WHO guidance for best practices for clinical trials

Strengthening clinical trials to improve evidence for health interventions

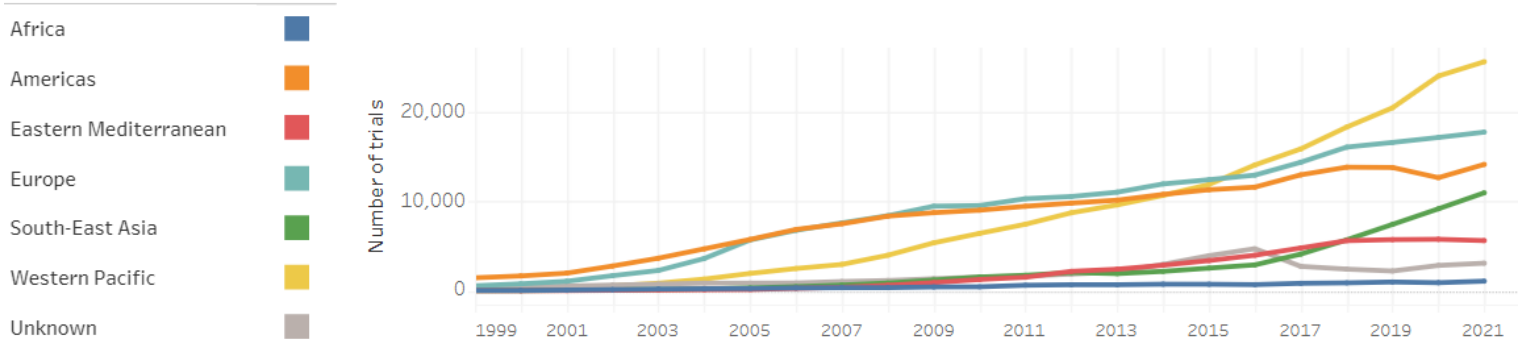
Research for health department
Science Division

25th September 2024

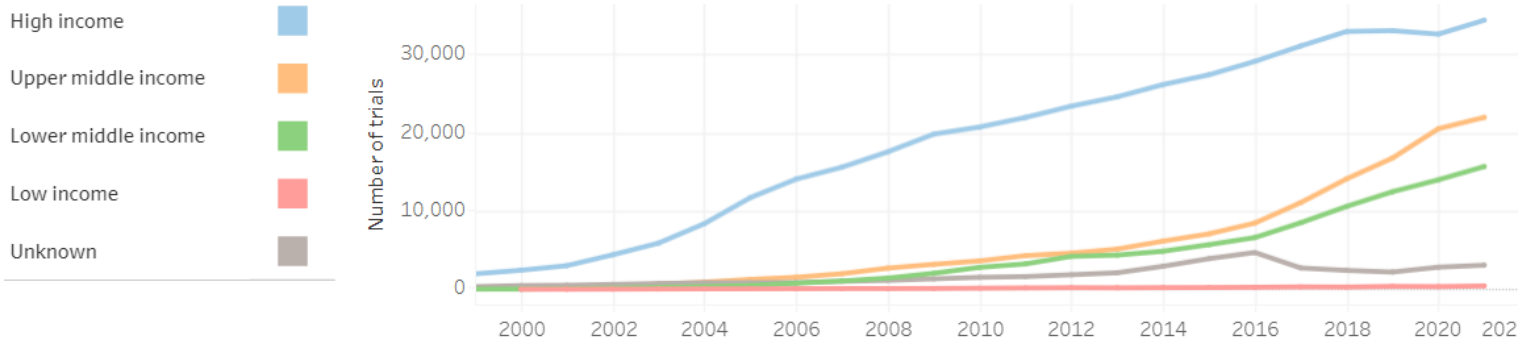
World Health Organization

Background: Growing number of clinical trials

A. Number of trials by year and WHO region (1999 to 2021)



B. Number of trials by income group (1999 to 2021)



Trial numbers are **growing** globally.

Some LMIC have **rapidly emerging** clinical research ecosystems

In 2021 alone, more than **34000 trials** were conducted in high-income countries.

Numbers of trials in AFRO and EMRO are **lower**.

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* WHO Observatory on Health Research and Development. https://www.who.int/observatories/global-observatory-on-health-research-and-development/monitoring/number-of-trial-registrations-by-year-location-disease-and-phase-of-development. Accessed on 10th Aug 2023.

Background: Research waste seen during the pandemic

2,024

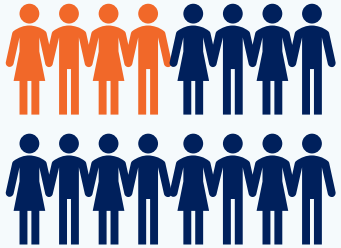
COVID-19 **clinical trials** registered

5%

of **trial arms** that were **appropriately** randomized and **sufficiently** powered

530,692

patients enrolled



26%

of the total **530K patients** contributed to generation of **useful evidence**

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* Trends in COVID-19 therapeutic clinical trials. https://www.nature.com/articles/d41573-021-00037-3. Accessed on 10th Sep 2024.

Background: Barriers in clinical trials put public health at risk

Poor trial design and implementation lead to uninformative trials wasting valuable resources.

Lack of engagement and non-inclusive clinical trials restrict generalizability of evidence and translation to effective policy and practice.

Major gaps in trial infrastructure and capabilities in many countries with high disease burden hinder the research to address pertinent needs.

Inefficiency in regulatory and ethics approval and oversight costs time, money and lives, and demotivates research and trials.

These barriers result in unethical conduct, delay of effective interventions, waste of resources, and loss of public trust in research.

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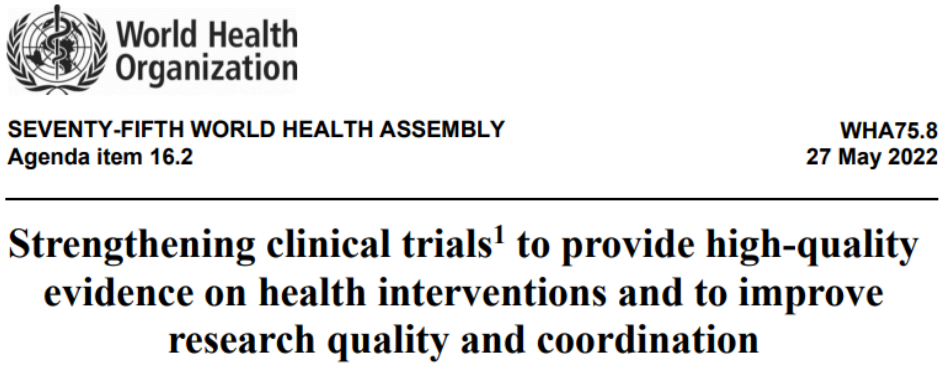
Background: WHA75.8 calls for actions to strengthening clinical trials



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SEVENTY-FIFTH WORLD HEALTH ASSEMBLY
Agenda item 16.2

WHA75.8
27 May 2022

Strengthening clinical trials[1] to provide high-quality evidence on health interventions and to improve research quality and coordination

Request to WHO Secretariat,

"To develop guidance on best practices for clinical trials built on existing guidance and consultations with Member States and Non-State Actors, on the design and conduct of clinical trials and in strengthening the global clinical trial ecosystem to meet the needs of major population groups that the intervention is intended to benefit, with a particular focus on under-represented populations".

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WHO guidance for best practices for clinical trials: development

WHA75.8 adopted

Online stakeholder consultation on best practices for clinical trials

A 16-member TAG established to guide the normative guidance development

Public consultation on draft guidance on key scientific and ethical consideration
Global stakeholder survey on barriers and priorities to strengthening ecosystem

Consultations with private sector
WHO regional consultations

Global clinical trials forum on addressing barriers in ecosystem

Final TAG review

Final draft

A consultative process to ensure that the guidance is relevant to all stakeholders

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WHO guidance for best practices for clinical trials: Key scientific and ethical considerations

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.

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WHO guidance for best practices for clinical trials: Strengthening the clinical trial ecosystem

Pillars of a sustainable strong continuous national clinical research ecosystem include

- ✓ established national clinical research governance that supports regional and global coordination and continuous funding.
- ✓ sustained clinical trial infrastructure and capabilities that effectively engage with affected populations and communities inclusively.
- ✓ appropriate research ethics oversight to ensure research is designed and conducted according to scientific and ethical principles.
- ✓ efficient and effective regulatory systems for data on safety and efficacy of health interventions to be accessible for the populations most in need.

Strengthening the clinical trial ecosystem is a collaborative process at national, regional, global levels through continuous monitoring, evaluation and learning.

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WHO guidance for best practices for clinical trials: Recommendations for researchers

Researchers, including sponsors and investigators, should

- ✓ identify and address relevant health research questions that fill gaps in evidence.
- ✓ enhance engagement with patients, communities and public throughout the trials lifecycle.
- ✓ ensure that trial populations are representative of populations that are most in need of interventions.
- ✓ design and conduct trials according to key scientific and ethical principles and adopt useful innovations.
- ✓ expand cross-border collaborations in health research and trials where mutually beneficial.
- ✓ promote transparency and reduce waste in clinical research including through timely registration and reporting and data sharing

Researchers are the driving force for well-designed and well-implemented clinical trials to generate high-quality evidence for effective health interventions.

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WHO guidance for best practices for clinical trials: Recommendations for policy-makers

Ministries of health, ethicists, regulators and funders, should

- ✓ provide an enabling environment and career development for local clinical researchers
- ✓ support ‘always on, always warm’ clinical trial networks through sustained infrastructure and funding.
- ✓ improve coordination and streamlining of regulatory and ethics review processes
- ✓ engage clinical practitioners to integrate trial capabilities into health system and practices.
- ✓ contribute to clinical trial ecosystem strengthening through ongoing reform, monitoring and evaluation.

Policy-makers are instrumental to creating an enabling environment for good clinical trials to be conducted effectively to respond to public health needs.

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Funding and collaboration

Donors

EDCTP

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UKaid from the British people

BILL & MELINDA GATES foundation

Department of Health & Social Care

Collaborating Center

THE GLOBAL HEALTH NETWORK
Enabling research by sharing knowledge

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The guidance incorporated or adapted guidance from

CIOMS

good clinical trials

Thank you

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