Improving the way we generate evidence: a reformed clinical trials framework

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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)

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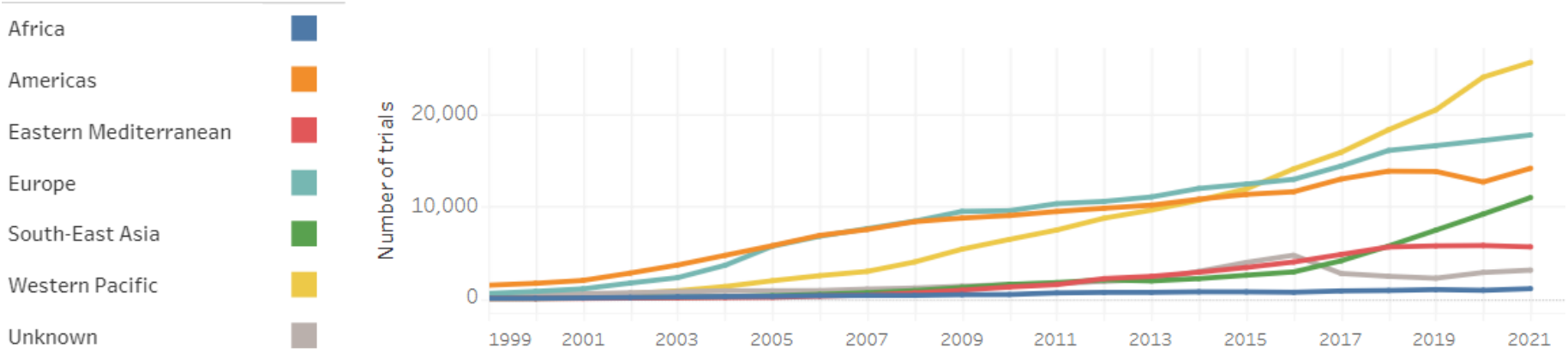
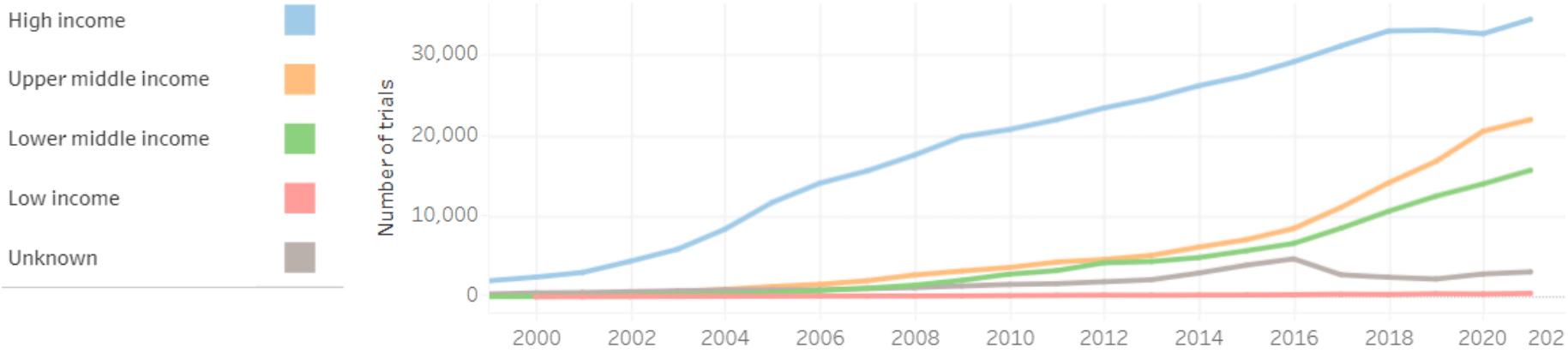
Background: More clinical trials, not representative

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.
- <3% trials in AFRO
- In 2021 alone, more than 30000 trials were conducted in high-income countries.
- <5% trials in EMRO

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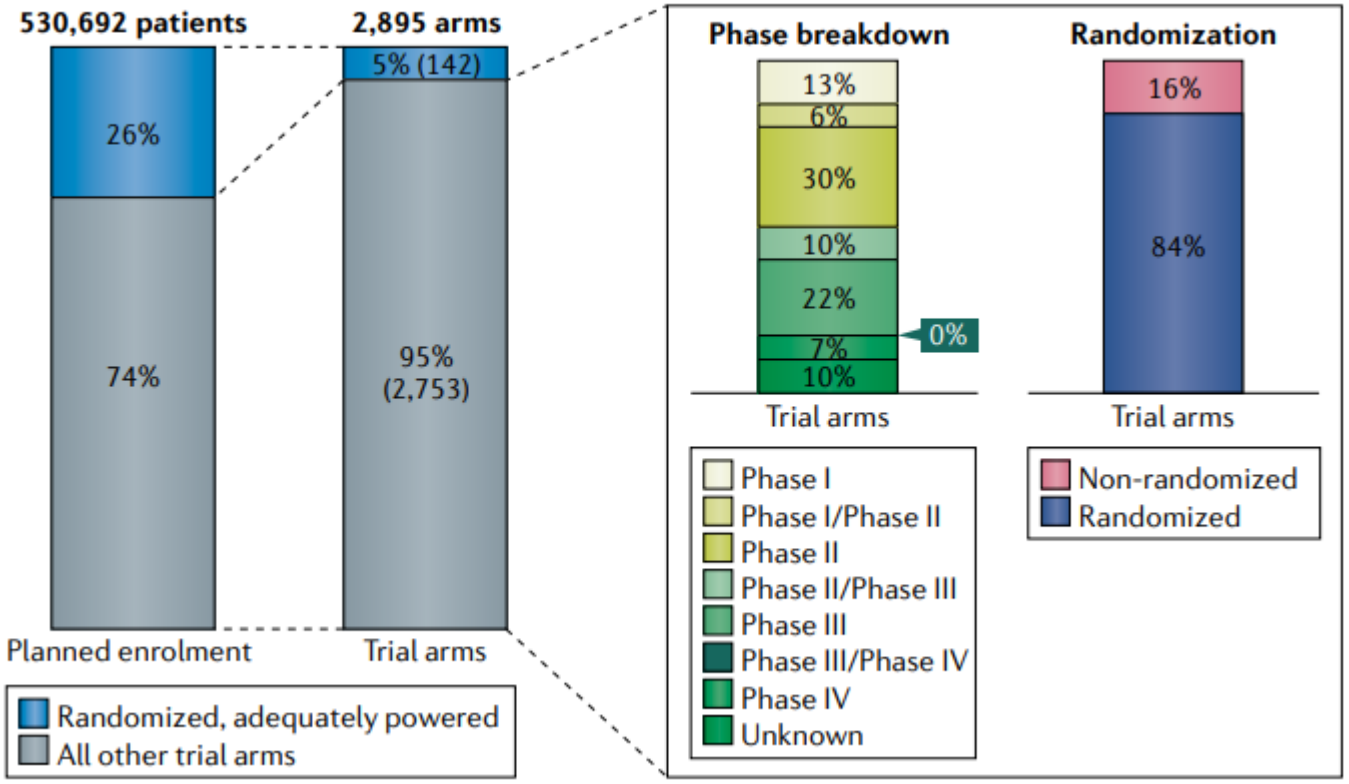
* WHO Observatory on Health Research and Development. https://www.who.int/observatories/global-observatory-on-health-research-and-development/monitoring/number-of-trial-registrations-by-year-location-disease-and-phase-of-development. Accessed on 10th Aug 2023.

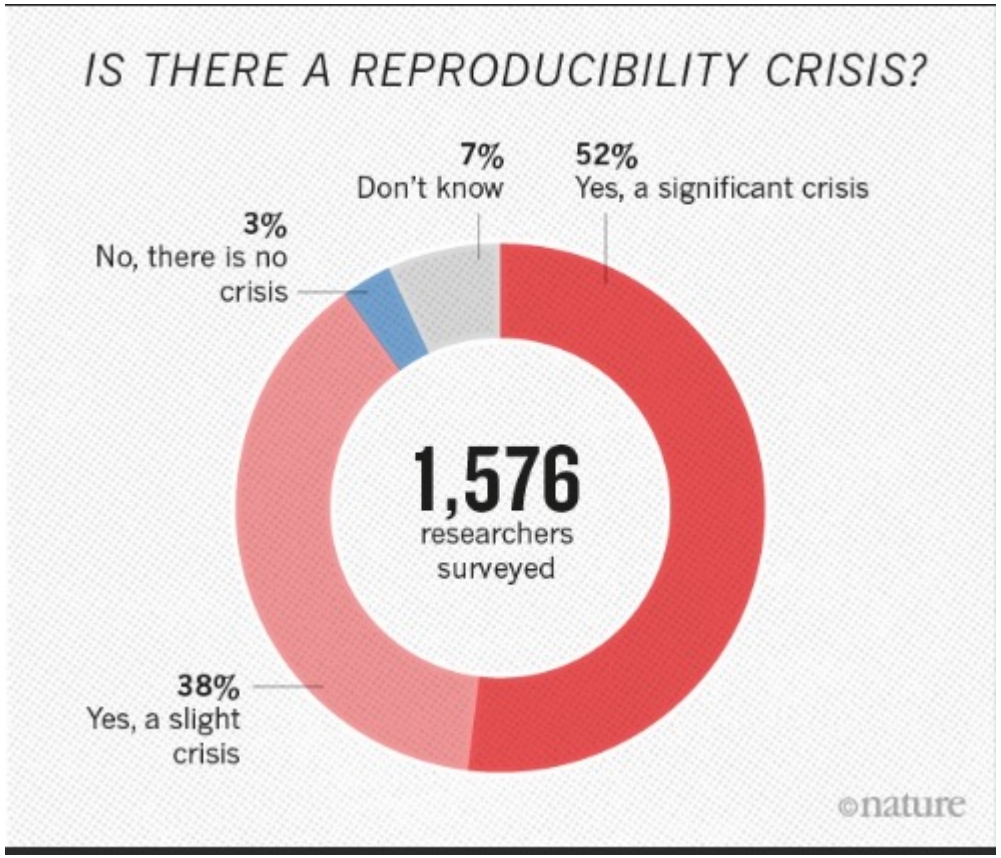
Research waste: More clinical trials ≠ High certainty evidence



- Multiple analyses that indicate that 60 – 95% of clinical trials are uninformative

* 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.

Research waste is linked to the reproducibility crisis



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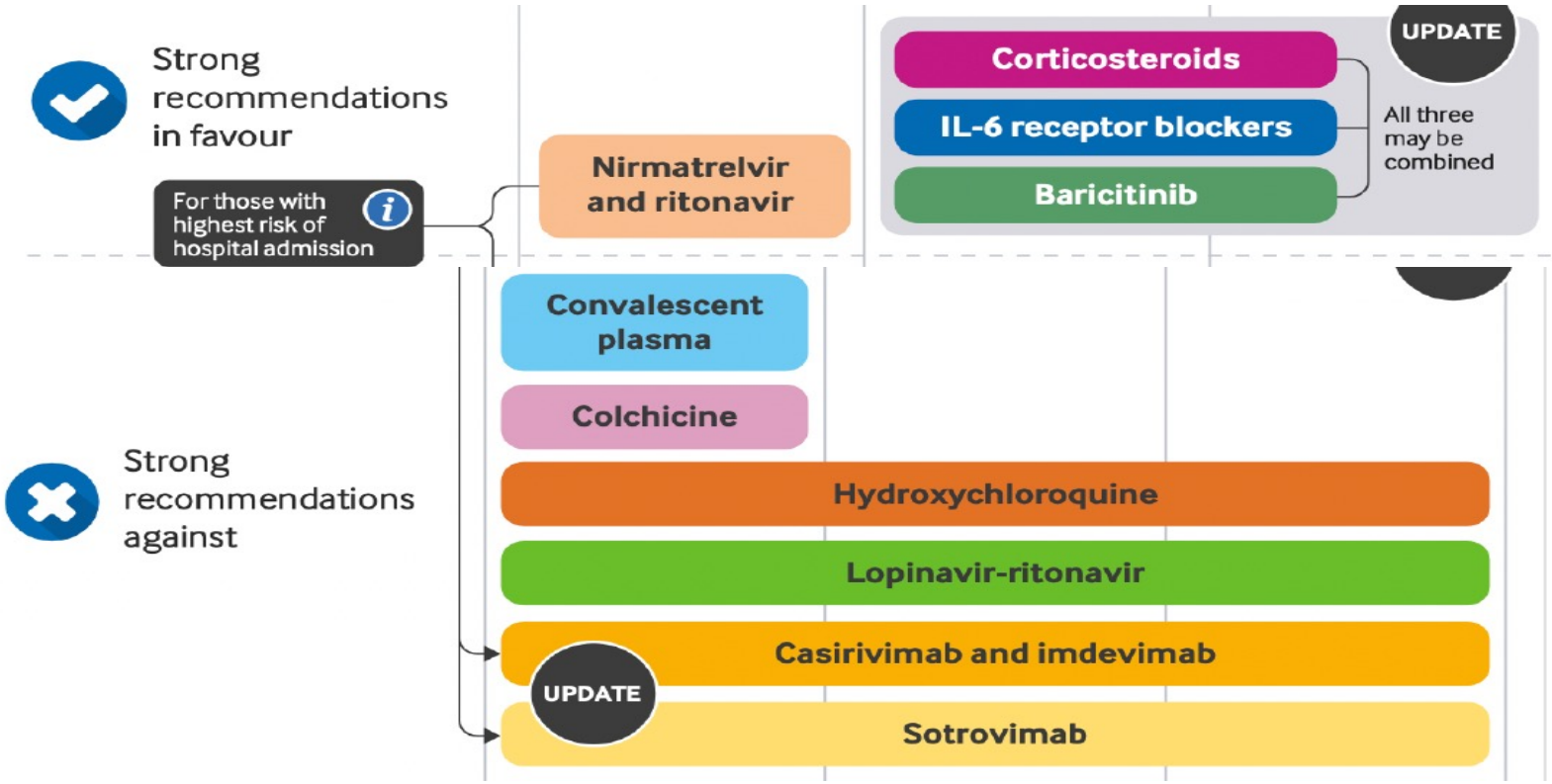
In the pandemic a few large trials generated much useful evidence and changed global practice



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Key barriers to timely, relevant evidence generation

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

Well-designed trials lead to **high quality evidence**

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

Community engagement and addressing **under-represented populations** are placed centrally

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

New framework to improve **clinical trial infrastructure and capabilities**

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

Creating **enabling, efficient environment for trials**

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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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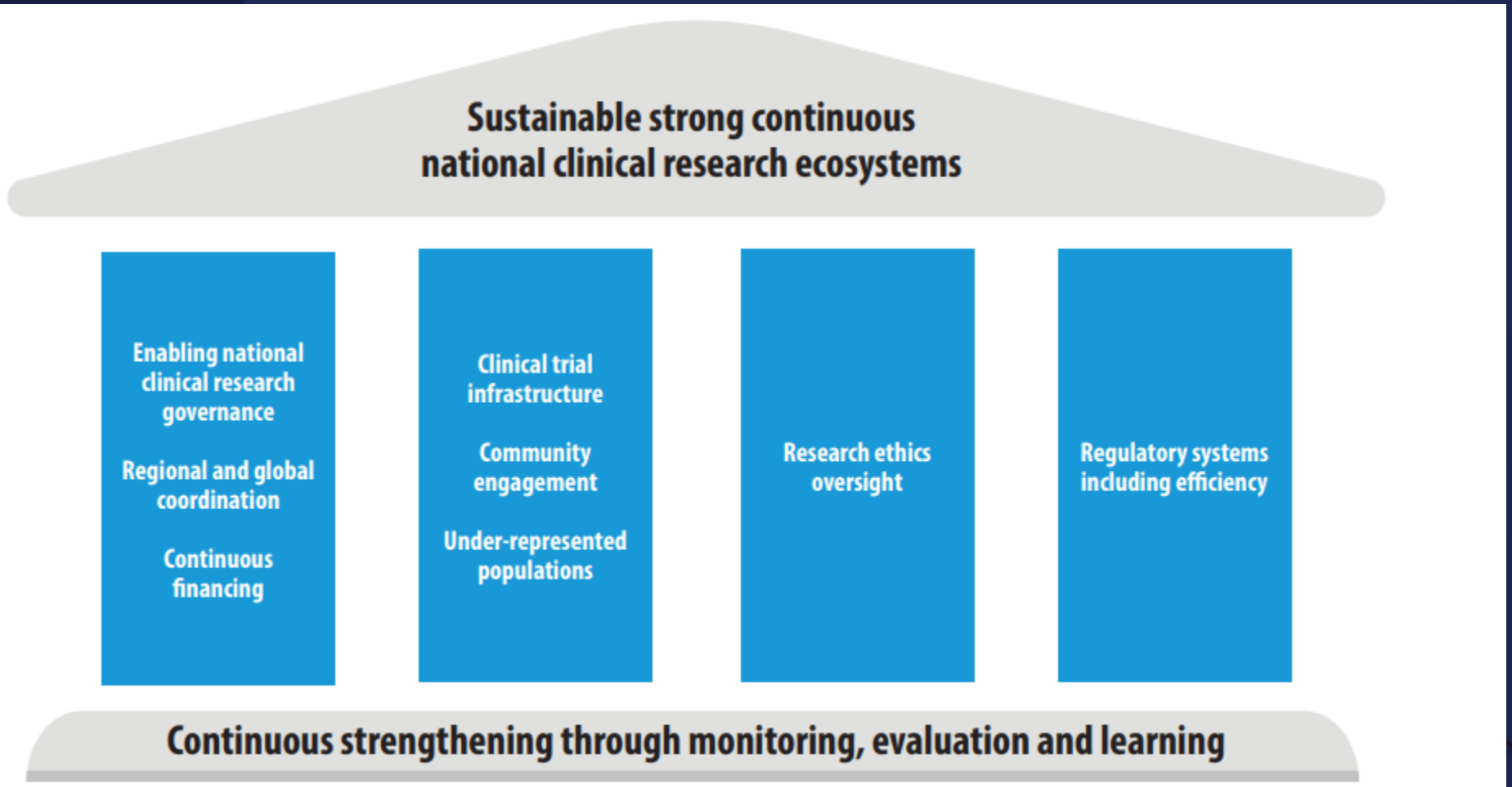

Source: Moorthy V, Abubakar I, Qadri F, Ogutu B, Zhang W, Reeder J, et al. The future of the global clinical trial ecosystem: a vision from the first WHO Global Clinical Trials Forum. The Lancet. 2024 Jan 13;403(10422):124–6 (https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(23)02798-8/fulltext).

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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 of results**

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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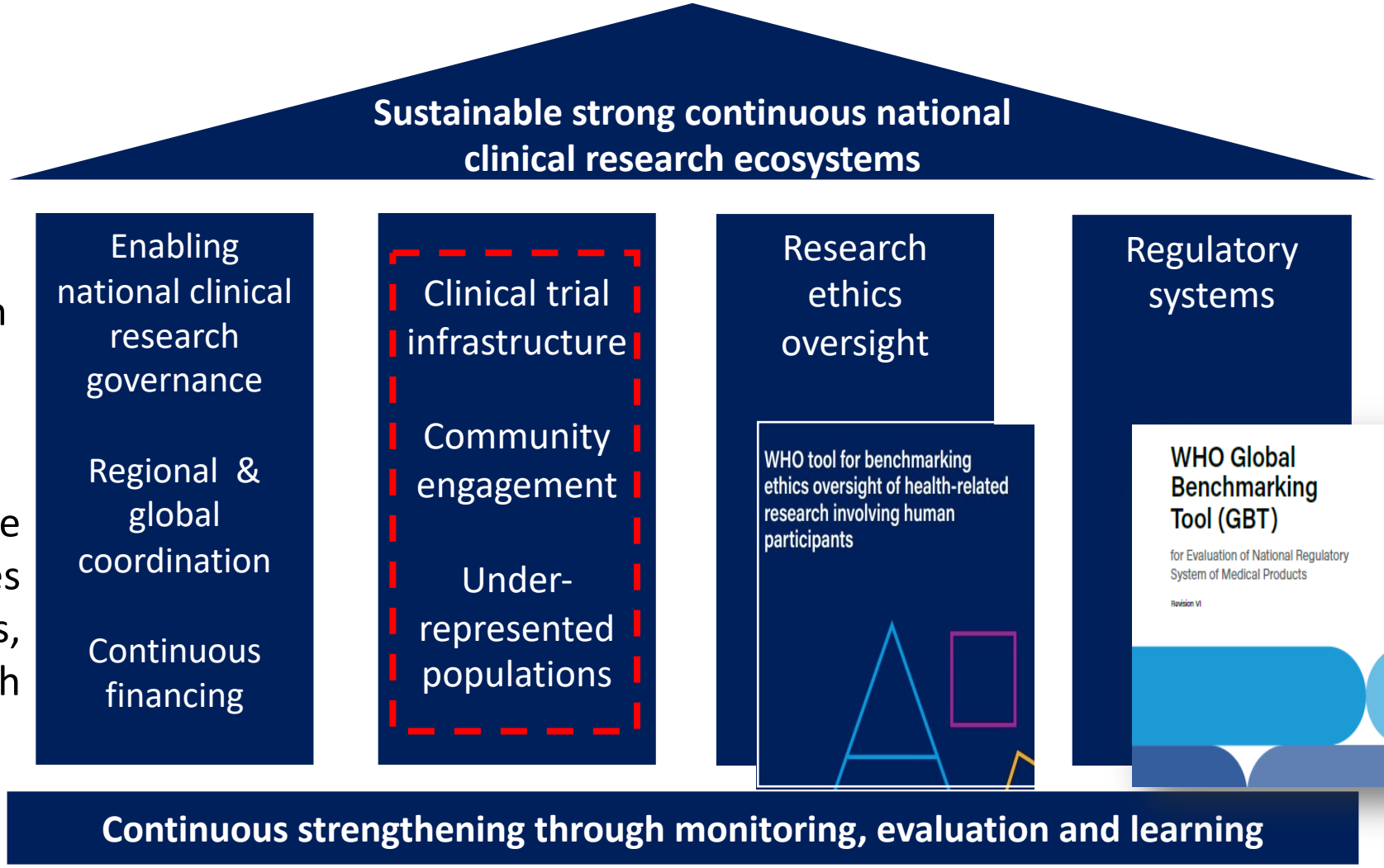
Develop practical tool to benchmark maturity of clinical trials units

- **Objective:**

The framework aims 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.



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Next steps

A global network of partners with shared objectives – **The Global Clinical Trial Forum (GCTF)**

Translations into French, Portuguese, Spanish, Arabic, Chinese, Russian

Developing training material suitable to different contexts and audiences

Developing and piloting implementation tools

6 regional workplans led by colleagues in WHO regional offices

Impact of the new guidance depends on engagement with stakeholders worldwide

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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

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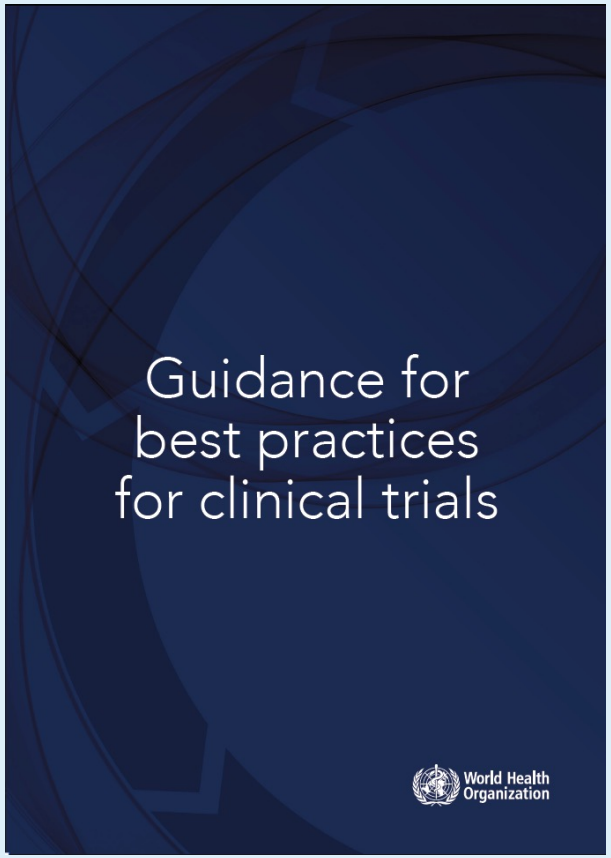
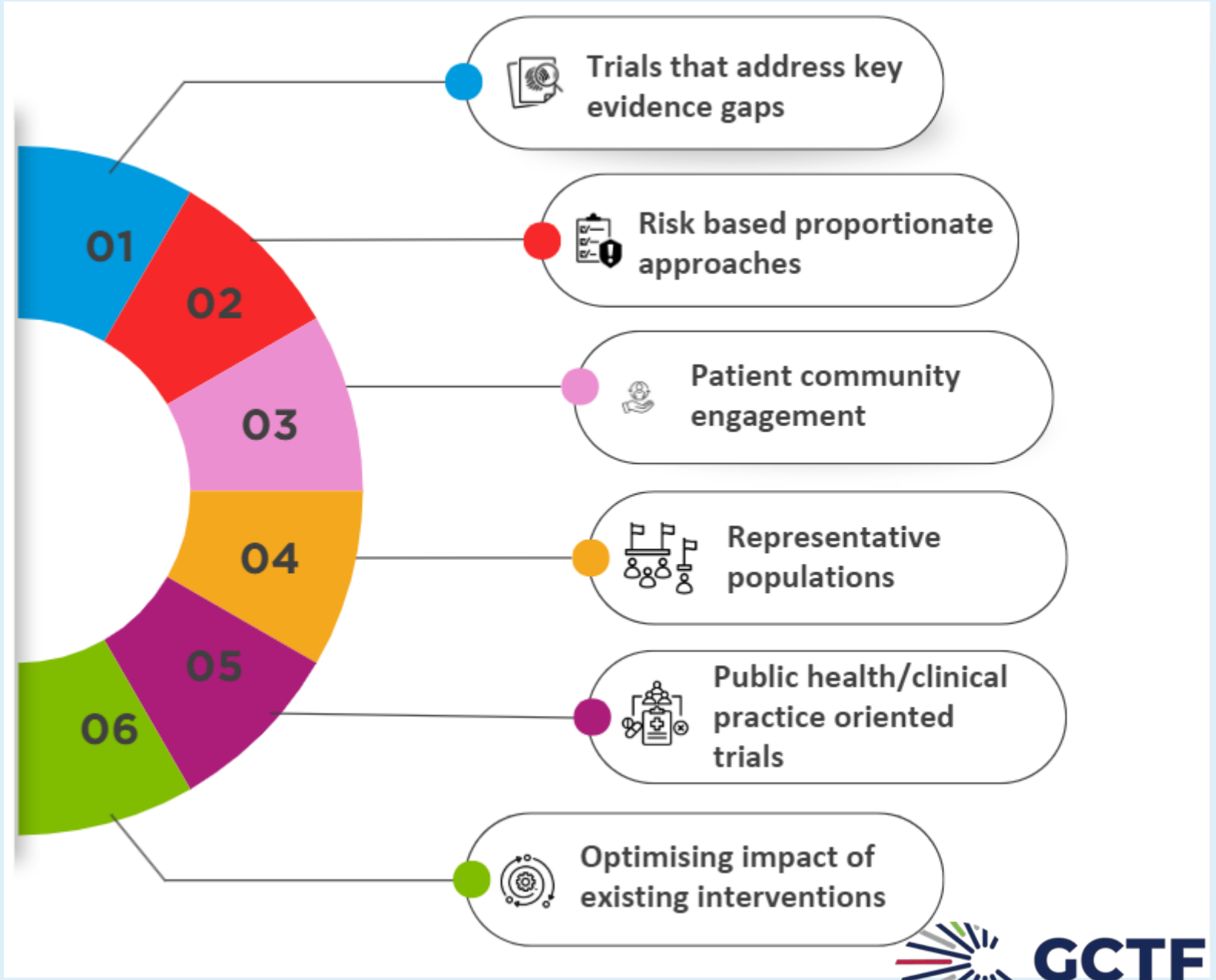
Action 9: Expand mutually beneficial multi-national health research and clinical trial collaboration

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

- To enable effective trials to address critical research questions, actions should be taken to accelerate the adoption of meaningful innovations and use of digital technologies.
- Specific measures include: **encouraging the use of standardized data protocols and core outcome sets in clinical research**
- Adopting adaptive and decentralized designs and implementations, including streamlining participant recruitment and randomization at point-of-care and in communities, when appropriate, to improve efficiency and responsiveness (see also Action 7)
- Using digital technologies, such as information and communication technology, wearable sensing technology and artificial intelligence, where appropriate, to improve efficiency and quality of study design, recruitment, data collection and management, analysis and dissemination of results
- Providing training to stakeholders to effectively adopt innovations and technologies while ensuring compliance with ethical standards (see also Action 5)
- Establishing digital systems to support regulatory and ethics oversight to ensure easy and transparent communication throughout research and trial activity cycles, **including for data management and sharing**. This includes transparency regarding document requirements for clinical trial approval

Implementing change





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Enabling environment

- Accessible tailored training/mentoring
- Moving beyond project funding for core research staff
- Sustained capacities/research as part of care
- Rationalised clinical trial approval processes
- Local leadership and national/government support
- Functional “always on” networks

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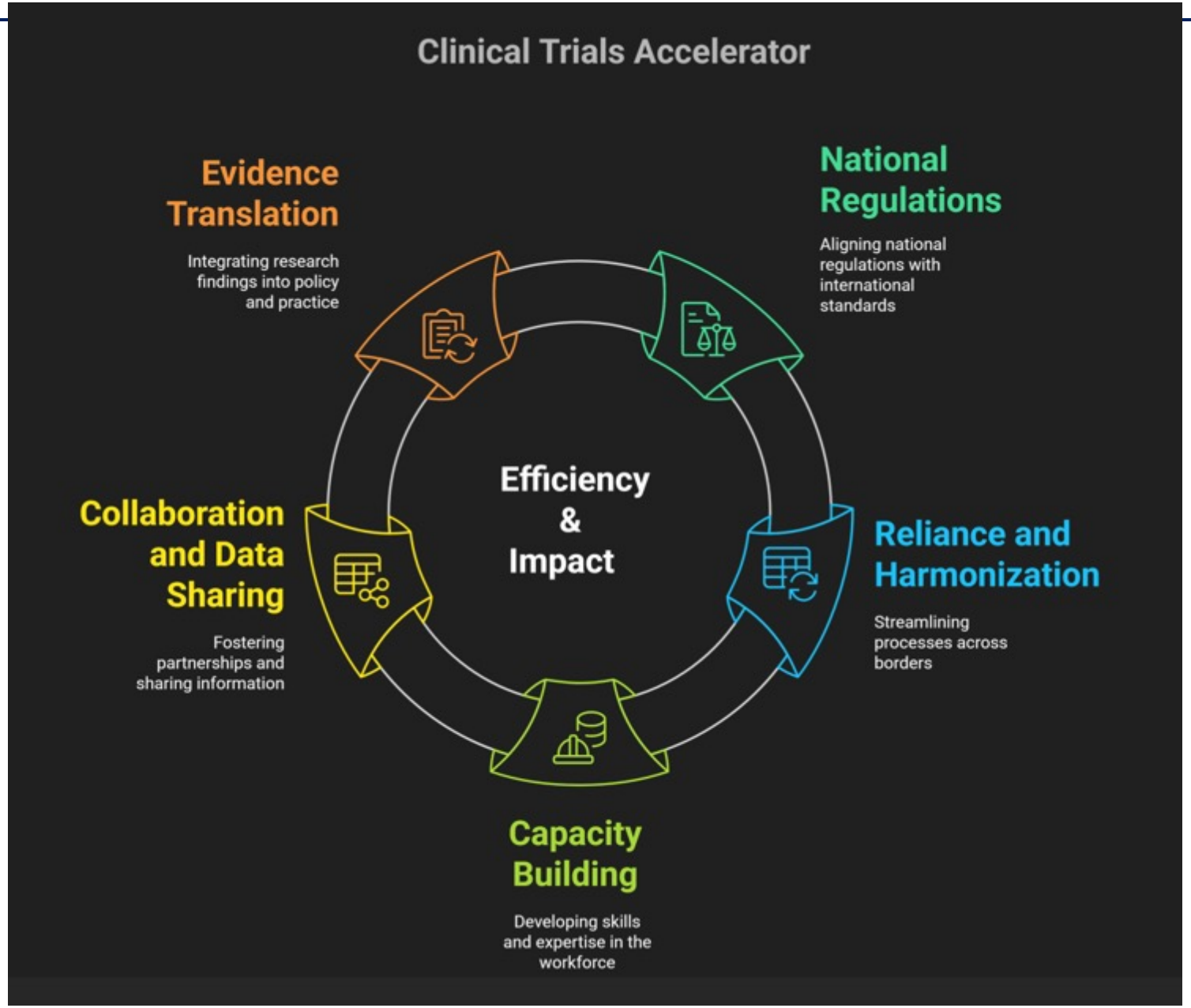

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Funding and collaboration

Donors

EDCTP

FUNDED BY NIHR National Institute for Health and Care Research

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

World Health Organization

The guidance incorporated or adapted guidance from

CIOMS

good clinical trials

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Thank you

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