WHO’s framework to improve the clinical trial environment, and reduce barriers to clinical trials

Vasee Moorthy FRCP PhD
Senior Advisor
Science for Health Department
Science Division

October 2025

Vasee Moorthy MD PhD | LinkedIn

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

2022

WHA resolution 75.8

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

2025

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

World Health Organization

What is the new WHO guidance mandated by WHA 75.8?

- **Guidance for non-commercial/investigator-initiated trials aimed at changing policy/guidelines but not to generate data for regulators**
  - Comparative effectiveness
  - Trials that do not involve medicinal products eg behavioural interventions
  - Cluster randomized trials
  - Service delivery improvement trials eg packages of interventions, improving adherence
- **Guidance for any stakeholder working to improve the clinical trial ecosystem, environment, infrastructure in their country/internationally**

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.

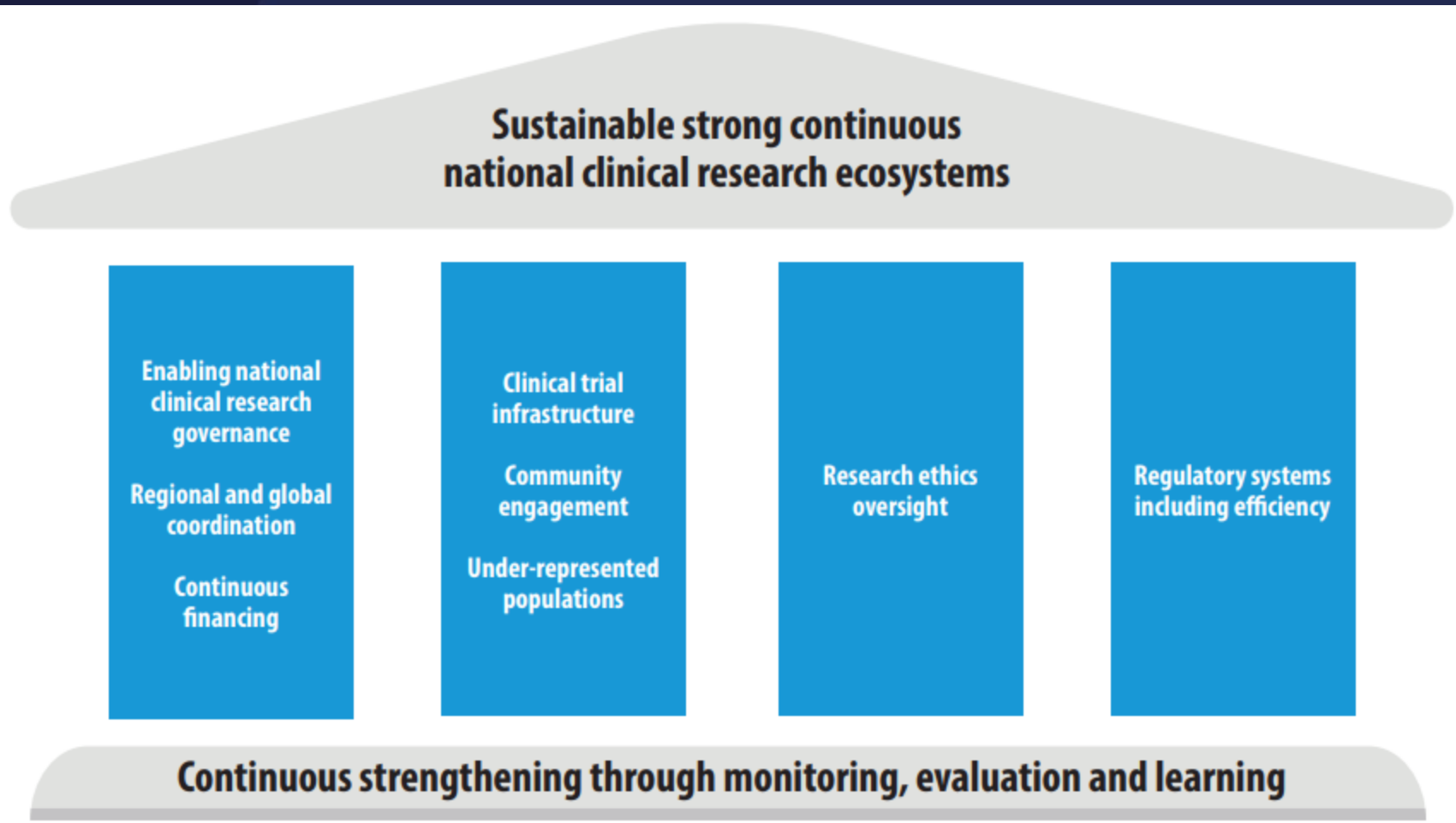
World Health Organization

Document link:

WHO Guidance translations

WHO guidance now available in seven languages

World Health Organization

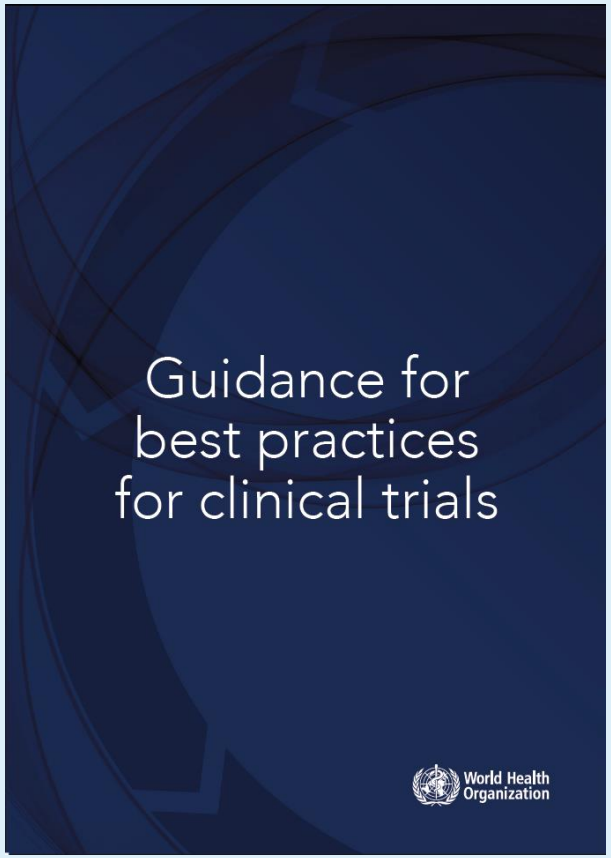


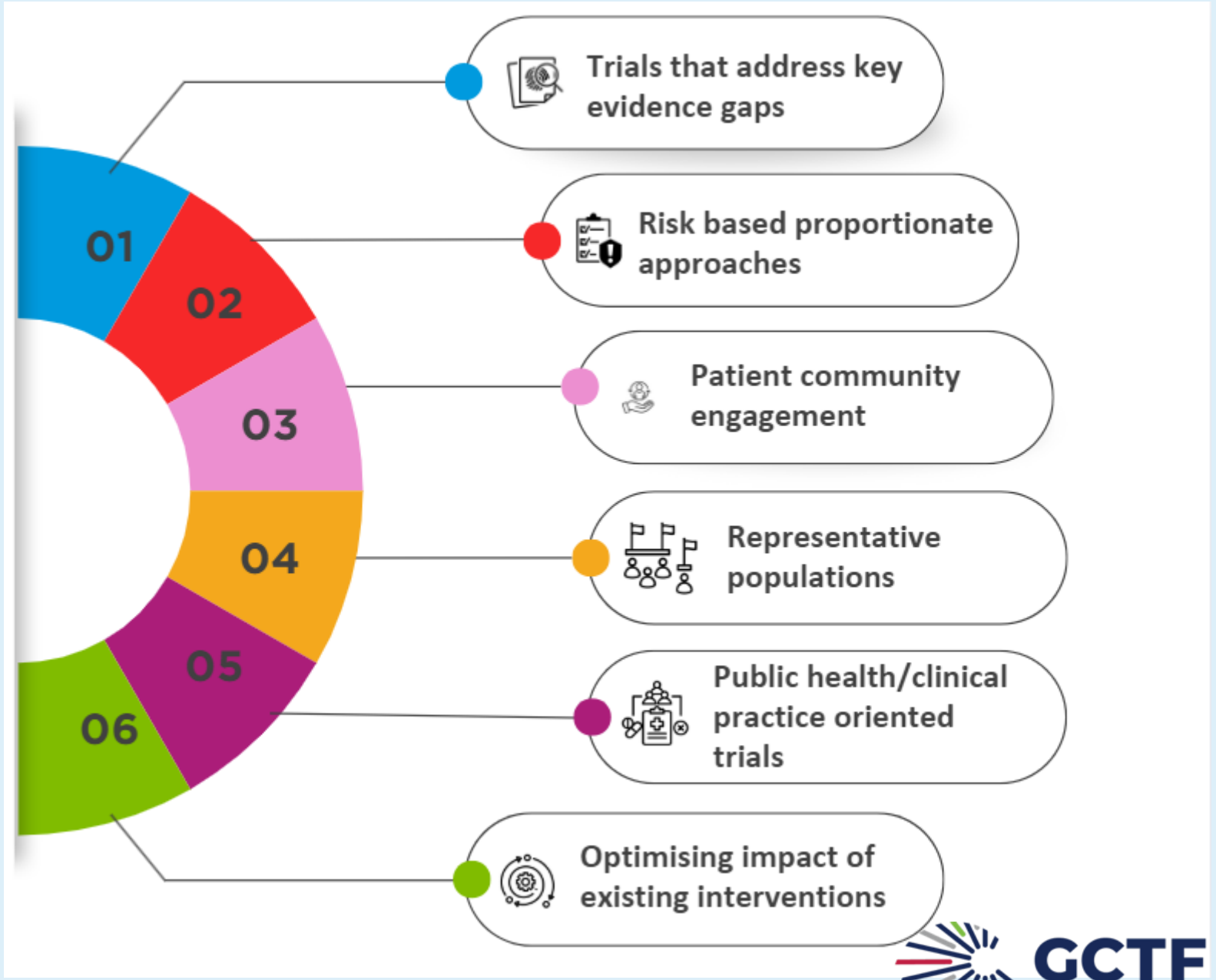
Source: Moorthy V, Abubakar I, Qadri F, Ogutu B, Zhang W, Reeder J, et al. The future of the global clinical trial ecosystem: a vision from the first WHO Global Clinical Trials Forum. The Lancet. 2024 Jan 13;403(10422):124–6 (https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(23)02798-8/fulltext).

World Health Organization

Document link:

Implementing change





World Health Organization

GCTF
Global clinical trials forum
WHO Managed Network

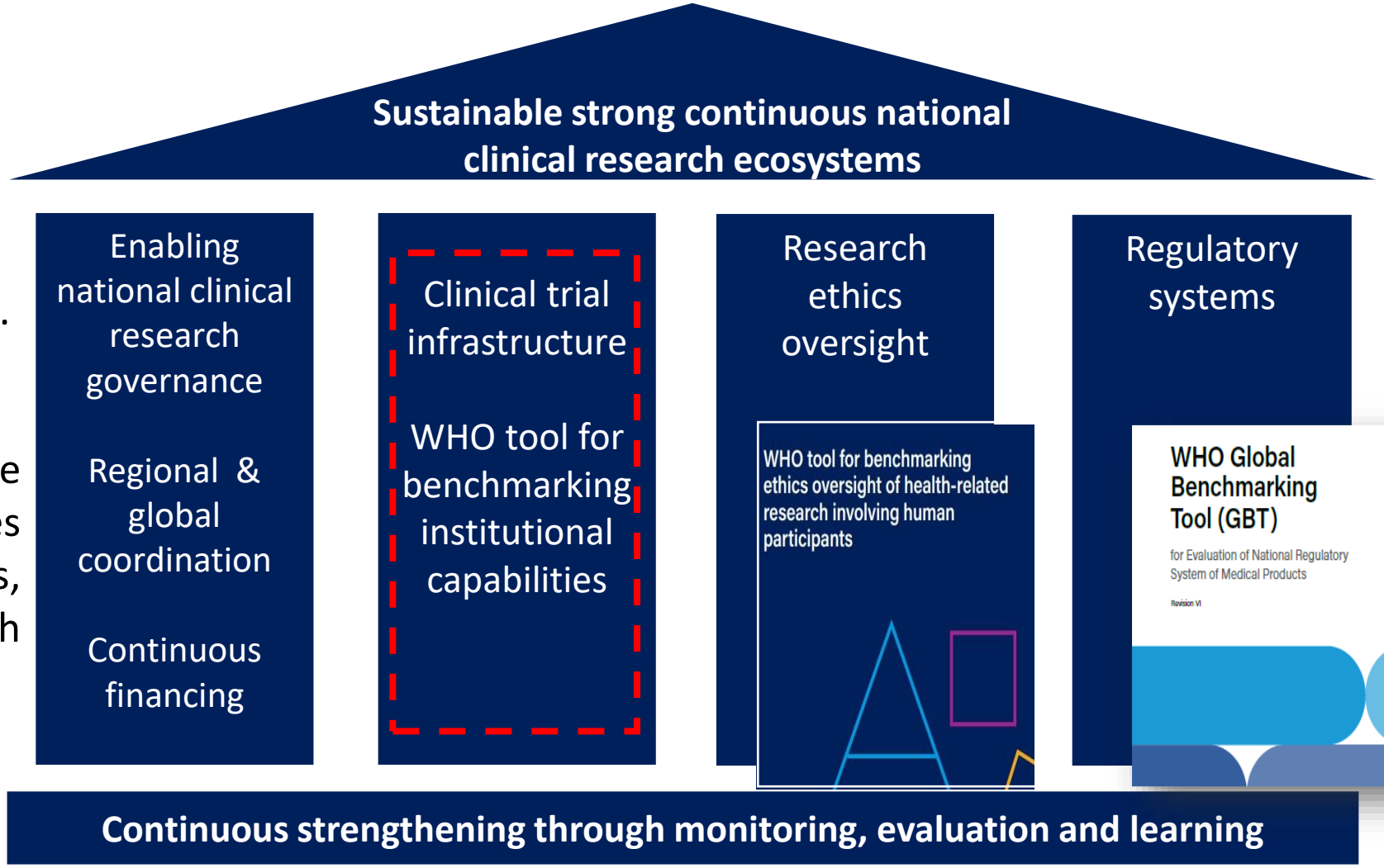
Develop benchmarking tool for institutional capability for clinical trials

- **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.



World Health Organization

Scope of WHO tool to support institutional clinical research capacities

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

World Health Organization

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 – now 13

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

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]

World Health Organization

Lancet series on Clinical Trials

Series

Open Access

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

Open Access

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

Open Access

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

Open Access

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

World Health Organization

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

Comment

Open Access

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

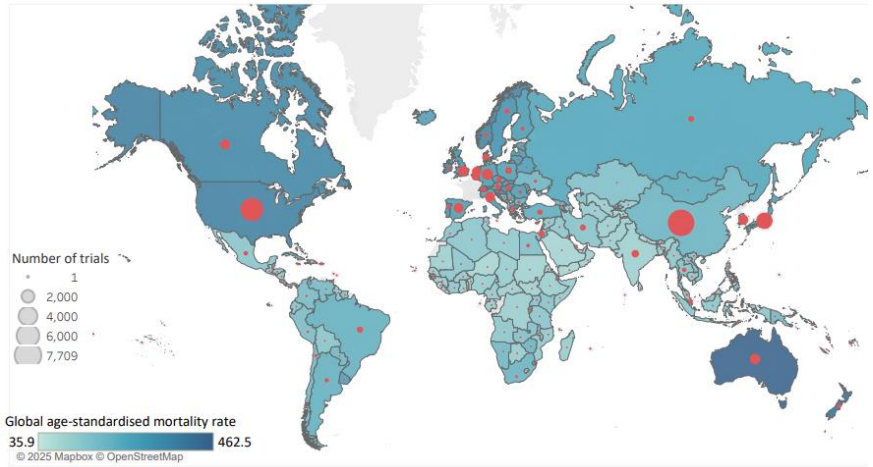
Vasee Moorthy, Nandi Siegfried, John Amuasi, Jing Li, Michael Makanga, Karla Soares-Weiser, et al.

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

World Health Organization

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.

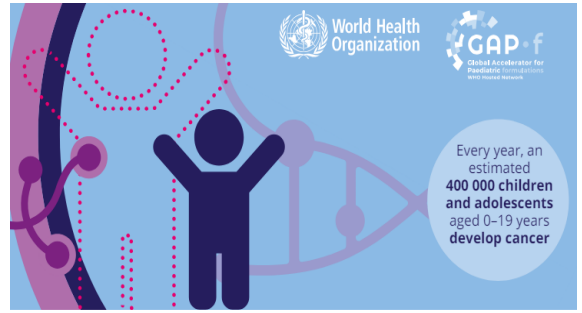


1. **WHO global report on cancer clinical trials** (in progress)
2. **Report on cancer R&D in the EU27 Region** (finalized)
3. **Global landscape analysis of cancer clinical trials** (revision in Nature Medicine)
4. **Snapshots**

Cancer research and development landscape

Overview of 1999–2022 period

To soon be launched



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

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.

World Health Organization

GCTF Global clinical trials forum WHO Managed Network


GCTF
Global clinical trials forum
WHO Managed Network


ACT
AEC
Accelerating
Clinical Trials
Accélérer les
Essais Cliniques


AVAC
Advocacy. Access. Equity.


NOT TO BE MINISTERED UNTO BUT TO MINISTER
CHRISTIAN MEDICAL COLLEGE
VELLORE
INDIA


CEPI


Cochrane


McMaster
University


International
Vaccine
Institute
VACCINES FOR A SAFER FUTURE


ecrin


EGYPTIAN DRUG AUTHORITY
EDA
هيئة الدواء المصرية


BECAUSE OF ME
HE SHALL LIVE
जीविष्यति मयैवासौ


St. John's
National Academy of
Health Sciences


EORTC
European Organisation for Research
and Treatment of Cancer
The future of cancer therapy


EUPATI


IFPMA


Indonesia
Clinical
Research
Center


ICR
MINISTRY OF HEALTH MALAYSIA
Research that matters to patients


MMV
Medicines for Malaria Venture
Ending malaria, rewriting the future


NEPAL HEALTH RESEARCH COUNCIL
ESTD. 1991


NUS
National University
of Singapore


PATH


protas

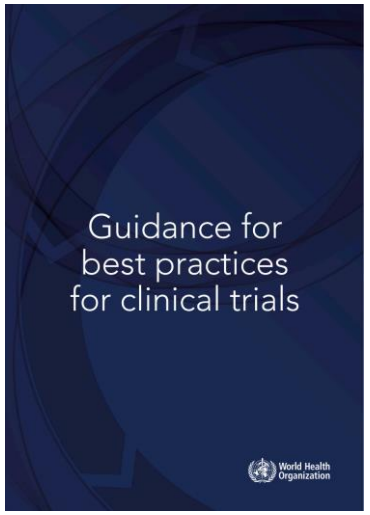

saMRC
advancinglife

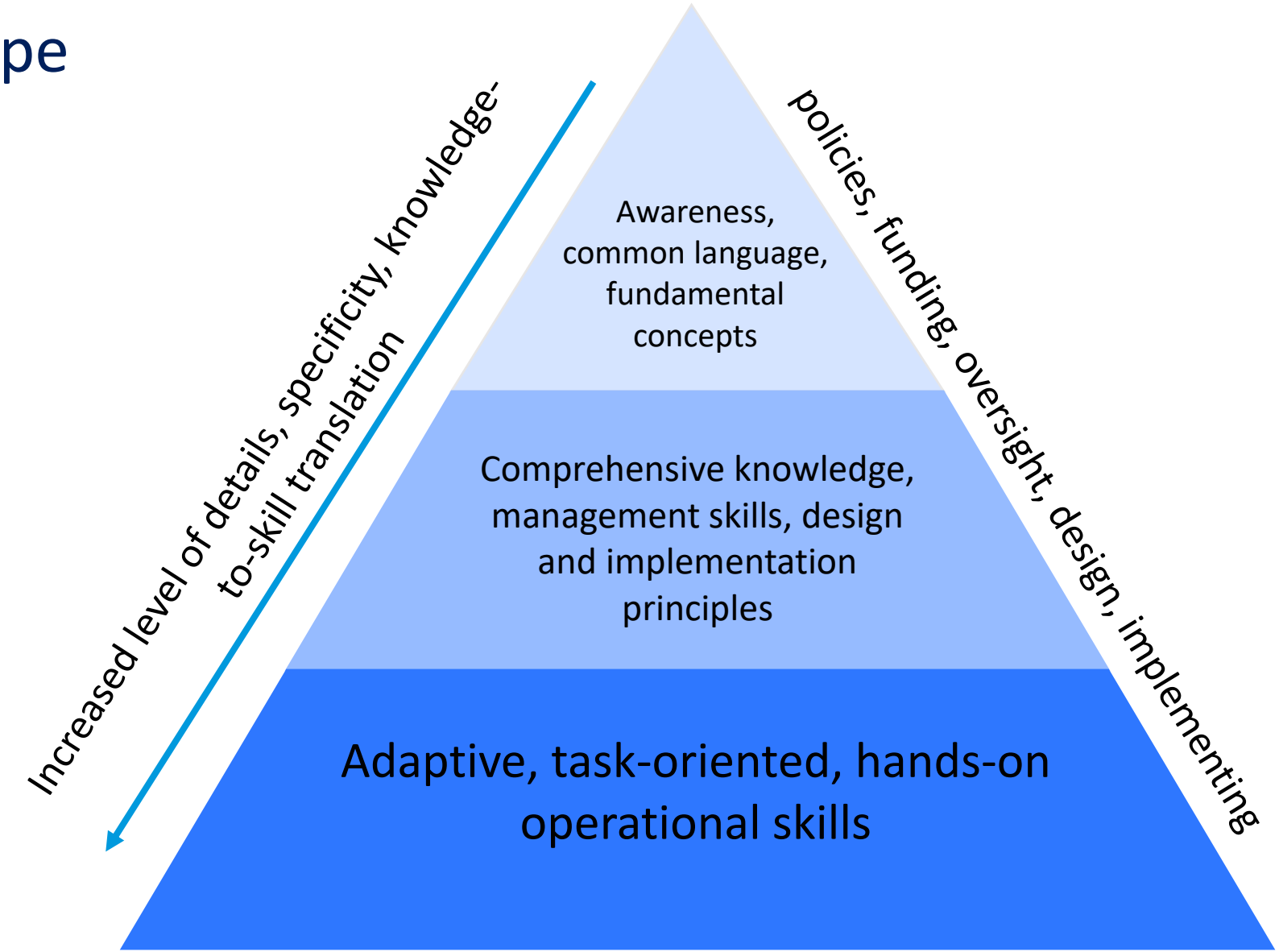

SINGAPORE
CLINICAL
RESEARCH
INSTITUTE


THE
GLOBAL
HEALTH
NETWORK
Enabling research by sharing knowledge


UNIVERSITY OF
OXFORD

Training needs and scope





World Health Organization

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.

World Health Organization

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

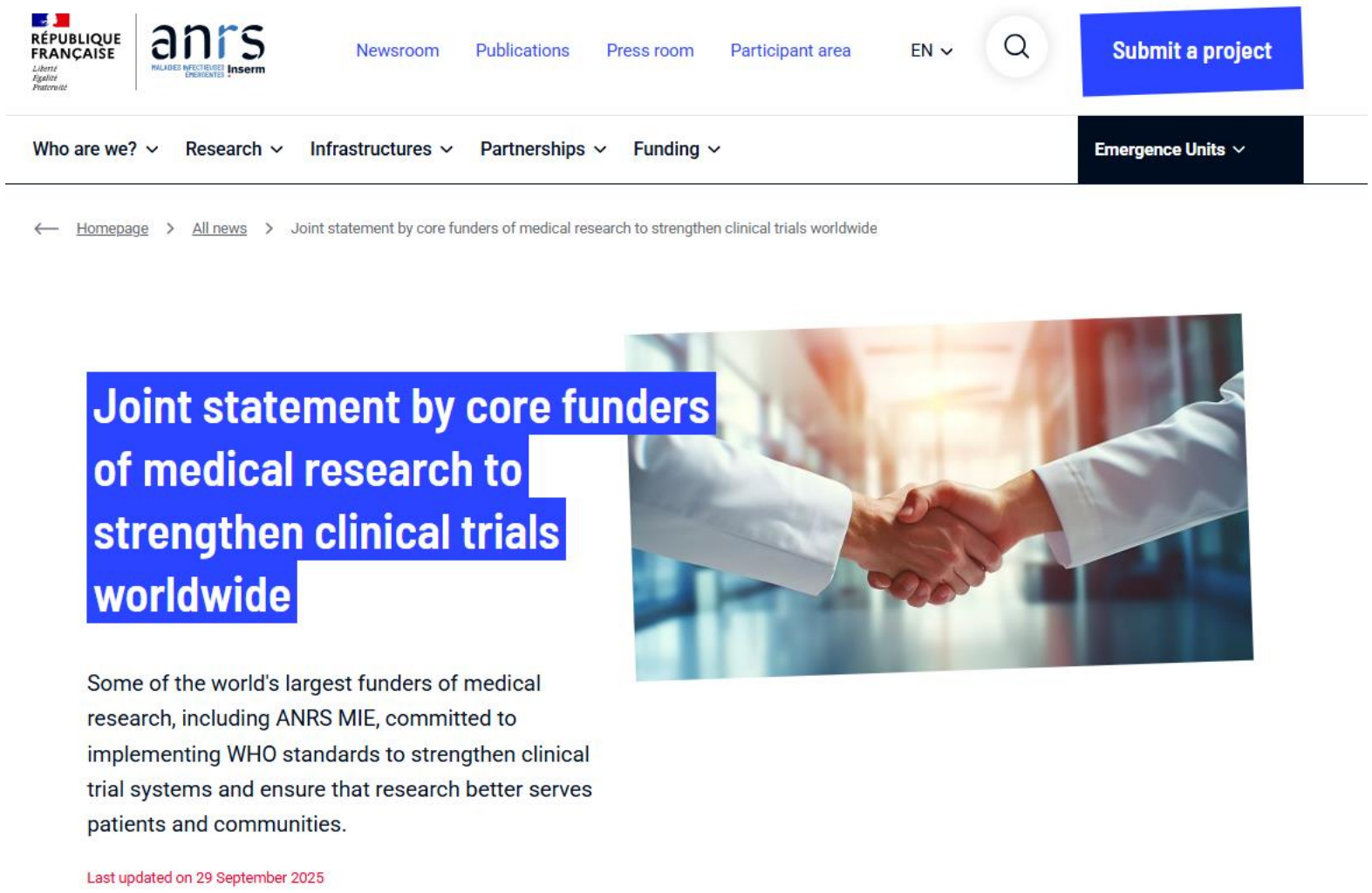
Next Step

- 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

France ANRS
Australian NHMRC
Canada CIHR
EDCTP3
France INSERM
Japan AMED
Korea NIH
Nepal HRC
Science for Africa
South Africa MRC
UK MRC
UK NIHR
Wellcome Trust



World Health Organization

Milestones

GCTF
Global clinical trials forum
WHO Managed Network

2022

WHA resolution 75.8

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

2025

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

World Health Organization

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

World Health Organization

Funding and collaboration

Donors

EDCTP

FUNDED BY NIHR National Institute for Health and Care Research

UKaid from the British people

Department of Health & Social Care

Collaborating Center

THE GLOBAL HEALTH NETWORK
Enabling research by sharing knowledge

World Health Organization

The guidance incorporated or adapted guidance from

CIOMS

good clinical trials

GCTF Global clinical trials forum WHO Managed Network

World Health Organization

Thank you

Vasee Moorthy MD PhD | LinkedIn

Document link:

World Health Organization