

Background

Clinical trials are the foundation of medical research, enabling the evaluation of potential breakthroughs in a controlled setting. People who participate in clinical trials are volunteers and help us characterize the safety and effectiveness of a medicine or vaccine. The more clinical trial participants reflect the diversity of the patient population for a disease or condition, the more we can understand the safety and effectiveness of the medicines and vaccines we are developing. At Pfizer, we also recognize that ensuring diversity in clinical trials is a matter of equity and can also aide in reducing disparities in healthcare.

Overcoming barriers and challenges to appropriate representation in clinical trials will not happen overnight nor can it be achieved by a single company. In the last two years, we have seen government- and industry-led efforts to advance clinical trial diversity, including new guidances by the Food and Drug Administration (FDA) and the first set of industry-wide principles aimed at creating greater health equity released by the Pharmaceutical Research and Manufacturers of America (PhRMA).^{1,2}

Diversity in Pfizer Clinical Trials

At Pfizer, we are applying the learnings from our landmark phase 3 COVID-19 vaccine clinical trial, which enrolled 46,331 participants, to advance clinical research in all therapeutic areas; this includes finding common solutions that increase diversity in clinical trials by improving access and awareness and, importantly, building trust.³ Together these commitments can help address the socioeconomic barriers to clinical trial participation. In addition, to better understand our clinical trial diversity, Pfizer conducted a rigorous, in-depth demographic analysis of the participants enrolled in our U.S. trials initiated between 2011 and 2020. Published in the July 2021 issue of *Contemporary Clinical Trials*, the analysis has enabled Pfizer to define which areas to focus on improving and which need continued vigilance.⁴

Pfizer's Policy

Pfizer is committed to increasing diverse participation of all races, ethnicities, biological sexes, ages, and/or abilities at or above United States population or disease prevalence levels (as appropriate) in all our clinical trials.⁵ To achieve this goal, Pfizer is working to:

- embed diversity within our organization,
- evolve site partnerships,
- build trust and awareness in multicultural communities,⁶
- address practical barriers to participation such as costs, and
- share our knowledge.

Pfizer's Call to Action

Pfizer is committed to working with all stakeholders, including those who are members of the multi-cultural community, to advance meaningful cross-sector approaches to improving the diversity of clinical trial participants; thus, helping to improve outcomes for all patients and reduce healthcare disparities. Pfizer recognizes the need to engage in open and transparent conversations with patients, patient advocacy groups, health care practitioners, community organizations, and others about how, together, we can build trust in medical research to better meet the needs of the communities we serve. Learning from our own experiences and efforts, Pfizer strongly encourages commitments by all stakeholders, including our peers and policymakers, to come together to take sustained action on improving the diversity of clinical trials.

¹ FDA Offers Guidance to Enhance Diversity in Clinical Trials, Encourage Inclusivity in Medical Product Development (www.fda.gov/news-events/press-announcements/fda-offers-guidance-enhance-diversity-clinical-trials-encourage-inclusivity-medical-product) and FDA Takes Important Steps to Increase Racial and Ethnic Diversity in Clinical Trials (www.fda.gov/news-events/press-announcements/fda-takes-important-steps-increase-racial-and-ethnic-diversity-clinical-trials).

² PhRMA Announces First-Ever, Industry-Wide Principles on Clinical Trial Diversity (phrma.org/Equity/clinical-trial-diversity).

³ See: www.pfizer.com/science/coronavirus/vaccine/about-our-landmark-trial and [COVID-19 must catalyse changes to clinical development](https://doi.org/10.1016/j.cct.2021.106421). *Nature Review Drug Discovery*.

⁴ Demographic diversity of participants in Pfizer sponsored clinical trials in the United States. *Contemporary Clinical Trials*. 2021. doi.org/10.1016/j.cct.2021.106421.

⁵ Pfizer is actively exploring opportunities to improve the participation of LGBTQ+ people in our clinical trials.

⁶ At Pfizer, we define multicultural community to include people of all races, ethnicities, biological sexes, LGBTQ+ identities, ages, and/or abilities.

Increase Transparency

Sharing baseline metrics is the first step in providing transparency on progress and future improvement around diversity in clinical trials. We believe our approach can serve as a benchmark for other companies to assess clinical trial diversity and allow for comparison across published data and standardized reporting in the future. At Pfizer, we plan to continue analyzing our data and encourage other companies to make similar commitments. While clinical development activities are typically considered competitive information, sponsors should commit to a new interpretation for what is truly proprietary and be freer in sharing information—including how to improve diversity. While the private sector can mobilize to achieve information exchange, government can help by sponsoring roundtables and encouraging partnerships where best practices can be shared.

Drive Awareness of Clinical Trials

Understanding, finding, and navigating clinical trials can be challenging. Pfizer encourages all stakeholders to partner in efforts to increase the understanding of and awareness about clinical trials, with a focus on diverse populations. Specifically, Pfizer supports the education of healthcare professionals who might inform patients on the value of clinical trial participation, recommend participation through referrals, and address misconceptions about participation. These efforts can be enhanced with the development and usage of health-literate, culturally-relevant materials for patient education. Addressing mistrust and misinformation in medical research is a critical part of increasing the understanding about the goals of clinical trials. Pfizer encourages government action to conduct public service campaigns about the value of clinical trials, developed in collaboration with multi-cultural community members and additional key stakeholders.

Increase Access by Addressing Barriers to Participation

Addressing known barriers to accessing clinical trials, with particular attention to those barriers with the greatest effect on underrepresented populations, is a critical step in improving diverse participation.⁷ Pfizer supports the development and conduct of clinical trials that have been planned to address access barriers, including out-of-pocket costs associated with participation (e.g., transportation, meals). Pfizer encourages policymakers to consider changes that would better enable sponsors to cover costs such as lost wages, co-pays, and deductibles due to participation in trials. Pfizer also supports inclusive clinical trial design that incorporates diverse perspectives to ensure that trials are designed and implemented to consider specific participation burdens.

Improve Clinical Trial Infrastructure

Improving awareness and access to clinical trials while reducing barriers to participation must also be accompanied by improvements in clinical trial infrastructure. Pfizer encourages the development and sustainment of a network of clinical trial sites in underserved communities and encourages non-traditional locations such as community health centers and pharmacies. Importantly, we also encourage an increase in multi-stakeholder efforts to further the development of more diverse clinical trial investigators. In addition, we support efforts focused on increasing diversity of clinical trial staff and institutional review board members. Recent reports have shown that the use of remote technologies and other decentralization tools can reduce perceived barriers to participation.⁸ Pfizer calls for broad stakeholder engagement to explore mechanisms to accelerate and increase the use of technology for remote trial participation. Opportunities might include partnerships with Federal agencies to support broader access to affordable broadband, telemedicine, and digital health technology tools such as mobile devices, apps, and wearables/sensors.

⁷ For examples see: [Barriers to Patient Enrollment in Therapeutic Clinical Trials for Cancer: A Landscape Report](#). American Cancer Society, Cancer Action Network.

⁸ Association of remote technology use and other decentralization tools with patient likelihood to enroll in cancer clinical trials. *JAMA Netw Open*. 2022. DOI: [10.1001/jamanetworkopen.2022.20053](https://doi.org/10.1001/jamanetworkopen.2022.20053).