World Health Organization
REGIONAL OFFICE FOR Africa

# MEETING REPORT

## REGIONAL WORKSHOP - STRENGTHENING CLINICAL TRIALS TO PROVIDE HIGH-QUALITY EVIDENCE ON HEALTH INTERVENTIONS AND TO IMPROVE RESEARCH QUALITY AND COORDINATION


**Lusaka, Zambia**
**17-18 October 2023**

*Funded in part by the EDCTP2 programme supported by the European Union (grant number CSA2023WHO-3454-WHORCT) with funds from the UK National Institute for Health Research (NIHR) using UK aid from the UK Government to support global health research. The NIHR Global Health Research portfolio supports high-quality applied health research for the direct and primary benefit of people in low- and middle-income countries, using international development funding from the UK Government. The views expressed in this publication are those of the authors and not necessarily those of EDCTP, NIHR or the UK Department of Health and Social Care*

## Meeting overview and background

At the 75th World Health Assembly, a resolution (WHA75.8) was passed with the mandate to prepare a global guidance on best practices to help guide Member States' implementation of scientifically and ethically sound clinical trials as well as guidance on best practices for non-State actors in the design and conduct of clinical trials and in strengthening the global clinical trial ecosystem.

Currently a draft guidance has been formulated from insights gathered from a Technical Advisory Group (TAG) with global leading experts in clinical trial and health research methodology, regulation, and research ethics. To ensure the relevance and usefulness of the guidance for successful implementation of the resolution, input is to be gathered from a global consultation and three regional consultations from WHO regions that will engage key stakeholders from government bodies, research organizations, academia, industry, and civil society to ensure the relevance and usefulness of the Guidance for successful implementation of the resolution. The final Guidance will be reviewed by the TAG and approved by WHO prior to its publication.

This workshop held in Lusaka Zambia over the course of two days was for the African region. The objectives of the workshop include to:

- discuss clinical trial landscape in the African Region
- explore challenges faced with clinical trials in the African Region
- identify priorities for clinical trial in the African Region
- explore strategies for improved clinical trial landscape in the African Region
- inform the Member States and stakeholders in the region about the resolution and the Guidance development process,
- discuss the draft Guidance based on the regional challenges and priorities,
- identify improvements to be made in the Guidance,
- discuss initiatives led by Member States and stakeholders in the region for implementation of the resolution on the way forward, and
- discuss possible development of training materials to assist in implementation of the guidance once it is finalized.

## Opening remarks

The WHO Country Representative of Zambia, **Dr Nathan Bakyaita**, welcomed the participants to Zambia and reiterated the importance of the workshop. He appreciated the participants for taking their time to be part of these important deliberations.

**Dr Vasee Moorthy, the Senior Advisor, R&D, WHO HQ** outlined the importance of the workshop and how the team had engaged other regions to get their perspective for input into the guidance. He emphasized on the importance of clinical trials in generating high quality evidence, highlighting some recent developments in trial design and the importance of trials answering questions about optimal use of existing interventions as well as those evaluating novel interventions. Well-designed trials may be investigator-initiated or commercially sponsored; both types of trial have an important role to play. He noted that Africa is in a unique position as it has regional entities like Africa CDC, the African Union and the African Vaccine Regulatory Forum (AVAREF) that cover the whole continent, necessary for collaboration frameworks for strengthening clinical trials. Dr Moorthy highlighted the importance of agreeing the best type of frameworks for developing needed efficient research capacities in an equitable manner and frameworks for prioritization based on the local needs. He suggested that one part is to

develop enabling aspects of the trials ecosystem. This entails developing regulatory capacities, ethics committees' capacities, and embedding research capacities into hospitals and communities as well as developing capacities to coordinate multi-centre trials and specific needs for first in human and other early-stage clinical trials. He did reiterate that across the African region, though there are low numbers of clinical trials compared to other regions, there is a significant proportion of high quality and high impact trials that have led to new interventions being licensed and rolled out across Africa including medicines and vaccines, saving many lives.

**Dr Nathan Bakyaita** delivered the opening remarks of **Dr Lindiwe Makubalo, the Assistant Regional Director (ARD)**, **for WHO in the African Region**. The ARD highlighted how there has been longstanding issues aligned with the clinical trials ecosystem particularly in the African region. This was highlighted by the COVID-19 pandemic which reaffirmed the importance of data-driven, evidence-informed action. However, during this period, the Member States of the African region failed to join the large Global Trials, including the WHO Solidarity trials, as they could not meet the criteria for prompt ethical and regulatory approvals. Only a few countries like South Africa, and Kenya made some significant strides. Therefore, there is a major need to better understand how research, ethics and regulatory capabilities can be developed in Africa to allow for large, high-impact trials to occur rapidly in the region that can address the priority public health and clinical questions, for the region.

The ARD mentioned that at a point, in 2020, the landscape of clinical trials showed 44 candidate vaccines in clinical evaluation, however, most trials and participants were in high income countries which shows a major gap in low to medium income countries. Though a few of the trials were situated in the African region, these were led by institutions outside the region. Additionally, the continent has some good examples of clinical trials, but these tend to focus on the big three infectious disease killers, HIV, malaria and tuberculosis, and data shows that there is a major disease burden in many other endemic infectious diseases, and increasingly in endemic NCDs including diabetes, cardiovascular disease, and cancer. Further, much of the inward investment has focused exclusively on trials for novel biopharmaceutical innovations such as new medicines and vaccines. She mentioned that some major challenges included lack of investment and capacity development of clinical trial units/NRAs/RECs/IRBs in our settings; gaps in clinical infrastructure and capabilities including multiple approval bodies leading to overly complex procedures which are disproportionate to risk; among others. She implored that the workshop participants to deliberate on the issues around leadership, prioritization and increasing capabilities across the region and reflect on what catalytic actions key stakeholders must take to put the correct clinical trials ecosystem in place with a focus on local priorities in order to concretely inform the guidance being developed by the WHO.

**Dr Ahmed Ogwell Ouma**, **the Deputy Director General of Africa CDC**, stated that the conversations going on globally around clinical trials are important, and the African perspective is important as only 3% of clinical trials are done in Africa yet Africa has a significant population and a high disease burden. This is in part due to the lessons learnt from the COVID-19 pandemic with the conversations around preparedness and response and building consortiums. The DDG reiterated that Africa CDC is committed to be part of ensuring that the WHA 75.8 resolution is implemented effectively and efficiently across the continent within the clinical trials ecosystem. The resolution aligns with the mandate of Africa CDC which is outlined in the organization's 10-year roadmap and will help create a more efficient environment for conducting clinical trials across the continent. The roadmap provides clear solutions to address the greatest challenges facing the effective implementation

of clinical trials in Africa and there is need to invest in a strong foundation for successful implementation of the roadmap guided by information that comes from the continent and priorities that have been set by the member states. Furthermore, Africa CDC is also in the process of developing an Africa health research agenda which is aimed in part to consolidate the health research efforts in Africa and assist in developing a better coordinated clinical health research environment. The African health systems has systemic challenges and the streamlined research agenda is aimed at collaborating and supporting experts and institutions through key partners.

The DDG mentioned the example of how the Africa CDC led the COVID-19 clinical trials consortium that brought together institutions and partners – the mindset of putting together consortiums is one he reiterated that participants should build upon so that institutions can work together to manufacture health products locally and respond to emergencies together. The aim is to work together systematically to address all the challenges by developing the tools and mechanisms in Africa that can help avert outbreaks across the region. He lamented that evidence currently used across the continent for clinical trials are not coming from the continent, so it is important to push locally generated evidence. There is a need to ensure that clinical trials are done in Africa by Africans and that the products reaching clinical trials stage are developed by Africans. Of note, the DDG acknowledged that Africa has well-established institutions and research on the continent is of good quality, it is now left to show that the continent has the expertise and capability to do the clinical trials in the continent. He urged participants to critically examine the opportunities and gaps that exist to improve coordination across the continent to build capacity for clinical trials, plan for resources and be well coordinated so that Africa can manufacture its own products by improving the strengths and lessening the gaps across the African ecosystem.

## Presentations:

### Presentation 1: The draft WHO Guidance on best practices for clinical trials

Dr Vasee Moorthy set the context of the workshop by outlining the current clinical trials ecosystem and some of the key problems that plague the ecosystem. This includes complexity added by regulatory systems involving multiple approval bodies resulting in costly clinical trials that take a long time. Many trials do not contribute to high quality evidence due to poor design, failure to enrol the planned numbers and trials that do complete often have poor external validity in that the populations included do not relate well to populations suffering the bulk of the disease burden. He noted that while there has been a great deal of progress with capacity development, there are major gaps in clinical trial infrastructure and capabilities in many countries with high disease burdens.

He mentioned the need for repositories such as the single collated WHO clinical trials website created[1], that has existing relevant WHO and TDR guidance and resources; existing relevant non-WHO guidance from ICH and other initiatives; a collation of 42 non-WHO initiatives identified relevant to WHA 75.8; a collated list of 112 Clinical trial networks for endemic (NCD and ID) and epidemic diseases; status of WHO benchmarking of maturity level of regulatory bodies related to clinical trials oversight and available benchmarking metrics for clinical trial activity, eg ICTRP and R&D observatory.

[1] Website: Implementation of the resolution on clinical trials (who.int)

Additionally, to contextualize the consultations for the WHA75.8 resolution, WHO asked for inputs in Q4 of 2022 on the status quo of clinical trials, and examples of good practices, improvements needed. The survey received 273 inputs were received, of which 53 were from Member States, including government agencies from the health and non-health sectors, and 63 were from non-State actors, with the permission of the participants, these full responses are public and have been made available on the WHA 75.8 website. The responses have been summarized in the report to EB 152 [2] where a longer supplementary report is also available [3]

Dr Moorthy stated that WHO has been requested to develop guidance for two distinct communities. These are:

- guidance on **best practices to help to guide Member States**' implementation of scientifically and ethically sound clinical trials within their national and regional contexts
- guidance on **best practices for non-State actors** in 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, developed in consultation with Member States and relevant non-State actors

The focus of these guidance documents are to outline and share best practices for clinical trials especially around:

- Sustainable clinical research capacities that enable ongoing clinical research that meets local and global needs: WHO guidance provides key priorities for the actions needed to achieve this
- Effective prioritization for use of these capacities
- Risk proportionate approaches to ethical, efficient, and informative trials focusing resources on trials that will be informative and providing a framework to reduce costs and timelines

This consultation workshop sought from the participants, high level guidance on design and implementation, strengthening the clinical trial ecosystem, addressing underserved populations and recommendations on roles of different stakeholders.

## Presentation 2: Preliminary input (online survey) to the draft Guidance

Dr Ryan Walker gave an overview of a survey that was developed as a collaboration between the WHO and The Global Health Network (TGHN), a WHO Collaborating Centre for research information sharing, e-learning and capacity development. The survey management and analysis were conducted by TGHN. This survey was conducted over a 2-week period between August and September 2023. It was developed in 4 languages (English, Spanish, French, Portuguese) and distributed via WHO and TGHN networks and communication channels (mail lists, social media, online platforms etc). The global response totalled was 2,953 of which the African region had 998 (33.8%). The summary of the African region's responses across the 5 key aspects asked in the survey are shown in the Table 1.

[2] https://apps.who.int/gb/ebwha/pdf_files/EB152/B152_13-en.pdf
[3] https://www.who.int/publications/m/item/supplementary-report-on-implementing-wha-resolution-75.8-on-strengthening-clinical-trials-to-provide-high-quality-evidence-on-health-interventions-and-to-improve-research-quality-and-coordination

**Table 1: Key Findings in the African Region**

| Aspect | Top 5 Findings |
|---|---|
| **Barriers to the design and conduct of clinical trials: AFRO regional findings** | • Inadequate funding sources<br>• Lack of adequate coordination, collaboration and communication mechanisms<br>• Inadequate numbers of capable clinal research units<br>• Inadequate patients and community engagement mechanisms<br>• Timelines for reviews of protocols by ethics committees |
| **Priorities to be addressed in the immediate future** | • Greater integration of clinical trials into healthcare delivery<br>• Greater focus on research design that can answer key questions robustly and produce reliably informative evidence<br>• Better involvement of engagement with patient public and communities in the clinical trials ecosystem including addressing language and culture barriers<br>• Support newer models of clinical trials (e.g. digital, decentralized)<br>• Creation of large scale national and international research networks in disease and/or geographical areas where there are current gaps with effective coordination mechanisms |
| **Best approaches for implementing the best practices for clinical trials** | • Providing locally applicable implementation materials, including online training in local languages<br>• Targeting research funding to key weakness identified locally<br>• Providing resources for in-person implementation workshops<br>• Establishing efficient prioritization and coordination mechanisms at national level<br>• Expanding adaptive platform trials with associated protocols moving to perpetual models for ongoing high priority trials linked to national regional and global priorities |
| **Key needs for training and/or technical support** | • Trial design, including protocol development<br>• Patient, public and community engagement approaches<br>• Implementation of trial protocols<br>• Prioritizing next steps in clinical research capacity building<br>• Capacity building for regulatory oversight |

## Presentation 3: Optimizing the efficiency and impact of the African Clinical Trials Ecosystem and the 10-year road map

Shingai Mashingaidze started off by explaining the mandate of the Africa CDC and the key role it plays in the ecosystem. She pointed out that many global health clinical trials are expected in the near future, so addressing infrastructure is critical. More than 50 low- and middle-income countries participate in global health clinical trial networks and in Africa the NIH and the EDCTP are funding the highest number of networks.

She went on to mention that the COVID-19 pandemic further validated a network approach for global health research which saw the Partnerships for African Vaccine Manufacturing (PAVM) being established by the African Union (AU) in 2021 to enable the African vaccine manufacturing industry to develop, produce, and supply over 60 percent of the total vaccine doses required on the continent by 2040 with interim goals of 10 percent by 2025 and 30 percent by 2030. Furthermore, African leaders

agreed in April 2021 to map out a continental strategy to achieve this ambition through the Framework for Action[4] . The Africa CDC aims to address a range of challenges within the current global health research ecosystem so that researchers can swiftly and efficiently design, secure approval for, and implement clinical trials, curate ideal incentives, support infrastructure development and governance mechanisms in the current research system and elevate innovations for clinical research that enable the large number of Phase 2 and Phase 3 trials for a range of diseases and modalities

Shingai went on to outline the 10-year roadmap that has the three pillars of **Design**, **Pilot** and **Scale**. These are outlined in Figure 1.

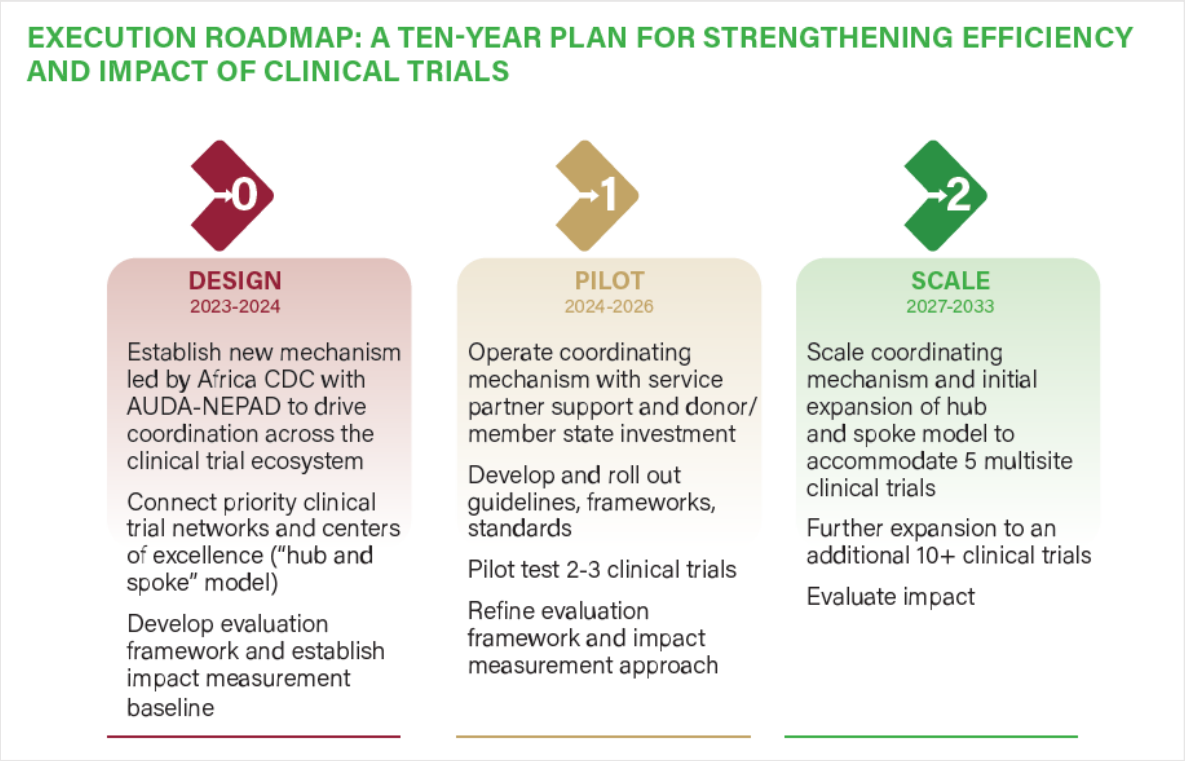


**Figure 1**: Africa CDC 10 Year Roadmap for Clinical Trials

Currently a key mechanisms has been the Clinical Trials Community Africa Platform which is a data repository that has been upgraded with additional information and capabilities to ensure data driven decision making on matching clinical trials pipelines and clinical trials capacity; research center data utilized to assess capacity, identify priority research centers/countries and identify strengthening needs based on projected clinical trials pipeline. Additionally other activities around implementation of the strategy have included the identification of priority areas for harmonization approaches and developing continental data and laboratory repositories or supporting more networked model of existing repositories and the development of a costed implementation plan, governance, mobilization plan and impact evaluation and a learning agenda network.

She concluded her presentation by reiterating that the future of the clinical trial ecosystem in Africa will employ innovative trial design and harmonised policies and practices to implement responsive Phase 1, 2, 3and 4 clinical trials across agile, efficient, sustainable, and financially viable clinical trial networks. Communities will be engaged as equal partners in the support of impactful clinical research.

[4] Framework for Action (FFA)

## Discussion and Feedback Sessions

### Discussion on regional priorities in strengthening the clinical trials ecosystem

The discourse for this session centred around mapping the required clinical trials ecosystems in Africa. It stemmed from the presentation done by Dr Thomas Nyirenda outlining the interpretation of the WHA75.8 resolution in Africa. The aim of the session was to build alignment on how ecosystem actors can work together in developing clinical trial capabilities, improve coordination and prioritization, harmonize regional and global clinical trial standards and increase efficiency in clinical trial approval and implementation. The session ended up with a mapping depicted in Figure 2 where the regional coordination, catalyzation and prioritization is done by organizations such as Africa CDC, WHO AFRO, AUDA-NEPAD etc who should work together in order to efficiently and effectively guide member states.

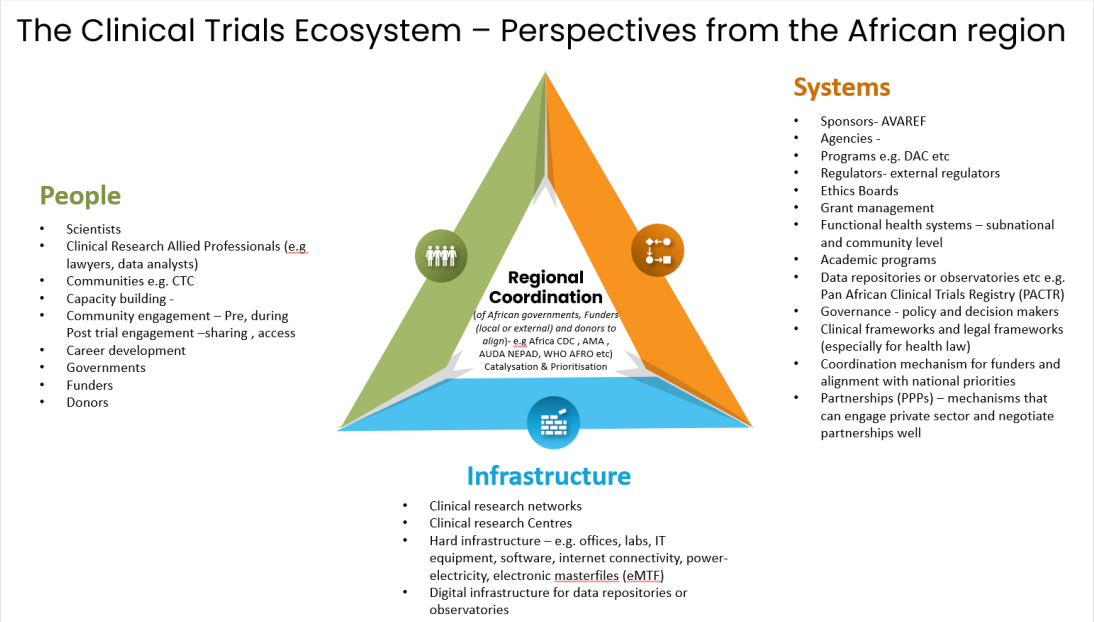


**Figure 2:** The African Region Clinical Trials Ecosystem

### Discussion on regional challenges in Clinical trials capabilities

The main barriers to collaboration across the African region with suggested solutions were highlighted in Table 2.

## Table 2: Main Barriers to Collaboration and Suggested Solutions

| Barriers to collaboration | Suggested solutions |
|---|---|
| **Language barriers:** The difference in language causes less collaboration amongst regions or visibility of work being undertaken by other institutions | • Language courses should be part of science training; translation of materials should be in most of the languages used across Africa; the use of certified audio translation |
| **Capacity disparities:** the continent has some countries that are more established than others and also focus on specific countries has spurred and strengthen their capabilities and functionalities | • Target funding activities to regional collaborations or targeted funding to under-represented groups including young researchers, targeted funding to level gender disparities<br>• Apply a hub and spoke model to reduce fragmentation |
| **Fragmented regions / Nationalistic mentality:** The region is segmented and hence has fewer collaborations | • Enhance local (south-south) linkages in training and conducting research; visas are a major barriers - ? offer diplomatic visas for senior scientists across the region |
| **Curriculum development:** There is a need to integrate training in the curriculum as some universities are not covering clinical trials | • Support curriculum development by engaging training institutions; have intercountry training where clinical trials experts are qualified to work across countries hence strengthening capacity |
| **Documentation of regional cases:** Most clinical trials publications and reports are not spearheaded by African institutions | • Develop more contextual cases studies of success and impact stories |
| **Regulatory constraints:** There are many procedures and regulations to meet in order to start a clinical trial and it becomes more complex when the clinical trials are across countries. | • Minimize regulatory constraints, have a central regulatory authority across the region |
| **Support infrastructure:** There is need for support staff (e.g. biostatisticians, clinical data managers) who understand data analysis of clinical trials | • Look at sustainability and how to train support staff to understand clinical trials so that data analysis and analytics is relevant; develop curriculum for support staff |
| **Brain drain:** a lot of experts are leaving for greener pastures and those left are overwhelmed | • Develop clear career pathways (e.g TDR grant by WHO[5] or the Africa CDC workforce development program[6]); offer attractive packages; look at ways of harnessing diaspora talent in the current clinical trials ecosystem for knowledge exchange; a mechanism that audits work environments |
| **Clinical Research Organisations (CRO):** There are a few accredited CROs in the region that can conduct local clinical trials. | • Set up local Contract Research Organizations (CROs) |
| **Infrastructure constraints:** There are a few accredited CROs in the region that can conduct local clinical trials | • Set up local CROs |
| **Infrastructure constraints:** There are a few accredited CROs in the region that can conduct local clinical trials. | • Investment in infrastructure |

[5] https://tdr.who.int/home/our-work/global-engagement/tdr-small-research-grants-scheme
[6] https://africacdc.org/institutes/africa-cdc-institute-for-workforce-development/

## Discussion on community engagement in clinical trials. Effective community engagement strategies are central to trust in, and participation in research practices

*Session guiding questions*

1. What is the status of disease-agnostic Good Participatory Practices guidance? What are needs for development of further guidance?
2. What is the status of a community of practice on community and public engagement to monitor and track the implementation of disease-agnostic Good Participatory Practices for multi-country clinical trials, which can represent African voices?
3. What is the vision and next steps in developing guidance, and an associated community of practice, including checklists for implementation of such guidance in trials in the region?

Dr Nina Gobat started off the discussion session by presenting an outline of what Good Participatory Practice (GPP) means when engaging communities in clinical trials. She gave an overview of some of the substantial guidance around GPP that WHO has developed which outline some key best practices in community engagement such as:

- *GPP in clinical trial governance and operational structure*: representation in trial governance structure and key decision-making groups as well as a communication and community engagement function/ role in trial team.

- *Minimum standards for GPP*: which encompass community engagement and communications plan; a community/ patient advisory mechanism; community / patient review on all public facing documents, recruitment, consent and follow up; proactive communication at key trial junctures; participant feedback mechanism; post-trial feedback of results to participants.

- *Wider trial ecosystem*: clinical trial registration that requires reporting of GPP; reporting guidelines (PRISMA): report GPP and ways in which trial protocol / procedures adapted in response; funders should see it in planning and reporting; journals should ask for it in reporting, particularly regarding results shared with participants.

Dr Gobat stated that to date all these tools and guides do not seem to be changing practice. There is need for more evidence on GPP and its added value looking at the importance of relationships, reciprocity and redistribution of power. There needs to be development of communities of practice which clinical trials networks and infrastructure with a rise in Clinical trial innovations: e.g. adaptive platform trials, master protocols, multi-country trials and new models which present new challenges.

**Feedback from participants:**

- There is a need for **co-identified research questions and participatory research** with communities as a mechanism to get buy in early planning stages of the clinical trial.
- There must be **feedback mechanisms** to measure what is meaningful and genuine engagement, when it comes to community engagement.
- There is a need to **invest in experts on community engagement** who can design and monitor what the impact of the clinical trials as scientists are not experts in community engagement.

- **Community and public engagement should be a requirement in clinical trials**. Researchers rarely look at this aspect, which is a huge bottleneck, it should be part of clinical trial design and conduct.
- **Funding usually has no budget for community engagement,** so scientists need clarity and guidelines on how to make a case for funding community engagement.
- There is a need to **influence institutional policies and procedures** that support community engagement such as the empowerment of community advisory boards
- Non - scientists should be supported to be comfortable with community engagement so as to support clinical trials.

With regards to a Community of Practice there was suggestion that this be included in the African Clinical Trials Forum that had been proposed as a key platform for collaboration. On the issues around community engagement guidance development there was reiteration for a need for

- Ethical monitoring systems
- A health systems agenda not just a research agenda
- Mechanisms to manage expectations as there is a need for transparency and honesty and engagement with communities with set expectations
- Standardized community health worker engagement where the community engagement is at the core of the clinical trials
- Accountability measures from funders

## Discussion on strategies for clinical trials and sustainable networks in the African Region:

In contrast to some other regions, there are several clinical trial and other research networks in the region. However, they are not all functional all the time and are generally limited to specific disease areas. The discussions focused on the questions and suggestions shown in the Table 3.

**Table 3: Discussion on Questions and Suggestions**

| Question | Suggestions |
|---|---|
| 1. *Which strategies are necessary to ensure clinical trials and long-term sustained regional networks?* | – Regulatory reviews that have reduced timelines, joint reviews and resilience<br>– Remapping of capacities to efficiently support capacity building |
| 2. *How can networks best support capacity that is embedded in clinical and public health services?* | Networks and collaborations need to be:<br>– Project specific<br>– Systems oriented<br>– Capacity building should be the primary deliverable for all clinical trials grants<br>– Look at sustainability and succession planning |
| 3. *What other strategies should be adopted to strengthen collaborative clinical trial research? Who should lead them?* | – Infrastructure strengthening<br>– Pulling efforts into one ecosystem across Africa and have a united vision<br>– Community engagement and engaging end-users in clinical trials<br>– Lab systems to be integrated to cover Phase 1 to 4 clinical trials<br>– Focus on ethics systems e.g have a single ethics review board at national level<br>– Develop grant management capacity |

| Question | Suggestions |
|---|---|
| | – Task shifting and task sharing of CHW to support research |
| 4. *Which mechanisms should be devised to increase opportunities for collaboration between different research stakeholders?* | a) A consolidated and clear research agenda and priorities: it is important align on a common research agenda and research priorities.<br>b) A consolidated database |
| 5. *What role should funders play in encouraging collaboration?* | Funders should aim for inclusion in strengthening clinical trials ecosystem. Emphasis is on regional inclusion that:<br>– has intentionality<br>– is guided by the Regional strategy, goals and objectives.<br>– funders need to justify their choice of funding strategy and focus<br>– inclusivity should take into account local philanthropic funders (such as Dangote or Strive Masiyiwa)<br>– monitor how much of the budget is spent doing the work in Africa |
| 6. How can we address barriers to cooperation and collaboration among countries of the Region? | 1. Have **joint planning** through having<br>o A database of partners<br>o Advocacy of the Clinical trials Community platform<br>o Presence of a regional strategy for guiding joint planning<br>2. Have **an interdisciplinary approach** on any collaboration that is initiated<br>3. Formation of the **African Clinical Trials Forum** |

## Discussion on advancing ethical and regulatory efficiency in the African Region

In this session it was highlighted that too many research ethics committees (RECs) must review the same trial. Numerous reviews by different RECs within the same jurisdiction (i.e., country, state) are often necessary, which in turn delays the processes required to launch trials without necessarily strengthening the trials from an ethics perspective. Additional reviews are further needed from different jurisdictions where trials are being conducted.

**Feedback from participants**:

- There is a need for a consolidated way of approving clinical trials that is valid across the countries where the clinical trials will be conducted without repetition.
- Capacity building is important as the region is losing experts and specialists
- There is a need for a global or region wide database that serves a referral point for clinical trials
- Harmonization of standards – there are strides in regional level harmonization but national level harmonization is still lacking
- Prioritization of clinical trials disease focus for Africa it is important to move out of infectious diseases and prioritize according to evidence and data from disease surveillance systems

## Discussion on Research capacities

This session looks at answering the following questions aligned with research capacities in the region

*Session guiding questions*

1. How can we enhance the capacities to conduct robust, high-impact clinical trials and avoid research waste? What are the different areas of specialization and skills that are needed for each relevant role? What has been successful in terms of bolstering individual skills, leadership, infrastructure, and available resources?
2. How can we augment capacities to secure funding, handle logistics, and ensure long-term viability?
3. How can we address the challenges to talent recruitment and retention in the Region?
4. How can we best maintain a centralized inventory of capacities and resources in the region? Review the example of ctc.africa and consider sustainability.
5. In order to enhance capacity to conduct clinical trials of all phases, is it necessary to develop capacity to conduct a prior type of research (e.g., basic research, animal research)? What strategies to transfer knowledge to local researchers are feasible and effective? How can we ensure that clinical trial capacities are responsive to emergencies?

It was highlighted there are still many gaps in clinical research capacities in the region. While researchers from the region obtain high-level training, capacity is often developed in institutions outside the continent especially due to brain drain. The issues around research had been lamented in other sessions but a recap of the main issues are around:

- *Brain drain*: due to lack of incentives, hostile work environments and lack of clear career development pathways for young scientists.
- *Lack of resources*: there are minimal research grants which
- *Support staff:* such as grant managers, community engagement experts etc help to improve the quality of clinical trials
- *Capacity building:* This entails also including supply chain management in the ecosystem of clinical trials as badly handled logistics can adversely affect clinical trials. It is important to upskill biostatisticians, bioinformatics etc
- *Mentoring programs:* to attract young talent and integrate professionals into the system
- *Workforce retainment:* Government should take ownership of incentivizing, attracting and retaining talent. There is need to be a framework
- *Harmozised curriculum building:* Having generic programs and platforms across African universities

## Key action points and way forward

The next steps for implementation of the resolution in the region and countries include global consultation on WHA75.8 stemming from regional consultations and finalization of a report of the key outcomes from the regional workshop.

## Appendix A - List of Participants

| # | NAME | PROFILE |
|---|---|---|
| 1 | Dr Junior Mudji | Chief of Research and Director of Education -Hôpital Evangélique de Vanga - DRC |
| 2 | Dr Bernhards Ogutu | Chief Research Officer - Kenya Medical Research Institute (KEMRI) |
| 3 | Prof. Samuel Kariuki | Director - Centre for Microbiology Research - KEMRI |
| 4 | Mr. Christopher Obwanga | Director - Clinical Operations, East & West Africa - IQVIA |
| 5 | Dr Francisca. A. Ongecha Owuor | Researcher – School of Public Health – Kenyatta University |
| 6 | Prof. Sayoki Mfinanga | Chief Research Scientist- National Institute for Medical Research, Tanzania |
| 7 | Dr. Seth Seaneke | Health Products Technologies Division Food and Drugs Authority - Ghana |
| 8 | Shingai G. Machingaidze | Acting Chief Science Officer - Africa CDC |
| 9 | Dr. Kingsley Amaechi Nnalue | Head, Research and Knowledge Management Division - MoH/Nigeria |
| 10 | Dr. Beno N. Yakubu | Deputy Director - National Agency for Food and Drug, Nigeria |
| 11 | Dr Nonhlanhla Yende-Zuma | Specialist Statistician -South Africa Medica Research Council |
| 12 | Dr. Thomas Elliot Nyirenda | Strategic Partnerships and Capacity Development Manager - EDCTP Africa |
| 13 | Ms. Marina Lazaridis | Chief Product Officer - nuvoteQ.io |
| 14 | Prof. Victor Chalwe | Deputy Director - National Health Research Authority - Zambia |
| 15 | Nosia Mhango | MoH Zambia |
| 16 | Moses Mwale | WHO/WCO Zambia |
| 17 | Ms Isabel FOSTER | Research and Policy Officer - GLOPID-R |
| 18 | Dr Vasee Moorthy | WHO/HQ |
| 19 | Dr Nina Gobat | WHO/HQ |
| 20 | Dr. Wei Zhang | WHO/HQ |
| 21 | Dr Joseph Okeibunor | Research Lead -RDI -– WHO/AFRO |
| 22 | Mrs Mireille Mavoungoud | Administrative Assistant– WHO/AFRO |
| 23 | Mrs Leocadie Voumby - Tchibinda | Administrative Assistant (Director's Office) – WHO/AFRO |
| 24 | Dr Chipo Ngongoni | Health Innovation Ecosystems Management Specialist – WHO/AFRO |