



Second World Health Organization Global Clinical Trials Forum: Action for impact

Geneva, 2–3 April 2025

Summary of proceedings



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Abbreviations and acronyms

AVAREF	African Vaccine Regulatory Forum
CTU	Clinical Trial Unit
EDCTP	European and Developing Countries Clinical Trials Partnership
EMA	European Medicines Agency
EUPATI	European Patients' Academy on Therapeutic Innovation
GAP-CTS	Global Action Plan for Clinical Trial Ecosystem Strengthening
GCTF	Global Clinical Trials Forum
GHTC	Global Health Technologies Coalition
ICTRP	International Clinical Trials Registry Platform
NTD	Neglected Tropical Diseases
RCTs	Randomized Controlled Trials
UK	United Kingdom of Great Britain and Northern Ireland
WHA75.8	World Health Assembly Resolution 75.8
WHO	World Health Organization

Executive summary

The Second WHO Global Clinical Trials Forum (GCTF25)¹, held at WHO Headquarters in Geneva from 2-3 April 2025, marked a strategic inflection point in the global effort to reform clinical trial ecosystems. Convened under the theme Action for Impact, the Forum brought together over 100 stakeholders, including representatives from governments, regulatory agencies, research funders, ethics bodies, patient and community advocates, and academic and industry association, from across WHO regions.

The Forum launched the Global Action Plan for Clinical Trial Ecosystem Strengthening (GAP-CTS)², which sets strategic directions to implement the best practices for clinical trials recommended by the WHO Guidance for Best Practices for Clinical Trials³ and advancing the implementation of World Health Assembly Resolution 75.8 (WHA75.8)⁴. Structured around nine action areas, GAP-CTS provides a practical, coordinated, and country-driven roadmap for building resilient, inclusive, and efficient clinical trial ecosystems.

Key themes emerging from GCTF25 included the need to embed trials into health systems, strengthen national leadership, advance inclusion of underrepresented populations, and institutionalize meaningful engagement with patients and communities. Country examples, from Nigeria's digital ethics review platform to Malaysia's coordinated governance framework, demonstrated the feasibility and value of whole-system approaches. Participants emphasized that sustainable transformation requires investment in long-term capacity, digital infrastructure, and context-specific innovation.

The participants of GCTF25 acknowledged WHO's role as a convenor, catalyst, and technical partner for GAP-CTS and committed to continued collaboration in this endeavor through the WHO managed network beyond the annual forum. The Global Clinical Trials Forum network will facilitate co-development of implementation tools, and platforms for knowledge exchange, and scaling-up best practices implementation in countries, where stakeholder organizations are leading actions aligned with their priorities.

GCTF25 shifted the clinical trials agenda from vision⁴ to delivery, laying the groundwork for coordinated, stakeholder-owned actions that serves public health, advances equity, and accelerates the generation of high-quality evidence where it is most needed.

¹ World Health Organization, Global momentum builds: World Health Organization (WHO) convenes second Global Clinical Trials Forum to drive efficiency and impact, accelerate clinical trials.

Website ([https://www.who.int/news/item/16-04-2025-global-momentum-builds-world-health-organization-\(who\)-convenes-second-global-clinical-trials-forum-to-drive-efficiency-and-impact--accelerate-clinical-trials](https://www.who.int/news/item/16-04-2025-global-momentum-builds-world-health-organization-(who)-convenes-second-global-clinical-trials-forum-to-drive-efficiency-and-impact--accelerate-clinical-trials)), accessed 15 May 2025)

² World Health Organization, Global action plan for clinical trial ecosystem strengthening. Website (<https://www.who.int/publications/i/item/B09338>), accessed 15 May 2025).

³ Guidance for best practices for clinical trials. Geneva: World Health Organization; 2024. <https://www.who.int/publications/i/item/9789240097711>

⁴ Resolution WHA75.8. Strengthening clinical trials to provide high-quality evidence on health interventions and to improve research quality and coordination. In: Seventy-fifth World Health Assembly, Geneva, 22-28 May 2022. resolutions and decisions, annexes. Geneva: World Health Organization; 2022 (WHA75/2022/REC/1 (https://apps.who.int/gb/ebwha/pdf_files/WHA75-REC1/A75_REC1_Interactive_en.pdf); accessed 15 May 2025)

⁵ First WHO Global Clinical Trials Forum puts forward a global vision for sustainable clinical research infrastructure. Website (<https://www.who.int/news/item/29-11-2023-first-who-global-clinical-trials-forum-puts-forward-a-global-vision-for-sustainable-clinical-research-infrastructure>), accessed 15 May 2025)

Context and objectives

WHA75.8, adopted by the World Health Assembly in 2022, calls on Member States to strengthen clinical trials to ensure high-quality, ethical, and relevant evidence for health policy. WHO responded by publishing the Guidance for Best Practices for Clinical Trials (2024) and subsequently developing the Global Action Plan for Clinical Trial Ecosystem Strengthening (GAP-CTS), a practical roadmap co-created with diverse stakeholders.

The Second Global Clinical Trials Forum (GCTF25) was convened by WHO as a strategic milestone in the global effort to strengthen clinical trial ecosystems worldwide. It was a follow-up to the first Forum held in November 2023⁶. Held under the theme *Action for Impact*, the Forum brought together diverse stakeholders to chart a practical path for implementing the Guidance and the operationalization of GAP-CTS. It served as a launchpad for coordinated, country-driven actions aligned with World Health Assembly resolution 75.8 (WHA75.8). GCTF25 served as the global platform to launch the GAP-CTS, align stakeholders on implementation, and initiate collaborative action under a WHO managed network.

The Global Clinical Trials Forum (GCTF)- a WHO managed network, will support the implementation of WHA75.8 and the operationalization of the WHO Guidance and GAP-CTS. The network will enable coordinated action by stakeholders to strengthen clinical trial ecosystem and infrastructure at national, regional, and global levels. GCTF operates under the auspices of WHO and aligns with the General Programme of Work (GPW14), fostering a platform for shared learning, technical exchange, and sustained capacity development.

The meeting objectives were:

- to convene partners to identify shared objectives between clinical trials stakeholders and WHO and thereby enable implementation of WHA 75.8, the WHO Guidance for Best Practices for Clinical Trials and GAP-CTS;
- to discuss and agree 12–18 month workplans and key deliverables for the 2025-2026 period related to implementation of the WHO guidance and GAP-CTS.

⁶ World Health Organization, First WHO Global Clinical Trials Forum puts forward a global vision for sustainable clinical research. Website (<https://www.who.int/news/item/29-11-2023-first-who-global-clinical-trials-forum-puts-forward-a-global-vision-for-sustainable-clinical-research-infrastructure>, accessed 15 May 2025)



Key deliberations

Over two days of dialogue, GCTF25 provided a global stage for stakeholders to engage in reflective, technically grounded conversations about how to implement WHO's Guidance for Best Practices for Clinical Trials and make clinical trials more efficient, effective and inclusive. From the outset, stakeholders emphasized that fragmented, project-based models must give way to a coordinated, system-strengthening approach, where clinical trials are embedded in national priorities and supported by resilient infrastructure.

National examples anchored this vision. Malaysia presented its comprehensive strategy to streamline ethics and regulatory processes through the National Medical Research Register and a harmonized digital platform linking trial sponsors and authorities. Nigeria highlighted significant progress with the National Health Research Ethics Committee, whose digital portal has cut ethics review timelines substantially. Pakistan and South Africa similarly emphasized governance reforms, public investment, and research integration into primary health systems. These country cases were more than informative; they were aspirational examples of how systems thinking can be applied across contexts to strengthen clinical trials.

The forum reaffirmed that **inclusion** as a scientific, ethical, and public health imperative, one that must move beyond rhetoric and be translated into measurable action across all phases of the clinical trial lifecycle. Building on the Guidance for Best Practices for Clinical Trials, participants emphasized that systematically excluding certain populations from research not only undermines the generalizability of findings but also perpetuates health inequities and delays access to innovation for those most in need.

Forum discussions highlighted a persistent gap between inclusion policies and practice. Despite global commitments, underrepresented groups—including children, older adults, pregnant and lactating women, persons with disabilities, and displaced populations—remain largely absent from the evidence base that shapes clinical and regulatory decisions. As one participant noted, “We cannot continue designing trials for the average adult male and calling the results universal.”

A dedicated breakout session on inclusion outlined concrete steps for embedding equity into clinical research systems. Participants called for the development and application of inclusion and equity indicators that can be used to monitor progress, identify gaps, and guide accountability. These indicators should be incorporated into protocol templates, ethics review forms, and funding applications, ensuring that inclusion is not an afterthought but a foundational design principle.

Funders and sponsors were urged to clearly articulate how inclusion will be achieved, particularly trials involving populations that have historically been left behind. Some participants stressed the importance of requiring justification for exclusion criteria, echoing principles found in paediatric and maternal health ethics frameworks.

The role of civil society and patient organizations was also emphasized as critical to co-designing inclusive recruitment and retention strategies. Participants pointed to successful models where communities contributed to tailored outreach, culturally sensitive materials, and supportive environments that enable participation by diverse groups. Such partnerships were seen as essential not only for trial design but also for post-trial engagement and feedback.

WHO was encouraged to support Member States in developing national research equity strategies, aligned with local priorities and legal frameworks. These strategies could include:

- context-specific definitions of underrepresented groups
- policy guidance for ethics committees and regulators
- incentive models for sponsors who meaningfully advance inclusion, and
- capacity-building programmes focused on inclusive trial design.

Participants also highlighted the need for regional dialogues to exchange good practices, and for WHO to coordinate a repository of tools and case studies illustrating successful approaches in different contexts.

Inclusion, as framed during the Forum, is not a checklist item, but central to research quality, ethical legitimacy, and public trust. GCTF25 made it clear that if clinical trials are to serve all people, everywhere, they must be designed with, and not just for, those who are most often left out.

The **integration of clinical trials into national health systems** was widely recognized as both a critical goal and a persistent challenge. Participants agreed that without such integration, trials will continue to function in silos, duplicating efforts, straining resources, and generating evidence that lacks real-world relevance. Embedding trials within existing health service delivery platforms, they argued, is essential for improving research efficiency, access, equity, and public trust.

Speakers from Canada, China, and the United Kingdom presented compelling examples of how trials can be successfully anchored within health systems. In Canada, the ACT (Accelerating Clinical Trials) Consortium illustrated how a national framework for single ethics review and harmonized contracting can streamline trial initiation and enhance system-wide coordination. In China, the integration of trial registration and ethics clearance into national digital health platforms has allowed research to be conducted more rapidly and transparently.

⁷ University of Oxford, Platform Randomized Trial of Treatments in the Community for Epidemic and Pandemic Illnesses (PRINCIPLE). Webpage (<https://www.principletrial.org/>, accessed 15 May 2025)

⁸ Califf, R. M., Cavazzoni, P. and J. Woodcock, Benefits of Streamlined Point-of-Care Trial Designs: Lessons Learned From the UK RECOVERY Study. *JAMA Intern Med* 182, 1243–1244 (2022).

From the UK, examples such as the PRINCIPLE⁶ and RECOVERY⁷ trials demonstrated how leveraging general practice and hospital networks enabled large scale trial recruitment at unprecedented speed during the COVID-19 pandemic.

However, participants from low- and middle-income countries (LMICs) emphasized the significant barriers to achieving similar levels of integration. Many health systems in these settings lack interoperable data systems, dedicated research infrastructure, and cross-trained personnel capable of delivering care and conducting research simultaneously. In these settings, trials are often perceived as external to the health system, dependent on donor funding, and disconnected from routine care pathways.

To address this, stakeholders urged WHO to support countries in identifying fit-for-purpose models of trial integration, tailored to their health system maturity levels, infrastructure readiness, and governance structures. Rather than proposing a one-size-fits-all solution, participants recommended the development of implementation typologies, detailing pathways for integration based on national capacity, policy environments, and research priorities. These could guide Ministries of Health and research institutions in gradually embedding trial functions into clinical workflows, electronic health records, and community care platforms.

Participants also highlighted the need to align integration efforts with ongoing health system reforms including digital transformation, universal health coverage (UHC), and primary care strengthening. Trials were described as ‘stress tests’ for system readiness and as potential accelerators for broader public health functions, such as surveillance, data quality, and community engagement.

Participants called for WHO to convene dialogue on trial integration, drawing on case studies from all regions to generate practical guidance and promote regional adaptation.

The Forum reinforced the view that embedding trials into health systems is not just a research issue, it is a health systems strengthening strategy. It offers a route toward equitable access to innovation, more responsive care delivery, and enhanced public confidence in research.

One of the strongest and most consistent messages was that **engagement with patients, communities, and the public** is not an optional add-on. It is a fundamental pillar of ethical, scientifically valid, and socially trusted clinical research. Participants called for a shift from tokenistic consultation toward sustained, meaningful involvement, built on shared values, co-creation, and mutual accountability.

Patient and community engagement was repeatedly described by many participants as a foundational principle rather than an auxiliary activity. Several participants acknowledged persistent gaps in how engagement is implemented and reported, particularly in multi-country trials. Participants agreed that a competency framework for community and patient involvement would be a potential game changer, especially when linked to mandatory training and shared Standard Operating Procedures (SOPs). Resources like the European Patients Academy on Therapeutic Innovation's (EUPATI's) learning lab and the planned WHO Clinical Trial Training Hub were cited as critical enablers to professionalize engagement practices across stakeholder groups.

Drawing on lessons from the COVID-19 pandemic, the Forum recognized that trust in research cannot be engineered during emergencies; it must be built over time through inclusive partnerships, transparent communication, and community leadership. A competency framework was viewed as a key enabler of this shift. When supported by tailored training, standardized procedures, and embedded reporting expectations, it offers a pathway to scale meaningful engagement across diverse settings and trial types

Participants emphasized that community involvement must be integrated across the entire trial lifecycle—from priority-setting and protocol development to ethics review, implementation, and dissemination.

This is especially critical in trials involving historically underrepresented populations, including children, pregnant and lactating women, older adults, displaced persons, and persons with disabilities. Speakers on engagement urged sponsors, funders, and regulator to embed clear engagement requirements into approvals, funding decisions, and monitoring processes, with a call for WHO to lead the development of core engagement indicators and shared metrics for accountability.

There was a call for a dedicated workstream under the GCTF to coordinate actions to scale meaningful engagement globally. This will include co-developing model SOPs, establishing a curated library of role-specific training resources, and supporting countries to adapt engagement tools to their national contexts. WHO was further urged to convene quarterly learning exchanges to facilitate peer support and ensure that lessons from community-driven research models are shared across regions and disciplines.

Methodological innovation emerged as a strategic imperative for making clinical trials more efficient, context-responsive, and fit for real world decision making. Participants emphasized that without innovation in trial design, clinical research will continue to lag behind the pace of evolving public health needs, particularly in low-resource settings where traditional models remain slow, costly, and inflexible.

The Forum highlighted the transformative potential of **adaptive, platform, and pragmatic trial designs**. These approaches, tested successfully in trials like PRINCIPLE and RECOVERY, enable flexible protocols, real time learning, and faster evidence generation. Relevant stakeholders argued that such designs are especially valuable in the context of health emergencies, complex interventions, or research in underserved populations. By embedding trials into routine care and leveraging existing data systems, pragmatic trials in particular offer a path toward evidence generation that is timely, cost-effective, and generalizable.

⁹EUPATI Learning Lab, Patient engagement training for academia and industry. Website (<https://eupati.eu/eupati-learning-lab/#:~:text=EUPATI%20Learning%20Lab%20is%20our%20training%20portfolio%20for,miss%20your%20chance%20to%20secure%20your%20spot%20today%21,> accessed 15 May 2025)

To address this, GCTF25 called on WHO to establish a global innovation workstream within the GCTF network. This workstream to focus on four interrelated goals:

- Participants stressed that this innovation agenda must be locally owned, regionally supported, and globally aligned. The aim is not to displace ethical rigor, but to evolve it—ensuring that oversight systems are capable of evaluating the risks and benefits of newer trial formats while upholding participant protection.

By unlocking methodological innovation, GCTF25 underscored the opportunity to recalibrate the clinical trial model, from one that often excludes,

The Forum participants unanimously identified **training and capacity building** as a cornerstone of clinical trial ecosystem strengthening. Participants emphasized that without a sustained and context-sensitive investment in people; regulators, researchers, ethics committee members, patient/community engagement partners, data managers, and beyond, the implementation of the Guidance for Best Practices for Clinical Trials would remain aspirational rather than actionable.

The WHO Guidance for Best Practices for Clinical Trials and GAP-CTS both stress the need for role-specific, layered, and fit-for-purpose training. Participants echoed this by advocating for differentiated learning content tailored to the diverse actors involved in clinical trials, from senior regulators and principal investigators to frontline health workers and patient representatives. Stakeholders also noted the importance of practical, experiential learning, especially in regions where formal academic pathways into clinical research are limited.

¹⁰African alliance, BRILLIANT consortium (BRinging Innovation to cLinical and Laboratory research to end HIV In Africa through New vaccine Technology). <https://africanalliance.org.za/brilliant-consortium-shut-down-home-page/>

¹¹ The Global Health Network (TGHN), Global Health Training Centre; <https://globalhealthtrainingcentre.tghn.org/>

¹² EUPATI, Open classroom, <https://learning.eupati.eu/>

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To support harmonization and coordination, WHO was requested to operationalize WHO Clinical Trial Training Hub, embedded within the GCTF network and linked to the WHO clinical trial training currently under development. This hub will serve as a curated repository of validated training materials, mapped to stakeholder roles and aligned with global standards. Participants stressed the need for clear quality criteria for training inclusion, as well as transparent processes for selecting and updating content.

The Forum also endorsed a Train-the-Trainer model to support scale up and sustainability. Regional and national trainers to be equipped to cascade learning, provide contextual adaptation, and support peer-to-peer mentorship across institutions. WHO and partners will define the scope, delivery mechanisms, and resource requirements for this initiative, ensuring equity of access and regional balance.

Importantly, training was not discussed in isolation. Participants framed it as part of a broader ecosystem investment, linked to institutional strengthening, career progression, and retention.

GCTF25 positioned training as a long-term enabler of trial quality, ethical conduct, and clinical trial system sustainability. By investing in people, and equipping them with the knowledge, tools, and institutional environments to lead, countries can build the foundation for clinical trials that are inclusive, credible, and resilient in the face of future challenges.

Several cross-cutting challenges emerged: the duplication of ethics reviews in multi-country trials; inconsistent interpretation of regulatory standards; lack of standardized engagement reporting; and insufficient long-term funding for trial infrastructure. These were not framed merely as technical issues, but as structural obstacles that undermine efficiency, inclusion, and trust. Proposed solutions included piloting joint ethics reviews, aligning regulatory guidance across agencies, introducing engagement metrics into trial registries, and building pooled funding mechanisms to support national trial platforms.

The overarching message was clear: a transactional approach to trials is no longer fit for purpose. What is needed is a transformational agenda, where trials serve as platforms for capacity strengthening, inclusive research, and health equity. GCTF25 marked a critical step in co-creating that agenda and catalyzing coordinated global action on the implementation of WHA75.8.

This report summarizes key challenges, strategic directions, and proposed actions discussed during the meeting. Full presentation slides are provided in the annex section.



Key outcomes

- Implementation priorities for 2025–2026:** A central outcome was the commitment to operationalize the nine GAP-CTS action areas through thematic GCTF workstreams. Institutions across WHO regions started volunteering to co-lead these workstreams, which will develop concrete workplans for 2025–2026. These workplans are expected to align with national priorities while supporting mutual accountability across the GCTF network. WHO will maintain a light convening role to facilitate alignment, coordination, and technical support without introducing unnecessary structural burden. Participants aligned on urgent need for coordinated actions, including training, regional workshops, piloting new tools, and developing shared reporting templates on some of the action areas such as patient/community engagement.
- Practical toolkits for community engagement:** Stakeholders endorsed the development of model SOPs, accountability mechanisms, and policy templates to support early and continuous engagement across the trial lifecycle. Building on the updated 2025 Consolidated Standards of Reporting Trials (CONSORT) guidelines, stakeholders also highlighted the priority of institutionalizing engagement metrics, such as integration into trial outcome assessment, ethics review checklists and funder reporting requirements.
- An umbrella ethical and inclusive trial design framework:** There was renewed commitment to inclusive and equitable trial design, including increased attention to populations historically excluded from research. Stakeholders highlighted the need for national legislation and policy support to institutionalize patient and community engagement, and to make diversity and inclusion requirements part of trial planning, funding, and ethics review processes. Built on the foundational work in inclusive design in children, pregnant and lactating women, older people and people with disabilities, stakeholders emphasized the need for an umbrella framework for ethical and inclusive trial design to ensure holistic approach to address the need of underrepresentation.
- Exemplification of innovative trial designs:** To advance pragmatic and innovative trial design, stakeholders called for exemplar case studies demonstrating good practices that help reduce regulatory and institutional barriers to innovation and facilitate uptake of fit-for-context designs that better reflect real-world conditions. Building on exemplar cases, co-development of practical toolkits and regulatory engagement strategies is expected to lead up to wider adoption of innovative design.
- Curation of fit-for-purpose training resources:** Stakeholders emphasized the importance of understanding different training needs for different stakeholder groups and mapping fit-for-purpose resources. Curated materials in the WHO Clinical Trial Training Hub and scale up delivery through Train-the-Trainer model is a great step forward to accelerate equitable access to context-specific training resources globally. Stakeholders also highlighted advocacy for sustained funding for training as an integral component in clinical trial capacity building is needed.
- Single digital submission system for clinical trial application:** Stakeholders agreed on the pertinence of digital infrastructure for efficiency improvement in clinical trials lifecycle. The discussion highlighted the key steps to a consensus of the requirements for a single digital submission system that will facilitate streamlined and efficient processes at the intersection of research design, registration, regulatory and ethics review as well as post-trial amendments and follow-up.
- Peer learning for equitable capacity development:** Participants concurred on the need for structured peer learning and systematic documentation of country experiences to support contextual adaptation and replication of effective practices. An information sharing mechanism is identified a useful starting point for clinical trial networks to exchange their experience and practices such as standard operating procedures (SOPs), engagement models, and efficient clinical research implementation strategies aligned with the WHO Guidance for Best Practices for Clinical Trials and GAP-CTS.

Conclusion

The GCTF25 meeting reaffirmed that the transformation of clinical trial systems is both urgent and achievable. The Forum crystallized a global consensus: clinical trials must evolve from isolated, episodic projects into embedded, equity-driven systems that are integral to public health. Delivering on this vision requires strategic alignment with WHA75.8, collective commitment to implementation of the WHO Guidance and the supplementary GAP-CTS, and co-investment in infrastructure, governance, and people.

Participants committed to translating the shared agenda into measurable progress over the 2025–2026 period. With the operationalization of GCTF workstreams, the formalization of collaborative platforms, and the piloting of new tools and approaches, GCTF25 initiated a shift from policy to practice. WHO will continue to support this transformation by facilitating coordination, documenting progress, and enabling adaptive learning across countries and networks.

WHO will retain a convening role to offer a platform for reflection on achievements, address remaining bottlenecks, and collectively advance a new era of clinical trials that are inclusive, trusted, and built to serve all people, everywhere.

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Annexes

Annex 1: GCTF25 agenda¹³

Annex 2: GCTF 25 list of participants¹⁴

Annex 3: GCTF25 slides¹⁵

¹³ World Health Organization, Second Global Clinical Trials Forum meeting agenda; Geneva, World Health Organization; 2025 https://cdn.who.int/media/docs/default-source/research-for-health/gctf25-agenda-final.pdf?sfvrsn=bb91ef22_3.

¹⁴ World Health Organization, Second Global Clinical Trials Forum meeting participants list; Geneva, World Health Organization; 2025 https://cdn.who.int/media/docs/default-source/research-for-health/final-list-of-participants-gctf25-8april25.xlsx?sfvrsn=539f5e2e_3

¹⁵ World Health Organization, Second Global Clinical Trials Forum meeting slides dec; Geneva, World Health Organization; 2025 https://cdn.who.int/media/docs/default-source/research-for-health/second-gctf-slide-deck.pdf?sfvrsn=e4c409fb_3

A group photo of participants attending the forum.
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