



Pfizer & BioNTech Announce a [Research Grant RFP](#)
COVID-19 Vaccine Development for LMICs
Competitive Grant Program - internal Pfizer review process

I. Background

Pfizer Global Medical Grants (GMG) and BioNTech support the global healthcare community's independent research initiatives to improve patient outcomes in areas of unmet medical need that are aligned with our medical and/or scientific strategies.

The competitive grant program involves a publicly posted general Request for Proposal (RFP) that provides detail regarding a general area of interest, sets timelines for review and approval, and uses an internal review process to make final grant decisions. Organizations may submit an application addressing the research areas as outlined in the specific RFP.

For all Investigator Sponsored Research (ISRs) and general research grants, the grant requester (and ultimately the grantee) is responsible for the design, implementation, sponsorship, and conduct of the independent initiative supported by the grant, including compliance with any regulatory requirements. Pfizer and BioNTech must not be involved in any aspect of study protocol or project development, nor the conduct or monitoring of the research program.

II. Eligibility

Geographic Scope:	<p>Global, with preference given to organizations with a presence in a low- and middle-income country (LMIC)*</p> <p>*Requests from China, Hong Kong, Macau, and Taiwan are ineligible as these markets are outside the Pfizer/BioNTech collaboration</p>
Applicant Eligibility Criteria	<ul style="list-style-type: none"> • The institution and principal investigator (PI) must be based in one of the eligible countries noted above. • Only organizations are eligible to receive grants, not individuals or medical practice groups. • The applicant (PI) must have a medical or postdoctoral degree (MD, PhD, or equivalent), an advanced nursing degree (BSN with a MS/PhD), or a degree in Pharmacy, Physiotherapy, or Social Work. • Applicant must be affiliated with a host institution • Requests from China, Hong Kong, Macau, and Taiwan are ineligible as these markets are outside the Pfizer/BioNTech collaboration

III. Requirements

Date RFP Issued	February 17, 2022
Clinical Area	Vaccine Preventable Diseases – COVID-19
General Area of Interest for this RFP:	<p>The intent of this RFP is to support COVID-19 vaccine development for LMICs. The support provided by Pfizer will be through the provision of the Pfizer-BioNTech COVID-19 Vaccine for comparator studies. No funding will be provided.</p> <p>We are particularly interested in supporting research in the following areas:</p> <ul style="list-style-type: none"> • Clinical studies designed to lead to approval and availability of new COVID-19 vaccine(s) • Such vaccine(s) must be intended to protect large populations in LMIC, based on study design, GMP manufacturing capacity, product characteristics, the applicant’s ability to manage timely GCP-compliant clinical trials and regulatory filings and other relevant factors <p>NOTE:</p> <ul style="list-style-type: none"> • Preclinical studies will not be considered unless there is a regulatory

	<p>GLP requirement to support clinical studies</p> <ul style="list-style-type: none"> Studies seeking to use doses of BNT162b2 procured through contracted supply or advanced purchase agreements are outside the scope of this RFP. Please contact Derek Warnick (derek.warnick@pfizer.com) for additional information.
<p>Additional Requirements:</p>	<p>In completing the proposal (see Appendix A), please ensure that the following points are covered:</p> <p>Goals</p> <p>Please provide the main elements of your vaccine development program.</p> <p>Needs Assessment</p> <p>Please summarize your need for BNT162b2 as a comparator vaccine.</p> <p>Target Regulatory Authorities</p> <p>Please outline your intended target regulatory authorities for clinical trial approvals and emergency use or marketing approvals or equivalent.</p> <p>Project Design and Methods</p> <ul style="list-style-type: none"> Describe concisely the research design and methods for achieving the stated goals. For each clinical interventional study, include main inclusion/exclusion criteria, primary endpoints and intended countries. For immunological assays please append assay protocol, evidence of assay validation and reference publications using your assay Please tabulate number of doses needed and timing of need Please justify number of doses required Please describe your strategy to ensure secure storage, distribution, and investigational product accountability, as well as safeguards to prevent unauthorized diversion <p>Innovation</p> <p>How will this proposal enhance vaccine availability in LMICs? Describe how this program builds upon previous vaccine development programs, existing work, or ongoing projects developed either by your institution or other institutions related to this project</p>

<p>Expected Approximate Monetary Range of Grant Applications:</p>	<ul style="list-style-type: none"> • We are only accepting drug-only (BNT162b2 vaccine) proposals • No funding will be provided
<p>Key Dates:</p>	<ul style="list-style-type: none"> • RFP start date: February 17, 2022 • RFP end date: December 31, 2022 • Grant applications may be submitted throughout the year and application reviews and decisions will be completed on a rolling basis • Anticipated Grant Award Notification Date: Our intent is to review and send out decision notifications within 8-10 weeks of submission • Grants will be distributed following a fully executed agreement and submission of Final Protocol, documentation of IRB/IEC approval, regulatory approval (if applicable), exemption or waiver • Anticipated Project Length: 1-2 years
<p>How to Submit:</p>	<ul style="list-style-type: none"> • All grant requests must be submitted via our grant management system. Please go www.cybergrants.com/pfizer/Research and sign in. First-time users should click “Create your password”. <i>[Note: there are individual portals for each grant application type (e.g., knowledge, LOI, research full proposal, and QI full proposal). Please be sure to use the URL above.]</i> • Click the “Start A New Research Grant Application” button. • In the Study Details section of the application: <ul style="list-style-type: none"> ○ For “Project Type” select Investigator Sponsored Research: Pre-clinical/Clinical (Includes focus on a Pfizer Drug or Compound) ○ For “Grant Request Type” select Drug Only ○ For “Pfizer Drug of Interest” select BNT162b2 ○ Select the following Primary Area of Interest: Vaccine Preventable Diseases – COVID-19 ○ For the question “Competitive Grant?” select Yes ○ Select the following Competitive Grant Program Name: 2022 VAC G: COVID-19 Vaccine Development for LMIC • Requirements for submission: Complete all required sections of the online application and upload your project proposal (see Appendix) in the Proposal/Protocol field. • If you encounter any technical difficulties with the website, please click the “Technical Questions” link at the bottom of the page. <p>IMPORTANT: Be advised applications submitted after the due date will not</p>

	<p>be reviewed.</p>
<p>Questions:</p>	<ul style="list-style-type: none"> • If you have questions regarding this RFP, please direct them in writing to the Grant Officer, Derek Warnick (derek.warnick@pfizer.com), with the subject line “COVID-19 Vaccine Development in LMIC.” • Please click here to view Frequently Asked Questions regarding the Competitive Grant Program
<p>Grant Agreements:</p>	<ul style="list-style-type: none"> • If your grant is approved, your institution will be required to enter into a written grant agreement with Pfizer and BioNTech. • The grant agreement will include terms requiring you to: <ul style="list-style-type: none"> (i) assume regulatory responsibilities as study Sponsor; (ii) provide certain study documentation to Pfizer/BioNTech; (iii) adhere to applicable research laws and regulations (e.g. Good Clinical Practice, data privacy regulations, global trade control laws and anti-bribery laws); (iv) obtain IRB/Ethics Committee approval and research informed consent from study participants; (v) report adverse events to Pfizer/BioNTech; (vi) grant Pfizer and BioNTech a non-exclusive license to any Pfizer-BioNTech COVID-19 Vaccine-related inventions; (vii) submit study manuscripts to Pfizer/BioNTech for prepublication review; (viii) obtain minimum levels of clinical trial insurance; and agree to binding arbitration for any disputes related to this RFP.
<p>Review and Approval Process</p>	<ul style="list-style-type: none"> • Grant requests received in response to a general RFP are reviewed by Pfizer and BioNTech to make final grant decisions.
<p>Mechanism by which Applicants will be Notified:</p>	<ul style="list-style-type: none"> • All applicants will be notified via email by the dates noted above. • Applicants may be asked for additional clarification during the review period.

Appendix A

General RFP Submission Requirements

Project Proposals/Protocols should be single-spaced using Calibri 12-point font and 1-inch margins. Note there is a 15-page limit exclusive of references. Please include the following:
**Please see the Additional Requirements section above for specific instructions for the elements below marked with an asterisk*.*

Goals and Objectives*	<ul style="list-style-type: none"> Provide the main goal of the study and the study population (if applicable). Provide a detailed definition that is directly linked to the primary objective
Assessment of Need for the Project*	<ul style="list-style-type: none"> This should reflect your study rationale. Provide a brief description of the medical/scientific question and the rationale of how this trial or study addresses the question
Target Audience*	<ul style="list-style-type: none"> Describe the primary audience(s) targeted for this project. For Investigator Sponsored Clinical Trials, please specify the age, gender and other demographic information for trial population Also indicate whom you believe will directly benefit from the project outcomes. Describe the overall population size as well as the size of your sample population
Project Design and Methods*	<ul style="list-style-type: none"> Describe concisely the research design and methods for achieving the stated goals. Include inclusion/exclusion criteria, treatment plan and statistical plan
Innovation*	<ul style="list-style-type: none"> How will this proposal enhance vaccine availability in LMICs? Describe how this program builds upon previous vaccine development programs, existing work, or ongoing projects developed either by your institution or other institutions related to this project
Evaluation and Outcomes	<ul style="list-style-type: none"> Specify type and frequency of safety, efficacy, and/or outcome measures. Also indicate the method(s) used to assess measures Provide a publication plan describing intended submission of abstracts to (a) congress(es) or intended submission of (a) publication(s) to peer-reviewed journals. All publications must follow ICH guidelines
Anticipated Project Timeline	<ul style="list-style-type: none"> Provide an anticipated timeline for your project including project start/end dates
Additional Information	<ul style="list-style-type: none"> If there is any additional information you feel Pfizer and BioNTech should be aware of concerning the importance of this project, please summarize here

Organization Detail	<ul style="list-style-type: none">• This information is used to assess the capability of the organizational resources available to perform the effort proposed. Identify the facilities to be used [laboratory, pre-clinical, clinical and “other”]. If appropriate, indicate their capacities, pertinent capabilities, relative proximity and extent of availability to the project
Partners/Collaborators	<ul style="list-style-type: none">• List any development partners or collaborators involved in this project and summarize their capabilities and qualifications
References	<ul style="list-style-type: none">• Bibliography of relevant references