Global action plan for clinical trial ecosystem strengthening

GCTF
Global clinical trials forum

World Health Organization

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Foreword

WHO's primary focus is on improving health outcomes, by means that include access to safe and effective interventions. WHO's guidance for best practices for clinical trials was published in 2024. In line with resolution WHA75.8 (2022 on strengthening clinical trials to provide high-quality evidence on health interventions and to improve research quality and coordination), this document calls for countries and non-State actors such as clinical trial sponsors, research institutions, investigators, regulators, national authorities tasked with the oversight of research ethics and research ethics committees, and research funders to implement needed reforms and improvements to their clinical trial environment and infrastructure. It also invites international nongovernmental organizations to explore opportunities to improve and support clinical trials.

To support the implementation of this guidance, WHO reformulated technical content from the guidance into a series of nine action areas, as outlined in this document. Although certain organizations may focus more on one or more actions, each one is critical. Thus, when countries consider improving their clinical trial ecosystems, they should review all the action areas to consider how to implement them in their country.

The WHO Secretariat is available to provide technical assistance, as far as resources allow.

Reformed research and clinical trial ecosystems will lead to more equitable access to research capacity, a better trained workforce of all those engaged in heath research, greater attractiveness for investments into clinical research institutions, and evidence of a higher quality to serve local patient and population needs.

Strengthening critical trials is one critical aspect of improving country ecosystems for research and development, together with work on improving local manufacturing and production, post-marketing surveillance and data systems, national regulatory authority functionality, research ethics committee strengthening, laboratory and pre-clinical capacities, and clinical science and medical education.

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Chief Scientist, World Health Organization

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The development of this action plan was overseen by Jeremy Farrar, Chief Scientist, John Reeder, Director, and Vasee Moorthy, Senior Advisor of the Department of Research for Health, Science Division.

The draft was developed by Vasee Moorthy and Wei Zhang, technical officer in the Department of Research for Health, reformulating content from WHO's guidance for best practices for clinical trials into a Global Action Plan format. John Owuor, consultant to the Department of Research for Health, supported stakeholder constituency consultations. The following WHO staff members and consultants contributed to the draft development: WHO Regional Office for Africa: Affoué Constance Assohou-Luty, Elise Sarah Farley and Kwasi Nyarko; WHO Regional Office for the Americas: Ludovic Reveiz, Carla Saenz and Patricia Saidon; WHO Regional Office for South-East Asia: Manju Rani; WHO Regional Office for Europe: Marge Reinap; WHO Regional Office for the Eastern Mediterranean: Arshad Altaf and Arash Rashidian; WHO Regional Office for the Western Pacific: Mengji Chen, Kidong Park, and Guixian Ong; WHO Health Emergencies Programme: Janet Diaz, Nina Gobat and Jamie Rylance; Global HIV, Hepatitis and STIs Programmes: Nathan Ford; Global TB Programme: Francesca Conradie, Fuad Mirzayey and Samuel Schumacher; Maternal, Newborn, Child and Adolescent Health and Ageing: Per Ashorn and Matteo Cesari; Regulation and Prequalification: Marion Laumonier and Marie Valentin; Research for Health: Tanja Kuchenmueller, Katherine Littler, Ghassan Karam, Martina Penazzato, Andreas Reis and Anna Laura Ross; Sexual and Reproductive Health and Research: Avni Amin, Mercedes Bonet Semenas and Mariana Widmer; Special Programme for Research & Training in Tropical Diseases: Anna Thorson and Mahnaz Vahedi.

The Technical Advisory Group for Development of Best Practices for Clinical Trials provided critical review to the draft: Akbar Fotouhi (Tehran University of Medical Sciences, Islamic Republic of Iran), Evelyn Gitau (African Population and Health Research Center, Ethiopia), Herman Goossens (University of Antwerp, Belgium), Marian Knight (University of Oxford, United Kingdom of Great Britain and Northern Ireland), Roli Mathur (Indian Council of Medical Research, India), Ann Meeker-O'Connell (Independent expert, United States of America, from 01 March 2023 to 19 January 2025), Sharon Nachman (Stony Brook Children's Hospital, United States of America), John Norrie (University of Edinburgh, United Kingdom of Great Britain and Northern Ireland), Thomas Nyirenda (European and Developing Countries Clinical Trials Partnership, South Africa), CS Pramesh (Tata Memorial Centre, India), Fiona Russell (University of Melbourne, Australia), Sofia P. Salas (Universidad del Desarrollo, Chile), Karla Soares-Weiser (Cochrane, United Kingdom of Great Britain and Northern Ireland), Fergus Sweeney (Independent expert, Ireland), Huixia Yang (Peking University First Hospital, China), and Nonhlanhla Yende-Zuma (Centre for the AIDS Programme of Research, South Africa). Advice was also received from An-Wen Chan, Chair of the International Clinical Trials Registry Platform (ICTRP) advisory group.

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Executive summary

Several consensus actions to strengthen capacities and efficiencies for clinical trials were agreed at the first WHO Global Clinical Trial Forum (Geneva, 20 and 21 November 2023). These include urgent reforms to the ways trials are funded, prioritized, approved, designed, implemented, monitored and reported. There was also agreement on the importance of coordination among pillars of the trial ecosystem so that good quality trials can be enabled, continuously functional clinical trial networks can be supported and careers of clinical researchers can be developed.

Key objectives include ensuring a focus on the key scientific and ethical considerations for well-designed and well-implemented randomized clinical trials (that is, implementing section 2 of WHO's Guidance for best practice for clinical trials); accelerating approval timelines for efficient, ethical and informative trials; advancing use of innovative approaches including digital, point-of-care and adaptive platform trials; enabling trials in under-represented populations; implementing agreed normative guidance on participant and community engagement; and ensuring that national clinical research ecosystems can incrementally improve efficiencies in approval and build sustained capacity through ongoing high quality, fit-for-purpose trials that inform policy and practice.

This global action plan for clinical trial ecosystem strengthening lays out actions that, when taken up by relevant stakeholders including regulators, national authorities tasked with the oversight of research ethics and research ethics committees, funders, researchers, private sector, civil society organizations and others, have the potential to build and sustain the efficient, responsive clinical trial ecosystem needed to drive identification of safe and effective interventions for populations most in need.

The expected outcomes, if the plan is realized, are to achieve: expanded functional, sustainable capacity for research linked to health systems around the world; agile, timely, yet also rigorous review, approval and monitoring systems; and better-quality evidence that drives positive health impacts. This approach to strengthening systems is envisaged for trials evaluating any interventional category, including pharmaceutical products (such as medicines and vaccines), medical devices, behavioral interventions and health systems processes. The reformed ecosystem will enable research and development (R&D) by linking discovery to delivery through the critical clinical development aspect of the end-to-end R&D process.

Background

During the Seventy-fifth World Health Assembly in May 2022, the World Health Organization's Member States adopted a resolution (WHA75.8) to enhance clinical trials worldwide, focusing on producing high-quality evidence and improving research quality and coordination *(1)*. The resolution aims to build equitable, locally-led clinical trial capabilities that can respond swiftly in emergencies and contribute to better health outcomes for all populations in need, especially those under-represented in current clinical trial populations. To advance these goals, the WHO Global Clinical Trials Forum convened in November 2023 *(2)* brought together a broad spectrum of stakeholders from the clinical trials communities in countries around the world to identify key challenges and to agree on a unified vision for strengthening clinical research, sustaining trial capabilities and enhancing clinical research infrastructure and capacities.

The key challenges identified during the forum include disparities in clinical trial investment and access across different regions, with a notable lack of trials in low- and middle-income countries despite their high disease burden, especially the African and Eastern Mediterranean regions with 3% and 5% of trials globally, respectively. These disparities are exacerbated by inadequate local public funding and a lack of functional collaborative networks. Furthermore, clinical trial ecosystems often experience inefficiencies, as was particularly highlighted during the pandemic of coronavirus disease (COVID-19), when many trials failed to produce useful results *(3)*. This inefficiency is attributed to redundant research efforts, poorly designed and implemented trials, a risk-averse culture that impedes innovative trial methods, and incentive structures that favor publications over scientific and social value of research.

Stakeholders recognized the critical need for reforms and called for actions to foster a more effective, efficient and responsive global clinical trial ecosystem

Additional barriers include inconsistent and inefficient clinical trial approval processes, which vary widely between countries and often involve lengthy timelines and complex regulatory requirements, especially for multinational trials. There is also a lack of consistent patient and community engagement in trial design and implementation, leading to trials that do not adequately consider the needs of diverse populations. This issue is compounded by the systematic exclusion of various groups such as pregnant women, children and older people, among others, resulting in trial outcomes that are not broadly applicable.

The stakeholders recognized the critical need for reforms and called for actions to foster a more effective, efficient and responsive global clinical trial ecosystem.

It is important to recognize many ongoing efforts such as (in alphabetical order and not an exhaustive list) the Australian Clinical Trials Alliance (ACTA), Accelerating Clinical Trials – Accélérer les Essais Cliniques Canada (ACT-AEC) *(5)*, the Accelerating Clinical Trials in the EU (ACT EU) initiative (ACT EU) *(6)* the Africa CDC Clinical Trial Ecosystem strengthening initiative *(7)*, the African Vaccine Regulatory Forum (AVAREF) *(8)*, the Design, Analyze and Communicate (DAC) programme at the Gates Foundation *(9)*, the Clinical Trials Transformation Initiative *(10)*, the European and Developing Countries Clinical Trials Partnership (EDCTP) *(10)*, the Good Clinical Trials Collaborative *(10)*, the Indian Clinical Trial And Education Network (INTENT)) *(13)*, the Health Research Authority *(14)* and the National Institute for Health Research in the United Kingdom *(15)*, and work by civil society and industry partners. The intention of this plan is to enable and further support the work of these and other aligned initiatives to strengthen, sustain and reform clinical trial ecosystems.

What is the vision?

The First WHO Global Clinical Trials Forum concluded with a vision for the future of global clinical trials, emphasizing the need for local relevance, streamlined frameworks for ethical and regulatory oversight in accordance with international standards, and sustained functioning capacities *(16)*, as elaborated below:

- the vital role of domestic country-level public financing and investment in the clinical trial ecosystem
- acknowledgement of the support provided by international donors and the private sector in ensuring sustained funding for clinical trials
- sustained national support for clinical trial infrastructure
- improved coordination and streamlined registration, regulatory and ethics review and approval processes
- enhanced meaningful engagement with patients, the public and communities at the earliest opportunity and throughout the trial process
- clinical trials enabled to address needs of under-represented populations such as children, pregnant women and older people
- clinical trials facilitated through digital and information technologies, including artificial intelligence
- established central role of research transparency, including clinical trial registries and reporting of results
- accelerated access to fit-for-purpose training packages for clinical trials, including innovative design and statistical methods
- engagement of clinical practitioners to integrate clinical trials into existing health systems and practices, and
- multinational collaboration, where mutually beneficial, to design clinical trials that can improve population health on a large scale.

These measures, elaborated in WHO's Guidance for best practice for clinical trials ("the Guidance") *(17)*, envisage that, by 2030, a clinical trials ecosystem will have achieved sustained capacities for clinical trials in all regions for infectious diseases and noncommunicable diseases; assurance of well-designed and well-implemented trials to address the needs of populations for whom interventions are intended to benefit; and gains from efficiencies and innovations to be brought to bear in the clinical trials field.

A vision for the future of global clinical trials, emphasizing the need for local relevance, streamlined frameworks for ethical and regulatory oversight in accordance with international standards, and sustained functioning capacities

What is the method to develop the GAP-CTS?

Recognizing the urgencies for concrete multistakeholder actions to implement the best practices outlined in the Guidance, WHO continues its efforts to convene the global stakeholders to operationalize the vision expounded in resolutionWHA75.8. The development of the GAP-CTS was coordinated by WHO's Science Division, in collaboration with all regional offices and relevant technical programmes across the Organization and in consultation with non-State actors in health research around the globe, including organizations for funding prioritization, regulatory and ethics oversight, patient and public engagement, product development and manufacturing, and research in any health intervention.

The WHO Secretariat prepared the initial draft between January and June 2024, with advice from the relevant WHO Technical Advisory Group, based on the guidance on strengthening the clinical trial ecosystem (the Guidance, Section 3) and recommendations for Member States, research funders and researchers (the Guidance, Annex 2). In-person and online stakeholder constituency consultations were hosted by WHO between June and November 2024 to ensure buy-in and to clarify stakeholders' roles and responsibilities for concrete activities. The draft was finalized in February 2025 to guide the discussions and devising a work plan in second WHO Global Clinical Trials Forum to be held in April 2025 to progress the actions through a WHO-managed network – the Global Clinical Trial Forum (GCTF).

What are the actions?

Action 1

Strengthen local leadership and national support for sustained infrastructure and funding

To enhance locally-led trial infrastructure and capabilities, actions are needed to promote local leadership through strengthening the governance of national health research and trials, with structural support and sustained funding. Specific measures include:

- establishment of priorities for health research aligned with the health needs of local populations thereby ensuring that the available resources are used efficiently, focusing on areas of greatest need and potential impact
- identifying strategic areas and providing targeted training and capacity-building across cadres of workforce in clinical research and trial conduct and oversight (see also Action 5)
- promoting cross-border and international collaboration in clinical research and trials, while ensuring relevance and sustainability by aligning collaborations to local health research agendas and public health priorities (see also Action 9)
- developing innovative funding models, including public-private partnerships and resource mobilization beyond health sectors, in order to contribute to long-term financial stability
- establishing the legal frameworks and platforms to improve efficient and transparent regulatory and ethics oversights adhering to international standards (see also Action 6), and to enhance engagement with patients, communities and public throughout the clinical research activity lifecycle (see also Action 2).

Successful actions should lead to increased clinical research and trial activities with domestic funding allocation led by local sponsors and investigators, especially in low- and middle-income countries.

Action 2

Enhance involvement and engagement with patients, communities and the public in clinical trial lifecycle

To build public trust and ensure inclusive participation, actions are needed to ensure implementation of universally applicable engagement norms, in ways that are appropriate for different cultural and socioeconomic contexts, and that meet engagement needs of individual trials. Specific measures include:

- training patient advocacy groups and community leaders to participate effectively in clinical trial activities and empowering communities to negotiate benefits from clinical research and protect participants' rights and well-being
- implementing continuous feedback mechanisms for patient advocacy groups and communities to voice their needs and concerns related to clinical research and trial activities
- reinforcing implementation of standards for meaningful involvement and engagement with patients, the public and communities at the earliest opportunity and throughout the research, from inception to result dissemination, through clear funder, regulatory, and ethics guidance and requirements
- allocating resources, both funding and technical expertise, for implementing involvement and engagement strategies in clinical research and trial activities.

Successful actions should lead to patient and community involvement and engagement being integrated appropriately into the trial life cycle.

Action 3

Address barriers to clinical trials in under-represented populations

To enable equitable participation in clinical research and trials, especially in under-represented populations, such as children, pregnant and lactating women and older people, actions require a multifaceted approach to transform guidelines, policies, and practices to ensure trials are designed to reflect the heterogeneity of those who will ultimately use or benefit from the intervention being evaluated and are conducted in diverse settings, including all major population groups the intervention is intended to benefit, with a particular focus on underrepresented populations. Specific measures include:

- where necessary, modifying existing normative frameworks for the ethical and regulatory oversight of research in order to avoid systematic exclusions from research, including clinical trials
- developing guidance to facilitate the responsible inclusion of populations that have been historically excluded from research, and strengthening capacities to conduct case-by-case analyses that are needed to implement the guidance
- prioritizing research and trials addressing evidence gaps and unmet health needs of under-represented populations
- developing tailored engagement, recruitment and retention strategies that address logistical and financial barriers and that increase outreach and inclusion of under-represented populations by integrating clinical research and trial activities at the point-of-care and in communities (see also Action 7).

Successful actions should lead to increased inclusion and balanced representation of populations in clinical trials, aligned with all major population groups that the intervention is intended to benefit.

Action 4

Enable effective trials through adoption of innovative designs and digital technologies

To enable effective trials to address critical research questions, actions should be taken to accelerate the adoption of meaningful innovations and use of digital technologies. Specific measures include:

- encouraging the use of standardized data protocols and core outcome sets in clinical research
- adopting adaptive and decentralized designs and implementations, including streamlining participant recruitment and randomization at point-of-care and in communities, when appropriate, to improve efficiency and responsiveness (see also Action 7)
- using digital technologies, such as information and communication technology, wearable sensing technology and artificial intelligence, where appropriate, to improve efficiency and quality of study design, recruitment, data collection and management, analysis and dissemination of results
- providing training to stakeholders to effectively adopt innovations and technologies while ensuring compliance with ethical standards (see also Action 5)
- establishing digital systems to support regulatory and ethics oversight to ensure easy and transparent communication throughout research and trial activity cycles, including for data management and sharing. This includes transparency regarding document requirements for clinical trial approval.

Successful actions should lead to increased completion of clinical trials using innovative designs, including community-based, point-of-care and decentralized trials, and digital technologies to address research questions in complex contexts.

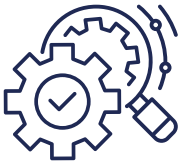
Action 5

Accelerate access to fit-for-purpose training packages for clinical trials

To build a skilled workforce for appropriate implementation of risk-based proportionate approaches in clinical trial design, conduct and oversight, actions are required to improve access to fit-for-purpose training resources. Specific measures include:

- scaling up training programmes appropriately in countries and within regions, as well as ensuring adaptability to specific contexts
- creating risk-based, proportionate approaches by developing tailored training curricula and empowering peer-support for a variety of stakeholders in clinical research and trials, including clinical trial sponsors, investigators, managers, clinicians, regulators, research ethics committees, as well as patient representative and advocacy groups, on risk-based and proportionate approaches
- accelerating access to targeted training in statistical methodology, innovative trial design and data management.

Successful actions should lead to increased participation of diverse workforces in a variety of clinical trials training programmes around the world, especially in low- and middle-income countries.



Action 6

Improve coordination and streamlining regulatory and ethics review

To reduce unnecessary burdens and to facilitate quicker access to safe and effective interventions, actions are needed to improve the efficiency and transparency of clinical trial authorization procedures. Specific measures include:

- clarifying the differences between ethical and regulatory oversight of research, as well as supporting the development of ethical and regulatory frameworks that adhere to international standards
- coordinating processes among review agencies for multicentre (including but not limited to multinational) clinical trials to enable timely review outcomes and to promote rapid responses by sponsors and investigators to requests
- promoting mechanisms to advance efficiency and avoid duplicative processes of ethical and regulatory review, including through cross-border reliance and regional harmonization of frameworks and requirements
- establishing transparency and accountability of oversight by publishing requirements and procedures of regulatory and ethics review and timelines, with support to sponsors and investigators to meet the requirements in clinical trial application and review processes
- enabling parallel regulatory and ethics review processes, wherever appropriate
- adopting single point of submissions that facilitate and accelerate trial registration, regulatory, and ethics review processes.

Successful actions should lead to improved efficiency with reduced delays in obtaining clinical trial approvals, especially for multicentre trials and transparency as to document requirements and timelines achieved.

Action 7

Engage clinical practitioners to integrate clinical trials into health systems and practices

To integrate trials better into health systems, actions can be taken to engage healthcare practitioners to make clinical research and trials accessible, applicable and representative of diverse patient populations and health systems, particularly those in primary and community care contexts. Specific measures include:

- engaging healthcare practitioners in identification, prioritization and planning of health research needs
- involving healthcare practitioners to better incorporate routine-care procedures in research and trial design and encouraging clinical researchers to conduct research activities directly in healthcare settings, where appropriate
- providing targeted training on methodology and skills relevant to practitioners' roles and responsibilities in clinical research and trials supporting adaptation to specific healthcare settings and requirements
- incentivizing healthcare practitioners' involvement in research and trial activities to advance relevant healthcare practice and delivery, with protected research time, recognition and professional career advancement
- transforming clinical trial sites from centralized, specialized facilities to decentralized, disease-agnostic sites embedded in healthcare facilities, especially in primary and community care facilities.

Successful actionss should lead to increased clinical trial activities conducted in healthcare facilities and enable large-scale trials where necessary.

Action 8

Step up the use of trial registries to improve research transparency

To ensure transparency and integrity in the conduct of clinical trials in line with internationally agreed standards and to support prioritization and coordination of research, actions are needed to reinforce trial registration and timely results reporting. Specific measures include:

- strengthening clinical research policy and regulations to mandate prospective registration and timely reporting of the results in publicly accessible trial registries that feed into WHO's International Clinical Trial Registration Platform (ICTRP)
- publishing clear requirements for clinical trial registration and for ensuring the availability of technical and financial resources for data quality control in trial registrations
- developing a minimum data set for clinical research and trial reporting and reinforcing compliance with reporting standards, as well as incorporating relevant data sharing plans into informed consent agreements
- facilitating data sharing across platforms of registries, especially for multicentre/country trials, and streamlining data input, especially for regulatory and ethics review processes
- providing targeted training to stakeholders to input data to trial registries as well as use of registry data for research purposes, including systematic reviews, landscaping exercises and gap analyses.

Successful actions should lead to improved availability, accessibility and quality of clinical trial registration data including through WHO's ICTRP.

Action 9

Expand international health research and clinical trial collaboration

To advance all the actions set out above, all stakeholders in health research and clinical trials should take actions to expand collaboration across health domains, functions in the ecosystem and national borders, where mutually beneficial, while reducing bureaucracy that may render collaborations ineffective. Specific measures include:

- directing international core clinical research and trial funding to align with local health needs and to support development of competencies in local clinical trial communities, particularly in low- and middle-income countries
- reducing bureaucratic barriers and inefficiency by harmonizing frameworks of health research guidelines, policies, regulations and ethics standards
- fostering international partnerships that prioritize public health needs and equitable capability and capacity in clinical research and trials, by enabling and maintaining "always on, always warm" clinical trial networks which embrace geographical and socioeconomic diversity.

Successful actions should lead to sustained clinical trial networks, supported through local as well as international funds, with diverse geocultural and socioeconomic representation.

How will WHO convene partners to enable collaborative progress towards the actions?

A WHO-managed network, the Global Clinical Trials Forum, will convene stakeholders and their organizations in continued advocacy and dissemination of norms and standards for clinical trials, as well as providing peer support on implementing good practices to strengthen clinical trial ecosystem. Terms of reference and the concept for the Global Clinical Trials Forum network, including proposed work packages to implement above actions, are detailed elsewhere *(18)*.

How to measure the progress

A framework for measuring the outcomes of GAP-CTS will be developed. The framework for measuring outcomes will include specific indicators to inform the progress of actions. The indicators will focus on information that can both inform the response and be collected without excessive human resources and financial cost. All stakeholders and partners will be encouraged to actively contribute, with their best efforts, to the outcome measures by providing needed data and technical support. This activity requires collective effort through contributing to the workplan of the Global Clinical Trials Forum, as well as individual stakeholder accountability for specific workplan activities and their being responsible for measuring the outcomes.

Alongside systematic data collection to measure the outcomes, success stories are powerful in demonstrating the impact of the GAP-CTS. Demonstration of this impact will include identifying exemplar clinical trials or networks which are enabled, sustained and/or translated into health policy and practices as results of the above actions. In addition, analysis and articulation of national or regional ecosystem reformation pathways through case studies (or implementation research) are critical to documenting what works and providing implementation models for more country initiatives.

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