How clinical research can advance health outcomes in Nepal: implications from the World Health Assembly resolution on clinical trials

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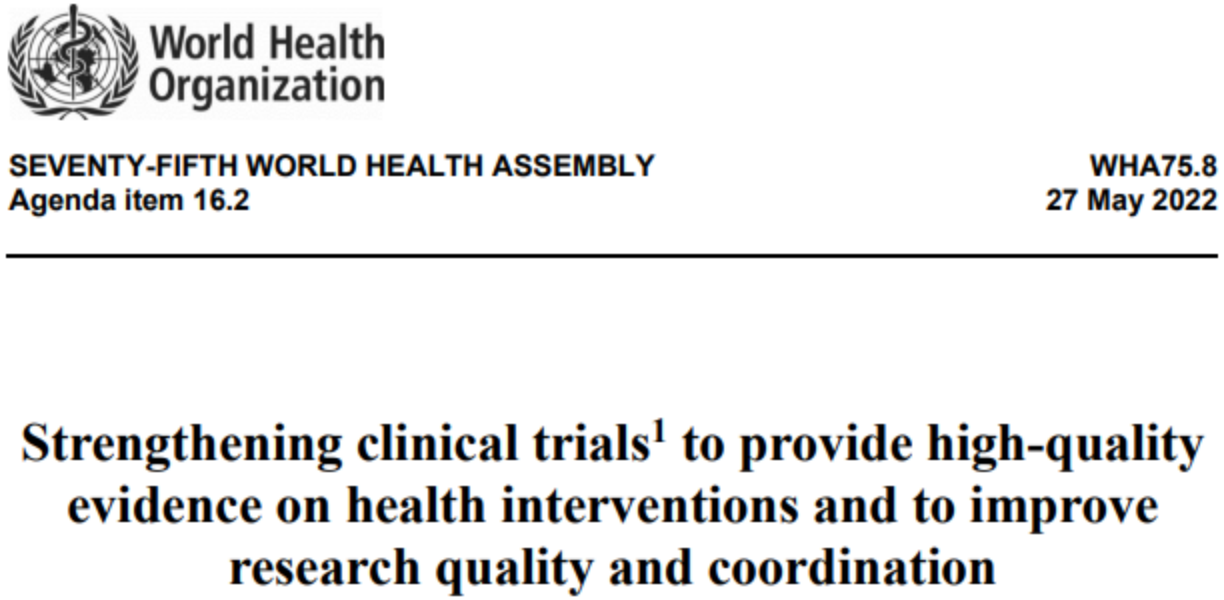
In 2022 all Member States adopted a resolution calling for strengthening of clinical trials to provide high quality evidence



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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

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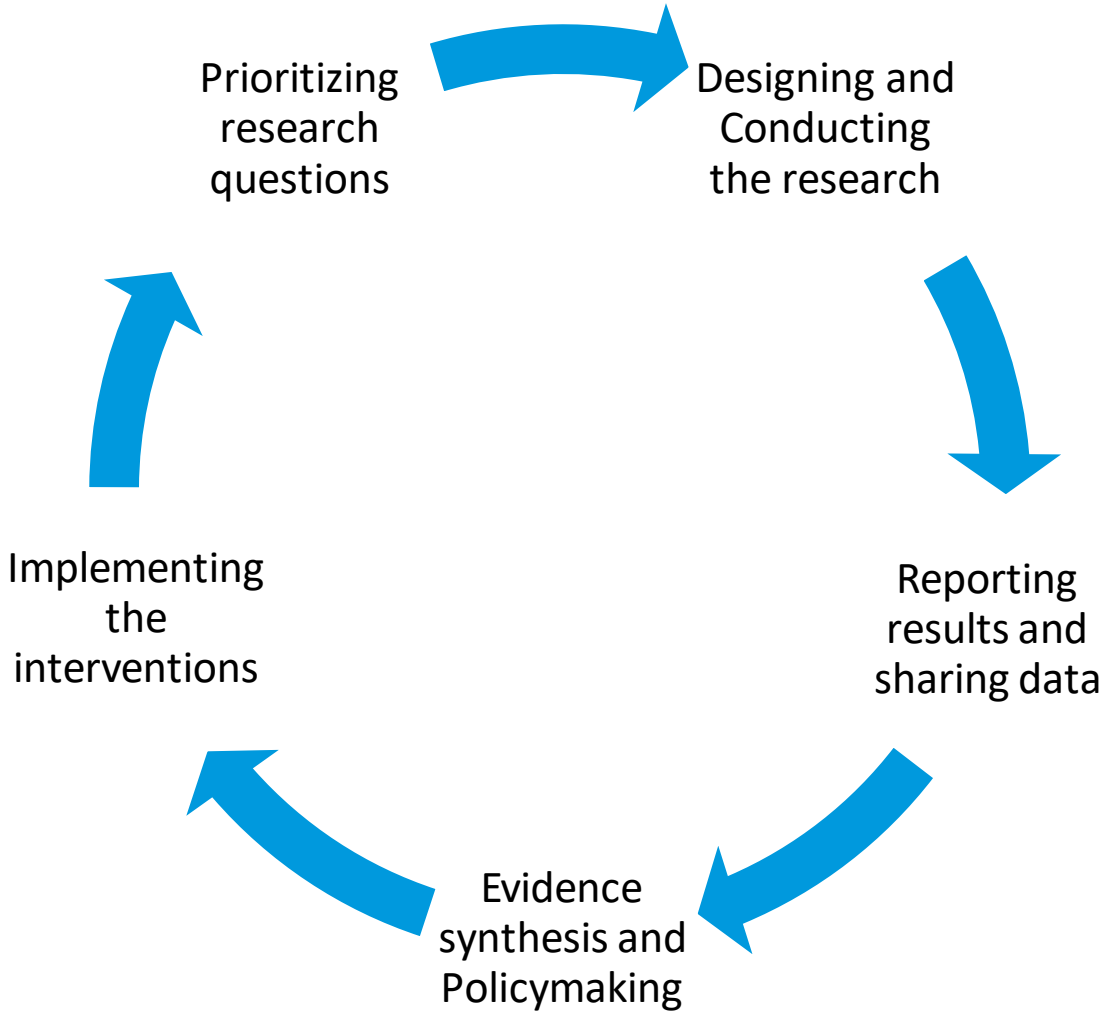
Research Processes as a Cycle rather than a Linear Pathway

Important to consider clinical trials as part of broader health research ecosystem…

… And to consider how best to link research capacity strengthening to health systems strengthening



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R&D ecosystem

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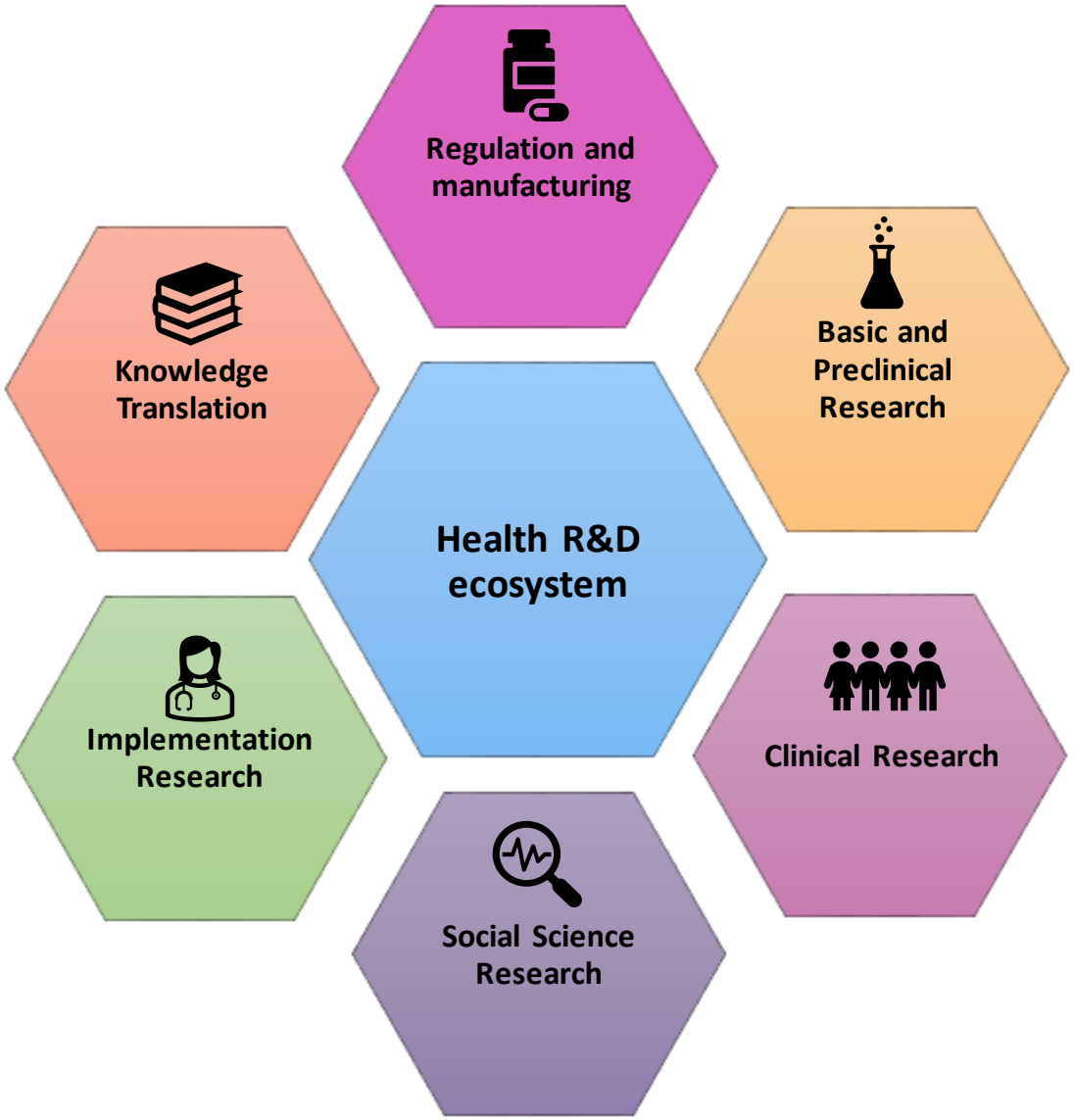

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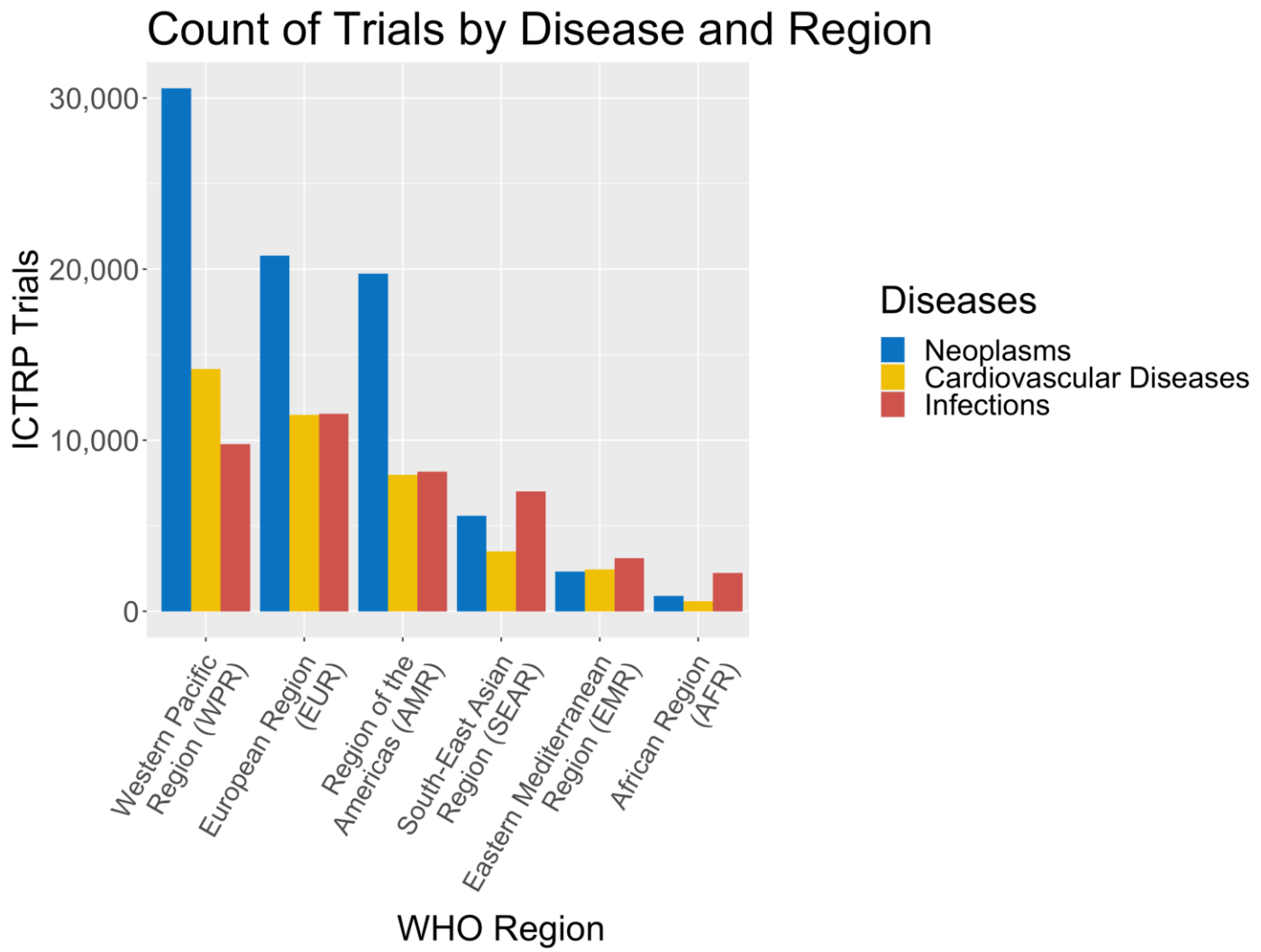
Mapping of clinical trials by disease area and region

- Clinical trials from 2018-2022 were mapped to WHO regions as well as the disease areas neoplasms, cardiovascular diseases, and infections
- Disease areas were defined using Medical Subject Headings (https://www.ncbi.nlm.nih.gov/mesh/)



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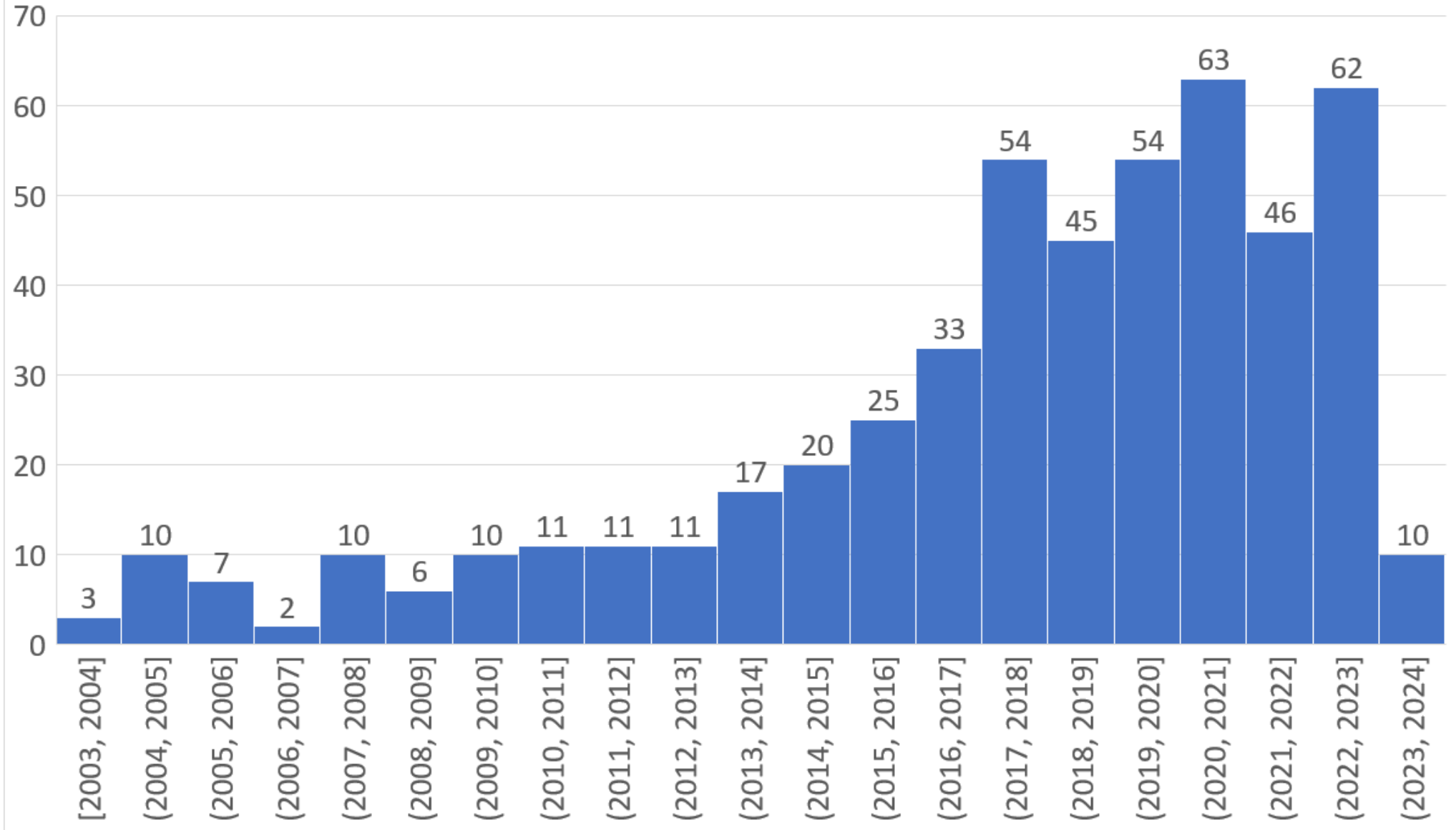
Nepal trial registrations in WHO ICTRP

ICTRP search portal (who.int)



Key problem statements with the current clinical trial ecosystem

- Regulatory systems involving multiple approval bodies may be overly complex and **not always proportionate to risk**; as a result of this complexity, good trials are too expensive, take too long, … costing many lives
  - How can we advance **the benefits of compelling well-designed trials** while maintaining appropriate safeguards? How to accelerate **benefits of adaptive, platform trials?**

- **Many trials do not contribute to high quality evidence**: *NB most uninformative trials are likely in high income countries, because most trials are in high income countries*
  - Most health policy/guidelines recommendations are not based on high certainty evidence (Intern Med J 2020 Jan;50(1):30-37) and therefore **most decision-making is not based on high certainty evidence**
  - There are **insufficient "levers" to prevent badly designed trials** that will not answer the scientific question

- **Major gaps in clinical infrastructure and capabilities exist in many countries with high disease burdens**; existence of capacities in high income countries does not guarantee efficient conduct of informative trials

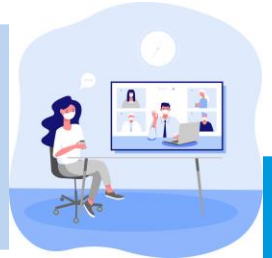
Guidance

- TAG constituted
- Public consultation July to September
- Likely to be finalized in 2024
- Online training materials to be developed in coordination with ICH, Ethics, Funders

Mapping

- Networks
- Funding
- National Regulations
- Sites/institutional capacities

Consultations



- 4th Member State consultation completed
- Private sector consultations: Geneva, May & Kigali October 2023
- Regional consultations: PAHO Oct 4-5, AFRO Oct 17-18, SEARO, Nov 10-11, EMRO Nov 14-15
- Global forum meeting with stakeholders (clinical researchers, ethics, regulatory, funders, patient, community organizations, private sector)

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Strengthening clinical trials to provide high-quality evidence on health interventions
Regional Consultation
#WHA75.8
Lusaka, Zambia 17-18 October 2023


OPAS 120
120 ANOS
TRABALHANDO PELA
SAÚDE E
BEM-ESTAR
DOS POVOS DAS
AMÉRICAS


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75
75 عامًا من تحسين الصحة العامة | 75 years of improving public health
75 années au service de l'amélioration de la santé publique
مباني منظمة الصحة العالمية خالية من التدخين | The WHO premises is a tmoke-free environment
L'Organisation mondiale de la Santé est un espace non fumeur


Regional Consultation on Health Research Governance and Management in South-East Asia
7–10 November 2023
World Health Organization
REGIONAL OFFICE FOR South-East Asia

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Similar issues emerged from the regional consultations, leading to an agreed global vision

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Key areas of focus for capacity development going forwards according to inputs received during regional consultations

- *Developing capabilities for research sustainably, linked to health systems, and kept "warm" through ongoing well designed clinical research; moving away from a "vertical" to a "horizontal" approach while keeping the best aspects of the vertical.*
- *Prioritisation for identified trials aligned between stakeholders*
- *Enabling international collaborations*
- *Improving capacities and efficiency in regulatory and research ethics systems; how to ensure a focus on the key issues in an efficient and risk proportionate way*
- *Improving efficiency and coordination between elements of the trials ecosystem*
- *Ensuring scientific validity and social value of research*
- *Patient and community engagement norms in clinical trials*
- *Supporting newer models for RCTs (including integration into healthcare, adaptive, platform, digital)*

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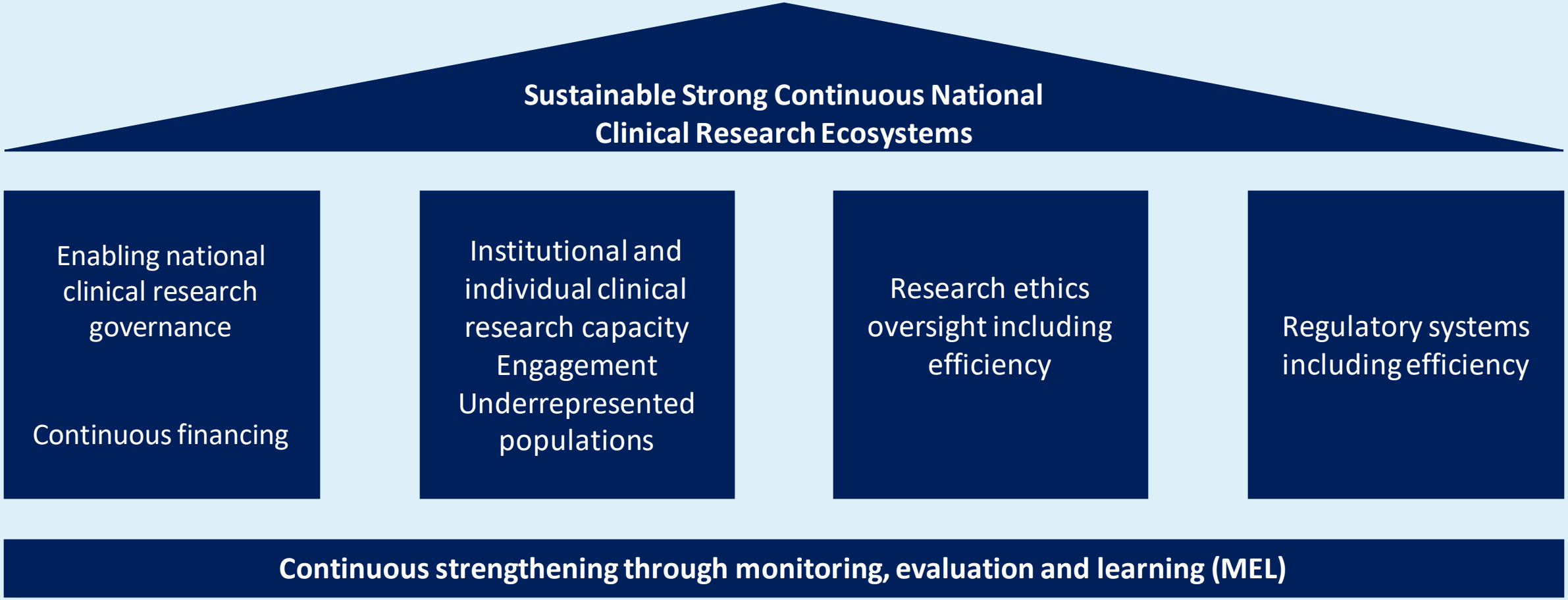

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Key themes: Vision emerging from the global forum

- **“Always on, Always busy”** – move to ongoing trials all the time for endemic use cases, which can pivot in times of crisis
- **Risk proportionate** approaches to well-designed and well-implemented trials
- **Domestic funding, enabling trials** linked to sustained capacities and priorities
- Embedding **under-represented populations** in the whole process
- Centrality of **patient and community engagement** in clinical research
- Models for large scale trials **embedded into health systems**

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Urgent reforms needed to enable key trials

- expansion of global south leadership for all key aspects of trials
- ongoing sustained capacity rather than project funding alone
- single REC review for clinical trials or effective REC coordination
- single submission systems for REC and NRA review
- parallel not sequential reviews
- coordinated approval processes between regulators and ethics
- ensuring scientific validity
- master clinical trial agreements
- overcoming barriers to importation of investigational products

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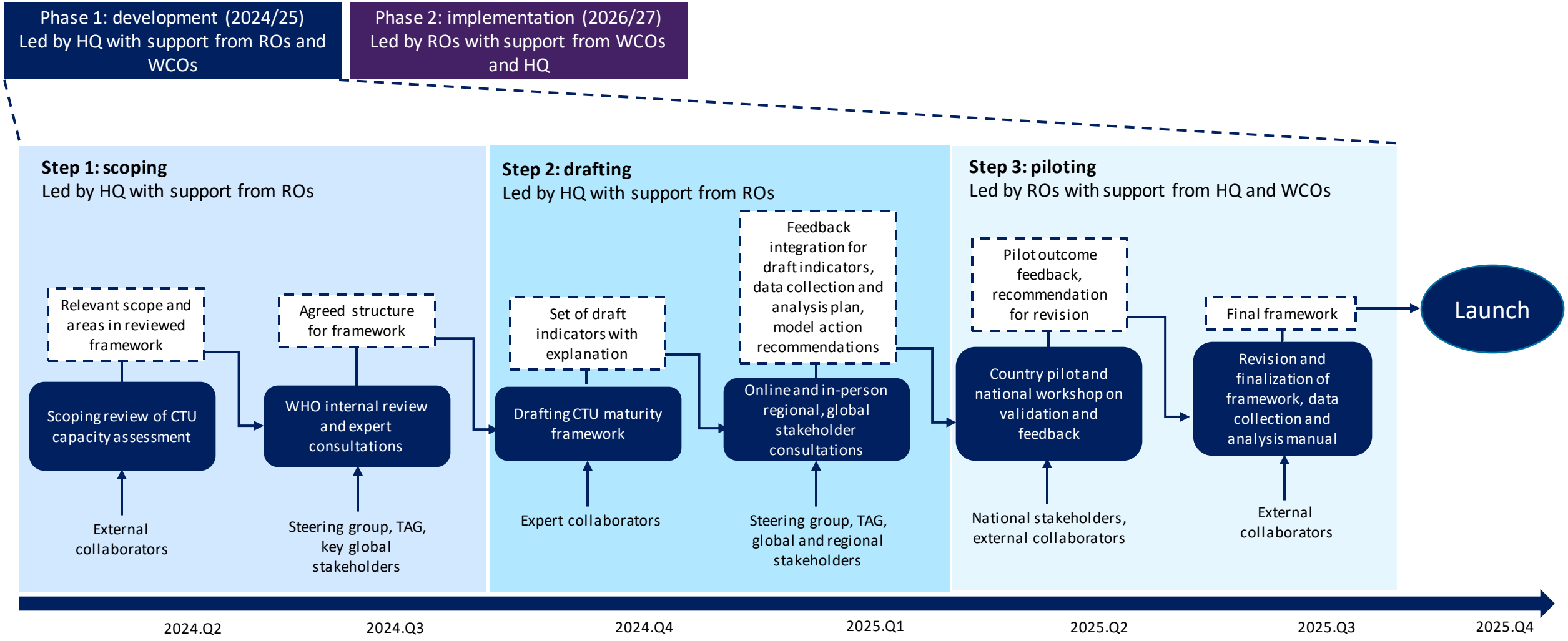
WHO maturity framework for clinical trial units

A self-assessment and benchmarking tool to guide the capacity development in clinical trials

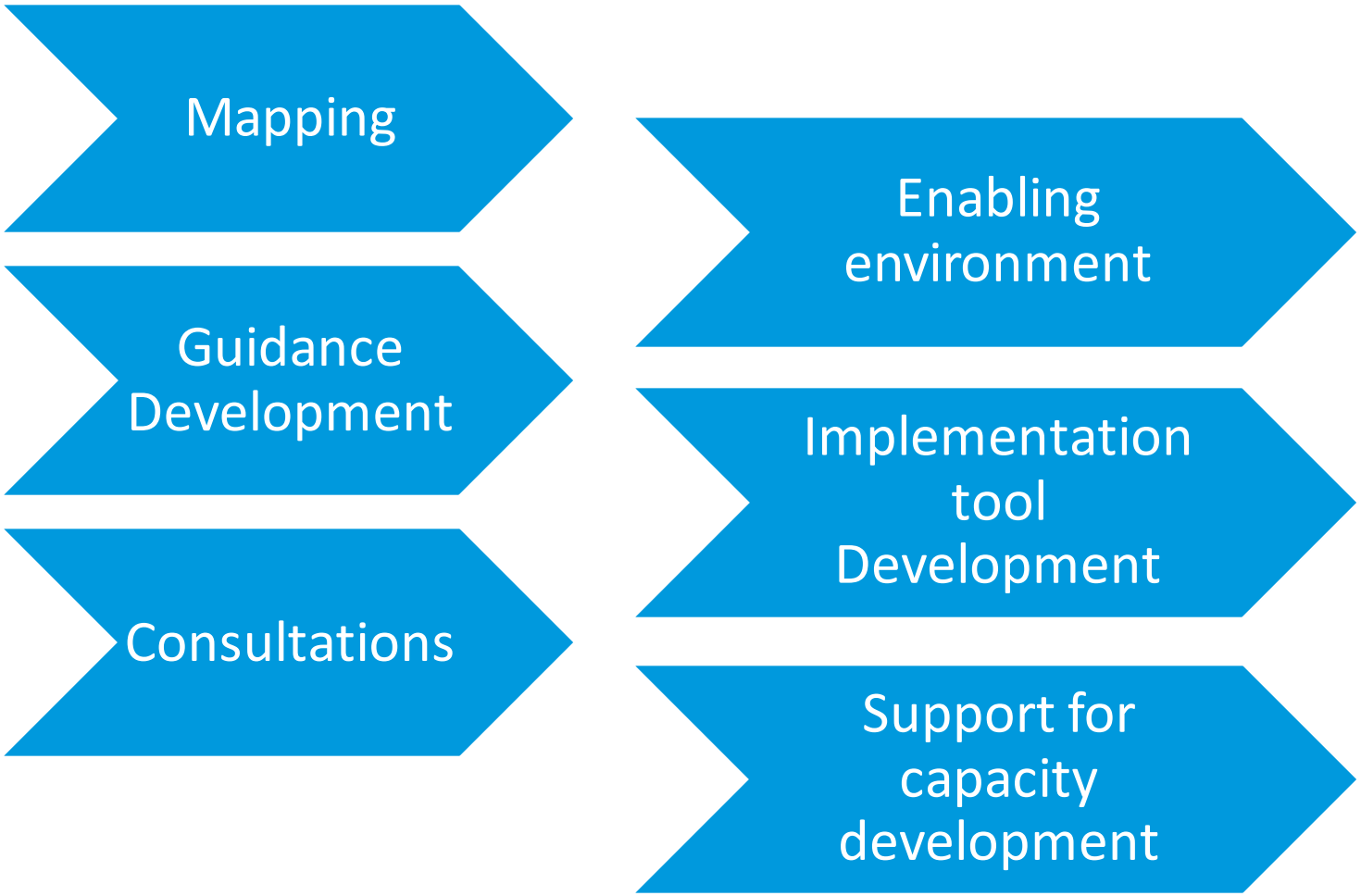


Working groups:

- *Steering group*: WHO regional advisors on research, selected country offices, staff of relevant technical programs in HQ
- *Technical Advisory Group (TAG) of Clinical Trials*
- *External collaborators*: contracting or collaborating research institutes or experts
- *Stakeholders*: global, regional or national interest institutions and individuals

2023

2024



- National capacities in NRAs
- Ethics committees
- Research institutions
- Patient/ Community engagement in research
- Inter-agency harmonization/ coordination
- Functional clinical research networks performing key trials

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Other major activities in WHO Research for Health Department

Guidance on:

- Health Foresight
- AI and health
- Genomics
- Responsible life sciences research / dual use research
- Human genome editing

Guidance on:

- Global Observatory on health R&D
- ICTRP (trial search portal)
- Research priority setting
- WHO Target Product Profiles
- WHO Coordinated Scientific Advice
- Product Development Partnerships

- Access to paediatric medicines
- Evidence to policy good practices

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Conclusion

Enabling the following:

- **Sustainable clinical research capacities** that enable ongoing clinical research that meets local and global needs:
- **Locally led** strengthening of national trials ecosystems: strive for efficiency – address bottlenecks
- **Effective prioritization** for use of these capacities
- Addressing **under-represented populations**
- **Risk proportionate** approaches to well-designed and well-implemented trials**.**

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Funding Acknowledgement

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