Joint statement on strengthening clinical trials 2025

25 September 2025

In 2022, WHO Member States adopted the World Health Assembly (WHA) resolution on strengthening clinical trials (WHA 75.8). WHO has since outlined the action required to deliver on this commitment through the WHO 'Guidance for Best Practices for Clinical Trials' and a 'Global Action Plan for clinical trial ecosystem strengthening' (GAP-CTS). This body of work recognizes the pivotal role research funders play in shaping and developing a clinical trial ecosystem that is coordinated and effective and that optimizes research outcomes for all populations. Improvement and alignment across clinical trial funding policies and systems are needed to deliver on this. Where possible, the statement builds on text already endorsed and agreed by funders, such as the 2017 WHO Joint statement on public disclosure of results from clinical trials, and the 2023 GloPID-R Funders Roadmap for Clinical Trial Coordination.

As research funders, we commit to adapting our policies and practice to support and promote:

I. Clinical trials that are integrated within sustained national trial infrastructure and align with relevant priorities, by designing funding programmes to:

- build on existing resources as far as possible by engaging established trial and health-care infrastructure. Where no infrastructure is in place, coordinate to support building local trial capacity and infrastructure;
- align with locally relevant research priorities identified, where possible, through early engagement with local stakeholders including communities and patients;
- directly support grantees to deliver on best-practice obligations, including data management, patient involvement/community engagement and representativeness of trial populations;
- permit trials to be responsive to ongoing engagement and evolving understanding of priorities, through flexible policies on grant implementation (without compromising methodological robustness); and
- support research on the design and implementation of high-quality, environmentally-sustainable trials in different contexts.

II. Clinical trials that are well-designed, answer unmet needs, and have best practice embedded by improving application processes and peer-review to:

- expect applicants to address (i) how the trial incorporates patient involvement and community and public engagement as outlined in section 2.3.1 and section 3.2.1 of the WHO guidance on best practices for clinical trials. This should be taken into account for trial operations and budget for the financial, time, and human resources and expertise required; (ii) how the trial will include all major population groups the intervention is intended to benefit, as outlined in section 2.1.3 of the WHO guidance, in an appropriate and

timely manner; and (iii) how they will manage and share data with robust safeguards to protect privacy, ideally through a data management plan ;
- expect inclusion of supporting evidence (i.e. systematic reviews) for the research gap that the trial aims to address; and
- review the appropriateness and practicality of the trial design to the research questions and ensure applicants have sufficiently considered issues of generalizability and representativeness.

III. Clinical trials that are supported to be conducted to meet best-practice standards, by including the following elements in trial policies or conditions of funding:

- clinical trials are conducted in line with the WHO Guidance for Best Practices for Clinical Trials;
- proportionate engagement of communities, to be conducted throughout the trial lifecycle, as an essential component of ethical trials;
- registration and update on trial progress in a publicly available, free to access, searchable, clinical trial registry complying with WHO's international agreed standards and updating of registries to include trial results, working towards a timeframe of 12 months from primary trial completion (in line with the WHO Joint Statement on the Public Disclosure of Results);
- encourage the use of standardized data protocols where available and Core Outcome Sets;
- ppen-access publication of clinical trial materials (such as trial protocols and statistical analysis plans) at the earliest opportunity, and preferably through trial registries;
- timely publication of results (working towards a timeframe of 12 months from primary study completion) including reporting of outcome and adverse event data disaggregated by sex/gender and age, preferably in an open access peer-reviewed journal, with a trial registration ID and data availability statement detailing how the data underlying the publication can be accessed;
- encourage researchers during a public health emergency to rapidly and responsibly share interpretable results, including negative results, with relevant authorities for clinical guideline development and emergency use listing; and
- encourage sharing of de-identified data (or meta-data where required), complying to international data standards, in a suitable repository with a persistent identifier.

Within the next six-months, we agree to develop a set of high-level, externally measurable indicators that can be used to track progress <u>across</u> research funders, as a collective rather than individually, and further drive implementation and delivery of the above.

Quotes from signatories

Australian National Health and Medical Research Council
Professor Steve Wesselingh, Chief Executive Officer
"To ensure NHMRC remains a world leader in clinical trials, we are committed to working with our global funders of health and medical research on implementing agreed standards that will improve

the clinical trial operating environment, ensuring a more robust, consistent and efficient international approach to best practice for clinical trials."

Nepal Health Research Council
Dr Pramod Joshi, Executive Chief-Member Secretary
"Nepal is committed to strengthening collaboration in health research. By working together across countries, we can address shared challenges more effectively and ensure that research translates into meaningful improvements in public health. In line with the new WHO guidelines, we are also prioritizing the development of a robust clinical trial ecosystem that upholds the highest standards of ethics, quality and transparency".

South African Medical Research Council
Prof Ntobeko Ntusi, President and CEO
"On behalf of the SAMRC, we are honoured to be a signatory to this important statement. Our organization is committed to ensuring that trials conducted in our region are registered in the PACTR and SANCTR Clinical Trial Registries. This strengthens transparency and accountability in clinical research. A well-coordinated clinical trial ecosystem is vital to the health system, as it accelerates innovation, supports evidence-based policy, strengthens regulatory decision-making and ensures equitable access to safe and effective interventions for all populations."

Wellcome Trust
John-Arne Rottingen, Chief Executive
"Clinical trials are a critical part of getting interventions and products to the people that need them most, as well as increasing our understanding of health conditions and diseases. Without representation and engagement with the communities affected, the products and policies resulting from clinical trials risk deepening disparities. As global health funders, we must support efforts to build sustainable clinical trial capabilities rooted in evidence-based best practice, which meets local needs within existing health systems. To truly achieve health equity and have the most impact, trials must be well-designed and reflect the diversity and context of the communities they aim to benefit."

Canadian Institutes of Health Research
Dr Paul Hébert, President
"Patient and community involvement is essential to building trust and ensuring that clinical trials are impactful and reflect the needs of those they serve, while transparency helps us reduce research waste. CIHR is pleased to be part of this joint commitment to promote clinical trials' best practices alongside valued research funding partners."

French National Institute of Health and Medical Research (Inserm)
Professor Didier Samuel, Chairman and CEO
"Inserm is proud to endorse the 2025 Joint Statement on Strengthening Clinical Trials as a clear policy commitment to coordinated, sustainable trial ecosystems that align with national priorities and global standards. By embedding WHO's best practices into funding policies—supporting robust design, inclusive participation, transparent reporting, and accountable data sharing—we can drive systemic improvements that make clinical research more effective, equitable, and responsive to public health needs."

Director of ANRS Emerging Infectious Disease, Inserm
Professor Yazdan Yazdanpanah,
“Clinical trials are key to identify efficacious innovations for prevention and care and to implement efficient interventions improving patients and communities’ health. ANRS Emerging Infectious Disease as an international funder is honoured to be a signatory of this important statement and to support efforts for clinical trials to align with national and regional priorities, meet best-practice standards, to ensure equitable access to effective interventions, and to be conducted through an international approach.”

Executive Director, Global Health EDCTP3
Dr Michael Makanga
“Strengthening the clinical trials ecosystem is a shared priority for Europe and Africa. As one of the major funders of cross-continental clinical research, Global Health EDCTP3 fully supports WHO’s call to enhance trial design and implementation, integrate trials within national health systems, prioritise unmet medical needs and populations, and ensure meaningful patient and community involvement - all essential components for improving public health outcomes and increasing rigour and trust in clinical trials.”

Signatories

1. ANRS Maladies infectieuses émergentes /ARNS Emerging Infectious Diseases) (ARNS MIE) (joined on 25 September 2025)
2. Australian National Health and Medical Research Council (NHMRC) (joined on 25 September 2025)
3. Global Health EDCTP3 (joined on 25 September 2025)
4. Institut national de la santé et de la recherche médicale / National Institute of Health and Medical Research (INSERM) (joined on 25 September 2025)
5. Japan Agency for Medical Research and Development (AMED) (joined on 25 September 2025)
6. National Institute of Health, Republic of Korea (joined on 25 September 2025)
7. Nepal Health Research Council (NHRC) (joined on 25 September 2025)
8. Science for Africa Foundation (SFA) (joined on 25 September 2025)
9. South Africa Medical Research Council (SAMRC) (joined on 25 September 2025)
10. The Canadian Institutes of Health Research (CIHR) (joined on 25 September 2025)
11. UK Medical Research Council (UKMRC) (joined on 25 September 2025)
12. UK National Institute of Health Research (UKNIHR) (joined on 25 September 2025)
13. Wellcome Trust (joined on 25 September 2025)