

WHO Guidance

Best practices for clinical trials

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Core role of WHO

- Support strengthening of country-led research and development (R&D) ecosystems advance health science and facilitate faster and more equitable access to safe and effective health interventions is of the utmost importance to a country's population health and economic well-being. Clinical trials are an essential component of a strong country-driven R&D ecosystem.
- In 2022 the World Health Assembly adopted resolution “Strengthening clinical trials to improve high quality evidence on health interventions and to improve research quality and coordination”

Enhancing clinical trial capacity is essential for all countries with many efficiency gains possible in high-income countries (HIC) as well as middle- and low-income countries (MLIC)

3 Key recommendations

- **Patient, participant and community engagement** are placed centrally in the trial planning and implementation phases to ensure the research meets public needs and maintains trust.
- Reforms that enable **trials in underrepresented populations** such as **children, pregnant women and older adults**.
- The guidance lays out how to **focus trial design and oversight on the key scientific and ethical** considerations that determine whether trials are ethical, efficient and informative. Here **risk based** and proportionate approaches are advocated

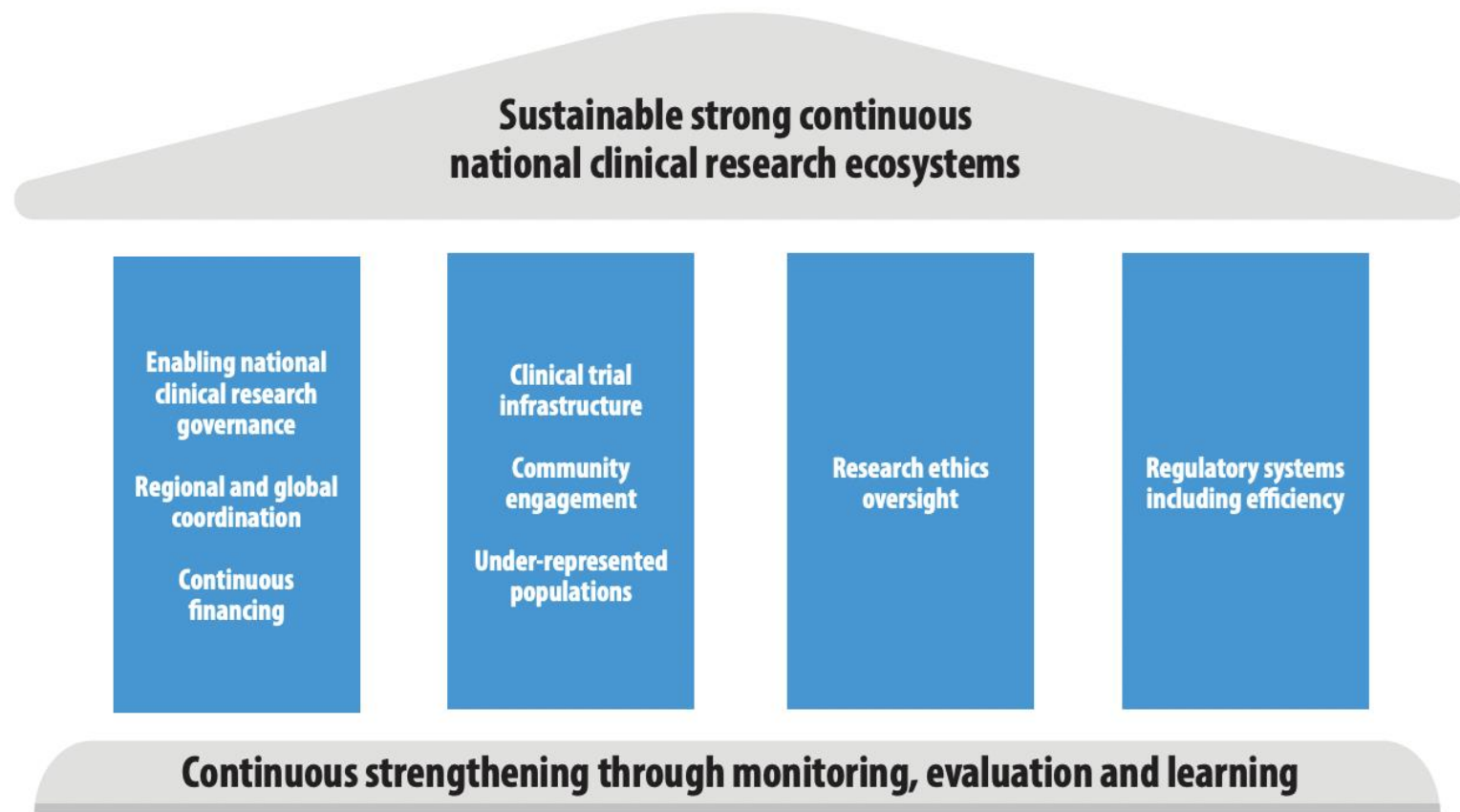
Recommendations

- Advance **efficient and sustained well-designed and well-implemented** clinical trials that address local health needs across all stages of clinical research in LMICs and other resource-limited settings, encompassing both communicable and noncommunicable diseases in order to address the morbidity and mortality risks affecting people in those settings
- Conducting **research in LMICs can foster capacity-building** can contribute to the development of the necessary infrastructure and resources to execute high-quality research in LMICs.

Call for a systematic end-to-end approach for ensuring that new interventions are globally affordable and accessible, from discovery through to development and distribution

- Trials where the disease burden in LMICs led to them being targeted for inclusion in clinical trials, yet these data were then used to file for marketing authorization in HICs, often leading to availability of interventions in the latter but not the former
- Trials of diagnostics that took place in LMICs or low-resource settings have sometimes failed to provide any post diagnostic support for those with the diagnosed condition

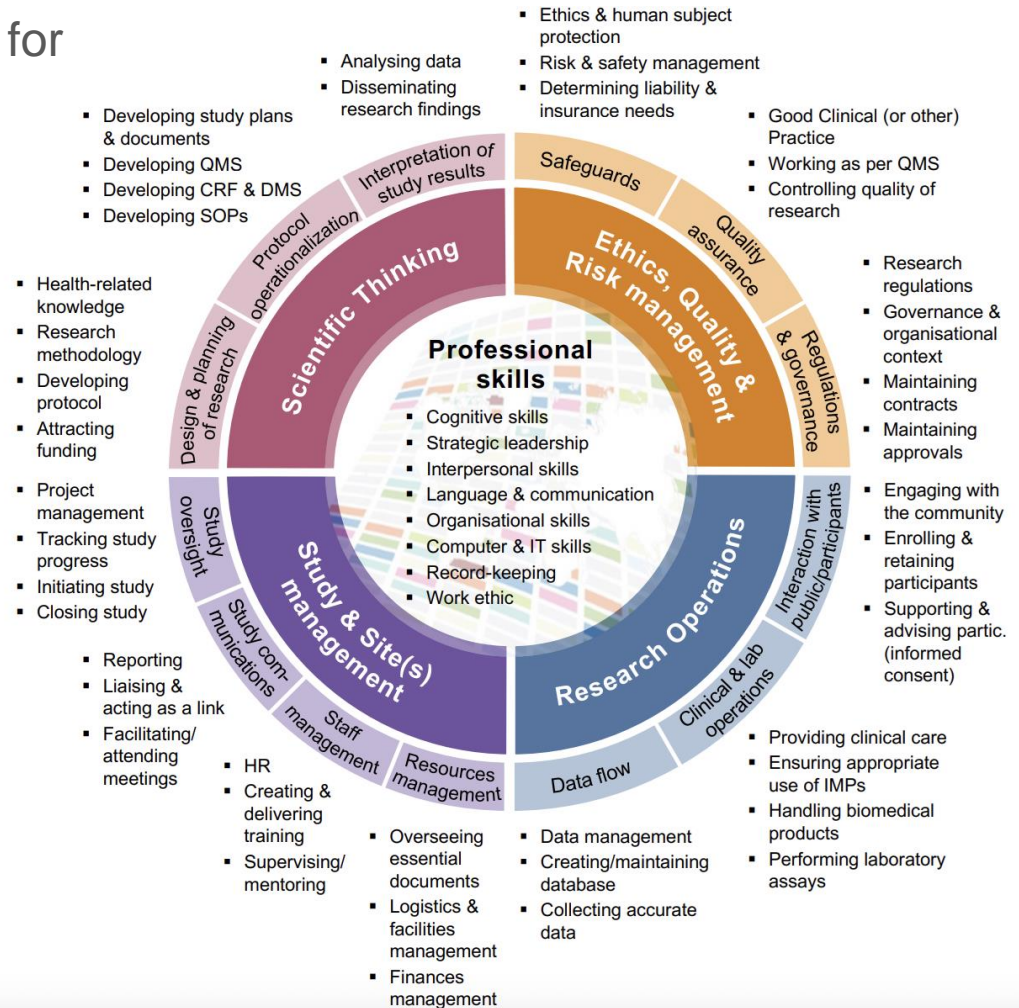
Figure 1. Clinical trial ecosystem pillars



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](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(23)02798-8/fulltext)).

TDR Global Competency Framework for Clinical Research

Lists all the competencies that should be demonstrated by a clinical research team to undertake a successful study



Four pillars can only optimally function if the following cross-cutting themes are enabled

- patient and community engagement
- collaboration, coordination and networking
- use of common systems and standards
- training and mentoring
- risk-proportionate efficient approaches
- sustainability
- innovation
- transparency

Potential benefits

- **Improved trust** between the public and the health research community
- Better **locally derived evidence** for clinical practitioners and public health decisions
- Improved health **outcomes**, faster and more **equitable access** to innovation and medical products that are better tailored to individual patient needs, and hence progress towards health-related sustainable development goals
- National resilience and security including a more robust clinical trial ecosystem ensuring **faster response to health crisis**
- Healthier populations and more productive economies

Summary

- Clinical trial ecosystem: **streamlined regulatory and ethics approval** processes ensuring the right review is done to protect patient safety and ethical aspects, communication, capacity-building, and the use of **fit for purpose innovation** in methodology and technology in trial designs
- Moving to **patient centricity** and serving underrepresented populations. This includes applying **diversity by design** as a scientific imperative, engaging communities to build trust in clinical research, as well as balancing inclusion and protection
- **Aligning** key principles for well-designed and well-implemented trials with **ICH guidance**

US may withdraw from WHO: Impacts on Clinical Trials

(US President's executive order)

- Data access limitations
- Reduced international collaboration
- Disruption of standards
- Funding challenges
- Impact on emerging infectious diseases