

WHO guidance for best practices for clinical trials

WHO's global guidance for more effective and equitable clinical trials

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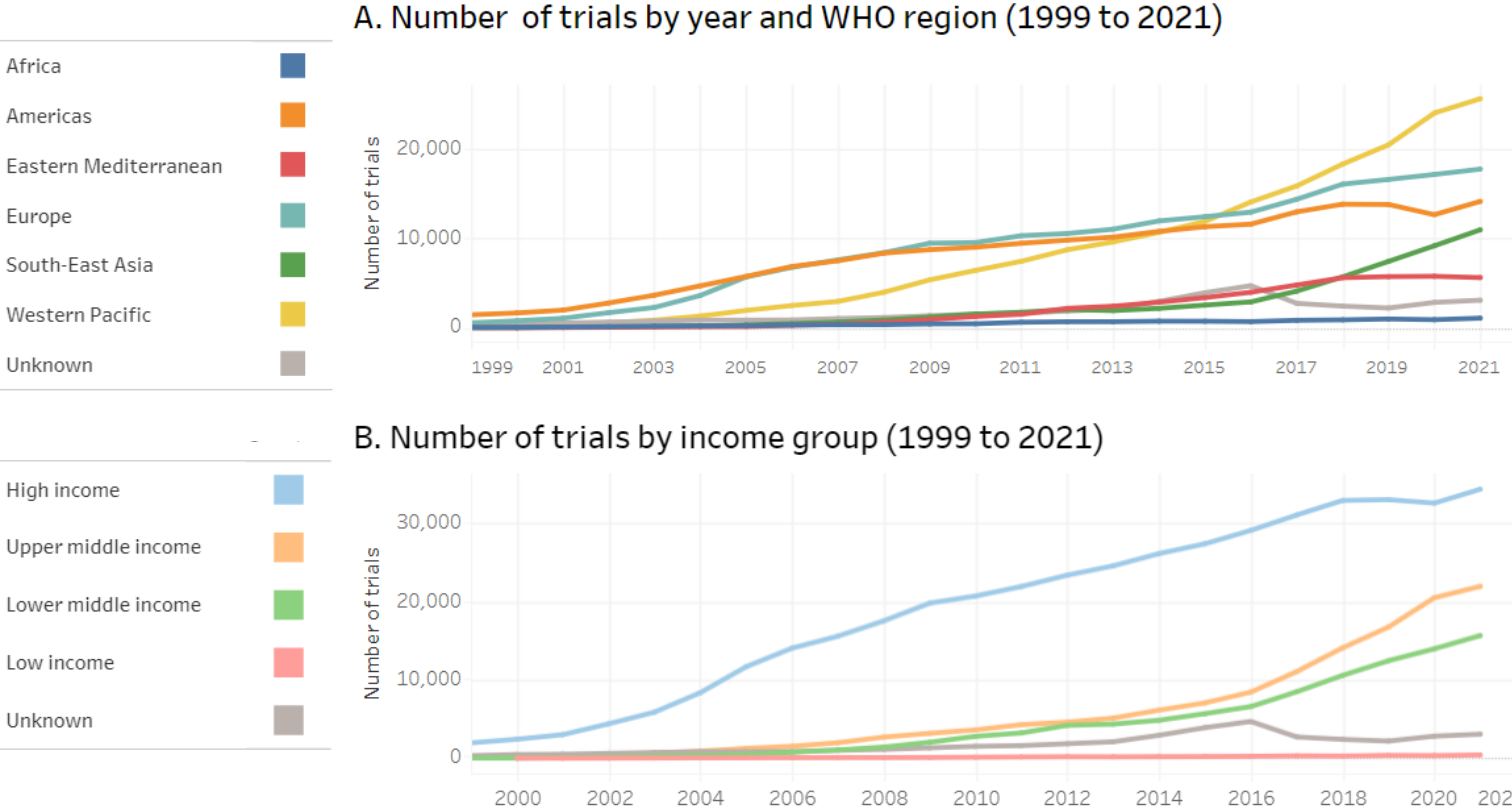
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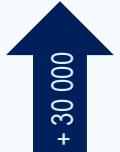
Background: Growing number of clinical trials



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**.

Background: Research waste seen during the pandemic



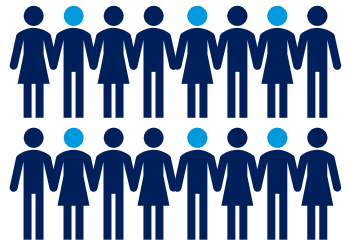
2,024

COVID-19 **clinical trials** registered



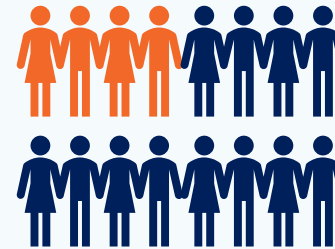
5%

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**

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.

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.



Sustainable strong continuous national clinical research ecosystems

Enabling national
clinical research
governance

Regional and global
coordination

Continuous
financing

Clinical trial
infrastructure

Community
engagement

Under-represented
populations

Research ethics
oversight

Regulatory systems
including efficiency

Continuous strengthening through monitoring, evaluation and learning

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)).



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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.**
- ✓ **adoption of useful innovations; pragmatic, point-of-care, decentralized, digital, adaptive, factorial etc.**
- ✓ **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.



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



Next steps

Translations into all UN languages

Developing/piloting clinical trial unit (CTU) maturity framework to support capacity development

Developing training material suitable to different contexts and audiences

Developing and piloting implementation tools

6 regional workplans led by colleagues in WHO regional offices

Supporting requests for support from countries wishing to use guidance to strengthen their clinical research ecosystems

Ongoing workstreams in a number of areas including primary care, underrepresented populations, community engagement, regulatory and ethics coordination/streamlining and others



Impact of the new guidance depends on engagement with stakeholders worldwide



GLOBAL ACTION PLAN FOR CLINICAL TRIAL ECOSYSTEM STRENGTHENING

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

Action 2: Enhance engagements with patients, communities and the public in trial life cycle

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

Action 4: Ensure trials are well designed including 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: Reduce waste, advance transparency

Action 9: Expand mutually beneficial multi-national health research and clinical trial collaboration

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What does success look like?

Ministries of health make plans to strengthen, and increase attractiveness of their clinical trials ecosystem

Clinical Trial Approval processes are rationalised:

Minimum number of necessary approval steps

Single/Rationalised REC models per country

Coordination of multi-agency approval processes

Single submission systems

Standard contracting templates/master contracts

Monitoring against timelines for approval

Monitoring how reforms affect enrolment rates

Proportionate approaches are widely adopted and supported by regulators/monitors/auditors

The need for RCTs beyond traditional pre-licensure trials is widely accepted and funded

Patient and community awareness, inclusion, engagement mainstreamed

Underrepresented populations included in RCT evidence base

Trials are enabled wherever key questions need to be answered eg primary care, community



What does success look like?

RCTs occur wherever disease burden indicates need – capacities are built

Local leadership capabilities are supported so that trials are led from the countries where the needs are

All trials are prospectively registered, and results are disclosed for all within reasonable timeframes

Fit for purpose clinical research training is available for all stakeholder groups

Large scale research networks operate in perpetuity and move away from the need to secure project funding for core staff – domestic long term support for research integrated into healthcare

If there is a pandemic tomorrow, we can swiftly pivot work to enable key high quality trials

2022

WHA RESOLUTION

2023

**GLOBAL CLINICAL
TRIAL FORUM**

2024

**LAUNCH OF
WHO GUIDANCE**

Researchers
Industry
Regulators
Ethics authorities
Funders
Patient groups
Health authorities

2025

**LAUNCH
OF
ACTION PLAN**

Researchers
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The guidance incorporated or adapted guidance from



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