG2020	1	10
		2/1 Month	22OCT2020	36	10
	[redacted]	1/Prevax	29AUG2020	1	10
		2/1 Month	12NOV2020	57	10
	[redacted]	1/Prevax	30AUG2020	1	10
		2/1 Month	22OCT2020	35	10
	[redacted]	1/Prevax	30AUG2020	1	10
		2/1 Month	22OCT2020	35	10
	[redacted]	1/Prevax	31AUG2020	1	730
		2/1 Month	23OCT2020	35	15
	[redacted]	1/Prevax	19AUG2020	1	10
		2/1 Month	21OCT2020	29	10
	[redacted]	1/Prevax	09SEP2020	1	10
		2/1 Month	28OCT2020	29	10
	[redacted]	1/Prevax	18AUG2020	1	280

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16.2.6.3 Listing of Assay Data – Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Participant	Dose/Sampling Time Point	Date of Sample	Rel Day[a]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)
		2/1 Month	07OCT2020	29	42
	[redacted]	1/Prevax	19AUG2020	1	43
		2/1 Month	08OCT2020	29	223
	[redacted]	1/Prevax	20AUG2020	1	10
		2/1 Month	09OCT2020	29	10
	[redacted]	1/Prevax	20AUG2020	1	10
		2/1 Month	08OCT2020	29	10
	[redacted]	1/Prevax	24AUG2020	1	10
		2/1 Month	13OCT2020	29	10
	[redacted]	1/Prevax	09SEP2020	1	10
		2/1 Month	28OCT2020	29	10
	[redacted]	1/Prevax	31AUG2020	1	10
		2/1 Month	24OCT2020	34	10
	[redacted]	1/Prevax	05SEP2020	1	15
		2/1 Month	24OCT2020	29	10
	[redacted]	1/Prevax	11SEP2020	1	10
		2/1 Month	30OCT2020	29	10
	[redacted]	1/Prevax	24OCT2020	1	10
		2/1 Month	12DEC2020	29	10
	[redacted]	1/Prevax	22AUG2020	1	10
		2/1 Month	12OCT2020	31	10
	[redacted]	1/Prevax	22SEP2020	1	123
		2/1 Month	11NOV2020	31	80
	[redacted]	1/Prevax	25SEP2020	1	10

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16.2.6.3 Listing of Assay Data – Nonpregnant Female Participants (Study C4591001)

Vaccine Group (as Randomized)	Participant	Dose/Sampling Time Point	Date of Sample	Rel Day[a]	Assay SARS-CoV-2 Neutralization Assay - NT50 (Titer)
		2/1 Month	18NOV2020	31	10
	[redacted]	1/Prevax	27SEP2020	1	10
		2/1 Month	13NOV2020	29	10
	[redacted]	1/Prevax	27SEP2020	1	10
		2/1 Month	13NOV2020	29	10

Abbreviations: NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Participants are a selected subset of age matched nonpregnant female Phase 3 participants.
a. Relative day (Rel Day) = date of blood draw - date of last vaccination + 1.
PFIZER CONFIDENTIAL Source Data: adva Table Generation: 01MAR2024 (02:40)
(Data cutoff date : C4591001 [31Aug2021]) Output File: ./nda3/C4591015_Bridging/adva_l001_brdg

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16.2.7.1 Adverse Events Legend Page

Category	Abbreviation	Text
Action - Investigational Vaccine Dose	N	No other action
	NA	Not applicable
	O	Other action taken
	UNK	Unknown
	P	Investigational product withdrawn
Action - Participant	TC	Concomitant drug treatment given
	TCN	Concomitant nondrug treatment given
	W	Withdrawn from study
Cause of AE	CD	Concomitant drug treatment
	CND	Concomitant nondrug treatment
	O	Other
Outcome	F	Fatal
	N	Not recovered/not resolved
	R	Recovered/resolved
	RS	Recovered/resolved with sequelae
	RG	Recovering/resolving
	UNK	Unknown
Toxicity Grade	1	Mild
	2	Moderate
	3	Severe
	4	Potentially life-threatening
System Organ Class	BLOOD	Blood and lymphatic system disorders
	CARD	Cardiac disorders
	CONG	Congenital, familial and genetic disorders
	EAR	Ear and labyrinth disorders
	ENDO	Endocrine disorders

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16.2.7.1 Adverse Events Legend Page

Category	Abbreviation	Text
	EYE	Eye disorders
	GASTR	Gastrointestinal disorders
	GENRL	General disorders and administration site conditions
	HEPAT	Hepatobiliary disorders
	IMMUN	Immune system disorders
	INFEC	Infections and infestations
	INJ&P	Injury poisoning and procedural complications
	INV	Investigations
	METAB	Metabolism and nutrition disorders
	MUSC	Musculoskeletal and connective tissue disorders
	NEOPL	Neoplasms benign, malignant and unspecified (incl cysts and polyps)
	NERV	Nervous system disorders
	PREG	Pregnancy, puerperium and perinatal conditions
	PI	Product issues
	PSYCH	Psychiatric disorders
	RENAL	Renal and urinary disorders
	REPRO	Reproductive system and breast disorders
	RESP	Respiratory, thoracic and mediastinal disorders
	SKIN	Skin and subcutaneous tissue disorders
	SOCCI	Social circumstances
	SURG	Surgical and medical procedures
	VASC	Vascular disorders

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
BNT162b2 (30 µg)	[redacted]	1	30APR2021	Redness (cu)			2	2	1	1	1		
				Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	Mild	N	N	N	N	02MAY2021	3
		2	24MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	20MAY2021	Redness (svt)	N	N		N	N		N		
				Swelling (svt)	N	N		N	N		N		
				Pain at the injection site	N	Mild		N	N		N	21MAY2021	1
		2	08JUN2021	Redness (svt)		N	N	N	N	N	N		
				Swelling (svt)		N	N	N	N	N	N		
				Pain at the injection site		N	N	N	N	N	N		
	[redacted]	1	08JUN2021	Redness (cu)			8	6				11JUN2021	2
				Redness (svt)	N	N	Mild	Mild			N		
				Swelling (cu)			6	3				10JUN2021	1
				Swelling (svt)	N	N	Mild	N			N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site	Mild	Mild	Mild	N			N	10JUN2021	3
		2	29JUN2021	Redness (cu)			9	8				02JUL2021	2
				Redness (svt)			Mild	Mild	N	N	N		
				Swelling (cu)			3	4					
				Swelling (svt)			N	N	N	N	N		
				Pain at the injection site			Mild	N	N	N	N	01JUL2021	1
	[redacted]	1	19FEB2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	Mild	N	N	N	N	N	20FEB2021	1
		2	12MAR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	N	N	N	N	N	13MAR2021	2
	[redacted]	1	13MAY2021	Redness (svt)	N	N	N	N	N	N			
				Swelling (svt)	N	N	N	N	N	N			
				Pain at the injection site	Mod	Mild	Mild	N	N	N		15MAY2021	3
		2	01JUN2021	Redness (cu)	1	3	4	3	2	1			
				Redness (svt)	N	N	N	N	N	N	N		
				Swelling (cu)		3	4	3					

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mod	Mild	Mild	N	N	N	04JUN2021	4
	[redacted]	1	20APR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	11MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	23APR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	N	N	N	N	N	24APR2021	2
		2	12MAY2021	Redness (svt)	N		N	N	N	N			
				Swelling (svt)	N		N	N	N	N			
				Pain at the injection site	Mild		N	N	N	N		12MAY2021	1
	[redacted]	1	26APR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site	Mild	Mod	Mild	Mild	N	N	N	29APR2021	4
		2	10JUN2021	Redness (svt)	N	N			N	N	N		
				Swelling (svt)	N	N			N	N	N		
				Pain at the injection site	Mild	Mild			N	N	N	11JUN2021	2
	[redacted]	1	29APR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mod	N	N	N	N	N	30APR2021	2
	[redacted]	1	05MAY2021	Redness (cu)	1								
				Redness (svt)	N	N	N		N	N			
				Swelling (svt)	N	N	N		N	N			
				Pain at the injection site	Mod	Mod	Mild		N	N		07MAY2021	3
		2	26MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mod	Mild	N	N	N	N	N	27MAY2021	2
	[redacted]	1	10MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site	Mild	Mild	N	N	N	N	N	11MAY2021	2
		2	01JUN2021	Redness (cu)		2							
				Redness (svt)		N	N	N	N	N	N		
				Swelling (cu)		7						02JUN2021	1
				Swelling (svt)		Mild	N	N	N	N	N		
				Pain at the injection site		Mod	Mild	N	N	N	N	03JUN2021	2
	[redacted]	1	17MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	Mild	N	N	N	N	N	18MAY2021	1
		2	07JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	Mild	Mild	N	N	N	N	09JUN2021	2
	[redacted]	1	20MAY2021	Redness (cu)		10	11					22MAY2021	2
				Redness (svt)	N	Mild	Mod	N	N	N	N		
				Swelling (cu)		10	11					22MAY2021	2
				Swelling (svt)	N	Mild	Mod	N	N	N	N		
				Pain at the injection site	Mild	Mild	N	N	N	N	N	21MAY2021	2
		2	09JUN2021	Redness (svt)	N	N	N	N	N	N			

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Swelling (svt)	N	N	N	N	N	N			
				Pain at the injection site	N	Mild	N	N	N	N		10JUN2021	1
	[redacted]	1	26MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	14JUN2021	Redness (svt)		N	N	N	N	N	N		
				Swelling (svt)		N	N	N	N	N	N		
				Pain at the injection site		Mod	N	N	N	N	N	15JUN2021	1
	[redacted]	1	27MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	N	N	N	N	N	28MAY2021	2
		2	18JUN2021	Redness (svt)					N	N	N		
				Swelling (svt)					N	N	N		
				Pain at the injection site					N	N	N		
	[redacted]	1	03JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site	Mild	Mod	Mild	N	N	N	N	05JUN2021	3
		2	20JUL2021	Redness (svt)	N	N	N	N	N	N			
				Swelling (svt)	N	N	N	N	N	N			
				Pain at the injection site	Mod	Mild	N	N	N	N		21JUL2021	2
	[redacted]	1	07JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	Mild	N	N	N	N	09JUN2021	3
		2	30JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	Mild	Mild	Mild	N	N	04JUL2021	5
	[redacted]	1	10JUN2021	Redness (cu)	1	3	2	1	1				
				Redness (svt)	N	N	N	N	N				
				Swelling (svt)	N	N	N	N	N				
				Pain at the injection site	Mild	Mod	Mild	Mild	Mild			16JUN2021	7
	[redacted]	1	11JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site	Mild	N	N	N	N	N	N	11JUN2021	1
		2	02JUL2021	Redness (svt)		N	N	N	N		N		
				Swelling (svt)		N	N	N	N		N		
				Pain at the injection site		Mild	N	N	N		N	03JUL2021	1
	[redacted]	1	18JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (cu)		1							
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	Mod	Mild	N	N	N	N	20JUN2021	2
		2	09JUL2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (cu)		1	1						
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	Mild	Mild	N	N	N	12JUL2021	4
	[redacted]	1	24JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	Mild	N	N	N	N	N	25JUN2021	1
	[redacted]	1	26APR2021	Redness (cu)		4	7	5				29APR2021	2
				Redness (svt)	N	N	Mild	Mild	N		N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Swelling (cu)		4	7					28APR2021	1
				Swelling (svt)	N	N	Mild	N	N		N		
				Pain at the injection site	N	Mild	N	N	N		N	27APR2021	1
		2	17MAY2021	Redness (cu)		5	5					19MAY2021	2
				Redness (svt)	N	Mild	Mild	N		N	N		
				Swelling (cu)	1	2	2	3					
				Swelling (svt)	N	N	N	N		N	N		
				Pain at the injection site	Mild	Mild	N	N		N	N	18MAY2021	2
	[redacted]	1	24MAY2021	Redness (cu)		2							
				Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mod	Mild	N	N	N	N	26MAY2021	3
		2	14JUN2021	Redness (svt)			N	N	N	N	N		
				Swelling (svt)			N	N	N	N	N		
				Pain at the injection site			Mild	N	N	N	N	16JUN2021	1
	[redacted]	1	31MAY2021	Redness (cu)	3								
				Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site	Mild	Mild	N	N	N	N	N	01JUN2021	2
		2	21JUN2021	Redness (svt)	N	N	N		N	N	N		
				Swelling (svt)	N	N	N		N	N	N		
				Pain at the injection site	Mod	Mild	Mild		N	N	N	23JUN2021	3
	[redacted]	1	01JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	Mild	Mild	N	N	N	N	03JUN2021	2
		2	22JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mod	Mild	Mild	N	N	N	25JUN2021	4
	[redacted]	1	03JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	N	N	N	N	N	N	03JUN2021	1
		2	24JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	N	N	N	N	N	N	24JUN2021	1

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
	[redacted]	1	03JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	25JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	10JUN2021	Redness (svt)	N			N	N	N	N		
				Swelling (svt)	N			N	N	N	N		
				Pain at the injection site	Mod			N	N	N	N	10JUN2021	1
	[redacted]	1	21MAY2021	Redness (svt)	N	N	N	N	N	N			
				Swelling (svt)	N	N	N	N	N	N			
				Pain at the injection site	N	N	N	N	N	N			
		2	11JUN2021	Redness (svt)	N		N	N		N	N		
				Swelling (svt)	N		N	N		N	N		
				Pain at the injection site	Mod		Mod	Mild		N	N	14JUN2021	4
	[redacted]	1	16JUN2021	Redness (svt)	N	N	N	N	N		N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Swelling (svt)	N	N	N	N	N		N		
				Pain at the injection site	Mild	Mild	Mild	N	N		N	18JUN2021	3
		2	06JUL2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	N	N	N	N	N	07JUL2021	2
	[redacted]	1	23MAR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (cu)		1							
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	Mod	Mild	N	N	N	N	25MAR2021	2
		2	14APR2021	Redness (cu)	1								
				Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	Mild	N	N	N	N	16APR2021	3
	[redacted]	1	25MAR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	Mild	N	N	N	N	N	26MAR2021	1
		2	16APR2021	Redness (cu)		2	2	2					
				Redness (svt)	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Swelling (cu)		2							
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	N	Mild	N	N	N	19APR2021	4
	[redacted]	1	14APR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mod	N	N	N	N	N	15APR2021	2
		2	05MAY2021	Redness (svt)	N	N		N			N		
				Swelling (svt)	N	N		N			N		
				Pain at the injection site	Mild	Mild		N			N	06MAY2021	2
	[redacted]	1	11MAR2021	Redness (cu)		3	4	1					
				Redness (svt)	N	N	N	N	N	N	N		
				Swelling (cu)		2	2						
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mod	Mild	N	N	N	N	13MAR2021	3
		2	31MAR2021	Redness (cu)	3	5	9	7				03APR2021	3
				Redness (svt)	N	Mild	Mild	Mild	N	N	N		
				Swelling (cu)	2	3	4	3	1				
				Swelling (svt)	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site	Mild	Mod	Mod	Mild	N	N	N	03APR2021	4
	[redacted]	1	17MAR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	Mod	Mild	N	N	N	N	19MAR2021	2
		2	12APR2021	Redness (svt)		N	N	N	N	N	N		
				Swelling (svt)		N	N	N	N	N	N		
				Pain at the injection site		Mild	Mild	Mild	N	N	N	15APR2021	3
	[redacted]	1	24MAR2021	Redness (svt)	N	N	N	N	N		N		
				Swelling (svt)	N	N	N	N	N		N		
				Pain at the injection site	N	Mild	N	N	N		N	25MAR2021	1
		2	12APR2021	Redness (cu)			2						
				Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	Mild	Mild	N	N	N	N	14APR2021	2
	[redacted]	1	12APR2021	Redness (svt)	N	N	N	N		N	N		
				Swelling (svt)	N	N	N	N		N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site	N	Mild	N	N		N	N	13APR2021	1
		2	04MAY2021	Redness (svt)		N	N	N	N	N	N		
				Swelling (svt)		N	N	N	N	N	N		
				Pain at the injection site		Mild	N	N	N	N	N	05MAY2021	1
	[redacted]	1	06MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mod	N	N	N	N	N	07MAY2021	2
		2	28MAY2021	Redness (cu)	1	1							
				Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	Mild	Mild	N	N	N	31MAY2021	4
	[redacted]	1	11MAY2021	Redness (svt)	N		N	N	N	N	N		
				Swelling (svt)	N		N	N	N	N	N		
				Pain at the injection site	Mod		Mild	Mild	N	N	N	14MAY2021	4
		2	01JUN2021	Redness (svt)		N	N	N	N	N	N		
				Swelling (svt)		N	N	N	N	N	N		
				Pain at the injection site		N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
	[redacted]	1	17JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	N	N	N	N	N	18JUN2021	2
		2	08JUL2021	Redness (svt)		N	N	N	N	N	N		
				Swelling (svt)		N	N	N	N	N	N		
				Pain at the injection site		Mod	Mild	N	N	N	N	10JUL2021	2
	[redacted]	1	20MAY2021	Redness (cu)		1	2	1					
				Redness (svt)	N	N	N	N		N	N		
				Swelling (cu)			2	1					
				Swelling (svt)	N	N	N	N		N	N		
				Pain at the injection site	N	Mod	Mod	Mild		N	N	23MAY2021	3
		2	10JUN2021	Redness (cu)		3	3	2	1	1			
				Redness (svt)	N	N	N	N	N	N	N		
				Swelling (cu)		3	3						
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mod	Mod	Mild	Mild	N	N	14JUN2021	5
	[redacted]	1	10MAR2021	Redness (svt)		N	N	N	N	N	N		
				Swelling (cu)		9						11MAR2021	1

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Swelling (svt)		Mild	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	Mild	N	N	N	N	12MAR2021	3
		2	29MAR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (cu)		11						30MAR2021	1
				Swelling (svt)	N	Mod	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	Mild	N	N	N	N	31MAR2021	3
	[redacted]	1	11MAR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	N	N	N	N	N	N	11MAR2021	1
		2	01APR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	13APR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	Mild	Mild	Mild	Mild	N	18APR2021	6
		2	03MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site	Mild	Mild	Mild	Mild	Mild	N	N	07MAY2021	5
	[redacted]	1	14MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	Mild	N	N	N	N	16MAY2021	3
		2	04JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	Mild	Mild	N	N	N	07JUN2021	4
	[redacted]	1	14MAY2021	Redness (svt)	N	N		N	N	N	N		
				Swelling (svt)	N	N		N	N	N	N		
				Pain at the injection site	N	Mild		N	N	N	N	15MAY2021	1
		2	11JUN2021	Redness (cu)			3						
				Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	16FEB2021	Redness (svt)	N	N	N	N			N		
				Swelling (svt)	N	N	N	N			N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site	Mild	Mild	N	N			N	17FEB2021	2
		2	08MAR2021	Redness (svt)			N	N	N	N	N		
				Swelling (svt)		Mild	Mild	N	N	N	N		
				Pain at the injection site		Mild	Mild	Mild	N	N	N	11MAR2021	3
	[redacted]	1	09MAR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	30MAR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	18FEB2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (cu)	2	1	1	1					
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mod	Mod	Mild	Mild	N	N	N	21FEB2021	4
		2	09MAR2021	Redness (cu)		3	1	1					
				Redness (svt)		N	N	N	N	N	N		
				Swelling (cu)		5	2	1				10MAR2021	1
				Swelling (svt)		Mild	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site		Mod	Mild	Mild	Mild	N	N	13MAR2021	4
	[redacted]	1	04MAR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	24MAR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	12MAR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	N	N	N	N	N	13MAR2021	2
		2	31MAR2021	Redness (svt)	N	N	N	N	N		N		
				Swelling (svt)	N	N	N	N	N		N		
				Pain at the injection site	Mild	Mod	N	N	N		N	01APR2021	2
	[redacted]	1	16MAR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	Mild	Mild	N	N	N	N	18MAR2021	2

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
		2	05APR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	Mild	N	N	N	N	07APR2021	3
	[redacted]	1	23MAR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mod	N	N	N	N	N	24MAR2021	2
		2	13APR2021	Redness (cu)			12					15APR2021	1
				Redness (svt)	N	N	Mod	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	Mild	Mild	N	N	N	N	15APR2021	2
	[redacted]	1	08APR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	N	N	N	N	N	09APR2021	2
		2	27APR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	N	N	N	N	N	28APR2021	2
	[redacted]	1	25MAR2021	Redness (svt)	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	N	N	N	N	N	26MAR2021	2
		2	13APR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	N	N	N	N	N	14APR2021	2
	[redacted]	1	09APR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	30APR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	11MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	N	N	N	N	N	12MAY2021	2
	[redacted]	1	28APR2021	Redness (svt)	N	N	N		N	N	N		
				Swelling (svt)	N	N	N		N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site	N	N	N		N	N	N		
		2	18MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	11MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	N	N	N	N	N	12MAY2021	2
		2	02JUN2021	Redness (svt)		N	N	N	N	N	N		
				Swelling (svt)		N	N	N	N	N	N		
				Pain at the injection site		Mild	N	N	N	N	N	03JUN2021	1
	[redacted]	1	13MAY2021	Redness (svt)	N	N		N	N		N		
				Swelling (svt)	N	N		N	N		N		
				Pain at the injection site	N	N		N	N		N		
		2	02JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
	[redacted]	1	18MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	N	N	N	N	N	19MAY2021	2
		2	09JUN2021	Redness (svt)						N	N		
				Swelling (svt)						N	N		
				Pain at the injection site						N	N		
	[redacted]	1	18MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	Mild	Mild	N	N	N	N	20MAY2021	2
		2	10JUN2021	Redness (svt)		N	N	N	N	N	N		
				Swelling (svt)		N	N	N	N	N	N		
				Pain at the injection site		N	N	N	N	N	N		
	[redacted]	1	20MAY2021	Redness (svt)	N	N	N	N	N		N		
				Swelling (svt)	N	N	N	N	N		N		
				Pain at the injection site	N	N	N	N	N		N		
		2	08JUN2021	Redness (svt)	N	N	N	N					
				Swelling (svt)	N	N	N	N					

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site	N	N	N	N					
	[redacted]	1	20MAY2021	Redness (svt)	N	N	N	N	N		N		
				Swelling (svt)	N	N	N	N	N		N		
				Pain at the injection site	N	N	N	N	N		N		
		2	08JUN2021	Redness (svt)	N	N	N	N					
				Swelling (svt)	N	N	N	N					
				Pain at the injection site	N	N	N	N					
	[redacted]	1	26MAY2021	Redness (svt)	N	N					N		
				Swelling (svt)	N	N					N		
				Pain at the injection site	N	N					N		
	[redacted]	1	08JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mod	N	N	N	N	N	09JUN2021	2
		2	28JUN2021	Redness (svt)		N	N		N	N	N		
				Swelling (svt)		N	N		N	N	N		
				Pain at the injection site		Mod	Mild		N	N	N	30JUN2021	2

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
	[redacted]	1	14JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mod	N	N	N	N	N	15JUN2021	2
		2	06JUL2021	Redness (svt)						N	N		
				Swelling (svt)						N	N		
				Pain at the injection site						N	N		
	[redacted]	1	18JUN2021	Redness (svt)		N	N	N	N	N	N		
				Swelling (svt)		N	N	N	N	N	N		
				Pain at the injection site		N	N	N	N	N	N		
		2	07JUL2021	Redness (svt)		N	N	N	N	N	N		
				Swelling (svt)		N	N	N	N	N	N		
				Pain at the injection site		N	N	N	N	N	N		
	[redacted]	1	18JUN2021	Redness (svt)				N	N		N		
				Swelling (svt)				N	N		N		
				Pain at the injection site				N	N		N		
		2	13JUL2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	13JUL2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	02AUG2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	27JUL2021	Redness (svt)	N	N	N	N	N		N		
				Swelling (svt)	N	N	N	N	N		N		
				Pain at the injection site	N	N	N	N	N		N		
		2	16AUG2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	30AUG2021	Redness (svt)	N	N	N	N		N	N		
				Swelling (svt)	N	N	N	N		N	N		
				Pain at the injection site	N	N	N	N		N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
		2	22SEP2021	Redness (svt)	N	N		N	N	N	N		
				Swelling (svt)	N	N		N	N	N	N		
				Pain at the injection site	N	N		N	N	N	N		
	[redacted]	1	08SEP2021	Redness (svt)	N			N	N	N	N		
				Swelling (svt)	N			N	N	N	N		
				Pain at the injection site	N			N	N	N	N		
		2	29SEP2021	Redness (svt)	N			N		N	N		
				Swelling (svt)	N			N		N	N		
				Pain at the injection site	N			N		N	N		
	[redacted]	1	08SEP2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	24FEB2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	N	N	N	N	N	25FEB2021	2
		2	17MAR2021	Redness (svt)		N	N	N	N	N	N		
				Swelling (svt)		N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site		Mild	N	N	N	N	N	18MAR2021	1
	[redacted]	1	15APR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	N	N	N	N	N	16APR2021	2
		2	06MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	N	N	N	N	N	07MAY2021	2
	[redacted]	1	06MAY2021	Redness (cu)		4							
				Redness (svt)	N	N	N	N	N	N	N		
				Swelling (cu)		1							
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	Mild	N	N	N	N	08MAY2021	3
		2	27MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	Mild	N	N	N	N	29MAY2021	3
	[redacted]	1	21APR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site	Mod	Mild	N	N	N	N	N	22APR2021	2
		2	13MAY2021	Redness (svt)							N		
				Swelling (svt)							N		
				Pain at the injection site							N		
	[redacted]	1	12MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mod	Mild	N	N	N	N	N	13MAY2021	2
		2	02JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mod	Mod	N	N	N	N	N	03JUN2021	2
	[redacted]	1	20MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	Mild	N	N	N	N	22MAY2021	3
		2	10JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
	[redacted]	1	04AUG2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	N	N	N	N	N	05AUG2021	2
		2	23AUG2021	Redness (cu)		4	6					25AUG2021	1
				Redness (svt)		N	Mild	N	N		N		
				Swelling (cu)		8	7					25AUG2021	2
				Swelling (svt)		Mild	Mild	N	N		N		
				Pain at the injection site		Mod	Mod	N	N		N	25AUG2021	2
	[redacted]	1	10AUG2021	Redness (svt)	N	N	N	N		N			
				Swelling (svt)	N	N	N	N		N			
				Pain at the injection site	Mild	Mod	Mild	N		N		12AUG2021	3
		2	30AUG2021	Redness (svt)	N	N	N	N		N			
				Swelling (svt)	N	N	N	N		N			
				Pain at the injection site	N	Mild	N	N		N		31AUG2021	1
	[redacted]	1	24MAR2021	Redness (cu)		5	3	2				25MAR2021	1
				Redness (svt)	N	Mild	N	N	N		N		
				Swelling (cu)		5	3	2				25MAR2021	1
				Swelling (svt)	N	Mild	N	N	N		N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site	Mild	Mild	Mild	Mild	N		N	27MAR2021	4
		2	12APR2021	Redness (cu)	2	2	1						
				Redness (svt)	N	N	N	N	N	N	N		
				Swelling (cu)	2	3	1						
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	Mild	Mild	N	N	N	15APR2021	4
	[redacted]	1	11MAY2021	Redness (svt)		N	N	N	N	N	N		
				Swelling (svt)		N	N	N	N	N	N		
				Pain at the injection site		Mild	Mild	N	N	N	N	13MAY2021	2
		2	03JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mod	Mild	Mild	N	N	N	06JUN2021	4
	[redacted]	1	26AUG2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	N	N	N	N	N	27AUG2021	2
		2	14SEP2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site	Mild	Mild	N	N	N	N	N	15SEP2021	2
	[redacted]	1	09SEP2021	Redness (svt)		N	N	N	N	N	N		
				Swelling (svt)		N	N	N	N	N	N		
				Pain at the injection site		N	N	N	N	N	N		
	[redacted]	1	17SEP2021	Redness (svt)	N		N	N	N	N	N		
				Swelling (svt)	N		N	N	N	N	N		
				Pain at the injection site	N		N	N	N	N	N		
		2	06OCT2021	Redness (svt)	N	N	N		N	N	N		
				Swelling (svt)	N	N	N		N	N	N		
				Pain at the injection site	N	Mild	N		N	N	N	07OCT2021	1
	[redacted]	1	07OCT2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	N	N	N	N	N	08OCT2021	2
		2	26OCT2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	Mild	N	N	N	N	28OCT2021	3

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
	[redacted]†	1	27OCT2021	Redness (svt)	N	N	N	N			N		
				Swelling (svt)	N	N	N	N			N		
				Pain at the injection site	N	Mod	N	N			N	28OCT2021	1
		2	16NOV2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	Mod	N	N	N	N	N	17NOV2021	1
	[redacted]	1	21JUL2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mod	Mod	N	N	N	N	N	22JUL2021	2
		2	10AUG2021	Redness (svt)		N	N	N	N	N	N		
				Swelling (svt)		N	N	N	N	N	N		
				Pain at the injection site		Mild	N	N	N	N	N	11AUG2021	1
	[redacted]	1	13AUG2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (cu)		2	6	4	2			15AUG2021	1
				Swelling (svt)	N	N	Mild	N	N	N	N		
				Pain at the injection site	N	Mild	N	N	N	N	N	14AUG2021	1
		2	03SEP2021	Redness (svt)	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	N	N	N	N	N	04SEP2021	2
	[redacted]	1	28AUG2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	17SEP2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	Mild	N	N	N	N	N	18SEP2021	1
	[redacted]	1	07SEP2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	29SEP2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	13SEP2021	Redness (svt)	N								
				Swelling (svt)	N								

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site	Mild							17SEP2021	5
		2	14OCT2021	Redness (svt)	N	N	N		N	N	N		
				Swelling (svt)	N	N	N		N	N	N		
				Pain at the injection site	Mild	N	N		N	N	N	14OCT2021	1
	[redacted]	1	13SEP2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	Mild	Mild	Mild	N	N	N	16SEP2021	3
		2	05OCT2021	Redness (svt)	N	N	N	N	N		N		
				Swelling (svt)	N	N	N	N	N		N		
				Pain at the injection site	Mild	Mild	N	N	N		N	06OCT2021	2
	[redacted]	1	14SEP2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	N	N	N	N	N	N	14SEP2021	1
		2	07OCT2021	Redness (svt)		N	N	N	N	N	N		
				Swelling (svt)		N	N	N	N	N	N		
				Pain at the injection site		N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
	[redacted]	1	28SEP2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	Mild	N	N	N	N	30SEP2021	3
		2	21OCT2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	N	N	N	N	N	22OCT2021	2
	[redacted]	1	29SEP2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	N	N	N	N	N	N	29SEP2021	1
		2	19OCT2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mod	Mild	N	N	N	N	N	20OCT2021	2
	[redacted]	1	07OCT2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	Mild	N	N	N	N	N	08OCT2021	1
		2	28OCT2021	Redness (cu)	20							28OCT2021	1
				Redness (svt)	Mod	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Swelling (cu)	20							28OCT2021	1
				Swelling (svt)	Mod	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	N	N	N	N	N	29OCT2021	2
	[redacted]	1	26OCT2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	N	N	N	N	N	27OCT2021	2
		2	17NOV2021	Redness (svt)	N	N		N	N	N	N		
				Swelling (svt)	N	N		N	N	N	N		
				Pain at the injection site	Mild	N		N	N	N	N	17NOV2021	1
	[redacted]	1	19OCT2021	Redness (svt)					N	N	N		
				Swelling (svt)					N	N	N		
				Pain at the injection site					N	N	N		
		2	09NOV2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	14OCT2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site	Mod	Mild	N	N	N	N	N	15OCT2021	2
		2	02NOV2021	Redness (svt)	N	N	N			N	N		
				Swelling (svt)	N	N	N			N	N		
				Pain at the injection site	Mild	N	N			N	N	02NOV2021	1
	[redacted]	1	21OCT2021	Redness (svt)	N	N	N	N	N		N		
				Swelling (svt)	N	N	N	N	N		N		
				Pain at the injection site	Mild	Mild	Mild	N	N		N	23OCT2021	3
		2	09NOV2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	N	N	N	N	N	10NOV2021	2
	[redacted]	1	28OCT2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	N	N	N	N	N	N	28OCT2021	1
		2	17NOV2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
	[redacted]†	1	05NOV2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mod	Mild	Mild	N	N	N	N	07NOV2021	3
		2	25NOV2021	Redness (svt)		N	N	N	N	N	N		
				Swelling (svt)		N	N	N	N	N	N		
				Pain at the injection site		Mod	Mild	N	N	N	N	27NOV2021	2
	[redacted]	1	02JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	Mild	N	N	N	N	04JUN2021	3
		2	23JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (cu)	2								
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	Mild	N	N	N	N	25JUN2021	3
	[redacted]	1	10JUN2021	Redness (cu)		6	7					12JUN2021	2
				Redness (svt)	N	Mild	Mild	N	N	N	N		
				Swelling (cu)		1	1						
				Swelling (svt)	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site	Mild	Mild	Mild	N	N	N	N	12JUN2021	3
		2	30JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	N	N	N	N	N	N	30JUN2021	1
	[redacted]	1	10JUN2021	Redness (cu)		4	2						
				Redness (svt)	N	N	N	N	N	N	N		
				Swelling (cu)	5	4	2					10JUN2021	1
				Swelling (svt)	Mild	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mod	Mild	N	N	N	N	12JUN2021	3
		2	30JUN2021	Redness (cu)	2	1							
				Redness (svt)	N	N		N		N	N		
				Swelling (cu)	2	1							
				Swelling (svt)	N	N		N		N	N		
				Pain at the injection site	Mod	Mod		N		N	N	01JUL2021	2
	[redacted]	1	14JUL2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	Mild	N	N	N	N	N	15JUL2021	1
		2	05AUG2021	Redness (svt)	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Swelling (cu)	11							05AUG2021	1
				Swelling (svt)	Mod	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	N	N	N	N	N	06AUG2021	2
	[redacted]	1	19JUL2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	Mild	N	N	N	N	N	20JUL2021	1
		2	09AUG2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	N	N	N	N	N	N	09AUG2021	1
	[redacted]	1	25AUG2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (cu)	1	1							
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mod	Mild	N	N	N	N	N	26AUG2021	2
		2	15SEP2021	Redness (cu)	1	1	1						
				Redness (svt)	N	N	N	N	N	N	N		
				Swelling (cu)	1	1	1						
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mod	Mod	Mild	N	N	N	N	17SEP2021	3

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Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
	[redacted]	1	11AUG2021	Redness (svt)	N	N	N	N		N	N		
				Swelling (svt)	N	N	N	N		N	N		
				Pain at the injection site	Mild	Mild	N	N		N	N	12AUG2021	2
	[redacted]†	1	19AUG2021	Redness (svt)		N	N	N	N	N	N		
				Swelling (svt)		N	N	N	N	N	N		
				Pain at the injection site		N	N	N	N	N	N		
		2	07SEP2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	N	N	N	N	N	N	07SEP2021	1
	[redacted]	1	18AUG2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	N	N	N	N	N	19AUG2021	2
		2	06SEP2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	N	N	N	N	N	N	06SEP2021	1
	[redacted]	1	20AUG2021	Redness (svt)	N	N	N	N	N	N	N		

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Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	08SEP2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	01SEP2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	Mild	N	N	N	N	N	02SEP2021	1
		2	20SEP2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mod	Mild	N	N	N	N	N	21SEP2021	2
	[redacted]†	1	03SEP2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	N	N	N	N	N	04SEP2021	2
		2	22SEP2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	N	N	N	N	N	23SEP2021	2

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
	[redacted]†	1	06SEP2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	Mild	N	N	N	N	N	07SEP2021	1
		2	27SEP2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	N	N	N	N	N	N	27SEP2021	1
	[redacted]†	1	20SEP2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	Mild	N	N	N	N	22SEP2021	3
		2	14OCT2021	Redness (svt)	N	N	N	N		N	N		
				Swelling (svt)	N	N	N	N		N	N		
				Pain at the injection site	Mod	Mild	Mod	N		N	N	16OCT2021	3
	[redacted]†	1	17SEP2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	N	N	N	N	N	18SEP2021	2
		2	08OCT2021	Redness (svt)				N		N	N		
				Swelling (svt)				N		N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site				N		N	N		
	[redacted]†	1	21SEP2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mod	N	N	N	N	N	22SEP2021	2
		2	14OCT2021	Redness (svt)	N		N	N	N	N	N		
				Swelling (svt)	N		N	N	N	N	N		
				Pain at the injection site	Mild		N	N	N	N	N	14OCT2021	1
	[redacted]†	1	05OCT2021	Redness (svt)		N	N	N	N	N	N		
				Swelling (cu)		6						06OCT2021	1
				Swelling (svt)		Mild	N	N	N	N	N		
				Pain at the injection site		Mod	N	N	N	N	N	06OCT2021	1
		2	25OCT2021	Redness (svt)	N	N	N	N	N				
				Swelling (cu)	12	13						26OCT2021	2
				Swelling (svt)	Mod	Mod	N	N	N				
				Pain at the injection site	Mod	Mod	N	N	N			26OCT2021	2
	[redacted]	1	06OCT2021	Redness (svt)	N	N			N	N			
				Swelling (svt)	N	N			N	N			

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site	Mild	Mild			N	N		07OCT2021	2
		2	27OCT2021	Redness (svt)	N		N	N	N	N	N		
				Swelling (svt)	N		N	N	N	N	N		
				Pain at the injection site	Mild		N	N	N	N	N	27OCT2021	1
	[redacted]†	1	14OCT2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	N	N	N	N	N	15OCT2021	2
		2	04NOV2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	N	N	N	N	N	N	04NOV2021	1
	[redacted]†	1	05NOV2021	Redness (svt)		N	N	N	N	N	N		
				Swelling (svt)		N	N	N	N	N	N		
				Pain at the injection site		N	N	N	N	N	N		
		2	26NOV2021	Redness (svt)			N	N	N	N	N		
				Swelling (svt)			N	N	N	N	N		
				Pain at the injection site			Mild	N	N	N	N	28NOV2021	1

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
	[redacted]	1	10JUN2021	Redness (svt)		N	N	N	N	N	N		
				Swelling (cu)		1							
				Swelling (svt)		N	N	N	N	N	N		
				Pain at the injection site		Mild	N	N	N	N	N	11JUN2021	1
		2	29JUN2021	Redness (svt)		N	N	N	N	N	N		
				Swelling (svt)		N	N	N	N	N	N		
				Pain at the injection site		Mild	N	N	N	N	N	30JUN2021	1
	[redacted]	1	11JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	Mild	N	N	N	N	N	12JUN2021	1
	[redacted]	1	04JUN2021	Redness (svt)	N	N	N	N	N		N		
				Swelling (svt)	N	N	N	N	N		N		
				Pain at the injection site	N	N	N	N	N		N		
		2	25JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
	[redacted]	1	04JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	Mild	N	N	N	N	N	05JUN2021	1
		2	25JUN2021	Redness (svt)	N	N	N	N	N	N			
				Swelling (svt)	N	N	N	N	N	N			
				Pain at the injection site	N	Mild	N	N	N	N		26JUN2021	1
	[redacted]	1	12AUG2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	N	N	N	N	N	13AUG2021	2
		2	02SEP2021	Redness (cu)		6	8	6	5	4		06SEP2021	4
				Redness (svt)	N	Mild	Mild	Mild	Mild	N	N		
				Swelling (cu)		4	3	3	2	2			
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	Mild	Mild	N	N	N	05SEP2021	4
	[redacted]	1	20AUG2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	N	N	N	N	N	21AUG2021	2

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
		2	09SEP2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	N	N	N	N	N	10SEP2021	2
	[redacted]	1	14MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mod	Mod	N	N	N	N	N	15MAY2021	2
	[redacted]	1	26MAY2021	Redness (cu)	2	1							
				Redness (svt)	N	N		N	N	N			
				Swelling (svt)	N	N		N	N	N			
				Pain at the injection site	Mod	Mod		N	N	N		27MAY2021	2
		2	17JUN2021	Redness (cu)		2							
				Redness (svt)		N		N	N		N		
				Swelling (svt)		N		N	N		N		
				Pain at the injection site		Sev		Mod	Mild		N	21JUN2021	4
	[redacted]	1	31AUG2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (cu)	10	21						01SEP2021	2
				Swelling (svt)	Mild	Sev	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site	N	Mod	N	N	N	N	N	01SEP2021	1
		2	22SEP2021	Redness (svt)		N	N	N	N	N	N		
				Swelling (cu)		9	9					24SEP2021	2
				Swelling (svt)		Mild	Mild	N	N	N	N		
				Pain at the injection site		Mild	Mild	Mild	N	N	N	25SEP2021	3
	[redacted]	1	01SEP2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	N	N	N	N	N	02SEP2021	2
		2	22SEP2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	Mild	N	N	N	N	24SEP2021	3
	[redacted]	1	03SEP2021	Redness (cu)		1							
				Redness (svt)	N	N	N	N	N	N	N		
				Swelling (cu)		1							
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mod	Mild	Mild	Mild	N	N	07SEP2021	5
		2	07OCT2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site	Mild	Mod	Mod	N	N	N	N	09OCT2021	3
	[redacted]	1	26MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	Mild	N	N	N	N	N	27MAY2021	1
		2	14JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	Mild	N	N	N	N	N	15JUN2021	1
	[redacted]	1	27MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	N	N	N	N	N	N	27MAY2021	1
		2	15JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mod	Mild	Mild	N	N	N	N	17JUN2021	3
	[redacted]	1	27MAY2021	Redness (cu)		3							
				Redness (svt)	N	N	N	N	N	N	N		
				Swelling (cu)		3							
				Swelling (svt)	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site	N	Mild	N	N	N	N	N	28MAY2021	1
		2	15JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	Mild	N	N	N	N	N	16JUN2021	1
	[redacted]	1	28MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	N	N	N	N	N	N	28MAY2021	1
		2	18JUN2021	Redness (cu)			3		2				
				Redness (svt)	N	N	N	N	N	N	N		
				Swelling (cu)		1	3						
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	28MAY2021	Redness (svt)	N	N	N	N	N	N			
				Swelling (svt)	N	N	N	N	N	N			
				Pain at the injection site	Mild	Mild	N	N	N	N		29MAY2021	2
		2	18JUN2021	Redness (svt)	N	N	N	N	N		N		
				Swelling (svt)	N	N	N	N	N		N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site	N	Mild	Mild	N	N		N	20JUN2021	2
	[redacted]	1	31MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	N	N	N	N	N	01JUN2021	2
		2	21JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (cu)		3							
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	N	N	N	N	N	22JUN2021	2
	[redacted]	1	31MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	Mild	N	N	N	N	N	01JUN2021	1
		2	21JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	02JUN2021	Redness (svt)	N	N	N	N		N	N		
				Swelling (svt)	N	N	N	N		N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site	Mild	Mod	N	N		N	N	03JUN2021	2
	[redacted]	1	02JUN2021	Redness (svt)	N	N	N	N	N		N		
				Swelling (svt)	N	N	N	N	N		N		
				Pain at the injection site	N	Mod	N	N	N		N	03JUN2021	1
		2	23JUN2021	Redness (svt)	N	N			N	N	N		
				Swelling (svt)	N	N			N	N	N		
				Pain at the injection site	N	N			N	N	N		
	[redacted]	1	02JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	Mild	N	N	N	N	N	03JUN2021	1
		2	23JUN2021	Redness (svt)	N	N	N		N	N	N		
				Swelling (svt)	N	N	N		N	N	N		
				Pain at the injection site	Mild	N	N		N	N	N	23JUN2021	1
	[redacted]	1	08JUN2021	Redness (svt)	N	N	N	N		N	N		
				Swelling (svt)	N	N	N	N		N	N		
				Pain at the injection site	Mod	Mild	N	N		N	N	09JUN2021	2

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
		2	29JUN2021	Redness (svt)	N	N		N	N	N			
				Swelling (cu)	14							29JUN2021	1
				Swelling (svt)	Mod	N		N	N	N			
				Pain at the injection site	Mod	Mild		N	N	N		30JUN2021	2
	[redacted]	1	08JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	Mild	N	N	N	N	N	09JUN2021	1
		2	29JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	Mild	N	N	N	N	N	30JUN2021	1
	[redacted]	1	11JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	N	N	N	N	N	N	11JUN2021	1
		2	02JUL2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	N	N	N	N	N	N	02JUL2021	1
	[redacted]	1	11JUN2021	Redness (svt)		N	N	N	N	N	N		

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Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Swelling (svt)		N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	N	N	N	N	N	12JUN2021	2
		2	02JUL2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	N	N	N	N	N	03JUL2021	2
	[redacted]	1	06AUG2021	Redness (svt)	N	N	N	N	N		N		
				Swelling (svt)	N	N	N	N	N		N		
				Pain at the injection site	N	Mild	N	N	N		N	07AUG2021	1
		2	30AUG2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	N	N	N	N	N	N	30AUG2021	1
	[redacted]	1	24SEP2021	Redness (svt)	N	N	N	N	N		N		
				Swelling (svt)	N	N	N	N	N		N		
				Pain at the injection site	N	Mild	N	N	N		N	25SEP2021	1
		2	15OCT2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		

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Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
	[redacted]	1	08JUN2021	Redness (svt)	N	N		N	N	N	N		
				Swelling (svt)	N	N		N	N	N	N		
				Pain at the injection site	N	Mod		N	N	N	N	09JUN2021	1
		2	29JUN2021	Redness (svt)			N	N	N	N	N		
				Swelling (svt)			N	N	N	N	N		
				Pain at the injection site			Mild	Mild	N	N	N	02JUL2021	2
	[redacted]	1	11JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	Mild	N	N	N	N	N	12JUN2021	1
		2	06JUL2021	Redness (svt)	N	N	N		N	N	N		
				Swelling (svt)	N	N	N		N	N	N		
				Pain at the injection site	Mod	Mod	Mild		N	N	N	08JUL2021	3
	[redacted]	1	12JUL2021	Redness (svt)	N	N			N	N	N		
				Swelling (svt)	N	N			N	N	N		
				Pain at the injection site	Mod	Mild			N	N	N	13JUL2021	2
		2	02AUG2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site	Mild	Mod	N	N	N	N	N	03AUG2021	2
	[redacted]	1	23JUL2021	Redness (svt)	N	N	N	N		N	N		
				Swelling (svt)	N	N	N	N		N	N		
				Pain at the injection site	Mild	Mild	Mild	N		N	N	25JUL2021	3
		2	12AUG2021	Redness (svt)	N	N	N		N	N			
				Swelling (svt)	N	N	N		N	N			
				Pain at the injection site	Mild	Mild	Mild		N	N		14AUG2021	3
	[redacted]	1	22JUL2021	Redness (svt)	N	N	N	N	N		N		
				Swelling (svt)	N	N	N	N	N		N		
				Pain at the injection site	N	N	N	N	N		N		
		2	12AUG2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	22JUL2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	Mild	N	N	N	N	N	23JUL2021	1

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
		2	12AUG2021	Redness (svt)		N	N	N	N	N	N		
				Swelling (svt)		N	N	N	N	N	N		
				Pain at the injection site		Mild	Mild	N	N	N	N	14AUG2021	2
	[redacted]	1	04AUG2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	N	N	N	N	N	05AUG2021	2
		2	24AUG2021	Redness (svt)		N	N	N	N	N	N		
				Swelling (svt)		N	N	N	N	N	N		
				Pain at the injection site		Mild	Mild	N	N	N	N	26AUG2021	2
	[redacted]	1	22JUL2021	Redness (svt)	N	N		N		N	N		
				Swelling (svt)	N	N		N		N	N		
				Pain at the injection site	Mild	N		N		N	N	22JUL2021	1
		2	11AUG2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mod	Mild	Mild	N	N	N	14AUG2021	4
	[redacted]	1	24JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (cu)		1							

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	Mild	N	N	N	N	N	25JUN2021	1
		2	16JUL2021	Redness (svt)		N	N	N	N	N	N		
				Swelling (svt)		N	N	N	N	N	N		
				Pain at the injection site		Mild	N	N	N	N	N	17JUL2021	1
	[redacted]	1	01JUN2021	Redness (svt)	N	N	N	N		N	N		
				Swelling (svt)	N	N	N	N		N	N		
				Pain at the injection site	Mild	Mod	Mild	N		N	N	03JUN2021	3
		2	22JUN2021	Redness (svt)	N	N	N	N	N	N			
				Swelling (svt)	N	N	N	N	N	N			
				Pain at the injection site	Mild	Mod	Mild	N	N	N		24JUN2021	3
	[redacted]	1	01JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	22JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	N	N	N	N	N	23JUN2021	2

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
	[redacted]	1	17JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	Mild	N	N	N	N	19JUN2021	3
		2	07JUL2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	Mild	N	N	N	N	09JUL2021	3
	[redacted]	1	08JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	Mild	N	N	N	N	10JUN2021	3
		2	28JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	Mild	N	N	N	N	30JUN2021	3
	[redacted]	1	01JUN2021	Redness (svt)	N	N	N	N	N	N			
				Swelling (svt)	N	N	N	N	N	N			
				Pain at the injection site	N	Mild	N	N	N	N		02JUN2021	1
		2	21JUN2021	Redness (svt)		N	N	N	N	N	N		
				Swelling (svt)		N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site		Mild	N	N	N	N	N	22JUN2021	1
	[redacted]	1	01JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mod	Mild	Mild	N	N	N	04JUN2021	4
		2	23JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	Mild	Mild	N	N	N	N	25JUN2021	2
	[redacted]	1	08JUN2021	Redness (svt)	N		N	N	N	N			
				Swelling (svt)	N		N	N	N	N			
				Pain at the injection site	Mild		Mild	N	N	N		10JUN2021	3
		2	29JUN2021	Redness (cu)				15	5	5		04JUL2021	3
				Redness (svt)	N	N	N	Mod	Mild	Mild	N		
				Swelling (cu)		1	3	5	5	5		04JUL2021	3
				Swelling (svt)	N	N	N	Mild	Mild	Mild	N		
				Pain at the injection site	Mod	Mod	Mild	Mild	Mild	Mild	Mild	06JUL2021	8
	[redacted]	1	09JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (cu)		1							

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	Mild	N	N	N	N	11JUN2021	3
		2	01JUL2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	Mild	Mild	N	N	N	N	03JUL2021	2
	[redacted]	1	14JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	N	N	N	N	N	15JUN2021	2
		2	05JUL2021	Redness (svt)	N	N	N		N	N			
				Swelling (svt)	N	N	N		N	N			
				Pain at the injection site	Mild	Mild	N		N	N		06JUL2021	2
	[redacted]	1	11JUN2021	Redness (svt)	N	N	N	N		N	N		
				Swelling (svt)	N	N	N	N		N	N		
				Pain at the injection site	N	Mild	N	N		N	N	12JUN2021	1
		2	01JUL2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	Mod	Mild	Mild	N	N	N	04JUL2021	3

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
	[redacted]	1	31AUG2021	Redness (svt)	N								
				Swelling (cu)	6								
				Swelling (svt)	Mild								
				Pain at the injection site	Mild								
	[redacted]	1	21SEP2021	Redness (svt)	N	N	N		N	N	N		
				Swelling (svt)	N	N	N		N	N	N		
				Pain at the injection site	Mild	Mild	N		N	N	N	22SEP2021	2
		2	12OCT2021	Redness (svt)	N	N			N	N	N		
				Swelling (svt)	N	N			N	N	N		
				Pain at the injection site	Mild	Mild			N	N	N	13OCT2021	2
Placebo	[redacted]	1	23MAR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	13APR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
	[redacted]	1	01APR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	22APR2021	Redness (svt)						N	N		
				Swelling (svt)						N	N		
				Pain at the injection site						N	N		
	[redacted]	1	30APR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	11JUN2021	Redness (svt)					N	N	N		
				Swelling (svt)					N	N	N		
				Pain at the injection site					N	N	N		
	[redacted]	1	07MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	20MAY2021	Redness (svt)	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	11JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	18JUN2021	Redness (svt)	N		N			N	N		
				Swelling (svt)	N		N			N	N		
				Pain at the injection site	N		N			N	N		
		2	08JUL2021	Redness (svt)		N	N	N	N	N	N		
				Swelling (cu)		10						09JUL2021	1
				Swelling (svt)		Mild	N	N	N	N	N		
				Pain at the injection site		N	Mod	N	N	N	N	10JUL2021	1
	[redacted]	1	05APR2021	Redness (svt)		N	N	N	N		N		
				Swelling (svt)		N	N	N	N		N		
				Pain at the injection site		N	N	N	N		N		
		2	26APR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	05APR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	30APR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	28APR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	17MAY2021	Redness (svt)		N	N	N	N	N	N		
				Swelling (svt)		N	N	N	N	N	N		
				Pain at the injection site		N	N	N	N	N	N		
	[redacted]	1	23APR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
		2	12MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	29APR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	20MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	30APR2021	Redness (svt)	N	N	N	N	N				
				Swelling (svt)	N	N	N	N	N				
				Pain at the injection site	Mild	N	N	N	N			30APR2021	1
		2	21MAY2021	Redness (cu)	1								
				Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	10MAY2021	Redness (svt)	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	01JUN2021	Redness (svt)	N	N	N			N	N		
				Swelling (svt)	N	N	N			N	N		
				Pain at the injection site	N	N	N			N	N		
	[redacted]	1	11MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	01JUN2021	Redness (svt)	N	N	N		N	N	N		
				Swelling (svt)	N	N	N		N	N	N		
				Pain at the injection site	Mild	N	N		N	N	N	01JUN2021	1
	[redacted]	1	18MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	09JUN2021	Redness (svt)		N	N	N	N	N	N		
				Swelling (svt)		N	N	N	N	N	N		
				Pain at the injection site		N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
	[redacted]	1	20MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	10JUN2021	Redness (svt)		N		N		N	N		
				Swelling (svt)		N		N		N	N		
				Pain at the injection site		N		N		N	N		
	[redacted]	1	21MAY2021	Redness (svt)	N			N	N	N	N		
				Swelling (svt)	N			N	N	N	N		
				Pain at the injection site	N			N	N	N	N		
		2	11JUN2021	Redness (svt)	N	N		N	N	N	N		
				Swelling (svt)	N	N		N	N	N	N		
				Pain at the injection site	N	N		N	N	N	N		
	[redacted]	1	25MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	15JUN2021	Redness (svt)	N	N	N	N	N	N			
				Swelling (svt)	N	N	N	N	N	N			

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site	N	N	N	N	N	N			
	[redacted]	1	02JUN2021	Redness (cu)	1								
				Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	24JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	N	N	N	N	N	N	24JUN2021	1
	[redacted]	1	04JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	09JUL2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	07JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site	N	N	N	N	N	N	N		
		2	27JUL2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	17JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	06JUL2021	Redness (svt)		N	N	N	N	N	N		
				Swelling (svt)		N	N	N	N	N	N		
				Pain at the injection site		N	Mild	N	N	N	N	08JUL2021	1
	[redacted]	1	22JUN2021	Redness (svt)	N	N				N	N		
				Swelling (svt)	N	N				N	N		
				Pain at the injection site	Mild	N				N	N	22JUN2021	1
		2	13JUL2021	Redness (svt)			N	N	N	N			
				Swelling (svt)			N	N	N	N			
				Pain at the injection site			N	N	N	N			

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
	[redacted]	1	28MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	18JUN2021	Redness (svt)	N		N	N	N	N	N		
				Swelling (svt)	N		N	N	N	N	N		
				Pain at the injection site	N		N	N	N	N	N		
	[redacted]	1	01JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	02JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (cu)				1					
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	N	N	N	N	N	N	02JUN2021	1
		2	23JUN2021	Redness (svt)	N	N	N		N	N	N		
				Swelling (svt)	N	N	N		N	N	N		
				Pain at the injection site	N	N	N		N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
	[redacted]	1	07JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	28JUN2021	Redness (svt)			N	N	N	N	N		
				Swelling (svt)			N	N	N	N	N		
				Pain at the injection site			N	N	N	N	N		
	[redacted]	1	08JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	Mild	N	N	N	11JUN2021	1
		2	29JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	N	N	N	N	N	30JUN2021	2
	[redacted]	1	01APR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	20APR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	07JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	12MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	01JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	06APR2021	Redness (cu)	2								
				Redness (svt)	N	N	N		N	N	N		
				Swelling (svt)	N	N	N		N	N	N		
				Pain at the injection site	N	N	N		N	N	N		
		2	27APR2021	Redness (svt)	N			N	N	N			
				Swelling (svt)	N			N	N	N			

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site	N			N	N	N			
	[redacted]	1	06MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	N	N	N	N	N	07MAY2021	2
		2	25MAY2021	Redness (svt)			N	N	N	N	N		
				Swelling (svt)			N	N	N	N	N		
				Pain at the injection site			Mod	Mod	Mod	Mild	Mild	03JUN2021	8
	[redacted]	1	05APR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	26APR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	15JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
		2	08JUL2021	Redness (svt)						N	N		
				Swelling (svt)						N	N		
				Pain at the injection site						N	N		
	[redacted]	1	22MAR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	12APR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	22MAR2021	Redness (svt)	N	N		N	N	N	N		
				Swelling (svt)	N	N		N	N	N	N		
				Pain at the injection site	N	N		N	N	N	N		
		2	12APR2021	Redness (svt)	N	N	N	N		N	N		
				Swelling (svt)	N	N	N	N		N	N		
				Pain at the injection site	N	N	N	N		N	N		
	[redacted]	1	24MAR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site	N	N	N	N	N	N	N		
		2	12APR2021	Redness (svt)	N	N	N	N	N		N		
				Swelling (svt)	N	N	N	N	N		N		
				Pain at the injection site	N	N	N	N	N		N		
	[redacted]	1	23APR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	12MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	04MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	24MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
	[redacted]	1	11MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	08JUN2021	Redness (svt)	N	N	N	N	N	N			
				Swelling (svt)	N	N	N	N	N	N			
				Pain at the injection site	N	N	N	N	N	N			
	[redacted]	1	02JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	23JUN2021	Redness (svt)	N	N	N		N	N	N		
				Swelling (svt)	N	N	N		N	N	N		
				Pain at the injection site	N	N	N		N	N	N		
	[redacted]	1	04JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	23JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	16MAR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	06APR2021	Redness (svt)		N		N	N	N	N		
				Swelling (svt)		N		N	N	N	N		
				Pain at the injection site		N		N	N	N	N		
	[redacted]	1	20APR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	11MAY2021	Redness (svt)	N	N	N	N	N		N		
				Swelling (svt)	N	N	N	N	N		N		
				Pain at the injection site	N	N	N	N	N		N		
	[redacted]	1	08APR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
		2	28APR2021	Redness (svt)		N	N	N	N	N	N		
				Swelling (svt)		N	N	N	N	N	N		
				Pain at the injection site		N	N	N	N	N	N		
	[redacted]	1	26APR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	17MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	27APR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	17MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	18MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site	N	N	N	N	N	N	N		
		2	09JUN2021	Redness (svt)		N	N	N	N	N	N		
				Swelling (svt)		N	N	N	N	N	N		
				Pain at the injection site		N	N	N	N	N	N		
	[redacted]	1	22FEB2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	16MAR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	N	N	N	N	N	N	16MAR2021	1
	[redacted]	1	02MAR2021	Redness (svt)	N	N	N	N	N	N			
				Swelling (svt)	N	N	N	N	N	N			
				Pain at the injection site	N	N	N	N	N	N			
	[redacted]	1	04MAR2021	Redness (svt)	N	N	N		N	N	N		
				Swelling (svt)	N	N	N		N	N	N		
				Pain at the injection site	N	N	N		N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
		2	25MAR2021	Redness (svt)	N	N	N	N		N	N		
				Swelling (svt)	N	N	N	N		N	N		
				Pain at the injection site	N	N	N	N		N	N		
	[redacted]	1	09MAR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	30MAR2021	Redness (svt)		N	N	N	N	N	N		
				Swelling (svt)		N	N	N	N	N	N		
				Pain at the injection site		N	N	N	N	N	N		
	[redacted]	1	17MAR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	05APR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	19MAR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site	N	N	N	N	N	N	N		
		2	09APR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	N	N	N	N	N	10APR2021	2
	[redacted]	1	21APR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	Mild	N	N	N	N	N	22APR2021	1
		2	11MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	N	N	N	N	N	N	11MAY2021	1
	[redacted]	1	31MAR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	20APR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
	[redacted]	1	02APR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	22APR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	08APR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	29APR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	13APR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	04MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	12MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	01JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	03MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (cu)	2								
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	24MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	13MAY2021	Redness (svt)		N	N	N	N	N			
				Swelling (svt)		N	N	N	N	N			

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site		Mild	N	N	N	N		14MAY2021	1
		2	01JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	N	N	N	N	N	02JUN2021	2
	[redacted]	1	18MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	18MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	09JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	26MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
		2	16JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	26MAY2021	Redness (svt)	N	N	N	N		N	N		
				Swelling (svt)	N	N	N	N		N	N		
				Pain at the injection site	N	N	N	N		N	N		
		2	16JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	02JUN2021	Redness (svt)		N	N	N	N	N	N		
				Swelling (svt)		N	N	N	N	N	N		
				Pain at the injection site		N	N	N	N	N	N		
	[redacted]	1	08JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	28JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	18JUN2021	Redness (svt)	N		N	N	N		N		
				Swelling (svt)	N		N	N	N		N		
				Pain at the injection site	N		N	N	N		N		
		2	09JUL2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	18JUN2021	Redness (svt)		N	N	N	N	N	N		
				Swelling (svt)		N	N	N	N	N	N		
				Pain at the injection site		N	N	N	N	N	N		
		2	07JUL2021	Redness (svt)			N		N	N			
				Swelling (svt)			N		N	N			
				Pain at the injection site			N		N	N			
	[redacted]	1	13JUL2021	Redness (svt)		N	N	N		N	N		
				Swelling (svt)		N	N	N		N	N		
				Pain at the injection site		N	N	N		N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
		2	03AUG2021	Redness (svt)	N	N	N						
				Swelling (svt)	N	N	N						
				Pain at the injection site	N	N	N						
	[redacted]	1	13JUL2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	20JUL2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	09AUG2021	Redness (svt)	N		N	N	N	N	N		
				Swelling (svt)	N		N	N	N	N	N		
				Pain at the injection site	N		N	N	N	N	N		
	[redacted]	1	27JUL2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	17AUG2021	Redness (svt)	N	N	N	N		N	N		
				Swelling (svt)	N	N	N	N		N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site	N	N	N	N		N	N		
	[redacted]	1	22SEP2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	22SEP2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	11OCT2021	Redness (svt)			N	N	N	N	N		
				Swelling (svt)			N	N	N	N	N		
				Pain at the injection site			N	N	N	N	N		
	[redacted]	1	13OCT2021	Redness (svt)	N	N	N	N	N		N		
				Swelling (svt)	N	N	N	N	N		N		
				Pain at the injection site	N	N	N	N	N		N		
		2	02NOV2021	Redness (svt)	N	N			N	N	N		
				Swelling (svt)	N	N			N	N	N		
				Pain at the injection site	N	N			N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
	[redacted]	1	17MAR2021	Redness (svt)	N	N	N	N	N	N			
				Swelling (svt)	N	N	N	N	N	N			
				Pain at the injection site	N	N	N	N	N	N			
		2	06APR2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	21APR2021	Redness (svt)	N	N		N	N	N	N		
				Swelling (svt)	N	N		N	N	N	N		
				Pain at the injection site	N	N		N	N	N	N		
		2	12MAY2021	Redness (svt)	N	N	N	N		N	N		
				Swelling (svt)	N	N	N	N		N	N		
				Pain at the injection site	N	N	N	N		N	N		
	[redacted]	1	11MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	01JUN2021	Redness (svt)				N	N	N	N		
				Swelling (svt)				N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site				N	N	N	N		
	[redacted]	1	12MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	02JUN2021	Redness (svt)			N	N	N	N	N		
				Swelling (svt)			N	N	N	N	N		
				Pain at the injection site			N	N	N	N	N		
	[redacted]	1	21MAY2021	Redness (svt)	N	N	N	N		N	N		
				Swelling (svt)	N	N	N	N		N	N		
				Pain at the injection site	N	N	N	N		N	N		
		2	11JUN2021	Redness (svt)	N				N	N	N		
				Swelling (svt)	N				N	N	N		
				Pain at the injection site	N				N	N	N		
	[redacted]	1	30SEP2021	Redness (svt)	N	N		N	N	N	N		
				Swelling (svt)	N	N		N	N	N	N		
				Pain at the injection site	N	N		N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
		2	14OCT2021	Redness (svt)	N	N				N	N		
				Swelling (svt)	N	N				N	N		
				Pain at the injection site	N	N				N	N		
	[redacted]	1	15OCT2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	05NOV2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	22OCT2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	12NOV2021	Redness (svt)	N		N	N	N	N			
				Swelling (svt)	N		N	N	N	N			
				Pain at the injection site	N		N	N	N	N			
	[redacted]	1	13MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site	N	N	N	N	N	N	N		
		2	03JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	N	N	N	N	N	N	03JUN2021	1
	[redacted]	1	24JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	15JUL2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	20AUG2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	11SEP2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
	[redacted]	1	25AUG2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	13SEP2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	28SEP2021	Redness (svt)		N		N		N			
				Swelling (svt)		N		N		N			
				Pain at the injection site		N		N		N			
		2	18OCT2021	Redness (cu)		1							
				Redness (svt)		N	N	N	N				
				Swelling (cu)		1							
				Swelling (svt)		N	N	N	N				
				Pain at the injection site		Mod	N	N	N			19OCT2021	1
	[redacted]	1	11OCT2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	N	N	N	N	N	N	11OCT2021	1

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
		2	03NOV2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]†	1	12OCT2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	02NOV2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	22OCT2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	10NOV2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	20MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	13AUG2021	Redness (svt)		N	N	N	N	N	N		
				Swelling (svt)		N	N	N	N	N	N		
				Pain at the injection site		N	N	N	N	N	N		
		2	01SEP2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mod	N	N	N	N	N	02SEP2021	2
	[redacted]	1	03SEP2021	Redness (svt)	N	N	N	N	N		N		
				Swelling (svt)	N	N	N	N	N		N		
				Pain at the injection site	N	N	N	N	N		N		
		2	23SEP2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	08SEP2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
		2	28SEP2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	07SEP2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	28SEP2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	14SEP2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	N	N	N	N	N	N	14SEP2021	1
		2	05OCT2021	Redness (svt)	N	N	N	N	N		N		
				Swelling (svt)	N	N	N	N	N		N		
				Pain at the injection site	Mild	N	N	N	N		N	05OCT2021	1
	[redacted]	1	20SEP2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site	N	N	N	N	N	N	N		
		2	28OCT2021	Redness (svt)		N	N		N		N		
				Swelling (svt)		N	N		N		N		
				Pain at the injection site		N	N		N		N		
	[redacted]	1	23SEP2021	Redness (svt)	N	N	N	N	N		N		
				Swelling (svt)	N	N	N	N	N		N		
				Pain at the injection site	N	N	N	N	N		N		
		2	14OCT2021	Redness (svt)	N	N		N	N	N	N		
				Swelling (svt)	N	N		N	N	N	N		
				Pain at the injection site	N	N		N	N	N	N		
	[redacted]	1	05OCT2021	Redness (svt)	N	N	N	N			N		
				Swelling (svt)	N	N	N	N			N		
				Pain at the injection site	N	N	N	N			N		
		2	26OCT2021	Redness (svt)	N	N		N	N	N	N		
				Swelling (svt)	N	N		N	N	N	N		
				Pain at the injection site	N	N		N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
	[redacted]	1	07OCT2021	Redness (svt)		N		N	N	N	N		
				Swelling (svt)		N		N	N	N	N		
				Pain at the injection site		N		N	N	N	N		
	[redacted]	1	14OCT2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	02NOV2021	Redness (svt)	N	N	N		N		N		
				Swelling (svt)	N	N	N		N		N		
				Pain at the injection site	N	N	N		N		N		
	[redacted]	1	19OCT2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	09NOV2021	Redness (cu)	1								
				Redness (svt)	N	N	N	N	N	N	N		
				Swelling (cu)	2								
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	N	N	N	N	N	N	09NOV2021	1

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
	[redacted]†	1	23OCT2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	N	Mod	Mild	N	N	N	26OCT2021	4
		2	15NOV2021	Redness (svt)						N			
				Swelling (svt)						N			
				Pain at the injection site						Mild		26NOV2021	7
	[redacted]	1	23OCT2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	15NOV2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	28OCT2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	17NOV2021	Redness (svt)		N	N	N	N	N	N		
				Swelling (svt)		N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site		N	N	N	N	N	N		
	[redacted]	1	05NOV2021	Redness (svt)		N	N	N	N	N	N		
				Swelling (svt)		N	N	N	N	N	N		
				Pain at the injection site		N	N	N	N	N	N		
		2	25NOV2021	Redness (svt)		N	N	N	N	N	N		
				Swelling (svt)		N	N	N	N	N	N		
				Pain at the injection site		N	N	N	N	N	N		
	[redacted]	1	02JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	23JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	07JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
		2	28JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	14JUL2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	05AUG2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	14JUL2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	02AUG2021	Redness (svt)	N	N	N		N	N	N		
				Swelling (svt)	N	N	N		N	N	N		
				Pain at the injection site	N	N	N		N	N	N		
	[redacted]	1	26JUL2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site	N	N	N	N	N	N	N		
		2	16AUG2021	Redness (svt)	N	N		N	N	N	N		
				Swelling (svt)	N	N		N	N	N	N		
				Pain at the injection site	N	N		N	N	N	N		
	[redacted]†	1	11AUG2021	Redness (cu)		4							
				Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	N	N	N	N	N	12AUG2021	2
		2	15SEP2021	Redness (svt)	N	N	N		N		N		
				Swelling (svt)	N	N	N		N		N		
				Pain at the injection site	N	N	N		N		N		
	[redacted]†	1	13AUG2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	20AUG2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (cu)	1								
				Swelling (svt)	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site	Mild	N	N	N	N	N	N	20AUG2021	1
		2	08SEP2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	N	N	N	N	N	N	08SEP2021	1
	[redacted]	1	27AUG2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	23SEP2021	Redness (svt)	N	N		N	N	N	N		
				Swelling (svt)	N	N		N	N	N	N		
				Pain at the injection site	N	N		N	N	N	N		
	[redacted]	1	27AUG2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	16SEP2021	Redness (svt)		N	N	N	N	N	N		
				Swelling (svt)		N	N	N	N	N	N		
				Pain at the injection site		N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
	[redacted]	1	01SEP2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	01OCT2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]†	1	07SEP2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	28SEP2021	Redness (svt)	N		N	N	N		N		
				Swelling (cu)	2								
				Swelling (svt)	N		N	N	N		N		
				Pain at the injection site	N		N	N	N		N		
	[redacted]†	1	07SEP2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mod	N	N	N	N	N	N	07SEP2021	1
		2	30SEP2021	Redness (svt)	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	Mild	N	N	N	N	N	01OCT2021	1
	[redacted]†	1	21SEP2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	12OCT2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]†	1	29SEP2021	Redness (svt)						N	N		
				Swelling (svt)						N	N		
				Pain at the injection site						N	N		
		2	20OCT2021	Redness (svt)	N	N			N	N	N		
				Swelling (svt)	N	N			N	N	N		
				Pain at the injection site	Mod	Mod			N	N	N	21OCT2021	2
	[redacted]†	1	20SEP2021	Redness (svt)	N	N	N	N	N	N			
				Swelling (svt)	N	N	N	N	N	N			

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site	N	N	N	N	N	N			
		2	11OCT2021	Redness (svt)	N		N		N	N	N		
				Swelling (svt)	N		N		N	N	N		
				Pain at the injection site	N		N		N	N	N		
	[redacted]	1	20SEP2021	Redness (svt)	N	N	N	N	N	N			
				Swelling (svt)	N	N	N	N	N	N			
				Pain at the injection site	N	N	N	N	N	N			
		2	14OCT2021	Redness (svt)	N	N				N	N		
				Swelling (svt)	N	N				N	N		
				Pain at the injection site	N	N				N	N		
	[redacted]†	1	15OCT2021	Redness (svt)		N	N	N	N	N	N		
				Swelling (cu)		1							
				Swelling (svt)		N	N	N	N	N	N		
				Pain at the injection site		N	N	N	N	N	N		
		2	04NOV2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
	[redacted]	1	14OCT2021	Redness (svt)	N	N	N		N		N		
				Swelling (svt)	N	N	N		N		N		
				Pain at the injection site	N	N	N		N		N		
	[redacted]	1	09JUN2021	Redness (svt)	N	N	N		N	N			
				Swelling (svt)	N	N	N		N	N			
				Pain at the injection site	N	N	N		N	N			
		2	30JUN2021	Redness (svt)	N	N	N	N		N	N		
				Swelling (svt)	N	N	N	N		N	N		
				Pain at the injection site	N	N	N	N		N	N		
	[redacted]	1	09JUN2021	Redness (svt)	N	N	N	N		N	N		
				Swelling (svt)	N	N	N	N		N	N		
				Pain at the injection site	N	N	N	N		N	N		
		2	30JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	05AUG2021	Redness (svt)	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	26AUG2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	26AUG2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	14SEP2021	Redness (svt)			N	N	N	N	N		
				Swelling (svt)			N	N	N	N	N		
				Pain at the injection site			N	N	N	N	N		
	[redacted]	1	19MAY2021	Redness (svt)	N	N		N	N	N			
				Swelling (svt)	N	N		N	N	N			
				Pain at the injection site	Mild	N		N	N	N		19MAY2021	1
	[redacted]	1	23JUL2021	Redness (svt)	N	N	N	N					
				Swelling (svt)	N	N	N	N					

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site	N	N	N	N					
		2	13AUG2021	Redness (svt)				N	N	N	N		
				Swelling (svt)				N	N	N	N		
				Pain at the injection site				N	N	N	N		
	[redacted]	1	17AUG2021	Redness (cu)		1							
				Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	13SEP2021	Redness (cu)		3							
				Redness (svt)		N	N		N	N	N		
				Swelling (svt)		N	N		N	N	N		
				Pain at the injection site		Mild	N		N	N	N	14SEP2021	1
	[redacted]	1	20OCT2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	05OCT2021	Redness (svt)	N	N	N	N		N	N		
				Swelling (svt)	N	N	N	N		N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site	N	N	N	N		N	N		
		2	26OCT2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	26MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	12JUL2021	Redness (svt)	N	N	N	N		N	N		
				Swelling (svt)	N	N	N	N		N	N		
				Pain at the injection site	N	N	N	N		N	N		
	[redacted]	1	27MAY2021	Redness (svt)	N				N	N			
				Swelling (svt)	N				N	N			
				Pain at the injection site	N				N	N			
		2	18JUN2021	Redness (svt)	N	N		N	N	N			
				Swelling (svt)	N	N		N	N	N			
				Pain at the injection site	N	N		N	N	N			

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
	[redacted]	1	27MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	28MAY2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	N	N	N	N	N	N	28MAY2021	1
		2	18JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mod	N	N	N	N	N	N	18JUN2021	1
	[redacted]	1	28MAY2021	Redness (svt)	N	N	N		N				
				Swelling (svt)	N	N	N		N				
				Pain at the injection site	N	N	N		N				
		2	18JUN2021	Redness (svt)	N			N	N	N	N		
				Swelling (svt)	N			N	N	N	N		
				Pain at the injection site	N			N	N	N	N		
	[redacted]	1	28MAY2021	Redness (svt)	N	N	N	N	N	N			

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Swelling (svt)	N	N	N	N	N	N			
				Pain at the injection site	N	N	N	N	N	N			
		2	18JUN2021	Redness (svt)		N	N	N	N		N		
				Swelling (svt)		N	N	N	N		N		
				Pain at the injection site	Mild	N	N	N	N		N	18JUN2021	1
	[redacted]	1	01JUN2021	Redness (svt)	N	N		N	N	N	N		
				Swelling (svt)	N	N		N	N	N	N		
				Pain at the injection site	N	N		N	N	N	N		
		2	22JUN2021	Redness (svt)	N	N	N	N		N	N		
				Swelling (svt)	N	N	N	N		N	N		
				Pain at the injection site	N	N	N	N		N	N		
	[redacted]	1	01JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	22JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
	[redacted]	1	07JUN2021	Redness (svt)	N	N	N	N	N	N			
				Swelling (svt)	N	N	N	N	N	N			
				Pain at the injection site	N	N	N	N	N	N			
		2	28JUN2021	Redness (svt)	N	N	N				N		
				Swelling (svt)	N	N	N				N		
				Pain at the injection site	N	N	N				N		
	[redacted]	1	07JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	28JUN2021	Redness (svt)	N	N	N	N		N			
				Swelling (svt)	N	N	N	N		N			
				Pain at the injection site	N	N	N	N		N			
	[redacted]	1	08JUN2021	Redness (svt)	N	N	N	N	N		N		
				Swelling (svt)	N	N	N	N	N		N		
				Pain at the injection site	N	N	N	N	N		N		
		2	30JUN2021	Redness (svt)	N	N		N	N	N	N		
				Swelling (svt)	N	N		N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site	N	N		N	N	N	N		
	[redacted]	1	09JUN2021	Redness (svt)	N	N	N	N					
				Swelling (svt)	N	N	N	N					
				Pain at the injection site	N	N	N	N					
	[redacted]	1	10JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	01JUL2021	Redness (svt)	N	N	N	N	N	N			
				Swelling (svt)	N	N	N	N	N	N			
				Pain at the injection site	N	N	N	N	N	N			
	[redacted]	1	25AUG2021	Redness (svt)	N	N	N		N	N	N		
				Swelling (svt)	N	N	N		N	N	N		
				Pain at the injection site	N	N	N		N	N	N		
		2	15SEP2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mod	N	N	N	N	N	N	15SEP2021	1

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
	[redacted]	1	15JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	08JUL2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	N	N	N	N	N	N	08JUL2021	1
	[redacted]	1	17JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	08JUL2021	Redness (svt)	N	N	N	N	N	N			
				Swelling (svt)	N	N	N	N	N	N			
				Pain at the injection site	N	N	N	N	N	N			
	[redacted]	1	10JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	10JUN2021	Redness (svt)	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	12JUL2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	02AUG2021	Redness (svt)	N	N	N	N	N		N		
				Swelling (svt)	N	N	N	N	N		N		
				Pain at the injection site	N	N	N	N	N		N		
	[redacted]	1	12JUL2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	02AUG2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	22JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site	N	N	N	N	N	N	N		
		2	13JUL2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	24AUG2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	17SEP2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	04JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	23JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
	[redacted]	1	04JUN2021	Redness (svt)	N	N	N		N	N	N		
				Swelling (svt)	N	N	N		N	N	N		
				Pain at the injection site	N	N	N		N	N	N		
		2	23JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	N	N	N	N	N	N	23JUN2021	1
	[redacted]	1	21JUN2021	Redness (svt)	N	N	N	N	N		N		
				Swelling (svt)	N	N	N	N	N		N		
				Pain at the injection site	N	Mild	N	Mild	N		N	24JUN2021	3
		2	12JUL2021	Redness (svt)		N	N	N	N	N	N		
				Swelling (svt)		N	N	N	N	N	N		
				Pain at the injection site		Mild	N	N	N	N	N	13JUL2021	1
	[redacted]	1	11JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	02JUL2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	07JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	28JUN2021	Redness (svt)		N		N	N	N	N		
				Swelling (svt)		N		N	N	N	N		
				Pain at the injection site		N		N	N	N	N		
	[redacted]	1	04JUN2021	Redness (svt)	N		N		N	N			
				Swelling (svt)	N		N		N	N			
				Pain at the injection site	N		N		N	N			
		2	23JUN2021	Redness (svt)			N	N	N		N		
				Swelling (svt)			N	N	N		N		
				Pain at the injection site			N	N	N		N		
	[redacted]	1	04JUN2021	Redness (svt)	N	N	N	N	N	N			
				Swelling (svt)	N	N	N	N	N	N			
				Pain at the injection site	Mild	N	N	N	N	N		04JUN2021	1

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
		2	23JUN2021	Redness (svt)	N	N	N	N	N		N		
				Swelling (svt)	N	N	N	N	N		N		
				Pain at the injection site	Mild	Mild	N	N	N		N	24JUN2021	2
	[redacted]	1	07JUN2021	Redness (cu)	7							07JUN2021	1
				Redness (svt)	Mild	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	Mild	N	N	N	N	N	08JUN2021	2
		2	29JUN2021	Redness (svt)	N	N	N	N		N			
				Swelling (svt)	N	N	N	N		N			
				Pain at the injection site	N	N	N	N		N			
	[redacted]	1	14JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	Mild	N	N	N	N	N	N	14JUN2021	1
		2	26JUL2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	07JUN2021	Redness (svt)			N	N	N		N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Swelling (svt)			N	N	N		N		
				Pain at the injection site			N	N	N		N		
		2	28JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	11JUN2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	02JUL2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
	[redacted]	1	16JUN2021	Redness (svt)	N	N	N	N		N			
				Swelling (svt)	N	N	N	N		N			
				Pain at the injection site	N	N	N	N		N			
		2	07JUL2021	Redness (svt)	N	N	N		N	N	N		
				Swelling (svt)	N	N	N		N	N	N		
				Pain at the injection site	N	N	N		N	N	N		

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16.2.7.2 Listing of All Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
	[redacted]	1	14SEP2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		
		2	05OCT2021	Redness (svt)	N	N	N	N	N	N	N		
				Swelling (svt)	N	N	N	N	N	N	N		
				Pain at the injection site	N	N	N	N	N	N	N		

Abbreviations: cu = caliper units; Dur = duration; Mod = moderate; N = none; Sev = severe; svt = severity.
Note: For a given day, if no data are displayed for all local reactions, it indicates that the participant did not make any electronic diary (e-diary) entries and/or no data were transmitted.
Note: † = Human immunodeficiency virus (HIV)-positive participant.
Note: Reactions reported as adverse events in the case report form within 7 days after the study vaccination were also included in the listing.
a. Relative day (Rel Day) = date of reaction - date of last vaccination + 1.
b. The maximum measurable size for redness and swelling in the electronic diary (e-diary) was 21 caliper units. Redness and swelling exceeding 21.0 caliper units are reported as >21.0. Study sites recorded injection site redness or swelling in centimeters. These were converted to caliper units (1 caliper unit = 0.5 centimeters).
c. Stop date is the date the reaction was last reported.
d. Duration (days) was calculated as the difference from the start of the first reported reaction to resolution of the last reported reaction, inclusive. If the reaction continued beyond Day 7, the calculation includes all days from the last electronic diary (e-diary) day until the date of resolution collected on the case report form. If the reaction was ongoing at the time of the subsequent vaccination, the end date/day for the reaction is the date/day that the next vaccine was administered, which was used for the duration calculation.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adfacevd Table Generation: 04MAY2023 (09:49) Output File: ./nda3/C4591015_BR/adce_l004_lr

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16.2.7.3: Listing of Severe and Grade 4 Local Reactions (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
BNT162b2 (30 µg)	[redacted]	2	17JUN2021	Pain at the injection site		Sev		Mod	Mild		N	21JUN2021	4
	[redacted]	1	31AUG2021	Swelling (cu)	10	21						01SEP2021	2
				Swelling (svt)	Mild	Sev	N	N	N	N	N		

Abbreviations: cu = caliper units; Dur = duration; Mod = moderate; N = none; Sev = severe; svt = severity.
Note: For a given day, if no data are displayed for all local reactions, it indicates that the participant did not make any electronic diary (e-diary) entries and/or no data were transmitted.
Note: Reactions reported as adverse events in the case report form within 7 days after the study vaccination were also included in the listing.
a. Relative day (Rel Day) = date of reaction - date of last vaccination + 1.
b. The maximum measurable size for redness and swelling in the electronic diary (e-diary) was 21 caliper units. Redness and swelling exceeding 21.0 caliper units are reported as >21.0. Study sites recorded injection site redness or swelling in centimeters. These were converted to caliper units (1 caliper unit = 0.5 centimeters).
c. Stop date is the date the reaction was last reported.
d. Duration (days) was calculated as the difference from the start of the first reported reaction to resolution of the last reported reaction, inclusive. If the reaction continued beyond Day 7, the calculation includes all days from the last electronic diary (e-diary) day until the date of resolution collected on the case report form. If the reaction was ongoing at the time of the subsequent vaccination, the end date/day for the reaction is the date/day that the next vaccine was administered, which was used for the duration calculation.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adfacevd Table Generation: 04MAY2023 (09:50) Output File: ./nda3/C4591015_BR/adce_l004_sevlr

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
BNT162b2 (30 µg)	[redacted]	1	30APR2021	Oral temperature (°C)	36.56	36.67	36.5	36.56	36.5	36.5	36.56		
				Fatigue	N	N	Mod	N	N	N	N	02MAY2021	1
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	24MAY2021	Oral temperature (°C)	36.67	36.67	36.39	36.67	36.67	36.67	36.67		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	Mild	N	N	N	N	N	25MAY2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	20MAY2021	Oral temperature (°C)	36.67	36.39		36.39	36.72		36.56		
				Fatigue	N	N		N	N		N		
				Headache	N	N		N	N		N		
				Chills	N	N		N	N		N		
				Vomiting	N	N		N	N		N		
				Diarrhea	N	N		N	N		N		
				New or worsened muscle pain	N	N		N	N		N		
				New or worsened joint pain	N	N		N	N		N		
		2	08JUN2021	Oral temperature (°C)		36.44	36.83	36.39	36.22	36.44	35.94		
				Fatigue		N	N	N	N	N	N		
				Headache		N	N	N	N	N	N		
				Chills		N	N	N	N	N	N		
				Vomiting		N	N	N	N	N	N		
				Diarrhea		N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain		N	N	N	N	N	N		
				New or worsened joint pain		N	N	N	N	N	N		
	[redacted]	1	08JUN2021	Oral temperature (°C)	36.56	37.06	36.44	36.89			36.39		
				Fatigue	Mild	N	N	N			N	08JUN2021	1
				Headache	N	N	N	N			N		
				Chills	N	N	N	N			N		
				Vomiting	N	N	N	N			N		
				Diarrhea	N	N	N	N			N		
				New or worsened muscle pain	N	N	N	N			N		
				New or worsened joint pain	N	N	N	N			N		
		2	29JUN2021	Oral temperature (°C)			36.94	36.61	36.89	37.11	36.94		
				Fatigue			N	N	N	N	N		
				Headache			N	N	N	N	N		
				Chills			N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting			N	N	N	N	N		
				Diarrhea			N	N	N	N	N		
				New or worsened muscle pain			N	N	N	N	N		
				New or worsened joint pain			N	N	N	N	N		
	[redacted]	1	19FEB2021	Oral temperature (°C)	36.11	35.72	35.67	36.44	35.72	35.28	36.06		
				Fatigue	N	Mod	Mod	Mod	Mod	Mild	Mod	12MAR2021	21
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	12MAR2021	Oral temperature (°C)	35.28	35.11	35.61	36.39	35.89	35.67	36.39		
				Fatigue	N	Mod	N	N	N	Mod	N	17MAR2021	5

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	Mild	Mild	N	N	N	N	N	13MAR2021	2
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	13MAY2021	Oral temperature (°C)	35.94	35.89	36.5	36.11	36.06	36.11			
				Fatigue	Mild	Mild	Mild	N	N	N		15MAY2021	3
				Headache	Mild	N	N	N	N	N		13MAY2021	1
				Chills	N	N	N	N	N	N			
				Vomiting	N	N	N	N	N	N			
				Diarrhea	N	Mild	Mild	N	N	N		15MAY2021	2
				New or worsened muscle pain	N	N	N	N	N	N			
				New or worsened joint pain	N	N	N	N	N	N			

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
		2	01JUN2021	Oral temperature (°C)	36.39	35.72	35.89	36.11	36.06	35.78	35.89		
				Fatigue	N	Mod	Mild	Mild	N	N	N	04JUN2021	3
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	Mod	Mild	Mild	N	N	N	04JUN2021	3
				New or worsened joint pain	N	Mild	N	N	N	N	N	02JUN2021	1
	[redacted]	1	20APR2021	Oral temperature (°C)	36.39	36.5	36.06	36.11	36.06	36.56	36.22		
				Fatigue	N	Mild	Mod	Mod	Mod	Mild	Mild	26APR2021	6
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	11MAY2021	Oral temperature (°C)	36.61	36.78	36.61	36.28	36.78	36.06	36.17		
				Fatigue	Mild	Mild	Mod	Mild	Mild	N	N	15MAY2021	5
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	Mod	N	N	15MAY2021	1
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	23APR2021	Oral temperature (°C)	36	36	35.5	36.61	36.06	35.89	36.06		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	Mild	N	N	27APR2021	1
				Chills	Mild	N	N	N	N	N	N	23APR2021	1
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	12MAY2021	Oral temperature (°C)	35.78		35.72	36.11	36.33	36.17			
				Fatigue	Mod		N	N	N	N		12MAY2021	1
				Headache	N		N	N	N	N			
				Chills	N		N	N	N	N			
				Vomiting	N		N	N	N	N			
				Diarrhea	N		N	N	N	N			
				New or worsened muscle pain	N		N	N	N	N			
				New or worsened joint pain	N		N	N	N	N			
	[redacted]	1	26APR2021	Oral temperature (°C)	35.5	36.11	35.72	35.5	35.72	35.83	36.11		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	10JUN2021	Oral temperature (°C)	35.5	35.83			35.39	35.83	35.78		
				Fatigue	N	Mod			N	N	N	11JUN2021	1
				Headache	N	Mild			N	N	N	11JUN2021	1
				Chills	N	N			N	N	N		
				Vomiting	N	N			N	N	N		
				Diarrhea	N	N			N	N	N		
				New or worsened muscle pain	N	Mild			N	N	N	11JUN2021	1
				New or worsened joint pain	N	Mild			N	N	N	11JUN2021	1
	[redacted]	1	29APR2021	Oral temperature (°C)	36.72	35.78	36.39	35.78	35.72	35.78	35.67		
				Fatigue	N	Mild	Mod	Mild	Mild	N	N	03MAY2021	4

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	Mild	Mod	Mod	N	N	N	N	01MAY2021	3
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	05MAY2021	Oral temperature (°C)	36.67	36.78	36.83		36.72	36.89			
				Fatigue	N	N	N		N	N			
				Headache	N	N	N		N	N			
				Chills	N	N	N		N	N			
				Vomiting	N	N	N		N	N			
				Diarrhea	N	N	N		N	N			
				New or worsened muscle pain	N	N	N		N	N			
				New or worsened joint pain	N	N	N		N	N			

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
		2	26MAY2021	Oral temperature (°C)	36.78	37	36.83	36.78	36.89	37	37.17		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	10MAY2021	Oral temperature (°C)	37	36.56	36.11	36.39	36.33	36.22	36.22		
				Fatigue	N	Mild	N	N	N	N	N	11MAY2021	1
				Headache	N	N	N	Mod	N	N	N	13MAY2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	01JUN2021	Oral temperature (°C)		36.56	36.61	36.33	36.11	36.11	36.44		
				Fatigue		Mod	Mild	N	N	N	N	03JUN2021	2
				Headache		N	N	N	N	N	N		
				Chills		N	N	N	N	N	N		
				Vomiting		N	N	N	N	N	N		
				Diarrhea		N	N	N	N	N	N		
				New or worsened muscle pain		N	N	N	N	N	N		
				New or worsened joint pain		N	N	N	N	N	N		
	[redacted]	1	17MAY2021	Oral temperature (°C)	36.78	36.56	36.56	35.67	36.39	36.72	35.89		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	07JUN2021	Oral temperature (°C)	36.56	37.44	35.94	36.39	36.94	35.33	36.83		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	20MAY2021	Oral temperature (°C)	36.89	37	36.89	37	36.89	37	37		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	09JUN2021	Oral temperature (°C)	37	36.67	37	36.78	37	37			
				Fatigue	N	N	N	N	N	N			
				Headache	N	N	N	N	N	N			
				Chills	N	N	N	N	N	N			
				Vomiting	N	N	N	N	N	N			
				Diarrhea	N	N	N	N	N	N			
				New or worsened muscle pain	N	N	N	N	N	N			
				New or worsened joint pain	N	N	N	N	N	N			
	[redacted]	1	26MAY2021	Oral temperature (°C)	36.22	36	36.44	35.5	36.44	35.17	35.56		
				Fatigue	N	Mild	N	N	N	Mod	N	31MAY2021	5

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	Mod	Mod	Mod	Mod	Mod	Mod	14JUN2021	19
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	14JUN2021	Oral temperature (°C)		37	36.39	36.67	36.56	36.33	36.5		
				Fatigue		Sev	Mild	Mild	N	Mild	Mild	21JUN2021	7
				Headache		Sev	Mod	Mod	Mod	Mild	Mild	14JUL2021	30
				Chills		Mild	N	N	N	N	N	15JUN2021	1
				Vomiting		N	N	N	N	N	N		
				Diarrhea		Mild	N	N	N	Mild	N	19JUN2021	5
				New or worsened muscle pain		Mod	Mod	N	N	N	N	16JUN2021	2
				New or worsened joint pain		N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	[redacted]	1	27MAY2021	Oral temperature (°C)	35.89	35.94	35.72	36.67	36.17	36.22	36.28		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	18JUN2021	Oral temperature (°C)					35.89	35.94	36.17		
				Fatigue					N	N	N		
				Headache					N	N	N		
				Chills					N	N	N		
				Vomiting					N	N	N		
				Diarrhea					N	N	N		
				New or worsened muscle pain					N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain					N	N	N		
	[redacted]	1	03JUN2021	Oral temperature (°C)	36.28	36.83	36.78	36.94	37	36.44	36.94		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	20JUL2021	Oral temperature (°C)	36.94	36.83	36.89	36.44	36.94	36.89			
				Fatigue	Mod	Mild	N	N	N	N		21JUL2021	2
				Headache	Mild	N	N	N	N	N		20JUL2021	1
				Chills	N	N	N	N	N	N			
				Vomiting	N	N	N	N	N	N			
				Diarrhea	N	N	N	N	N	N			

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	N	N	N	N			
				New or worsened joint pain	N	N	N	N	N	N			
	[redacted]	1	07JUN2021	Oral temperature (°C)	35.33	35.17	36.5	35.39	36.33	36.06	33.94		
				Fatigue	N	Mild	Mild	Mild	Mild	Mild	Mild	14JUN2021	7
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	30JUN2021	Oral temperature (°C)	37	36.67	35.17	35.56	35.28	36	35.56		
				Fatigue	Mild	Mild	Mild	Mild	Mild	Mild	Mild	07JUL2021	8
				Headache	N	Mod	N	N	N	N	N	01JUL2021	1
				Chills	N	Mild	N	N	N	N	N	01JUL2021	1

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	Mild	N	N	N	N	N	01JUL2021	1
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	Mild	N	N	N	N	N	01JUL2021	1
				New or worsened joint pain	N	Mild	N	N	N	N	N	01JUL2021	1
	[redacted]	1	10JUN2021	Oral temperature (°C)	35.94	36.89	36.11	37	36.44				
				Fatigue	Mod	Mild	N	Mild	N			13JUN2021	4
				Headache	N	N	N	N	N				
				Chills	N	N	N	Mild	Mild			15JUN2021	3
				Vomiting	N	N	N	N	N				
				Diarrhea	N	N	N	N	N				
				New or worsened muscle pain	N	N	N	N	N				
				New or worsened joint pain	N	N	N	N	N				
	[redacted]	1	11JUN2021	Oral temperature (°C)	35.94	35.83	36.17	36.67	36.56	36.39	36.56		
				Fatigue	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	02JUL2021	Oral temperature (°C)		36.72	36.17	36.28	35.94		36.11		
				Fatigue		N	N	N	N		N		
				Headache		N	N	N	N		N		
				Chills		N	N	N	N		N		
				Vomiting		N	N	N	N		N		
				Diarrhea		N	N	N	N		N		
				New or worsened muscle pain		N	N	N	N		N		
				New or worsened joint pain		N	N	N	N		N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	[redacted]	1	18JUN2021	Oral temperature (°C)	36.22	36.33	36.22	36.44	36.28	36.22	36.44		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	Mild	N	N	N	Mild	N	23JUN2021	5
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	09JUL2021	Oral temperature (°C)	36.33	36.56	36.33	36.44	36.28	36.17	36.44		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	Mild	Mild	N	N	N	N	11JUL2021	2
				New or worsened muscle pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	24JUN2021	Oral temperature (°C)	36.56	36.72	36.67	36.5	36.67	37.22	36.67		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	Mild	Mild	N	N	N	27JUN2021	2
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	26APR2021	Oral temperature (°C)	37.28	36.89	37	36.56	36.33		36.67		
				Fatigue	N	N	N	Mild	N		N	29APR2021	1
				Headache	N	N	N	N	N		N		
				Chills	N	N	N	N	N		N		
				Vomiting	N	N	N	N	N		N		
				Diarrhea	N	N	N	N	N		N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	N	N	N		N		
				New or worsened joint pain	N	N	N	N	N		N		
		2	17MAY2021	Oral temperature (°C)	37.28	37.5	37.39	36.39		36.44	36.17		
				Fatigue	N	N	N	N		N	N		
				Headache	N	N	N	N		N	N		
				Chills	N	N	N	N		N	N		
				Vomiting	N	N	N	N		N	N		
				Diarrhea	N	N	N	N		N	N		
				New or worsened muscle pain	N	N	N	Mild		N	N	20MAY2021	1
				New or worsened joint pain	N	N	N	N		N	N		
	[redacted]	1	24MAY2021	Oral temperature (°C)	36.5	36.9	36.4	36.5	36.2	36.5	36.5		
				Fatigue	N	Mod	N	N	N	N	N	25MAY2021	1
				Headache	Mild	N	N	N	N	N	N	24MAY2021	1
				Chills	Mild	N	N	N	Mild	N	N	28MAY2021	5

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	14JUN2021	Oral temperature (°C)			36.5	36.4	36.5	36.5	36.5		
				Fatigue			Mild	Mod	Mod	N	N	18JUN2021	3
				Headache			N	N	N	N	N		
				Chills			Mod	Mod	Mod	N	N	18JUN2021	3
				Vomiting			N	N	N	N	N		
				Diarrhea			N	N	N	N	N		
				New or worsened muscle pain			Mod	N	N	N	N	16JUN2021	1
				New or worsened joint pain			N	N	N	N	N		
	[redacted]	1	31MAY2021	Oral temperature (°C)	35.8	35.8	35.9	35.6	35.7	35.6	35.9		
				Fatigue	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	21JUN2021	Oral temperature (°C)	35.6	36.5	35.6		35.3	36	35.3		
				Fatigue	N	N	N		N	N	N		
				Headache	N	N	N		N	N	N		
				Chills	N	N	N		N	N	N		
				Vomiting	N	N	N		N	N	N		
				Diarrhea	N	N	N		N	N	N		
				New or worsened muscle pain	N	N	N		N	N	N		
				New or worsened joint pain	N	N	N		N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	[redacted]	1	01JUN2021	Oral temperature (°C)	36.1	35.8	36.2	36.1	36.2	35.9	35.5		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	Mild	N	N	05JUN2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	Mild	N	N	05JUN2021	1
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	22JUN2021	Oral temperature (°C)	35.8	36.4	36.8	36.5	35.6	35.6	36		
				Fatigue	N	Sev	N	N	N	Mild	N	27JUN2021	5
				Headache	Mild	Mod	Mod	N	Mild	Mod	N	27JUN2021	6
				Chills	N	Sev	Mild	N	N	N	N	24JUN2021	2
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	Sev	Mild	N	N	N	N	24JUN2021	2

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	Mod	Mild	N	N	N	N	24JUN2021	2
	[redacted]	1	03JUN2021	Oral temperature (°C)	36.4	36.1	36	36.2	36.2	36	36.6		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	24JUN2021	Oral temperature (°C)	36.2	36.1	35.9	36.2	36	36	36		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	03JUN2021	Oral temperature (°C)	36.1	36.2	36.2	36.4	36.4	36.2	36.2		
				Fatigue	Mild	Mild	N	N	N	N	N	04JUN2021	2
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	25JUN2021	Oral temperature (°C)	36.4	36.2	36.4	36.5	36.2	36.2	36.4		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	10JUN2021	Oral temperature (°C)	36.2			35.2	35.4	35.4	35.4		
				Fatigue	N			Mild	Mod	Mild	N	15JUN2021	3
				Headache	N			N	Mild	N	N	14JUN2021	1
				Chills	Mild			N	N	N	N	10JUN2021	1
				Vomiting	N			N	N	N	N		
				Diarrhea	N			N	N	N	N		
				New or worsened muscle pain	Mod			Mild	Mod	Mild	Mild	16JUN2021	7
				New or worsened joint pain	Mod			Mild	Mod	Mild	Mild	16JUN2021	7
	[redacted]	1	21MAY2021	Oral temperature (°C)	36.56	36.44	36.22	35.94	35.94	36			
				Fatigue	N	Mod	Mild	Mild	N	N		24MAY2021	3

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	N	N	N	N	N			
				Chills	N	N	N	N	N	N			
				Vomiting	N	N	N	N	N	N			
				Diarrhea	N	N	N	N	N	N			
				New or worsened muscle pain	N	Mod	N	N	N	N		22MAY2021	1
				New or worsened joint pain	N	N	N	N	N	N			
		2	11JUN2021	Oral temperature (°C)	36.56		36.56	32.28		33.61	34.67		
				Fatigue	N		Mod	N		N	N	13JUN2021	1
				Headache	Mod		Mild	Mild		N	N	14JUN2021	4
				Chills	N		N	N		N	N		
				Vomiting	N		N	N		N	N		
				Diarrhea	N		N	N		N	N		
				New or worsened muscle pain	N		Mild	N		N	N	13JUN2021	1
				New or worsened joint pain	N		N	N		N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	[redacted]	1	16JUN2021	Oral temperature (°C)	36.72	36.17	36.78	36.22	35.83		36.72		
				Fatigue	N	N	N	Mild	N		N	19JUN2021	1
				Headache	N	N	N	N	N		N		
				Chills	N	N	N	N	N		N		
				Vomiting	N	N	N	N	N		N		
				Diarrhea	N	N	N	N	N		N		
				New or worsened muscle pain	N	N	N	N	N		N		
				New or worsened joint pain	N	N	N	N	N		N		
		2	06JUL2021	Oral temperature (°C)	36.67	36.39	36.83	36.39	36.72	36.5	36.78		
				Fatigue	N	Mild	Mild	Mild	N	N	N	09JUL2021	3
				Headache	N	Mild	N	N	N	N	N	07JUL2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	Mild	N	N	N	Mild	12JUL2021	5
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	Mild	N	Mild	N	N	N	09JUL2021	3

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	23MAR2021	Oral temperature (°C)	36.44	36.61	36.5	36.28	36.44	36.44	36.28		
				Fatigue	Mild	Mild	Mild	Mild	Mild	Mild	Mild	14APR2021	23
				Headache	N	Mild	N	N	N	N	N	24MAR2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	14APR2021	Oral temperature (°C)	37.56	37.17	36	35.94	36.61	36.28	36.61		
				Fatigue	Mod	Mod	Mild	Mild	Mild	Mild	Mod	23MAY2021	40
				Headache	N	Mod	N	N	N	N	N	15APR2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	Mild	Mod	N	N	N	N	N	15APR2021	2
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	25MAR2021	Oral temperature (°C)	36	36.11	36	36	36.61	36.5	36.39		
				Fatigue	Mild	Mod	N	Mild	N	Mild	N	30MAR2021	6
				Headache	N	N	Mild	N	N	N	N	27MAR2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	Mild	N	N	N	N	N	26MAR2021	1
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	16APR2021	Oral temperature (°C)	36.06	36.67	36.06	36.06	35.83	35.83	35.61		
				Fatigue	Mod	Mod	Mod	Mild	N	N	N	19APR2021	4
				Headache	Mild	N	N	N	N	N	N	16APR2021	1
				Chills	N	Mod	N	N	N	N	N	17APR2021	1

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	Mild	N	N	N	N	N	17APR2021	1
				New or worsened muscle pain	N	Mod	N	N	N	N	N	17APR2021	1
				New or worsened joint pain	N	Mod	N	N	N	N	N	17APR2021	1
	[redacted]	1	14APR2021	Oral temperature (°C)	36.06	36.17	36.22	36.06	35.78	35.72	36.56		
				Fatigue	N	N	N	N	N	N	Mild	21APR2021	2
				Headache	N	N	N	N	N	N	Mild	21APR2021	2
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	Mod	Mild	21APR2021	3
				New or worsened joint pain	N	N	N	N	N	Mild	N	19APR2021	1
		2	05MAY2021	Oral temperature (°C)	35.89	35.83		36.28			36.5		
				Fatigue	Mild	N		N			N	05MAY2021	1

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	Mild	N		N			N	05MAY2021	1
				Chills	N	Mild		N			N	06MAY2021	1
				Vomiting	N	N		N			N		
				Diarrhea	N	N		N			N		
				New or worsened muscle pain	N	Mild		N			N	06MAY2021	1
				New or worsened joint pain	N	N		N			N		
	[redacted]	1	11MAR2021	Oral temperature (°C)	36.89	36.83	36.33	36.28	36.22	36.17	36.22		
				Fatigue	Mod	Mod	Mild	N	N	Mild	N	16MAR2021	6
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	Mild	N	N	N	N	13MAR2021	1
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
		2	31MAR2021	Oral temperature (°C)	37.17	37.72	37.28	36.89	36.39	36.44	36.33		
				Fatigue	Mod	Mod	Mild	Mild	Mild	N	N	04APR2021	5
				Headache	N	Mod	N	N	N	N	N	01APR2021	1
				Chills	N	Mild	N	N	N	N	N	01APR2021	1
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	Mild	N	N	N	N	N	N	31MAR2021	1
	[redacted]	1	17MAR2021	Oral temperature (°C)	36.44	36.56	36.17	36.61	36.22	36.67	36.67		
				Fatigue	Mod	Mod	Mild	Mild	Mild	Mild	N	22MAR2021	6
				Headache	Mild	Mod	Mild	Mild	N	N	N	20MAR2021	4
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	12APR2021	Oral temperature (°C)		37.83	37.67	36.5	36.39	36.39	36.39		
				Fatigue		Mod	Mild	Mild	N	N	N	15APR2021	3
				Headache		Mild	Mild	Mild	N	N	N	15APR2021	3
				Chills		Mod	N	N	N	N	N	13APR2021	1
				Vomiting		N	N	N	N	N	N		
				Diarrhea		N	N	N	N	N	N		
				New or worsened muscle pain		N	N	N	N	N	N		
				New or worsened joint pain		N	N	N	N	N	N		
	[redacted]	1	24MAR2021	Oral temperature (°C)	36.22	37.11	37	36.78	36.67		36.39		
				Fatigue	Mod	N	N	Mild	N		N	27MAR2021	4
				Headache	Mod	N	Mod	N	N		N	26MAR2021	3
				Chills	N	N	N	N	N		N		
				Vomiting	N	N	N	N	N		N		
				Diarrhea	N	N	Mild	N	Mild		N	28MAR2021	3

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	N	N	N		N		
				New or worsened joint pain	N	N	N	N	N		N		
		2	12APR2021	Oral temperature (°C)	36.67	36.94	36.89	36.61	37	36.44	36.78		
				Fatigue	Mild	Mild	N	N	Mild	N	N	16APR2021	5
				Headache	N	N	Mild	N	N	N	N	14APR2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	12APR2021	Oral temperature (°C)	36.61	36.61	36.61	36.61		36.61	36.61		
				Fatigue	N	Mild	Mild	Mild		N	Mild	19APR2021	7
				Headache	N	N	N	N		N	Mild	19APR2021	2
				Chills	N	N	N	N		N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N		N	N		
				Diarrhea	N	N	N	N		N	N		
				New or worsened muscle pain	N	N	N	N		N	N		
				New or worsened joint pain	N	N	N	N		N	N		
		2	04MAY2021	Oral temperature (°C)		36.61	36.61	36.56	36.61	36.61	36.56		
				Fatigue		Mod	N	N	N	N	N	05MAY2021	1
				Headache		N	N	N	N	N	N		
				Chills		N	N	N	N	N	N		
				Vomiting		N	N	N	N	N	N		
				Diarrhea		N	N	N	N	N	N		
				New or worsened muscle pain		Mod	N	N	N	N	N	05MAY2021	1
				New or worsened joint pain		Mod	N	N	N	N	N	05MAY2021	1
	[redacted]	1	06MAY2021	Oral temperature (°C)	36.94	37.28	37.33	37.17	36.89	36.89	36.94		
				Fatigue	N	N	Mild	Mild	N	N	Mod	13MAY2021	6

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	Mild	Mild	Mild	Mild	N	N	N	09MAY2021	4
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	Mild	N	N	Mild	N	N	N	09MAY2021	4
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	28MAY2021	Oral temperature (°C)	36.94	37.67	37	37	36.67	36.72	36.83		
				Fatigue	N	Mod	Mild	Mild	N	N	N	31MAY2021	3
				Headache	N	Mod	Mild	Mild	N	N	N	31MAY2021	3
				Chills	Mod	Mild	N	N	N	N	N	29MAY2021	2
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	Mild	N	N	N	N	N	N	28MAY2021	1
				New or worsened joint pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	[redacted]	1	11MAY2021	Oral temperature (°C)	36.28		36.44	36.72	36.44	36.44	36.78		
				Fatigue	Mild		N	Mild	Mild	N	Mod	19MAY2021	9
				Headache	Mild		N	N	Mild	N	N	15MAY2021	5
				Chills	N		N	N	N	N	N		
				Vomiting	N		N	N	N	N	N		
				Diarrhea	N		N	N	N	N	N		
				New or worsened muscle pain	N		N	N	N	N	Mild	19MAY2021	3
				New or worsened joint pain	N		N	N	N	N	N		
		2	01JUN2021	Oral temperature (°C)		35.78	35.83	35.94	35.89	35.78	36.17		
				Fatigue		N	N	N	N	N	N		
				Headache		N	N	N	N	N	N		
				Chills		N	N	N	N	N	N		
				Vomiting		N	N	N	N	N	N		
				Diarrhea		N	N	N	N	N	N		
				New or worsened muscle pain		N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain		N	N	N	N	N	N		
	[redacted]	1	17JUN2021	Oral temperature (°C)	37.11	37.11	37	37.11	37.06	37	36.94		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	08JUL2021	Oral temperature (°C)		37	37.22	37	36.89	36.78	37.06		
				Fatigue		N	Mild	N	N	N	N	10JUL2021	1
				Headache		N	N	N	N	N	N		
				Chills		N	N	N	N	N	N		
				Vomiting		N	Mild	N	N	N	N	10JUL2021	1
				Diarrhea		N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain		N	N	N	N	N	N		
				New or worsened joint pain		N	N	N	N	N	N		
	[redacted]	1	20MAY2021	Oral temperature (°C)	35.44	36.11	36.44	35.56		36.39	36.44		
				Fatigue	Mild	Mod	Sev	N		Mild	N	25MAY2021	6
				Headache	Mild	N	Sev	N		Mod	Mild	28MAY2021	9
				Chills	N	N	N	N		N	N		
				Vomiting	N	N	N	N		N	N		
				Diarrhea	N	N	N	N		N	N		
				New or worsened muscle pain	N	N	N	N		N	N		
				New or worsened joint pain	N	N	N	N		N	N		
		2	10JUN2021	Oral temperature (°C)	36	37.44	36.11	36	36.44	37.17	35.89		
				Fatigue	N	Sev	Mod	N	N	N	N	12JUN2021	2
				Headache	N	Sev	Mod	N	N	N	N	12JUN2021	2
				Chills	N	Mod	N	N	N	N	N	11JUN2021	1

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	Mild	N	N	N	N	N	11JUN2021	1
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	Mod	N	N	N	N	N	11JUN2021	1
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	10MAR2021	Oral temperature (°C)		37	36.89	37.06	36.61	37.11	37		
				Fatigue		N	N	N	N	N	N		
				Headache		N	Mild	N	Mild	N	N	14MAR2021	3
				Chills		N	N	N	N	N	N		
				Vomiting		N	N	N	N	N	N		
				Diarrhea		N	N	N	N	N	N		
				New or worsened muscle pain		N	N	N	N	N	N		
				New or worsened joint pain		N	N	N	N	N	N		
		2	29MAR2021	Oral temperature (°C)	36.28	37.11	36.94	36.61	37	37.17	36.61		
				Fatigue	Mild	Mild	N	N	N	N	N	30MAR2021	2

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	Mild	N	N	Mild	N	N	02APR2021	4
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	11MAR2021	Oral temperature (°C)	36.67	36.89	36.56	36.83	36.78	36.72	36.83		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
		2	01APR2021	Oral temperature (°C)	37.17	36.94	37.11	36.94	36.83	36.94	37.06		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	13APR2021	Oral temperature (°C)	36.44	37.22	36.61	36.78	36.67	36.61	36.61		
				Fatigue	Mild	Mod	Mod	Mod	Mild	N	N	17APR2021	5
				Headache	N	Mild	N	N	N	N	N	14APR2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	03MAY2021	Oral temperature (°C)	36.33	36.78	36.94	36.89	36.89	37.11	36.33		
				Fatigue	Mild	Mod	Mod	Mod	Mild	Mild	Mild	11MAY2021	9
				Headache	N	Mild	Mod	Mild	N	N	N	06MAY2021	3
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	Mild	N	N	N	N	05MAY2021	1
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	14MAY2021	Oral temperature (°C)	36.56	34.78	36.17	35.78	36.56	36.28	34.11		
				Fatigue	N	Mild	Mild	Mild	N	N	Mild	20MAY2021	6
				Headache	N	Mild	N	N	N	N	N	15MAY2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	Mild	N	Mild	Mild	Mild	N	Mild	25MAY2021	12

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	Mod	Mild	N	N	18MAY2021	2
		2	04JUN2021	Oral temperature (°C)	36.33	36.61	35.72	35.89	35.94	36.22	35.78		
				Fatigue	N	Mod	Mild	N	N	N	N	06JUN2021	2
				Headache	N	Mild	N	N	N	N	Mod	11JUN2021	7
				Chills	N	Mild	N	N	N	N	N	05JUN2021	1
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	Mild	N	N	N	07JUN2021	1
				New or worsened muscle pain	N	Mild	N	N	N	N	N	05JUN2021	1
				New or worsened joint pain	N	Mild	N	N	N	N	N	05JUN2021	1
	[redacted]	1	14MAY2021	Oral temperature (°C)	36.5	37.11		35.78	36.5	36.83	36.28		
				Fatigue	N	N		N	N	N	N		
				Headache	N	N		Mild	Mod	N	N	18MAY2021	2
				Chills	N	N		N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N		N	N	N	N		
				Diarrhea	N	N		N	N	N	N		
				New or worsened muscle pain	N	N		N	N	N	N		
				New or worsened joint pain	N	N		N	N	N	N		
		2	11JUN2021	Oral temperature (°C)	36.22	36.72	36.17	36.72	36.22	36.28	36.61		
				Fatigue	N	Mild	N	Mod	N	N	N	14JUN2021	3
				Headache	N	Mild	N	Mod	N	N	N	14JUN2021	3
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	Mild	Mild	N	N	N	N	13JUN2021	2
				New or worsened joint pain	N	Mild	N	N	N	N	N	12JUN2021	1
	[redacted]	1	16FEB2021	Oral temperature (°C)	36.72	36.94	36.17	37.06			36.56		
				Fatigue	N	N	N	N			N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	Mod	N	N	N			N	16FEB2021	1
				Chills	N	N	N	N			N		
				Vomiting	N	N	N	N			N		
				Diarrhea	N	N	Mild	N			N	18FEB2021	1
				New or worsened muscle pain	N	N	N	N			N		
				New or worsened joint pain	N	N	N	N			N		
		2	08MAR2021	Oral temperature (°C)			36.11	36.22	36.72	36.78	36.72		
				Fatigue			Mild	N	N	N	N	10MAR2021	1
				Headache			N	N	N	N	N		
				Chills			N	N	N	N	N		
				Vomiting			N	N	N	N	N		
				Diarrhea			Mild	N	N	N	N	10MAR2021	1
				New or worsened muscle pain			N	N	N	N	N		
				New or worsened joint pain			N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	[redacted]	1	09MAR2021	Oral temperature (°C)	36.22	37	36.5	35.89	36	36.44	35.89		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	30MAR2021	Oral temperature (°C)	35.78	35.89	35.94	36.06	36.5	36.56	37.11		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	18FEB2021	Oral temperature (°C)	36.33	37.61	36.72	36.61	35.78	36.44	36.22		
				Fatigue	Mild	Mod	Mild	Mild	N	N	N	21FEB2021	4
				Headache	N	Mod	N	N	N	N	N	19FEB2021	1
				Chills	N	Mod	N	N	N	N	N	19FEB2021	1
				Vomiting	N	Mild	N	N	N	N	N	19FEB2021	1
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	Mod	N	N	N	N	N	19FEB2021	1
				New or worsened joint pain	N	Mod	Mild	N	N	N	N	20FEB2021	2
		2	09MAR2021	Oral temperature (°C)		37.39	36.17	36.67	36.83	36.44	36.44		
				Fatigue		Mod	Mild	N	N	N	N	11MAR2021	2
				Headache		Mod	Mild	N	N	N	N	11MAR2021	2
				Chills		Mild	N	N	N	N	N	10MAR2021	1
				Vomiting		N	N	N	N	N	N		
				Diarrhea		N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain		Mod	N	Mild	N	N	N	12MAR2021	3
				New or worsened joint pain		Mod	N	N	N	N	N	10MAR2021	1
	[redacted]	1	04MAR2021	Oral temperature (°C)	36.17	35.61	36.17	35.72	36.33	37	35.61		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	24MAR2021	Oral temperature (°C)	36.17	35.61	35.56	36.72	36.11	36.28	36.17		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	12MAR2021	Oral temperature (°C)	36.39	36.56	34.67	35.78	35.78	36.28	36		
				Fatigue	N	Mild	Mild	Mild	N	N	N	15MAR2021	3
				Headache	N	N	N	Mild	N	N	N	15MAR2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	31MAR2021	Oral temperature (°C)	36.28	36.5	35.94	36.22	36.83		36.44		
				Fatigue	N	Mod	Mild	N	N		N	02APR2021	2

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	Mild	N	N	N		N	01APR2021	1
				Chills	N	Mod	N	N	N		N	01APR2021	1
				Vomiting	N	N	N	N	N		N		
				Diarrhea	N	N	N	N	N		N		
				New or worsened muscle pain	N	Mild	N	N	N		N	01APR2021	1
				New or worsened joint pain	N	N	N	N	N		N		
	[redacted]	1	16MAR2021	Oral temperature (°C)	36.94	37.17	36.94	36.94	36.67	36.67	36.89		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
		2	05APR2021	Oral temperature (°C)	37.06	38.44	37.17	36.89	37	37.06	37	06APR2021	1
				Fatigue	N	Mod	N	N	N	N	N	06APR2021	1
				Headache	N	Mild	Mild	N	N	N	N	07APR2021	2
				Chills	N	Mild	N	N	N	N	N	06APR2021	1
				Vomiting	N	Mild	N	N	N	N	N	06APR2021	1
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	Mod	N	N	N	N	N	06APR2021	1
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	23MAR2021	Oral temperature (°C)	36	36.17	36.28	36.22	36.39	36.56	36.28		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	13APR2021	Oral temperature (°C)	36.44	36	36.72	36.33	36.39	36.39	36.33		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	Mild	N	N	N	16APR2021	1
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	08APR2021	Oral temperature (°C)	36.39	36.61	36.22	36.61	36.28	36.22	36.22		
				Fatigue	Mod	Mild	N	N	Mild	Mild	Mild	14APR2021	7
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	27APR2021	Oral temperature (°C)	36.11	36.39	36.39	36.39	36.28	36.44	36.39		
				Fatigue	Mild	Mod	Mild	N	N	N	N	29APR2021	3
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	Mild	N	N	N	N	N	28APR2021	1
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	25MAR2021	Oral temperature (°C)	36.11	36.11	36.39	35.78	36.56	36.39	36.39		
				Fatigue	Mild	N	Mod	N	N	N	N	27MAR2021	3
				Headache	N	Mild	Mod	N	N	N	N	27MAR2021	2
				Chills	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	13APR2021	Oral temperature (°C)	36.17	36.22	36.67	36.5	35.89	36.78	35.28		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	09APR2021	Oral temperature (°C)	36.72	36.44	36.83	36.78	36.56	36.83	36.89		
				Fatigue	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	30APR2021	Oral temperature (°C)	37.06	36.72	36.28	35.72	36.17	36.83	36.33		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	[redacted]	1	11MAY2021	Oral temperature (°C)	37.61	36.78	37.06	37.11	37.06	36.56	36.83		
				Fatigue	Mild	Mild	N	N	N	N	N	12MAY2021	2
				Headache	N	Mild	N	N	N	Mild	N	16MAY2021	5
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	28APR2021	Oral temperature (°C)	36.44	36.44	36.5		36.78	36.39	36.78		
				Fatigue	N	N	N		N	N	N		
				Headache	N	N	N		N	N	N		
				Chills	N	N	N		N	N	N		
				Vomiting	N	N	N		N	N	N		
				Diarrhea	N	N	N		N	N	N		
				New or worsened muscle pain	N	N	N		N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N		N	N	N		
		2	18MAY2021	Oral temperature (°C)	36.78	36.94	36.56	36.56	36.83	36.56	36.39		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	11MAY2021	Oral temperature (°C)	35.72	36.67	36.94	36.11	35.67	36.06	36.06		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	02JUN2021	Oral temperature (°C)		36.11	36.44	36.5	36.44	36.44	36.5		
				Fatigue		N	N	N	N	N	N		
				Headache		N	N	N	N	N	N		
				Chills		N	N	N	N	N	N		
				Vomiting		N	N	N	N	N	N		
				Diarrhea		N	N	N	N	N	N		
				New or worsened muscle pain		N	N	N	N	N	N		
				New or worsened joint pain		N	N	N	N	N	N		
	[redacted]	1	13MAY2021	Oral temperature (°C)	36.94	36.78		36.56	36.56		37.06		
				Fatigue	N	N		N	N		N		
				Headache	N	N		N	N		N		
				Chills	N	N		N	N		N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N		N	N		N		
				Diarrhea	N	N		N	N		N		
				New or worsened muscle pain	N	N		N	N		N		
				New or worsened joint pain	N	N		N	N		N		
		2	02JUN2021	Oral temperature (°C)	37	36.28	37.06	37	37.06	37.11	37.06		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	18MAY2021	Oral temperature (°C)	36.11	36.72	36.11	36.11	36.11	35.67	36.11		
				Fatigue	N	Mild	Mild	N	N	N	N	20MAY2021	2

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	N	N	N	N	N	N		
				Chills	N	Mild	N	N	N	N	N	19MAY2021	1
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	09JUN2021	Oral temperature (°C)						35.56	35.61		
				Fatigue						N	N		
				Headache						N	N		
				Chills						N	N		
				Vomiting						N	N		
				Diarrhea						N	N		
				New or worsened muscle pain						N	N		
				New or worsened joint pain						N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	[redacted]	1	18MAY2021	Oral temperature (°C)	36.11	36.33	36.11	36.11	36.11	36.11	36.11		
				Fatigue	N	N	Mild	Mild	Mild	Mild	N	23MAY2021	4
				Headache	N	N	Mod	Mild	Mild	Mild	N	23MAY2021	4
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	10JUN2021	Oral temperature (°C)		36.94	36.56	36.56	37.17	37.06	36.61		
				Fatigue		N	N	N	N	N	N		
				Headache		N	N	N	N	N	N		
				Chills		N	N	N	N	N	N		
				Vomiting		N	N	N	N	N	N		
				Diarrhea		N	N	N	N	N	N		
				New or worsened muscle pain		N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain		N	N	N	N	N	N		
	[redacted]	1	20MAY2021	Oral temperature (°C)	37.06	37.06	37.06	37	37.06		36.94		
				Fatigue	N	N	N	N	N		N		
				Headache	N	N	N	N	N		N		
				Chills	N	N	N	N	N		N		
				Vomiting	N	N	N	N	N		N		
				Diarrhea	N	N	N	N	N		N		
				New or worsened muscle pain	N	N	N	N	N		N		
				New or worsened joint pain	N	N	N	N	N		N		
		2	08JUN2021	Oral temperature (°C)	36.94	37	37.11	37.06					
				Fatigue	N	N	N	N					
				Headache	N	N	N	N					
				Chills	N	N	N	N					
				Vomiting	N	N	N	N					
				Diarrhea	N	N	N	N					

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	N	N					
				New or worsened joint pain	N	N	N	N					
	[redacted]	1	20MAY2021	Oral temperature (°C)	37	37	37	37.11	37		37		
				Fatigue	N	N	N	N	N		N		
				Headache	N	N	N	N	N		N		
				Chills	N	N	N	N	N		N		
				Vomiting	N	N	N	N	N		N		
				Diarrhea	N	N	N	N	N		N		
				New or worsened muscle pain	N	N	N	N	N		N		
				New or worsened joint pain	N	N	N	N	N		N		
		2	08JUN2021	Oral temperature (°C)	37.06	37.06	37.17	36.56					
				Fatigue	N	N	N	N					
				Headache	N	N	N	N					
				Chills	N	N	N	N					

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N					
				Diarrhea	N	N	N	N					
				New or worsened muscle pain	N	N	N	N					
				New or worsened joint pain	N	N	N	N					
	[redacted]	1	26MAY2021	Oral temperature (°C)	37.11	37.11					37.06		
				Fatigue	N	N					N		
				Headache	N	N					N		
				Chills	N	N					N		
				Vomiting	N	N					N		
				Diarrhea	N	N					N		
				New or worsened muscle pain	N	N					N		
				New or worsened joint pain	N	N					N		
	[redacted]	1	08JUN2021	Oral temperature (°C)	36.61	36.61	36.61	36.61	36.56	36.56	37.17		
				Fatigue	Mild	Mild	N	N	N	N	N	09JUN2021	2

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	Mod	N	N	N	N	N	N	08JUN2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	Mild	N	N	N	N	10JUN2021	1
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	28JUN2021	Oral temperature (°C)		36.61	37.17		37.06	37.17	37.06		
				Fatigue		Mod	Mild		Mod	Mild	Mild	04JUL2021	6
				Headache		Mod	N		Mod	Mild	Mild	04JUL2021	6
				Chills		Mod	N		N	N	N	29JUN2021	1
				Vomiting		N	N		N	Mild	N	03JUL2021	1
				Diarrhea		N	N		N	N	N		
				New or worsened muscle pain		N	N		N	N	N		
				New or worsened joint pain		Mild	N		N	N	N	29JUN2021	1

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	[redacted]	1	14JUN2021	Oral temperature (°C)	35.67	36.11	36.39	36.56	36.22	36.61	36.28		
				Fatigue	N	Mild	Mod	Mild	N	N	N	17JUN2021	3
				Headache	N	N	Mod	Mod	Mod	Sev	Mod	20JUN2021	5
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	06JUL2021	Oral temperature (°C)						36.94	36.56		
				Fatigue						N	N		
				Headache						N	N		
				Chills						N	N		
				Vomiting						N	N		
				Diarrhea						N	N		
				New or worsened muscle pain						N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain						N	N		
	[redacted]	1	18JUN2021	Oral temperature (°C)		36.44	36.33	36	36.28	36.33	36.39		
				Fatigue		N	N	N	N	N	N		
				Headache		N	N	N	N	N	N		
				Chills		N	N	N	N	N	N		
				Vomiting		N	N	N	N	N	N		
				Diarrhea		N	N	N	N	N	N		
				New or worsened muscle pain		N	N	N	N	N	N		
				New or worsened joint pain		N	N	N	N	N	N		
		2	07JUL2021	Oral temperature (°C)		36.44	36.56	36.06	36	37.06	36.94		
				Fatigue		N	N	N	N	N	N		
				Headache		N	N	N	N	N	N		
				Chills		N	N	N	N	N	N		
				Vomiting		N	N	N	N	N	N		
				Diarrhea		N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain		N	N	N	N	N	N		
				New or worsened joint pain		N	N	N	N	N	N		
	[redacted]	1	18JUN2021	Oral temperature (°C)				37.11	36.94		36.67		
				Fatigue				N	N		N		
				Headache				N	N		N		
				Chills				N	N		N		
				Vomiting				N	N		N		
				Diarrhea				N	N		N		
				New or worsened muscle pain				N	N		N		
				New or worsened joint pain				N	N		N		
		2	13JUL2021	Oral temperature (°C)	37.17	37.11	36.83	37.11	36	36.67	37.06		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	13JUL2021	Oral temperature (°C)	36.44	36.39	36.83	36.44	36.44	36.39	36.94		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	02AUG2021	Oral temperature (°C)	36.44	36.89	36.44	36.56	36.17	36.17	36.17		
				Fatigue	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	27JUL2021	Oral temperature (°C)	36.5	36.39	36.94	36	36.56		37		
				Fatigue	N	N	N	N	N		N		
				Headache	N	N	N	N	N		N		
				Chills	N	N	N	N	N		N		
				Vomiting	N	N	N	N	N		N		
				Diarrhea	N	N	N	N	N		N		
				New or worsened muscle pain	N	N	N	N	N		N		
				New or worsened joint pain	N	N	N	N	N		N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
		2	16AUG2021	Oral temperature (°C)	36.56	37.11	36.5	36.61	37.11	37.11	36.5		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	30AUG2021	Oral temperature (°C)	37	36.83	36.44	36.44		36.61	36.72		
				Fatigue	N	N	N	N		N	N		
				Headache	N	N	N	N		N	N		
				Chills	N	N	N	N		N	N		
				Vomiting	N	N	N	N		N	N		
				Diarrhea	N	N	N	N		N	N		
				New or worsened muscle pain	N	N	N	N		N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N	N		N	N		
		2	22SEP2021	Oral temperature (°C)	36.11	36.67		36.17	35.61	35.72	36.83		
				Fatigue	N	Mild		N	N	N	N	23SEP2021	1
				Headache	N	Mild		N	N	N	N	23SEP2021	1
				Chills	N	N		N	N	N	N		
				Vomiting	N	N		N	N	N	N		
				Diarrhea	N	N		N	N	N	N		
				New or worsened muscle pain	N	N		N	N	N	N		
				New or worsened joint pain	N	N		N	N	N	N		
	[redacted]	1	08SEP2021	Oral temperature (°C)	37.06			36.61	36.56	37.06	37.06		
				Fatigue	N			N	N	N	N		
				Headache	N			N	N	N	N		
				Chills	N			N	N	N	N		
				Vomiting	N			N	N	N	N		
				Diarrhea	N			N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N			N	N	N	N		
				New or worsened joint pain	N			N	N	N	N		
		2	29SEP2021	Oral temperature (°C)	36.5			36.72		36.61	36.67		
				Fatigue	N			N		N	N		
				Headache	N			N		N	N		
				Chills	N			N		N	N		
				Vomiting	N			N		N	N		
				Diarrhea	N			N		N	N		
				New or worsened muscle pain	N			N		N	N		
				New or worsened joint pain	N			N		N	N		
	[redacted]	1	08SEP2021	Oral temperature (°C)	36.72	36.56	36.61	36.78	36.61	36.78	36.61		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	24FEB2021	Oral temperature (°C)	36.67	37.11	36.56	37.17	36.56	36.67	36.78		
				Fatigue	N	Mild	N	N	N	N	Mild	02MAR2021	6
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	17MAR2021	Oral temperature (°C)		36.67	36.67	36.61	36.28	36.67	36.22		
				Fatigue		N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache		N	N	N	N	N	N		
				Chills		N	N	N	N	N	N		
				Vomiting		N	N	N	N	N	N		
				Diarrhea		N	N	N	N	N	N		
				New or worsened muscle pain		N	N	N	N	N	N		
				New or worsened joint pain		N	N	N	N	N	N		
	[redacted]	1	15APR2021	Oral temperature (°C)	35.56	36.28	36.17	36.94	36	37	36.67		
				Fatigue	Mild	Mild	Mild	N	N	Mild	N	20APR2021	6
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
		2	06MAY2021	Oral temperature (°C)	36.06	35.94	36.56	36	36.28	36.89	37.06		
				Fatigue	N	Mod	N	N	N	N	N	07MAY2021	1
				Headache	N	Mild	N	N	N	N	N	07MAY2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	06MAY2021	Oral temperature (°C)	36.56	36.44	36.83	36.56	36.44	36.67	36.83		
				Fatigue	N	N	Mild	N	Mild	N	N	10MAY2021	3
				Headache	Mild	N	N	N	N	N	N	06MAY2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	27MAY2021	Oral temperature (°C)	36.89	36.28	36.22	36.78	36.72	36.5	36.67		
				Fatigue	Mild	Mod	N	N	N	N	N	28MAY2021	2
				Headache	N	Mild	N	N	N	N	N	28MAY2021	1
				Chills	N	Mod	N	N	N	N	N	28MAY2021	1
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	Mod	N	N	N	N	N	28MAY2021	1
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	21APR2021	Oral temperature (°C)	37	37	36.83	37	37	37	37		
				Fatigue	Mild	Mild	N	N	N	N	N	22APR2021	2
				Headache	N	Mild	N	N	N	N	N	22APR2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	13MAY2021	Oral temperature (°C)							36.5		
				Fatigue							N		
				Headache							N		
				Chills							N		
				Vomiting							N		
				Diarrhea							N		
				New or worsened muscle pain							N		
				New or worsened joint pain							N		
	[redacted]	1	12MAY2021	Oral temperature (°C)	36.33	36.72	37.06	36.56	36.72	37.33	36.61		
				Fatigue	Mod	N	N	N	N	N	N	12MAY2021	1
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	Mod	N	N	N	15MAY2021	1
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	02JUN2021	Oral temperature (°C)	36	36.56	36.94	37	36.22	36.72	36.44		
				Fatigue	Mod	Mod	N	N	N	N	N	03JUN2021	2
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	20MAY2021	Oral temperature (°C)	36.67	36.5	36.83	36.89	36.67	36.61	36.67		
				Fatigue	N	N	Mild	Mild	N	N	Mild	10JUN2021	20

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	N	Mild	Mild	N	N	Mild	27MAY2021	6
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	Mild	N	N	N	N	22MAY2021	1
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	10JUN2021	Oral temperature (°C)	36.61	36.67	36.78	36.61	36.44	36.67	36.78		
				Fatigue	N	Mild	N	N	N	N	N	11JUN2021	1
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	[redacted]	1	04AUG2021	Oral temperature (°C)	35.9	35	36	36.1	36.2	36.1	36.1		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	23AUG2021	Oral temperature (°C)		36	36.4	36.2	36.2		36		
				Fatigue		N	N	N	N		N		
				Headache		N	N	Mod	N		N	26AUG2021	1
				Chills		N	N	N	N		N		
				Vomiting		N	N	N	N		N		
				Diarrhea		N	N	N	N		N		
				New or worsened muscle pain		N	N	N	N		N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain		N	N	N	N		N		
	[redacted]	1	10AUG2021	Oral temperature (°C)	36.6	36.5	36.5	36.4		35.6			
				Fatigue	N	N	N	N		N			
				Headache	N	N	N	N		N			
				Chills	N	N	N	N		N			
				Vomiting	N	N	N	N		N			
				Diarrhea	N	N	N	N		N			
				New or worsened muscle pain	N	N	N	N		N			
				New or worsened joint pain	N	N	N	N		N			
		2	30AUG2021	Oral temperature (°C)	36.6	36.2	36.2	36.4		35.6			
				Fatigue	N	N	N	N		N			
				Headache	N	N	N	N		N			
				Chills	N	N	N	N		N			
				Vomiting	N	N	N	N		N			
				Diarrhea	Mild	N	N	N		N		30AUG2021	1

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	N	N		N			
				New or worsened joint pain	N	N	N	N		N			
	[redacted]	1	24MAR2021	Oral temperature (°C)	36.56	36.44	36.67	36.78	37.06		36.83		
				Fatigue	Mod	Mild	Mild	Mild	N		N	27MAR2021	4
				Headache	N	N	N	N	N		N		
				Chills	N	N	N	N	N		N		
				Vomiting	N	N	N	N	N		N		
				Diarrhea	N	N	Mild	N	N		N	26MAR2021	1
				New or worsened muscle pain	N	N	N	N	N		N		
				New or worsened joint pain	N	N	N	N	N		N		
		2	12APR2021	Oral temperature (°C)	37.06	37.17	37.17	37.06	36.94	37.06	37.06		
				Fatigue	N	Mod	N	N	N	N	N	13APR2021	1
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	Mild	N	N	N	N	N	13APR2021	1
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	11MAY2021	Oral temperature (°C)		37.06	37.06	37.06	36.89	37.17	37.06		
				Fatigue		N	Mild	N	N	N	N	13MAY2021	1
				Headache		N	N	N	N	Mild	N	16MAY2021	1
				Chills		N	N	N	N	N	N		
				Vomiting		N	N	N	N	N	N		
				Diarrhea		N	N	N	N	N	N		
				New or worsened muscle pain		N	N	N	N	N	N		
				New or worsened joint pain		N	N	N	N	N	N		
		2	03JUN2021	Oral temperature (°C)	36.67	36.72	36.44	36.44	36.22	36.5	36.78		
				Fatigue	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	Mod	Mild	N	N	N	N	05JUN2021	2
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	Mod	N	N	N	N	N	04JUN2021	1
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	26AUG2021	Oral temperature (°C)	36	36.1	36.4	36.2	35.8	35.9	36.3		
				Fatigue	N	N	Mild	N	Mod	N	N	30AUG2021	3
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
		2	14SEP2021	Oral temperature (°C)	35.9	36.3	36.7	36.5	35.8	36.6	35.8		
				Fatigue	Mild	N	N	N	N	N	N	14SEP2021	1
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	09SEP2021	Oral temperature (°C)		35.2	32.7	33.1	36.1	36.1	35.2		
				Fatigue		N	Mild	N	N	N	N	11SEP2021	1
				Headache		N	N	N	N	N	N		
				Chills		N	N	N	N	N	N		
				Vomiting		N	N	N	N	N	N		
				Diarrhea		N	N	N	N	N	N		
				New or worsened muscle pain		N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain		N	N	N	N	N	N		
	[redacted]	1	17SEP2021	Oral temperature (°C)	36.8		36.2	36.5	36.6	37.1	36.8		
				Fatigue	N		N	N	N	N	N		
				Headache	N		N	N	N	N	N		
				Chills	N		N	N	N	N	N		
				Vomiting	N		N	N	N	N	N		
				Diarrhea	N		N	N	N	N	N		
				New or worsened muscle pain	N		N	N	N	N	N		
				New or worsened joint pain	N		N	N	N	N	N		
		2	06OCT2021	Oral temperature (°C)	36.6	36.7	36.8		36.6	36.3	36.3		
				Fatigue	N	N	N		N	N	N		
				Headache	N	N	N		N	N	N		
				Chills	N	N	N		N	N	N		
				Vomiting	N	N	N		N	N	N		
				Diarrhea	N	N	N		N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	N		N	N	N		
				New or worsened joint pain	N	N	N		N	N	N		
	[redacted]	1	07OCT2021	Oral temperature (°C)	36.2	36.5	36.7	36.2	36.7	36.6	36.7		
				Fatigue	N	Mild	N	N	N	N	N	08OCT2021	1
				Headache	N	N	N	N	N	Mild	Mild	13OCT2021	2
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	Mild	N	N	N	N	N	08OCT2021	1
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	26OCT2021	Oral temperature (°C)	36.4	36.2	36.6	36.2	36.2	36.4	36.5		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]†	1	27OCT2021	Oral temperature (°C)	36.5	36.7	36.7	37.1			37.2		
				Fatigue	N	N	N	N			N		
				Headache	N	N	N	N			N		
				Chills	N	N	N	N			N		
				Vomiting	N	N	N	N			N		
				Diarrhea	N	N	N	N			N		
				New or worsened muscle pain	N	N	N	N			N		
				New or worsened joint pain	N	N	N	N			N		
		2	16NOV2021	Oral temperature (°C)	36.8	36.3	36.9	36.2	36.9	36.4	35.6		
				Fatigue	Mild	N	N	N	N	N	N	16NOV2021	1

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	21JUL2021	Oral temperature (°C)	36.9	36.7	36.8	36.7	36.6	36.7	36.6		
				Fatigue	N	Mod	N	N	N	N	N	22JUL2021	1
				Headache	N	Mod	N	N	N	N	N	22JUL2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
		2	10AUG2021	Oral temperature (°C)		36.1	36.5	36.8	36.7	36.3	36.6		
				Fatigue		N	N	N	N	N	N		
				Headache		Mild	N	N	N	N	N	11AUG2021	1
				Chills		N	N	N	N	N	N		
				Vomiting		N	N	N	N	N	N		
				Diarrhea		N	N	N	N	N	N		
				New or worsened muscle pain		N	N	N	N	N	N		
				New or worsened joint pain		N	N	N	N	N	N		
	[redacted]	1	13AUG2021	Oral temperature (°C)	39.7	37.1	36.8	37.1	36.2	35	36	13AUG2021	1
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	03SEP2021	Oral temperature (°C)	33	33	32.2	35.2	36.3	36.6	36.3		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	28AUG2021	Oral temperature (°C)	36.6	36.4	35.5	35.4	34.5	35.5	35.6		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	17SEP2021	Oral temperature (°C)	35.4	35.6	35.8	35.7	35.6	35.4	35.8		
				Fatigue	N	Mild	N	N	N	N	N	18SEP2021	1
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	07SEP2021	Oral temperature (°C)	36.6	35.9	32.3	32.2	32.3	36.3	35.7		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	29SEP2021	Oral temperature (°C)	36.4	35.9	36.5	36.4	34.5	34.3	36.3		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	13SEP2021	Oral temperature (°C)	36.1								
				Fatigue	N								

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N								
				Chills	N								
				Vomiting	N								
				Diarrhea	N								
				New or worsened muscle pain	N								
				New or worsened joint pain	N								
		2	14OCT2021	Oral temperature (°C)	35.8	36	35.9		36.2	36.9	35.7		
				Fatigue	N	Mild	N		N	N	N	15OCT2021	1
				Headache	N	N	N		N	N	N		
				Chills	N	N	N		N	N	N		
				Vomiting	N	N	N		N	N	N		
				Diarrhea	N	N	N		Mild	N	N	18OCT2021	1
				New or worsened muscle pain	N	N	N		N	N	N		
				New or worsened joint pain	N	N	N		N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	[redacted]	1	13SEP2021	Oral temperature (°C)	36.5	36.4	35.8	36.2	36	36.7	36.1		
				Fatigue	N	N	Mild	Mild	Mild	Mild	N	18SEP2021	4
				Headache	N	N	N	Mild	N	Mild	N	18SEP2021	3
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	Mild	N	18SEP2021	1
				New or worsened muscle pain	N	Mild	Mild	N	N	N	N	15SEP2021	2
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	05OCT2021	Oral temperature (°C)	36.4	36.5	36.4	36.2	36.4		36.4		
				Fatigue	N	Mild	N	Mild	N		N	08OCT2021	3
				Headache	N	N	Mild	Mild	N		N	08OCT2021	2
				Chills	N	N	N	N	N		N		
				Vomiting	N	N	N	N	N		N		
				Diarrhea	N	N	N	Mild	N		N	08OCT2021	1
				New or worsened muscle pain	N	N	N	N	N		N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N	N	N		N		
	[redacted]	1	14SEP2021	Oral temperature (°C)	36.1	35.7	35.6	35.5	35.2	36.2	36.1		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	07OCT2021	Oral temperature (°C)		36.2	36.3	35.6	36.4	36.1	36.1		
				Fatigue		N	N	N	N	N	N		
				Headache		N	N	N	N	N	N		
				Chills		N	N	N	N	N	N		
				Vomiting		N	N	N	N	N	N		
				Diarrhea		N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain		N	N	N	N	N	N		
				New or worsened joint pain		N	N	N	N	N	N		
	[redacted]	1	28SEP2021	Oral temperature (°C)	36.8	36.3	35.8	35.6	35.7	35.8	36.5		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	21OCT2021	Oral temperature (°C)	36.4	35.7	35.3	36.1	35.8	35.8	35.8		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	Mild	N	N	N	N	N	22OCT2021	1
				Chills	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	29SEP2021	Oral temperature (°C)	35.2	35.1	35.4	35.1	35.3	35.2	35.1		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	Mild	N	N	Mild	N	Mild	06OCT2021	7
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	19OCT2021	Oral temperature (°C)	35.6	35.8	35.4	35.4	36.4	35.3	35.4		
				Fatigue	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	Mild	N	24OCT2021	1
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	07OCT2021	Oral temperature (°C)	36.1	36	35.8	36.2	35.8	35.7	36.5		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	Mild	N	N	N	N	N	N	07OCT2021	1
				New or worsened joint pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
		2	28OCT2021	Oral temperature (°C)	35	36.1	35.7	34.8	35	36.2	35.8		
				Fatigue	N	N	N	N	N	Mild	Mild	04NOV2021	3
				Headache	N	Mild	N	N	N	N	Mild	04NOV2021	7
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	Mild	N	N	N	Mild	Mild	04NOV2021	7
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	26OCT2021	Oral temperature (°C)	35.8	35.8	35.6	35.7	35.8	36.1	35.8		
				Fatigue	Mild	N	N	N	N	N	Mild	02NOV2021	8
				Headache	N	N	N	N	Mild	N	N	30OCT2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	17NOV2021	Oral temperature (°C)	35.8	36		36	35.6	35.6	35.6		
				Fatigue	N	N		N	N	N	N		
				Headache	N	N		N	N	N	N		
				Chills	N	N		N	N	N	N		
				Vomiting	N	N		N	N	N	N		
				Diarrhea	N	N		N	N	N	N		
				New or worsened muscle pain	N	N		N	N	N	N		
				New or worsened joint pain	N	N		N	N	N	N		
	[redacted]	1	19OCT2021	Oral temperature (°C)					37.4	36.5	36.5		
				Fatigue					N	N	N		
				Headache					N	N	N		
				Chills					N	N	N		
				Vomiting					N	N	N		
				Diarrhea					N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain					N	N	N		
				New or worsened joint pain					N	N	N		
		2	09NOV2021	Oral temperature (°C)	35.3	35.4	35.4	35.5	35.4	35.4	36		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	14OCT2021	Oral temperature (°C)	36.6	37.9	36.7	37.3	36.8	36.8	37		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	Mod	Mod	25OCT2021	7
				Chills	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	02NOV2021	Oral temperature (°C)	36.2	36.9	36.4			36.1	36.8		
				Fatigue	N	N	N			N	N		
				Headache	N	N	N			N	N		
				Chills	N	N	N			N	N		
				Vomiting	N	N	N			N	N		
				Diarrhea	N	N	N			N	N		
				New or worsened muscle pain	N	N	N			N	N		
				New or worsened joint pain	N	N	N			N	N		
	[redacted]	1	21OCT2021	Oral temperature (°C)	35.5	36.2	36.1	36.4	36.1		36.5		
				Fatigue	N	N	N	N	N		N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	N	N	N	N		N		
				Chills	N	N	N	N	N		N		
				Vomiting	N	N	N	N	N		N		
				Diarrhea	N	N	N	N	N		Mild	27OCT2021	1
				New or worsened muscle pain	N	N	N	N	N		N		
				New or worsened joint pain	N	N	N	N	N		N		
		2	09NOV2021	Oral temperature (°C)	35.4	36.1	35.7	36.5	34.9	35	36		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	[redacted]	1	28OCT2021	Oral temperature (°C)	35.6	35.5	35.8	34.8	36.3	35.6	35.7		
				Fatigue	Mild	N	N	N	N	N	N	28OCT2021	1
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	Mild	N	N	N	N	N	29OCT2021	1
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	17NOV2021	Oral temperature (°C)	36.2	36.3	36.2	36.4	36.2	36.2	36.1		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]†	1	05NOV2021	Oral temperature (°C)	36.2	36.5	36.8	36.3	36.8	36.6	37.6		
				Fatigue	Mod	N	N	N	N	N	N	05NOV2021	1
				Headache	Mod	N	N	N	N	N	N	05NOV2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	Mod	Mild	N	Mild	N	N	09NOV2021	4
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	25NOV2021	Oral temperature (°C)		37.2	36.4	37.4	37.5	36.2	36.2		
				Fatigue		Mod	N	N	N	N	N	26NOV2021	1
				Headache		N	N	N	N	N	N		
				Chills		N	N	N	N	N	N		
				Vomiting		N	N	N	N	N	N		
				Diarrhea		N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain		Mod	Mild	N	N	N	N	27NOV2021	2
				New or worsened joint pain		N	N	N	N	N	N		
	[redacted]	1	02JUN2021	Oral temperature (°C)	35.7	36.1	36.4	35.7	35.9	35.6	35.6		
				Fatigue	N	Mild	Mild	N	N	N	N	04JUN2021	2
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	23JUN2021	Oral temperature (°C)	36.2	35.3	35	35.6	35.4	35.7	36		
				Fatigue	N	Mild	Mild	Mild	N	N	Mild	07JUL2021	14
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	10JUN2021	Oral temperature (°C)	35.9	36.2	36	36	36.3	36	36.6		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	30JUN2021	Oral temperature (°C)	36.1	36.2	35.5	35.9	36.1	36.1	36.1		
				Fatigue	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	N	N	N	N	Mild	N	05JUL2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	10JUN2021	Oral temperature (°C)	35.9	35.9	35.2	36.2	35.6	35.3	35.1		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
		2	30JUN2021	Oral temperature (°C)	35.6	35.4		35.9		35.6	35.2		
				Fatigue	Mild	Mod		N		N	N	01JUL2021	2
				Headache	N	N		N		N	N		
				Chills	N	N		N		N	N		
				Vomiting	N	N		N		N	N		
				Diarrhea	N	N		N		N	N		
				New or worsened muscle pain	N	Mild		N		N	N	01JUL2021	1
				New or worsened joint pain	N	N		N		N	N		
	[redacted]	1	14JUL2021	Oral temperature (°C)	35.6	36.3	36.5	36	35.6	36.1	35.6		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	05AUG2021	Oral temperature (°C)	35.5	35.8	35.3	35.5	35.1	36.3	36.2		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	19JUL2021	Oral temperature (°C)	35.3	36.1	36.1	36.7	36.5	36.2	36.5		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	Mild	N	N	N	N	N	20JUL2021	1
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	09AUG2021	Oral temperature (°C)	35.3	36.2	36.3	36.2	36.5	36.6	36.6		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	25AUG2021	Oral temperature (°C)	36.2	35.4	36	35.8	35.8	35.9	35.9		
				Fatigue	N	N	Mild	N	N	N	N	27AUG2021	1
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	Mild	Mild	N	N	N	N	N	26AUG2021	2
				New or worsened joint pain	Mild	N	N	N	N	N	N	25AUG2021	1
		2	15SEP2021	Oral temperature (°C)	36.4	36.4	36.3	36.1	35.1	35.4	35.4		
				Fatigue	N	Mod	Mild	N	N	N	N	17SEP2021	2
				Headache	N	Mild	Mild	N	N	N	Mild	21SEP2021	6
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	Mod	N	N	N	N	N	16SEP2021	1
				New or worsened joint pain	N	Mod	N	N	N	N	N	16SEP2021	1
	[redacted]	1	11AUG2021	Oral temperature (°C)	35.8	35.4	36.2	36.2		36.1	35.4		
				Fatigue	N	N	N	N		N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	N	N	N		N	N		
				Chills	N	N	N	N		N	N		
				Vomiting	N	N	N	N		N	N		
				Diarrhea	N	N	N	N		N	N		
				New or worsened muscle pain	N	N	N	N		N	N		
				New or worsened joint pain	N	N	N	N		N	N		
	[redacted]†	1	19AUG2021	Oral temperature (°C)		36.2	35.2	35.6	35.8	36	35.6		
				Fatigue		Mild	N	N	N	N	N	20AUG2021	1
				Headache		Mild	N	N	N	N	N	20AUG2021	1
				Chills		N	N	N	N	N	N		
				Vomiting		N	N	N	N	N	N		
				Diarrhea		N	N	N	N	N	N		
				New or worsened muscle pain		N	N	N	N	N	N		
				New or worsened joint pain		N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
		2	07SEP2021	Oral temperature (°C)	35.5	35.8	35.4	35	35.1	36.1	36.2		
				Fatigue	N	Mild	N	N	N	N	N	08SEP2021	1
				Headache	Mild	N	N	N	N	Mild	N	12SEP2021	6
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	18AUG2021	Oral temperature (°C)	34	35	36.4	36	36	34	36.3		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	06SEP2021	Oral temperature (°C)	36	36.4	36.2	35.8	36.1	36	36.3		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	20AUG2021	Oral temperature (°C)	36.2	35.3	36.1	35.2	35.7	35.8	35.8		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	08SEP2021	Oral temperature (°C)	35.8	35.6	35.9	35.6	36.4	36.2	36.5		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]†	1	01SEP2021	Oral temperature (°C)	36.3	35.8	35.9	35.7	36.4	35.7	36.2		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	Mild	N	N	N	N	N	02SEP2021	1
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	20SEP2021	Oral temperature (°C)	36.2	35.7	36.3	35.7	36.4	36.2	36.1		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	Mod	N	N	N	N	N	N	20SEP2021	1
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]†	1	03SEP2021	Oral temperature (°C)	36.2	36.3	36.6	36.2	35.9	35.8	36		
				Fatigue	N	Mild	N	N	N	N	Mild	11SEP2021	8

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	22SEP2021	Oral temperature (°C)	35.6	36.1	36.2	35.9	35.1	35.6	36.1		
				Fatigue	Mild	N	N	N	N	N	N	22SEP2021	1
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	Mild	N	27SEP2021	1
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	[redacted]†	1	06SEP2021	Oral temperature (°C)	36.2	35.4	35.1	34.4	35.4	36.1	35.7		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	27SEP2021	Oral temperature (°C)	36.3	36.2	36	35.6	35.8	35.4	35.6		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	Mild	N	N	N	N	N	28SEP2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]†	1	20SEP2021	Oral temperature (°C)	35.1	35.6	34.4	36.1	34.1	34.2	35.4		
				Fatigue	N	Mild	N	N	N	N	N	21SEP2021	1
				Headache	N	N	Mild	N	N	N	N	22SEP2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	14OCT2021	Oral temperature (°C)	35.3	34.1	34.9	34.6		34.1	35.1		
				Fatigue	Mild	Mod	Mod	N		N	N	16OCT2021	3
				Headache	Mild	Mild	Mod	Mod		N	Mod	27OCT2021	14
				Chills	N	N	N	N		N	N		
				Vomiting	N	N	N	N		N	N		
				Diarrhea	N	N	N	N		N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	N	N		N	N		
				New or worsened joint pain	N	N	N	N		N	N		
	[redacted]†	1	17SEP2021	Oral temperature (°C)	36	36	36	36.2	36.2	35.5	35.7		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	Mild	N	N	N	N	N	18SEP2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	08OCT2021	Oral temperature (°C)				36		36.8	35.8		
				Fatigue				N		N	N		
				Headache				N		N	N		
				Chills				N		N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting				N		N	N		
				Diarrhea				N		N	N		
				New or worsened muscle pain				N		N	N		
				New or worsened joint pain				N		N	N		
	[redacted]†	1	21SEP2021	Oral temperature (°C)	36.3	36.2	36.2	36.1	36.5	36.1	36.1		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	14OCT2021	Oral temperature (°C)	36.5		35.4	36.3	36.5	36.2	36.3		
				Fatigue	N		N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N		N	N	N	N	N		
				Chills	N		N	N	N	N	N		
				Vomiting	N		N	N	N	N	N		
				Diarrhea	N		N	N	N	N	N		
				New or worsened muscle pain	N		N	N	N	N	N		
				New or worsened joint pain	N		N	N	N	N	N		
	[redacted]†	1	05OCT2021	Oral temperature (°C)		36.2	36.1	36.2	36.4	36.2	36.5		
				Fatigue		N	Mild	N	N	N	N	07OCT2021	1
				Headache		N	N	N	N	N	N		
				Chills		N	N	N	N	N	N		
				Vomiting		N	N	N	N	N	Mild	12OCT2021	2
				Diarrhea		N	N	N	N	N	N		
				New or worsened muscle pain		N	N	N	N	N	N		
				New or worsened joint pain		N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
		2	25OCT2021	Oral temperature (°C)	36.4	36.7	36.1	36.3	36.1				
				Fatigue	N	Mod	N	Mild	N			28OCT2021	3
				Headache	Mild	Mod	Mild	N	Mild			29OCT2021	5
				Chills	N	N	N	N	N				
				Vomiting	Mod	Mild	Mild	Mild	Mild			29OCT2021	5
				Diarrhea	N	N	N	Mild	N			28OCT2021	1
				New or worsened muscle pain	N	Mild	N	N	N			26OCT2021	1
				New or worsened joint pain	N	N	N	N	N				
	[redacted]	1	06OCT2021	Oral temperature (°C)	36.1	35.7			36	36.3			
				Fatigue	Mild	Mild			N	Mild		11OCT2021	6
				Headache	N	N			N	N			
				Chills	N	N			N	N			
				Vomiting	N	N			N	N			
				Diarrhea	N	N			Mild	N		10OCT2021	1
				New or worsened muscle pain	N	Mod			Mild	N		10OCT2021	4

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N			N	N			
		2	27OCT2021	Oral temperature (°C)	36.1		36.2	35.9	35.8	36.1	36.2		
				Fatigue	Mod		N	N	Mild	N	N	31OCT2021	5
				Headache	N		Mild	N	N	N	N	29OCT2021	1
				Chills	N		N	N	N	N	N		
				Vomiting	N		N	N	Mild	N	N	31OCT2021	1
				Diarrhea	N		N	N	N	N	N		
				New or worsened muscle pain	N		Mild	N	N	N	N	29OCT2021	1
				New or worsened joint pain	N		N	N	N	N	N		
	[redacted]†	1	14OCT2021	Oral temperature (°C)	36.8	36.4	36.5	36.2	37	36.3	36.4		
				Fatigue	Mod	N	N	N	N	N	N	14OCT2021	1
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	04NOV2021	Oral temperature (°C)	36.5	37	36.7	36.8	36.4	36.4	36.7		
				Fatigue	Mild	Mod	N	N	N	N	N	05NOV2021	2
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	Mild	N	N	08NOV2021	1
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	Mod	N	N	N	N	N	05NOV2021	1
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]†	1	05NOV2021	Oral temperature (°C)		36.6	36.4	36.3	36.8	36.6	36.7		
				Fatigue		Mod	Mod	Mild	N	N	N	08NOV2021	3
				Headache		N	N	N	N	Mod	Sev	26NOV2021	17
				Chills		N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting		N	N	N	N	N	N		
				Diarrhea		Mild	N	N	N	N	N	06NOV2021	1
				New or worsened muscle pain		Mild	Mild	N	N	N	N	07NOV2021	2
				New or worsened joint pain		Mild	N	N	N	N	N	06NOV2021	1
		2	26NOV2021	Oral temperature (°C)			37.2	36.9	36.7	36.5	36.5		
				Fatigue			Mod	Mod	Sev	N	N	30NOV2021	3
				Headache	Mod	Mod	Mod	Mod	N	N	N	29NOV2021	4
				Chills			N	Mod	N	N	N	29NOV2021	1
				Vomiting			Mild	N	N	N	N	28NOV2021	1
				Diarrhea			N	N	N	N	N		
				New or worsened muscle pain			N	Mod	N	N	N	29NOV2021	1
				New or worsened joint pain			Mild	Sev	Mod	N	N	30NOV2021	3
	[redacted]	1	10JUN2021	Oral temperature (°C)		32.2	36.6	36.4	36.2	36.2	36.5		
				Fatigue		N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache		N	N	N	N	N	N		
				Chills		N	N	N	N	N	N		
				Vomiting		N	N	N	N	N	N		
				Diarrhea		N	N	N	N	N	N		
				New or worsened muscle pain		N	N	N	N	N	N		
				New or worsened joint pain		N	N	N	N	N	N		
		2	29JUN2021	Oral temperature (°C)		36.6	36.6	36.6	36.6	36.6	36.6		
				Fatigue		N	N	N	N	N	N		
				Headache		N	N	N	N	N	N		
				Chills		N	N	N	N	N	N		
				Vomiting		N	N	N	N	N	N		
				Diarrhea		N	N	N	N	N	N		
				New or worsened muscle pain		N	N	N	N	N	N		
				New or worsened joint pain		N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	[redacted]	1	11JUN2021	Oral temperature (°C)	33	32.5	35.5	34.5	36.9	36.5	36.4		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	04JUN2021	Oral temperature (°C)	36.1	36	35.7	35.7	35.7		36.1		
				Fatigue	N	N	N	N	N		N		
				Headache	N	N	N	N	N		N		
				Chills	N	N	N	N	N		N		
				Vomiting	N	N	N	N	N		N		
				Diarrhea	N	N	N	N	N		N		
				New or worsened muscle pain	N	N	N	N	N		N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N	N	N		N		
		2	25JUN2021	Oral temperature (°C)	36	36	35.7	36	35.7	36	35.8		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	04JUN2021	Oral temperature (°C)	35.9	36.1	36.1	36.2	36.3	35.9	35.8		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	25JUN2021	Oral temperature (°C)	36.1	36.1	36.2	36.1	36.2	36			
				Fatigue	N	N	N	N	N	N			
				Headache	N	Mild	N	N	N	N		26JUN2021	1
				Chills	N	N	N	N	N	N			
				Vomiting	N	N	N	N	N	N			
				Diarrhea	N	N	N	N	N	N			
				New or worsened muscle pain	N	N	N	N	N	N			
				New or worsened joint pain	N	N	N	N	N	N			
	[redacted]	1	12AUG2021	Oral temperature (°C)	36.2	36.4	36.1	36.1	36.2	36	36		
				Fatigue	Mild	N	N	N	N	N	N	12AUG2021	1
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	02SEP2021	Oral temperature (°C)	36	36.1	36	36.2	36.2	36	36		
				Fatigue	Mild	Mild	N	N	N	N	N	03SEP2021	2
				Headache	N	Mild	N	Mild	N	N	N	05SEP2021	3
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	20AUG2021	Oral temperature (°C)	35.8	36	35.8	36.3	36	35.8	35.8		
				Fatigue	Mild	Mod	N	Mild	N	Mod	N	25AUG2021	6

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	N	N	N	N	Mild	N	25AUG2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	Mild	N	Mod	N	25AUG2021	3
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	09SEP2021	Oral temperature (°C)	36.2	35.8	35.6	35.8	36.2	36.7	36.8		
				Fatigue	N	Mod	N	Mild	Mod	N	N	13SEP2021	4
				Headache	Mild	Mod	N	Mild	N	Mild	N	14SEP2021	6
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	[redacted]	1	14MAY2021	Oral temperature (°C)	36.72	37.28	36.89	36.67	36.67	37.28	37.11		
				Fatigue	N	Mod	N	N	N	N	N	15MAY2021	1
				Headache	N	Mod	N	N	N	N	N	15MAY2021	1
				Chills	N	Mod	N	N	N	N	N	15MAY2021	1
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	Mod	N	N	N	N	N	15MAY2021	1
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	26MAY2021	Oral temperature (°C)	36.67	37.11		37.11	37.11	36.39			
				Fatigue	Mod	Mild		N	N	Mild		04JUN2021	10
				Headache	N	N		N	N	N			
				Chills	N	N		N	N	N			
				Vomiting	N	N		N	N	N			
				Diarrhea	N	N		N	N	N			
				New or worsened muscle pain	N	N		N	N	N			

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N		N	N	N			
		2	17JUN2021	Oral temperature (°C)		38.06		36.11	36.78		36.39	18JUN2021	1
				Fatigue		Mod		N	N		Mod	23JUN2021	6
				Headache		Mod		N	Mod		N	21JUN2021	4
				Chills		N		N	N		N		
				Vomiting		N		N	N		N		
				Diarrhea		N		N	N		N		
				New or worsened muscle pain		Mod		N	N		N	18JUN2021	1
				New or worsened joint pain		Mod		Mod	N		N	20JUN2021	3
	[redacted]	1	31AUG2021	Oral temperature (°C)	36.89	37.06	37	35.61	37	37.06	37		
				Fatigue	N	N	Mild	Mild	N	N	N	03SEP2021	2
				Headache	N	N	N	N	N	N	N		
				Chills	Mild	N	N	N	N	N	N	31AUG2021	1
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	N	N	Mild	N	N	04SEP2021	1
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	22SEP2021	Oral temperature (°C)		36.17	36.28	36.22	36.72	36.17	35.72		
				Fatigue		N	N	N	N	N	N		
				Headache		Mild	Mod	N	N	N	N	24SEP2021	2
				Chills		N	N	N	N	N	N		
				Vomiting		N	N	N	N	N	N		
				Diarrhea		N	N	N	N	N	N		
				New or worsened muscle pain		N	N	N	N	N	Mild	30SEP2021	3
				New or worsened joint pain		N	N	N	N	N	N		
	[redacted]	1	01SEP2021	Oral temperature (°C)	36.5	36.28	36.28	36.28	36.28	37	36.28		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	22SEP2021	Oral temperature (°C)	36.83	36.28	36.89	36.28	36.28	36.28	36.56		
				Fatigue	Mild	N	Mod	N	N	N	N	24SEP2021	3
				Headache	Mild	Mild	Mild	Mild	N	Mild	N	27SEP2021	6
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	Mild	N	N	N	N	24SEP2021	1
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	Mild	Mod	N	N	N	N	24SEP2021	2
				New or worsened joint pain	N	Mod	N	N	N	N	N	23SEP2021	1
	[redacted]	1	03SEP2021	Oral temperature (°C)	37.39	37.56	37.22	36.78	37.44	37.17	37.33		
				Fatigue	Mild	Mod	Mild	Mild	N	Mild	N	08SEP2021	6

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	Mod	N	N	N	N	N	04SEP2021	1
				Chills	N	Mod	N	N	N	N	N	04SEP2021	1
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	Mild	Mod	N	N	N	N	N	04SEP2021	2
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	07OCT2021	Oral temperature (°C)	37.11	38.17	36.78	36.61	37.17	36.72	37.28	08OCT2021	1
				Fatigue	N	Mod	Mod	Mild	N	N	N	10OCT2021	3
				Headache	N	Mild	N	N	N	N	N	08OCT2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	[redacted]	1	26MAY2021	Oral temperature (°C)	34.7	35.7	35.7	35.7	35.6	35.6	35.7		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	14JUN2021	Oral temperature (°C)	36.4	35.7	35.6	36.5	36.7	36.8	36.2		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	27MAY2021	Oral temperature (°C)	36.5	36.6	36.3	36.5	36.4	36.5	36.4		
				Fatigue	N	N	N	N	Mild	N	N	31MAY2021	1
				Headache	N	Mild	N	N	N	N	N	28MAY2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	Mild	Mild	Mild	N	01JUN2021	3
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	15JUN2021	Oral temperature (°C)	36.4	35.7	35.8	35.5	35.8	35.7	36.1		
				Fatigue	Mod	N	Mild	N	N	N	N	17JUN2021	3
				Headache	N	N	N	N	N	N	N		
				Chills	Mod	N	N	N	N	N	N	15JUN2021	1
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	Mild	N	N	N	N	N	N	15JUN2021	1
	[redacted]	1	27MAY2021	Oral temperature (°C)	36.4	36.6	36.5	36.2	36.3	36.4	36.4		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	15JUN2021	Oral temperature (°C)	36.2	36.3	36.2	36.5	35.4	36.2	35.5		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	28MAY2021	Oral temperature (°C)	35.8	36.3	36.3	36.1	36.1	35.9	36		
				Fatigue	N	N	N	Mild	N	N	N	31MAY2021	1
				Headache	N	N	Mod	N	N	N	N	30MAY2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	18JUN2021	Oral temperature (°C)	35.6	36.1	35.8	36.1	35.8	35.9	36		
				Fatigue	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	28MAY2021	Oral temperature (°C)	34.2	38.2	36.9	33.8	32.4	33.3		29MAY2021	1
				Fatigue	N	Mild	N	N	N	N		29MAY2021	1
				Headache	N	N	N	N	N	N			
				Chills	N	N	N	N	N	N			
				Vomiting	N	Mild	N	N	N	N		29MAY2021	1
				Diarrhea	N	N	N	N	N	N			
				New or worsened muscle pain	N	N	N	N	N	N			
				New or worsened joint pain	N	N	N	N	N	N			

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
		2	18JUN2021	Oral temperature (°C)	34.2	33.2	32.4	32.6	34.4		34		
				Fatigue	N	N	Mild	N	N		N	20JUN2021	1
				Headache	N	N	N	N	N		N		
				Chills	N	N	N	N	N		N		
				Vomiting	N	N	N	N	N		N		
				Diarrhea	N	N	N	N	N		N		
				New or worsened muscle pain	N	N	N	N	N		N		
				New or worsened joint pain	N	N	N	N	N		N		
	[redacted]	1	31MAY2021	Oral temperature (°C)	36.2	36.2	36.3	36.2	36.3	36.4	36.4		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	21JUN2021	Oral temperature (°C)	36.5	36.3	36.1	36.4	36.2	36.4	36.1		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	31MAY2021	Oral temperature (°C)	35.7	36.6	36.9	36.3	36.5	37	37.1		
				Fatigue	Mild	N	N	N	N	N	N	31MAY2021	1
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	21JUN2021	Oral temperature (°C)	35.9	36.5	36.1	36.7	36.6	36.7	36.6		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	02JUN2021	Oral temperature (°C)	36.8	36.2	36.2	36.6		36.7	36		
				Fatigue	N	N	N	N		N	N		
				Headache	Mild	Mild	N	N		N	N	03JUN2021	2
				Chills	N	N	N	N		N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N		N	N		
				Diarrhea	N	N	N	N		N	N		
				New or worsened muscle pain	N	N	N	N		N	N		
				New or worsened joint pain	N	N	N	N		N	N		
	[redacted]	1	02JUN2021	Oral temperature (°C)	36.2	36.3	35.2	35.7	35.8		35.9		
				Fatigue	Mild	N	N	N	N		N	02JUN2021	1
				Headache	N	N	N	N	N		N		
				Chills	N	N	N	N	N		N		
				Vomiting	N	N	N	N	N		N		
				Diarrhea	N	N	N	N	N		N		
				New or worsened muscle pain	N	Mild	N	N	N		N	03JUN2021	1
				New or worsened joint pain	N	N	N	N	N		N		
		2	23JUN2021	Oral temperature (°C)	34.5	34.8			34.5	34.5	34.5		
				Fatigue	N	N			N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	N			N	N	N		
				Chills	N	N			N	N	N		
				Vomiting	N	N			N	N	N		
				Diarrhea	N	N			N	N	N		
				New or worsened muscle pain	N	N			N	N	N		
				New or worsened joint pain	N	N			N	N	N		
	[redacted]	1	02JUN2021	Oral temperature (°C)	36	36	35.6	35.8	35.8	35.8	35.7		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	Mild	N	N	N	N	N	03JUN2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
		2	23JUN2021	Oral temperature (°C)	35.8	35.8	35.7		35.9	36.1	35.8		
				Fatigue	N	N	N		N	N	N		
				Headache	N	N	N		N	N	N		
				Chills	N	N	N		N	N	N		
				Vomiting	N	N	N		N	N	N		
				Diarrhea	N	N	N		N	N	N		
				New or worsened muscle pain	N	N	N		N	N	N		
				New or worsened joint pain	N	N	N		N	N	N		
	[redacted]	1	08JUN2021	Oral temperature (°C)	33	35.8	34.5	34.7		34.5	35		
				Fatigue	N	N	N	N		Mild	N	13JUN2021	1
				Headache	N	N	N	N		Sev	N	13JUN2021	1
				Chills	N	N	N	N		N	N		
				Vomiting	N	N	N	N		N	Mild	14JUN2021	1
				Diarrhea	N	N	N	N		N	N		
				New or worsened muscle pain	N	N	N	N		N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N	N		N	N		
		2	29JUN2021	Oral temperature (°C)	35.2	34		35.4	34.7	35.2			
				Fatigue	Mod	Mod		N	N	N		30JUN2021	2
				Headache	Mod	Mod		N	N	N		30JUN2021	2
				Chills	Mild	Mod		N	N	N		30JUN2021	2
				Vomiting	N	Mild		N	N	N		30JUN2021	1
				Diarrhea	N	N		N	N	N			
				New or worsened muscle pain	Mod	Mod		N	N	N		30JUN2021	2
				New or worsened joint pain	N	N		N	N	N			
	[redacted]	1	08JUN2021	Oral temperature (°C)	35.7	35.9	36.1	35.8	35.6	36.1	35.9		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	29JUN2021	Oral temperature (°C)	35.2	34.4	35.3	34	35.9	36.2	35.8		
				Fatigue	N	Mild	N	N	N	N	N	30JUN2021	1
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	11JUN2021	Oral temperature (°C)	35.2	35.4	35.3	35.3	35.3	35.4	35.4		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	Mild	N	16JUN2021	1
				Chills	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	Mild	N	16JUN2021	1
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	02JUL2021	Oral temperature (°C)	34.7	34.6	34.5	34.5	34.5	34.5	34.7		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	Mild	N	N	N	N	N	03JUL2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	Mild	N	N	N	N	N	03JUL2021	1
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	11JUN2021	Oral temperature (°C)		36	36.6	36.4	36.4	36.5	36.5		
				Fatigue		N	Mild	Mild	Mild	Mod	N	16JUN2021	4

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache		N	N	N	N	N	N		
				Chills		N	N	N	N	N	N		
				Vomiting		N	N	N	N	N	N		
				Diarrhea		N	N	N	N	N	N		
				New or worsened muscle pain		N	N	N	N	N	N		
				New or worsened joint pain		N	N	N	N	N	N		
		2	02JUL2021	Oral temperature (°C)	36.4	36.4	36.6	36.5	36.6	36.6	36.5		
				Fatigue	N	N	N	N	N	Mild	N	07JUL2021	1
				Headache	N	Mild	Mild	Mild	Mild	N	N	06JUL2021	4
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	[redacted]	1	06AUG2021	Oral temperature (°C)	36.2	35.2	35.2	35.3	35.3		35.4		
				Fatigue	N	N	N	N	N		Mild	12AUG2021	1
				Headache	Mild	N	N	N	N		N	06AUG2021	1
				Chills	N	Mild	N	N	N		N	07AUG2021	1
				Vomiting	N	N	N	N	N		N		
				Diarrhea	N	N	Mild	N	N		N	08AUG2021	1
				New or worsened muscle pain	N	N	N	N	N		N		
				New or worsened joint pain	N	N	N	N	N		N		
		2	30AUG2021	Oral temperature (°C)	35.1	35.2	36.1	35.4	35.2	35.2	35.3		
				Fatigue	N	Mild	N	N	N	N	N	31AUG2021	1
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	24SEP2021	Oral temperature (°C)	35.3	34.9	35.8	35.6	36.4		36.5		
				Fatigue	N	N	N	N	N		N		
				Headache	N	N	N	N	N		N		
				Chills	Mild	N	N	N	N		N	24SEP2021	1
				Vomiting	N	N	N	N	N		N		
				Diarrhea	N	N	N	N	N		N		
				New or worsened muscle pain	N	N	N	N	N		N		
				New or worsened joint pain	N	N	N	N	N		N		
		2	15OCT2021	Oral temperature (°C)	36.5	36.5	36.6	35.9	36.1	36.7	36.5		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	08JUN2021	Oral temperature (°C)	37.4	37		36.9	37.4	36.8	37.2		
				Fatigue	N	N		N	N	N	N		
				Headache	N	N		N	N	N	N		
				Chills	N	N		N	N	N	N		
				Vomiting	N	N		N	N	N	N		
				Diarrhea	N	N		N	N	N	N		
				New or worsened muscle pain	N	N		N	N	N	N		
				New or worsened joint pain	N	N		N	N	N	N		
		2	29JUN2021	Oral temperature (°C)			36.6	37.1	36.9	36.7	37		
				Fatigue			Mild	N	N	N	Mod	06JUL2021	6
				Headache			Mild	N	N	N	N	01JUL2021	1
				Chills			N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting			N	N	N	N	N		
				Diarrhea			N	N	N	N	N		
				New or worsened muscle pain			N	N	N	N	N		
				New or worsened joint pain			N	N	N	N	N		
	[redacted]	1	11JUN2021	Oral temperature (°C)	36.5	36.2	36.2	36.1	36.4	36	36.4		
				Fatigue	Mod	Mod	Mild	Mild	N	N	N	14JUN2021	4
				Headache	Mild	Mild	Mild	N	N	N	N	13JUN2021	3
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	06JUL2021	Oral temperature (°C)	36.5	36.4	35.8		36.4	36.5	35.7		
				Fatigue	Mild	Mild	Mild		Mild	Mild	Mod	20JUL2021	15

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	N	N		N	Mild	N	11JUL2021	1
				Chills	N	N	N		N	N	N		
				Vomiting	N	N	N		N	N	N		
				Diarrhea	N	N	N		N	N	N		
				New or worsened muscle pain	N	N	N		N	N	N		
				New or worsened joint pain	N	N	N		N	N	N		
	[redacted]	1	12JUL2021	Oral temperature (°C)	36.2	36.6			36.6	36.7	36.6		
				Fatigue	Mild	Mod			N	Mild	Mild	02AUG2021	22
				Headache	Mild	Mod			N	N	N	13JUL2021	2
				Chills	N	N			N	N	N		
				Vomiting	N	N			N	N	N		
				Diarrhea	N	N			N	N	N		
				New or worsened muscle pain	N	N			N	N	N		
				New or worsened joint pain	N	N			N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
		2	02AUG2021	Oral temperature (°C)	36.2	36.4	36.2	36.2	36.2	36.2	36.2		
				Fatigue	N	Mod	Mild	Mild	N	N	Mild	10AUG2021	8
				Headache	N	Mild	N	N	N	N	N	03AUG2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	Mild	N	N	N	05AUG2021	1
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	23JUL2021	Oral temperature (°C)	36.4	36.2	36.4	35.9		36.2	36.5		
				Fatigue	N	N	N	N		N	N		
				Headache	N	N	N	N		N	N		
				Chills	N	N	N	N		N	N		
				Vomiting	N	N	N	N		N	N		
				Diarrhea	N	N	N	N		N	N		
				New or worsened muscle pain	N	N	N	N		N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N	N		N	N		
		2	12AUG2021	Oral temperature (°C)	36.5	Unknown	36		36	35.7		13AUG2021	1
				Fatigue	N	Mild	N		N	N		13AUG2021	1
				Headache	N	N	N		N	N			
				Chills	N	N	N		N	N			
				Vomiting	N	N	N		N	N			
				Diarrhea	N	N	N		N	N			
				New or worsened muscle pain	N	Mild	N		N	N		13AUG2021	1
				New or worsened joint pain	N	Mild	N		N	N		13AUG2021	1
	[redacted]	1	22JUL2021	Oral temperature (°C)	36.1	36	36.2	36.5	36		36		
				Fatigue	N	N	N	N	N		N		
				Headache	N	N	N	N	N		N		
				Chills	N	N	N	N	N		N		
				Vomiting	N	N	N	N	N		N		
				Diarrhea	N	N	N	N	N		N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	N	N	N		N		
				New or worsened joint pain	N	N	N	N	N		N		
		2	12AUG2021	Oral temperature (°C)	36.5	36.4	34.5	36.2	36.5	36.3	36.7		
				Fatigue	N	Mod	N	N	N	N	N	13AUG2021	1
				Headache	Mild	N	Mod	N	N	N	N	14AUG2021	3
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	Mild	Mild	N	N	N	N	N	13AUG2021	2
				New or worsened joint pain	N	Mild	N	N	N	N	N	13AUG2021	1
	[redacted]	1	22JUL2021	Oral temperature (°C)	35.3	35.9	35.8	36.1	35.9	36.3	36.2		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	Mild	N	N	26JUL2021	1
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	12AUG2021	Oral temperature (°C)		36.8	36.2	36.2	36.1	36.1	36		
				Fatigue		N	N	N	N	N	N		
				Headache		Mod	Mild	N	N	N	N	14AUG2021	2
				Chills		N	N	N	N	N	N		
				Vomiting		N	N	N	N	N	N		
				Diarrhea		N	N	N	N	N	N		
				New or worsened muscle pain		N	N	N	N	N	N		
				New or worsened joint pain		N	N	N	N	N	N		
	[redacted]	1	04AUG2021	Oral temperature (°C)	37.2	37.2	36.7	36.8	37.1	37.2	36.9		
				Fatigue	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	24AUG2021	Oral temperature (°C)		37.6	37.1	37.5	36.9	36.9	37.2		
				Fatigue		Mod	N	N	N	N	N	25AUG2021	1
				Headache		Mod	N	N	N	N	N	25AUG2021	1
				Chills		N	N	N	N	N	N		
				Vomiting		N	N	Mild	N	N	N	27AUG2021	1
				Diarrhea		N	N	N	N	N	N		
				New or worsened muscle pain		Mod	N	N	N	N	N	25AUG2021	1
				New or worsened joint pain		Mod	N	N	N	N	N	25AUG2021	1

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	[redacted]	1	22JUL2021	Oral temperature (°C)	36.5	35.7		35.8		35.6	36.1		
				Fatigue	Mild	N		N		Mild	N	27JUL2021	6
				Headache	Mild	N		N		N	N	22JUL2021	1
				Chills	N	N		N		N	N		
				Vomiting	N	N		N		N	N		
				Diarrhea	N	N		N		N	N		
				New or worsened muscle pain	N	N		N		N	N		
				New or worsened joint pain	N	N		N		N	N		
		2	11AUG2021	Oral temperature (°C)	35.7	36.9	35.9	35.9	35.8	35.9	36		
				Fatigue	Mod	Mod	N	N	N	Mod	N	16AUG2021	6
				Headache	N	Mod	N	N	N	N	N	12AUG2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	Mod	N	N	N	N	N	12AUG2021	1

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	Mod	N	N	N	N	N	12AUG2021	1
	[redacted]	1	24JUN2021	Oral temperature (°C)	35.7	35.9	36.9	36.8	36.1	36.1	35.9		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	16JUL2021	Oral temperature (°C)		37.1	36.5	36.3	36.3	36.7	36.6		
				Fatigue		Mod	N	Mild	N	N	N	19JUL2021	3
				Headache		Mod	N	N	N	N	N	17JUL2021	1
				Chills		N	N	N	N	N	N		
				Vomiting		N	N	N	N	N	N		
				Diarrhea		N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain		Mod	N	N	N	N	N	17JUL2021	1
				New or worsened joint pain		N	N	N	N	N	N		
	[redacted]	1	01JUN2021	Oral temperature (°C)	35.7	35.8	35.2	35.7		35.2	35.3		
				Fatigue	N	Mild	N	N		N	N	02JUN2021	1
				Headache	Mild	Mild	N	N		N	N	02JUN2021	2
				Chills	N	N	N	N		N	N		
				Vomiting	N	N	N	N		N	N		
				Diarrhea	N	N	N	N		N	N		
				New or worsened muscle pain	N	N	N	N		N	N		
				New or worsened joint pain	N	N	N	N		N	N		
		2	22JUN2021	Oral temperature (°C)	35.4	36.2	36.3	35.2	35.3	35.6			
				Fatigue	N	N	Mod	N	N	N		24JUN2021	1
				Headache	N	Mild	Mild	N	N	N		24JUN2021	2
				Chills	N	N	N	N	N	N			

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N	N	N			
				Diarrhea	N	N	N	N	N	N			
				New or worsened muscle pain	N	N	Mild	N	N	N		24JUN2021	1
				New or worsened joint pain	N	N	N	N	N	N			
	[redacted]	1	01JUN2021	Oral temperature (°C)	34.7	36	35.5	35.9	35.8	35.7	35.6		
				Fatigue	N	Mod	N	N	Mild	N	Mod	08JUN2021	7
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	Mild	N	N	N	04JUN2021	1
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	22JUN2021	Oral temperature (°C)	34.9	36	35.4	34.7	34.7	34.5	35		
				Fatigue	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	17JUN2021	Oral temperature (°C)	36.2	35.4	35.9	35.9	35.9	35.7	35.3		
				Fatigue	Mild	Mild	Mild	N	Mild	Mild	Mild	24JUN2021	8
				Headache	N	N	Mild	N	N	N	N	19JUN2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	Mild	N	N	21JUN2021	1
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
		2	07JUL2021	Oral temperature (°C)	35.3	34.9	35.5	35.9	35.4	35.5	35.4		
				Fatigue	Mild	Mild	N	N	N	Mild	Mild	14JUL2021	8
				Headache	N	Mild	N	N	N	N	N	08JUL2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	08JUN2021	Oral temperature (°C)	35.6	36.3	35.6	35.6	35.6	36.1	36.2		
				Fatigue	Mod	Mod	Mod	Mod	Mod	Mod	N	13JUN2021	6
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	28JUN2021	Oral temperature (°C)	36.2	35.6	35.5	35.2	35.4	35.4	36.1		
				Fatigue	Mod	Mod	Mod	Mod	Mod	Mod	Mod	05JUL2021	8
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	01JUN2021	Oral temperature (°C)	37	36.9	37	36.5	36.8	36.5			
				Fatigue	N	Mild	Mild	Mod	N	N		04JUN2021	3
				Headache	N	N	Mod	Mod	N	N		04JUN2021	2
				Chills	N	N	N	N	N	N			
				Vomiting	N	N	N	N	N	N			
				Diarrhea	N	Mild	N	N	N	N		02JUN2021	1

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	N	N	N	N			
				New or worsened joint pain	N	N	N	N	N	N			
		2	21JUN2021	Oral temperature (°C)		37.3	36.3	36.1	36.7	36.9	35.9		
				Fatigue		Mod	N	N	N	N	N	22JUN2021	1
				Headache		Mild	Mild	N	N	N	N	23JUN2021	2
				Chills		N	N	N	N	N	N		
				Vomiting		N	N	N	N	N	N		
				Diarrhea		N	N	N	N	N	N		
				New or worsened muscle pain		N	N	N	N	N	N		
				New or worsened joint pain		N	N	N	N	N	N		
	[redacted]	1	01JUN2021	Oral temperature (°C)	36.5	36.2	36.7	35.8	36.1	36.5	36.1		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	23JUN2021	Oral temperature (°C)	36.2	36.4	36.4	36.3	36.3	36.5	36.2		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	08JUN2021	Oral temperature (°C)	36.3		36.5	36.4	36	35.6			
				Fatigue	Mod		Mod	Mod	Mod	Mild		13JUN2021	6

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N		N	N	N	N			
				Chills	N		N	N	N	N			
				Vomiting	N		N	N	N	N			
				Diarrhea	N		Mild	Mild	N	N		11JUN2021	2
				New or worsened muscle pain	N		N	N	N	N			
				New or worsened joint pain	N		N	N	N	N			
		2	29JUN2021	Oral temperature (°C)	35.6	36.7	35.6	35.9	35.5	35.9	36.2		
				Fatigue	N	Mod	Mod	Mild	Mod	Mod	Mod	06JUL2021	7
				Headache	N	Mild	Mild	N	N	N	N	01JUL2021	2
				Chills	N	Mod	N	N	N	N	N	30JUN2021	1
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	Mild	N	N	N	N	N	30JUN2021	1

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	[redacted]	1	09JUN2021	Oral temperature (°C)	36.7	36.5	36.9	36.6	37	36.7	36.8		
				Fatigue	N	Mild	Mod	N	N	N	N	11JUN2021	2
				Headache	N	N	N	N	Mod	Mod	N	14JUN2021	2
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	01JUL2021	Oral temperature (°C)	36.8	36.7	35.4	36.1	36.4	36.3	36.4		
				Fatigue	N	Mild	Mild	N	N	N	N	03JUL2021	2
				Headache	N	Mild	N	N	N	N	N	02JUL2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	14JUN2021	Oral temperature (°C)	36.3	36.1	36.2	36.3	35.9	36.3	36.3		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	05JUL2021	Oral temperature (°C)	36.5	36.3	36.1		36.3	36.4			
				Fatigue	N	N	N		N	N			
				Headache	N	N	N		N	N			
				Chills	N	N	N		N	N			
				Vomiting	N	N	N		N	N			
				Diarrhea	N	N	N		N	N			

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	N		N	N			
				New or worsened joint pain	N	N	N		N	N			
	[redacted]	1	11JUN2021	Oral temperature (°C)	36.5	36	36.2	36.4		37.4	36.5		
				Fatigue	N	N	N	N		Mod	Mod	19JUN2021	4
				Headache	N	N	N	N		N	N		
				Chills	N	N	N	N		N	N		
				Vomiting	N	N	N	N		N	N		
				Diarrhea	N	N	N	N		N	Mod	18JUN2021	2
				New or worsened muscle pain	N	N	N	N		N	N		
				New or worsened joint pain	N	N	N	N		N	N		
		2	01JUL2021	Oral temperature (°C)	36.5	35.7	36.2	35.7	36.1	36.1	36.4		
				Fatigue	N	Mod	Mild	N	N	N	N	03JUL2021	2
				Headache	N	Mild	N	N	N	N	Mild	07JUL2021	6
				Chills	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	31AUG2021	Oral temperature (°C)	36.7								
				Fatigue	N								
				Headache	N								
				Chills	N								
				Vomiting	N								
				Diarrhea	N								
				New or worsened muscle pain	N								
				New or worsened joint pain	N								
	[redacted]	1	21SEP2021	Oral temperature (°C)	36.2	36.8	36.8		36.5	37.2	36.3		
				Fatigue	N	N	N		N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	N	N		N	N	N		
				Chills	N	N	N		N	N	N		
				Vomiting	N	N	N		N	N	N		
				Diarrhea	N	N	N		N	N	N		
				New or worsened muscle pain	N	N	N		N	N	N		
				New or worsened joint pain	N	N	N		N	N	N		
		2	12OCT2021	Oral temperature (°C)	36.4	36.4			36.5	36.7	36.2		
				Fatigue	N	N			N	N	N		
				Headache	N	N			N	N	N		
				Chills	N	N			N	N	N		
				Vomiting	N	N			N	N	N		
				Diarrhea	N	N			N	N	N		
				New or worsened muscle pain	N	N			N	N	N		
				New or worsened joint pain	N	N			N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
Placebo	[redacted]	1	23MAR2021	Oral temperature (°C)	36.78	36.78	36.78	36.72	36.72	36.78	36.72		
				Fatigue	N	Mod	Mod	N	Mod	N	N	27MAR2021	4
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	13APR2021	Oral temperature (°C)	37	37	36.78	36.83	36.78	36.83	36.72		
				Fatigue	N	Mod	Mod	N	N	N	N	15APR2021	2
				Headache	Mod	Mod	N	Mod	N	N	N	16APR2021	4
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	01APR2021	Oral temperature (°C)	37.17	36.78	36.89	36.94	37.28	37.28	36.56		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	22APR2021	Oral temperature (°C)						36.94	36.83		
				Fatigue						N	N		
				Headache						N	N		
				Chills						N	N		
				Vomiting						N	N		
				Diarrhea						N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain						N	N		
				New or worsened joint pain						N	N		
	[redacted]	1	30APR2021	Oral temperature (°C)	36.94	36.89	36.94	36.89	36.94	36.94	36.83		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	Mild	N	N	N	N	N	01MAY2021	1
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	11JUN2021	Oral temperature (°C)					36.89	36.83	36.61		
				Fatigue					N	N	N		
				Headache					N	N	N		
				Chills					N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting					N	N	N		
				Diarrhea					N	N	N		
				New or worsened muscle pain					N	N	N		
				New or worsened joint pain					N	N	N		
	[redacted]	1	07MAY2021	Oral temperature (°C)	36.72	37.17	36.94	37.28	37.5	37.11	36.94		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	20MAY2021	Oral temperature (°C)	37.11	37.06	36.83	36.78	36.83	37	36.89		
				Fatigue	Mild	N	N	N	N	N	N	20MAY2021	1

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	Mild	N	N	N	N	N	N	20MAY2021	1
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	11JUN2021	Oral temperature (°C)	36.89	36.83	36.67	36.72	36.83	36.78	36.89		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	[redacted]	1	18JUN2021	Oral temperature (°C)	36.11		36.11			37.06	36.11		
				Fatigue	N		N			N	N		
				Headache	N		Mild			N	N	20JUN2021	1
				Chills	N		N			N	N		
				Vomiting	N		N			N	N		
				Diarrhea	N		N			N	N		
				New or worsened muscle pain	N		N			N	N		
				New or worsened joint pain	N		N			N	N		
		2	08JUL2021	Oral temperature (°C)		36.39	36.67	36.5	36.06	36.89	36.22		
				Fatigue		N	N	N	N	N	N		
				Headache		N	N	N	N	N	N		
				Chills		N	N	N	N	N	N		
				Vomiting		N	N	N	N	N	N		
				Diarrhea		N	N	N	N	N	N		
				New or worsened muscle pain		N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain		N	N	N	N	N	N		
	[redacted]	1	05APR2021	Oral temperature (°C)		35.39	35.61	36.22	35.56		36.44		
				Fatigue		N	N	N	N		N		
				Headache		N	N	N	N		N		
				Chills		N	N	N	N		N		
				Vomiting		N	N	N	N		N		
				Diarrhea		N	N	N	N		N		
				New or worsened muscle pain		N	N	N	N		N		
				New or worsened joint pain		N	N	N	N		N		
		2	26APR2021	Oral temperature (°C)	36.22	35.56	36.28	35.56	36.39	36.11	36.78		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	05APR2021	Oral temperature (°C)	36.33	36.61	36.72	36.28	35.89	36.28	35.94		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	Mild	24APR2021	14
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	30APR2021	Oral temperature (°C)	36.39	36.39	36.72	36.17	36.11	36.11	36.33		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	28APR2021	Oral temperature (°C)	35.83	35.83	36.06	35.78	36.33	36.33	35.72		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	17MAY2021	Oral temperature (°C)		36.06	36.39	35.56	36.11	36.61	35.94		
				Fatigue		N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache		N	N	N	N	N	N		
				Chills		N	N	N	N	N	N		
				Vomiting		N	N	N	N	N	N		
				Diarrhea		N	N	N	N	N	N		
				New or worsened muscle pain		N	N	N	N	N	N		
				New or worsened joint pain		N	N	N	N	N	N		
	[redacted]	1	23APR2021	Oral temperature (°C)	37.11	36.5	36.61	36.89	36.83	37.11	36.94		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
		2	12MAY2021	Oral temperature (°C)	37.17	36.94	37.06	37.28	37.11	37	36.83		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	29APR2021	Oral temperature (°C)	35.94	36.39	35.61	35.61	35.56	35.61	35.67		
				Fatigue	N	N	N	N	N	N	N		
				Headache	Mild	N	N	N	N	N	N	29APR2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	20MAY2021	Oral temperature (°C)	35.56	35.61	36	35.72	35.56	36.28	35.89		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	30APR2021	Oral temperature (°C)	36.39	36.61	36.61	35.44	36.56				
				Fatigue	N	N	N	N	N				
				Headache	N	Mild	N	N	N			01MAY2021	1
				Chills	N	N	N	N	N				
				Vomiting	N	N	N	N	N				
				Diarrhea	N	N	N	N	N				

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	N	N	N				
				New or worsened joint pain	N	N	N	N	N				
		2	21MAY2021	Oral temperature (°C)	36.22	36.28	36.61	36.67	36.72	36.72	36.78		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	10MAY2021	Oral temperature (°C)	36.33	36.5	36.06	36	36.44	36.33	36.06		
				Fatigue	Mild	N	N	N	N	N	N	10MAY2021	1
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	01JUN2021	Oral temperature (°C)	36.39	36.06	36.44			36	36.56		
				Fatigue	Mild	N	N			N	N	01JUN2021	1
				Headache	Mod	N	N			N	N	01JUN2021	1
				Chills	N	N	N			N	N		
				Vomiting	N	N	N			N	N		
				Diarrhea	N	N	N			N	N		
				New or worsened muscle pain	N	N	N			N	N		
				New or worsened joint pain	N	N	N			N	N		
	[redacted]	1	11MAY2021	Oral temperature (°C)	36.56	35.83	35.78	36.22	35.56	35.67	36.28		
				Fatigue	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	Mod	N	N	N	N	13MAY2021	1
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	01JUN2021	Oral temperature (°C)	36.22	36.72	35.89		36.11	35.83	36.61		
				Fatigue	Mild	N	N		N	N	N	01JUN2021	1
				Headache	N	N	N		N	N	N		
				Chills	N	N	N		N	N	N		
				Vomiting	N	N	N		N	N	N		
				Diarrhea	N	N	N		N	N	N		
				New or worsened muscle pain	N	N	N		N	N	N		
				New or worsened joint pain	N	N	N		N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	[redacted]	1	18MAY2021	Oral temperature (°C)	36.28	36.72	35.72	36.44	36.72	36.39	36.72		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	Mild	N	N	N	N	20MAY2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	09JUN2021	Oral temperature (°C)		36.72	36.56	36.06	36.33	36.83	36.61		
				Fatigue		N	N	N	N	N	N		
				Headache		N	N	N	N	N	N		
				Chills		N	N	N	N	N	N		
				Vomiting		N	N	N	N	N	N		
				Diarrhea		N	N	N	N	N	N		
				New or worsened muscle pain		N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain		N	N	N	N	N	N		
	[redacted]	1	20MAY2021	Oral temperature (°C)	36.28	36.5	36.44	36.5	36.44	36.33	36.94		
				Fatigue	N	N	Mod	N	Mild	Mild	N	25MAY2021	4
				Headache	N	N	N	N	Mild	N	N	24MAY2021	1
				Chills	N	N	N	N	Mild	Mild	N	25MAY2021	2
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	Mod	N	Mild		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	10JUN2021	Oral temperature (°C)		36.72		36.72		36.56	35.72		
				Fatigue		N		N		N	N		
				Headache		N		N		N	N		
				Chills		N		N		N	N		
				Vomiting		N		N		N	N		
				Diarrhea		N		N		N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain		N		N		N	N		
				New or worsened joint pain		N		N		N	N		
	[redacted]	1	21MAY2021	Oral temperature (°C)	35.61			35.28	35.56	35.22	34.44		
				Fatigue	N			N	N	N	N		
				Headache	N			N	N	N	N		
				Chills	N			N	N	N	N		
				Vomiting	N			N	N	N	N		
				Diarrhea	N			N	N	N	N		
				New or worsened muscle pain	N			N	N	N	N		
				New or worsened joint pain	N			N	N	N	N		
		2	11JUN2021	Oral temperature (°C)	34.5	35		35.11	35.56	35.89	35.56		
				Fatigue	N	N		N	N	N	N		
				Headache	N	N		N	N	N	N		
				Chills	N	N		N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N		N	N	N	N		
				Diarrhea	N	N		N	N	N	N		
				New or worsened muscle pain	N	N		N	N	N	N		
				New or worsened joint pain	N	N		N	N	N	N		
	[redacted]	1	25MAY2021	Oral temperature (°C)	36.44	36.5	36.67	36.11	36.22	36.72	36.39		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	15JUN2021	Oral temperature (°C)	36.5	36.56	36.67	36.44	36.56	36.44			
				Fatigue	N	N	N	N	N	N			

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	N	N	N	N	N			
				Chills	N	N	N	N	N	N			
				Vomiting	N	N	N	N	N	N			
				Diarrhea	N	N	N	N	N	N			
				New or worsened muscle pain	N	N	N	N	N	N			
				New or worsened joint pain	N	N	N	N	N	N			
	[redacted]	1	02JUN2021	Oral temperature (°C)	36	35.83	36.06	35.78	35.83	35.72	35.78		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
		2	24JUN2021	Oral temperature (°C)	36.06	35.94	36.61	36.22	35.89	36	36.17		
				Fatigue	N	Mod	N	N	N	N	N	25JUN2021	1
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	04JUN2021	Oral temperature (°C)	36.56	36.33	36.44	36.33	36.61	36.5	36.44		
				Fatigue	Mild	N	N	N	N	N	N	04JUN2021	1
				Headache	Mild	N	N	N	N	N	N	04JUN2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	09JUL2021	Oral temperature (°C)	37.06	36.56	36.56	36.5	37	37	37		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	07JUN2021	Oral temperature (°C)	36.78	36.28	36.39	37	36.17	36.28	36.56		
				Fatigue	N	N	N	Mod	N	N	N	10JUN2021	1
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	Mild	N	N	N	10JUN2021	1
				Vomiting	N	N	N	Mod	N	N	N	10JUN2021	1
				Diarrhea	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	27JUL2021	Oral temperature (°C)	36.28	36.44	36.56	36.06	35.83	36.39	35.83		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	17JUN2021	Oral temperature (°C)	36.22	36.11	36.33	36.39	36.44	36.33	36.28		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	06JUL2021	Oral temperature (°C)		36.56	36.61	36.39	36.56	36.39	36.39		
				Fatigue		N	N	N	N	N	N		
				Headache		N	N	N	N	N	N		
				Chills		N	N	N	N	N	N		
				Vomiting		N	N	N	N	N	N		
				Diarrhea		N	N	N	N	N	N		
				New or worsened muscle pain		N	N	N	N	N	N		
				New or worsened joint pain		N	N	N	N	N	N		
	[redacted]	1	22JUN2021	Oral temperature (°C)	36.72	35.72				35.78	35.78		
				Fatigue	N	N				N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	N				N	N		
				Chills	N	N				N	N		
				Vomiting	N	N				N	N		
				Diarrhea	N	N				N	N		
				New or worsened muscle pain	N	N				N	N		
				New or worsened joint pain	N	N				N	N		
		2	13JUL2021	Oral temperature (°C)			36.33	36.39	36.33	36.44			
				Fatigue			N	N	N	N			
				Headache			N	N	N	N			
				Chills			N	N	N	N			
				Vomiting			N	N	N	N			
				Diarrhea			N	N	N	N			
				New or worsened muscle pain			N	N	N	N			
				New or worsened joint pain			N	N	N	N			

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	[redacted]	1	28MAY2021	Oral temperature (°C)	36.5	35.9	35.8	36.2	36.1	36.2	36.2		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	Mod	Mild	N	02JUN2021	2
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	18JUN2021	Oral temperature (°C)	36.6		36.4	36.2	36.5	36.5	36.2		
				Fatigue	N		N	N	N	N	N		
				Headache	N		N	N	N	Mod	N	23JUN2021	1
				Chills	N		N	N	N	N	N		
				Vomiting	N		N	N	N	N	N		
				Diarrhea	N		N	N	N	N	N		
				New or worsened muscle pain	N		N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N		N	N	N	N	N		
	[redacted]	1	01JUN2021	Oral temperature (°C)	36.4	36.5	36.3	36.4	36.2	36.5	36.2		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	02JUN2021	Oral temperature (°C)	36.1	36	36.3	35.8	36.1	35.8	35.6		
				Fatigue	Mild	N	N	N	N	N	N	02JUN2021	1
				Headache	Mild	N	N	N	N	N	N	02JUN2021	1
				Chills	Mild	N	N	N	N	N	N	02JUN2021	1
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	23JUN2021	Oral temperature (°C)	35.8	36.1	36.1		36.3	36.1	36.4		
				Fatigue	Mild	Mild	N		N	N	N	24JUN2021	2
				Headache	N	Mild	Mild		N	N	N	25JUN2021	2
				Chills	N	N	N		N	N	N		
				Vomiting	N	N	N		N	N	N		
				Diarrhea	N	N	N		N	N	N		
				New or worsened muscle pain	N	N	N		N	N	N		
				New or worsened joint pain	N	N	N		N	N	N		
	[redacted]	1	07JUN2021	Oral temperature (°C)	35.8	35.7	36.4	36	35.7	35.8	35.7		
				Fatigue	N	N	N	N	N	N	N		
				Headache	Mild	N	Mod	N	N	Mild	N	12JUN2021	6
				Chills	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	28JUN2021	Oral temperature (°C)			36.1	36	35.8	35.8	35.7		
				Fatigue			N	N	N	N	N		
				Headache			N	N	N	N	N		
				Chills			N	N	N	N	N		
				Vomiting			N	N	N	N	N		
				Diarrhea			N	N	N	N	N		
				New or worsened muscle pain			N	N	N	N	N		
				New or worsened joint pain			N	N	N	N	N		
	[redacted]	1	08JUN2021	Oral temperature (°C)	36.7	36.2	36.1	36	35.8	36.5	36.4		
				Fatigue	Mild	N	N	N	N	N	N	08JUN2021	1

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	N	N	N	N	N	N		
				Chills	N	Mild	N	N	N	N	N	09JUN2021	1
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	29JUN2021	Oral temperature (°C)	36.6	36.5	35.9	35.8	36.5	35.6	35.7		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	Mod	10JUL2021	6
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	Mod	N	N	Mild	N	04JUL2021	4
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	[redacted]	1	01APR2021	Oral temperature (°C)	36.5	36.33	36.22	36.06	36.11	36	36.17		
				Fatigue	N	N	N	N	Mild	Mild	Mild	08APR2021	4
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	Mild	N	N	Mild	N	Mild	07APR2021	6
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	20APR2021	Oral temperature (°C)	36.67	36.33	36.5	35.56	35.61	35.56	35.61		
				Fatigue	Mild	N	N	N	N	N	N	20APR2021	1
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	07JUN2021	Oral temperature (°C)	36.39	36.67	36.28	36.83	36.83	36.78	36.56		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	12MAY2021	Oral temperature (°C)	36.06	36.33	36.28	36.33	36.28	36.28	36.5		
				Fatigue	N	Mild	N	Mild	Mod	Mod	Mod	19MAY2021	7
				Headache	N	Mild	N	N	N	N	Mild	19MAY2021	7
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	N	N	Mod	N	N	16MAY2021	1
				New or worsened joint pain	N	N	N	N	Mild	N	N	16MAY2021	1
		2	01JUN2021	Oral temperature (°C)	36.5	36.22	35.72	36.44	36.5	36.11	35.72		
				Fatigue	N	N	Mod	Mod	Mod	Mod	Mod	08JUN2021	6
				Headache	N	N	N	Mild	Mild	N	N	05JUN2021	2
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	Mild	Mild	N	N	Mild	08JUN2021	6
	[redacted]	1	06APR2021	Oral temperature (°C)	36.17	35.83	36.11		36.17	35.89	35.67		
				Fatigue	N	N	N		Mod	Mod	N	11APR2021	2
				Headache	N	N	N		N	Mod	N	11APR2021	1
				Chills	N	N	N		N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N		N	N	N		
				Diarrhea	N	N	N		N	N	N		
				New or worsened muscle pain	N	N	N		N	N	N		
				New or worsened joint pain	N	N	N		N	N	N		
		2	27APR2021	Oral temperature (°C)	36.17			36.56	36.56	36.06			
				Fatigue	N			N	N	N			
				Headache	N			N	N	N			
				Chills	N			N	N	N			
				Vomiting	N			N	N	N			
				Diarrhea	N			N	N	N			
				New or worsened muscle pain	N			N	N	N			
				New or worsened joint pain	N			N	N	N			
	[redacted]	1	06MAY2021	Oral temperature (°C)	36.44	36.44	36.5	36.5	36.28	36.39	36.56		
				Fatigue	Mod	Mod	Mod	Mod	Mod	Mod	Mod	25MAY2021	20

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	N	N	Mod	Mod	Mod	N	11MAY2021	3
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	Mild	N	N	N	N	Mild	N	11MAY2021	6
				New or worsened muscle pain	N	N	N	N	N	N	Mod	25MAY2021	14
				New or worsened joint pain	N	N	N	N	N	Mod	Mod	12MAY2021	2
		2	25MAY2021	Oral temperature (°C)			36.44	36.39	36.56	36.44	36.28		
				Fatigue			Mod	Mod	Mod	Mod	Mod	17JUN2021	22
				Headache			N	N	N	N	Mod	04JUN2021	5
				Chills			N	N	N	N	N		
				Vomiting			N	N	N	N	N		
				Diarrhea			N	N	N	N	N		
				New or worsened muscle pain			N	N	N	Mod	N	30MAY2021	1
				New or worsened joint pain			N	Mod	N	Mod	Mod	17JUN2021	21

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	[redacted]	1	05APR2021	Oral temperature (°C)	37.11	36.94	37.11	36.94	36.94	37.06	36.94		
				Fatigue	Mod	N	N	Mild	N	Mod	Mild	26APR2021	22
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	26APR2021	Oral temperature (°C)	36.89	36.28	36.56	36.22	36.78	36.22	36.67		
				Fatigue	Mild	Mild	Mod	Mod	Mild	Mild	Mod	24MAY2021	29
				Headache	N	N	N	N	N	N	Mild	10MAY2021	9
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	Mild	N	N	N	29APR2021	1

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	Mild	N	N	N	N	28APR2021	1
	[redacted]	1	15JUN2021	Oral temperature (°C)	36.44	36.83	36.44	36.56	36.67	36.5	36.28		
				Fatigue	Mod	Mod	Mod	Mod	Mild	Mod	Mod	08JUL2021	24
				Headache	N	Mild	Mod	N	N	N	Mild	21JUN2021	6
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	Mod	N	N	N	N	17JUN2021	1
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	08JUL2021	Oral temperature (°C)						36.67	36.56		
				Fatigue						Mod	Mod	21JUL2021	9
				Headache						N	N		
				Chills						N	N		
				Vomiting						N	N		
				Diarrhea						Mild	N	13JUL2021	1

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain						N	N		
				New or worsened joint pain						N	N		
	[redacted]	1	22MAR2021	Oral temperature (°C)	36.39	36.39	36.94	36.33	36.28	36.56	36.78		
				Fatigue	N	Mild	N	N	N	N	N	23MAR2021	1
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	12APR2021	Oral temperature (°C)	36.61	36.56	36.72	36.44	36.44	36.39	36.78		
				Fatigue	N	Mild	Mild	Mod	N	N	N	15APR2021	3
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	Mild	N	N	16APR2021	1
	[redacted]	1	22MAR2021	Oral temperature (°C)	36.61	36.39		36.33	36.33	36.39	36.33		
				Fatigue	N	N		N	N	N	N		
				Headache	N	N		N	N	N	N		
				Chills	N	N		N	N	N	N		
				Vomiting	N	N		N	N	N	N		
				Diarrhea	N	N		N	N	N	N		
				New or worsened muscle pain	N	N		N	N	N	N		
				New or worsened joint pain	N	N		N	N	N	N		
		2	12APR2021	Oral temperature (°C)	36.83	36.44	36.44	36.56		36.44	36.44		
				Fatigue	N	N	N	N		N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	N	N	N		N	N		
				Chills	N	N	N	N		N	N		
				Vomiting	N	N	N	N		N	N		
				Diarrhea	N	N	N	N		N	N		
				New or worsened muscle pain	N	N	N	N		N	N		
				New or worsened joint pain	N	N	N	N		N	N		
	[redacted]	1	24MAR2021	Oral temperature (°C)	37.22	36.83	36.94	36.94	37	36.94	37		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
		2	12APR2021	Oral temperature (°C)	37.44	37	36.67	36.56	36.56		36.94		
				Fatigue	Mild	Mild	N	N	N		N	13APR2021	2
				Headache	N	N	N	N	N		N		
				Chills	N	N	N	N	N		N		
				Vomiting	N	N	N	N	N		N		
				Diarrhea	N	N	N	N	N		N		
				New or worsened muscle pain	N	N	N	N	N		N		
				New or worsened joint pain	N	N	N	N	N		N		
	[redacted]	1	23APR2021	Oral temperature (°C)	37.39	36.5	36.5	36.83	36.72	37	37.78		
				Fatigue	N	Mild	N	N	Mod	N	Mod	30APR2021	7
				Headache	N	Mild	Mild	Mild	N	N	N	26APR2021	3
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	12MAY2021	Oral temperature (°C)	36.78	35.83	37.28	36.72	36.5	36.17	37.22		
				Fatigue	N	Mod	N	N	N	N	N	13MAY2021	1
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	04MAY2021	Oral temperature (°C)	36.33	35.94	36.61	37.11	36.78	36.61	37.17		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	24MAY2021	Oral temperature (°C)	36.44	36.5	36.44	36.17	36.17	36.56	37.17		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	11MAY2021	Oral temperature (°C)	35.56	35.56	35.56	35.56	35.56	35.56	35.56		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	08JUN2021	Oral temperature (°C)	35.56	35.56	35.56	35.56	35.56	35.56			
				Fatigue	N	N	N	N	N	N			
				Headache	N	N	N	N	N	N			
				Chills	N	N	N	N	N	N			
				Vomiting	N	N	N	N	N	N			
				Diarrhea	N	N	N	N	N	N			
				New or worsened muscle pain	N	N	N	N	N	N			
				New or worsened joint pain	N	N	N	N	N	N			
	[redacted]	1	02JUN2021	Oral temperature (°C)	36.28	36.83	36.44	36.61	37	36.33	36.67		
				Fatigue	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	23JUN2021	Oral temperature (°C)	36.67	36.83	36.67		36.78	36.61	36.67		
				Fatigue	N	Mild	Mild		Mild	Mild	Mild	02JUL2021	9
				Headache	N	N	N		N	N	N		
				Chills	N	N	N		N	N	N		
				Vomiting	N	N	N		N	N	N		
				Diarrhea	N	N	N		N	N	N		
				New or worsened muscle pain	N	N	N		N	N	N		
				New or worsened joint pain	N	N	N		N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	[redacted]	1	04JUN2021	Oral temperature (°C)	36.22	36.67	36.83	36.67	36.89	36.89	36.67		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	23JUN2021	Oral temperature (°C)	36.67	36.56	36.67	36.61	36.67	36.72	36.44		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	16MAR2021	Oral temperature (°C)	36.17	35.78	36.83	36.17	35.56	36.17	36.72		
				Fatigue	Mild	Mild	Mild	Mild	N	Mild	N	21MAR2021	6
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	06APR2021	Oral temperature (°C)		36.5		35.33	36.61	36.72	34.44		
				Fatigue		N		Mild	Mild	Mild	Mild	14APR2021	6
				Headache		N		N	N	N	N		
				Chills		N		N	N	N	N		
				Vomiting		N		N	N	N	N		
				Diarrhea		N		N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain		N		N	N	N	N		
				New or worsened joint pain		N		N	N	N	N		
	[redacted]	1	20APR2021	Oral temperature (°C)	36.06	35.72	35.94	35.94	35.94	36.11	35.94		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	11MAY2021	Oral temperature (°C)	36.11	36.5	36.39	36.61	36.44		36.56		
				Fatigue	N	N	N	N	N		N		
				Headache	N	N	N	N	N		N		
				Chills	N	N	N	N	N		N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N	N		N		
				Diarrhea	N	N	N	N	N		N		
				New or worsened muscle pain	N	N	N	N	N		N		
				New or worsened joint pain	N	N	N	N	N		N		
	[redacted]	1	08APR2021	Oral temperature (°C)	34.83	35.61	35.61	33	36.5	35.61	34.89		
				Fatigue	Mild	Mild	Mild	Mild	Mod	Mod	Mild	15APR2021	8
				Headache	N	N	N	N	N	N	Mild	15APR2021	2
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	Mild	N	13APR2021	1
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	28APR2021	Oral temperature (°C)		36.5	35.89	36.39	36.11	36.72	35.89		
				Fatigue		Mild	Mild	N	N	N	Mild	05MAY2021	7

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache		N	N	N	N	N	N		
				Chills		N	N	N	N	N	N		
				Vomiting		Mild	N	N	N	N	N	29APR2021	1
				Diarrhea		N	N	N	N	N	N		
				New or worsened muscle pain		N	N	N	N	N	N		
				New or worsened joint pain		N	N	N	N	N	N		
	[redacted]	1	26APR2021	Oral temperature (°C)	36.28	35.72	35.28	36.94	36.28	36.83	36.94		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	Mild	Mild	N	N	N	Mod	03MAY2021	7
				Chills	N	N	N	N	N	N	N		
				Vomiting	Mod	N	N	N	N	N	N	26APR2021	1
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
		2	17MAY2021	Oral temperature (°C)	36.78	36.22	37	36.83	36.94	36.83	36.78		
				Fatigue	N	N	N	N	N	N	N		
				Headache	Mild	N	N	N	N	N	Mod	24MAY2021	8
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	Mild	N	N	N	N	19MAY2021	1
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	27APR2021	Oral temperature (°C)	36.67	36.28	36.67	36.5	36.11	36.61	36.61		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	17MAY2021	Oral temperature (°C)	36.61	36.61	36.61	36.5	36.39	36.28	36.56		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	18MAY2021	Oral temperature (°C)	36.5	36.5	36.78	36.72	36.56	36.5	36.61		
				Fatigue	N	N	N	N	N	N	N		
				Headache	Mild	Mild	N	N	N	N	N	19MAY2021	2
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	09JUN2021	Oral temperature (°C)		36.5	36.61	36.56	36.5	36.56	36.5		
				Fatigue		N	N	N	N	N	N		
				Headache		N	N	N	N	N	N		
				Chills		N	N	N	N	N	N		
				Vomiting		N	N	N	N	N	N		
				Diarrhea		N	N	N	N	N	N		
				New or worsened muscle pain		N	N	N	N	N	N		
				New or worsened joint pain		N	N	N	N	N	N		
	[redacted]	1	22FEB2021	Oral temperature (°C)	36.94	36.94	36.89	36.94	36.83	36.67	37.11		
				Fatigue	Mild	Mild	Mild	Mild	Mild	Mild	N	27FEB2021	6
				Headache	Mild	N	N	N	N	N	N	22FEB2021	1
				Chills	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	Mild	01MAR2021	2
				New or worsened joint pain	N	N	N	N	N	N	Mild	01MAR2021	2
		2	16MAR2021	Oral temperature (°C)	37.11	36.89	36.89	36.89	36.61	37.22	36.78		
				Fatigue	Mild	Mild	Mild	Mild	Mild	Mild	N	21MAR2021	6
				Headache	N	Mild	Mild	N	N	N	N	18MAR2021	2
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	Mild	Mild	N	N	N	19MAR2021	2
				New or worsened joint pain	N	N	Mild	N	N	N	N	18MAR2021	1
	[redacted]	1	02MAR2021	Oral temperature (°C)	36.61	37.17	36.5	36.22	36.22	36.39			
				Fatigue	N	Mod	N	N	N	N		03MAR2021	1

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	N	N	Mild	N	N		05MAR2021	1
				Chills	N	N	N	N	N	N			
				Vomiting	N	Mod	N	Mild	N	N		05MAR2021	3
				Diarrhea	N	N	N	N	N	N			
				New or worsened muscle pain	N	Mod	N	N	N	N		03MAR2021	1
				New or worsened joint pain	N	N	N	N	N	N			
	[redacted]	1	04MAR2021	Oral temperature (°C)	36.78	37.06	36.56		36.94	36.94	36.56		
				Fatigue	N	N	N		N	N	N		
				Headache	N	Mild	N		N	N	N	05MAR2021	1
				Chills	N	N	N		N	N	N		
				Vomiting	N	N	N		N	N	N		
				Diarrhea	N	N	N		N	N	N		
				New or worsened muscle pain	N	N	N		N	N	N		
				New or worsened joint pain	N	N	N		N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
		2	25MAR2021	Oral temperature (°C)	36.94	36.44	36.78	36.83		36.56	36.56		
				Fatigue	N	N	N	N		N	N		
				Headache	N	N	N	N		N	N		
				Chills	N	N	N	N		N	N		
				Vomiting	N	N	N	N		N	N		
				Diarrhea	N	N	N	N		N	N		
				New or worsened muscle pain	N	N	N	N		N	N		
				New or worsened joint pain	N	N	N	N		N	N		
	[redacted]	1	09MAR2021	Oral temperature (°C)	36.5	36.61	36.61	36.72	36.61	36.56	36.61		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	30MAR2021	Oral temperature (°C)		36.67	36.61	36.67	36.56	36.67	36.61		
				Fatigue		N	N	N	N	N	N		
				Headache		N	N	N	N	N	N		
				Chills		N	N	N	N	N	N		
				Vomiting		N	N	N	N	N	N		
				Diarrhea		N	N	N	N	N	N		
				New or worsened muscle pain		N	N	N	N	N	N		
				New or worsened joint pain		N	N	N	N	N	N		
	[redacted]	1	17MAR2021	Oral temperature (°C)	36.44	36.5	36.39	36.5	36.5	36.5	36.56		
				Fatigue	N	N	Mod	N	N	N	N	19MAR2021	1
				Headache	N	N	Mod	N	N	N	N	19MAR2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	05APR2021	Oral temperature (°C)	36.56	36.56	36.56	36.56	36.56	36.56	36.56		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	19MAR2021	Oral temperature (°C)	36.17	36.56	36.39	36.72	36.83	36.56	36.28		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	Mod	N	N	N	N	N	20MAR2021	1
				New or worsened joint pain	N	Mod	N	N	N	N	N	20MAR2021	1
		2	09APR2021	Oral temperature (°C)	36.22	36.44	36.78	36.28	36.33	36.56	36.44		
				Fatigue	N	Mild	N	N	N	Mild	N	14APR2021	5
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	21APR2021	Oral temperature (°C)	36.78	37.28	36.72	36.78	36.67	37.22	36.83		
				Fatigue	Mod	N	N	Mild	N	N	Mild	11MAY2021	21

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	Mild	Mild	N	N	N	N	N	22APR2021	2
				Chills	N	N	N	N	N	N	N		
				Vomiting	Mod	N	N	N	N	N	Mild	11MAY2021	21
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	Mild	N	N	N	N	N	22APR2021	1
				New or worsened joint pain	N	N	Mild	N	N	N	N	23APR2021	1
		2	11MAY2021	Oral temperature (°C)	37.67	37.17	36.89	37.44	36.89	37.22	37.11		
				Fatigue	Mild	Mild	N	Mild	N	Mod	N	16MAY2021	6
				Headache	Mod	Mild	Mild	Mild	Mild	Mod	Mod	18MAY2021	8
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	Mod	Mild	Mild	Mild	N	N	15MAY2021	4
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	[redacted]	1	31MAR2021	Oral temperature (°C)	36.39	36.72	36.67	36.83	36.78	36.78	37.11		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	20APR2021	Oral temperature (°C)	36.94	36.78	36.94	36.94	36.61	36.67	36.78		
				Fatigue	Mild	Mild	Mild	Mild	Mild	Mild	Mild	27APR2021	8
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	02APR2021	Oral temperature (°C)	36.56	36.56	36.39	36.61	36.44	36.56	36.44		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	22APR2021	Oral temperature (°C)	35.94	36.56	36.39	36.89	36.78	36.72	36.56		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	08APR2021	Oral temperature (°C)	36.44	36.11	36.67	36.44	36.11	36.67	36.5		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	Mild	N	13APR2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	29APR2021	Oral temperature (°C)	36.78	36.44	36.11	37.06	36.56	36.72	36.11		
				Fatigue	Mild	Mild	N	Mod	N	N	N	02MAY2021	4
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	13APR2021	Oral temperature (°C)	36.56	37.06	37.06	37.17	37.06	37	37.06		
				Fatigue	N	Mild	N	N	N	N	N	14APR2021	1
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	Mod	N	N	N	16APR2021	1
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	04MAY2021	Oral temperature (°C)	37.06	37.06	37.06	37.06	37.06	37.06	37.06		
				Fatigue	Mild	Mod	N	N	N	N	N	05MAY2021	2

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	Mild	N	N	N	N	N	05MAY2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	12MAY2021	Oral temperature (°C)	36.67	36.28	36.17	36.67	36.56	36.78	36.33		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	Mod	N	N	N	N	N	13MAY2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
		2	01JUN2021	Oral temperature (°C)	36.78	36.5	36.72	36.61	37.17	36.61	37.11		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	Mild	N	N	N	N	N	02JUN2021	1
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	03MAY2021	Oral temperature (°C)	36.94	36.39	36.61	36.61	37.33	37	36.67		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	24MAY2021	Oral temperature (°C)	36.56	36.67	36.67	37	37.11	36.83	35.56		
				Fatigue	N	Mod	Mod	Mod	Mod	Mod	Mod	31MAY2021	7
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	13MAY2021	Oral temperature (°C)		36.56	36.67	36.67	36.56	36.67			
				Fatigue		N	Mild	Mild	N	Mild		18MAY2021	4
				Headache		N	N	Mild	N	N		16MAY2021	1
				Chills		N	N	N	N	N			
				Vomiting		N	N	N	N	N			
				Diarrhea		N	N	N	N	N			

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain		N	N	N	N	N			
				New or worsened joint pain		N	N	N	N	N			
		2	01JUN2021	Oral temperature (°C)	37.06	37.06	36.94	36.83	37.06	36.94	37		
				Fatigue	Mild	N	Mild	N	N	N	N	03JUN2021	3
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	18MAY2021	Oral temperature (°C)	36.17	35.94	35.94	36.5	36.44	35.94	37.06		
				Fatigue	N	N	Mild	N	N	N	N	20MAY2021	1
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	18MAY2021	Oral temperature (°C)	37.06	37	37	37	37	37.06	37.06		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	09JUN2021	Oral temperature (°C)	37.11	37.06	37.06	37.17	37.17	37.17	37.17		
				Fatigue	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	26MAY2021	Oral temperature (°C)	37.06	36.44	36.44	36.94	36.44	36.83	36.56		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
		2	16JUN2021	Oral temperature (°C)	36.89	36.44	37.06	37	36.28	37	37.11		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	26MAY2021	Oral temperature (°C)	37.17	35.72	35.78	36.89		36.94	37.06		
				Fatigue	N	N	N	N		N	N		
				Headache	N	N	N	N		N	N		
				Chills	N	N	N	N		N	N		
				Vomiting	N	N	N	N		N	N		
				Diarrhea	N	N	N	N		N	N		
				New or worsened muscle pain	N	N	N	N		N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N	N		N	N		
		2	16JUN2021	Oral temperature (°C)	36.11	36.83	35.83	36.56	36.83	36.61	36.28		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	02JUN2021	Oral temperature (°C)		36.56	37	37.11	37	37	37.17		
				Fatigue		N	N	N	N	N	N		
				Headache		N	N	N	N	N	N		
				Chills		N	N	N	N	N	N		
				Vomiting		N	N	N	N	N	N		
				Diarrhea		N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain		N	N	N	N	N	N		
				New or worsened joint pain		N	N	N	N	N	N		
	[redacted]	1	08JUN2021	Oral temperature (°C)	36	36.17	36.67	36.67	36.17	36.17	36.22		
				Fatigue	N	N	N	N	N	N	N		
				Headache	Mild	N	N	N	N	N	N	08JUN2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	28JUN2021	Oral temperature (°C)	36.72	36.72	36.22	36.28	36.28	36.17	36.28		
				Fatigue	Mild	N	N	N	N	N	N	28JUN2021	1
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	18JUN2021	Oral temperature (°C)	37.06		36.61	36.61	37.11		37.06		
				Fatigue	N		N	N	N		N		
				Headache	N		N	N	N		N		
				Chills	N		N	N	N		N		
				Vomiting	N		N	N	N		N		
				Diarrhea	N		N	N	N		N		
				New or worsened muscle pain	N		N	N	N		N		
				New or worsened joint pain	N		N	N	N		N		
		2	09JUL2021	Oral temperature (°C)	36.89	37.06	37.06	37.06	37	36.89	36.56		
				Fatigue	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	18JUN2021	Oral temperature (°C)		37.11	37.67	37.11	37.72	35.56	37.78		
				Fatigue		N	N	N	N	N	N		
				Headache		N	N	N	N	N	N		
				Chills		N	N	N	N	N	N		
				Vomiting		N	N	N	N	N	N		
				Diarrhea		N	N	N	N	N	N		
				New or worsened muscle pain		N	N	N	N	N	N		
				New or worsened joint pain		N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
		2	07JUL2021	Oral temperature (°C)			37.22		37.22	37.22			
				Fatigue			N		N	N			
				Headache			N		N	N			
				Chills			N		N	N			
				Vomiting			N		N	N			
				Diarrhea			N		N	N			
				New or worsened muscle pain			N		N	N			
				New or worsened joint pain			N		N	N			
	[redacted]	1	13JUL2021	Oral temperature (°C)		37.06	36.94	37.06		36.44	36.56		
				Fatigue		N	N	N		N	N		
				Headache		N	N	N		N	N		
				Chills		N	N	N		N	N		
				Vomiting		N	N	N		N	N		
				Diarrhea		N	N	N		N	N		
				New or worsened muscle pain		N	N	N		N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain		N	N	N		N	N		
		2	03AUG2021	Oral temperature (°C)	37.06	36.39	36.56						
				Fatigue	N	N	N						
				Headache	N	N	N						
				Chills	N	N	N						
				Vomiting	N	N	N						
				Diarrhea	N	N	N						
				New or worsened muscle pain	N	N	N						
				New or worsened joint pain	N	N	N						
	[redacted]	1	13JUL2021	Oral temperature (°C)	35.78	36.56	36	36.56	36.89	37.17	36.33		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	20JUL2021	Oral temperature (°C)	37.11	36.61	37.06	37	37.06	36.28	36.56		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	09AUG2021	Oral temperature (°C)	36.56		37.06	36.56	36.5	37.06	36.78		
				Fatigue	N		N	N	N	N	N		
				Headache	N		N	N	N	N	N		
				Chills	N		N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N		N	N	N	N	N		
				Diarrhea	N		N	N	N	N	N		
				New or worsened muscle pain	N		N	N	N	N	N		
				New or worsened joint pain	N		N	N	N	N	N		
	[redacted]	1	27JUL2021	Oral temperature (°C)	36	36.33	36.44	36.5	36.5	36.44	36.44		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	17AUG2021	Oral temperature (°C)	36.5	36.5	36.5	36.56		36.56	36.44		
				Fatigue	N	N	N	N		N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	N	N	N		N	N		
				Chills	N	N	N	N		N	N		
				Vomiting	N	N	N	N		N	N		
				Diarrhea	N	N	N	N		N	N		
				New or worsened muscle pain	N	N	N	N		N	N		
				New or worsened joint pain	N	N	N	N		N	N		
	[redacted]	1	22SEP2021	Oral temperature (°C)	37	36.56	37	36.56	36.56	36.56	36.56		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	[redacted]	1	22SEP2021	Oral temperature (°C)	36.56	36.5	36.83	37.11	36.5	36.5	36.39		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	11OCT2021	Oral temperature (°C)			36.83	36.5	36.39	36.94	36.5		
				Fatigue			N	N	N	N	N		
				Headache			N	N	N	N	N		
				Chills			N	N	N	N	N		
				Vomiting			N	N	N	N	N		
				Diarrhea			N	N	N	N	N		
				New or worsened muscle pain			N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain			N	N	N	N	N		
	[redacted]	1	13OCT2021	Oral temperature (°C)	36.56	35.94	36.28	36.17	35.61		36.33		
				Fatigue	N	N	N	N	N		N		
				Headache	N	N	N	N	N		N		
				Chills	N	N	N	N	N		N		
				Vomiting	N	N	N	N	N		N		
				Diarrhea	N	N	N	N	N		N		
				New or worsened muscle pain	N	N	N	N	N		N		
				New or worsened joint pain	N	N	N	N	N		N		
		2	02NOV2021	Oral temperature (°C)	36.22	36.17			36.78	36.22	36.22		
				Fatigue	N	N			N	N	N		
				Headache	N	N			N	N	N		
				Chills	N	N			N	N	N		
				Vomiting	N	N			N	N	N		
				Diarrhea	N	N			N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N			N	N	N		
				New or worsened joint pain	N	N			N	N	N		
	[redacted]	1	17MAR2021	Oral temperature (°C)	36.22	36.5	36.33	36.39	36.39	36.17			
				Fatigue	Mild	Mild	Mild	Mild	Mild	Mild		06APR2021	21
				Headache	N	Mild	N	N	N	N		18MAR2021	1
				Chills	N	N	N	N	N	N			
				Vomiting	N	N	N	N	N	N			
				Diarrhea	N	N	N	N	N	N			
				New or worsened muscle pain	N	Mild	N	N	N	N		18MAR2021	1
				New or worsened joint pain	N	N	N	N	N	N			
		2	06APR2021	Oral temperature (°C)	37.11	37.28	36.28	36.78	36.44	36.78	36.83		
				Fatigue	Mild	Mild	Mild	Mild	Mild	Mod	Mild	13APR2021	8
				Headache	N	N	Mild	N	N	N	N	08APR2021	1
				Chills	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	Mild	N	Mild	Mild	Mild	13APR2021	6
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	21APR2021	Oral temperature (°C)	36.56	36.61		36.06	36.72	36.39	36.72		
				Fatigue	N	Mod		Mild	Mod	Mild	N	26APR2021	5
				Headache	Mild	N		N	N	N	N	21APR2021	1
				Chills	N	N		N	N	N	N		
				Vomiting	N	N		N	N	N	N		
				Diarrhea	N	N		N	N	N	N		
				New or worsened muscle pain	N	N		N	N	N	N		
				New or worsened joint pain	N	N		N	N	N	N		
		2	12MAY2021	Oral temperature (°C)	36.44	36.44	36.61	36.06		37	36.78		
				Fatigue	N	N	N	N		N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	N	N	N		N	N		
				Chills	N	N	N	N		N	N		
				Vomiting	N	N	N	N		N	N		
				Diarrhea	N	N	N	N		N	N		
				New or worsened muscle pain	N	N	N	N		N	N		
				New or worsened joint pain	N	N	N	N		N	N		
	[redacted]	1	11MAY2021	Oral temperature (°C)	36.33	36.72	36.89	36.5	36.33	36.78	36.5		
				Fatigue	Mild	Mild	Mild	N	N	N	N	13MAY2021	3
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
		2	01JUN2021	Oral temperature (°C)				36.61	36.78	36.94	36.61		
				Fatigue				N	N	N	N		
				Headache				N	N	N	N		
				Chills				N	N	N	N		
				Vomiting				N	N	N	N		
				Diarrhea				N	N	N	N		
				New or worsened muscle pain				N	N	N	N		
				New or worsened joint pain				N	N	N	N		
	[redacted]	1	12MAY2021	Oral temperature (°C)	36.11	36.67	36.78	37.22	36.44	36.89	36.28		
				Fatigue	Mod	N	N	N	N	Mild	N	17MAY2021	6
				Headache	N	N	N	Mild	N	Mild	N	17MAY2021	3
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	02JUN2021	Oral temperature (°C)			36.78	36.33	36.33	36.67	36.28		
				Fatigue			N	N	N	N	N		
				Headache			N	N	N	N	N		
				Chills			N	N	N	N	N		
				Vomiting			N	N	N	N	N		
				Diarrhea			N	N	N	N	N		
				New or worsened muscle pain			N	N	N	N	N		
				New or worsened joint pain			N	N	N	N	N		
	[redacted]	1	21MAY2021	Oral temperature (°C)	36.78	36.33	36.83	36.39		36.28	36.67		
				Fatigue	N	N	N	N		N	N		
				Headache	N	N	N	N		N	N		
				Chills	N	N	N	N		N	N		
				Vomiting	N	N	N	N		N	N		
				Diarrhea	N	N	N	N		N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	N	N		N	N		
				New or worsened joint pain	N	N	N	N		N	N		
		2	11JUN2021	Oral temperature (°C)	36.78				36.67	36.39	36.72		
				Fatigue	N				N	N	N		
				Headache	N				N	N	N		
				Chills	N				N	N	N		
				Vomiting	N				N	N	N		
				Diarrhea	N				N	N	N		
				New or worsened muscle pain	N				N	N	N		
				New or worsened joint pain	N				N	N	N		
	[redacted]	1	30SEP2021	Oral temperature (°C)	35.8	36.2		36	36.3	35.9	36.2		
				Fatigue	N	N		N	N	N	N		
				Headache	N	N		N	N	N	N		
				Chills	N	N		N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N		N	N	N	N		
				Diarrhea	N	N		N	N	N	N		
				New or worsened muscle pain	N	N		N	N	N	N		
				New or worsened joint pain	N	N		N	N	N	N		
		2	14OCT2021	Oral temperature (°C)	36.2	36.2				35.6	36		
				Fatigue	N	N				N	N		
				Headache	N	N				N	N		
				Chills	N	N				N	N		
				Vomiting	N	N				N	N		
				Diarrhea	N	N				N	N		
				New or worsened muscle pain	N	N				N	N		
				New or worsened joint pain	N	N				N	N		
	[redacted]	1	15OCT2021	Oral temperature (°C)	36.1	36.4	36.4	36.6	36.5	36.2	36.5		
				Fatigue	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	05NOV2021	Oral temperature (°C)	36.3	36.5	36.1	36.4	36.4	36.1	36		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	[redacted]	1	22OCT2021	Oral temperature (°C)	36.1	36.6	35.9	36.2	36.2	36.5	36.4		
				Fatigue	Mod	N	N	N	N	N	N	22OCT2021	1
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	12NOV2021	Oral temperature (°C)	36.2		36.5	37	36.6	36.1			
				Fatigue	N		N	N	N	N			
				Headache	N		N	N	N	N			
				Chills	N		N	N	N	N			
				Vomiting	N		N	N	N	N			
				Diarrhea	N		N	N	N	N			
				New or worsened muscle pain	N		N	N	N	N			

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N		N	N	N	N			
	[redacted]	1	13MAY2021	Oral temperature (°C)	36.78	36.06	37	36.78	37.06	37.06	36.67		
				Fatigue	N	Mod	Mild	Mod	Mod	Mod	N	18MAY2021	5
				Headache	N	N	N	Mild	N	Mod	N	18MAY2021	3
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	Mild	Mod	N	Mild	03JUN2021	19
				New or worsened joint pain	N	N	Mod	Mild	N	N	Mild	03JUN2021	20
		2	03JUN2021	Oral temperature (°C)	36.67	36.61	36.78	37.17	36.67	36.83	36.78		
				Fatigue	N	Mild	Mod	N	N	N	Mild	14JUN2021	11
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	Mild	Mild	N	N	N	N	05JUN2021	2
	[redacted]	1	24JUN2021	Oral temperature (°C)	36.72	36.5	36.78	36.89	36.78	36.89	36.61		
				Fatigue	Mild	Mild	Mild	Mild	Mild	Mild	Mild	15JUL2021	22
				Headache	N	N	N	N	Mild	N	N	28JUN2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	15JUL2021	Oral temperature (°C)	36.78	36.61	36.33	36.5	37.06	36.44	36.67		
				Fatigue	Mild	Mild	Mild	N	Mild	Mod	Mild	27AUG2021	44
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	20AUG2021	Oral temperature (°C)	35.9	35.1	35.6	36.5	36.8	36.3	36.1		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	Mild	N	N	N	N	N	21AUG2021	1
				New or worsened muscle pain	N	N	N	N	Mild	N	N	24AUG2021	1
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	11SEP2021	Oral temperature (°C)	36.2	36.5	36.2	36.7	36.3	36.1	36.4		
				Fatigue	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	Mild	Mild	N	N	15SEP2021	2
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	25AUG2021	Oral temperature (°C)	36	36.2	36.1	35.8	34.9	36.6	36.7		
				Fatigue	N	N	Mild	N	N	N	N	27AUG2021	1
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	Mild	N	N	N	N	27AUG2021	1
				New or worsened joint pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
		2	13SEP2021	Oral temperature (°C)	35.9	36.4	36.2	36.4	35	35.8	35.1		
				Fatigue	Mild	N	N	N	Mild	N	N	17SEP2021	5
				Headache	N	N	N	N	Mild	Mild	N	18SEP2021	2
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	28SEP2021	Oral temperature (°C)		33.3		36.4		37.4			
				Fatigue		Mod		N		N		29SEP2021	1
				Headache		N		N		N			
				Chills		N		N		N			
				Vomiting		N		N		N			
				Diarrhea		N		N		N			
				New or worsened muscle pain		N		N		N			

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain		N		N		N			
		2	18OCT2021	Oral temperature (°C)		35.3	34.6	35.7	36.2				
				Fatigue		Mod	N	N	N			19OCT2021	1
				Headache		N	N	N	N				
				Chills		N	N	N	N				
				Vomiting		N	N	N	N				
				Diarrhea		N	N	N	N				
				New or worsened muscle pain		N	N	N	N				
				New or worsened joint pain		N	N	N	N				
	[redacted]	1	11OCT2021	Oral temperature (°C)	37.6	36.6	36.7	36.8	36.4	36.6	36		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	03NOV2021	Oral temperature (°C)	35.8	35.9	36.3	36	36.6	36.4	36.6		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted] †	1	12OCT2021	Oral temperature (°C)	35.8	36.6	36.5	36.2	36.9	36.8	35.7		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	02NOV2021	Oral temperature (°C)	35.4	35.5	36.3	36.4	36.6	37.2	36.9		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	22OCT2021	Oral temperature (°C)	32.2	36.2	36.1	36.5	36	36.3	36.3		
				Fatigue	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	10NOV2021	Oral temperature (°C)	36.3	36.2	35.9	36.3	36.2	36.3	36.2		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	[redacted]	1	20MAY2021	Oral temperature (°C)	36.56	36.44	36.44	36.44	36.72	36.17	36.78		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	Mild	N	N	24MAY2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	13AUG2021	Oral temperature (°C)		32.2	33.1	33.4	32.3	32.4	33.4		
				Fatigue		N	Mod	N	N	N	N	15AUG2021	1
				Headache		Mild	N	N	N	N	N	14AUG2021	1
				Chills		N	N	N	N	N	N		
				Vomiting		N	N	N	N	N	N		
				Diarrhea		N	N	N	N	N	N		
				New or worsened muscle pain		N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain		N	N	N	N	N	N		
		2	01SEP2021	Oral temperature (°C)	33.5	32.5	34.2	35.2	34.2	32.5	33.6		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	Mild	N	N	N	N	N	02SEP2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	03SEP2021	Oral temperature (°C)	36.2	38.2	38.3	36.2	36.3		38.2	09SEP2021	6
				Fatigue	N	N	N	N	N		N		
				Headache	N	N	N	N	N		N		
				Chills	N	N	N	N	N		N		
				Vomiting	N	N	N	N	N		N		
				Diarrhea	N	N	N	N	N		N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	N	N	N		N		
				New or worsened joint pain	N	N	N	N	N		N		
		2	23SEP2021	Oral temperature (°C)	36.4	36.2	36.3	37.3	36.3	36.3	36.4		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	08SEP2021	Oral temperature (°C)	33	36.7	35.8	36.3	36.9	36.7	35.3		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	28SEP2021	Oral temperature (°C)	36.7	36.9	36.1	36.9	36.4	36.3	36		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	07SEP2021	Oral temperature (°C)	36	36.5	36.2	36.4	36	36.4	36.8		
				Fatigue	N	N	N	N	N	Mild	Mod	18SEP2021	7

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	N	N	N	Mild	Mild	Mod	15SEP2021	5
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	28SEP2021	Oral temperature (°C)	36.2	37	36.4	36.5	36.4	36.7	37.4		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	[redacted]	1	14SEP2021	Oral temperature (°C)	36.4	36.3	35.6	35.8	36.5	36.2	36.6		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	05OCT2021	Oral temperature (°C)	36	36	36.1	36	35.7		35.6		
				Fatigue	Mild	N	N	N	N		N	05OCT2021	1
				Headache	N	N	N	N	N		N		
				Chills	N	N	N	N	N		N		
				Vomiting	N	N	N	N	N		N		
				Diarrhea	N	N	N	N	N		N		
				New or worsened muscle pain	Mild	N	N	N	N		N	05OCT2021	1

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	Mild	N	N	N	N		N	05OCT2021	1
	[redacted]	1	20SEP2021	Oral temperature (°C)	34.6	36.5	36.2	36.4	35.4	37.2	36.6		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	Mild	N	N	N	N	22SEP2021	1
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	28OCT2021	Oral temperature (°C)		35.4	35.6		36.4		36.3		
				Fatigue		N	N		N		N		
				Headache		N	Mild		N		N	30OCT2021	1
				Chills		N	N		N		N		
				Vomiting		N	N		N		N		
				Diarrhea		N	N		N		N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain		N	N		N		N		
				New or worsened joint pain		N	N		N		N		
	[redacted]	1	23SEP2021	Oral temperature (°C)	36.2	36.2	36.1	36.1	36.1		35.8		
				Fatigue	N	Mild	Mild	N	N		N	25SEP2021	2
				Headache	N	N	N	N	N		N		
				Chills	N	N	N	N	N		N		
				Vomiting	N	N	Mild	N	N		N	25SEP2021	1
				Diarrhea	N	N	N	N	N		N		
				New or worsened muscle pain	N	N	N	N	N		N		
				New or worsened joint pain	N	N	N	N	N		N		
		2	14OCT2021	Oral temperature (°C)	36.4	35.9		36.4	36.2	36.2	36.4		
				Fatigue	N	N		N	N	N	N		
				Headache	N	N		N	N	N	N		
				Chills	N	N		N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N		N	N	N	N		
				Diarrhea	N	N		N	N	N	N		
				New or worsened muscle pain	N	N		N	N	N	N		
				New or worsened joint pain	N	N		N	N	N	N		
	[redacted]	1	05OCT2021	Oral temperature (°C)	35.6	36.1	35.8	36.5			36.3		
				Fatigue	N	N	N	N			N		
				Headache	N	N	N	N			N		
				Chills	N	N	N	N			N		
				Vomiting	N	N	N	N			N		
				Diarrhea	N	N	N	N			N		
				New or worsened muscle pain	N	N	N	N			N		
				New or worsened joint pain	N	N	N	N			N		
		2	26OCT2021	Oral temperature (°C)	35.2	36.5		35.4	35.6	35.6	35.5		
				Fatigue	N	N		N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	N		N	N	N	N		
				Chills	N	N		N	N	N	N		
				Vomiting	N	N		N	N	N	N		
				Diarrhea	N	N		N	N	N	N		
				New or worsened muscle pain	N	N		N	N	N	N		
				New or worsened joint pain	N	N		N	N	N	N		
	[redacted]	1	07OCT2021	Oral temperature (°C)		35.3		35.4	34.6	36.3	35.8		
				Fatigue		N		N	N	N	N		
				Headache		N		N	N	N	N		
				Chills		N		N	N	N	N		
				Vomiting		N		N	N	N	N		
				Diarrhea		N		N	N	N	N		
				New or worsened muscle pain		N		N	N	N	N		
				New or worsened joint pain		N		N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	[redacted]	1	14OCT2021	Oral temperature (°C)	36.6	36.1	35.6	35.9	36.4	36.2	35.9		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	02NOV2021	Oral temperature (°C)	35.8	35.8	36.1		36.2		35.2		
				Fatigue	N	N	N		N		N		
				Headache	N	N	N		N		N		
				Chills	N	N	N		N		N		
				Vomiting	N	N	N		N		N		
				Diarrhea	N	N	N		N		N		
				New or worsened muscle pain	N	N	N		N		N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N		N		N		
	[redacted]	1	19OCT2021	Oral temperature (°C)	35.3	36.1	35.8	35.2	36.9	36.2	35.8		
				Fatigue	Mild	Mild	N	Mild	Mod	N	N	23OCT2021	5
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	09NOV2021	Oral temperature (°C)	36.2	35.2	35.2	36.2	35.2	36.2	35.2		
				Fatigue	Mild	N	N	N	N	N	N	09NOV2021	1
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]†	1	23OCT2021	Oral temperature (°C)	36.2	36.2	36.6	35.4	36.5	35.7	35.8		
				Fatigue	N	N	Mild	N	N	N	N	25OCT2021	1
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	Mild	N	28OCT2021	1
				New or worsened joint pain	N	Mild	N	Mild	Mild	N	N	27OCT2021	4
		2	15NOV2021	Oral temperature (°C)						35.2			
				Fatigue						Mild		28NOV2021	9
				Headache						N			
				Chills						N			

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting						N			
				Diarrhea						N			
				New or worsened muscle pain						Mod		28NOV2021	9
				New or worsened joint pain						N			
	[redacted]	1	23OCT2021	Oral temperature (°C)	35.6	36.1	36.2	36.2	36.3	36.3	36.1		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	15NOV2021	Oral temperature (°C)	36.3	36.4	36.1	36	36.2	36.1	36		
				Fatigue	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	28OCT2021	Oral temperature (°C)	35.2	35.4	35.2	32.5	32.7	32.3	35.8		
				Fatigue	N	N	N	N	N	N	N		
				Headache	Mild	N	N	N	N	N	N	28OCT2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
		2	17NOV2021	Oral temperature (°C)		34.5	35.6	35.8	35.9	36.1	35.9		
				Fatigue		N	N	N	N	N	N		
				Headache		N	N	N	N	N	N		
				Chills		N	N	N	N	N	N		
				Vomiting		N	N	N	N	N	N		
				Diarrhea		N	N	N	N	N	N		
				New or worsened muscle pain		N	N	N	N	N	N		
				New or worsened joint pain		N	N	N	N	N	N		
	[redacted]	1	05NOV2021	Oral temperature (°C)		35.9	36.6	36.7	36.5	36.6	36.3		
				Fatigue		N	N	N	N	N	N		
				Headache		N	N	N	N	N	N		
				Chills		N	N	N	N	N	N		
				Vomiting		N	N	N	N	N	N		
				Diarrhea		N	N	N	N	N	N		
				New or worsened muscle pain		N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain		N	N	N	N	N	N		
		2	25NOV2021	Oral temperature (°C)		36.5	36.6	36.8	36.6	36.5	36.5		
				Fatigue		N	N	N	N	N	N		
				Headache		N	N	N	N	N	N		
				Chills		N	N	N	N	N	N		
				Vomiting		N	N	N	N	N	N		
				Diarrhea		N	N	N	N	N	N		
				New or worsened muscle pain		N	N	N	N	N	N		
				New or worsened joint pain		N	N	N	N	N	N		
	[redacted]	1	02JUN2021	Oral temperature (°C)	35.9	35.7	35.9	36	35.8	36.2	35.7		
				Fatigue	N	Mild	Mild	Mild	N	N	N	05JUN2021	3
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	Mild	N	N	N	N	04JUN2021	1
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	23JUN2021	Oral temperature (°C)	35.9	35.9	35.9	35.8	36.2	35.9	36.2		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	07JUN2021	Oral temperature (°C)	36.2	35.8	36.7	36.2	36.5	36.1	35.6		
				Fatigue	N	Mild	Mild	N	N	N	N	09JUN2021	2
				Headache	Mild	N	N	N	N	N	N	07JUN2021	1
				Chills	N	Mild	N	N	N	N	N	08JUN2021	1

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	Mild	N	N	N	N	N	08JUN2021	1
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	28JUN2021	Oral temperature (°C)	35.9	36.4	35.9	36.7	36.2	36.4	36.1		
				Fatigue	Mild	Mod	N	Mod	N	Mild	N	03JUL2021	6
				Headache	N	N	N	Mild	N	Mild	N	03JUL2021	3
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	14JUL2021	Oral temperature (°C)	36.3	35.7	35.9	35.7	35.7	35.6	35.7		
				Fatigue	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	Mild	N	19JUL2021	1
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	05AUG2021	Oral temperature (°C)	36.1	35.8	35.7	36.3	36.1	35.9	36.1		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	[redacted]	1	14JUL2021	Oral temperature (°C)	35.6	35.6	35.6	35.7	35.5	35.6	35.9		
				Fatigue	N	Mod	N	N	N	N	N	15JUL2021	1
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	02AUG2021	Oral temperature (°C)	36.1	35.9	35.9		35.9	36.1	35.6		
				Fatigue	N	N	N		N	N	N		
				Headache	N	N	N		N	N	N		
				Chills	N	N	N		N	N	N		
				Vomiting	N	N	N		N	N	N		
				Diarrhea	N	N	N		N	N	N		
				New or worsened muscle pain	N	N	N		N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N		N	N	N		
	[redacted]	1	26JUL2021	Oral temperature (°C)	35.6	35.8	36	35.8	35.6	35.8	35.8		
				Fatigue	Mild	Mild	Mild	Mild	Mild	Mild	Mild	16AUG2021	22
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	16AUG2021	Oral temperature (°C)	36.5	35.7		35.6	36.2	35.8	35.9		
				Fatigue	Mild	Mild		Mild	Mod	Mild	Mild	22AUG2021	7
				Headache	N	N		N	N	N	N		
				Chills	N	N		N	N	N	N		
				Vomiting	N	N		N	N	N	N		
				Diarrhea	N	N		N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N		N	Mild	Mild	N	21AUG2021	2
				New or worsened joint pain	N	N		N	N	N	N		
	[redacted]†	1	11AUG2021	Oral temperature (°C)	34.6	35.8	35.6	35.6	35.9	36.2	37		
				Fatigue	N	Mild	Mild	N	N	N	N	13AUG2021	2
				Headache	Mild	Mod	Mod	Mild	Mild	Mod	Mod	20AUG2021	10
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	Mild	Mild	N	Mild	N		
				New or worsened muscle pain	N	Mild	N	N	N	N	N	12AUG2021	1
				New or worsened joint pain	N	Mild	Mild	N	N	N	N	13AUG2021	2
		2	15SEP2021	Oral temperature (°C)	35.7	35.4	36		36.1		36.2		
				Fatigue	N	N	N		N		N		
				Headache	N	N	N		N		N		
				Chills	N	N	N		N		N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N		N		N		
				Diarrhea	N	N	N		N		N		
				New or worsened muscle pain	N	N	N		N		N		
				New or worsened joint pain	N	N	N		N		N		
	[redacted]†	1	13AUG2021	Oral temperature (°C)	35.2	35.6	34.6	34.9	34.8	35	35.2		
				Fatigue	N	N	N	N	N	Mild	N	18AUG2021	1
				Headache	N	N	N	Mild	N	N	N	16AUG2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	20AUG2021	Oral temperature (°C)	36.8	36.2	36.6	36.4	36.2	36.6	36.4		
				Fatigue	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	Mild	Mild	N	N	N	N	22AUG2021	2
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	Mild	N	N	24AUG2021	1
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	08SEP2021	Oral temperature (°C)	36.2	36.4	36.8	36.4	36.4	36.6	36.7		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	[redacted]	1	27AUG2021	Oral temperature (°C)	36.2	35.7	36.2	36.4	35.8	36.4	34.3		
				Fatigue	Mild	Mild	Mild	N	Mild	N	Mild	03SEP2021	8
				Headache	Mild	N	Mild	N	Mod	N	N	31AUG2021	5
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	23SEP2021	Oral temperature (°C)	35.8	35		36.1	36.8	35.9	34		
				Fatigue	Mild	N		N	N	N	N	23SEP2021	1
				Headache	N	N		N	N	N	N		
				Chills	N	N		N	N	N	N		
				Vomiting	N	N		N	N	N	N		
				Diarrhea	N	N		N	N	N	N		
				New or worsened muscle pain	N	N		N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N		N	N	N	N		
	[redacted]	1	27AUG2021	Oral temperature (°C)	36.5	35.4	36.7	37.2	36.7	36	36.6		
				Fatigue	N	N	Mild	N	N	Mild	N	01SEP2021	4
				Headache	N	N	Mild	Mod	N	N	N	30AUG2021	2
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	Mild	Mild	N	N	N	N	29AUG2021	2
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	16SEP2021	Oral temperature (°C)		36.1	35.2	36.2	35	36.2	35.5		
				Fatigue		Mild	N	N	N	N	N	17SEP2021	1
				Headache		Mod	N	N	N	N	N	17SEP2021	1
				Chills		N	N	N	N	N	N		
				Vomiting		N	N	N	N	N	N		
				Diarrhea		Mild	Mild	N	N	N	N	18SEP2021	2

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain		N	N	N	N	N	N		
				New or worsened joint pain		N	N	N	N	N	N		
	[redacted]	1	01SEP2021	Oral temperature (°C)	39.2	36.3	36.6	36.2	36.3	36.4	36.6	01SEP2021	1
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	01OCT2021	Oral temperature (°C)	36.6	36.2	36	36.3	36.4	36.4	36.5		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]†	1	07SEP2021	Oral temperature (°C)	36.2	36.1	36.1	37	37.2	36	36.9		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	Mild	N	N	N	N	N	08SEP2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	28SEP2021	Oral temperature (°C)	36.2		37.2	36.7	36		36.2		
				Fatigue	Mod		N	N	N		N	28SEP2021	1

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N		N	N	N		N		
				Chills	N		N	N	N		N		
				Vomiting	N		N	N	N		N		
				Diarrhea	N		N	N	N		N		
				New or worsened muscle pain	N		N	N	N		N		
				New or worsened joint pain	N		N	N	N		N		
	[redacted]†	1	07SEP2021	Oral temperature (°C)	34.8	35.9	36.2	35.6	35.7	34.8	35.6		
				Fatigue	Mod	N	N	N	N	N	N	07SEP2021	1
				Headache	Mod	Mod	N	N	N	N	N	08SEP2021	2
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	Mild	N	N	N	N	N	08SEP2021	1

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
		2	30SEP2021	Oral temperature (°C)	36.2	35.4	35.4	35.2	35.9	34.4	36.5		
				Fatigue	Mild	Mild	N	N	N	N	N	01OCT2021	2
				Headache	Mild	N	N	N	Mod	N	N	04OCT2021	5
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	Sev	09OCT2021	4
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]†	1	21SEP2021	Oral temperature (°C)	36.5	36.4	36.2	36.7	36.6	36.9	36.1		
				Fatigue	N	Mod	N	N	N	N	N	22SEP2021	1
				Headache	N	Mild	N	N	N	N	N	22SEP2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	Mild	Mild	N	N	Mild	Mild	29SEP2021	8
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	12OCT2021	Oral temperature (°C)	36.7	36.5	36.3	36	36.2	36.2	36.3		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	Mild	N	N	N	N	N	13OCT2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	Mild	N	N	N	Mild	20OCT2021	7
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]†	1	29SEP2021	Oral temperature (°C)						35.5	36.7		
				Fatigue						N	N		
				Headache						N	N		
				Chills						N	N		
				Vomiting						N	N		
				Diarrhea						Mild	N	04OCT2021	1

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain						N	N		
				New or worsened joint pain						Mild	Mod	12OCT2021	9
		2	20OCT2021	Oral temperature (°C)	36.5	36.4			36.5	35.6	36.4		
				Fatigue	Mod	Mod			N	Mod	N	25OCT2021	6
				Headache	Mild	Mild			N	N	N	21OCT2021	2
				Chills	N	N			N	N	N		
				Vomiting	N	N			N	N	N		
				Diarrhea	N	Mild			N	N	N	21OCT2021	1
				New or worsened muscle pain	N	N			N	N	N		
				New or worsened joint pain	N	N			N	N	N		
	[redacted]†	1	20SEP2021	Oral temperature (°C)	37.2	37	37.2	36.9	36.4	37			
				Fatigue	Mod	Sev	Sev	Sev	Sev	Sev		11OCT2021	22
				Headache	N	N	N	N	Mod	N		24SEP2021	1
				Chills	N	N	N	N	N	N			

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N	N	N			
				Diarrhea	N	N	N	N	N	N			
				New or worsened muscle pain	Mod	N	N	Mod	N	N		23SEP2021	4
				New or worsened joint pain	N	N	N	N	N	N			
		2	11OCT2021	Oral temperature (°C)	36.2		36.3		36.9	38	35.9	16OCT2021	1
				Fatigue	Mod		Sev		Sev	Sev	Sev	20OCT2021	10
				Headache	Mod		N		N	Mod	N	16OCT2021	6
				Chills	N		N		N	N	N		
				Vomiting	N		N		N	N	N		
				Diarrhea	N		N		N	N	N		
				New or worsened muscle pain	N		N		N	N	Sev	20OCT2021	4
				New or worsened joint pain	N		N		N	N	Sev	20OCT2021	4
	[redacted]	1	20SEP2021	Oral temperature (°C)	36.3	35.7	36.1	35.5	35.8	36.3			
				Fatigue	Mod	N	N	N	N	N		20SEP2021	1

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	Mod	N	Mild	N	N	N		22SEP2021	3
				Chills	N	N	N	N	N	N			
				Vomiting	N	N	N	N	N	N			
				Diarrhea	N	N	N	N	N	N			
				New or worsened muscle pain	N	N	N	N	N	N			
				New or worsened joint pain	N	N	N	N	N	N			
		2	14OCT2021	Oral temperature (°C)	36.1	35.7				35.8	35.7		
				Fatigue	N	N				N	N		
				Headache	N	N				N	N		
				Chills	N	N				N	N		
				Vomiting	N	N				N	N		
				Diarrhea	N	N				N	N		
				New or worsened muscle pain	N	N				N	N		
				New or worsened joint pain	N	N				N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	[redacted]†	1	15OCT2021	Oral temperature (°C)		35.7	35.7	37	35.2	35.5	36.2		
				Fatigue		N	N	N	N	N	N		
				Headache		N	N	N	N	N	N		
				Chills		N	N	Mild	Mod	N	N	19OCT2021	2
				Vomiting		N	N	N	N	N	N		
				Diarrhea		N	N	N	N	N	N		
				New or worsened muscle pain		N	N	N	N	N	N		
				New or worsened joint pain		N	N	N	N	N	N		
		2	04NOV2021	Oral temperature (°C)	35.2	36.4	35.3	36.3	35.1	35.4	35.7		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	Mild	N	N	Mild	N	N	08NOV2021	4
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	14OCT2021	Oral temperature (°C)	36.5	36.6	36.2		37.2		36		
				Fatigue	Mild	N	Mild		N		Mild	24OCT2021	11
				Headache	Mild	Mod	Mod		Sev		N	18OCT2021	5
				Chills	N	N	N		N		N		
				Vomiting	N	N	Mod		Mod		N	18OCT2021	3
				Diarrhea	N	Mild	N		N		N	15OCT2021	1
				New or worsened muscle pain	N	N	N		N		N		
				New or worsened joint pain	N	N	N		N		N		
	[redacted]	1	09JUN2021	Oral temperature (°C)	35.9	36	35.7		35.7	36.1			
				Fatigue	Mod	Mod	Sev		N	Mod		15JUN2021	7
				Headache	N	N	N		N	N			
				Chills	N	N	N		N	N			
				Vomiting	N	N	Mild		Mild	Mild		15JUN2021	5
				Diarrhea	N	N	N		N	N			

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	N		N	N			
				New or worsened joint pain	N	N	N		N	N			
		2	30JUN2021	Oral temperature (°C)	36.2	36.2	36.2	36.4		36.3	36.2		
				Fatigue	N	N	N	N		N	N		
				Headache	N	N	N	N		N	N		
				Chills	N	N	N	N		N	N		
				Vomiting	N	N	N	N		N	N		
				Diarrhea	N	N	N	N		N	N		
				New or worsened muscle pain	N	N	N	N		N	N		
				New or worsened joint pain	N	N	N	N		N	N		
	[redacted]	1	09JUN2021	Oral temperature (°C)	36.4	36.2	36.6	36.8		35.4	36.7		
				Fatigue	N	N	N	N		N	N		
				Headache	N	N	N	N		N	N		
				Chills	N	N	N	N		N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N		N	N		
				Diarrhea	N	N	N	N		N	N		
				New or worsened muscle pain	N	N	N	N		N	N		
				New or worsened joint pain	N	N	N	N		N	N		
		2	30JUN2021	Oral temperature (°C)	36.5	36.3	36.6	36.1	36.2	36.5	36.3		
				Fatigue	Mild	Mild	N	N	N	N	N	01JUL2021	2
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	05AUG2021	Oral temperature (°C)	35.9	36	36.2	36.5	36.2	36	35.8		
				Fatigue	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	26AUG2021	Oral temperature (°C)	36.5	35.9	35.9	36.3	36.2	36	36		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	[redacted]	1	26AUG2021	Oral temperature (°C)	36.2	36.4	36.3	36.4	36.9	36.5	36.6		
				Fatigue	Mild	Mod	Mod	Mod	Mod	Mod	Mod	14SEP2021	20
				Headache	N	N	N	N	N	N	Mod	02SEP2021	2
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	14SEP2021	Oral temperature (°C)			36	36.4	36.3	36.2	36.4		
				Fatigue			Mod	Mild	Mod	Mod	Mod	22SEP2021	7
				Headache	Mod	Mod	Mod	N	N	N	N	16SEP2021	3
				Chills			N	N	N	N	N		
				Vomiting			N	N	N	N	N		
				Diarrhea			N	N	N	N	N		
				New or worsened muscle pain			N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain			N	N	N	N	N		
	[redacted]	1	19MAY2021	Oral temperature (°C)	36.67	36.61		37.22	36.67	35.56			
				Fatigue	N	N		Mild	Mild	N		23MAY2021	2
				Headache	Mild	N		Mild	Mild	Mild		24MAY2021	6
				Chills	N	N		N	N	Mild		24MAY2021	1
				Vomiting	N	N		N	N	N			
				Diarrhea	N	Mild		Mild	Mild	Mild		24MAY2021	5
				New or worsened muscle pain	N	N		Mod	Mild	N		23MAY2021	2
				New or worsened joint pain	N	N		N	N	N			
	[redacted]	1	23JUL2021	Oral temperature (°C)	34.22	34.11	34.11	34.22					
				Fatigue	N	N	N	N					
				Headache	N	N	N	N					
				Chills	N	N	N	N					
				Vomiting	N	N	N	N					
				Diarrhea	N	N	N	N					

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	N	N					
				New or worsened joint pain	N	N	N	N					
		2	13AUG2021	Oral temperature (°C)				36.78	35.67	35.11	33.39		
				Fatigue				N	N	N	N		
				Headache				N	N	N	N		
				Chills				N	N	N	N		
				Vomiting				N	N	N	N		
				Diarrhea				N	N	N	N		
				New or worsened muscle pain				N	N	N	N		
				New or worsened joint pain				N	N	N	N		
	[redacted]	1	17AUG2021	Oral temperature (°C)	37.11	35.94	35.72	37.06	36.11	35.94	35.67		
				Fatigue	N	N	N	Mild	Mild	Mild	Mild	25AUG2021	6
				Headache	Mild	Mild	N	Mod	Mild	Mild	Mild	24AUG2021	8
				Chills	N	N	N	Mild	N	N	Mild	23AUG2021	4

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	Mild	N	N	N	20AUG2021	1
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	13SEP2021	Oral temperature (°C)		37.06	36.28		36.44	36.06	36.44		
				Fatigue		Mild	Mild		Mild	N	N	17SEP2021	4
				Headache		Mild	Mild		Mild	N	N	17SEP2021	4
				Chills		N	N		N	N	N		
				Vomiting		N	N		N	N	N		
				Diarrhea		N	N		N	N	N		
				New or worsened muscle pain		Mild	N		N	N	N	14SEP2021	1
				New or worsened joint pain		N	N		N	N	N		
	[redacted]	1	20OCT2021	Oral temperature (°C)	36.28	36.94	36.94	36.61	36.67	36.83	36.72		
				Fatigue	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	05OCT2021	Oral temperature (°C)	36.11	34.89	36.5	35.56		36.11	36.72		
				Fatigue	N	Mild	N	N		N	N	06OCT2021	1
				Headache	N	N	N	N		N	Mod	12OCT2021	2
				Chills	N	N	N	N		N	N		
				Vomiting	N	N	N	N		N	N		
				Diarrhea	N	N	N	N		N	N		
				New or worsened muscle pain	N	N	N	N		N	N		
				New or worsened joint pain	N	N	N	N		N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
		2	26OCT2021	Oral temperature (°C)	36.11	36.83	36.72	36.89	36.28	36.39	36.11		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	Mod	N	N	N	29OCT2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	26MAY2021	Oral temperature (°C)	36.6	35.7	36.2	36.6	38	37.2	36.7	30MAY2021	1
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	Mod	Mod	01JUN2021	2
				Chills	N	N	N	N	N	Mild	N	31MAY2021	1
				Vomiting	N	N	N	N	Mild	N	N	30MAY2021	1
				Diarrhea	N	N	N	Mild	N	N	N	29MAY2021	1
				New or worsened muscle pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	12JUL2021	Oral temperature (°C)	36.2	36.5	35.2	36.4		36.2	36.4		
				Fatigue	N	N	N	N		N	N		
				Headache	N	N	N	N		N	N		
				Chills	N	N	N	N		N	N		
				Vomiting	N	N	N	N		N	N		
				Diarrhea	N	N	N	N		N	N		
				New or worsened muscle pain	N	N	N	N		N	N		
				New or worsened joint pain	N	N	N	N		N	N		
	[redacted]	1	27MAY2021	Oral temperature (°C)	35.6				35.6	35.6			
				Fatigue	N				N	N			
				Headache	N				N	N			
				Chills	N				N	N			
				Vomiting	N				N	N			
				Diarrhea	N				N	N			

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N				N	N			
				New or worsened joint pain	N				N	N			
		2	18JUN2021	Oral temperature (°C)	35.6	35.6		35.6	35.6	35.6			
				Fatigue	N	N		N	N	N			
				Headache	N	N		N	N	N			
				Chills	N	N		N	N	N			
				Vomiting	N	N		N	N	N			
				Diarrhea	N	N		N	N	N			
				New or worsened muscle pain	N	N		N	N	N			
				New or worsened joint pain	N	N		N	N	N			
	[redacted]	1	27MAY2021	Oral temperature (°C)	36.6	35.6	36	35.8	35.9	36.1	36		
				Fatigue	N	Mild	Mild	Mod	Mild	Mild	N	01JUN2021	5
				Headache	N	N	N	Mild	Mild	N	N	31MAY2021	2
				Chills	N	N	N	Mild	Mild	N	N	31MAY2021	2

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	Mild	N	N	N	30MAY2021	1
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	28MAY2021	Oral temperature (°C)	36.8	36.7	36	36.7	36.7	35.7	36.7		
				Fatigue	N	N	Mild	N	N	N	N	30MAY2021	1
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	Mild	N	N	Mild	04JUN2021	5
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	18JUN2021	Oral temperature (°C)	36	36.7	36.6	36	36.7	36.8	36.6		
				Fatigue	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	Mod	N	N	N	N	N	N	18JUN2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	Mild	N	N	N	N	N	19JUN2021	1
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	28MAY2021	Oral temperature (°C)	36.5	36.7	36.5		36.2				
				Fatigue	N	N	N		N				
				Headache	Mild	N	N		N			28MAY2021	1
				Chills	N	N	N		N				
				Vomiting	N	N	N		N				
				Diarrhea	N	N	N		N				
				New or worsened muscle pain	N	N	N		N				
				New or worsened joint pain	N	N	N		N				

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
		2	18JUN2021	Oral temperature (°C)	36.2			36.2	36.3	36.2	36.5		
				Fatigue	N			N	N	N	N		
				Headache	N			N	N	N	N		
				Chills	N			N	N	N	N		
				Vomiting	N			N	N	N	N		
				Diarrhea	N			N	N	N	N		
				New or worsened muscle pain	N			N	N	N	N		
				New or worsened joint pain	N			N	N	N	N		
	[redacted]	1	28MAY2021	Oral temperature (°C)	35.2	36.2	36.2	36.3	36.2	36.2			
				Fatigue	N	N	Mild	N	N	N		30MAY2021	1
				Headache	N	N	N	N	N	N			
				Chills	N	N	N	N	N	N			
				Vomiting	N	N	N	N	N	N			
				Diarrhea	N	N	N	N	N	N			
				New or worsened muscle pain	N	N	N	N	N	N			

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N	N	N	N			
		2	18JUN2021	Oral temperature (°C)		36.2	36.5	36.2	36.3		36.2		
				Fatigue		N	N	N	N		N		
				Headache		N	Mild	N	N		N	20JUN2021	1
				Chills		N	Mild	N	N		N	20JUN2021	1
				Vomiting		N	Mild	N	N		N	20JUN2021	1
				Diarrhea		N	N	N	N		N		
				New or worsened muscle pain		N	N	N	N		N		
				New or worsened joint pain		N	N	N	N		N		
	[redacted]	1	01JUN2021	Oral temperature (°C)	36.9	36.5		36.9	36.9	36.9	36.9		
				Fatigue	N	N		N	N	N	N		
				Headache	N	N		N	N	N	N		
				Chills	N	N		N	N	N	N		
				Vomiting	N	N		N	N	N	N		
				Diarrhea	N	N		N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N		N	N	N	N		
				New or worsened joint pain	N	N		N	N	N	N		
		2	22JUN2021	Oral temperature (°C)	35.5	35.6	34.6	35.4		35.8	35.7		
				Fatigue	N	N	N	N		N	N		
				Headache	N	N	N	N		N	N		
				Chills	N	N	N	N		N	N		
				Vomiting	N	N	N	N		N	N		
				Diarrhea	N	N	N	N		N	N		
				New or worsened muscle pain	N	N	N	N		N	N		
				New or worsened joint pain	N	N	N	N		N	N		
	[redacted]	1	01JUN2021	Oral temperature (°C)	35.4	35.1	35.4	35.4	35.5	35.9	35.3		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	22JUN2021	Oral temperature (°C)	35.7	35.1	35.8	35.6	35.5	35.4	35.5		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	Mod	N	N	N	N	24JUN2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	07JUN2021	Oral temperature (°C)	43.3	35.3	32.5	34.2	35.2	34.2			
				Fatigue	N	N	N	N	N	N			

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	N	N	N	N	N			
				Chills	N	N	N	N	N	N			
				Vomiting	N	N	N	N	N	N			
				Diarrhea	N	N	N	N	N	N			
				New or worsened muscle pain	N	N	N	N	N	N			
				New or worsened joint pain	N	N	N	N	N	N			
		2	28JUN2021	Oral temperature (°C)	35.2	35.3	34.8				34.2		
				Fatigue	N	N	N				N		
				Headache	N	N	Mild				N	30JUN2021	1
				Chills	N	N	N				N		
				Vomiting	N	N	N				N		
				Diarrhea	N	N	N				N		
				New or worsened muscle pain	N	N	N				N		
				New or worsened joint pain	N	N	N				N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	[redacted]	1	07JUN2021	Oral temperature (°C)	36.2	36.1	36.2	36.3	36.3	36.2	36.2		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	Mod	N	N	Mod	N	N	11JUN2021	4
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	28JUN2021	Oral temperature (°C)	36.1	36.2	36.4	36.2		36.2			
				Fatigue	N	N	N	N		N			
				Headache	N	Mod	N	N		Mod		04JUL2021	6
				Chills	N	N	N	N		N			
				Vomiting	N	N	N	N		N			
				Diarrhea	N	N	N	N		N			
				New or worsened muscle pain	N	N	N	N		N			

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N	N		N			
	[redacted]	1	08JUN2021	Oral temperature (°C)	36	36	36	36	36		36		
				Fatigue	N	N	N	N	N		N		
				Headache	N	N	Mild	Mod	N		N	11JUN2021	2
				Chills	N	N	N	N	N		N		
				Vomiting	N	Mild	N	N	Mild		N	12JUN2021	4
				Diarrhea	N	N	N	N	N		N		
				New or worsened muscle pain	N	N	N	N	N		N		
				New or worsened joint pain	N	N	N	N	N		N		
		2	30JUN2021	Oral temperature (°C)	36	36		36	36	36	36		
				Fatigue	N	N		N	N	N	N		
				Headache	N	N		N	Mild	N	N	04JUL2021	1
				Chills	N	N		N	N	N	N		
				Vomiting	N	N		N	N	N	N		
				Diarrhea	N	N		N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N		N	N	N	N		
				New or worsened joint pain	N	N		N	N	N	N		
	[redacted]	1	09JUN2021	Oral temperature (°C)	36.3	36.3	36.2	36.3					
				Fatigue	Mod	N	N	N				09JUN2021	1
				Headache	N	N	N	N					
				Chills	N	N	N	N					
				Vomiting	N	N	N	N					
				Diarrhea	N	N	N	N					
				New or worsened muscle pain	N	N	N	N					
				New or worsened joint pain	N	N	N	N					
	[redacted]	1	10JUN2021	Oral temperature (°C)				33.1	34.2	37.2	32.3		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	Mild	N	N	N	13JUN2021	1
				Chills	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	01JUL2021	Oral temperature (°C)	36.3	37.4	38.2	36.3	36.2	36.2		03JUL2021	1
				Fatigue	N	N	N	N	N	N			
				Headache	N	N	N	N	N	N			
				Chills	N	N	N	N	N	N			
				Vomiting	N	N	N	N	N	N			
				Diarrhea	N	N	N	N	N	N			
				New or worsened muscle pain	N	N	N	N	N	N			
				New or worsened joint pain	N	N	N	N	N	N			
	[redacted]	1	25AUG2021	Oral temperature (°C)	36.4	36.5	36.5		36.6	36.6	36.6		
				Fatigue	N	Mild	N		N	N	N	26AUG2021	1

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	Mild	Mild		N	N	N	27AUG2021	2
				Chills	N	N	N		N	N	N		
				Vomiting	N	N	N		Mild	N	N	29AUG2021	1
				Diarrhea	N	N	N		Mild	N	N	29AUG2021	1
				New or worsened muscle pain	Mod	N	Mild		N	N	N	27AUG2021	3
				New or worsened joint pain	N	N	N		N	N	N		
		2	15SEP2021	Oral temperature (°C)	36.7	35.9	36.6	36.6	35.8	36.7	36.6		
				Fatigue	Mod	N	N	Mild	N	N	N	18SEP2021	4
				Headache	N	N	N	Mild	Mild	Mild	N	20SEP2021	3
				Chills	N	N	N	N	N	N	N		
				Vomiting	Mod	N	N	Mod	N	Mild	N	20SEP2021	6
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	Mild	Mod	N	20SEP2021	2
				New or worsened joint pain	N	N	N	N	N	Mild	N	20SEP2021	1

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	[redacted]	1	15JUN2021	Oral temperature (°C)	37.4	36.7	36.7	36.4	36.1	36.4	35.9		
				Fatigue	N	Mild	N	Mild	Mild	N	N	19JUN2021	4
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	08JUL2021	Oral temperature (°C)	36.4	36.4	36.2	36.4	36.2	36.4	36.5		
				Fatigue	Mod	N	N	N	N	N	Mild	04AUG2021	28
				Headache	Mild	N	N	N	N	N	N	08JUL2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	Mild	N	N	N	N	N	N	08JUL2021	1
				New or worsened muscle pain	Mild	N	N	N	N	N	N	08JUL2021	1

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	17JUN2021	Oral temperature (°C)	36.8	36	35.9	36.5	36.4	36.6	36.3		
				Fatigue	N	Mild	N	Mod	Mod	N	Mild	08JUL2021	21
				Headache	N	Mild	N	N	N	N	N	18JUN2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	08JUL2021	Oral temperature (°C)	36.7	36.7	36.5	36.5	36.7	36.7			
				Fatigue	Mild	N	Mild	Mod	Mild	Mild		03AUG2021	27
				Headache	Mild	N	N	Mild	N	N		11JUL2021	4
				Chills	N	N	N	N	N	N			
				Vomiting	N	N	N	N	N	N			
				Diarrhea	N	N	N	Mod	Mild	N		12JUL2021	2

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	N	N	N	N			
				New or worsened joint pain	N	N	N	N	N	N			
	[redacted]	1	10JUN2021	Oral temperature (°C)	36.5	36.4	36.3	36.4	36.3	36.5	37.2		
				Fatigue	N	N	N	Mod	N	N	Mod	05JUL2021	23
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	10JUN2021	Oral temperature (°C)	36.1	35.5	35.8	35.8	35.7	36.2	35.7		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	12JUL2021	Oral temperature (°C)	36	35.9	35.9	35.9	35.9	36.2	35.9		
				Fatigue	N	N	N	N	Mod	Mod	Mild	01AUG2021	17
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	Mild	N	17JUL2021	1
				Diarrhea	N	N	N	N	N	Mild	N	17JUL2021	1
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	02AUG2021	Oral temperature (°C)	35.9	35.9	36	36	35.9		36		
				Fatigue	Mild	Mild	Mild	Mild	Mild	Mild	Mild	09SEP2021	39

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	N	N	N	N		N		
				Chills	N	N	N	N	N		N		
				Vomiting	N	N	N	N	N		N		
				Diarrhea	N	N	N	N	N		N		
				New or worsened muscle pain	N	N	N	N	N		N		
				New or worsened joint pain	N	N	N	N	N		N		
	[redacted]	1	12JUL2021	Oral temperature (°C)	35.7	35.7	36	35.9	36.1	35.9	36.2		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
		2	02AUG2021	Oral temperature (°C)	36.2	36.1	36.5	35.8	35.8	36.1	35.9		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	22JUN2021	Oral temperature (°C)	35.7	36.4	36.3	35.8	36	36.1	35.9		
				Fatigue	N	Mod	Mod	N	N	N	Mod	13JUL2021	21
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	13JUL2021	Oral temperature (°C)	35.8	36.8	36.1	36.4	35.7	35.6	36.7		
				Fatigue	Mild	Mod	Mod	N	N	N	N	15JUL2021	3
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	Mod	Mild	N	N	N	N	15JUL2021	2
				New or worsened joint pain	N	Mod	N	N	N	N	N	14JUL2021	1
	[redacted]	1	24AUG2021	Oral temperature (°C)	36.1	36.8	36.7	37.2	36.9	36.9	35.9		
				Fatigue	N	N	N	Mod	Mild	Mod	Mod	03SEP2021	8
				Headache	Mild	Mild	N	N	Mild	Mod	Mod	03SEP2021	11
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	Mild	N	29AUG2021	1
		2	17SEP2021	Oral temperature (°C)	36.3	36.5	36.4	36.5	36.4	36.3	36.5		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	Mild	23SEP2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	04JUN2021	Oral temperature (°C)	36.1	36.3	36.9	36.5	36.7	36.4	36.2		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	23JUN2021	Oral temperature (°C)	36.5	36.6	36.4	36.8	36.5	36.7	36.7		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	04JUN2021	Oral temperature (°C)	35.2	35.9	35.9		35.9	36.1	35.9		
				Fatigue	N	Mild	N		N	Mild	N	09JUN2021	5

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	N	N		N	N	N		
				Chills	N	N	N		N	N	N		
				Vomiting	N	N	N		N	N	N		
				Diarrhea	N	N	N		N	N	N		
				New or worsened muscle pain	N	N	N		N	N	N		
				New or worsened joint pain	N	N	N		N	N	N		
		2	23JUN2021	Oral temperature (°C)	35.5	35.5	35.5	35.5	35.5	35.5	35.9		
				Fatigue	Mild	N	N	N	N	N	Mild	05JUL2021	13
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	[redacted]	1	21JUN2021	Oral temperature (°C)	35.7	35.9	36.4	36	35.6		36.2		
				Fatigue	N	Mild	N	Mild	N		N	24JUN2021	3
				Headache	N	Mild	N	N	N		N	22JUN2021	1
				Chills	N	N	N	N	N		N		
				Vomiting	N	N	N	N	N		N		
				Diarrhea	N	N	N	N	N		N		
				New or worsened muscle pain	N	N	N	N	N		N		
				New or worsened joint pain	N	N	N	N	N		N		
		2	12JUL2021	Oral temperature (°C)		35.9	35.5	35.6	35.7	35.7	35.8		
				Fatigue		Mod	Mild	Mod	N	N	N	15JUL2021	3
				Headache		Mild	N	N	Mod	N	N	16JUL2021	4
				Chills		N	N	N	N	N	N		
				Vomiting		N	N	N	N	N	N		
				Diarrhea		N	N	N	N	N	N		
				New or worsened muscle pain		N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain		N	N	N	N	N	N		
	[redacted]	1	11JUN2021	Oral temperature (°C)	36	36.6	36.2	36.4	36.5	36.5	36.3		
				Fatigue	N	N	N	Mild	N	N	N	14JUN2021	1
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	Mild	Mild	N	Mild	N	N	N	14JUN2021	4
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	02JUL2021	Oral temperature (°C)	35.7	35.7	36	36	36	36.5	36		
				Fatigue	N	N	N	N	N	N	N		
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	07JUN2021	Oral temperature (°C)	36.6	36.9	36.4	36.5	36.5	36.4	36.6		
				Fatigue	N	N	Mild	N	N	N	N	09JUN2021	1
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	28JUN2021	Oral temperature (°C)		36.7		36.4	36.4	36.5	36.6		
				Fatigue		Mild		N	Mild	Mild	N	03JUL2021	5
				Headache		N		N	N	N	N		
				Chills		N		N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting		N		N	N	N	N		
				Diarrhea		N		N	N	N	N		
				New or worsened muscle pain		N		N	N	N	N		
				New or worsened joint pain		N		N	N	N	N		
	[redacted]	1	04JUN2021	Oral temperature (°C)	36.5		36.8		36.5	36.3			
				Fatigue	N		N		N	N			
				Headache	N		N		N	N			
				Chills	N		N		N	N			
				Vomiting	N		N		N	N			
				Diarrhea	N		N		N	N			
				New or worsened muscle pain	N		N		N	N			
				New or worsened joint pain	N		N		N	N			
		2	23JUN2021	Oral temperature (°C)			36.2	36.5	36.6		36.2		
				Fatigue			N	N	N		N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache			N	N	N		N		
				Chills			N	N	N		N		
				Vomiting			N	N	N		N		
				Diarrhea			N	N	N		N		
				New or worsened muscle pain			N	N	N		N		
				New or worsened joint pain			N	N	N		N		
	[redacted]	1	04JUN2021	Oral temperature (°C)	36.4	36.6	36.3	36.3	36	36.8			
				Fatigue	N	N	N	N	N	N			
				Headache	N	N	N	N	N	N			
				Chills	N	N	N	N	N	N			
				Vomiting	N	N	N	N	N	N			
				Diarrhea	N	N	N	N	N	N			
				New or worsened muscle pain	N	N	N	N	N	N			
				New or worsened joint pain	N	N	N	N	N	N			

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
		2	23JUN2021	Oral temperature (°C)	36.6	36.7	35.9	36.4	36.3		36.2		
				Fatigue	N	N	N	N	N		N		
				Headache	N	N	N	N	N		N		
				Chills	N	N	N	N	N		N		
				Vomiting	N	N	N	N	N		N		
				Diarrhea	N	N	N	N	N		N		
				New or worsened muscle pain	N	N	N	N	N		N		
				New or worsened joint pain	N	N	N	N	N		N		
	[redacted]	1	07JUN2021	Oral temperature (°C)	36.1	36.2	36.1	36	36.2	36.2	36.2		
				Fatigue	N	Mod	N	N	N	N	N	08JUN2021	1
				Headache	Mild	Mod	Mod	Mild	N	N	N	10JUN2021	4
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	29JUN2021	Oral temperature (°C)	35.4	36	36.2	36.1		36.2			
				Fatigue	N	N	N	N		N			
				Headache	N	N	N	N		N			
				Chills	N	N	N	N		N			
				Vomiting	N	N	N	N		N			
				Diarrhea	N	N	N	N		N			
				New or worsened muscle pain	N	N	N	N		N			
				New or worsened joint pain	N	N	N	N		N			
	[redacted]	1	14JUN2021	Oral temperature (°C)	35.7	36	35.9	35.6	35.7	36.1	35.6		
				Fatigue	Mild	Mild	Mild	Mild	Mild	Mod	Mod	20JUN2021	7
				Headache	N	N	N	N	N	N	Mild	21JUN2021	2
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	26JUL2021	Oral temperature (°C)	36	36	36.1	36.5	36.2	35.8	35.8		
				Fatigue	N	N	N	N	N	N	N		
				Headache	Mild	N	N	N	N	N	N	26JUL2021	1
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	07JUN2021	Oral temperature (°C)			36.5	36.2	36.7		36.6		
				Fatigue			Mod	N	Mod		Mod	15JUN2021	7
				Headache			N	N	N		N		
				Chills			N	N	N		N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Vomiting			N	N	N		N		
				Diarrhea			N	N	N		N		
				New or worsened muscle pain			N	N	N		N		
				New or worsened joint pain			N	N	N		N		
		2	28JUN2021	Oral temperature (°C)	36.9	36.9	36.7	36.7	36.6	36.5	36.1		
				Fatigue	Mod	Mild	Mod	N	Mild	Mild	N	03JUL2021	6
				Headache	Mild	N	Mild	N	N	N	N	30JUN2021	3
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
	[redacted]	1	11JUN2021	Oral temperature (°C)	36.4	36.7	36.1	36.1	36.3	36.5	36.7		
				Fatigue	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	Mod	N	N	N	N	13JUN2021	1
		2	02JUL2021	Oral temperature (°C)	36.2	36.1	36.4	36	35.9	36.6	35.9		
				Fatigue	N	N	Mod	N	N	N	N	04JUL2021	1
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	[redacted]	1	16JUN2021	Oral temperature (°C)	37	36.6	36.3	36.7		36.6			
				Fatigue	N	N	N	N		N			
				Headache	N	N	N	N		N			
				Chills	N	N	N	N		N			
				Vomiting	N	N	N	N		N			
				Diarrhea	N	N	N	N		N			
				New or worsened muscle pain	N	N	N	N		N			
				New or worsened joint pain	N	N	N	N		N			
		2	07JUL2021	Oral temperature (°C)	36.2	36.6	36.4		36.4	36.6	36.7		
				Fatigue	N	N	N		N	N	N		
				Headache	N	N	N		N	N	N		
				Chills	N	N	N		N	N	N		
				Vomiting	N	N	N		N	N	N		
				Diarrhea	N	N	N		N	N	N		
				New or worsened muscle pain	N	N	N		N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened joint pain	N	N	N		N	N	N		
	[redacted]	1	14SEP2021	Oral temperature (°C)	36.5	36.9	36.9	36.9	36.7	36.3	36.8		
				Fatigue	Mild	Mod	Mod	Mod	Mod	Mod	Mild	22SEP2021	9
				Headache	N	N	N	N	N	N	N		
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		
		2	05OCT2021	Oral temperature (°C)	36.5	36.6	36.6	36.5	36.5	36.3	36.6		
				Fatigue	N	N	N	N	N	N	Mod	13OCT2021	3
				Headache	N	N	Mod	Mod	N	N	N	08OCT2021	2
				Chills	N	N	N	N	N	N	N		
				Vomiting	N	N	N	N	N	N	N		
				Diarrhea	N	N	N	N	N	N	N		

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16.2.7.4 Listing of All Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	N	N	N	N	N		
				New or worsened joint pain	N	N	N	N	N	N	N		

Abbreviations: Dur = duration; Mod = moderate; N = none; Sev = severe.
Note: For a given day, if no data are displayed for all systemic events, it indicates that the participant did not make any electronic diary (e-diary) entries and/or no data were transmitted.
Note: † = Human immunodeficiency virus (HIV)-positive participant.
Note: Events reported as adverse events in the case report form within 7 days after the study vaccination were also included in the listing.
a. Relative day (Rel Day) = date of event - date of last vaccination + 1.
b. Stop date is the date the event was last reported.
c. Duration (days) was calculated as the difference from the start of the first reported event to resolution of the last reported event, inclusive. If the event continued beyond Day 7, the calculation includes all days from the last electronic diary (e-diary) day until the date of resolution collected on the case report form. If the event is ongoing at the time of the subsequent vaccination, the end date/day for the event is the date/day that the next vaccine was administered, which was used for the duration calculation.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adfacevd Table Generation: 04MAY2023 (09:50) Output File: ./nda3/C4591015_BR/adce_l004_se

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16.2.7.5: Listing of Severe and Grade 4 Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
BNT162b2 (30 µg)	[redacted]	2	14JUN2021	Fatigue		Sev	Mild	Mild	N	Mild	Mild	21JUN2021	7
				Headache		Sev	Mod	Mod	Mod	Mild	Mild	14JUL2021	30
	[redacted]	2	22JUN2021	Fatigue	N	Sev	N	N	N	Mild	N	27JUN2021	5
				Chills	N	Sev	Mild	N	N	N	N	24JUN2021	2
				New or worsened muscle pain	N	Sev	Mild	N	N	N	N	24JUN2021	2
	[redacted]	1	20MAY2021	Fatigue	Mild	Mod	Sev	N		Mild	N	25MAY2021	6
				Headache	Mild	N	Sev	N		Mod	Mild	28MAY2021	9
		2	10JUN2021	Fatigue	N	Sev	Mod	N	N	N	N	12JUN2021	2
				Headache	N	Sev	Mod	N	N	N	N	12JUN2021	2
	[redacted]	1	14JUN2021	Headache	N	N	Mod	Mod	Mod	Sev	Mod	20JUN2021	5
	[redacted]	1	13AUG2021	Oral temperature (°C)	39.7	37.1	36.8	37.1	36.2	35	36	13AUG2021	1
	[redacted]†	1	05NOV2021	Headache		N	N	N	N	Mod	Sev	26NOV2021	17
		2	26NOV2021	Fatigue			Mod	Mod	Sev	N	N	30NOV2021	3
				New or worsened joint pain			Mild	Sev	Mod	N	N	30NOV2021	3
	[redacted]	1	08JUN2021	Headache	N	N	N	N		Sev	N	13JUN2021	1

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16.2.7.5: Listing of Severe and Grade 4 Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
Placebo	[redacted]	1	01SEP2021	Oral temperature (°C)	39.2	36.3	36.6	36.2	36.3	36.4	36.6	01SEP2021	1
	[redacted]†	2	30SEP2021	Diarrhea	N	N	N	N	N	N	Sev	09OCT2021	4
	[redacted]†	1	20SEP2021	Fatigue	Mod	Sev	Sev	Sev	Sev	Sev		11OCT2021	22
		2	11OCT2021	Fatigue	Mod		Sev		Sev	Sev	Sev	20OCT2021	10
				New or worsened muscle pain	N		N		N	N	Sev	20OCT2021	4
				New or worsened joint pain	N		N		N	N	Sev	20OCT2021	4
	[redacted]	1	14OCT2021	Headache	Mild	Mod	Mod		Sev		N	18OCT2021	5
	[redacted]	1	09JUN2021	Fatigue	Mod	Mod	Sev		N	Mod		15JUN2021	7

Abbreviations: Dur = duration; Mod = moderate; N = none; Sev = severe.
Note: For a given day, if no data are displayed for all systemic events, it indicates that the participant did not make any electronic diary (e-diary) entries and/or no data were transmitted.
Note: † = Human immunodeficiency virus (HIV)-positive participant.
Note: Events reported as adverse events in the case report form within 7 days after the study vaccination were also included in the listing.
a. Relative day (Rel Day) = date of event - date of last vaccination + 1.
b. Stop date is the date the event was last reported.
c. Duration (days) was calculated as the difference from the start of the first reported event to resolution of the last reported event, inclusive. If the event continued beyond Day 7, the calculation includes all days from the last electronic diary (e-diary) day until the date of resolution collected on the case report form. If the event is ongoing at the time of the subsequent vaccination, the end date/day for the event is the date/day that the next vaccine was administered, which was used for the duration calculation.

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16.2.7.5: Listing of Severe and Grade 4 Systemic Events (Maternal)

Vaccine Group (as Administered)	Participant	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]

PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adfacevd Table Generation: 04MAY2023 (09:51) Output File: ./nda3/C4591015_BR/adce_l004_sevse

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16.2.7.6: Listing of Severe E-Diary Reactions or Events and Corresponding Assessments at Unscheduled Visits Within 7 Days After Each Dose (Maternal)

Vaccine Group (as Administered)	Participant	Country	Age (Years)	Assessment Date	Dose No.	Rel Day[a]	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement (Caliper Units) E-Diary[b]	Stop Date[c]	Dur (Days)[d]
BNT162b2 (30 µg)	[redacted]	USA	21	15JUN2021	2	2	E-diary	Headache	Severe	14JUL2021	30
							Unscheduled clinical assessment	Redness	None		
								Swelling	None		
								Pain at the injection site	Moderate	15JUN2021	1
								Fever (°C)	None/36.5		
								Fatigue	Severe	21JUN2021	7
								Headache	Severe	14JUL2021	30
								Chills	Mild	15JUN2021	1
								Vomiting	None		
								Diarrhea	None		
								New or worsened muscle pain	Moderate	16JUN2021	2
								New or worsened joint pain	None		
	[redacted]	BRA	24	23JUN2021	2	2	E-diary	Fatigue	Severe	27JUN2021	5

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16.2.7.6: Listing of Severe E-Diary Reactions or Events and Corresponding Assessments at Unscheduled Visits Within 7 Days After Each Dose (Maternal)

Vaccine Group (as Administered)	Participant	Country	Age (Years)	Assessment Date	Dose No.	Rel Day[a]	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement (Caliper Units) E-Diary[b]	Stop Date[c]	Dur (Days)[d]
								Chills	Severe	24JUN2021	2
								New or worsened muscle pain	Severe	24JUN2021	2
				24JUN2021	2	3	Unscheduled clinical assessment	Redness	None		
								Swelling	None		
								Pain at the injection site	None		
								Fever (°C)	None/36.8		
								Fatigue	None		
								Headache	None		
								Chills	Mild	24JUN2021	2
								Vomiting	None		
								Diarrhea	None		
								New or worsened muscle pain	None		
								New or worsened joint pain	Mild	24JUN2021	2

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16.2.7.6: Listing of Severe E-Diary Reactions or Events and Corresponding Assessments at Unscheduled Visits Within 7 Days After Each Dose (Maternal)

Vaccine Group (as Administered)	Participant	Country	Age (Years)	Assessment Date	Dose No.	Rel Day[a]	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement (Caliper Units) E-Diary[b]	Stop Date[c]	Dur (Days)[d]
	[redacted]	USA	31	22MAY2021	1	3	E-diary	Fatigue	Severe	25MAY2021	6
								Headache	Severe	28MAY2021	9
				11JUN2021	2	2	E-diary	Fatigue	Severe	12JUN2021	2
								Headache	Severe	12JUN2021	2
				15JUN2021	2	6	Unscheduled clinical assessment	Redness	None		
								Swelling	None		
								Pain at the injection site	None		
								Fever (°C)	None/37.17		
								Fatigue	None		
								Headache	None		
								Chills	None		
								Vomiting	None		
								Diarrhea	None		
								New or worsened muscle pain	None		
								New or worsened joint pain	None		

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16.2.7.6: Listing of Severe E-Diary Reactions or Events and Corresponding Assessments at Unscheduled Visits Within 7 Days After Each Dose (Maternal)

Vaccine Group (as Administered)	Participant	Country	Age (Years)	Assessment Date	Dose No.	Rel Day[a]	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement (Caliper Units) E-Diary[b]	Stop Date[c]	Dur (Days)[d]
	[redacted]†	ZAF	23	11NOV2021	1	7	E-diary	Headache	Severe	26NOV2021	17
				26NOV2021	2	1	Unscheduled clinical assessment	Headache	Moderate	29NOV2021	4
				27NOV2021	2	2	Unscheduled clinical assessment	Headache	Moderate	29NOV2021	4
				29NOV2021	2	4	E-diary	New or worsened joint pain	Severe	30NOV2021	3
				30NOV2021	2	5	E-diary	Fatigue	Severe	30NOV2021	3
							Unscheduled clinical assessment	Redness	None		
								Swelling	None		
								Pain at the injection site	None		
								Fever (°C)	None/36.7		
								Fatigue	None		
								Headache	None		
								Chills	None		
								Vomiting	None		

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16.2.7.6: Listing of Severe E-Diary Reactions or Events and Corresponding Assessments at Unscheduled Visits Within 7 Days After Each Dose (Maternal)

Vaccine Group (as Administered)	Participant	Country	Age (Years)	Assessment Date	Dose No.	Rel Day[a]	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement (Caliper Units) E-Diary[b]	Stop Date[c]	Dur (Days)[d]
								Diarrhea	None		
								New or worsened muscle pain	None		
								New or worsened joint pain	Mild	30NOV2021	3
Placebo	[redacted]†	ZAF	22	06OCT2021	2	7	E-diary	Diarrhea	Severe	09OCT2021	4
							Unscheduled clinical assessment	Redness	None		
								Swelling	None		
								Pain at the injection site	None		
								Fever (°C)	None/36.5		
								Fatigue	None		
								Headache	None		
								Chills	None		
								Vomiting	None		
								Diarrhea	Mild	09OCT2021	4

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16.2.7.6: Listing of Severe E-Diary Reactions or Events and Corresponding Assessments at Unscheduled Visits Within 7 Days After Each Dose (Maternal)

Vaccine Group (as Administered)	Participant	Country	Age (Years)	Assessment Date	Dose No.	Rel Day[a]	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement (Caliper Units) E-Diary[b]	Stop Date[c]	Dur (Days)[d]
								New or worsened muscle pain	None		
								New or worsened joint pain	None		
	[redacted]†	ZAF	26	21SEP2021	1	2	E-diary	Fatigue	Severe	11OCT2021	22
				22SEP2021	1	3	E-diary	Fatigue	Severe	11OCT2021	22
				23SEP2021	1	4	E-diary	Fatigue	Severe	11OCT2021	22
							Unscheduled clinical assessment	Redness	None		
								Swelling	None		
								Pain at the injection site	None		
								Fever (°C)	None/36.7		
								Fatigue	Severe	11OCT2021	22
								Headache	None		
								Chills	None		
								Vomiting	None		
								Diarrhea	None		

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16.2.7.6: Listing of Severe E-Diary Reactions or Events and Corresponding Assessments at Unscheduled Visits Within 7 Days After Each Dose (Maternal)

Vaccine Group (as Administered)	Participant	Country	Age (Years)	Assessment Date	Dose No.	Rel Day[a]	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement (Caliper Units) E-Diary[b]	Stop Date[c]	Dur (Days)[d]
								New or worsened muscle pain	None		
								New or worsened joint pain	None		
				24SEP2021	1	5	E-diary	Fatigue	Severe	11OCT2021	22
				25SEP2021	1	6	E-diary	Fatigue	Severe	11OCT2021	22
				13OCT2021	2	3	E-diary	Fatigue	Severe	20OCT2021	10
				15OCT2021	2	5	E-diary	Fatigue	Severe	20OCT2021	10
				16OCT2021	2	6	E-diary	Fatigue	Severe	20OCT2021	10
				17OCT2021	2	7	E-diary	Fatigue	Severe	20OCT2021	10
								New or worsened muscle pain	Severe	20OCT2021	4
								New or worsened joint pain	Severe	20OCT2021	4
	[redacted]	ZAF	33	18OCT2021	1	5	E-diary	Headache	Severe	18OCT2021	5
							Unscheduled clinical assessment	Redness	None		

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16.2.7.6: Listing of Severe E-Diary Reactions or Events and Corresponding Assessments at Unscheduled Visits Within 7 Days After Each Dose (Maternal)

Vaccine Group (as Administered)	Participant	Country	Age (Years)	Assessment Date	Dose No.	Rel Day[a]	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement (Caliper Units) E-Diary[b]	Stop Date[c]	Dur (Days)[d]
								Swelling	None		
								Pain at the injection site	None		
								Fever (°C)	None/37.2		
								Fatigue	None		
								Headache	Mild	18OCT2021	5
								Chills	None		
								Vomiting	None		
								Diarrhea	None		
								New or worsened muscle pain	None		
								New or worsened joint pain	None		

Note: † = Human immunodeficiency virus (HIV)-positive participant.
Note: Temperature measurement is included at an unscheduled visit only when pain at the injection site, redness, or swelling assessment is also collected.
Note: The maximum measurable size in the electronic diary (e-diary) is 21 caliper units. Redness and swelling exceeding 21 caliper units cannot be precisely recorded and are therefore reported as >21. For all measurements, 1 caliper unit = 0.5 centimeters.
Note: Reactions reported as adverse events in the case report form within 7 days after the study vaccination were also included in the listing.
a. Relative day (Rel Day) = date of local reaction or systemic event - date of last vaccination + 1.
b. Severity for redness and swelling: mild: >2.0 to 5.0 cm; moderate: >5.0 to 10.0 cm; severe: >10.0 cm; Grade 4: necrosis (redness and swelling categories) or exfoliative dermatitis (redness category only). Severity for pain at the injection site: mild: does not interfere with activity; moderate: interferes with activity; severe: prevents daily activity. Grade 4: emergency room visit or hospitalization for severe pain at the injection site.
c. If the reaction or event lasted 7 days or less, the stop date is the last day the reaction or event was recorded in the electronic diary (e-diary). If the reaction or event continued beyond Day 7, the stop date was collected on the participant's case report form.

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16.2.7.6: Listing of Severe E-Diary Reactions or Events and Corresponding Assessments at Unscheduled Visits Within 7 Days After Each Dose (Maternal)

Vaccine Group (as Administered)	Participant	Country	Age (Years)	Assessment Date	Dose No.	Rel Day[a]	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement (Caliper Units) E-Diary[b]	Stop Date[c]	Dur (Days)[d]

d. Duration (days) was calculated as the difference from the start of the first reported reaction or event to resolution of the last reported reaction or event, inclusive.

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16.2.7.7.1 Listing of Adverse Events (Maternal)

Vaccine Group (as Administered)/ Participant	Age (Years)	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day[a]	Dur (Days)[b]	Toxicity Grade	Vax Rel[c]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE/ Imm AE (Yes/No)
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Pre-eclampsia/ Preeclampsia	1	26JUN2021	19	25	1	No	O: Unknown	NA/TC	R (20JUL2021)	Y/N
			Failed induction of labour/ Failed Induction of Labor	2	20JUL2021	22	1	1	No	O: Unknown	NA/TCN	R (20JUL2021)	Y/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	MUSC	Myalgia/ Muscle pain	1	04MAY2021	15	1	1	No	O: Pregnancy	NA	RS (04MAY2021)	N/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	RESP	Cough/ Cough^		31AUG2021	106	4	1	No	O: viral	NA	R (03SEP2021)	N/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Pre-eclampsia/ Pre-eclampsia	2	25JUN2021	12	1	2	No	O: Pregnancy	NA	RS (25JUN2021)	N/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	GENRL	Hypothermia/ Hypothermia	1	25MAY2021	2	8	1	No	O: Unknown causality	NA	R (01JUN2021)	N/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	MUSC	Arthralgia/ Arthralgia	2	23JUN2021	2	2	1	No	CND	NA/TC	R (24JUN2021)	N/N
BNT162b2 (30 µg)/	[redacted]	PREG	Foetal distress syndrome/ Fetal distress	2	15JUL2021	22	2	1	No	O: The cause of fetal stress was not a drug	NA	R (16JUL2021)	N/N

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16.2.7.7.1 Listing of Adverse Events (Maternal)

Vaccine Group (as Administered)/ Participant	Age (Years)	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day[a]	Dur (Days)[b]	Toxicity Grade	Vax Rel[c]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE/ Imm AE (Yes/No)
[redacted]										cause, it was something natural that ca			
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Gestational diabetes/ Gestational Diabetes	2	16JUL2021	36	15	1	No	O: unknown	NA	R (30JUL2021)	N/N
			Oligohydramnios/ Oligohydramnios	2	29JUL2021	49	1	1	No	O: unknown	NA	R (29JUL2021)	N/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Arrested labour/ Arrest of Labor	2	10SEP2021	67	1	1	No	O: uknown	NA	R (10SEP2021)	N/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Prolonged rupture of membranes/ Prolonged rupture of membranes	2	11MAY2021	28	3	1	No	O: Physiological	NA	R (13MAY2021)	N/N
			Cephalo-pelvic disproportion/ Cephalo Pelvic Disproportion	2	13MAY2021	30	1	1	No	O: Physiological	NA	R (13MAY2021)	N/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	EYE	Vision blurred/ BLURRY VISION	2	26APR2021	27	3	1	No	O: PREGNANCY EYE CHANGES	NA	R (28APR2021)	N/N
		GASTR	Abdominal pain/ ABDOMINAL PAIN	2	08APR2021	9	3	2	No	O: No labor or significant etiology	NA/TC	R (10APR2021)	N/N
		HEPAT	Cholestasis/ INTRAHEPATIC CHOLESTASIS	2	25APR2021	26	15	2	No	O: LIVER CHANGES DUE TO BILE ACID ELEVATION	NA	R (09MAY2021)	N/N

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16.2.7.7.1 Listing of Adverse Events (Maternal)

Vaccine Group (as Administered)/ Participant	Age (Years)	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day[a]	Dur (Days)[b]	Toxicity Grade	Vax Rel[c]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE/ Imm AE (Yes/No)
		PREG	Foetal hypokinesia/ DECREASED FETAL MOVEMENT, THIRD TRIMESTER	2	06APR2021	7	5	3	No	O: UNKNOWN	NA	R (10APR2021)	Y/N
		SKIN	Pruritus/ PRURITUS OF PREGNANCY	2	05APR2021	6	9	3	No	O: No evidence of cholestasis in pregnancy; probable skin issue	NA/TC	R (13APR2021)	Y/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	BLOOD	Normocytic anaemia/ NORMOCYTIC ANEMIA	2	14MAY2021	33	3	2	No	O: BLOOD LOSS	NA	R (16MAY2021)	N/N
		CARD	Sinus bradycardia/ SINUS BRADYCARDIA	2	15MAY2021	34	1	2	No	O: BLOOD FLOW	NA/TC	R (15MAY2021)	N/N
		GENRL	Oedema peripheral/ EDEMA IN BOTH LEGS	2	12MAY2021	31	5	2	No	O: PREGNANCY	NA/TC	R (16MAY2021)	N/N
		INJ&P	Lip injury/ LEFT LABIAL LACERATION	2	07MAY2021	26	1	2	No	O: DELIVERY TRAUMA	NA/TC	R (07MAY2021)	N/N
			Skin laceration/ SECOND DEGREE MIDLINE LACERATION	2	07MAY2021	26	1	2	No	O: DELIVERY TRAUMA	NA/TC	R (07MAY2021)	N/N
		INV	Brain natriuretic peptide increased/ ELEVATED BRAIN NATRIURETIC PEPTIDE	2	15MAY2021	34	2	2	No	O: DELIVERY	NA	R (16MAY2021)	N/N

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16.2.7.7.1 Listing of Adverse Events (Maternal)

Vaccine Group (as Administered)/ Participant	Age (Years)	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day[a]	Dur (Days)[b]	Toxicity Grade	Vax Rel[c]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE/ Imm AE (Yes/No)
			Electrocardiogram QT prolonged/ PROLONGED QT	2	15MAY2021	34	1	2	No	O: Unknown	NA	R (15MAY2021)	N/N
		PREG	Umbilical cord around neck/ NUCHAL CORD X 1	2	07MAY2021	26	1	1	No	O: FETAL MOVEMENT	NA	R (07MAY2021)	N/N
			Pre-eclampsia/ PRE-ECLAMPSIA POSTPARTUM	2	12MAY2021	31	5	3	No	O: FLUID SHIFTS IN PREGNANCY	NA/TC	R (16MAY2021)	Y/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Foetal hypokinesia/ DECREASED FETAL MOVEMENT IN 3RD TRIMESTER	2	01JUN2021	29	24	2	No	O: TERM STATUS	NA	R (24JUN2021)	N/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	GASTR	Gastrooesophageal reflux disease/ WORSENING OF ACID REFLUX	2	20JUN2021	24	46	2	No	O: THIRD TRIMESTER PREGNANCY	NA/TC	R (04AUG2021)	N/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Pre-eclampsia/ Pre-eclampsia	2	12AUG2021	36	6	1	No	O: pregnancy complication	NA	R (17AUG2021)	N/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	CARD	Tachycardia/ MILD TACHYCARDIA	2	11JUN2021	2	1	1	No	O: SECONDARY TO SHORTNESS OF BREATH	NA	R (11JUN2021)	N/N
		GASTR	Abdominal pain lower/ LOWER LEFT QUADRANT ABDOMINAL PAIN	2	09AUG2021	61	2	1	No	O: UNKNOWN	NA/TC/TCN	R (10AUG2021)	N/N

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16.2.7.7.1 Listing of Adverse Events (Maternal)

Vaccine Group (as Administered)/ Participant	Age (Years)	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day[a]	Dur (Days)[b]	Toxicity Grade	Vax Rel[c]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE/ Imm AE (Yes/No)
		PREG	Haemorrhage in pregnancy/ VAGINAL BLEEDING 2ND TRIMESTER-SINGLE EPISODE	1	27MAY2021	8	1	1	No	O: UNKNOWN	NA	R (27MAY2021)	N/N
			Hyperemesis gravidarum/ HYPEREMESIS GRAVIDARUM	2	11JUN2021	2	2	1	No	O: UNKNOWN	NA/TC	R (12JUN2021)	N/N
		RESP	Tachypnoea/ TACHYPNEA	2	11JUN2021	2	1	1	Yes		NA	R (11JUN2021)	N/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	CARD	Bradycardia/ bradycardia	2	03MAY2021	36	3	1	No	O: unknown etiology, unexpected and unrelated to the study	NA	R (05MAY2021)	N/N
		PREG	Gestational hypertension/ Gestational Hypertension	2	03MAY2021	36	6	1	No	O: pregnancy complication	NA	R (08MAY2021)	N/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	GASTR	Dyspepsia/ heartburn	2	22APR2021	22	54	2	No	O: common pregnancy complication	NA/TC	R (14JUN2021)	N/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	CARD	Tachycardia/ tachycardia	2	23JUN2021	52	1	1	No	O: unknown etiology, likely associated with discomfort	NA	R (23JUN2021)	N/N
		PREG	Pre-eclampsia/ pre-eclampsia	2	24JUN2021	53	65	3	No	O: common pregnancy complication	NA/TC	R (27AUG2021)	Y/N

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16.2.7.7.1 Listing of Adverse Events (Maternal)

Vaccine Group (as Administered)/ Participant	Age (Years)	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day[a]	Dur (Days)[b]	Toxicity Grade	Vax Rel[c]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE/ Imm AE (Yes/No)
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Gestational hypertension/ gestational hypertension	2	26JUL2021	53	16	2	No	O: common pregnancy complication	NA/TC	R (10AUG2021)	Y/N
			Pre-eclampsia/ mild pre-eclampsia	2	27JUL2021	54	107	2	No	O: common pregnancy complication	NA	R (10NOV2021)	Y/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	GASTR	Toothache/ tooth pain	2	18JUN2021	8	7	2	No	O: unknown etiology	NA/TC	R (24JUN2021)	N/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	RESP	Rhinorrhoea/ Rhinorrhea	2	09MAR2021	2	2	1	No	O: Pregnancy.	NA	R (10MAR2021)	N/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Placenta accreta/ Placenta Accreta	2	25MAR2021	17	16	1	No	O: Unknown.	NA	R (09APR2021)	N/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	REPRO	Uterine disorder/ Large Uterine Window with Bulging Membranes	2	23JUN2021	58	1	1	No	O: History of previous C-sections	NA	R (23JUN2021)	Y/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	PSYCH	Perinatal depression/ POSTPARTUM DEPRESSION	2	28JUN2021	27	C	1	No	O: unknown	NA/TC	RG	N/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	BLOOD	Anaemia/ anaemia	2	24SEP2021	33	C	1	No	O: unknown	NA/TC	N	N/N

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16.2.7.7.1 Listing of Adverse Events (Maternal)

Vaccine Group (as Administered)/ Participant	Age (Years)	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day[a]	Dur (Days)[b]	Toxicity Grade	Vax Rel[c]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE/ Imm AE (Yes/No)
		INFEC	Nasopharyngitis/ common cold	2	27AUG2021	5	6	1	No	O: viral	NA/TC	R (01SEP2021)	N/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	GASTR	Haemorrhoids/ HAEMORRHOIDS	2	01SEP2021	3	31	1	No	O: UNKNOWN	NA/TC	R (01OCT2021)	N/N
		PREG	Prolonged labour/ poor progress in labour	2	22SEP2021	24	1	1	No	O: pt is small built	NA	R (22SEP2021)	N/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Uterine contractions during pregnancy/ uterine contractions during pregnancy	2	24APR2021	13	1	1	No	O: pregnancy	NA	R (24APR2021)	N/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	INFEC	Pyelonephritis/ Pyelonephritis	2	17JUL2021	45	16	3	No	O: UTI	NA/TC	R (01AUG2021)	Y/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Retained placenta or membranes/ RETAINED PLACENTA	2	22NOV2021	48	3	2	No	O: POST-DELIVERY COMPLICATION	NA	R (24NOV2021)	Y/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Foetal distress syndrome/ FOETAL DISTRESS	2	27JAN2022	94	3	2	No	O: Pregnancy related	NA/TC/TCN	R (29JAN2022)	Y/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	CARD	Bradycardia foetal/ Fetal bradycardia	2	15SEP2021	37	1	4	No	O: Loss of fetal well-being	NA/TCN	R (15SEP2021)	Y/N

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16.2.7.7.1 Listing of Adverse Events (Maternal)

Vaccine Group (as Administered)/ Participant	Age (Years)	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day[a]	Dur (Days)[b]	Toxicity Grade	Vax Rel[c]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE/ Imm AE (Yes/No)
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Foetal distress syndrome/ Fetal distress	2	14NOV2021	27	1	2	No	O: meconium stained liquor	NA	R (14NOV2021)	Y/N
			Meconium stain/ Meconium stained liquor Grade II	2	14NOV2021	27	1	2	No	O: Meconium stained liquor	NA/TC	R (14NOV2021)	Y/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Cephalo-pelvic disproportion/ Cephalopelvic disproportion	2	14JAN2022	59	2	2	No	O: cephalopelvic disproportion	NA/TC	R (15JAN2022)	Y/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	INFEC	Lower respiratory tract infection/ Lower respiratory tract infection	1	20OCT2021	7	6	3	No	O: Viral infection	NA/TC	R (25OCT2021)	Y/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	INFEC	Endometritis/ Endometritis	2	09SEP2021	36	5	3	No	O: Endometritis	NA/TC	R (13SEP2021)	Y/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	MUSC	Back pain/ back pain	2	13OCT2021	29	61	1	No	O: gestation	NA	R (12DEC2021)	N/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Breech presentation/ BREECH PRESENTATION	1	14AUG2021	4	35	1	No	O: UNKNOWN	NA/TC	R (17SEP2021)	Y/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	INJ&P	Soft tissue injury/ SOFT TISSUE INJURY*		14AUG2021	-4	17	1	No	O: UNKNOWN	NA	R (30AUG2021)	N/N

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16.2.7.7.1 Listing of Adverse Events (Maternal)

Vaccine Group (as Administered)/ Participant	Age (Years)	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day[a]	Dur (Days)[b]	Toxicity Grade	Vax Rel[c]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE/ Imm AE (Yes/No)
BNT162b2 (30 µg)/ [redacted]†	[redacted]	BLOOD	Anaemia/ SYMPTOMATIC ANAEMIA	2	16OCT2021	27	5	3	No	O: UNKNOWN	NA/TC	R (20OCT2021)	Y/N
		PREG	Foetal death/ INTRAUTERINE FETAL DEATH	2	16OCT2021	27	1	3	No	O: UNKNOWN	NA/TC	R (16OCT2021)	Y/N
			Postpartum haemorrhage/ POSTPARTUM HAEMORRHAHE	2	16OCT2021	27	5	3	No	O: UNKNOWN	NA	R (20OCT2021)	Y/N
			Premature separation of placenta/ ABRUPTIO PLACENTA	2	16OCT2021	27	5	3	No	O: unknown	NA/TC/TCN	R (20OCT2021)	Y/N
BNT162b2 (30 µg)/ [redacted]†	[redacted]	PREG	Foetal distress syndrome/ FETAL DISTRESS	2	28NOV2021	46	1	3	No	O: pregnancy related	NA	R (28NOV2021)	Y/N
BNT162b2 (30 µg)/ [redacted]†	[redacted]	INFEC	Urinary tract infection/ UTI	2	27OCT2021	3	6	1	No	O: INFECTION	NA/TC	R (01NOV2021)	N/N
		REPRO	Vaginal discharge/ VAGINAL DISCHARGE SYNDROME	1	14OCT2021	10	3	1	No	O: INFECTION	NA/TC	R (16OCT2021)	N/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	MUSC	Back pain/ BACK PAIN	2	01NOV2021	6	6	1	No	O: UNKNOWN	NA/TC	R (06NOV2021)	N/N

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16.2.7.7.1 Listing of Adverse Events (Maternal)

Vaccine Group (as Administered)/ Participant	Age (Years)	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day[a]	Dur (Days)[b]	Toxicity Grade	Vax Rel[c]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE/ Imm AE (Yes/No)
BNT162b2 (30 µg)/ [redacted]	[redacted]	INV	Blood pressure increased/ increased blood pressure	2	29JUL2021	31	1	1	No	O: pregnancy hypertension	NA	R (29JUL2021)	N/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	REPRO	Vaginal haemorrhage/ vaginal bleeding^		25JUL2021	27	1	2	No	O: Related to delivery	NA/TC	R (25JUL2021)	N/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Gestational hypertension/ Worsening Gestational Hypertension	1	09SEP2021	21	1	1	No	O: Gestational hypertension	NA	R (09SEP2021)	N/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	NERV	Headache/ Headache	2	01JUL2021	15	3	1	No	O: Unknown	NA	R (03JUL2021)	N/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	BLOOD	Anaemia/ Anemia	2	24OCT2021	18	1	3	No	O: anemia problem	NA/TCN	R (24OCT2021)	N/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	INJ&P	Vulvovaginal injury/ Laceration of left vaginal wall	2	20JUL2021	33	1	1	No	O: Complication of childbirth	NA	R (20JUL2021)	N/N
		SURG	Episiotomy/ Mid-lateral right epistomy	2	20JUL2021	33	1	1	No	O: Complication of childbirth	NA	R (20JUL2021)	N/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	INFEC	Urinary tract infection/ Urinary tract infection in treatment	2	01JUL2021	11	7	1	No	O: Unknown	NA/TC	R (07JUL2021)	N/N

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16.2.7.7.1 Listing of Adverse Events (Maternal)

Vaccine Group (as Administered)/ Participant	Age (Years)	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day[a]	Dur (Days)[b]	Toxicity Grade	Vax Rel[c]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE/ Imm AE (Yes/No)
BNT162b2 (30 µg)/ [redacted]	[redacted]	MUSC	Osteoarthritis/ Worsening of arthrosis	1	09AUG2021	69	C	2	No	O: Unknown	NA/TC	RG	Y/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Foetal growth restriction/ Intrauterine growth restriction	2	04AUG2021	43	C	1	No	O: Unknown	NA/TCN	RG	Y/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	INJ&P	Skin laceration/ First degree laceration	2	26AUG2021	59	1	1	No	O: Unknown	NA/TCN	R (26AUG2021)	N/N
		PREG	Postpartum haemorrhage/ Postpartum uterine bleeding	2	26AUG2021	59	1	1	No	O: Risk factor due to multiparity	NA/TC/TCN	R (26AUG2021)	N/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	INFEC	Urinary tract infection/ Urinary Infection	2	02AUG2021	32	8	1	No	O: Unknown	NA/TC	R (09AUG2021)	N/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	GASTR	Abdominal wall haematoma/ Hematoma of the abdominal wall	2	07JAN2022	85	1	1	No	O: Operative wound hamatoma	NA/TCN	R (07JAN2022)	Y/N
		PREG	Foetal distress syndrome/ Suspected Fetal Distress	2	19DEC2021	66	1	2	No	O: Emergency Cesarean	NA/TCN	R (19DEC2021)	Y/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	GENRL	Chest pain/ Chest pains	2	01AUG2021	34	2	1	No	O: no underlying factors found. All tests normal ECG / Chest Xray	NA/TC	R (02AUG2021)	N/N

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16.2.7.7.1 Listing of Adverse Events (Maternal)

Vaccine Group (as Administered)/ Participant	Age (Years)	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day[a]	Dur (Days)[b]	Toxicity Grade	Vax Rel[c]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE/ Imm AE (Yes/No)
		VASC	Deep vein thrombosis/ Occlusive thrombus in left leg common femoral vein	2	01AUG2021	34	C	1	No	O: post natal 2 weeks	NA/TC/TCN	RG	Y/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	GASTR	Abdominal pain/ Abdominal pains	2	20AUG2021	46	8	1	No	O: Birth of baby	NA/TC	R (27AUG2021)	N/N
		SURG	Retained placenta operation/ Removal of retained placenta	2	20AUG2021	46	1	1	No	O: Birth of the baby	NA/TC	R (20AUG2021)	N/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	BLOOD	Anaemia/ ANEMIA	2	01OCT2021	61	C	2	No	O: BIRTH	NA/TC	RG	N/N
		GASTR	Nausea/ nausea	2	28AUG2021	27	35	2	No	O: pregnancy	NA/TC	R (01OCT2021)	N/N
			Abdominal discomfort/ Unspecific digestive discomfort	2	09OCT2021	69	C	1	No	O: Unespecific	NA/TC	RG	N/N
		IMMUN	Hypersensitivity/ allergy	2	13AUG2021	12	3	2	No	O: pregnancy	NA/TC	R (15AUG2021)	N/N
		INFEC	Urinary tract infection/ urine infection	2	22AUG2021	21	11	2	No	O: pregnancy	NA/TC	R (01SEP2021)	N/N
			Mastitis/ MASTITIS	2	16OCT2021	76	8	2	No	O: BREASTFEEDING	NA/TC	R (23OCT2021)	N/N
		METAB	Vitamin D deficiency/ vitamin D deficiency	2	26OCT2021	86	C	2	No	O: in case study	NA/TC	RG	N/N

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16.2.7.7.1 Listing of Adverse Events (Maternal)

Vaccine Group (as Administered)/ Participant	Age (Years)	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day[a]	Dur (Days)[b]	Toxicity Grade	Vax Rel[c]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE/ Imm AE (Yes/No)
		MUSC	Groin pain/ PUBALGIA: GROIN PAIN	1	23JUL2021	12	6	2	No	O: PREGNANCY	NA/TC	R (28JUL2021)	N/N
		NERV	Sciatica/ SCIATICA	1	23JUL2021	12	6	2	No	O: PREGNANCY	NA/TC	R (28JUL2021)	N/N
			Presyncope/ PREsyncope	1	30JUL2021	19	1	2	No	O: PREGNANCY	NA/TC	R (30JUL2021)	N/N
			Headache/ headache	2	12AUG2021	11	4	1	No	O: pregnancy	NA/TC	R (15AUG2021)	N/N
		REPRO	Uterine disorder/ irregular uterine dynamics	2	18SEP2021	48	2	1	No	O: related to the development of pregnancy	NA/TC	R (19SEP2021)	Y/N
			Rectocele/ SYMPTOMATIC RECTOCELE^		18MAR2022	229	C	2	No	O: PREGNANCY	NA/TCN	RG	N/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Afterbirth pain/ MUSCULAR PAIN (Post-delivery)	2	16SEP2021	36	11	2	No	O: delivery	NA/TC	R (26SEP2021)	N/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	SURG	Episiotomy/ EPISOTOMY	2	11SEP2021	31	27	2	No	O: DELIVERY	NA	R (07OCT2021)	N/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	SURG	Episiotomy/ episiotomy	2	21OCT2021	71	1	1	No	O: tear prevention	NA/TC	R (21OCT2021)	N/N
BNT162b2 (30 µg)/	[redacted]	INFEC	Cystitis/ CYSTITIS	1	22AUG2021	19	2	2	No	O: URINARY TRACT INFECTION	NA/TC	R (23AUG2021)	N/N

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16.2.7.7.1 Listing of Adverse Events (Maternal)

Vaccine Group (as Administered)/ Participant	Age (Years)	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day[a]	Dur (Days)[b]	Toxicity Grade	Vax Rel[c]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE/ Imm AE (Yes/No)
[redacted]													
			Urinary tract infection/ Urinary tract infection	2	02SEP2021	10	10	1	No	O: unknow	NA/TC	R (11SEP2021)	N/N
		RENAL	Renal colic/ COLIC NEPHRITIC	1	22AUG2021	19	2	2	No	O: kidney stones in the urinary tract	NA/TC	R (23AUG2021)	N/N
			Renal colic/ COLIC NEPHRITIC	2	26AUG2021	3	8	3	No	O: Acute destruction in these areas caused by a lithiasis (stone or kidney stone).	NA/TC	R (02SEP2021)	N/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	INFEC	Candida infection/ Candidiasis*		08JUN2021	-9	8	1	No	O: unknown	NA/TC	R (15JUN2021)	N/N
			Genital herpes simplex/ Herpes simple (genital)*		08JUN2021	-9	7	1	No	O: unknown	NA/TC	R (14JUN2021)	N/N
		PREG	Uterine contractions during pregnancy/ uterine contractions during pregnancy	1	29JUN2021	13	1	1	No	O: unknown	NA	R (29JUN2021)	N/N
		REPRO	Genital haemorrhage/ Episode of self-limited genital bleeding.	1	29JUN2021	13	1	1	No	O: unknown	NA	R (29JUN2021)	N/N
BNT162b2 (30 µg)/ [redacted]	[redacted]	INFEC	Gastroenteritis/ Gastroenteritis (Diarrhoea)	1	16JUN2021	6	4	1	No	O: other viral infection	NA	R (19JUN2021)	N/N
BNT162b2 (30 µg)/	[redacted]	BLOOD	Anaemia/ Anemia	1	27SEP2021	7	C	2	No	O: Anemia of pregnancy	NA/TC	N	N/N

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16.2.7.7.1 Listing of Adverse Events (Maternal)

Vaccine Group (as Administered)/ Participant	Age (Years)	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day[a]	Dur (Days)[b]	Toxicity Grade	Vax Rel[c]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE/ Imm AE (Yes/No)
[redacted]													
		GASTR	Abdominal pain/ Abdominal pain	2	14OCT2021	3	2	1	No	O: Pregnancy	NA	R (15OCT2021)	N/N
		PREG	Haemorrhage in pregnancy/ Antepartum haemorrhage	2	15OCT2021	4	2	3	No	O: Unknown cause	NA/TCN	RS (16OCT2021)	Y/N
		REPRO	Cervical polyp/ Vascular Cervical Polyp	2	19OCT2021	8	C	1	No	O: Pregnancy	NA	N	N/N
			Vaginal haemorrhage/ Per vaginal bleeding small amount, 2 episodes 19/10/21 30/11/21	2	19OCT2021	8	44	2	No	O: PV bleeding in pregnancy	NA	R (01DEC2021)	N/N
Placebo/ [redacted]	[redacted]	INJ&P	Fall/ Fall on stairs during pregnancy	2	04MAY2021	13	1	1	No	O: Accidental Fall	NA	R (04MAY2021)	N/N
Placebo/ [redacted]	[redacted]	CARD	Nonreassuring foetal heart rate pattern/ Non-reassuring Fetal Heart Tones	2	27JUL2021	47	1	1	No	O: non-reassuring fetal heart tones requiring operative vaginal delivery	NA	R (27JUL2021)	N/N
Placebo/ [redacted]	[redacted]	INFEC	Mastitis/ Mastitis	2	16AUG2021	67	8	1	No	O: Unknown	NA/TC	R (23AUG2021)	N/N
Placebo/ [redacted]	[redacted]	GENRL	Injection site erythema/ Redness at Injection Site^	x1	05NOV2021	2	4	1	Yes		NA	R (08NOV2021)	N/N
			Injection site pain/ Pain at Injection site^	x1	05NOV2021	2	4	1	Yes		NA	R (08NOV2021)	N/N

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16.2.7.7.1 Listing of Adverse Events (Maternal)

Vaccine Group (as Administered)/ Participant	Age (Years)	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day[a]	Dur (Days)[b]	Toxicity Grade	Vax Rel[c]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE/ Imm AE (Yes/No)
			Injection site swelling/ Swelling at Injection Site^	x1	05NOV2021	2	4	1	Yes		NA	R (08NOV2021)	N/N
Placebo/ [redacted]	[redacted]	METAB	Dehydration/ Dehydration	1	16APR2021	12	1	2	No	O: Not staying hydrated	NA	R (16APR2021)	N/N
Placebo/ [redacted]	[redacted]	RESP	Respiratory disorder/ Upper respiratory illness^	x1	20AUG2021	17	9	1	No	O: Viral	NA	R (28AUG2021)	N/N
Placebo/ [redacted]	[redacted]	RESP	Respiratory disorder/ Upper Respiratory Illness^		03OCT2021	116	10	1	No	O: Viral infection	NA	R (12OCT2021)	N/N
Placebo/ [redacted]	[redacted]	GENRL	Injection site pain/ Injection site pain^	x2	31AUG2021	2	8	1	Yes		NA	R (07SEP2021)	N/N
		NERV	Ageusia/ Loss of taste^	x1	17AUG2021	9	C	1	No	O: Viral	NA	N	N/N
			Anosmia/ loss of smell^	x1	21AUG2021	13	C	1	No	O: Viral	NA	N	N/N
Placebo/ [redacted]	[redacted]	GASTR	Gastrooesophageal reflux disease/ Gastroesophageal Reflux Disease	2	06JUL2021	1	45	1	No	O: Pregnancy	NA/TC	R (19AUG2021)	N/N
Placebo/ [redacted]	[redacted]	GENRL	Injection site pain/ Pain at the injection site^	x2	14SEP2021	1	2	1	Yes		NA	R (15SEP2021)	N/N
Placebo/ [redacted]	[redacted]	GENRL	Injection site oedema/ Edema in the injection site^	x2	08SEP2021	1	7	1	Yes		NA	R (14SEP2021)	N/N

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16.2.7.7.1 Listing of Adverse Events (Maternal)

Vaccine Group (as Administered)/ Participant	Age (Years)	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day[a]	Dur (Days)[b]	Toxicity Grade	Vax Rel[c]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE/ Imm AE (Yes/No)
			Injection site pain/ Pain at the injection site^	x2	08SEP2021	1	7	1	Yes		NA	R (14SEP2021)	N/N
Placebo/ [redacted]	[redacted]	GENRL	Injection site pain/ Pain at the injection site^	x2	16SEP2021	1	2	1	Yes		NA	R (17SEP2021)	N/N
		INFEC	Postoperative wound infection/ Surgical wound infection the pubic region	2	06AUG2021	45	8	2	No	CND	NA/TC	R (13AUG2021)	N/N
		NERV	Headache/ Headache^	x1	26AUG2021	1	1	2	Yes		NA/TC	R (26AUG2021)	N/N
Placebo/ [redacted]	[redacted]	GASTR	Diarrhoea/ Diarrhea	2	30JUN2021	2	6	1	No	O: unknown case	NA	R (05JUL2021)	N/N
		MUSC	Pain in extremity/ Left Upper Limb Pain^	x1	02SEP2021	1	2	1	Yes		NA	R (03SEP2021)	N/N
Placebo/ [redacted]	[redacted]	HEPAT	Cholelithiasis/ Cholelithiasis	2	02JUL2021	39	11	1	No	O: Gallstones	NA	R (12JUL2021)	Y/N
		RESP	Nasal congestion/ Nasal Congestion^	x1	01AUG2021	18	5	1	No	O: Allergies	NA	R (05AUG2021)	N/N
Placebo/ [redacted]	[redacted]	GASTR	Gastrooesophageal reflux disease/ ACID REFLUX	2	21APR2021	10	8	2	No	O: PREGNANCY-RELATED	NA/TC	R (28APR2021)	N/N
		INV	Foetal heart rate abnormal/ Fetal heartrate abnormality	2	28APR2021	17	1	4	No	O: delivery complications	NA	R (28APR2021)	Y/N

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16.2.7.7.1 Listing of Adverse Events (Maternal)

Vaccine Group (as Administered)/ Participant	Age (Years)	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day[a]	Dur (Days)[b]	Toxicity Grade	Vax Rel[c]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE/ Imm AE (Yes/No)
		PREG	Meconium stain/ Moderate Meconium Staining	2	28APR2021	17	1	2	No	O: BIRTH STRESS	NA	R (28APR2021)	N/N
			Premature separation of placenta/ Marginal Placenta Abruption	2	28APR2021	17	1	3	No	O: Marginal Placenta Abruption	NA	R (28APR2021)	Y/N
Placebo/ [redacted]	[redacted]	PREG	Breech presentation/ BREECH PRESENTATION	2	06JUN2021	56	1	2	No	O: OLIGOHYDRAMNIOS IN THIRD TRIMESTER	NA/TCN	R (06JUN2021)	N/N
			Oligohydramnios/ OLIGOHYDRAMNIOS IN THIRD TRIMESTER	2	06JUN2021	56	1	2	No	O: SLOW LEAKAGE OF AMNIOTIC FLUID	NA/TCN	R (06JUN2021)	N/N
Placebo/ [redacted]	[redacted]	INFEC	Puncture site infection/ NOSE PIERCING INFECTION^	x2	30SEP2021	32	C	2	No	O: NASAL BACTERIA	NA/TC	N	N/N
		INJ&P	Nerve injury/ NERVE DAMAGE IN NIPPLES^	x1	16AUG2021	8	C	1	No	O: DUE TO BABY'S POOR LATCH	NA	N	N/N
		PREG	Premature labour/ PRETERM LABOR	2	28MAY2021	17	43	2	No	O: SECOND PREGNANCY NORMAL VARIANCE	NA/TC	R (09JUL2021)	N/N
Placebo/ [redacted]	[redacted]	INFEC	Viral infection/ VIRAL INFECTION^	x2	08SEP2021	10	3	1	No	O: irritation from drainage	NA	R (10SEP2021)	N/N
Placebo/ [redacted]	[redacted]	GASTR	Constipation/ Constipation	2	02JUL2021	25	36	1	No	O: Pregnancy	NA/TC	R (06AUG2021)	N/N

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16.2.7.7.1 Listing of Adverse Events (Maternal)

Vaccine Group (as Administered)/ Participant	Age (Years)	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day[a]	Dur (Days)[b]	Toxicity Grade	Vax Rel[c]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE/ Imm AE (Yes/No)
			Haemorrhoids/ HEMORRHOIDS	2	04AUG2021	58	23	2	No	O: BIRTH PRESSURE	NA/TC	R (26AUG2021)	N/N
		INV	Streptococcus test positive/ POSITIVE GROUP B STREP TEST	2	04AUG2021	58	1	2	No	O: BACTERIAL CONTAMINATE	NA/TC	RS (04AUG2021)	N/N
Placebo/ [redacted]	[redacted]	INJ&P	Vulvovaginal injury/ 3RD DEGREE VAGINAL LACERATION	2	27JUL2021	35	43	2	No	O: DELIVERY TRAUMA	NA/TC	R (07SEP2021)	N/N
		INV	Streptococcus test positive/ GROUP B STREP POSITIVE	2	27JUL2021	35	1	2	No	O: STREP BACTERIAL COLONIZATION	NA/TC	R (27JUL2021)	N/N
		PREG	Omphalorrhexis/ UMBILICAL CORD RUPTURE	2	27JUL2021	35	1	4	No	O: UMBILICAL CORD RUPTURE	NA/TCN	R (27JUL2021)	Y/N
Placebo/ [redacted]	[redacted]	GENRL	Injection site pain/ pain at injection site^	x1	01JUL2021	1	4	1	Yes		NA	R (04JUL2021)	N/N
			Fatigue/ fatigue^	x1	02JUL2021	2	2	2	Yes		NA	R (03JUL2021)	N/N
			Injection site erythema/ Redness at injection site^	x1	03JUL2021	3	2	1	Yes		NA	R (04JUL2021)	N/N
			Injection site pain/ Pain at injection site^	x2	20JUL2021	1	3	1	Yes		NA	R (22JUL2021)	N/N
		NERV	Headache/ headache^	x1	02JUL2021	2	2	1	Yes		NA	R (03JUL2021)	N/N

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16.2.7.7.1 Listing of Adverse Events (Maternal)

Vaccine Group (as Administered)/ Participant	Age (Years)	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day[a]	Dur (Days)[b]	Toxicity Grade	Vax Rel[c]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE/ Imm AE (Yes/No)
Placebo/ [redacted]	[redacted]	CARD	Nonreassuring foetal heart rate pattern/ Non-reassuring fetal heart tones	2	29MAY2021	32	1	4	No	O: common delivery complication	NA/TC	R (29MAY2021)	Y/N
		GENRL	Pain/ body ache^	x1	24JUN2021	2	3	1	Yes		NA	R (26JUN2021)	N/N
			Fatigue/ fatigue^	x2	30JUL2021	1	4	2	Yes		NA	R (02AUG2021)	N/N
		INFEC	Amniotic cavity infection/ intrauterine inflammation or infection or both	2	29MAY2021	32	1	1	No	O: common delivery complication	NA	R (29MAY2021)	N/N
		MUSC	Myalgia/ muscle aches^	x2	30JUL2021	1	4	1	Yes		NA	R (02AUG2021)	N/N
		NERV	Headache/ headache^	x1	24JUN2021	2	3	1	Yes		NA	R (26JUN2021)	N/N
			Headache/ headache^	x2	30JUL2021	1	4	2	Yes		NA	R (02AUG2021)	N/N
			Dizziness/ dizziness^	x2	01AUG2021	3	2	2	Yes		NA	R (02AUG2021)	N/N
		PREG	Prolonged rupture of membranes/ prolonged rupture of membranes	2	28MAY2021	31	2	2	No	O: unknown etiology	NA	R (29MAY2021)	N/N
			Arrested labour/ arrest of dilation	2	29MAY2021	32	1	3	No	O: common pregnancy complication	NA	R (29MAY2021)	Y/N
		REPRO	Suppressed lactation/ decreased milk supply^	x2	02AUG2021	4	8	1	No	O: unknown etiology	NA	R (09AUG2021)	N/N

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16.2.7.7.1 Listing of Adverse Events (Maternal)

Vaccine Group (as Administered)/ Participant	Age (Years)	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day[a]	Dur (Days)[b]	Toxicity Grade	Vax Rel[c]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE/ Imm AE (Yes/No)
		SKIN	Rash/ Rash on abdomen above incision	2	01JUN2021	35	5	1	No	O: surgical cleansing	NA/TC	R (05JUN2021)	N/N
Placebo/ [redacted]	[redacted]	GENRL	Injection site pain/ pain at injection site^	x1	08JUL2021	2	3	1	Yes		NA	R (10JUL2021)	N/N
			Chills/ chills^	x2	26JUL2021	1	2	2	Yes		NA	R (27JUL2021)	N/N
			Injection site pain/ injection site pain^	x2	26JUL2021	1	3	1	Yes		NA	R (28JUL2021)	N/N
		MUSC	Arthralgia/ joint ache^	x2	26JUL2021	1	2	2	Yes		NA	R (27JUL2021)	N/N
			Myalgia/ muscle aches^	x2	26JUL2021	1	2	2	Yes		NA	R (27JUL2021)	N/N
Placebo/ [redacted]	[redacted]	GENRL	Injection site pain/ Injection site pain^	x1	03AUG2021	1	3	1	Yes		NA	R (05AUG2021)	N/N
			Injection site pain/ injection site pain^	x2	23AUG2021	1	3	1	Yes		NA	R (25AUG2021)	N/N
			Fatigue/ fatigue^	x2	24AUG2021	2	1	2	Yes		NA	R (24AUG2021)	N/N
			Pain/ body aches^	x2	24AUG2021	2	1	2	Yes		NA	R (24AUG2021)	N/N
Placebo/ [redacted]	[redacted]	BLOOD	Anaemia/ Anemia	2	18JUN2021	10	10	1	No	O: common pregnancy complication	NA/TC	R (27JUN2021)	N/N
		GASTR	Dyspepsia/ heartburn	1	28MAY2021	11	3	1	No	O: common pregnancy complication	NA/TC	R (30MAY2021)	N/N

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16.2.7.7.1 Listing of Adverse Events (Maternal)

Vaccine Group (as Administered)/ Participant	Age (Years)	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day[a]	Dur (Days)[b]	Toxicity Grade	Vax Rel[c]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE/ Imm AE (Yes/No)
		GENRL	Oedema peripheral/ bilateral lower leg edema	1	01JUN2021	15	34	1	No	O: common pregnancy complication	NA/TC	R (04JUL2021)	N/N
			Injection site pain/ injection site pain^	x1	19JUL2021	1	3	1	Yes		NA	R (21JUL2021)	N/N
			Injection site pain/ injection site pain^	x2	09AUG2021	1	4	1	Yes		NA	R (12AUG2021)	N/N
		MUSC	Muscle spasms/ leg cramps	1	01JUN2021	15	27	1	No	O: bilateral lower edema	NA/TC	R (27JUN2021)	N/N
		NERV	Headache/ headache^	x1	19JUL2021	1	1	2	Yes		NA/TC	R (19JUL2021)	N/N
			Headache/ headache^	x2	09AUG2021	1	3	1	Yes		NA	R (11AUG2021)	N/N
		PREG	Gestational hypertension/ gestational hypertension	2	27JUN2021	19	18	2	No	O: common pregnancy complication	NA	R (14JUL2021)	Y/N
		REPRO	Vaginal discharge/ Vaginal discharge	2	09JUN2021	1	19	1	No	O: common pregnancy complication	NA	R (27JUN2021)	N/N
			Vaginal haemorrhage/ Vaginal spotting	2	18JUN2021	10	3	1	No	O: vaginal exam	NA	R (20JUN2021)	N/N
Placebo/ [redacted]	[redacted]	GENRL	Pyrexia/ Fever^	x2	02AUG2021	28	2	1	No	O: Flu symptoms	NA	R (03AUG2021)	N/N
		RESP	Cough/ Cough^	x2	02AUG2021	28	2	1	No	O: Flu symptoms	NA	R (03AUG2021)	N/N
Placebo/ [redacted]	[redacted]	CARD	Bradycardia foetal/ Decreased fetal heart rate	2	27MAY2021	29	1	1	No	O: Birth related	NA	R (27MAY2021)	N/N

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16.2.7.7.1 Listing of Adverse Events (Maternal)

Vaccine Group (as Administered)/ Participant	Age (Years)	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day[a]	Dur (Days)[b]	Toxicity Grade	Vax Rel[c]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE/ Imm AE (Yes/No)
Placebo/ [redacted]	[redacted]	GENRL	Pyrexia/ Fever^	x1	16AUG2021	1	3	1	No	O: Unknown	NA/TC	R (18AUG2021)	N/N
Placebo/ [redacted]	[redacted]	BLOOD	Anaemia of pregnancy/ ANAEMIA AFFECTING PREGNANCY	2	15JUN2021	15	29	1	No	O: PREGNANCY RELATED	NA/TC	R (13JUL2021)	N/N
Placebo/ [redacted]	[redacted]	CARD	Nonreassuring foetal heart rate pattern/ Non Reassuring fetal heart rate	2	02SEP2021	71	1	3	No	O: Unknown	NA/TCN	R (02SEP2021)	Y/N
Placebo/ [redacted]	[redacted]	GENRL	Chills/ Chills^	x2	10JUN2021	1	3	1	Yes		NA	R (12JUN2021)	N/N
			Pain/ Body Aches^	x2	10JUN2021	1	3	1	Yes		NA	R (12JUN2021)	N/N
			Pyrexia/ Fever^	x2	10JUN2021	1	3	2	Yes		NA/TC	R (12JUN2021)	N/N
		NERV	Headache/ Intermittent Headache^	x2	10JUN2021	1	8	2	Yes		NA/TC	R (17JUN2021)	N/N
Placebo/ [redacted]	[redacted]	INFEC	Vulvovaginal mycotic infection/ Vaginal Yeast Infection^	x1	07SEP2021	9	6	1	No	O: unknown	NA/TC	R (12SEP2021)	N/N
Placebo/ [redacted]	[redacted]	PREG	Gestational diabetes/ GESTATIONAL DIABETES	2	11JUN2021	10	42	1	No	O: unknown	NA	R (22JUL2021)	N/N
Placebo/ [redacted]	[redacted]	GENRL	Fatigue/ Fatigue	2	13AUG2021	64	C	1	No	O: Generalized Fatigue/Subject takes daily iron supplement for fatigue	NA/TC	RG	N/N

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16.2.7.7.1 Listing of Adverse Events (Maternal)

Vaccine Group (as Administered)/ Participant	Age (Years)	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day[a]	Dur (Days)[b]	Toxicity Grade	Vax Rel[c]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE/ Imm AE (Yes/No)
		INFEC	Amniotic cavity infection/ Chorioamnionitis	2	03AUG2021	54	1	1	No	O: Labor complication	NA/TC	R (03AUG2021)	N/N
Placebo/ [redacted]	[redacted]	PREG	Premature delivery/ PRETERM DELIVERY	2	01DEC2021	27	1	1	No	O: UNKNOWN	NA/TC	R (01DEC2021)	N/N
Placebo/ [redacted]	[redacted]	INFEC	Skin candida/ candida intertrigo^	x1	01FEB2022	16	5	2	No	O: common in women	NA/TC	R (05FEB2022)	N/N
Placebo/ [redacted]	[redacted]	INFEC	Oral herpes/ oral herpes simplex infection^	x2	12AUG2021	4	12	1	No	O: Stress	NA	R (23AUG2021)	N/N
		NERV	Carpal tunnel syndrome/ Carpal Tunnel Syndrome	1	17MAY2021	5	107	1	No	O: Pregnancy related	NA	R (31AUG2021)	N/N
		PREG	Abnormal labour/ Arrest of descent	2	28JUN2021	26	1	3	No	O: maternal exhaustion	NA/TCN	R (28JUN2021)	N/N
Placebo/ [redacted]	[redacted]	NERV	Headache/ Frequent Headaches	1	12JUL2021	19	38	1	No	O: Pregnancy related	NA	R (18AUG2021)	N/N
		PREG	Premature separation of placenta/ Placental Abruption	2	18AUG2021	35	1	3	No	O: Pregnancy	NA/TCN	R (18AUG2021)	Y/N
		SKIN	Skin hyperpigmentation/ Left thigh hyperpigmentation	1	12JUL2021	19	C	1	No	O: Pregnancy related	NA	RG	N/N
Placebo/ [redacted]†	[redacted]	PREG	Failed trial of labour/ Failed vaginal delivery	2	28DEC2021	57	1	3	No	O: FAILED VAGINAL DELIVERY	NA	R (28DEC2021)	Y/N

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16.2.7.7.1 Listing of Adverse Events (Maternal)

Vaccine Group (as Administered)/ Participant	Age (Years)	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day[a]	Dur (Days)[b]	Toxicity Grade	Vax Rel[c]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE/ Imm AE (Yes/No)
		RENAL	Leukocyturia/ Leukocyturia	2	26NOV2021	25	C	1	No	O: Pregnancy	NA/TCN	N	N/N
Placebo/ [redacted]	[redacted]	PREG	Cephalo-pelvic disproportion/ CAPHALOPELVIC DISPROPORTION	2	20DEC2021	41	1	2	No	O: UNKNOWN	NA/TCN	R (20DEC2021)	Y/N
Placebo/ [redacted]	[redacted]	PREG	Pre-eclampsia/ Preeclampsia	2	04AUG2021	58	2	1	No	O: Medical condition	NA	R (05AUG2021)	Y/N
			Abnormal labour/ arrest of decent	2	05AUG2021	59	1	1	No	O: arrest of descent	NA/TCN	R (05AUG2021)	N/N
Placebo/ [redacted]	[redacted]	PREG	Cephalo-pelvic disproportion/ Cephalopelvic Disproportion	2	17OCT2021	47	1	3	No	O: Big baby	NA/TC	R (17OCT2021)	Y/N
Placebo/ [redacted]	[redacted]	INFEC	COVID-19/ COVID-19^	x2	08DEC2021	2	9	1	No	O: SARS COV-19 VIRUS	NA/TC	R (16DEC2021)	N/N
		PREG	Foetal distress syndrome/ Fetal distress	2	25OCT2021	28	1	2	No	O: Placental insufficiency	NA	R (25OCT2021)	Y/N
			Placental insufficiency/ Placental Insufficiency	2	25OCT2021	28	1	3	No	O: intrauterine growth retardation	NA/TC	R (25OCT2021)	Y/N
		RESP	Epistaxis/ Epistaxis	1	15SEP2021	9	2	1	No	O: Unknown	NA/TC	R (16SEP2021)	N/N
Placebo/ [redacted]	[redacted]	INFEC	Pyelonephritis/ Pyelonephritis	1	03OCT2021	20	8	1	No	O: Bacterial origin	NA/TC	R (10OCT2021)	N/N

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16.2.7.7.1 Listing of Adverse Events (Maternal)

Vaccine Group (as Administered)/ Participant	Age (Years)	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day[a]	Dur (Days)[b]	Toxicity Grade	Vax Rel[c]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE/ Imm AE (Yes/No)
Placebo/ [redacted]	[redacted]	PREG	Pre-eclampsia/ Preeclampsia	1	24SEP2021	5	12	3	No	O: Preeclampsia	NA/TC/TCN	R (05OCT2021)	Y/N
Placebo/ [redacted]	[redacted]	INFEC	COVID-19/ COvid-19^	x2	08DEC2021	2	8	1	No	O: SARS COV-19 VIRUS	NA/TC	R (15DEC2021)	N/N
Placebo/ [redacted]	[redacted]	PREG	Foetal distress syndrome/ Fetal distress	2	05JAN2022	50	1	2	No	O: Induced Labour	NA/TC	R (05JAN2022)	Y/N
Placebo/ [redacted]	[redacted]	INFEC	Urinary tract infection/ Urinary tract infection	2	29JUN2021	7	8	1	No	O: urinary tract infection	NA/TC	R (06JUL2021)	N/N
		INV	Heart rate increased/ INTERMITTENT INCREASED HEART RATE	1	05JUN2021	4	3	1	No	O: UNKNOWN. OTHER EPISODES PRIOR TO THE START OF THE STUDY.	NA	R (07JUN2021)	N/N
Placebo/ [redacted]	[redacted]	NERV	Headache/ CEPHALEA	2	30JUN2021	3	2	1	No	O: UNKNOWN.	NA	R (01JUL2021)	N/N
		RESP	Cough/ COUGH	2	30JUN2021	3	2	1	No	O: UNKNOWN.	NA	R (01JUL2021)	N/N
Placebo/ [redacted]	[redacted]	REPRO	Vaginal haemorrhage/ VAGINAL BLEEDING	2	30AUG2021	26	1	3	No	O: breastfeeding	NA	R (30AUG2021)	N/N
Placebo/ [redacted]†	[redacted]	INFEC	Body tinea/ Tinea corporis	1	15SEP2021	36	5	1	No	O: INFECTION	NA/TC	R (19SEP2021)	N/N
		PREG	Foetal hypokinesia/ REDUCED FETAL MOVEMENTS	2	12OCT2021	28	3	1	No	O: UNKNOWN	NA	R (14OCT2021)	Y/N

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16.2.7.7.1 Listing of Adverse Events (Maternal)

Vaccine Group (as Administered)/ Participant	Age (Years)	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day[a]	Dur (Days)[b]	Toxicity Grade	Vax Rel[c]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE/ Imm AE (Yes/No)
Placebo/ [redacted]†	[redacted]	BLOOD	Anaemia/ ANAEMIA	2	18NOV2021	79	C	1	No	O: PREGNANCY	NA	N	N/N
Placebo/ [redacted]	[redacted]	RENAL	Glycosuria/ GLUCOSURIA	2	07OCT2021	15	46	1	No	O: UNKNOWN	NA	R (21NOV2021)	N/N
Placebo/ [redacted]	[redacted]	PREG	Cephalo-pelvic disproportion/ CEPHALOPELVIC DISPROPORTION	2	25NOV2021	71	1	3	No	O: PREGNANCY	NA/TC	R (25NOV2021)	Y/N
Placebo/ [redacted]†	[redacted]	GASTR	Dyspepsia/ heartburn	2	12OCT2021	15	18	1	No	O: pregnancy	NA/TC	R (29OCT2021)	N/N
		PREG	Cephalo-pelvic disproportion/ cephalopelvic disproportion	2	04DEC2021	68	1	3	No	O: unknown	NA	R (04DEC2021)	Y/N
Placebo/ [redacted]†	[redacted]	PREG	Foetal distress syndrome/ FETAL DISTRESS	2	01DEC2021	63	1	3	No	O: UNKNOWN	NA	R (01DEC2021)	Y/N
		SKIN	Dermatitis allergic/ ALLERGIC RASH (CHEST)	1	23SEP2021	17	10	1	No	O: UNKNOWN	NA/TC	R (02OCT2021)	N/N
			Dermatitis allergic/ ALLERGIC RASH (ARM)	2	20OCT2021	21	7	1	No	O: UNKNOWN	NA/TC	R (26OCT2021)	N/N
Placebo/ [redacted]	[redacted]	GASTR	Abdominal pain/ ABDOMINAL PAIN	2	17OCT2021	4	5	2	No	O: UNKNOWN	NA/TC	R (21OCT2021)	N/N

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		GENRL	Injection site pain/ PAIN AT INJECTION SITE^	x1	07DEC2021	1	13	1	Yes		NA/TC	R (19DEC2021)	N/N
		PREG	Preterm premature rupture of membranes/ PRETERM PRELABOUR RUPTURE OF MEMBRANE	2	14NOV2021	32	3	2	No	O: UNKNOWN	NA/TC	R (16NOV2021)	Y/N
			Postpartum haemorrhage/ POSTPARTUM HAEMORRHAGE	2	16NOV2021	34	1	2	No	O: UNKNOWN	NA/TC	R (16NOV2021)	Y/N
Placebo/ [redacted]†	[redacted]	NERV	Headache/ Headache^	x2	08MAR2022	15	4	1	No	O: unknown	NA	R (11MAR2022)	N/N
		RESP	Cough/ Cough^	x2	08MAR2022	15	4	1	No	O: unknown	NA	R (11MAR2022)	N/N
			Rhinorrhoea/ Runny Nose^	x2	08MAR2022	15	4	1	No	O: unknown	NA	R (11MAR2022)	N/N
Placebo/ [redacted]	[redacted]	GENRL	Injection site pain/ Local injection site pain^	x2	13DEC2021	1	2	1	Yes		NA	RG (14DEC2021)	N/N
			Pyrexia/ Fever (38.3)^	x2	14DEC2021	2	1	2	Yes		NA/TC	R (14DEC2021)	N/N
		MUSC	Arthralgia/ Joint pain (generalized)^	x2	14DEC2021	2	2	2	Yes		NA	RG (15DEC2021)	N/N
Placebo/ [redacted]	[redacted]	BLOOD	Iron deficiency anaemia/ Iron defiency anaemia	1	01SEP2021	7	C	1	No	O: Newly diagnosed Iron deficiency Anaemia	NA/TC	N	N/N

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Vaccine Group (as Administered)/ Participant	Age (Years)	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day[a]	Dur (Days)[b]	Toxicity Grade	Vax Rel[c]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE/ Imm AE (Yes/No)
			Lymphadenopathy/ Left axillary lymphadenopathy^	x1	18DEC2021	2	2	1	Yes		NA	R (19DEC2021)	N/N
		GENRL	Fatigue/ Fatigue	2	14SEP2021	1	9	2	No	O: DUE TO ANAEMIA	NA	R (22SEP2021)	N/N
			Injection site pain/ Local injection site pain^	x1	18DEC2021	2	2	2	Yes		NA	R (19DEC2021)	N/N
			Injection site pain/ LOCAL INJECTION SITE PAIN^	x2	17JAN2022	1	3	1	Yes		NA	R (19JAN2022)	N/N
			Injection site erythema/ LOCAL INJECTION SITE ERYTHEMA^	x2	18JAN2022	2	14	1	Yes		NA	RG (31JAN2022)	N/N
Placebo/ [redacted]	[redacted]	INJ&P	Urinary tract procedural complication/ Intraoperative bladder injury/laceration	2	17JUL2021	6	15	2	No	O: Surgical procedure	NA/TC	R (31JUL2021)	Y/N
Placebo/ [redacted]	[redacted]	GASTR	Abdominal pain/ Abdominal pain in colics	2	04JUL2021	17	9	1	No	O: The event is probably related to progression of pregnancy	NA	R (12JUL2021)	N/N
Placebo/ [redacted]	[redacted]	INFEC	Urinary tract infection/ Urinary Infection^	x1	10SEP2021	17	4	1	No	O: Unknown	NA/TC	R (13SEP2021)	N/N
		PREG	Meconium abnormal/ Abnormal meconium	2	26JUL2021	39	1	1	No	O: Unknown	NA	R (26JUL2021)	N/N
Placebo/ [redacted]	[redacted]	GASTR	Abdominal pain/ Abdominal cramps	2	27JUN2021	10	9	1	No	O: Unknown	NA	R (05JUL2021)	N/N

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		INJ&P	Post lumbar puncture syndrome/ Post-spinal anesthesia headache	2	10JUL2021	23		2	No	O: Unknown	NA	UNK	N/N
		INV	Blood pressure systolic increased/ Increase in systolic blood pressure of 130-140mmHg	1	01JUN2021	5	1	2	No	O: Unknown	NA	R (01JUN2021)	N/N
Placebo/ [redacted]	[redacted]	GENRL	Injection site pain/ PAIN AT THE INJECTION SITE	2	18JUN2021	1	1	1	Yes		NA	R (18JUN2021)	N/Y
Placebo/ [redacted]	[redacted]	INFEC	Urinary tract infection bacterial/ Urinary tract infection/asymptomatic bacteriuria	1	14JUN2021	14	8	1	No	O: Unknown	NA/TC	R (21JUN2021)	N/N
Placebo/ [redacted]	[redacted]	GENRL	Injection site pain/ Injection site pain^	x2	18AUG2021	1	2	1	Yes		NA	R (19AUG2021)	N/N
		NERV	Headache/ Headache^	x2	18AUG2021	1	2	1	Yes		NA/TC	R (19AUG2021)	N/N
Placebo/ [redacted]	[redacted]	PREG	Meconium in amniotic fluid/ Meconium in the amniotic fluid	2	17JUL2021	20	1	2	No	O: Unknown	NA	R (17JUL2021)	Y/N
Placebo/ [redacted]	[redacted]	VASC	Hypertension/ Hypertension	2	27AUG2021	59	4	1	No	O: Unknown	NA/TC	R (30AUG2021)	N/N

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Placebo/ [redacted]	[redacted]	PREG	Gestational diabetes/ Gestational diabetes	1	16JUN2021	7	72	2	No	O: PATIENT WAS DIAGNOSED WITH GESTATIONAL DIABETES AN ORAL GLUCOSE TOLERANCE TEST	NA	R (26AUG2021)	N/N
			Oligohydramnios/ Oligohydramnio	2	29AUG2021	60	1	1	No	O: Unknown	NA	R (29AUG2021)	N/N
Placebo/ [redacted]	[redacted]	INFEC	Urinary tract infection/ Urinary Infection	2	04DEC2021	81	10	1	No	O: Information not reported in hospital document	NA/TC	R (13DEC2021)	Y/N
Placebo/ [redacted]	[redacted]	INFEC	Gastroenteritis viral/ stomach flu^	x1	01OCT2021	10	1	1	No	O: viral	NA	R (01OCT2021)	N/N
		PREG	Polyhydramnios/ mild polyhydramnios	1	29JUN2021	20	57	1	No	O: pregnancy	NA	R (24AUG2021)	N/N
		RESP	Productive cough/ Productive Cough^	x1	11OCT2021	20	12	1	No	O: related to possible FLU	NA	R (22OCT2021)	N/N
Placebo/ [redacted]	[redacted]	MUSC	Myalgia/ MUSCULAR PAIN	2	11SEP2021	41	3	2	No	O: DELIVERY	NA/TC	R (13SEP2021)	N/N
Placebo/ [redacted]	[redacted]	INV	Ultrasound foetal abnormal/ Abnormal fetal doppler and signs of decompensation	2	31AUG2021	50	3	1	No	O: Changes during pregnancy - USS updates	NA	R (02SEP2021)	Y/N
Placebo/ [redacted]	[redacted]	PREG	Prolonged rupture of membranes/ Prolonged Rupture of Membranes	2	03DEC2021	78	4	1	No	O: Variant of pregnancy	NA/TC	R (06DEC2021)	Y/N

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16.2.7.7.1 Listing of Adverse Events (Maternal)

Vaccine Group (as Administered)/ Participant	Age (Years)	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day[a]	Dur (Days)[b]	Toxicity Grade	Vax Rel[c]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE/ Imm AE (Yes/No)
Placebo/ [redacted]	[redacted]	GASTR	Haemorrhoids/ Hemorrhoids.	2	01JUL2021	9	C	1	No	O: unknown	NA/TC	RG	N/N
Placebo/ [redacted]	[redacted]	GENRL	Asthenia/ Asthenia^	x2	17SEP2021	1	2	2	Yes		NA/TC	R (18SEP2021)	N/N
		MUSC	Myalgia/ Myalgia^	x2	17SEP2021	1	2	2	Yes		NA/TC	R (18SEP2021)	N/N
Placebo/ [redacted]	[redacted]	GENRL	Malaise/ General ill feeling^	x2	09SEP2021	1	2	3	Yes		NA/TC	R (10SEP2021)	N/N
			Pyrexia/ Fever 39 degrees^	x2	09SEP2021	1	2	3	Yes		NA/TC	R (10SEP2021)	N/N
		MUSC	Myalgia/ Myalgia^	x2	09SEP2021	1	2	3	Yes		NA/TC	R (10SEP2021)	N/N
		NERV	Headache/ Headache^	x2	09SEP2021	1	2	3	Yes		NA/TC	R (10SEP2021)	N/N
Placebo/ [redacted]	[redacted]	INFEC	Mastitis/ mastitis^	x2	28OCT2021	15	C	1	No	O: event related with let-down breast milk	NA/TC	N	N/N
Placebo/ [redacted]	[redacted]	INFEC	Pneumonia/ Secondary Bilateral Pneumonia	1	01JUL2021	18	6	3	No	O: Covid 19	NA/TC/TCN	R (06JUL2021)	Y/N
Placebo/ [redacted]	[redacted]	BLOOD	Anaemia/ Anaemia	2	18JUL2021	21	C	1	No	O: Lost blood after pregnancy	NA/TC	RG	N/N
		EAR	Vertigo/ Vertigo	1	23JUN2021	17	2	3	No	O: Uncertain of causality-not a known symptom from IB.	NA	R (24JUN2021)	N/N

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16.2.7.7.1 Listing of Adverse Events (Maternal)

Vaccine Group (as Administered)/ Participant	Age (Years)	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day[a]	Dur (Days)[b]	Toxicity Grade	Vax Rel[c]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE/ Imm AE (Yes/No)
										Possibly pregnancy related.			
		PREG	Foetal hypokinesia/ Reduced fetal movements	2	15JUL2021	18	4	1	No	O: No evidence to suggest reasonable possibility of a relationship	NA/TC	R (18JUL2021)	Y/N
			Postpartum haemorrhage/ Post-partum hemorrhage	2	18JUL2021	21	1	4	No	O: No evidence to suggest reasonable possibility of a relationship	NA/TC	R (18JUL2021)	Y/N
Placebo/ [redacted]	[redacted]	PREG	Foetal hypokinesia/ Reduced fetal movements for about 48 hours	1	26JUN2021	16	3	1	No	O: Can be an indicator of fetal distress in pregnancy	NA	R (28JUN2021)	N/N
Placebo/ [redacted]	[redacted]	GASTR	Constipation/ Constipation	2	03AUG2021	28	7	2	No	O: Post surgery	NA/TC	R (09AUG2021)	N/N
		PREG	Premature delivery/ Preterm delivery	2	03AUG2021	28	2	3	No	O: Placental abruption	NA	R (04AUG2021)	N/N
			Premature separation of placenta/ Placental abruption	2	04AUG2021	29	1	4	No	O: Unknown reason	NA/TCN	R (04AUG2021)	Y/N
Placebo/ [redacted]	[redacted]	PREG	Foetal hypokinesia/ Reduced fetal movement	1	23SEP2021	10	2	1	No	O: Unknown cause	NA/TCN	R (24SEP2021)	N/N

Abbreviations: C = continuing; Dur = duration; FU = follow-up; Imm = immediate. Refer to the AE legend page (Listing 16.2.7.1) for additional definitions.
Note: x1 = First dose of BNT162b2 (30 µg); x2 = Second dose of BNT162b2 (30 µg).
Note: * = Pre-vaccination adverse event; ^ = Event reported after participant was unblinded.
Note: MedDRA (v25.1) coding dictionary applied.
Note: † = Human immunodeficiency virus (HIV)-positive participant.

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16.2.7.7.1 Listing of Adverse Events (Maternal)

Vaccine Group (as Administered)/ Participant	Age (Years)	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day[a]	Dur (Days)[b]	Toxicity Grade	Vax Rel[c]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE/ Imm AE (Yes/No)

Note: Nonserious adverse events related to study intervention with onset within 7 days (excluding immediate adverse event and adverse events leading to withdrawal) after vaccination and identified as reactogenicity events were excluded from the analysis of adverse events. These events were included in the analysis of reactogenicity events.

a. Relative day (Rel Day) = AE start date - date of last vaccination + 1. For an AE that occurred before the date of the first study vaccination, +1 was not added to compute relative day.

b. Duration (days) was calculated as the difference from the start of the first reported event to resolution of the last reported event, inclusive.

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16.2.7.7.2 Listing of Adverse Events (Infant)

Maternal Vaccine Group (as Administered)/ Participant	GA at Birth/ Sex	System Organ Class	Preferred Term/ AE Investigator Text	Onset Date	Dur (Days)[a]	Toxicity Grade	Vax Rel[b]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE (Yes/No)
BNT162b2 (30 µg)/ [redacted]	[redacted]	INV	Apgar score low/ Low Apgar score	09APR2021	1	1	No	O: Normal consequences of delivery	NA	R (09APR2021)	N
BNT162b2 (30 µg)/ [redacted]	[redacted]	INV	Apgar score low/ Low Apgar Score	01JUN2021	1	1	No	O: Difficult Birth - Breathing effort/O2 required	NA	R (01JUN2021)	N
BNT162b2 (30 µg)/ [redacted]	[redacted]	INV	Apgar score low/ Low Apgar Score	26JUN2021	1	1	No	O: Low O2 due to meconium and nuchal cord	NA	R (26JUN2021)	N
BNT162b2 (30 µg)/ [redacted]	[redacted]	INV	Apgar score low/ Low APGAR Score	04AUG2021	1	1	No	O: Normal Birth	NA	R (04AUG2021)	N
BNT162b2 (30 µg)/ [redacted]	[redacted]	INV	Oxygen saturation decreased/ Low O2 saturations at birth	27APR2021	1	1	No	O: Low O2 at birth	NA/TCN	R (27APR2021)	N
BNT162b2 (30 µg)/ [redacted]	[redacted]	RESP	Nasal congestion/ Nasal Congestion^	05JAN2022	C	1	No	O: unknown	NA	N	N
BNT162b2 (30 µg)/ [redacted]	[redacted]	METAB	Hypoglycaemia/ Hypoglycemia	13MAY2021	1	1	No	O: physiological	NA	R (13MAY2021)	N
		PREG	Meconium stain/ light meconium stain	13MAY2021	1	1	No	O: physiological	NA	R (13MAY2021)	N

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16.2.7.7.2 Listing of Adverse Events (Infant)

Maternal Vaccine Group (as Administered)/ Participant	GA at Birth/ Sex	System Organ Class	Preferred Term/ AE Investigator Text	Onset Date	Dur (Days)[a]	Toxicity Grade	Vax Rel[b]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE (Yes/No)
		RESP	Tachypnoea/ tachypnea	13MAY2021	1	1	No	O: physiological	NA	R (13MAY2021)	N
BNT162b2 (30 µg)/ [redacted]	[redacted]	INFEC	Beta haemolytic streptococcal infection/ SUSPECTED GROUP B STREPTOCOCCAL INFECTION	07JUN2021	3	1	No	O: POSSIBLE MATERNAL GROUP B STREPTOCOCCAL INFECTION	NA	R (09JUN2021)	N
BNT162b2 (30 µg)/ [redacted]	[redacted]	INV	Cardiac murmur/ GRADE 1/6 SEM (HEART MURMUR)	04AUG2021	3	1	No	O: NORMAL FLOW PATTERNS	NA	R (06AUG2021)	N
BNT162b2 (30 µg)/ [redacted]	[redacted]	CONG	Congenital naevus/ Mongolian Spot	15AUG2021	19	1	No	O: Unknown	NA	R (02SEP2021)	N
		MUSC	Small fontanelle/ SMALL ANTERIOR FONTANELLE FLAT AND SOFT	15AUG2021	26	1	No	O: Unknown	NA	R (09SEP2021)	N
		PREG	Caput succedaneum/ CAPUT SUCCEDANEUM	15AUG2021	26	1	No	O: Unknown	NA	R (09SEP2021)	N
		SKIN	Macule/ ERYTHEMATOUS MACULE ON UPPER MID ABDOMEN	15AUG2021	C	1	No	O: Unknown	NA	N	N
BNT162b2 (30 µg)/ [redacted]	[redacted]	INFEC	Fungal infection/ Yeast infection	26SEP2021	8	1	No	O: unk	NA/TC	R (03OCT2021)	N

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16.2.7.7.2 Listing of Adverse Events (Infant)

Maternal Vaccine Group (as Administered)/ Participant	GA at Birth/ Sex	System Organ Class	Preferred Term/ AE Investigator Text	Onset Date	Dur (Days)[a]	Toxicity Grade	Vax Rel[b]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE (Yes/No)
BNT162b2 (30 µg)/ [redacted]	[redacted]	GENRL	Hypothermia/ hypothermic episode 36.3C	04MAY2021	1	1	No	O: unknown etiology, unrelated to study treatment	NA	R (04MAY2021)	N
BNT162b2 (30 µg)/ [redacted]	[redacted]	CONG	Ankyloglossia congenital/ simple tongue-tie	16JUN2021	C	1	No	O: unknown etiology	NA	N	N
		MUSC	Joint noise/ left hip click	15JUN2021	119	1	No	O: unknown etiology	NA	R (11OCT2021)	N
BNT162b2 (30 µg)/ [redacted]	[redacted]	CONG	Microcephaly/ microcephaly	22JUN2021	C	3	No	O: unknown etiology	NA	N	Y
		PREG	Jaundice neonatal/ neonatal jaundice	25JUN2021	C	1	No	O: unknown etiology	NA	N	N
			Small for dates baby/ small for gestational age	25JUN2021	C	3	No	O: unknown etiology	NA	N	Y
BNT162b2 (30 µg)/ [redacted]	[redacted]	CONG	Atrial septal defect/ fenestrated atrial septal defect	27JUL2021	C	1	No	O: unknown etiology	NA	N	Y
BNT162b2 (30 µg)/ [redacted]	[redacted]	RESP	Nasal congestion/ Significant nasal congestion	17APR2021	8	1	No	O: Unknown	NA	R (24APR2021)	N
BNT162b2 (30 µg)/	[redacted]	PREG	Jaundice neonatal/ Neonatal Jaundice: Mild	09APR2021	3	1	No	O: Birth Related	NA	R (11APR2021)	N

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16.2.7.7.2 Listing of Adverse Events (Infant)

Maternal Vaccine Group (as Administered)/ Participant	GA at Birth/ Sex	System Organ Class	Preferred Term/ AE Investigator Text	Onset Date	Dur (Days)[a]	Toxicity Grade	Vax Rel[b]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE (Yes/No)
[redacted]											
BNT162b2 (30 µg)/ [redacted]	[redacted]	INJ&P	Clavicle fracture/ Displaced Midclavicular Diaphyseal Fracture	15MAY2021	C	1	No	O: Birth related injury	NA	RG	N
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Jaundice neonatal/ Neonatal Jaundice	05JUN2021	2	1	No	O: Physiologic Occurrence in Neonates	NA	R (06JUN2021)	N
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Jaundice neonatal/ Neonatal Jaundice	25MAY2021	17	1	No	O: Physiologic occurrence	NA	R (10JUN2021)	N
			Large for dates baby/ Large for gestational age	25MAY2021	17	1	No	O: Family history of large babies	NA	R (10JUN2021)	N
BNT162b2 (30 µg)/ [redacted]	[redacted]	GASTR	Allergic colitis/ Allergic Colitis.	20AUG2021	116	1	No	O: Unknown	NA	R (13DEC2021)	Y
			Allergic gastroenteritis/ Allergic Gastroenterocolitis	20AUG2021	116	1	No	O: Unknown	NA	R (13DEC2021)	Y
		INV	Cardiac murmur/ Cardiac Murmur	30JUL2021	96	1	No	O: Congenital anomaly or birth defect	NA	R (02NOV2021)	Y
		PREG	Jaundice neonatal/ Neonatal Jaundice	03AUG2021	18	1	No	O: Physiologic condition in neonates	NA	R (20AUG2021)	N
BNT162b2 (30 µg)/	[redacted]	INV	Cardiac murmur/ Physiologic cardiac murmur	25AUG2021	2	1	No	O: Physiologic occurrence	NA	R (26AUG2021)	N

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16.2.7.7.2 Listing of Adverse Events (Infant)

Maternal Vaccine Group (as Administered)/ Participant	GA at Birth/ Sex	System Organ Class	Preferred Term/ AE Investigator Text	Onset Date	Dur (Days)[a]	Toxicity Grade	Vax Rel[b]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE (Yes/No)
[redacted]											
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Shoulder dystocia/ Shoulder Dystocia	03JUL2021	C	1	No	O: Birth Injury	NA	RG	N
BNT162b2 (30 µg)/ [redacted]	[redacted]	CONG	Polydactyly/ Polydactyly of fingers on bilateral hands.	14AUG2021	C	1	No	O: History of polydactyly in father and father's siblings	NA	N	Y
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Large for dates baby/ Large for gestational age	09AUG2021	11	1	No	O: Mother with type 1 diabetes	NA	R (19AUG2021)	N
BNT162b2 (30 µg)/ [redacted]	[redacted]	CONG	Naevus flammeus/ NEVUS SIPLEX TO GLABELLA	03NOV2021	C	1	No	O: PHYSIOLOGICAL OCCURENCE	NA	RG	N
		PREG	Jaundice neonatal/ Neonatal Jaundice	04NOV2021	9	1	No	O: Physiologic Occurrence.	NA	R (12NOV2021)	N
BNT162b2 (30 µg)/ [redacted]	[redacted]	CONG	Congenital naevus/ Mongolian spot	25OCT2021	C	1	No	O: Birth Mark	NA	N	N
		NEOPL	Melanocytic naevus/ Nevus on Right Forearm	25OCT2021	C	1	No	O: Unknown	NA	RG	N
		PREG	Jaundice neonatal/ Neonatal Jaundice	27OCT2021	9	1	No	O: Physiologic Occurrence	NA	R (04NOV2021)	N

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16.2.7.7.2 Listing of Adverse Events (Infant)

Maternal Vaccine Group (as Administered)/ Participant	GA at Birth/ Sex	System Organ Class	Preferred Term/ AE Investigator Text	Onset Date	Dur (Days)[a]	Toxicity Grade	Vax Rel[b]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE (Yes/No)
BNT162b2 (30 µg)/ [redacted]	[redacted]	CONG	Congenital naevus/ Mongolian Spot	14DEC2021	C	1	No	O: Birth Mark	NA	RG	N
		SKIN	Hypertrichosis/ Tuft of hair on the lower Back	14DEC2021	C	1	No	O: Unknown	NA	RG	N
BNT162b2 (30 µg)/ [redacted]	[redacted]	CONG	Atrial septal defect/ patent foramen ovale	13MAY2021	C	1	No	O: common congenital abnormality	NA	N	Y
BNT162b2 (30 µg)/ [redacted]	[redacted]	CONG	Atrial septal defect/ Atrial septal defect	26JUL2021	C	2	No	O: Unknown (this is a common abnormality seen in newborns)	NA	N	Y
		NERV	Nervous system disorder/ Neonatal central nervous system abnormality	26JUL2021	C	3	No	O: Possible unknown genetic condition	NA/TC/TCN	N	Y
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Low birth weight baby/ LOW BIRTH WEIGHT	22SEP2021	C	1	No	O: UNKNOWN	NA	N	N
BNT162b2 (30 µg)/ [redacted]	[redacted]	HEPAT	Hyperbilirubinaemia neonatal/ Neonatal hyperbilirubinemia	09AUG2021	4	1	No	O: Immature hepatocytes	NA	R (12AUG2021)	N
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Small for dates baby/ Small for gestational age	15NOV2021	1	1	No	O: Unknown	NA	R (15NOV2021)	N

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16.2.7.7.2 Listing of Adverse Events (Infant)

Maternal Vaccine Group (as Administered)/ Participant	GA at Birth/ Sex	System Organ Class	Preferred Term/ AE Investigator Text	Onset Date	Dur (Days)[a]	Toxicity Grade	Vax Rel[b]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE (Yes/No)
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Jaundice neonatal/ Neonatal jaundice	29JAN2022	3	1	No	O: Physiological	NA	R (31JAN2022)	Y
		RESP	Meconium aspiration syndrome/ Mecanium aspiration syndrome	27JAN2022	3	2	No	O: Delivery	NA/TC	R (29JAN2022)	Y
BNT162b2 (30 µg)/ [redacted] †	[redacted]	PREG	Small for dates baby/ SMALL FOR GESTATIONAL AGE	02JAN2022	1	1	No	O: UNKNOWN	NA	R (02JAN2022)	N
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Jaundice neonatal/ Neonatal Jaundice	18SEP2021	4	1	No	O: Jaundice	NA/TCN	R (21SEP2021)	Y
BNT162b2 (30 µg)/ [redacted]	[redacted]	RESP	Meconium aspiration syndrome/ Meconium aspiration syndrome	11DEC2021	3	2	No	O: meconium aspiration	NA/TC	R (13DEC2021)	Y
BNT162b2 (30 µg)/ [redacted]	[redacted]	CONG	Syndactyly/ Syndactyly toes,bilateral	30DEC2021	C	1	No	O: congenital anomaly	NA	N	Y
BNT162b2 (30 µg)/ [redacted]	[redacted]	CONG	Congenital rubella syndrome/ Congenital Rubella Syndrome	23DEC2021	C	2	No	O: Congenital Rubella	NA	N	Y
			Mucopolysaccharidosis/ Mucopolysaccharidosis	23DEC2021	C	2	No	O: Congenital anomaly	NA	N	Y

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16.2.7.7.2 Listing of Adverse Events (Infant)

Maternal Vaccine Group (as Administered)/ Participant	GA at Birth/ Sex	System Organ Class	Preferred Term/ AE Investigator Text	Onset Date	Dur (Days)[a]	Toxicity Grade	Vax Rel[b]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE (Yes/No)
		INFEC	Neonatal pneumonia/ Neonatal Pneumonia	23DEC2021	5	2	No	O: Aspirated liqor in utero	NA/TC/TCN	R (27DEC2021)	Y
BNT162b2 (30 µg)/ [redacted]	[redacted]	CONG	Trisomy 21/ down's syndrome	23JUL2021	C	3	No	O: down's syndrome	NA	N	Y
BNT162b2 (30 µg)/ [redacted]†	[redacted]	INFEC	Pneumonia/ PNEUMONIA^	12MAY2022	6	4	No	O: INFECTION	NA/W	F (17MAY2022)	Y
BNT162b2 (30 µg)/ [redacted]	[redacted]	INFEC	Bronchiolitis/ nonspecific viral bronchiolitis^	14JAN2022	C	2	No	O: virus	NA/TC	N	Y
BNT162b2 (30 µg)/ [redacted]	[redacted]	GASTR	Infantile colic/ Infant Colic^	08SEP2021	3	1	No	O: Unknown	NA	R (10SEP2021)	N
		PREG	Jaundice neonatal/ Neonatal Jaundice	11AUG2021	8	1	No	O: common for preterm babies	NA/TCN	R (18AUG2021)	N
		SKIN	Dermatitis atopic/ Atopic Dermatitis^	08SEP2021	C	1	No	O: unknown	NA	N	N
BNT162b2 (30 µg)/ [redacted]	[redacted]	CONG	Hydrocele/ Hydrocele	28JUL2021		1	No	O: Unknown	NA	UNK	N
BNT162b2 (30 µg)/	[redacted]	PREG	Jaundice neonatal/ Neonatal jaundice	05AUG2021	1	1	No	O: Physiological	NA	R (05AUG2021)	N

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16.2.7.7.2 Listing of Adverse Events (Infant)

Maternal Vaccine Group (as Administered)/ Participant	GA at Birth/ Sex	System Organ Class	Preferred Term/ AE Investigator Text	Onset Date	Dur (Days)[a]	Toxicity Grade	Vax Rel[b]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE (Yes/No)
[redacted]											
BNT162b2 (30 µg)/ [redacted]	[redacted]	RESP	Cyanosis neonatal/ Neonatal cyanosis	12JUL2021	1	2	No	O: Unknown	NA	R (12JUL2021)	N
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Birth trauma/ Birth trauma grade II	20JUL2021	36	1	No	O: Unknown	NA/TC	R (24AUG2021)	N
			Caput succedaneum/ Caput succedaneum	20JUL2021	36	1	No	O: Unknown	NA/TC	R (24AUG2021)	N
			Jaundice neonatal/ Neonatal jaundice	21JUL2021		1	No	O: Unknown	NA/TCN	UNK	N
BNT162b2 (30 µg)/ [redacted]	[redacted]	CARD	Bradycardia/ Bradycardia	23AUG2021	1	2	No	O: Delayed fetal extraction	NA/TC	R (23AUG2021)	N
		NERV	Hypotonia/ Hypotonia	23AUG2021	1	1	No	O: Delayed fetal extraction	NA/TC	R (23AUG2021)	N
		RESP	Respiratory distress/ Adaptive respiratory distress	23AUG2021	1	1	No	O: Elective cesarean	NA/TC	R (23AUG2021)	N
		VASC	Cyanosis/ Cyanosis	23AUG2021	1	1	No	O: Delayed fetal extraction	NA/TC	R (23AUG2021)	N
BNT162b2 (30 µg)/ [redacted]	[redacted]	NERV	Hypotonia/ Hypotonia	23AUG2021	1	1	No	O: Hypoxia due to prolonged labor	NA	R (23AUG2021)	N

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16.2.7.7.2 Listing of Adverse Events (Infant)

Maternal Vaccine Group (as Administered)/ Participant	GA at Birth/ Sex	System Organ Class	Preferred Term/ AE Investigator Text	Onset Date	Dur (Days)[a]	Toxicity Grade	Vax Rel[b]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE (Yes/No)
		PREG	Caput succedaneum/ Caput succedaneum	23AUG2021	2	1	No	O: Passage of the head in the birth canal for a prolonged time.	NA	R (24AUG2021)	N
			Jaundice neonatal/ NEONATAL JAUNDICE	25AUG2021	2	1	No	O: Physiological jaundice	NA	R (26AUG2021)	N
		RESP	Meconium aspiration syndrome/ Meconium aspiration	23AUG2021	1	1	No	O: Prolonged labor	NA	R (23AUG2021)	N
			Nasal obstruction/ Nasal obstruction	23AUG2021	1	1	No	O: Etiology unknown	NA	R (23AUG2021)	N
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Low birth weight baby/ Low birth weight	04AUG2021	C	1	No	O: Unknown	NA/TCN	RG	Y
BNT162b2 (30 µg)/ [redacted]	[redacted]	CONG	Hydrocele/ Hydrocele	06AUG2021	C	1	No	O: Unknown	NA	RG	N
		PREG	Jaundice neonatal/ NEONATAL JAUNDICE	08AUG2021		1	No	O: Unknown	NA	UNK	N
		RESP	Respiratory disorder/ Respiratory discomfort	06AUG2021	1	1	No	O: Unknown	NA/TCN	R (06AUG2021)	N
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Jaundice neonatal/ Jaundice neonatal	27AUG2021	4	1	No	O: Physiological Jaundice	NA/TCN	R (30AUG2021)	Y
		SKIN	Transient neonatal pustular melanosis/	26AUG2021	C	1	No	O: Etiology unknown	NA	RG	N

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Maternal Vaccine Group (as Administered)/ Participant	GA at Birth/ Sex	System Organ Class	Preferred Term/ AE Investigator Text	Onset Date	Dur (Days)[a]	Toxicity Grade	Vax Rel[b]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE (Yes/No)
			TRANSIENT NEONATAL PUSTULAR MELANOSIS								
BNT162b2 (30 µg)/ [redacted]	[redacted]	GENRL	Macrosomia/ Macrosomia	25AUG2021	1	1	No	O: Unknown	NA	R (25AUG2021)	N
BNT162b2 (30 µg)/ [redacted]	[redacted]	GASTR	Constipation/ constipation	12SEP2021	3	1	No	O: intestinal immaturity	NA	R (14SEP2021)	N
BNT162b2 (30 µg)/ [redacted]	[redacted]	EYE	Dacryostenosis acquired/ dacryostenosis acquired	04NOV2021	6	1	No	O: Tear duct obstruction	NA/TC	R (09NOV2021)	N
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Jaundice neonatal/ Neonatal jaundice	21SEP2021	4	1	No	O: high bilirubin levels	NA	R (24SEP2021)	Y
		SURG	Tongue tie operation/ lingual frenulum (frenectomy)	19SEP2021	41	1	No	O: ligament that connects the tongue to the palate	NA/TC	R (29OCT2021)	N
BNT162b2 (30 µg)/ [redacted]	[redacted]	GASTR	Gastrooesophageal reflux disease/ gastroesophageal reflux^	24OCT2021	C	2	No	O: feeding issues	NA/TC	RG	N
BNT162b2 (30 µg)/ [redacted]	[redacted]	GENRL	Pyrexia/ fever post bexsero vaccination^	01DEC2021	2	1	No	O: Bexsero vaccination	NA	R (02DEC2021)	N

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Maternal Vaccine Group (as Administered)/ Participant	GA at Birth/ Sex	System Organ Class	Preferred Term/ AE Investigator Text	Onset Date	Dur (Days)[a]	Toxicity Grade	Vax Rel[b]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE (Yes/No)
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Jaundice neonatal/ Hyperbilirubinaemia neonatal - neonatal jaundice	04AUG2021	4	3	No	O: Unknown	NA	R (07AUG2021)	Y
BNT162b2 (30 µg)/ [redacted]	[redacted]	CONG	DiGeorge's syndrome/ Digeorge syndrome	15JUL2021	C	3	No	O: congenital disease	NA	N	Y
		INFEC	Pyelonephritis acute/ acute pyelonephritis	23JUL2021	6	4	No	O: Bacterial infection. Urineculture with E. coli and Enterococcus faecalis.	NA/TC	R (28JUL2021)	Y
			Pyelonephritis/ pyelonephritis^	23AUG2021	5	3	No	O: infection	NA/TC	R (27AUG2021)	Y
			Pyelonephritis/ pyelonephritis^	23DEC2021	3	3	No	O: infection	NA/TC	R (25DEC2021)	Y
		RENAL	Vesicoureteric reflux/ Vesicoureteral reflux	15JUL2021	C	4	No	O: UNK	NA	N	Y
			Pyelocaliectasis/ Right distal ureteral dilation with bilateral pyele ectasia	22JUL2021	C	2	No	O: congenital anomaly	NA	N	N
BNT162b2 (30 µg)/ [redacted]	[redacted]	INFEC	Bronchiolitis/ Acute Bronchiolitis^	06DEC2021	7	3	No	O: respiratory syncytial virus	NA/TC/TCN	R (12DEC2021)	Y
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Jaundice neonatal/ Neonatal Jaundice	22JUL2021	4	1	No	O: very usual event in newly born	NA/TCN	R (25JUL2021)	Y

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BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Low birth weight baby/ low birth weight	05SEP2021	5	1	No	O: usual event related to pregnancy	NA	R (09SEP2021)	N
			Jaundice neonatal/ Neonatal Jaundice	07SEP2021	3	1	No	O: very usual event in newly born	NA/TCN	R (09SEP2021)	Y
Placebo/ [redacted]	[redacted]	CONG	Ankyloglossia congenital/ Congenital Ankyloglossia	08AUG2021	2	1	No	O: unknown	NA	R (09AUG2021)	Y
		GASTR	Dysphagia/ Dysphagia	08AUG2021	2	1	No	O: Unkown	NA	R (09AUG2021)	Y
Placebo/ [redacted]	[redacted]	INV	Apgar score low/ Low Apgar score of 4	05JUL2021	2	2	No	O: low oxygen at birth	NA	R (06JUL2021)	N
Placebo/ [redacted]	[redacted]	INFEC	Pneumonia respiratory syncytial viral/ RSV pneumonia^	22SEP2021	12	3	No	O: Viral	NA/TC	R (03OCT2021)	Y
Placebo/ [redacted]	[redacted]	CONG	Ventricular septal defect/ Ventricular Septal Defect	13AUG2021	C	1	No	O: congenital anamoly	NA	N	Y
		RESP	Hypoxia/ Hypoxia	13AUG2021	5	2	No	O: Periodic desaturations requiring CPAP to provide resipratory support.	NA/TC/TCN	R (17AUG2021)	Y
Placebo/ [redacted]	[redacted]	INV	Cardiac murmur/ Soft Heart Murmur	12JUN2021	1	1	No	O: Physiological	NA	R (12JUN2021)	N
		PREG	Hypothermia neonatal/ mild hypothermia after birth	12JUN2021	1	1	No	O: Physiological	NA	R (12JUN2021)	N

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Maternal Vaccine Group (as Administered)/ Participant	GA at Birth/ Sex	System Organ Class	Preferred Term/ AE Investigator Text	Onset Date	Dur (Days)[a]	Toxicity Grade	Vax Rel[b]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE (Yes/No)
Placebo/ [redacted]	[redacted]	CONG	Ankyloglossia congenital/ mild congenital ankyloglossia	17JUN2021	3	1	No	O: Frenectomy performed	NA	R (19JUN2021)	N
			Congenital skin dimples/ Simple Sacral dimple	17JUN2021	C	1	No	O: congenital anomaly	NA	RG	Y
Placebo/ [redacted]	[redacted]	BLOOD	Coagulopathy/ COAGULOPATHY	28APR2021	11	3	No	O: BIRTH TRAUMA	NA/TC	R (08MAY2021)	Y
			Thrombocytopenia/ Thrombocytopenia	30APR2021	9	2	No	O: LOW PLATELET PRODUCTION	NA	R (08MAY2021)	Y
		ENDO	Adrenal insufficiency/ ADRENAL INSUFFICIENCY	28APR2021	14	2	No	O: UNPRODUCTIVE ADRENAL GLANDS	NA/TC	R (11MAY2021)	N
		GASTR	Intestinal perforation/ INTESTINAL PERFORATION	05MAY2021	8	3	No	O: HYPOXIC ISCHEMIC ENCEPHALOPATHY	NA	R (12MAY2021)	Y
			Pneumoperitoneum/ Pneumoperitoneum	05MAY2021	1	3	No	O: INTESTINAL PERFORATION	NA	R (05MAY2021)	Y
		HEPAT	Hepatic function abnormal/ LIVER DYSFUNCTION	28APR2021	14	2	No	O: HYPOXIC ISCHEMIC ENCEPHALOPATHY	NA	R (11MAY2021)	N
		INFEC	Sepsis/ SEPSIS	13MAY2021	7	3	No	O: BACTERIAL INFECTION	NA/TC	R (19MAY2021)	Y
		METAB	Hypoglycaemia neonatal/ NEONATAL HYPOGLYCEMIA	28APR2021	7	2	No	O: HYPOXIC ISCHEMIC ENCEPHALOPATHY	NA	R (04MAY2021)	N
			Metabolic acidosis/ Metabolic Acidosis	28APR2021	7	4	No	O: BIRTH ASPHYXIA	NA/TC	R (04MAY2021)	Y
			Hypernatraemia/ HYPERNATREMIA	08MAY2021	4	2	No	O: KIDNEY DYSFUNCTION	NA	R (11MAY2021)	N

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			Hypercalcaemia/ HYPERCALCEMIA	25MAY2021	115	2	No	O: KIDNEY FAILURE TREATMENT	NA	R (16SEP2021)	N
		NERV	Coma/ COMA	28APR2021	2	3	No	O: HYPOXIC ISCHEMIA ENCEPHOLOPATHY	NA	R (29APR2021)	Y
			Hypoxic-ischaemic encephalopathy/ Hypoxic Ischemic Encephalopathy	28APR2021	C	4	No	O: delivery complications	NA/TC	N	Y
			Intraventricular haemorrhage neonatal/ Neonatal Germinal Matrix Hemorrhage Grade 1	28APR2021	3	2	No	O: Delivery	NA	R (30APR2021)	N
			Seizure/ SEIZURES	03MAY2021	1	2	No	O: HYPOXIC ISCHEMIC ENCEPHALOPATHY	NA/TC	R (03MAY2021)	Y
		RENAL	Renal tubular necrosis/ Renal Failure (Acute Tubular Necrosis)	28APR2021	28	3	No	O: HYPOXIC ISCHEMIC ENCEPHALOPATHY	NA/TC	R (25MAY2021)	Y
		RESP	Pulmonary hypertension/ PULMONARY HYPERTENSION	28APR2021	7	3	No	O: HYPOXIC ISCHEMIC ENCEPHALOPATHY	NA	R (04MAY2021)	Y
			Respiratory failure/ RESPIRATORY FAILURE	28APR2021	7	3	No	O: HYPOXIC ISCHEMIC ENCEPHALOPATHY	NA/TCN	R (04MAY2021)	Y
			Tachypnoea/ TACHYPNEA	04MAY2021	21	2	No	O: PULMONARY HYPERTENSION	NA	R (24MAY2021)	N
		VASC	Hypoperfusion/ HYPOPERFUSION	28APR2021	2	3	No	O: HYPOXIC ISCHEMIA ENCEPHALOPATHY	NA	R (29APR2021)	Y
			Hypotension/ HYPOTENSION	28APR2021	6	3	No	O: SHOCK	NA	R (03MAY2021)	Y

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			Shock/ SHOCK	28APR2021	1	3	No	O: HYPOXIC ISCHEMIC ENCEPHALOPATHY	NA	R (28APR2021)	Y
			Renovascular hypertension/ HYPERTENSION - RENOVASCULAR ONLY	04MAY2021	3	2	No	O: ACUTE TUBULAR NECROSIS	NA	R (06MAY2021)	N
			Hypotension/ HYPOTENSION	06MAY2021	2	2	No	O: HYPOXIC ISCHEMIC ENCEPHALOPATHY	NA	R (07MAY2021)	Y
			Hypertension/ HYPERTENSION	10MAY2021	C	2	No	O: PULMONARY HYPERTENSION	NA/TC	N	N
Placebo/ [redacted]	[redacted]	METAB	Hypoglycaemia neonatal/ NEONATAL HYPOGLYCEMIA	24MAY2021	2	2	No	O: MECONIUM ASPIRATION SYNDROME	NA/TC	R (25MAY2021)	N
		PREG	Caput succedaneum/ CAPUT SUCCEDANEUM	24MAY2021	3	1	No	O: BIRTH TRAUMA	NA	R (26MAY2021)	N
		RESP	Meconium aspiration syndrome/ MECONIUM ASPIRATION SYNDROME	24MAY2021	1	2	No	O: MECONIUM STAINED AMIOTIC FLUID	NA	R (24MAY2021)	N
		VASC	Cyanosis/ Cyanosis	24MAY2021	1	2	No	O: NEONATAL HYPOGLYCEMIA	NA	R (24MAY2021)	N
Placebo/ [redacted]	[redacted]	INFEC	Candida infection/ Thrush	03AUG2021	4	2	No	O: Bottle feeding	NA/TC	R (06AUG2021)	N
Placebo/ [redacted]	[redacted]	CONG	Phimosis/ PHIMOSIS	29JUL2021	1	2	No	O: tightening of the foreskin	NA/TCN	R (29JUL2021)	N
		INJ&P	Contusion/ BRUISING TO FACE AND HEAD	27JUL2021	36	2	No	O: BIRTH TRAUMA	NA	R (31AUG2021)	N

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			Exposure to communicable disease/ Exposure to confirm Positive Group B Strep	27JUL2021	1	1	No	O: None	NA	R (27JUL2021)	N
		PREG	Caput succedaneum/ MODERATE CAPUT SUCCEDANEUM TO POSTERIOR SCALP	27JUL2021	C	2	No	O: BIRTH TRAUMA	NA	N	N
			Shoulder dystocia/ SHOULDER DYSTOCIA	27JUL2021	1	2	No	O: Large baby, stuck in birth canal during birth.	NA	R (27JUL2021)	N
		RESP	Neonatal respiratory distress/ RESPIRATORY DISTRESS IN THE NEONATE	27JUL2021	1	3	No	O: BIRTH TRAUMA	NA/TCN	R (27JUL2021)	Y
Placebo/ [redacted]	[redacted]	PREG	Umbilical cord around neck/ Nuchal cord	29APR2021	1	1	No	O: common anomaly	NA	R (29APR2021)	N
Placebo/ [redacted]	[redacted]	INFEC	Infection/ Infection of unknown origin	29MAY2021	3	1	No	O: unknown etiology	NA/TC	R (31MAY2021)	N
		INV	Apgar score low/ Low Apgar score	29MAY2021	1	3	No	O: pneumothorax in infant	NA	R (29MAY2021)	N
		RESP	Neonatal pneumothorax/ pneumothorax in infant	29MAY2021	1	4	No	O: unknown etiology	NA/TC/TCN	R (29MAY2021)	Y
			Neonatal respiratory failure/ Respiratory failure in newborn	29MAY2021	3	4	No	O: Pneumothorax	NA/TCN	R (31MAY2021)	Y
Placebo/ [redacted]	[redacted]	PREG	Umbilical cord around neck/ Loose nuchal cord	11JUN2021	1	1	No	O: common delivery complication	NA	R (11JUN2021)	N

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Placebo/ [redacted]	[redacted]	GENRL	Hypothermia/ hypothermic episode	13JUL2021	1	1	No	O: unknown etiology	NA	R (13JUL2021)	N
Placebo/ [redacted]	[redacted]	CONG	Congenital skin dimples/ Congenital Pilonidal dimple	28JUN2021	C	1	No	O: unknown etiology	NA	N	N
			Ankyloglossia congenital/ Ankyloglossia congenital	29JUN2021	1	2	No	O: unknown etiology	NA	R (29JUN2021)	Y
		GENRL	Hypothermia/ Hypothermic episode	28JUN2021	1	2	No	O: unknown etiology	NA	R (28JUN2021)	N
		HEPAT	Hyperbilirubinaemia neonatal/ neonatal hyperbilirubinemia	29JUN2021	5	3	No	O: unknown etiology	NA	R (03JUL2021)	Y
Placebo/ [redacted]	[redacted]	HEPAT	Hyperbilirubinaemia neonatal/ Neonatal Unconjugated Hyperbilirubinemia	27MAY2021	2	1	No	O: Physiologic Occurrence	NA	R (28MAY2021)	N
		PREG	Small for dates baby/ Small for Gestational Age	26MAY2021	C	1	No	O: Intrauterine Cannabis Exposure	NA	RG	N
			Umbilical cord around neck/ Nuchal Cord x1	26MAY2021	1	3	No	O: Unknown	NA	R (26MAY2021)	N
Placebo/ [redacted]	[redacted]	RESP	Transient tachypnoea of the newborn/ Transient tachypnea of newborn	10MAY2021	3	1	No	O: Physiological occurrence	NA	R (12MAY2021)	N
Placebo/ [redacted]	[redacted]	PREG	Jaundice neonatal/ Neonatal Jaundice	18JUL2021	3	1	No	O: Physiologic Occurrence	NA/TCN	R (20JUL2021)	N
			Small for dates baby/ Small for Gestational Age	18JUL2021	8	1	No	O: Small sized parent	NA	R (25JUL2021)	N

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		SKIN	Erythema toxicum neonatorum/ Erythema Toxicum	18JUL2021	C	1	No	O: Cause-Unknown	NA	RG	N
Placebo/ [redacted]	[redacted]	PREG	Jaundice neonatal/ Neonatal Jaundice	30MAY2021	2	1	No	O: Physiologic occurrence in neonates	NA	R (31MAY2021)	N
Placebo/ [redacted]	[redacted]	PREG	Jaundice neonatal/ Newborn Physiologic Jaundice	17MAY2021	2	1	No	O: Normal Physiologic Occurrence in Neonate	NA	R (18MAY2021)	N
			Small for dates baby/ Small for Gestational Age Neonate	17MAY2021	2	1	No	O: Birth Related	NA	R (18MAY2021)	N
Placebo/ [redacted]	[redacted]	CONG	Ankyloglossia congenital/ Ankyloglossia Congenital	11JUN2021	18	2	No	O: Unknown	NA/TCN	R (28JUN2021)	N
		PREG	Foetal cardiac disorder/ Fetal Pericardial Effusion	11JUN2021	3	1	No	O: Physiologic Occurrence in Neonates	NA	RS (13JUN2021)	N
			Jaundice neonatal/ Neonatal Jaundice	11JUN2021	3	1	No	O: Physiologic Occurrence in Neonates	NA	R (13JUN2021)	N
Placebo/ [redacted]	[redacted]	PREG	Jaundice neonatal/ Neonatal Jaundice	29JUL2021	6	1	No	O: Physiologic Occurrence	NA	R (03AUG2021)	N
Placebo/ [redacted]	[redacted]	PREG	Jaundice neonatal/ Neonatal Jaundice	25JUL2021	3	1	No	O: Physiological Occurrence	NA	R (27JUL2021)	N
Placebo/ [redacted]	[redacted]	CONG	Atrial septal defect/ Patent Foramen Oval (PFO)	15JUN2021	65	1	No	O: Genetic	NA	R (18AUG2021)	Y

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			Patent ductus arteriosus/ Small Patent Ductus Arteriosus	15JUN2021	65	1	No	O: Genetic	NA	R (18AUG2021)	Y
Placebo/ [redacted]	[redacted]	PREG	Umbilical cord around neck/ Nuchal Cord x 2	30JUL2021	1	1	No	O: Unknown	NA	R (30JUL2021)	N
Placebo/ [redacted]	[redacted]	PREG	Postmature baby/ Post term neonate	17AUG2021	1	1	No	O: Unknown	NA	R (17AUG2021)	N
Placebo/ [redacted]	[redacted]	PREG	Small for dates baby/ Small for Gestational Age	23JUL2021	8	1	No	O: Intrauterine Cannabis Exposure	NA	R (30JUL2021)	N
Placebo/ [redacted]	[redacted]	EYE	Dacryostenosis acquired/ Left Nasolacrimal duct stenosis	30AUG2021	17	2	No	O: Unknown	NA	R (15SEP2021)	N
		GASTR	Constipation/ Functional Constipation	30AUG2021	C	1	No	O: unknown	NA	RG	N
		HEPAT	Hyperbilirubinaemia neonatal/ Neonatal Hyperbilirubinemia	13AUG2021	6	1	No	O: Physiologic Occurrence in neonates.	NA	R (18AUG2021)	N
		INFEC	Conjunctivitis/ Acute Conjuctivitis of the left eye	30AUG2021	17	2	No	O: Left Nasolacrimal duct stenosis	NA	R (15SEP2021)	N
		INJ&P	Traumatic intracranial haemorrhage/ Traumatic Intracranial Hemorrhage	12AUG2021	2	1	No	O: Birth related injury	NA	R (13AUG2021)	Y
		PREG	Caput succedaneum/ Caput Succedaneum	12AUG2021	2	1	No	O: Vacuum extraction delivery	NA	R (13AUG2021)	Y
		VASC	Subgaleal haemorrhage/ Subgaleal Hemorrhage	11AUG2021	3	1	No	O: Vacuum extraction delivery	NA	R (13AUG2021)	Y

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Placebo/ [redacted]	[redacted]	PREG	Jaundice neonatal/ Neonatal jaundice	21AUG2021	10	1	No	O: Physiologic occurrence	NA	R (30AUG2021)	N
Placebo/ [redacted]	[redacted]	HEPAT	Hyperbilirubinaemia neonatal/ NEONATAL UNCONJUGATED HYPERBILIRUBINEMIA	12OCT2021	11	1	No	O: PHYSIOLOGICAL OCCURENCE	NA	R (22OCT2021)	N
		PREG	Umbilical cord around neck/ LOOSE NUCHAL CORD	12OCT2021	1	1	No	O: UNKNOWN	NA	R (12OCT2021)	N
Placebo/ [redacted]	[redacted]	PREG	Jaundice neonatal/ Neonatal Jaundice	25SEP2021	10	2	No	O: Physiologic occurrence in neonates	NA/TCN	R (04OCT2021)	N
Placebo/ [redacted]	[redacted]	CONG	Congenital naevus/ Mongolian Spot	03DEC2021	C	1	No	O: Birth mark	NA	N	N
		HEPAT	Hyperbilirubinaemia neonatal/ NEONATAL HYPERBILIRUBINEMIA	05DEC2021	9	1	No	O: PHYSIOLOGICAL OCCURENCE	NA	R (13DEC2021)	N
Placebo/ [redacted]	[redacted]	RESP	Apnoea/ Apnea	28MAY2021	1	1	No	O: meconium aspiration	NA/TCN	R (28MAY2021)	N
Placebo/ [redacted]	[redacted]	PREG	Low birth weight baby/ LOW BIRTH WEIGHT	01DEC2021	C	1	No	O: PRETERM DELIVERY	NA	RG	N
Placebo/ [redacted]	[redacted]	METAB	Feeding disorder/ feeding difficulty	20DEC2021	2	2	No	O: unknown	NA/TCN	R (21DEC2021)	N

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16.2.7.7.2 Listing of Adverse Events (Infant)

Maternal Vaccine Group (as Administered)/ Participant	GA at Birth/ Sex	System Organ Class	Preferred Term/ AE Investigator Text	Onset Date	Dur (Days)[a]	Toxicity Grade	Vax Rel[b]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE (Yes/No)
Placebo/ [redacted]	[redacted]	INFEC	Ophthalmia neonatorum/ NEONATAL CONJUNCTIVITIS	13NOV2021	4	1	No	O: SUSPECTED BACTERIAL INFECTION	NA/TC	R (16NOV2021)	N
Placebo/ [redacted]	[redacted]	GASTR	Meconium plug syndrome/ Meconium plug	24NOV2021	4	3	No	O: Meconium plug in rectum	NA/TC/TCN	R (27NOV2021)	Y
Placebo/ [redacted] †	[redacted]	INFEC	Gastroenteritis/ Acute gastroenteritis^	07FEB2022	18	3	No	O: Viral or bacterial infection	NA/TC/TCN	RS (24FEB2022)	Y
			Gastroenteritis/ Acute gastroenteritis^	09MAR2022	6	3	No	O: Viral Infection	NA/TC	R (14MAR2022)	Y
			Urinary tract infection/ Urinary tract infection^	09MAR2022	6	1	No	O: Bacterial infection	NA/TC	R (14MAR2022)	Y
		INJ&P	Exposure to communicable disease/ HIV EXPOSED	28DEC2021	C	1	No	O: MATERNAL FACTOR	NA/TC	N	N
		METAB	Dehydration/ Hypernatraemic dehydration^	09FEB2022	9	3	No	O: Acute gastroenteritis	NA/TC	R (17FEB2022)	Y
		NERV	Superior sagittal sinus thrombosis/ Sagittal sinus thrombosis^	14FEB2022	11	2	No	O: Hypernatraemic dehydration	NA/TC	RS (24FEB2022)	Y
Placebo/ [redacted]	[redacted]	PREG	Jaundice neonatal/ mild neonatal jaundice	05AUG2021	2	1	No	O: increased bilirubin level	NA	R (06AUG2021)	N
Placebo/ [redacted] †	[redacted]	CONG	Polydactyly/ POLYDACTYLY	18NOV2021	C	1	No	O: CONGENITAL	NA	N	N

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16.2.7.7.2 Listing of Adverse Events (Infant)

Maternal Vaccine Group (as Administered)/ Participant	GA at Birth/ Sex	System Organ Class	Preferred Term/ AE Investigator Text	Onset Date	Dur (Days)[a]	Toxicity Grade	Vax Rel[b]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE (Yes/No)
Placebo/ [redacted]	[redacted]	INJ&P	Injury to brachial plexus due to birth trauma/ LEFT ARM ERB PALSY	04DEC2021	C	3	No	O: UNKNOWN	NA/TCN	N	Y
		NERV	Encephalopathy neonatal/ NEONATAL ENCEPHALOPATHY	04DEC2021	7	3	No	O: HYPOXAEMIA AT BIRTH	NA/TCN	RS (10DEC2021)	Y
		RESP	Respiratory distress/ RESPIRATORY DISTRESS	04DEC2021	7	3	No	O: UNKNOWN	NA/TC/TCN	R (10DEC2021)	Y
Placebo/ [redacted]	[redacted]	INFEC	Sepsis neonatal/ NEONATAL SEPSIS	29NOV2021	11	3	No	O: INFECTION	NA/TC	R (09DEC2021)	Y
Placebo/ [redacted]†	[redacted]	INFEC	Neonatal pneumonia/ neonatal pneumonia	04DEC2021	3	2	No	O: unknown	NA/TC	R (06DEC2021)	Y
Placebo/ [redacted]	[redacted]	INFEC	Neonatal pneumonia/ neonatal pneumonia	16NOV2021	7	4	No	O: CONGENITAL INFECTION	NA/TC/W	F (22NOV2021)	Y
Placebo/ [redacted]†	[redacted]	PREG	Jaundice neonatal/ neonatal jaundice	05JAN2022	1	1	No	O: physiological	NA	R (05JAN2022)	N
		SKIN	Dermatitis diaper/ nappy rash^	26JAN2022	13	1	No	O: unknown	NA/TC	R (07FEB2022)	N
Placebo/ [redacted]	[redacted]	GASTR	Infantile colic/ Infant Colic	29JUL2021	83	1	No	O: Unknown	NA	R (19OCT2021)	N
			Abdominal distension/ Abdominal Distention	05AUG2021	76	1	No	O: Unknown	NA	R (19OCT2021)	N
		PREG	Jaundice neonatal/ Neonatal Jaundice	29JUL2021	30	1	No	O: Unknown	NA	R (27AUG2021)	N

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16.2.7.7.2 Listing of Adverse Events (Infant)

Maternal Vaccine Group (as Administered)/ Participant	GA at Birth/ Sex	System Organ Class	Preferred Term/ AE Investigator Text	Onset Date	Dur (Days)[a]	Toxicity Grade	Vax Rel[b]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE (Yes/No)
		SKIN	Seborrhoeic dermatitis/ Seborrheic Dermatitis	27AUG2021	1	1	No	O: Unknown	NA	R (27AUG2021)	N
Placebo/ [redacted]	[redacted]	PREG	Caput succedaneum/ Caput Succedanum	26SEP2021	16	1	No	O: as PI stated, often occur during first pregnancy	NA	R (11OCT2021)	N
Placebo/ [redacted]	[redacted]	EYE	Eye discharge/ right eye discharge	17OCT2021	13	1	No	O: unknown	NA	R (29OCT2021)	N
		GASTR	Abdominal pain/ colic^	17NOV2021	15	1	No	O: unknown	NA/TC	R (01DEC2021)	N
		PREG	Jaundice neonatal/ neonatal jaundice	17OCT2021	32	1	No	O: unknown	NA/TCN	R (17NOV2021)	N
		SKIN	Dermal cyst/ Dermal right occipital rice size cyst	17OCT2021	C	1	No	O: unknown	NA	RG	N
Placebo/ [redacted]	[redacted]	HEPAT	Jaundice/ Jaundice	18NOV2021	65	1	No	O: UNKNOWN	NA	R (21JAN2022)	N
		INV	Cardiac murmur/ Heart Murmur	23NOV2021	28	1	No	O: Unknown	NA	RS (20DEC2021)	N
Placebo/ [redacted]	[redacted]	INFEC	Bronchiolitis/ Bronchiolitis^	09AUG2021	12	3	No	O: Unknown	NA/TC/TCN	R (20AUG2021)	Y
Placebo/ [redacted]	[redacted]	PREG	Foetal macrosomia/ Macrosomia (weight=4,200kg)	06AUG2021	C	1	No	O: Unknown	NA	RG	N
Placebo/ [redacted]	[redacted]	RESP	Nasal congestion/ nasal congestion	17JUL2021	4	1	No	O: Unknown	NA	R (20JUL2021)	N

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16.2.7.7.2 Listing of Adverse Events (Infant)

Maternal Vaccine Group (as Administered)/ Participant	GA at Birth/ Sex	System Organ Class	Preferred Term/ AE Investigator Text	Onset Date	Dur (Days)[a]	Toxicity Grade	Vax Rel[b]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE (Yes/No)
Placebo/ [redacted]	[redacted]	GASTR	Tooth development disorder/ Neonatal tooth	01AUG2021	2	1	No	O: Unknown	NA	R (02AUG2021)	N
Placebo/ [redacted]	[redacted]	PREG	Jaundice neonatal/ Neonatal jaundice	30JUL2021	3	1	No	O: Hepatic immaturity	NA/TCN	R (01AUG2021)	Y
Placebo/ [redacted]	[redacted]	EYE	Conjunctival haemorrhage/ Conjunctival hemorrhage in left eye	21AUG2021		1	No	O: Unknown	NA	UNK	N
			Eyelid oedema/ Palpebral edema	21AUG2021	2	1	No	O: Unknown	NA	R (22AUG2021)	N
		MUSC	Newborn head moulding/ NEWBORN HEAD MOLDING	20AUG2021	2	1	No	O: Unknown	NA	R (21AUG2021)	N
		NERV	Hypotonia/ Hypotonia	20AUG2021	1	2	No	O: Unknown	NA	R (20AUG2021)	N
		PREG	Jaundice neonatal/ NEONATAL JAUNDICE	22AUG2021		1	No	O: Unknown	NA	UNK	N
		SKIN	Ecchymosis/ Ecchymotic Mask	20AUG2021	2	1	No	O: Unknown	NA	R (21AUG2021)	N
Placebo/ [redacted]	[redacted]	METAB	Hypoglycaemia neonatal/ Hypoglycemia neonatal on the day of delivery	17JUL2021	3	1	No	O: Unknown	NA	R (19JUL2021)	Y
Placebo/ [redacted]	[redacted]	PREG	Jaundice neonatal/ Jaundice neonatal	26AUG2021	3	1	No	O: Unknown	NA/TCN	R (28AUG2021)	N
Placebo/ [redacted]	[redacted]	PREG	Jaundice neonatal/ Newborn jaundice	08DEC2021	2	1	No	O: Unknown	NA/TCN	R (09DEC2021)	Y

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16.2.7.7.2 Listing of Adverse Events (Infant)

Maternal Vaccine Group (as Administered)/ Participant	GA at Birth/ Sex	System Organ Class	Preferred Term/ AE Investigator Text	Onset Date	Dur (Days)[a]	Toxicity Grade	Vax Rel[b]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE (Yes/No)
Placebo/ [redacted]	[redacted]	INFEC	Sepsis neonatal/ potential neonatal sepsis	05AUG2021	4	1	No	O: infection	NA	R (08AUG2021)	Y
Placebo/ [redacted]	[redacted]	PREG	Jaundice neonatal/ neonatal isoinmune jaundice	19AUG2021	3	1	No	O: isoinmune	NA/TCN	R (21AUG2021)	Y
Placebo/ [redacted]	[redacted]	RESP	Neonatal respiratory distress/ Respiratory distress of the newborn	09SEP2021	8	1	No	O: Immature lung	NA/TCN	R (16SEP2021)	Y
Placebo/ [redacted]	[redacted]	NEOPL	Haemangioma of bone/ left scapular hemangioma	14JUL2021	C	1	No	O: unk	NA	RG	N
Placebo/ [redacted]	[redacted]	RESP	Tachypnoea/ transient tachypnea	30JUL2021	5	3	No	O: unknown	NA/TC/TCN	R (03AUG2021)	Y
Placebo/ [redacted]	[redacted]	RESP	Neonatal respiratory distress syndrome/ Neonatal respiratory distress syndrome	18JUL2021	3	4	No	O: Unknown	NA/TC	R (20JUL2021)	Y
Placebo/ [redacted]	[redacted]	GASTR	Haematochezia/ blood in stool^	25DEC2021	7	1	No	O: unknown	NA	R (31DEC2021)	N
			Mucous stools/ Mucus in stool^	25DEC2021	7	1	No	O: Unknown	NA	R (31DEC2021)	N
		METAB	Hypokalaemia/ Hypokalemia	11AUG2021	3	2	No	O: Neonatal weight loss	NA	R (13AUG2021)	N
		PREG	Premature baby/ Preterm birth	04AUG2021	5	4	No	O: Placental abruption	NA	R (08AUG2021)	Y

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16.2.7.7.2 Listing of Adverse Events (Infant)

Maternal Vaccine Group (as Administered)/ Participant	GA at Birth/ Sex	System Organ Class	Preferred Term/ AE Investigator Text	Onset Date	Dur (Days)[a]	Toxicity Grade	Vax Rel[b]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE (Yes/No)
			Jaundice neonatal/ Neonatal jaundice	11AUG2021	3	2	No	O: Unknown	NA/TCN	R (13AUG2021)	Y
			Weight decrease neonatal/ Neonatal weight loss	11AUG2021	7	3	No	O: Born preterm	NA	R (17AUG2021)	Y

Abbreviations: C = continuing; D = day(s); Dur = duration; FU = follow-up; GA = gestational age; W = weeks. Refer to the AE legend page (Listing 16.2.7.1) for additional definitions.
Note: ^ = Event reported after maternal participant was unblinded.
Note: MedDRA (v25.1) coding dictionary applied.
Note: † = Infant born to human immunodeficiency virus (HIV)-positive participant.
a. Duration (days) was calculated as the difference from the start of the first reported event to resolution of the last reported event, inclusive.
b. Vaccine related (Vax Rel): Relationship to study intervention as assessed by the investigator.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 04MAY2023 (09:54) Output File: ./nda3/C4591015_BR/adae_l002_nonser_gr3_inf

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16.2.7.8.1 Listing of Deaths (Maternal)

Vaccine Group (as Administered)	Participant	Country	Dose No.	Rel Day[a]	Date of Death	Age at Death (Years)	Primary Cause of Death	Secondary Cause(s) of Death
No participant meets the reporting criteria.								

a. Relative Day (Rel Day) = date of death - date of last vaccination + 1.

PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:14) Source Data: adsl Table Generation: 03MAY2023 (10:38) Output File: ./nda3/C4591015_BR/cdl_dth_all_p3

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16.2.7.8.2 Listing of Deaths (Infant)

Maternal Vaccine Group (as Administered)	Participant	Country	GA at Birth/ Sex	Date of Death	Age at Death (Weeks)	Primary Cause of Death	Secondary Cause(s) of Death
BNT162b2 (30 µg)	[redacted]†	ZAF	40W/M	17MAY2022	0	Pneumonia	
Placebo	[redacted]	ZAF	32W 3D/F	22NOV2021	0	Disease progression	

Abbreviations: D = day(s); GA = gestational age; W = weeks; ZAF = south africa.
Note: † = Infant born to human immunodeficiency virus (HIV)-positive participant.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:14) Source Data: adsl Table Generation: 03MAY2023 (10:38) Output File: ./nda3/C4591015_BR/cdl_dth_all_p3_inf

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16.2.7.9.1 Listing of Serious Adverse Events (Maternal)

Vaccine Group (as Administered)/ Participant	Age (Years)	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day[a]	Dur (Days)[b]	Toxicity Grade	Vax Rel[c]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE/ Imm AE (Yes/No)	SAE Hospitalization (Yes/No)
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Pre-eclampsia/ Preeclampsia	1	26JUN2021	19	25	1	No	O: Unknown	NA/TC	R (20JUL2021)	Y/N	Y
			Failed induction of labour/ Failed Induction of Labor	2	20JUL2021	22	1	1	No	O: Unknown	NA/TCN	R (20JUL2021)	Y/N	Y
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Foetal hypokinesia/ DECREASED FETAL MOVEMENT, THIRD TRIMESTER	2	06APR2021	7	5	3	No	O: UNKNOWN	NA	R (10APR2021)	Y/N	Y
		SKIN	Pruritus/ PRURITUS OF PREGNANCY	2	05APR2021	6	9	3	No	O: No evidence of cholestasis in pregnancy; probable skin issue	NA/TC	R (13APR2021)	Y/N	Y
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Pre-eclampsia/ PRE-ECLAMPSIA POSTPARTUM	2	12MAY2021	31	5	3	No	O: FLUID SHIFTS IN PREGNANCY	NA/TC	R (16MAY2021)	Y/N	Y
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Pre-eclampsia/ pre-eclampsia	2	24JUN2021	53	65	3	No	O: common pregnancy complication	NA/TC	R (27AUG2021)	Y/N	Y
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Gestational hypertension/ gestational hypertension	2	26JUL2021	53	16	2	No	O: common pregnancy complication	NA/TC	R (10AUG2021)	Y/N	Y
			Pre-eclampsia/ mild pre-eclampsia	2	27JUL2021	54	107	2	No	O: common pregnancy complication	NA	R (10NOV2021)	Y/N	Y
BNT162b2 (30 µg)/ [redacted]	[redacted]	REPRO	Uterine disorder/ Large Uterine Window with Bulging Membranes	2	23JUN2021	58	1	1	No	O: History of previous C-sections	NA	R (23JUN2021)	Y/N	N
BNT162b2 (30 µg)/ [redacted]	[redacted]	INFEC	Pyelonephritis/ Pyelonephritis	2	17JUL2021	45	16	3	No	O: UTI	NA/TC	R (01AUG2021)	Y/N	Y

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16.2.7.9.1 Listing of Serious Adverse Events (Maternal)

Vaccine Group (as Administered)/ Participant	Age (Years)	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day[a]	Dur (Days)[b]	Toxicity Grade	Vax Rel[c]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE/ Imm AE (Yes/No)	SAE Hospitalization (Yes/No)
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Retained placenta or membranes/ RETAINED PLACENTA	2	22NOV2021	48	3	2	No	O: POST-DELIVERY COMPLICATION	NA	R (24NOV2021)	Y/N	Y
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Foetal distress syndrome/ FOETAL DISTRESS	2	27JAN2022	94	3	2	No	O: Pregnancy related	NA/TC/TCN	R (29JAN2022)	Y/N	Y
BNT162b2 (30 µg)/ [redacted]	[redacted]	CARD	Bradycardia foetal/ Fetal bradycardia	2	15SEP2021	37	1	4	No	O: Loss of fetal well-being	NA/TCN	R (15SEP2021)	Y/N	Y
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Foetal distress syndrome/ Fetal distress	2	14NOV2021	27	1	2	No	O: meconium stained liquor	NA	R (14NOV2021)	Y/N	Y
			Meconium stain/ Meconium stained liquor Grade II	2	14NOV2021	27	1	2	No	O: Meconium stained liquor	NA/TC	R (14NOV2021)	Y/N	Y
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Cephalo-pelvic disproportion/ Cephalopelvic disproportion	2	14JAN2022	59	2	2	No	O: cephalopelvic disproportion	NA/TC	R (15JAN2022)	Y/N	Y
BNT162b2 (30 µg)/ [redacted]	[redacted]	INFEC	Lower respiratory tract infection/ Lower respiratory tract infection	1	20OCT2021	7	6	3	No	O: Viral infection	NA/TC	R (25OCT2021)	Y/N	Y
BNT162b2 (30 µg)/ [redacted]	[redacted]	INFEC	Endometritis/ Endometritis	2	09SEP2021	36	5	3	No	O: Endometritis	NA/TC	R (13SEP2021)	Y/N	Y
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Breech presentation/ BREECH PRESENTATION	1	14AUG2021	4	35	1	No	O: UNKNOWN	NA/TC	R (17SEP2021)	Y/N	Y

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16.2.7.9.1 Listing of Serious Adverse Events (Maternal)

Vaccine Group (as Administered)/ Participant	Age (Years)	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day[a]	Dur (Days)[b]	Toxicity Grade	Vax Rel[c]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE/ Imm AE (Yes/No)	SAE Hospitalization (Yes/No)
BNT162b2 (30 µg)/ [redacted]†	[redacted]	BLOOD	Anaemia/ SYMPTOMATIC ANAEMIA	2	16OCT2021	27	5	3	No	O: UNKNOWN	NA/TC	R (20OCT2021)	Y/N	Y
		PREG	Foetal death/ INTRAUTERINE FETAL DEATH	2	16OCT2021	27	1	3	No	O: UNKNOWN	NA/TC	R (16OCT2021)	Y/N	Y
			Postpartum haemorrhage/ POSTPARTUM HAEMORRHAHE	2	16OCT2021	27	5	3	No	O: UNKNOWN	NA	R (20OCT2021)	Y/N	Y
			Premature separation of placenta/ ABRUPTIO PLACENTA	2	16OCT2021	27	5	3	No	O: unknown	NA/TC/TCN	R (20OCT2021)	Y/N	Y
BNT162b2 (30 µg)/ [redacted]†	[redacted]	PREG	Foetal distress syndrome/ FETAL DISTRESS	2	28NOV2021	46	1	3	No	O: pregnancy related	NA	R (28NOV2021)	Y/N	Y
BNT162b2 (30 µg)/ [redacted]	[redacted]	MUSC	Osteoarthritis/ Worsening of arthrosis	1	09AUG2021	69	C	2	No	O: Unknown	NA/TC	RG	Y/N	Y
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Foetal growth restriction/ Intrauterine growth restriction	2	04AUG2021	43	C	1	No	O: Unknown	NA/TCN	RG	Y/N	N
BNT162b2 (30 µg)/ [redacted]	[redacted]	GASTR	Abdominal wall haematoma/ Hematoma of the abdominal wall	2	07JAN2022	85	1	1	No	O: Operative wound hamatoma	NA/TCN	R (07JAN2022)	Y/N	N
		PREG	Foetal distress syndrome/ Suspected Fetal Distress	2	19DEC2021	66	1	2	No	O: Emergency Cesarean	NA/TCN	R (19DEC2021)	Y/N	N
BNT162b2 (30 µg)/ [redacted]	[redacted]	VASC	Deep vein thrombosis/ Occlusive thrombus in left leg common femoral vein	2	01AUG2021	34	C	1	No	O: post natal 2 weeks	NA/TC/TCN	RG	Y/N	Y

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16.2.7.9.1 Listing of Serious Adverse Events (Maternal)

Vaccine Group (as Administered)/ Participant	Age (Years)	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day[a]	Dur (Days)[b]	Toxicity Grade	Vax Rel[c]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE/ Imm AE (Yes/No)	SAE Hospitalization (Yes/No)
BNT162b2 (30 µg)/ [redacted]	[redacted]	REPRO	Uterine disorder/ irregular uterine dynamics	2	18SEP2021	48	2	1	No	O: related to the development of pregnancy	NA/TC	R (19SEP2021)	Y/N	Y
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Haemorrhage in pregnancy/ Antepartum haemorrhage	2	15OCT2021	4	2	3	No	O: Unknown cause	NA/TCN	RS (16OCT2021)	Y/N	Y
Placebo/ [redacted]	[redacted]	HEPAT	Cholelithiasis/ Cholelithiasis	2	02JUL2021	39	11	1	No	O: Gallstones	NA	R (12JUL2021)	Y/N	Y
Placebo/ [redacted]	[redacted]	INV	Foetal heart rate abnormal/ Fetal heartrate abnormality	2	28APR2021	17	1	4	No	O: delivery complications	NA	R (28APR2021)	Y/N	Y
		PREG	Premature separation of placenta/ Marginal Placenta Abruption	2	28APR2021	17	1	3	No	O: Marginal Placenta Abruption	NA	R (28APR2021)	Y/N	Y
Placebo/ [redacted]	[redacted]	PREG	Omphalorrhexis/ UMBILICAL CORD RUPTURE	2	27JUL2021	35	1	4	No	O: UMBILICAL CORD RUPTURE	NA/TCN	R (27JUL2021)	Y/N	N
Placebo/ [redacted]	[redacted]	CARD	Nonreassuring foetal heart rate pattern/ Non-reassuring fetal heart tones	2	29MAY2021	32	1	4	No	O: common delivery complication	NA/TC	R (29MAY2021)	Y/N	Y
		PREG	Arrested labour/ arrest of dilation	2	29MAY2021	32	1	3	No	O: common pregnancy complication	NA	R (29MAY2021)	Y/N	Y
Placebo/ [redacted]	[redacted]	PREG	Gestational hypertension/ gestational hypertension	2	27JUN2021	19	18	2	No	O: common pregnancy complication	NA	R (14JUL2021)	Y/N	Y
Placebo/ [redacted]	[redacted]	CARD	Nonreassuring foetal heart rate pattern/ Non Reassuring fetal heart rate	2	02SEP2021	71	1	3	No	O: Unknown	NA/TCN	R (02SEP2021)	Y/N	N

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16.2.7.9.1 Listing of Serious Adverse Events (Maternal)

Vaccine Group (as Administered)/ Participant	Age (Years)	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day[a]	Dur (Days)[b]	Toxicity Grade	Vax Rel[c]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE/ Imm AE (Yes/No)	SAE Hospitalization (Yes/No)
Placebo/ [redacted]	[redacted]	PREG	Premature separation of placenta/ Placental Abruption	2	18AUG2021	35	1	3	No	O: Pregnancy	NA/TCN	R (18AUG2021)	Y/N	N
Placebo/ [redacted] †	[redacted]	PREG	Failed trial of labour/ Failed vaginal delivery	2	28DEC2021	57	1	3	No	O: FAILED VAGINAL DELIVERY	NA	R (28DEC2021)	Y/N	Y
Placebo/ [redacted]	[redacted]	PREG	Cephalo-pelvic disproportion/ CAPHALOPELVIC DISPROPORTION	2	20DEC2021	41	1	2	No	O: UNKNOWN	NA/TCN	R (20DEC2021)	Y/N	Y
Placebo/ [redacted]	[redacted]	PREG	Pre-eclampsia/ Preeclampsia	2	04AUG2021	58	2	1	No	O: Medical condition	NA	R (05AUG2021)	Y/N	Y
Placebo/ [redacted]	[redacted]	PREG	Cephalo-pelvic disproportion/ Cephalopelvic Disproportion	2	17OCT2021	47	1	3	No	O: Big baby	NA/TC	R (17OCT2021)	Y/N	Y
Placebo/ [redacted]	[redacted]	PREG	Foetal distress syndrome/ Fetal distress	2	25OCT2021	28	1	2	No	O: Placental insufficiency	NA	R (25OCT2021)	Y/N	Y
			Placental insufficiency/ Placental Insufficiency	2	25OCT2021	28	1	3	No	O: intrauterine growth retardation	NA/TC	R (25OCT2021)	Y/N	Y
Placebo/ [redacted]	[redacted]	PREG	Pre-eclampsia/ Preeclampsia	1	24SEP2021	5	12	3	No	O: Preeclampsia	NA/TC/TCN	R (05OCT2021)	Y/N	Y
Placebo/ [redacted]	[redacted]	PREG	Foetal distress syndrome/ Fetal distress	2	05JAN2022	50	1	2	No	O: Induced Labour	NA/TC	R (05JAN2022)	Y/N	Y
Placebo/ [redacted] †	[redacted]	PREG	Foetal hypokinesia/ REDUCED FETAL MOVEMENTS	2	12OCT2021	28	3	1	No	O: UNKNOWN	NA	R (14OCT2021)	Y/N	Y
Placebo/ [redacted]	[redacted]	PREG	Cephalo-pelvic disproportion/	2	25NOV2021	71	1	3	No	O: PREGNANCY	NA/TC	R (25NOV2021)	Y/N	Y

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16.2.7.9.1 Listing of Serious Adverse Events (Maternal)

Vaccine Group (as Administered)/ Participant	Age (Years)	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day[a]	Dur (Days)[b]	Toxicity Grade	Vax Rel[c]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE/ Imm AE (Yes/No)	SAE Hospitalization (Yes/No)
			CEPHALOPELVIC DISPROPORTION											
Placebo/ [redacted]†	[redacted]	PREG	Cephalo-pelvic disproportion/ cephalopelvic disproportion	2	04DEC2021	68	1	3	No	O: unknown	NA	R (04DEC2021)	Y/N	Y
Placebo/ [redacted]†	[redacted]	PREG	Foetal distress syndrome/ FETAL DISTRESS	2	01DEC2021	63	1	3	No	O: UNKNOWN	NA	R (01DEC2021)	Y/N	Y
Placebo/ [redacted]	[redacted]	PREG	Preterm premature rupture of membranes/ PRETERM PRELABOUR RUPTURE OF MEMBRANE	2	14NOV2021	32	3	2	No	O: UNKNOWN	NA/TC	R (16NOV2021)	Y/N	Y
			Postpartum haemorrhage/ POSTPARTUM HAEMORRHAGE	2	16NOV2021	34	1	2	No	O: UNKNOWN	NA/TC	R (16NOV2021)	Y/N	Y
Placebo/ [redacted]	[redacted]	INJ&P	Urinary tract procedural complication/ Intraoperative bladder injury/laceration	2	17JUL2021	6	15	2	No	O: Surgical procedure	NA/TC	R (31JUL2021)	Y/N	Y
Placebo/ [redacted]	[redacted]	PREG	Meconium in amniotic fluid/ Meconium in the amniotic fluid	2	17JUL2021	20	1	2	No	O: Unknown	NA	R (17JUL2021)	Y/N	N
Placebo/ [redacted]	[redacted]	INFEC	Urinary tract infection/ Urinary Infection	2	04DEC2021	81	10	1	No	O: Information not reported in hospital document	NA/TC	R (13DEC2021)	Y/N	Y
Placebo/ [redacted]	[redacted]	INV	Ultrasound foetal abnormal/ Abnormal fetal doppler and signs of decompensation	2	31AUG2021	50	3	1	No	O: Changes during pregnancy - USS updates	NA	R (02SEP2021)	Y/N	Y

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16.2.7.9.1 Listing of Serious Adverse Events (Maternal)

Vaccine Group (as Administered)/ Participant	Age (Years)	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day[a]	Dur (Days)[b]	Toxicity Grade	Vax Rel[c]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE/ Imm AE (Yes/No)	SAE Hospitalization (Yes/No)
Placebo/ [redacted]	[redacted]	PREG	Prolonged rupture of membranes/ Prolonged Rupture of Membranes	2	03DEC2021	78	4	1	No	O: Variant of pregnancy	NA/TC	R (06DEC2021)	Y/N	Y
Placebo/ [redacted]	[redacted]	INFEC	Pneumonia/ Secondary Bilateral Pneumonia	1	01JUL2021	18	6	3	No	O: Covid 19	NA/TC/TCN	R (06JUL2021)	Y/N	Y
Placebo/ [redacted]	[redacted]	PREG	Foetal hypokinesia/ Reduced fetal movements	2	15JUL2021	18	4	1	No	O: No evidence to suggest reasonable possibility of a relationship	NA/TC	R (18JUL2021)	Y/N	Y
			Postpartum haemorrhage/ Post-partum hemorrhage	2	18JUL2021	21	1	4	No	O: No evidence to suggest reasonable possibility of a relationship	NA/TC	R (18JUL2021)	Y/N	N
Placebo/ [redacted]	[redacted]	PREG	Premature separation of placenta/ Placental abruption	2	04AUG2021	29	1	4	No	O: Unknown reason	NA/TCN	R (04AUG2021)	Y/N	Y

Abbreviations: C = continuing; Dur = duration; FU = follow-up; Imm = immediate. Refer to the AE legend page (Listing 16.2.7.1) for additional definitions.
Note: MedDRA (v25.1) coding dictionary applied.
Note: † = Human immunodeficiency virus (HIV)-positive participant.
a. Relative Day (Rel Day) = AE start date - date of last vaccination + 1. For an AE that occurred before the date of the first study vaccination, +1 was not added to compute relative day.
b. Duration (days) was calculated as the difference from the start of the first reported event to resolution of the last reported event, inclusive.
c. Vaccine related (Vax Rel): Relationship to investigational vaccine as assessed by the investigator.
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16.2.7.9.2 Listing of Serious Adverse Events (Infant)

Maternal Vaccine Group (as Administered)/ Participant	GA at Birth/ Sex	System Organ Class	Preferred Term/ AE Investigator Text	Onset Date	Dur (Days)[a]	Toxicity Grade	Vax Rel[b]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE (Yes/No)	SAE Hospitalization (Yes/No)
BNT162b2 (30 µg)/ [redacted]	[redacted]	CONG	Microcephaly/ microcephaly	22JUN2021	C	3	No	O: unknown etiology	NA	N	Y	N
		PREG	Small for dates baby/ small for gestational age	25JUN2021	C	3	No	O: unknown etiology	NA	N	Y	N
BNT162b2 (30 µg)/ [redacted]	[redacted]	CONG	Atrial septal defect/ fenestrated atrial septal defect	27JUL2021	C	1	No	O: unknown etiology	NA	N	Y	N
BNT162b2 (30 µg)/ [redacted]	[redacted]	GASTR	Allergic colitis/ Allergic Colitis.	20AUG2021	116	1	No	O: Unknown	NA	R (13DEC2021)	Y	N
			Allergic gastroenteritis/ Allergic Gastroenterocolitis	20AUG2021	116	1	No	O: Unknown	NA	R (13DEC2021)	Y	N
		INV	Cardiac murmur/ Cardiac Murmur	30JUL2021	96	1	No	O: Congenital anomaly or birth defect	NA	R (02NOV2021)	Y	N
BNT162b2 (30 µg)/ [redacted]	[redacted]	CONG	Polydactyly/ Polydactyly of fingers on bilateral hands.	14AUG2021	C	1	No	O: History of polydactyly in father and father's siblings	NA	N	Y	N
BNT162b2 (30 µg)/ [redacted]	[redacted]	CONG	Atrial septal defect/ patent foramen ovale	13MAY2021	C	1	No	O: common congenital abnormality	NA	N	Y	N
BNT162b2 (30 µg)/ [redacted]	[redacted]	CONG	Atrial septal defect/ Atrial septal defect	26JUL2021	C	2	No	O: Unknown (this is a common abnormality seen in newborns)	NA	N	Y	N
		NERV	Nervous system disorder/ Neonatal central nervous system abnormality	26JUL2021	C	3	No	O: Possible unknown genetic condition	NA/TC/TCN	N	Y	Y

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16.2.7.9.2 Listing of Serious Adverse Events (Infant)

Maternal Vaccine Group (as Administered)/ Participant	GA at Birth/ Sex	System Organ Class	Preferred Term/ AE Investigator Text	Onset Date	Dur (Days)[a]	Toxicity Grade	Vax Rel[b]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE (Yes/No)	SAE Hospitalization (Yes/No)
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Jaundice neonatal/ Neonatal jaundice	29JAN2022	3	1	No	O: Physiological	NA	R (31JAN2022)	Y	Y
		RESP	Meconium aspiration syndrome/ Mecanium aspiration syndrome	27JAN2022	3	2	No	O: Delivery	NA/TC	R (29JAN2022)	Y	Y
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Jaundice neonatal/ Neonatal Jaundice	18SEP2021	4	1	No	O: Jaundice	NA/TCN	R (21SEP2021)	Y	Y
BNT162b2 (30 µg)/ [redacted]	[redacted]	RESP	Meconium aspiration syndrome/ Meconium aspiration syndrome	11DEC2021	3	2	No	O: meconium aspiration	NA/TC	R (13DEC2021)	Y	Y
BNT162b2 (30 µg)/ [redacted]	[redacted]	CONG	Syndactyly/ Syndactyly toes,bilateral	30DEC2021	C	1	No	O: congenital anomaly	NA	N	Y	N
BNT162b2 (30 µg)/ [redacted]	[redacted]	CONG	Congenital rubella syndrome/ Congenital Rubella Syndrome	23DEC2021	C	2	No	O: Congenital Rubella	NA	N	Y	N
			Mucopolysaccharidosis/ Mucopolysaccharidosis	23DEC2021	C	2	No	O: Congenital anomaly	NA	N	Y	N
		INFEC	Neonatal pneumonia/ Neonatal Pneumonia	23DEC2021	5	2	No	O: Aspirated liqor in utero	NA/TC/TCN	R (27DEC2021)	Y	Y
BNT162b2 (30 µg)/ [redacted]	[redacted]	CONG	Trisomy 21/ down's syndrome	23JUL2021	C	3	No	O: down's syndrome	NA	N	Y	Y
BNT162b2 (30 µg)/	[redacted]	INFEC	Pneumonia/ PNEUMONIA^	12MAY2022	6	4	No	O: INFECTION	NA/W	F (17MAY2022)	Y	N

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16.2.7.9.2 Listing of Serious Adverse Events (Infant)

Maternal Vaccine Group (as Administered)/ Participant	GA at Birth/ Sex	System Organ Class	Preferred Term/ AE Investigator Text	Onset Date	Dur (Days)[a]	Toxicity Grade	Vax Rel[b]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE (Yes/No)	SAE Hospitalization (Yes/No)
[redacted]†												
BNT162b2 (30 µg)/ [redacted]	[redacted]	INFEC	Bronchiolitis/ nonspecific viral bronchiolitis^	14JAN2022	C	2	No	O: virus	NA/TC	N	Y	Y
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Low birth weight baby/ Low birth weight	04AUG2021	C	1	No	O: Unknown	NA/TCN	RG	Y	N
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Jaundice neonatal/ Jaundice neonatal	27AUG2021	4	1	No	O: Physiological Jaundice	NA/TCN	R (30AUG2021)	Y	Y
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Jaundice neonatal/ Neonatal jaundice	21SEP2021	4	1	No	O: high bilirubin levels	NA	R (24SEP2021)	Y	Y
BNT162b2 (30 µg)/ [redacted]	[redacted]	PREG	Jaundice neonatal/ Hyperbilirubinaemia neonatal - neonatal jaundice	04AUG2021	4	3	No	O: Unknown	NA	R (07AUG2021)	Y	Y
BNT162b2 (30 µg)/ [redacted]	[redacted]	CONG	DiGeorge's syndrome/ Digeorge syndrome	15JUL2021	C	3	No	O: congenital disease	NA	N	Y	N
		INFEC	Pyelonephritis acute/ acute pyelonephritis	23JUL2021	6	4	No	O: Bacterial infection. Urineculture with E. coli and Enterococcus faecalis.	NA/TC	R (28JUL2021)	Y	Y
			Pyelonephritis/ pyelonephritis^	23AUG2021	5	3	No	O: infection	NA/TC	R (27AUG2021)	Y	Y
			Pyelonephritis/ pyelonephritis^	23DEC2021	3	3	No	O: infection	NA/TC	R (25DEC2021)	Y	Y

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16.2.7.9.2 Listing of Serious Adverse Events (Infant)

Maternal Vaccine Group (as Administered)/ Participant	GA at Birth/ Sex	System Organ Class	Preferred Term/ AE Investigator Text	Onset Date	Dur (Days)[a]	Toxicity Grade	Vax Rel[b]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE (Yes/No)	SAE Hospitalization (Yes/No)
		RENAL	Vesicoureteric reflux/ Vesicoureteral reflux	15JUL2021	C	4	No	O: UNK	NA	N	Y	N
BNT162b2 (30 µg)/		INFEC	Bronchiolitis/ Acute Bronchiolitis^	06DEC2021	7	3	No	O: respiratory syncytial virus	NA/TC/TCN	R (12DEC2021)	Y	Y
BNT162b2 (30 µg)/		PREG	Jaundice neonatal/ Neonatal Jaundice	22JUL2021	4	1	No	O: very usual event in newly born	NA/TCN	R (25JUL2021)	Y	Y
BNT162b2 (30 µg)/		PREG	Jaundice neonatal/ Neonatal Jaundice	07SEP2021	3	1	No	O: very usual event in newly born	NA/TCN	R (09SEP2021)	Y	Y
Placebo/		CONG	Ankyloglossia congenital/ Congenital Ankyloglossia	08AUG2021	2	1	No	O: unknown	NA	R (09AUG2021)	Y	N
		GASTR	Dysphagia/ Dysphagia	08AUG2021	2	1	No	O: Unkown	NA	R (09AUG2021)	Y	N
Placebo/		INFEC	Pneumonia respiratory syncytial viral/ RSV pneumonia^	22SEP2021	12	3	No	O: Viral	NA/TC	R (03OCT2021)	Y	Y
Placebo/		CONG	Ventricular septal defect/ Ventricular Septal Defect	13AUG2021	C	1	No	O: congenital anamoly	NA	N	Y	N
		RESP	Hypoxia/ Hypoxia	13AUG2021	5	2	No	O: Periodic desaturations requiring CPAP to provide resipratory support.	NA/TC/TCN	R (17AUG2021)	Y	Y
Placebo/		CONG	Congenital skin dimples/ Simple Sacral dimple	17JUN2021	C	1	No	O: congenital anomaly	NA	RG	Y	N

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16.2.7.9.2 Listing of Serious Adverse Events (Infant)

Maternal Vaccine Group (as Administered)/ Participant	GA at Birth/ Sex	System Organ Class	Preferred Term/ AE Investigator Text	Onset Date	Dur (Days)[a]	Toxicity Grade	Vax Rel[b]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE (Yes/No)	SAE Hospitalization (Yes/No)
Placebo/ [redacted]	[redacted]	BLOOD	Coagulopathy/ COAGULOPATHY	28APR2021	11	3	No	O: BIRTH TRAUMA	NA/TC	R (08MAY2021)	Y	Y
			Thrombocytopenia/ Thrombocytopenia	30APR2021	9	2	No	O: LOW PLATELET PRODUCTION	NA	R (08MAY2021)	Y	Y
		GASTR	Intestinal perforation/ INTESTINAL PERFORATION	05MAY2021	8	3	No	O: HYPOXIC ISCHEMIC ENCEPHALOPATHY	NA	R (12MAY2021)	Y	Y
			Pneumoperitoneum/ Pneumoperitoneum	05MAY2021	1	3	No	O: INTESTINAL PERFORATION	NA	R (05MAY2021)	Y	Y
		INFEC	Sepsis/ SEPSIS	13MAY2021	7	3	No	O: BACTERIAL INFECTION	NA/TC	R (19MAY2021)	Y	Y
		METAB	Metabolic acidosis/ Metabolic Acidosis	28APR2021	7	4	No	O: BIRTH ASPHYXIA	NA/TC	R (04MAY2021)	Y	Y
		NERV	Coma/ COMA	28APR2021	2	3	No	O: HYPOXIC ISCHEMIA ENCEPHOLOPATHY	NA	R (29APR2021)	Y	Y
			Hypoxic-ischaemic encephalopathy/ Hypoxic Ischemic Encephalopathy	28APR2021	C	4	No	O: delivery complications	NA/TC	N	Y	Y
			Seizure/ SEIZURES	03MAY2021	1	2	No	O: HYPOXIC ISCHEMIC ENCEPHALOPATHY	NA/TC	R (03MAY2021)	Y	Y
		RENAL	Renal tubular necrosis/ Renal Failure (Acute Tubular Necrosis)	28APR2021	28	3	No	O: HYPOXIC ISCHEMIC ENCEPHALOPATHY	NA/TC	R (25MAY2021)	Y	Y
		RESP	Pulmonary hypertension/ PULMONARY HYPERTENSION	28APR2021	7	3	No	O: HYPOXIC ISCHEMIC ENCEPHALOPATHY	NA	R (04MAY2021)	Y	Y
			Respiratory failure/ RESPIRATORY FAILURE	28APR2021	7	3	No	O: HYPOXIC ISCHEMIC ENCEPHALOPATHY	NA/TCN	R (04MAY2021)	Y	Y
		VASC	Hypoperfusion/ HYPOPERFUSION	28APR2021	2	3	No	O: HYPOXIC ISCHEMIA ENCEPHALOPATHY	NA	R (29APR2021)	Y	Y

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16.2.7.9.2 Listing of Serious Adverse Events (Infant)

Maternal Vaccine Group (as Administered)/ Participant	GA at Birth/ Sex	System Organ Class	Preferred Term/ AE Investigator Text	Onset Date	Dur (Days)[a]	Toxicity Grade	Vax Rel[b]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE (Yes/No)	SAE Hospitalization (Yes/No)
			Hypotension/ HYPOTENSION	28APR2021	6	3	No	O: SHOCK	NA	R (03MAY2021)	Y	Y
			Shock/ SHOCK	28APR2021	1	3	No	O: HYPOXIC ISCHEMIC ENCEPHALOPATHY	NA	R (28APR2021)	Y	Y
			Hypotension/ HYPOTENSION	06MAY2021	2	2	No	O: HYPOXIC ISCHEMIC ENCEPHALOPATHY	NA	R (07MAY2021)	Y	Y
Placebo/ [redacted]	[redacted]	RESP	Neonatal respiratory distress/ RESPIRATORY DISTRESS IN THE NEONATE	27JUL2021	1	3	No	O: BIRTH TRAUMA	NA/TCN	R (27JUL2021)	Y	N
Placebo/ [redacted]	[redacted]	RESP	Neonatal pneumothorax/ pneumothorax in infant	29MAY2021	1	4	No	O: unknown etiology	NA/TC/TCN	R (29MAY2021)	Y	Y
			Neonatal respiratory failure/ Respiratory failure in newborn	29MAY2021	3	4	No	O: Pneumothorax	NA/TCN	R (31MAY2021)	Y	Y
Placebo/ [redacted]	[redacted]	CONG	Ankyloglossia congenital/ Ankyloglossia congenital	29JUN2021	1	2	No	O: unknown etiology	NA	R (29JUN2021)	Y	N
		HEPAT	Hyperbilirubinaemia neonatal/ neonatal hyperbilirubinemia	29JUN2021	5	3	No	O: unknown etiology	NA	R (03JUL2021)	Y	Y
Placebo/ [redacted]	[redacted]	CONG	Atrial septal defect/ Patent Foramen Oval (PFO)	15JUN2021	65	1	No	O: Genetic	NA	R (18AUG2021)	Y	N
			Patent ductus arteriosus/ Small Patent Ductus Arteriosus	15JUN2021	65	1	No	O: Genetic	NA	R (18AUG2021)	Y	N
Placebo/ [redacted]	[redacted]	INJ&P	Traumatic intracranial haemorrhage/ Traumatic Intracranial Hemorrhage	12AUG2021	2	1	No	O: Birth related injury	NA	R (13AUG2021)	Y	Y
		PREG	Caput succedaneum/ Caput Succedaneum	12AUG2021	2	1	No	O: Vacuum extraction delivery	NA	R (13AUG2021)	Y	Y

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16.2.7.9.2 Listing of Serious Adverse Events (Infant)

Maternal Vaccine Group (as Administered)/ Participant	GA at Birth/ Sex	System Organ Class	Preferred Term/ AE Investigator Text	Onset Date	Dur (Days)[a]	Toxicity Grade	Vax Rel[b]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE (Yes/No)	SAE Hospitalization (Yes/No)
		VASC	Subgaleal haemorrhage/ Subgaleal Hemorrhage	11AUG2021	3	1	No	O: Vacuum extraction delivery	NA	R (13AUG2021)	Y	Y
Placebo/ [redacted]	[redacted]	GASTR	Meconium plug syndrome/ Meconium plug	24NOV2021	4	3	No	O: Meconium plug in rectum	NA/TC/TCN	R (27NOV2021)	Y	Y
Placebo/ [redacted]†	[redacted]	INFEC	Gastroenteritis/ Acute gastroenteritis^	07FEB2022	18	3	No	O: Viral or bacterial infection	NA/TC/TCN	RS (24FEB2022)	Y	Y
			Gastroenteritis/ Acute gastroenteritis^	09MAR2022	6	3	No	O: Viral Infection	NA/TC	R (14MAR2022)	Y	Y
			Urinary tract infection/ Urinary tract infection^	09MAR2022	6	1	No	O: Bacterial infection	NA/TC	R (14MAR2022)	Y	Y
		METAB	Dehydration/ Hypernatraemic dehydration^	09FEB2022	9	3	No	O: Acute gastroenteritis	NA/TC	R (17FEB2022)	Y	Y
		NERV	Superior sagittal sinus thrombosis/ Sagittal sinus thrombosis^	14FEB2022	11	2	No	O: Hypernatraemic dehydration	NA/TC	RS (24FEB2022)	Y	Y
Placebo/ [redacted]	[redacted]	INJ&P	Injury to brachial plexus due to birth trauma/ LEFT ARM ERB PALSY	04DEC2021	C	3	No	O: UNKNOWN	NA/TCN	N	Y	Y
		NERV	Encephalopathy neonatal/ NEONATAL ENCEPHALOPATHY	04DEC2021	7	3	No	O: HYPOXAEMIA AT BIRTH	NA/TCN	RS (10DEC2021)	Y	Y
		RESP	Respiratory distress/ RESPIRATORY DISTRESS	04DEC2021	7	3	No	O: UNKNOWN	NA/TC/TCN	R (10DEC2021)	Y	Y
Placebo/ [redacted]	[redacted]	INFEC	Sepsis neonatal/ NEONATAL SEPSIS	29NOV2021	11	3	No	O: INFECTION	NA/TC	R (09DEC2021)	Y	Y
Placebo/ [redacted]†	[redacted]	INFEC	Neonatal pneumonia/ neonatal pneumonia	04DEC2021	3	2	No	O: unknown	NA/TC	R (06DEC2021)	Y	Y

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16.2.7.9.2 Listing of Serious Adverse Events (Infant)

Maternal Vaccine Group (as Administered)/ Participant	GA at Birth/ Sex	System Organ Class	Preferred Term/ AE Investigator Text	Onset Date	Dur (Days)[a]	Toxicity Grade	Vax Rel[b]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE (Yes/No)	SAE Hospitalization (Yes/No)
Placebo/ [redacted]	[redacted]	INFEC	Neonatal pneumonia/ neonatal pneumonia	16NOV2021	7	4	No	O: CONGENITAL INFECTION	NA/TC/W	F (22NOV2021)	Y	Y
Placebo/ [redacted]	[redacted]	INFEC	Bronchiolitis/ Bronchiolitis^	09AUG2021	12	3	No	O: Unknown	NA/TC/TCN	R (20AUG2021)	Y	Y
Placebo/ [redacted]	[redacted]	PREG	Jaundice neonatal/ Neonatal jaundice	30JUL2021	3	1	No	O: Hepatic immaturity	NA/TCN	R (01AUG2021)	Y	Y
Placebo/ [redacted]	[redacted]	METAB	Hypoglycaemia neonatal/ Hypoglycemia neonatal on the day of delivery	17JUL2021	3	1	No	O: Unknown	NA	R (19JUL2021)	Y	Y
Placebo/ [redacted]	[redacted]	PREG	Jaundice neonatal/ Newborn jaundice	08DEC2021	2	1	No	O: Unknown	NA/TCN	R (09DEC2021)	Y	Y
Placebo/ [redacted]	[redacted]	INFEC	Sepsis neonatal/ potential neonatal sepsis	05AUG2021	4	1	No	O: infection	NA	R (08AUG2021)	Y	Y
Placebo/ [redacted]	[redacted]	PREG	Jaundice neonatal/ neonatal isoinmune jaundice	19AUG2021	3	1	No	O: isoinmune	NA/TCN	R (21AUG2021)	Y	Y
Placebo/ [redacted]	[redacted]	RESP	Neonatal respiratory distress/ Respiratory distress of the newborn	09SEP2021	8	1	No	O: Immature lung	NA/TCN	R (16SEP2021)	Y	Y
Placebo/ [redacted]	[redacted]	RESP	Tachypnoea/ transient tachypnea	30JUL2021	5	3	No	O: unknown	NA/TC/TCN	R (03AUG2021)	Y	Y
Placebo/ [redacted]	[redacted]	RESP	Neonatal respiratory distress syndrome/ Neonatal respiratory distress syndrome	18JUL2021	3	4	No	O: Unknown	NA/TC	R (20JUL2021)	Y	Y

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16.2.7.9.2 Listing of Serious Adverse Events (Infant)

Maternal Vaccine Group (as Administered)/ Participant	GA at Birth/ Sex	System Organ Class	Preferred Term/ AE Investigator Text	Onset Date	Dur (Days)[a]	Toxicity Grade	Vax Rel[b]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE (Yes/No)	SAE Hospitalization (Yes/No)
Placebo/ [redacted]	[redacted]	PREG	Premature baby/ Preterm birth	04AUG2021	5	4	No	O: Placental abruption	NA	R (08AUG2021)	Y	Y
			Jaundice neonatal/ Neonatal jaundice	11AUG2021	3	2	No	O: Unknown	NA/TCN	R (13AUG2021)	Y	Y
			Weight decrease neonatal/ Neonatal weight loss	11AUG2021	7	3	No	O: Born preterm	NA	R (17AUG2021)	Y	Y

Abbreviations: C = continuing; D = day(s); Dur = duration; FU = follow-up; GA = gestational age; W = weeks. Refer to the AE legend page (Listing 16.2.7.1) for additional definitions.
Note: ^ = Event reported after maternal participant was unblinded.
Note: MedDRA (v25.1) coding dictionary applied.
Note: † = Infant born to human immunodeficiency virus (HIV)-positive participant.
a. Duration (days) was calculated as the difference from the start of the first reported event to resolution of the last reported event, inclusive.
b. Vaccine related (Vax Rel): Relationship to study intervention as assessed by the investigator.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 04MAY2023 (09:56) Output File: ./nda3/C4591015_BR/adae_l002_ser_gr4_inf

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16.2.7.10.1 Listing of Adverse Events Leading to Discontinuation (Maternal)

Vaccine Group (as Administered)/ Participant	Age (Years)	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day[a]/ Dur (Days)[b]	Toxicity Grade	Vax Rel[c]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE/ Imm AE (Yes/No)
No participant meets the reporting criteria.												

Abbreviations: Dur = duration; FU = follow-up; Imm = immediate. Refer to the AE legend page (Listing 16.2.7.1) for additional definitions.
Note: MedDRA (v25.1) coding dictionary applied.
Note: Nonserious adverse events related to study intervention with onset within 7 days (excluding immediate adverse event and adverse events leading to withdrawal) after vaccination and identified as reactogenicity events were excluded from the analysis of adverse events. These events were included in the analysis of reactogenicity events.
a. Relative Day (Rel Day) = AE start date - date of last vaccination + 1. For an AE that occurred before the date of the first study vaccination, + 1 was not added to compute relative day.
b. Duration (days) was calculated as the difference from the start of the first reported event to resolution of the last reported event, inclusive.
c. Vaccine related (Vax Rel): Relationship to study intervention as assessed by the investigator.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 04MAY2023 (12:12) Output File: ./nda3/C4591015_BR/adae_l002_disc_all_p3

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16.2.7.10.2 Listing of Adverse Events Leading to Discontinuation (Infant)

Maternal Vaccine Group (as Administered)/ Participant	GA at Birth/ Sex	System Organ Class	Preferred Term/ AE Investigator Text	Onset Date	Dur (Days)[a]	Toxicity Grade	Vax Rel[b]	Cause of AE	Action: Investigational Vaccine Dose, Participant	Outcome (End Date)	SAE (Yes/No)
BNT162b2 (30 µg)/ [redacted] †	[redacted]	INFEC	Pneumonia/ PNEUMONIA^	12MAY2022	6	4	No	O: INFECTION	NA/W	F (17MAY2022)	Y
Placebo/ [redacted]	[redacted]	INFEC	Neonatal pneumonia/ neonatal pneumonia	16NOV2021	7	4	No	O: CONGENITAL INFECTION	NA/TC/W	F (22NOV2021)	Y

Abbreviations: D = day(s); Dur = duration; FU = follow-up; GA = gestational age; W = weeks. Refer to the AE legend page (Listing 16.2.7.1) for additional definitions.
Note: MedDRA (v25.1) coding dictionary applied.
Note: † = Infant born to human immunodeficiency virus (HIV)-positive participant.
a. Duration (days) was calculated as the difference from the start of the first reported event to resolution of the last reported event, inclusive.
b. Vaccine related (Vax Rel): Relationship to study intervention as assessed by the investigator.
PFIZER CONFIDENTIAL SDTM Creation: 03APR2023 (10:10) Source Data: adae Table Generation: 04MAY2023 (09:57) Output File: ./nda3/C4591015_BR/adae_l002_disc_all_p3_inf

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16.2.8.1 Listing of Participants With First COVID-19 Occurrence After Dose 1 Based on Protocol or CDC Definition – Blinded and Open-Label Follow-Up Period – Dose 1 All-Available Efficacy Population (Maternal)

Vaccine Group (as Randomized)	Participant (Country/Age in Years)	Dose/Rel Day[a]	Start Date	Stop Date	Visit 1 N-Binding Assay/ Visit 1 NAAT/ Visit 2 NAAT	Signs and Symptoms	SARS-CoV-2 NAAT Result (Central Lab/Local Lab[b])	Protocol-Defined or CDC-Defined
BNT162b2 (30 µg)	[redacted]	Dose 2/132*	19SEP2021	04OCT2021	Neg/Neg/Neg	Chills	Pos	Both
						Fever		
						New or increased cough		
						New or increased muscle pain		
						New or increased shortness of breath		
	[redacted]	Dose 2/249*	15JAN2022	25JAN2022	Neg/Neg/Neg	Chills	Pos	Both
						Fever		
						New or increased cough		
						New or increased muscle pain		
	[redacted]	Dose 2/153*	25OCT2021	03NOV2021	Neg/Neg/Neg	Chills	Pos	Both
						New loss of taste or smell		
						New or increased cough		
						New or increased shortness of breath		

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16.2.8.1 Listing of Participants With First COVID-19 Occurrence After Dose 1 Based on Protocol or CDC Definition – Blinded and Open-Label Follow-Up Period – Dose 1 All-Available Efficacy Population (Maternal)

Vaccine Group (as Randomized)	Participant (Country/Age in Years)	Dose/Rel Day[a]	Start Date	Stop Date	Visit 1 N-Binding Assay/ Visit 1 NAAT/ Visit 2 NAAT	Signs and Symptoms	SARS-CoV-2 NAAT Result (Central Lab/Local Lab[b])	Protocol-Defined or CDC-Defined
	[redacted]	Dose 2/222*	16JAN2022	25JAN2022	Neg/Neg/Neg	Sore throat New or increased muscle pain	Pos	Both
	[redacted]	Dose 2/204*	19JAN2022	06FEB2022	Neg/Neg/Neg	Sore throat New or increased cough	Pos	Both
	[redacted]	Dose 2/95*	17OCT2021	06NOV2021	Neg/Neg/Neg	Diarrhea Fever New loss of taste or smell New or increased cough New or increased muscle pain New or increased shortness of breath	Pos	Both
	[redacted]	Dose 2/69	14SEP2021	22SEP2021	Neg/Neg/Neg	Sore throat Chills	Pos	Both

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16.2.8.1 Listing of Participants With First COVID-19 Occurrence After Dose 1 Based on Protocol or CDC Definition – Blinded and Open-Label Follow-Up Period – Dose 1 All-Available Efficacy Population (Maternal)

Vaccine Group (as Randomized)	Participant (Country/Age in Years)	Dose/Rel Day[a]	Start Date	Stop Date	Visit 1 N-Binding Assay/ Visit 1 NAAT/ Visit 2 NAAT	Signs and Symptoms	SARS-CoV-2 NAAT Result (Central Lab/Local Lab[b])	Protocol-Defined or CDC-Defined
						New loss of taste or smell New or increased cough New or increased shortness of breath		
	[redacted]	Dose 2/236*	03JAN2022	14JAN2022	Neg/Neg/Neg	Fever	Pos	Both
	[redacted]	Dose 2/192*	02MAR2022	25MAR2022	Neg/Neg/Neg	New or increased cough Fatigue#	Pos	Both
	[redacted]	Dose 2/221*	09JAN2022	17JAN2022	Neg/Neg/Neg	New or increased shortness of breath Sore throat Headache# Nasal congestion#	Pos	Both
	[redacted]	Dose 2/161*	12JAN2022	22JAN2022	Neg/Neg/Neg	New or increased cough Fever Headache#	Pos	Both

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16.2.8.1 Listing of Participants With First COVID-19 Occurrence After Dose 1 Based on Protocol or CDC Definition – Blinded and Open-Label Follow-Up Period – Dose 1 All-Available Efficacy Population (Maternal)

Vaccine Group (as Randomized)	Participant (Country/Age in Years)	Dose/Rel Day[a]	Start Date	Stop Date	Visit 1 N-Binding Assay/ Visit 1 NAAT/ Visit 2 NAAT	Signs and Symptoms	SARS-CoV-2 NAAT Result (Central Lab/Local Lab[b])	Protocol-Defined or CDC-Defined
	[redacted]	Dose 2/27*	22DEC2021	05JAN2022	Neg/Neg/Neg	New or increased cough Diarrhea	Pos	Both
	[redacted]	Dose 2/123*	02JAN2022	10JAN2022	Neg/Neg/Neg	Chills Fever New or increased cough Rhinorrhoea# Sore throat	Pos	Both
	[redacted]	Dose 2/13	03JUL2021	06JUL2021	Neg/Neg/Neg	Nasal congestion# New loss of taste or smell	Pos	Both
	[redacted]	Dose 2/166*	19DEC2021	24DEC2021	Neg/Neg/Neg	Chills Fever Headache# Sore throat	Pos	Both

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16.2.8.1 Listing of Participants With First COVID-19 Occurrence After Dose 1 Based on Protocol or CDC Definition – Blinded and Open-Label Follow-Up Period – Dose 1 All-Available Efficacy Population (Maternal)

Vaccine Group (as Randomized)	Participant (Country/Age in Years)	Dose/Rel Day[a]	Start Date	Stop Date	Visit 1 N-Binding Assay/ Visit 1 NAAT/ Visit 2 NAAT	Signs and Symptoms	SARS-CoV-2 NAAT Result (Central Lab/Local Lab[b])	Protocol-Defined or CDC-Defined
	[redacted]	Dose 2/199*	05JAN2022	06JAN2022	Neg/Neg/Neg	Fever	Pos	Both
	[redacted]	Dose 2/136*	24FEB2022	28FEB2022	Neg/Neg/Neg	Fatigue#	Pos	Both
						Fever		
						New or increased cough		
						Sore throat		
Placebo	[redacted]	Dose 2/16	28JUL2021	07AUG2021	Neg/Neg/Neg	New or increased cough	Pos	Both
						New or increased muscle pain		
						Sore throat		
	[redacted]	Dose 2/32	13DEC2021	17DEC2021	Neg/Neg/Neg	Nasal congestion#	Pos	CDC-Defined
	[redacted]	Dose 2/30	04DEC2021	13DEC2021	Pos/Neg/Neg	New or increased cough	Pos	Both
						New or increased muscle pain		
						Sore throat		

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16.2.8.1 Listing of Participants With First COVID-19 Occurrence After Dose 1 Based on Protocol or CDC Definition – Blinded and Open-Label Follow-Up Period – Dose 1 All-Available Efficacy Population (Maternal)

Vaccine Group (as Randomized)	Participant (Country/Age in Years)	Dose/Rel Day[a]	Start Date	Stop Date	Visit 1 N-Binding Assay/ Visit 1 NAAT/ Visit 2 NAAT	Signs and Symptoms	SARS-CoV-2 NAAT Result (Central Lab/Local Lab[b])	Protocol-Defined or CDC-Defined
	[redacted]	Dose 1/5	30MAY2021	09JUN2021	Neg/Neg/Pos	Fever	Pos	Both
						Nausea#		
						New loss of taste or smell		
						New or increased cough		
						New or increased muscle pain		
						Sore throat		
						Vomiting		
	[redacted]	Dose 2/117	09JAN2022		Neg/Neg/Neg	Fever	Pos	Both
						Nasal congestion#		
						New or increased muscle pain		
	[redacted]	Dose 1/3	26AUG2021	03SEP2021	Neg/Pos/Pos	New or increased cough	Pos	Both
						Sore throat		

Abbreviations: BRA = Brazil; ESP = Spain; GBR = United Kingdom of Great Britain and Northern Ireland; N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; Neg = negative; Pos = positive; RT-PCR = reverse transcription–polymerase chain reaction; SARS-CoV-2 = severe

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16.2.8.1 Listing of Participants With First COVID-19 Occurrence After Dose 1 Based on Protocol or CDC Definition – Blinded and Open-Label Follow-Up Period – Dose 1 All-Available Efficacy Population (Maternal)

Vaccine Group (as Randomized)	Participant (Country/Age in Years)	Dose/Rel Day[a]	Start Date	Stop Date	Visit 1 N-Binding Assay/ Visit 1 NAAT/ Visit 2 NAAT	Signs and Symptoms	SARS-CoV-2 NAAT Result (Central Lab/Local Lab[b])	Protocol-Defined or CDC-Defined

acute respiratory syndrome coronavirus 2; Unk = unknown; ZAF = South Africa.
Note: † = Human immunodeficiency virus (HIV)-positive participant.
Note: * Indicates COVID-19 occurrence after the participant was unblinded.
Note: # Indicates CDC defined COVID-19 symptom.
a. Relative day (Rel Day) = date of first symptom - date of last dose before first symptom + 1.
b. SARS-CoV-2 NAAT results from the local laboratory are based on the Cepheid Xpert Xpress SARS-CoV-2 test, Roche cobas SARS-CoV-2 real-time RT-PCR test (EUA200009/A001), or Abbott RealTime SARS-CoV-2 assay (EUA200023/A001) only.
PFIZER CONFIDENTIAL SDTM Creation: 12DEC2023 (22:15) Source Data: adsympt Table Generation: 29JAN2024 (22:08) Output File: ./nda3/C4591015_EFF/adsy_l001_cdc_d1_aai1m

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16.2.8.1.1 Listing of Participants With First COVID-19 Occurrence After Birth Based on Protocol or CDC Definition – Blinded and Open-Label Follow-Up Period – All-Available Efficacy Population (Infant)

Maternal Vaccine Group (as Randomized)	Participant (Country/Gestational Age in Weeks)	Birth Date	Start Date	Stop Date	Signs and Symptoms	SARS-CoV-2 NAAT Result (Central Lab/Local Lab[a])	Breast Feeding Status at Visit 6	Breast Feeding Status at Visit 8	Protocol-Defined or CDC-Defined
BNT162b2 (30 µg)	[redacted]	[redacted]	22JAN2022*	06FEB2022	New or increased cough	Pos	Y	N	Both
	[redacted]	[redacted]	17OCT2021*	06NOV2021	Diarrhea	Pos	Y		Both
					Fever				
					New or increased cough				
					New or increased shortness of breath				
	[redacted]	[redacted]	27JAN2022*	04FEB2022	Diarrhea	Pos	Y	Y	Both
					Fever				
					New or increased cough				
					New or increased shortness of breath				
					Vomiting				
	[redacted]	[redacted]	24JAN2022*	01FEB2022	New or increased cough	Pos	Y	Y	Both

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16.2.8.1.1 Listing of Participants With First COVID-19 Occurrence After Birth Based on Protocol or CDC Definition – Blinded and Open-Label Follow-Up Period – All-Available Efficacy Population (Infant)

Maternal Vaccine Group (as Randomized)	Participant (Country/Gestational Age in Weeks)	Birth Date	Start Date	Stop Date	Signs and Symptoms	SARS-CoV-2 NAAT Result (Central Lab/Local Lab[a])	Breast Feeding Status at Visit 6	Breast Feeding Status at Visit 8	Protocol-Defined or CDC-Defined
	[redacted]	[redacted]	03JAN2022*	09JAN2022	Fever	Pos	Y	Y	Both
					Nasal congestion#				
					New or increased cough				
	[redacted]	[redacted]	02JAN2022*	19JAN2022	Fever	Pos	Y	N	Both
					New or increased cough				
	[redacted]†	[redacted]	11APR2022*	24APR2022	Nasal congestion#	Pos	N	N	Both
					New or increased cough				
	[redacted])	[redacted]	10JAN2022*	17JAN2022	Fever	Pos	Y	Y	Both
					New or increased cough				
	[redacted])	[redacted]	20DEC2021*	24DEC2021	Fever	Pos	Y	N	Both

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16.2.8.1.1 Listing of Participants With First COVID-19 Occurrence After Birth Based on Protocol or CDC Definition – Blinded and Open-Label Follow-Up Period – All-Available Efficacy Population (Infant)

Maternal Vaccine Group (as Randomized)	Participant (Country/Gestational Age in Weeks)	Birth Date	Start Date	Stop Date	Signs and Symptoms	SARS-CoV-2 NAAT Result (Central Lab/Local Lab[a])	Breast Feeding Status at Visit 6	Breast Feeding Status at Visit 8	Protocol-Defined or CDC-Defined
Placebo	[redacted]	[redacted]	16AUG2021*	20AUG2021	Rhinorrhoea# Fever	Pos	Y	N	Both
	[redacted]	[redacted]	10JAN2022*	25JAN2022	New or increased cough	Pos	Y	Y	Both
	[redacted]	[redacted]	30JUL2021*	12AUG2021	Fever	Pos	Y	N	Both
	[redacted]	[redacted]	12JUL2021*	28JUL2021	New or increased cough Poor appetite# Diarrhea	Pos	Y	Y	Both
	[redacted]	[redacted]	29SEP2021*	04OCT2021	Fever Nasal congestion# Vomiting Fever	Pos	Y	Y	Both

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16.2.8.1.1 Listing of Participants With First COVID-19 Occurrence After Birth Based on Protocol or CDC Definition – Blinded and Open-Label Follow-Up Period – All-Available Efficacy Population (Infant)

Maternal Vaccine Group (as Randomized)	Participant (Country/Gestational Age in Weeks)	Birth Date	Start Date	Stop Date	Signs and Symptoms	SARS-CoV-2 NAAT Result (Central Lab/Local Lab[a])	Breast Feeding Status at Visit 6	Breast Feeding Status at Visit 8	Protocol-Defined or CDC-Defined
					Nasal congestion#				
			10DEC2021*	18DEC2021	Nasal congestion#	Pos	Y	Y	CDC-Defined
			30JAN2022*	09FEB2022	Fever	Pos	N	N	Both
					New or increased cough				
			11JAN2022*	17JAN2022	Diarrhea	Pos	Y	Y	Both
			24MAY2022*		Nasal congestion#	Pos	Y	Y	Both
					New or increased cough				
			28JAN2022*	07FEB2022	Fever	Pos	Y	Y	Both
			21MAR2022*	27MAR2022	Diarrhea	Pos	Y	Y	Both
					Fever				

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16.2.8.1.1 Listing of Participants With First COVID-19 Occurrence After Birth Based on Protocol or CDC Definition – Blinded and Open-Label Follow-Up Period – All-Available Efficacy Population (Infant)

Maternal Vaccine Group (as Randomized)	Participant (Country/Gestational Age in Weeks)	Birth Date	Start Date	Stop Date	Signs and Symptoms	SARS-CoV-2 NAAT Result (Central Lab/Local Lab[a])	Breast Feeding Status at Visit 6	Breast Feeding Status at Visit 8	Protocol-Defined or CDC-Defined

Abbreviations: ESP = Spain; GBR = United Kingdom of Great Britain and Northern Ireland; N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; Neg = negative; Pos = positive; RT-PCR = reverse transcription–polymerase chain reaction; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; Unk = unknown; ZAF = South Africa.
Note: † = Born to human immunodeficiency virus (HIV)-positive maternal participant.
Note: * Indicates COVID-19 occurrence after the maternal participant was unblinded.
Note: # Indicates CDC defined COVID-19 symptom.
a. SARS-CoV-2 NAAT results from the local laboratory are based on the Cepheid Xpert Xpress SARS-CoV-2 test, Roche cobas SARS-CoV-2 real-time RT-PCR test (EUA200009/A001), or Abbott RealTime SARS-CoV-2 assay (EUA200023/A001) only.
PFIZER CONFIDENTIAL SDTM Creation: 12DEC2023 (22:15) Source Data: adsympt Table Generation: 29JAN2024 (21:36) Output File: ./nda3/C4591015_EFF/adsy_l001_cdc_d1_aaii

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16.2.8.2 Listing of Participants With First Severe COVID-19 Occurrence After Dose 1 Based on Protocol or CDC Definition – Blinded and Open-Label Follow-Up Period – Dose 1 All-Available Efficacy Population (Maternal)

Vaccine Group (as Randomized)	Participant (Country/Age in Years)	Dose/Rel Day[a]	Start Date	Stop Date	Visit 1 N-Binding Assay/ Visit 1 NAAT/ Visit 2 NAAT	Signs, Symptoms, and Events	SARS-CoV-2 NAAT Result (Central Lab/Local Lab[b])	Protocol-Defined or CDC-Defined
No participant meets the reporting criteria.								

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; RT-PCR = reverse transcription-polymerase chain reaction; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

a. Relative day (Rel Day) = date of first symptom - date of last dose before first symptom + 1.

b. SARS-CoV-2 NAAT results from the local laboratory are based on the Cepheid Xpert Xpress SARS-CoV-2 test, Roche cobas SARS-CoV-2 real-time RT-PCR test (EUA200009/A001), or Abbott RealTime SARS-CoV-2 assay (EUA200023/A001) only.

PFIZER CONFIDENTIAL SDTM Creation: 12DEC2023 (22:15) Source Data: adsympt Table Generation: 29JAN2024 (22:14) Output File: ./nda3/C4591015_EFF/adsy_l001_cdc_d1sev_aai1m

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16.2.8.2.1 Listing of Participants With First Severe COVID-19 Occurrence After Birth Based on Protocol or CDC Definition – Blinded and Open-Label Follow-Up Period – All-Available Efficacy Population (Infant)

Maternal Vaccine Group (as Randomized)	Participant (Country/Gestational Age in Weeks)	Birth Date	Start Date	Stop Date	Signs, Symptoms, and Events	SARS-CoV-2 NAAT Result (Central Lab/Local Lab[a])	Breast Feeding Status at Visit 6	Breast Feeding Status at Visit 8	Protocol-Defined or CDC-Defined
BNT162b2 (30 µg)	[redacted]	[redacted]	26JAN2022*		RR = 46 breaths/minute	Pos	Y	N	Protocol-Defined
	[redacted]	[redacted]	31JAN2022*		RR = 42 breaths/minute	Pos	Y	Y	Protocol-Defined
	[redacted]	[redacted]	21APR2022*		RR = 46 breaths/minute	Pos	N	N	Protocol-Defined
	[redacted]	[redacted]	11JAN2022*		RR = 48 breaths/minute	Pos	Y	Y	Protocol-Defined
	[redacted]	[redacted]	21DEC2021*		SBP = 84 mm Hg RR = 36 breaths/minute	Pos	Y	N	Protocol-Defined
Placebo	[redacted]	[redacted]	17AUG2021*		SBP = 97 mm Hg HR = 184 beats/minute	Pos	Y	N	Protocol-Defined
	[redacted]	[redacted]	10JAN2022*		RR = 50 breaths/minute RR = 40 breaths/minute	Pos	Y	Y	Protocol-Defined

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16.2.8.2.1 Listing of Participants With First Severe COVID-19 Occurrence After Birth Based on Protocol or CDC Definition – Blinded and Open-Label Follow-Up Period – All-Available Efficacy Population (Infant)

Maternal Vaccine Group (as Randomized)	Participant (Country/Gestational Age in Weeks)	Birth Date	Start Date	Stop Date	Signs, Symptoms, and Events	SARS-CoV-2 NAAT Result (Central Lab/Local Lab[a])	Breast Feeding Status at Visit 6	Breast Feeding Status at Visit 8	Protocol-Defined or CDC-Defined
	[redacted]	[redacted]	31JUL2021*		RR = 50 breaths/minute	Pos	Y	N	Protocol-Defined
					SBP = 96 mm Hg				
			03AUG2021*	10AUG2021	Needs oxygen therapy	Pos	Y	N	Protocol-Defined
	[redacted]	[redacted]	13JUL2021*		RR = 36 breaths/minute	Pos	Y	Y	Protocol-Defined
					SBP = 90 mm Hg				
	[redacted]†	[redacted]	14JAN2022*		RR = 46 breaths/minute	Pos	Y	Y	Protocol-Defined
	[redacted]	[redacted]	27MAY2022*		RR = 41 breaths/minute	Pos	Y	Y	Protocol-Defined

Abbreviations: ESP = Spain; HR = heart rate; N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; Neg = negative; Pos = positive; RR = respiratory rate; RT-PCR = reverse transcription–polymerase chain reaction; SBP = systolic blood pressure; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; Unk = unknown; ZAF = South Africa.

Note: † = Born to human immunodeficiency virus (HIV)-positive maternal participant.

Note: * Indicates COVID-19 occurrence after the maternal participant was unblinded.

a. SARS-CoV-2 NAAT results from the local laboratory are based on the Cepheid Xpert Xpress SARS-CoV-2 test, Roche cobas SARS-CoV-2 real-time RT-PCR test (EUA200009/A001), or Abbott RealTime SARS-CoV-2 assay (EUA200023/A001) only.

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16.2.8.3 Listing of Participants With MIS-C Case Occurrence After Birth – Blinded and Open-Label Follow-Up Period – All-Available Efficacy Population (Infant)

Maternal Vaccine Group (as Randomized)	Participant (Country/Gestational Age in Weeks)	Start Date	Stop Date	Signs and Symptoms	SARS-CoV-2 NAAT Result (Central Lab/Local Lab[a])	Breast Feeding Status at Visit 6	Breast Feeding Status at Visit 8
No participant meets the reporting criteria.							

Abbreviations: NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

a. SARS-CoV-2 NAAT results from the local laboratory are based on the Cepheid Xpert Xpress SARS-CoV-2 test, Roche cobas SARS-CoV-2 real-time RT-PCR test (EUA200009/A001), or Abbott RealTime SARS-CoV-2 assay (EUA200023/A001) only.

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