IFPMA | Ethoscope

Diversity and inclusion in clinical trials: Bioethical perspective and principles

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As IFPMA members, we believe that the knowledge gained from clinical trials should be used to support the development and use of innovative medicines, vaccines, and other therapies, in order to develop the right treatment for the right patient. We believe that patient populations in clinical trials should be reflective of the epidemiology and demographics of those who would benefit from the therapeutic agent. To this end, we believe that diversity and inclusion in clinical trials is a matter of both equity and scientific rigor and, as such, that all individuals should have equal opportunity to participate in relevant clinical trials. The biopharmaceutical industry is committed to take affirmative steps to increase clinical trial diversity.

Diversity is multidimensional: it includes factors such as age, sex, ancestry, race, ethnicity, and gender, as well as environmental factors such as geography, socio-economic status, and access to healthcare. Moreover, demographics are shifting globally, which is impacting the global epidemiology of disease. Diversity among clinical trial participants is integral to understanding how the full range of patients who are most likely to benefit will respond to a treatment.

We believe that all individuals should have the opportunity to participate in clinical research, and that sponsors of clinical research have an ethical responsibility to ensure that participant diversity is incorporated into their research and development programs. We recognize that the research community has a responsibility to reduce barriers to clinical trial participation, especially for members of groups who have been historically under-represented. We should seek ways to improve equity of access for all across all phases of clinical research.

Recently, there has been increased recognition that underrepresentation of certain populations in clinical research is a global health equity issue. The COVID-19 pandemic has heightened awareness of this troubling issue, including the visibly disproportionate impact of the pandemic along racial, ethnic, and socioeconomic lines. This growing awareness of the need for global health equity was reflected strongly in the ensuing effort to ensure that the COVID-19 vaccine candidates were tested in the populations that reflected the demographics of the disease.

The pandemic continues to underscore the critical need for the global healthcare community, including the biopharmaceutical industry, to strive to understand the root causes of health

inequities and to employ strategies to eliminate those inequities, including adopting strategies to address diversity in clinical trial participation.[1][2]

As IFPMA members, we have a responsibility to recognize and act on the need for diverse representation and inclusion in clinical trials from a global perspective by implementing policies and practices within our own organizations to support diverse enrollment into studies in every country where we conduct clinical trials. We recognize that each country, and every disease, brings unique opportunities and challenges. Countries vary in their societal, legal, ethical, and regulatory positions on the complex issues of race, ethnicity, sex, and other facets of diversity. This document is not intended to offer a comprehensive solution nor to suggest specific tactics, but rather to provide principles that support continuous and sustainable improvement in clinical trial diversity globally. It should be viewed in the context of broader discussion of bioethics, equity, and scientific rigor of clinical research.

Many of the important foundational documents guiding bioethics in clinical research and practice were prompted by historical mistreatment of research participants that violated their basic human rights. Today, the ethical frameworks that guide research involving human subjects provide strong protections for individuals who choose to participate and specifically guard against the kinds of abuse of human rights that took place in the past. The inclusion of a diverse population of participants in clinical trials is aligned with these core bioethical principles.

The seminal work Principles of Biomedical Ethics[3] by Beauchamp and Childress and the Belmont Report[4] published by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1978, outline specific ethical principles (justice, fairness, beneficence, and non-maleficence) that guide decision-making in medical practice and research with human subjects. With these important ethical considerations in mind, we believe in the following Principles:

- → **The biopharmaceutical industry, as sponsors of clinical research, should commit to identifying barriers to participation by diverse groups in clinical research, and strive to implement strategies that help to reduce or overcome those barriers.** The barriers to participation can be individual and/or systemic, and include factors such as lack of trust in the medical and/or biopharmaceutical industry, lack of awareness of clinical trial options, the time and financial costs associated with participating, restrictive eligibility criteria, lack of supportive infrastructure, and physician/investigator and/or study team bias. The

[1] See International Ethical Guidelines for Health-Related Research Involving Humans, Fourth Edition. Geneva. Council for International Organizations of Medical Sciences (CIOMS); 2016. https://cioms.ch/publications/

[2] 2 In addition, in 2020, PhRMA added to its global "Principles on the Conduct of Clinical Trials, Communication of Trial Results" by publishing industry-wide principles on clinical trial diversity. The PhRMA principles are focused on enhancing diversity in clinical trial populations to help lead to studies better reflecting the patient populations most likely to use the product under study if it achieves regulatory approval. PhRMA's principles include a commitment to build trust with underrepresented populations, reduce barriers to clinical trial access, use real-world data to enhance information on diverse populations, and enhance information about diversity and inclusion in clinical trial participation. https://www.phrma.org/en/Equity/Clinical-Trial-Diversity

[3] Beauchamp TL, Childress JF (2019). Principles of Biomedical Ethics. Eighth edn. New York, NY: Oxford University Press.

[4] UNITED STATES. (1978) The Belmont report: Ethical Principles and Guidelines for the Protection of Human Subjects Research. [Bethesda, Md.], The Commission.

biopharmaceutical industry needs to tailor outreach to meaningfully engage, understand barriers, and work to provide solutions that enable participation.

- **Learning about and understanding the specific needs and challenges of diverse groups is a prerequisite to clinical trial population diversity and the benefits that follow.** The means to achieve this learning and understanding may vary by context. For example, it may be facilitated through outreach and dialogue with key stakeholders serving diverse groups, including community organizations and healthcare professionals serving diverse groups, or other means tailored to facilitating dialogue. As this is a shared challenge, member organizations are encouraged to work collaboratively and to share best practices.
- **It is important to conduct clinical research in the widest range of populations that a potential therapeutic agent is intended to help.** This goal should be incorporated into the design and execution of clinical trials. For example, this goal may be advanced by striving to embed diversity considerations – including the patient voice - into protocol development, eligibility criteria, site and investigator selection, and recruitment strategies, but also by including diversity considerations as early as possible in the research and development process.
- **Diversity within the clinical research community, including sponsors, research teams, investigators, study coordinators, practice nurses, pharmacists, IRBs/ECs, and others, can be a driver of greater diversity in patient participation.** The research community and the biopharmaceutical industry have a responsibility to contribute to improvement in diversity of the whole clinical research ecosystem; for example, through improving diversity in key roles internally within sponsor organizations, encouraging more diverse healthcare professionals to engage in clinical research, supporting the training of diverse investigators, study staff, and other stakeholders including regulators and health authorities, and helping to establish research capabilities at sites located in underrepresented and diverse communities.

These principles underscore and will guide the biopharmaceutical industry's strategy and tactics to increase clinical trial diversity. We will meet our collective responsibility to reduce barriers to clinical trial participation. As IFPMA members, we strive to further improve diversity and inclusion in our clinical trials.