

IFPMA Perspective on:

CLINICAL RESEARCH IN RESOURCE-LIMITED SETTINGS

The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) congratulates the Council for International Organizations of Medical Sciences (CIOMS) and the work of its technical working group for the very comprehensive report on Clinical research in resource-limited settings¹. The biopharmaceutical industry is already actively engaged and contributes to the evolving clinical research ecosystem.

IFPMA members conduct high quality, science-driven studies to develop innovative medicines & vaccines for unmet patient needs. These studies are conducted consistently according to international ethical and regulatory standards, such as the Declaration of Helsinki and ICH standards to ensure patient safety and data integrity. We also conduct our research in compliance with local regulations and ethical requirements. In addition, we are committed to support local policy makers to align on global and local standards as part of capacity building and a sustainable ecosystem.

The private sector is a crucial contributor to this ecosystem due to its vast experience in designing, initiating, and running global clinical trials according to the highest regulatory and ethical standards to deliver robust data for the development of innovative medicines & vaccines for patients worldwide.

The speed and mutual success of our development efforts depends on close collaboration with other partners. The availability of an ethical and scientific clinical research ecosystem ensures participant safety and can deliver high quality results that meet regulators' expectations. The creation of such a sustainable ecosystem requires open and transparent collaboration between all stakeholders to build trust, long term investment to develop sufficient capacity of trained clinical trial researchers, adequate healthcare infrastructure, quality assurance mechanisms and data collection tools.

IFPMA welcomes the opportunity to contribute our experience and knowledge to expand the clinical research infrastructure in LMICs, which will drive advancement of healthcare systems and address the needs of local and global patients' population. For example:



We are committed to conducting clinical trials globally according to the same high ethical and regulatory standards and respecting local laws and traditions, regardless of location. We apply ICH good clinical practice (ICH E6) implemented into regulatory frameworks in major markets around the world. We support and continue to advocate for adoption of these international standards across all countries participating in clinical research. Industry supports strengthening of clinical trial capability in LMICs to allow participation in global studies, and more broadly to ensure that all clinical studies can be conducted according to a single global standard.



We collaborate with academic researchers, clinicians, patient groups, and other healthcare participants to identify the unmet medical needs and ensure that our clinical trials are designed to meet them, while generating quality evidence even in resource-limited settings. To do this, we participate in patient community advisory boards, conduct expert advisory input forums and investigator trainings, and establish external data monitoring boards in specific cases.



We use innovative study designs, such as master protocols or quality by design, in a fit for purpose manner, as well as novel digital technologies where possible, to optimize the clinical trial conduct and patient experience. IFPMA is a standing observer to ICH and our experts are participating in the development of new international guidance on clinical trials². In addition, some of our members are working in several initiatives³ to improve the patient trial experience through involvement, shared decision making, and electronic tools.



We are currently actively working on increasing population diversity in our trials and consider this as a priority goal. Principles for design and conduct of multi-regional clinical trials (ICH E17) as well as consideration of ethnic differences in global clinical trials (ICH E5) are being implemented in our trial designs.



We are committed to scientific data integrity, transparency, and confidentiality of personal data according to national laws and regulations. We continue to support disclosure of clinical trial information via clinical trial registries and databases as well as the timely publication of clinical trial results in the scientific literature⁴. We are committed to responsible clinical trial data sharing with patients and researchers⁵.

We recognize the increased number of countries adhering to international ethical and regulatory standards and call for all countries to move towards this direction to ensure patient safety regardless of the country in which the trial is conducted. This will facilitate the conduct of global and multi-regional trials and enable capacity building and inclusion of more clinical trial sites in LMICs.

The industry remains supportive towards this goal and will continue to contribute when necessary. We call on funders to coordinate initiatives and invest in building sustainable regional and international networks with sufficient capacity and scale that can speedily deliver high quality data for regulatory and other use.

IFPMA and its members stand ready to actively collaborate and contribute our scientific and professional experience in conducting clinical research in multiple regions around the globe.

1 Council for International Organizations of Medical Sciences (CIOMS). [Clinical Research in resource-limited settings](#). A consensus by a CIOMS Working Group. Geneva, Switzerland: CIOMS; 2021. Accessed 26 May 2022.

2 E.g., ICH E6(R3) on Good Clinical Practices; ICH E8(R1) on Revision of General Considerations for Clinical Trials; ICH E9 on Statistical Principles of Clinical Trials and ICH E20 on Adaptive Clinical Trials

3 Examples of initiatives are: [CTTi](#), [DiME](#), [DTRA](#), [EU-Pearl](#); [TransCelerate](#), [Principles on Conduct of Clinical Trials | PhRMA](#); [Sharing clinical trial information \(efpia.eu\)](#); [EFPIA statement on EMA's "Accelerating Clinical Trials in the EU \(ACT EU\)" initiative](#)

4 [IFPMA Clinical trials position papers](#)

5 Biopharmaceutical companies are committed to enhancing public health through responsible [sharing of clinical trial data](#) in a manner that is consistent with the following Principles: Safeguarding the privacy of patients, respecting the integrity of national regulatory systems, maintaining incentives for investment in biomedical research. [IFPMA Principles](#); [EFPIA Principles](#).