Progress with accelerating clinical trials globally

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Document link:

World Health Organization

Several framings for a systems approach to clinical trial ecosystem strengthening

Clinical trials pillar of R&D/innovation ecosystem

Research integration into clinical care/health system

Clinical trials pillar of preparedness framework

World Health Organization

A global framework to improve the environment and infrastructure

GCTF
Global clinical trials forum
WHO Managed Network

WHA resolution 75.8

2022

2023

Global clinical trial forum (GCTF)

Proposed a new vision for clinical trials

2024

Launch of WHO Guidance

Researchers, industry, regulators ethics authorities, funders, patient groups, health authorities

Launch of global action plan for strengthening clinical trials (GAP-CTS)

2025

World Health Organization

WHO guidance for best practices for clinical trials – launched 2024: All clinical trials should address these five elements

Good clinical trials

✓ are designed to produce scientifically sound answers to relevant questions

✓ respect the rights and well-being of participants

✓ are collaborative and transparent

✓ are feasible for context

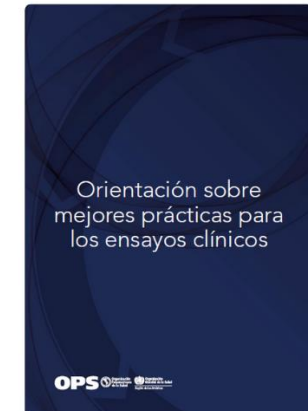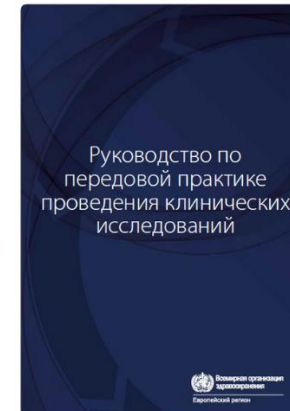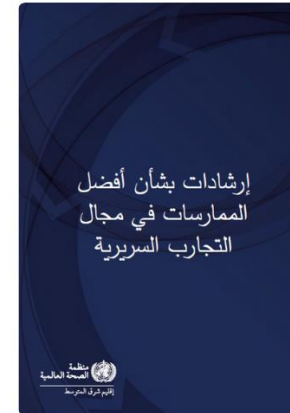✓ manage quality effectively and efficiently

The guidance is relevant to all clinical trials addressing any health intervention for commercial or non-commercial purpose, for any role involved and in any health system setting.

Document link:

World Health Organization

WHO Guidance translations

WHO guidance now available in seven languages

Source: Moorthy V, Abubakar I, Qadri F, Ogutu B, Zhang W, Reeder J, et al. The future of the global clinical trial ecosystem: a vision from the first WHO Global Clinical Trials Forum. The Lancet. 2024 Jan 13;403(10422):124–6 (https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(23)02798-8/fulltext).

Implementing change

Guidance for best practices for clinical trials

World Health Organization

- **01** Trials that address key evidence gaps
- **02** Risk based proportionate approaches
- **03** Patient community engagement
- **04** Representative populations
- **05** Public health/clinical practice oriented trials
- **06** Optimising impact of existing interventions
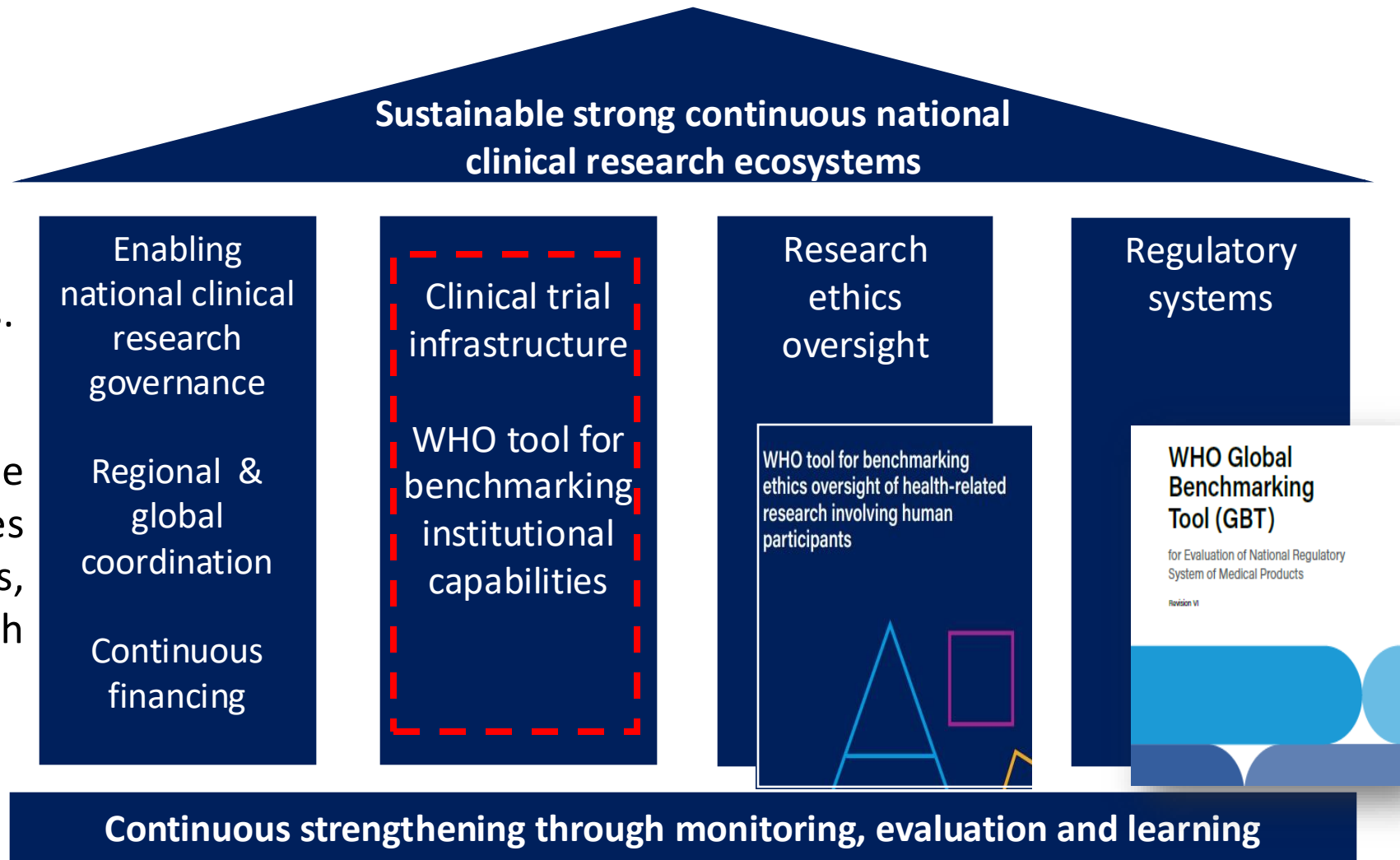
Develop benchmarking tool for institutional capability for clinical trials

- **Purpose:**

To support benchmarking of infrastructure, capabilities, and capacities of institutions in conducting clinical trials and related clinical research activities.

- **Target audience:**

The primary target users of the framework are research institutes involved in clinical trial activities, and national health research agencies.

Sustainable strong continuous national clinical research ecosystems

Enabling national clinical research governance	Clinical trial infrastructure	Research ethics oversight	Regulatory systems
Regional & global coordination	WHO tool for benchmarking institutional capabilities		
Continuous financing			

WHO tool for benchmarking ethics oversight of health-related research involving human participants

WHO Global Benchmarking Tool (GBT)

for Evaluation of National Regulatory System of Medical Products

Revision VI

Continuous strengthening through monitoring, evaluation and learning

World Health Organization

Scope

Focus on **functions**:

- Activity: throughout the trial lifecycle, e.g., planning, design, management, coordination, implementation, reporting, etc.

- Context: multi-national vs. national/local; coordinator vs. site; public-health oriented vs. commercial/regulatory compliance, etc.

Facilitate various **operation models** to implement function:

- Human resources, facility & equipment, quality management systems, etc.

Support diverse institution's **development objectives**:

- Achieve and maintain standards of functions

- Expand scope of functions

Pilot plan (in 2026)

➢ To refine benchmark indicators in various trial contexts.

➢ To identify operational challenges and prepare for further support.

➢ To contextualize implementing benchmarking tool within national or regional clinical trial ecosystem strengthening initiatives.

| Introduce the tool and pilot process | Institution's self-assessment | Consolidate assessment and analyze feedback | Report pilot outcome | Stakeholder feedback and inform next steps |

Considerations:

✓ Institutions (samples) in pilots represent diverse contexts and capabilities.

✓ Alignment with national / regional initiatives and priorities.

✓ Collaboration with relevant national, regional stakeholders and WHO.

World Health Organization

Global action plan for clinical trial ecosystem strengthening

GCTF — Global clinical trials forum

World Health Organization

Action 1
Strengthen local leadership and national support for sustained infrastructure and funding

Action 2
Enhance involvement and engagement with patients, communities and the public in clinical trial lifecycle

Action 3
Address barriers to clinical trials in under-represented populations

Action 4
Enable effective trials through adoption of innovative designs and digital technologies

Action 5
Accelerate access to fit-for-purpose training packages for clinical trials

Action 6
Improve coordination and streamlining regulatory and ethics review

Action 7
Engage clinical practitioners to integrate clinical trials into health systems and practices

Action 8
Step up the use of trial registries to improve research transparency

Action 9
Expand international health research and clinical trial collaboration

Lancet papers outlining working group activities

The future of the global clinical trial ecosystem: a vision from the first WHO Global Clinical Trials Forum

Tracking maturity of the enabling environment for clinical trials

Artificial intelligence and clinical trials: a framework for effective adoption ☆

National research ecosystems: protecting populations and building health security worldwide

World Health Organization

Elizabeth S Higgs [1], Arshad Altaf [2], Nicole Lurie [3], Akbar Fotouhi [4], Peter H Kilmarx [5], Tom Nyirenda [6], Bernhards Ogutu [7], Manju Rani [8], Seydou Doumbia [9], Dominique Sprumont [10], Johannes J M van Delden [11], Robert A Sorenson [12], Vasee Moorthy [13], Jeremy Farrar [14]

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Lancet series on Clinical Trials

Series

Better engagement, better evidence: working in partnership with patients, the public, and communities in clinical trials with involvement and good participatory practice

Nina Gobat, Catherine Slack, Stacey Hannah, Jessica Salzwedel, Georgia Bladon, Juan Garcia Burgos, et al.

The Lancet Global Health, Vol. 13, No. 4, e716-e731

Strengthening the paediatric clinical trial ecosystem to better inform policy and programmes

James A Berkley, Judd L Walson, Glenda Gray, Fiona Russell, Zulfiqar Bhutta, Per Ashorn, et al.

The Lancet Global Health, Vol. 13, No. 4, e732-e739

Advancing maternal and perinatal health through clinical trials: key insights from a WHO global consultation

Teesta Dey, Mariana Widmer, Arri Coomarasamy, Shivaprasad S Goudar, Mabel Berrueta, Estela Coutinho, et al.

The Lancet Global Health, Vol. 13, No. 4, e740-e748

Democratising clinical trials research to strengthen primary health care

Christopher C Butler, Robert Mash, Nina Gobat, Paul Little, Mpundu Makasa, Martha Makwero, et al.

The Lancet Global Health, Vol. 13, No. 4, e749-e758

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Lancet series on clinical trials - 2

Reporting summary results in clinical trial registries: updated guidance from WHO

An-Wen Chan, Ghassan Karam, Justin Pymento, Lisa M Askie, Luiza R da Silva, Ségolène Aymé, et al.

, Vol. 13, No. 4, e759-e768

Open Access

A roadmap for fostering timely regulatory and ethics approvals of international clinical trials in support of global health research systems

Marco Cavaleri, Claudiosvam M Alves de Sousa, Adam Hacker, Elisabeth S Higgs, Murray M Lumpkin, Christiane S Maia, et al.

The Lancet Global Health, Vol. 13, No. 4, e769-e777
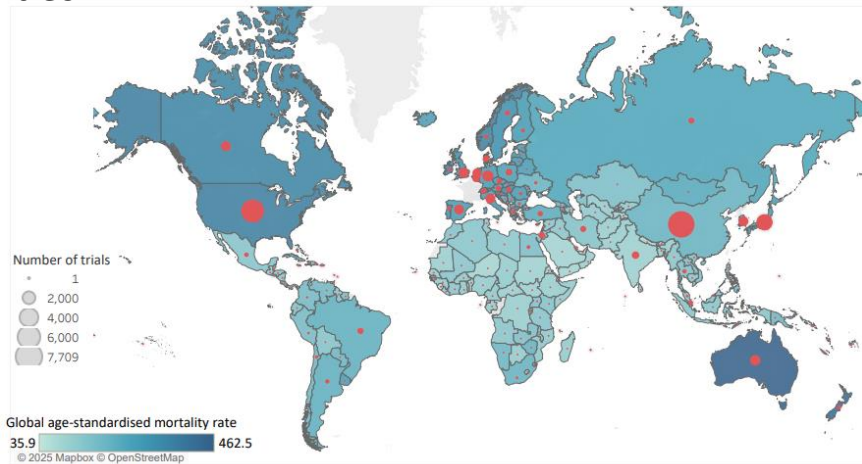
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Open Access

Improving the clinical trial environment and infrastructure: moving from global resolution to action

Vasee Moorthy, Nandi Siegfried, John Amuasi, Jing Li, Michael Makanga, Karla Soares-Weiser, et al.

The Lancet Global Health, Vol. 13, No. 4, e608-e610

Cancer work through ICTRP: data to inform actions

- **89,069** interventional cancer trials analyzed (1999-2022).
- Distribution by geography, economic development status, and disease burden (globally and by geography).
- Characterization of cancer clinical trials based on multiple variables of interest.
- Identification of trends, major gaps, and persistent disparities.

Number of trials
- 1
- 2,000
- 4,000
- 6,000
- 7,709

Global age-standardised mortality rate
35.9 — 462.5
© 2025 Mapbox © OpenStreetMap

1. **WHO global report on cancer clinical trials** (in progress)
2. **Report on cancer R&D in the EU27 Region** (finalized)
3. **Global landscape analysis of cancer clinical trials** (revision in Nature Medicine)
4. **Snapshots**

In 2023, 76% of cancer trials were conducted in high-income countries

Cancer research and development landscape

Overview of 1999–2022 period

To soon be launched

Every year, an estimated 400 000 children and adolescents aged 0–19 years develop cancer

Research and development landscape for childhood cancer: a 2023 perspective

Already published

Foundation for the development of a comprehensive WHO strategy aimed at promoting well-designed, patient-centered, locally relevant, and equitable cancer clinical trials.

Global Clinical Trials Forum (GCTF) – Launch (October 7)

- GCTF is a WHO-managed network supporting the implementation of WHA75.8 resolution

- Own identity - visual identifier (logo) for use in related activities

- Activities guided by Global action plan for clinical trial ecosystem strengthening (GAP CTS)

- Not a separate entity, operates under WHO policies

GCTF
Global clinical trials forum
WHO Managed Network

World Health Organization

Who can join?

- Diverse organizational membership
- Members must align with WHO Constitution, WHA75.8 resolution, WHO Guidance for Best Practices for Clinical Trials and Global action plan for clinical trials ecosystem strengthening (GAP-CTS)

State actors

- Examples; National Research Councils /Authorities (NRA's).

Non state actors

- Examples; research institutes, academia, funders, private sector via associations and patient/community engagement advocates.
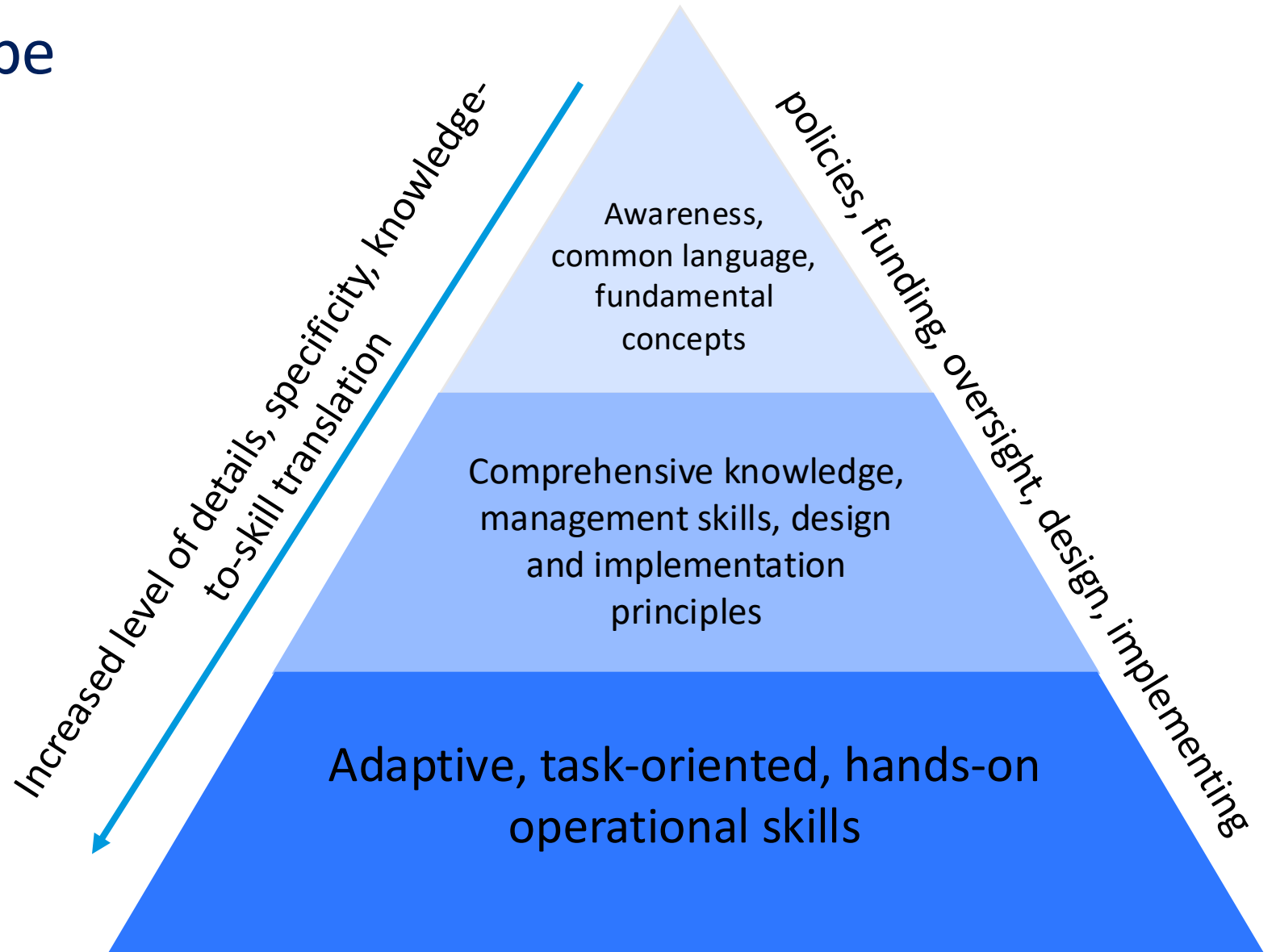
Training needs and scope

Guidance for best practices for clinical trials

WHO Global Benchmarking Tool (GBT) for Evaluation of National Regulatory System of Medical Products

WHO tool for benchmarking ethics oversight of health-related research involving human participants

Benchmarking tool for institutional capability for clinical trials

Increased level of details, specificity, knowledge-to-skill translation

policies, funding, oversight, design, implementing

Awareness, common language, fundamental concepts

Comprehensive knowledge, management skills, design and implementation principles

Adaptive, task-oriented, hands-on operational skills

Online Course: WHO Good Practices for Clinical Trial Design and Implementation (to be launched in 2025)
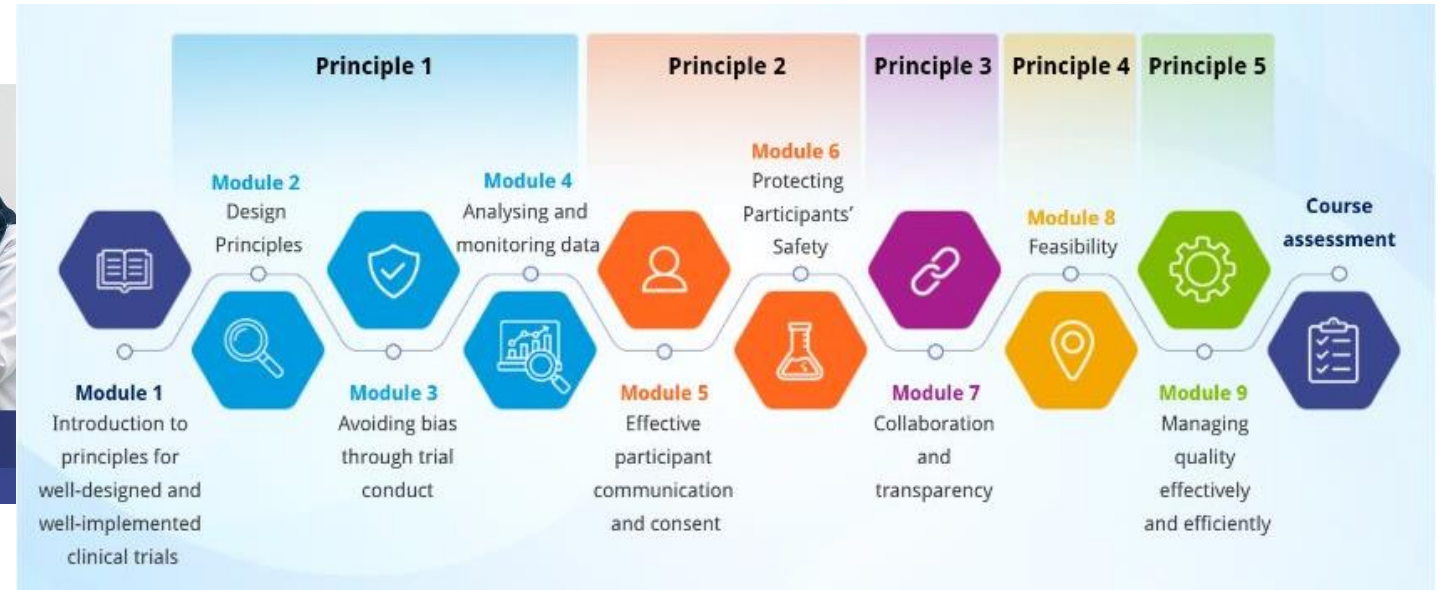
- For a wide range of stakeholders: researchers, regulators, funders, ethics committees, community representatives.
- Hosted on WHO Academy platform.
- Self-paced online course introducing the principles over 9 modules.
- Certificate of completion is awarded upon completing all modules and passing a final assessment.

Joint statement on strengthening clinical trials ecosystems worldwide (Funders statement).
25 September 2025.

Key commitments

- Embed trials in sustainable systems

- Design trials to answer unmet needs

- Meet best-practice standards

Why it matters

- Reduces duplication and inefficiency

- Ensures evidence reflects the needs of diverse populations

- Builds global trust in research outcomes

Next Step

- Develop high-level indicators to track progress within six months.

Signatories (Sept 2025): ARNS MIE, Australia NHMRC, EDCTP3, INSERM, NIH Korea, Nepal NHRC, Science for Africa, South Africa MRC, CIHR (Canada), UK MRC, UK NIHR, Wellcome Trust

World Health Organization

Milestones

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Guidance for best practices for clinical trials

World Health Organization

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Conclusions/ next steps

- Countries and partners have a global framework and reference standard to work with to improve the clinical trial environment wherever they work

- This is not a one time project

- Countries should prioritise this as an ongoing improvement and sustainability need for clinical trials within their health system, health science and innovation approach

- Countries that follow up can attract investment, develop and retain talent, and improve outcomes for patients, and options for doctors

- This framework is also the clinical trials pillar of the R&D system for countries that seek a thriving biotechnology sector

- Countries that do not may get left behind, and will be critically vulnerable during the next pandemic

Funding and collaboration

Donors

Collaborating Center

The guidance incorporated or adapted guidance from

Thank you

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