African Union

AFRICA CDC
Centres for Disease Control and Prevention
Safeguarding Africa's Health

AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

Optimizing Efficiency and Impact in the

African Clinical Trials Ecosystem

Meeting Report | May 2023

Executive Summary

In May 2023, Africa CDC and AUDA-NEPAD convened sixty experts from across the continent and the globe to discuss concrete solutions for strengthening the impact and efficiency of the African clinical trials ecosystem, with the goal of speeding access to new lifesaving technologies in line with public health priorities. This meeting—rooted in aspirations of Africa's Agenda 2063 and informed by the World Health Assembly clinical trials resolution—built upon discussions forged at the 2019 Pan African Clinical Trials Alliance meeting and in the sidelines of the 2022 Grand Challenges Annual Meeting. It was designed to:

- Diagnose and develop a collective vision for strengthening the African clinical trial ecosystem to drive more impact.
- Co-design a roadmap to drive efficiency and optimal impact for clinical trial pipelines in line with global initiatives on clinical trials.
- Identify priority funding, areas of harmonization in policy and practices, and opportunities for meeting participants to contribute to strengthening the ecosystem.

Participants agreed that despite the strengths and assets within the current clinical trial ecosystem, it is not equipped to effectively manage a global health product pipeline that is expected to grow in both complexity and size. A lack of overall coordination and ecosystem-wide weaknesses mean that individual investments in areas such as capacity strengthening and retention, digital infrastructure, trial design, and network strengthening have often yielded transactional gains that cannot be sustained over time.

Over three days, meeting participants examined all aspects of the clinical trial ecosystem and proposed concrete solutions, ultimately agreeing that there is an urgent need to reconfigure how coordination happens and how information, data, processes, and tools are shared and reported. They examined the opportunity to improve coordination across the continent to build more predictability for researchers, clinical trial funders, and sponsors; a stronger clinical trials workforce; more streamlined and efficient systems for collaboration; harmonized ethics and regulatory reviews; and better responsiveness to the needs of African research centers.

Participants together developed a shared vision for the African clinical trial ecosystem and developed several priority solutions that would enable this vision. They ultimately agreed that a coordination mechanism was needed to enable increased efficiency and impact and recommended that this mechanism be housed at Africa CDC and managed in partnership with AUDA-NEPAD, WHO AFRO, and AVAREF. This mechanism should foster collaboration across funders and research sponsors, research networks and centers, industry partners, and community representatives, and that its mandate should include evaluation of the pipeline of clinical trials in line with African public health and research priorities, aligning on financing needs and mechanisms, building cohesive capacity strengthening partnerships, and driving evaluation of the impact of these changes on the clinical trial ecosystem. Participants prioritized a set of solutions that should be coordinated through this mechanism, including those that would strengthen clinical trial networks, advance innovative clinical trial design, harness digital innovations and efficiencies, ensure sufficient capacity and capacity strengthening across the ecosystem, standardize policies and practices, and ensure effective engagement of communities and the public.

In the coming months, Africa CDC and AUDA-NEPAD will continue to engage with the African clinical research ecosystem and African Member States to shape and refine this coordination role, including through the evolution of a ten-year execution roadmap.

Acronyms

AMA	African Medicines Agency
AMRH	African Medicines Regulatory Harmonization
AU	African Union
AUDA-NEPAD	African Union Development Agency-New Partnership for Africa's Development
AVAREF	African Vaccine Regulatory Forum
C/PE	Community and public engagement
CEPI	Coalition for Epidemic Preparedness Innovations
ctc.Africa	Clinical trials community
EC	European Commission
eCRF	Electronic case report form
eCRT	Electronic case report tabulation
eCTD	Electronic common technical document
EDCTP	European and Developing Countries Clinical Trials Partnership
EHR	Electronic health record
ePRO	Electronic patient-reported outcomes
eTMF	Electronic trial master file
EU	European Union
EUA	Emergency use authorization
EUL	Emergency use listing
G-FINDER	Global Funding of Innovation for Neglected Diseases
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
GIZ	German Agency for International Cooperation
GLoPID-R	Global Research Collaboration for Infectious Disease Preparedness
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ICT	Information and communications technology
ICTRP	International Clinical Trials Registry Platform
IRB	Institutional review boards
NCD	Non-communicable disease
NGO	Non-governmental organization
PACTA	Pan-African Clinical Trials Alliance
PACTR	Pan-African Clinical Trials Registry
PAVM	Partnerships for African Vaccine Manufacturing
POPIA	Protection of Personal Information Act
RCORE	Regional Centres of Regulatory Excellence
REC	Research Ethics Committee
TDR	Special Programme for Research and Training in Tropical Diseases
TPP	Target product profile
WANETAM	West African Network for Tuberculosis, AIDS and Malaria
WHO	World Health Organization

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Overview

Meeting background

Investments in research and development, largely from the global north, have helped to build a strong pipeline of products ready to enter phase two and three clinical trials in Africa and with potential to save more lives faster than ever before. The growing scope and complexity of clinical trials anticipated over the next decade means we can expect a growing need for human and financial resources to support them. In a context of limited resources, a greater focus on increasing efficiency and optimizing impact of the Africa clinical trial ecosystem to respond to pandemic and non-pandemic priorities is required. Yet clinical trial capacity and capabilities remain concentrated within a few countries and institutions, which can leave them overburdened while other research centers falter or struggle to retain their experts. Additionally, clinical trials are often uncoordinated and with limited harmonization of tools and practices, which may lead to greater dependence on high-income country partners while driving increased costs and inefficiencies. Without stronger coordination, funders, sponsors, and researchers are limited in their ability to address these challenges, translate research findings into practices at scale and deliver sustainable impact.

This meeting was rooted in aspirations for the Africa We Want as represented in Agenda 2063:

1. A prosperous Africa based on inclusive growth and sustainable development
2. An integrated continent, politically united and based on the ideals of Pan-Africanism and the vision of Africa's Renaissance
3. An Africa of good governance, democracy, respect for human rights, justice and the rule of law
4. A peaceful and secure Africa
5. An Africa with a strong cultural identity, common heritage, shared values and ethics
6. An Africa whose development is people-driven, relying on the potential of African people, especially its women and youth, and caring for children
7. Africa as a strong, united and influential global player and partner

In May 2023, African and global experts came together to discuss the challenges facing clinical research in Africa, with a vision of examining solutions that could enable a more efficient and impactful clinical trial ecosystem for the future. This meeting built upon a side discussion convened in late 2022 during the Grand Challenges Annual Meeting in Brussels, Belgium, and the 2019 Pan African Clinical Trials Alliance (PACTA) meeting. Both meetings acknowledged the importance of strengthening the clinical trial ecosystem within low- and middle-income countries, including through approaches like better visibility of research capabilities in Africa and enhanced clinical trials registration. In Brussels, participants made a call to action for a paradigm shift to develop a cohesive, LMIC-centric approach to clinical trial pipeline prioritization, capacity strengthening, and efficient execution to ultimately drive better impact through coordinated, fit-for-purpose networks of clinical trials. A World Health Assembly resolution passed in May 2022 validated the need for improving research quality and coordination through strengthened clinical trials to provide stronger quality evidence about new health interventions. Africa is poised to lead this shift in innovation in clinical trials to complement a continental vision of coordinated ecosystems of research, ethics, regulation, manufacturing and equitable access to newly developed products.

*The **Optimizing Efficiency and Impact in the Africa Clinical Trial Ecosystem*** meeting, convened on May 16-18, 2023 and supported by the Bill & Melinda Gates Foundation and EDCTP, examined the opportunity to improve coordination across the continent to build more predictability for researchers, clinical trial funders, and sponsors; a stronger clinical trials workforce; more streamlined and efficient systems for collaboration; harmonized ethics and regulatory reviews; and better responsiveness to the needs of African research centers. Over three days, Africa CDC and AUDA-NEPAD convened 60 experts drawn from across research centers and networks, clinical research funders, the private sector, regional and normative agencies, civil society, research partners, and others to examine the greatest challenges facing the implementation of clinical trials in Africa and to develop a vision for a harmonized and impactful clinical trial ecosystem future. As participants examined future needs and began to develop solutions to address them, they committed that these solutions be rooted in the public health needs of the African continent, anchored by African research priorities, and driven by African leaders and experts, towards the ambitious goal of ensuring sure that new, high-quality, lifesaving and affordable technologies reach those who need them with speed and precision.

MEETING OBJECTIVES

Africa CDC and AUDA-NEPAD convened this meeting of experts with the following objectives in mind:

- Diagnose and develop a collective vision for strengthening the African clinical trial ecosystem to drive more impact.
- Co-design a roadmap to drive efficiency and optimal impact for clinical trial pipelines in line with global initiatives on clinical trials.
- Identify priority funding, areas of harmonization in policy and practices, and opportunities for meeting participants to contribute to strengthening the ecosystem.

It was expected that the meeting would result in alignment on a draft 10-year execution roadmap for strengthening the impact and efficiency of African clinical trials and a set of clear solutions to address the greatest challenges facing the effective implementation of clinical trials in Africa.

Framing the future of clinical trials to meet the needs of the African continent

In the first formal session of the meeting, several presenters provided data and evidence to illustrate the current state of the African clinical trial ecosystem and to lay a foundation for further discussion about an aspirational future state.

Shingai Machingaidze, Africa CDC began the meeting by presenting the current state and future vision for clinical trials in Africa. More than 50 low- and middle-income countries house research institutions that participate in clinical trial networks; we are now reaching a stage where we need to 'network the networks.' There are many lessons to be learned from clinical research during COVID-19 including that research institutions and funders reportedly operated with more of a consortium mindset and built upon existing capacity, infrastructure, and community engagement to save time and costs. However, we also learnt that a lot of the clinical trials conducted were not useful informing policy decisions due to poor clinical trial design. The Partnership for African Vaccine Manufacturing (PAVM), established to deliver an enabling vaccine manufacturing ecosystem in Africa, may provide a useful example of the type of regional coordination and collaboration we need to drive a coordinated systems shift within research and development (R&D). A draft execution roadmap was presented to illustrate how we could build towards a more coordinated, impactful, and efficient African clinical trial ecosystem through 3 stages of work over the next 10 years, with the vision that meeting participants would continue to contribute to and shape the roadmap throughout the course of the meeting.

Dr Nick Chapman, Policy Cures Research provided a review of the anticipated clinical trials globally over the coming 5-10 years and discussed how they align with African health priorities. There are 745 currently active candidates in the R&D pipeline for neglected infectious disease; 40% of these are for vaccines, and half cover HIV, TB, and malaria. Alignment of this pipeline with African priorities varies. For instance, the eight neglected diseases prioritized with the PAVM/Africa CDC Framework for Action list of vaccine priorities account for 71% of all vaccine candidates in the neglected disease pipeline, representing a strong degree of alignment. However, more work needs to be done to define African priorities in other areas, and to define the extent to which these align with available TPPs. Areas such as TB vaccines and diagnostics for example have weaker alignment with these TPPs—although in the case of TB vaccine this is in part because of the stage of development of product candidates, some many of which are too early to determine alignment.

Professor Collet Dandara, University of Cape Town, presented on the suitability of the clinical trial pipeline and diversity to drive African R&D priorities. Africa is the most genetically diverse continent, which has a huge bearing on clinical trial outcomes. Most clinical trials conducted in Africa are phase 2 and 3, with phase 1 being conducted elsewhere and this may mean that products that reach phase 2 and phase 3 clinical trials in Africa may not be optimal for the African populations. For example, some allele frequencies exist only in African populations. It is important to study different populations across the continent to understand the impact of R&D candidates on different groups, particularly if candidates will be used in Africa. Other factors, such as the impact of climate on health, diet, and exposure to pathogens, vary widely among African populations as well as between African and other settings.

Thy Pham, Bill & Melinda Gates Foundation, discussed efficiency, optimization, and sustainable impact in clinical trials. There are unintended consequences of our current approach: enrollment drives our patient and community engagement, we rebuild the same capacities repeatedly, and we are plagued by system-wide issues that individual organizations must tackle alone. We could move from a transactional to a system-wide approach in which disease burden and impact drive our relationship with patients/trial participants and communities. In implementing a new approach, we must be willing to measure our progress and proactively adjust our approach. There are several indications that will tell us whether a new, more coordinated approach is working, including that regulatory and ethics reviews happen more quickly, there are shorter contracting timelines and more on-target enrollment, deployed digital technology is interoperable, patients have access to their individual results, and recruitment/retention/reallocation of research talent happens regularly.

During the subsequent discussion, meeting participants raised several additional issues:

- Current issues of locked borders, with no movement of human resources, is a real barrier, especially for workforce development. We need to think about free movement of experts as part of the strategy.
- Running clinical trials is part of a larger topic. There is also a need to consider procurement, accessibility and access to products once they are developed. This is particularly evident for products for children, which can be considered a neglected market segment.
- We must link the African health research agenda and integrate 'users' of trial outcomes evidence to the beginning of clinical trial design phases, to avoid the issues that arose during COVID-19 of most clinical trials having limited or no policy impact.
- The Networks of Excellence (funded by EDCTP) are "excellent" because they have sustainable income from non-product development work – i.e., they cover the whole spectrum of research.

Africa CDC's vision for the future of the African clinical trials ecosystem

In a keynote address, **H.E. Dr Jean Kaseya, the Director General of Africa CDC**, emphasized the importance of advancing the African clinical trial ecosystem. With a high burden of disease in Africa, clinical trials play a critical role in addressing health challenges. Africa CDC, through its role in strengthening capacity and addressing health threats, has gained valuable insights into the research landscape across the continent. The establishment of the Consortium for COVID-19 Vaccine Clinical Trials (CONCVACT) during the COVID-19 response highlighted the value of strong coordination mechanisms and collaboration among research institutions. African preparedness for future pandemics must be prioritized and the number of clinical trials conducted in Africa must increase.

There is a historical lack of representation of Africa's research priorities in global research agendas, which must shift to account for African-driven research. Sustainable investments in research and the adoption of new technologies to strengthen the clinical trial ecosystem are both needed, and it will be important to harmonize policies and practices across African countries to improve efficiency and effectiveness in research. Dr. Kaseya outlined four key elements for the transformation of the clinical trial ecosystem in Africa: 1) African-driven research priorities, 2) sustainable investments, 3) harmonization of policies and practices, and 4) the utilization of new innovations.

Africa CDC aims to drive a paradigm shift in the African clinical trial ecosystem and will work in collaboration with partners, particularly AUDA-NEPAD, to develop and implement a new vision for clinical research in Africa. Dr Kaseya called for the collective efforts of experts and stakeholders in shaping this shared vision and affirmed Africa CDC's commitment to making the transformation a reality. A new coordination platform provided by Africa CDC will play a crucial role in facilitating clinical trials across the continent and defining a continental agenda for research.

Key Recommendations towards an Optimal African Clinical Trials Ecosystem

Over the course of the meeting, participants worked together to develop a shared common vision for the future state of the African clinical trial ecosystem, and identified several priority solutions that would need to be implemented to achieve this future vision.

The Future State of the African Clinical Trials Ecosystem

The future clinical trial ecosystem in Africa will employ innovative trial design and harmonized policies and practices to implement responsive Phase 1, 2, 3 and 4 clinical trials across agile, efficient, sustainable, and financially viable clinical trial networks. Communities will be actively engaged as equal partners in support of impactful clinical research. Actors within the ecosystem will have strengthened and sustained capacity and will harness digital technology to improve efficiency in the review and conduct of clinical trials and dissemination of their results.

Specifically, the ecosystem will accommodate:

- Innovative clinical trial design that is strategic, streamlined and allows pragmatic (adaptive) product development applying simplified trial design and optimizing trial conduct, including use of technology advancements as appropriate to the context in which the trial is conducted.
- Capacity development, including discovery research in Africa to feed into a comprehensive clinical development product pipeline, developing Phase 1 clinical trial centers across Africa to meet international standards and optimizing Phase 2 and 3 clinical trial sites to support the broader health agenda, increasing capacity of Phase 4 clinical trials, developing capacities and accreditation systems for laboratories to include toxicology and genomic analyses. Workforce development in the planning and execution of clinical trials should be accelerated and scaled up using an "Africa-aware" multilingual training curricula.
- Clinical trial networks that are business-oriented, African-led entities with agility, sustainability, and flexibility that align to the continental health research agenda; they should also be resilient and scalable, with government endorsement, and offer a unique value proposition to diverse stakeholders.
- A thriving digital technologies ecosystem that encompasses and supports all activities across the clinical trial process.
- Efficiency and financial viability ensuring the sustainability of clinical centers and their supporting laboratories and ICT infrastructure.
- A comprehensive legal framework and harmonised policies, procedures and guidelines to enable predictable and efficient clinical trial review and oversight and linking other regulatory functions with clinical trial processes.
- People-centered clinical trials that enable active, equitable, mutually beneficial, inclusive and quality engagement and partnership of communities.

Collective Vision on the Future State of African Clinical Trial Ecosystem

To achieve this bold vision, a set of ambitious and feasible solutions must be advanced by regional stakeholders.

Participants endorsed a proposal to **establish a new mechanism, housed at Africa CDC and led in partnership with AUDA-NEPAD**, **to drive overall coordination of the African clinical trial ecosystem** including collaboration across funders and research sponsors, research networks and centers, industry partners, and community representatives to evaluate the pipeline of clinical trials in line with African public health and research priorities, align on financing needs and mechanisms, build cohesive capacity strengthening partnerships, and drive evaluation of the impact of these changes on the clinical trial ecosystem.

Additional recommended packages of solutions included:

Cross-cutting solutions to strengthen networks and financing

1. Establish a **connected set of African priority clinical trial networks and research centers**--to include research sites, labs, pharmacies, and contract research organizations (CROs)-that operate in line with forecasted clinical trial pipelines and strategic use of resources to advance African R&D and public health priorities.
2. Build a **centralized knowledge management electronic repository** to include access to information about the capabilities of various entities across the clinical trial ecosystem, to feature mapping of the

human capabilities and infrastructure (including ICT/digital) of clinical trial networks and centers of excellence, research pharmacies and laboratories, and CROs. This should include further assessment of non-pandemic and pandemic surge capacity and community and public engagement capabilities. Information could be organized within different tiers and in hub-and-spoke models in line with clinical trial pipelines. Existing platforms such as ctc.Africa may be used for as a knowledge repository.

3. Develop an **investment case for domestic and pooled AU Member State funding** to position and reinforce the value of clinical trials for economic development, health and national security in Africa.

Solutions to advance innovative clinical trial design

4. Develop and disseminate **guidelines for innovative trial design in Africa**, to include adaptive and decentralized clinical trials and the inclusion of genetically and gender-diverse clinical trial populations.
5. Provide **recommendations for harmonization of tools, practices, and standard protocols** for clinical trials (including electronic health records).
6. Develop a **mechanism for ensuring the accountability for informativeness of clinical trials and efficient translation** of research findings into policies and practices.

Solutions to harness digital innovations and efficiencies

7. Develop a **legislative framework and accountability mechanism for the use of digital technologies and digital data in African Member States** in line with global standards (GDPR, POPIA, Global Regulations) and in consideration of the strong regulatory standards surrounding clinical trials.
8. Develop an **African framework for the use of interoperable digital innovations in clinical trials** (including artificial intelligence/machine learning), practical digital technologies (e-recruitment, e-consent), platforms for clinical trials (e.g., eSource, eTMF, eCRF, ePRO) and data use and governance.

Solutions to ensure sufficient capacity and capacity strengthening across the ecosystem

9. Develop **certification programs** for:
    - Interoperable **digital infrastructure** for big data analytics, genomic sequencing, bioinformatics and translational research in support of priority clinical trials.
    - **Training programs that build upon existing programming to strengthen capacity across all phases of clinical trials**, with intentionality around Africa-specific contexts (culture, ethics, genetics, legal issues, environmental impact, and community and public engagement)
    - Joint **AU-WHO accreditation framework** for clinical trials, research pharmacies and laboratories, and CROs.

Solutions to standardize policies and practices

10. **Endorse a framework for harmonized ethics standards and joint review mechanisms specific to African clinical trials**.
11. **Expand and optimize AVAREF** clinical trial oversight functions, in line with the African Medicines Agency and the AU Model Law.
12. Develop and align country and continental **legislative frameworks for clinical trials in emergency contexts** and Emergency Use Listing and Emergency Use Authorization for African public health priorities.
13. **Harmonize country, regional, and continental policies** for incentivizing local clinical trials and pharmacovigilance studies.

Solutions to ensure effective engagement of communities and the public

14. Establish an African focused **framework, standards, and accountability measures for funders** and research implementers to fund, execute, and report on **community and public engagement**.
15. Begin an **African 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, and which can represent African voices in WHO-led consultative processes on clinical trials and ethics.

Executing upon a collective vision

Meeting participants examined a draft execution roadmap, outlining three stages of work over a period of ten years. They provided recommendations for refining the roadmap as illustrated in the figures below.

EXECUTION ROADMAP: A TEN-YEAR PLAN FOR STRENGTHENING EFFICIENCY AND IMPACT OF CLINICAL TRIALS

DESIGN
2023-2024

Establish new mechanism led by Africa CDC with AUDA-NEPAD to drive coordination across the clinical trial ecosystem

Connect priority clinical trial networks and centers of excellence ("hub and spoke" model)

Develop evaluation framework and establish impact measurement baseline

PILOT
2024-2026

Operate coordinating mechanism with service partner support and donor/ member state investment

Develop and roll out guidelines, frameworks, standards

Pilot test 2-3 clinical trials

Refine evaluation framework and impact measurement approach

SCALE
2027-2033

Scale coordinating mechanism and initial expansion of hub and spoke model to accommodate 5 multisite clinical trials

Further expansion to an additional 10+ clinical trials

Evaluate impact

THE SOLUTIONS

During the preliminary design stage of execution, Africa CDC and AUDA-NEPAD will establish a new mechanism, housed at Africa CDC and led in partnership with AUDA-NEPAD, to drive overall coordination of the African clinical trial ecosystem. In collaboration with partners, they will:

1. Establish a connected set of African priority clinical trial networks and research centers
2. Build a centralized knowledge management electronic repository
3. Develop an investment case for domestic and pooled AU Member State funding
4. Conduct a comprehensive mapping and assess opportunities to harmonize tools, guidelines, standards, policies, and practices.

THE OUTCOMES

- Upgraded https://ctc.africa/ site and data repository with additional information and capability to effectively drive decision-making on matching clinical trials pipeline and clinical trials capacity; research center data utilized to assess capacity, identify priority research centers/countries and identify capacity strengthening needs based on projected clinical trials pipeline in next 3-5 years.
- Priority areas identified for harmonization of approaches for clinical trials capacity site assessment, performance measurement, certification, contracts, and tools (master protocols, DAC, data management framework; streamlined EC/IRB applications, SOPs, sample repositories, enrollment support, community engagement); availability of harmonized tools and approaches in several languages.
- Priority areas identified for developing continental data and laboratory repositories or supporting a more networked model of existing repositories.
- Alignment on continental and regional policies and practices for advancing clinical trials in pandemic and non-pandemic contexts (e.g., Data sharing; EUA, EUL, PCV, post-trial access, Digital Health, technology validation, import/export challenges).
- Strengthened connection across research efforts through a model of intentionally networked Africa clinical trials with predictive pipelines, costing/efficiency models through a continental coordinating mechanism backed by an Africa-based implementation service provider.
- Approved costed implementation plan, governance / resource mobilization plan, and impact evaluation / learning agenda framework.
- AU member states aligned to own clinical research as an important part of R&D for the continent and coordinate resources from AU member states and the broader funding community.

PILOT
2024-2026

THE SOLUTIONS

During the pilot stage of execution, the coordinating mechanism will begin to operate (housed at Africa CDC and managed in partnership with AUDA-NEPAD). Additional implementation/service partners will be identified and put in place to provide technical support. Multiple funder/sponsor investments will be expected to support capacity strengthening and clinical trial implementation.

This coordinating mechanism will work with partners to:

- Develop and disseminate guidelines for innovative trial design in Africa.
- Provide recommendations for harmonization of tools, practices, and standard protocols for clinical trials.
- Develop a mechanism for ensuring the accountability for informativeness of trials and efficient translation of research findings into policies and practices.
- Develop a legislative framework and accountability mechanism for the use of digital technologies and digital data in African Member States in line with global standards.
- Develop an African framework for the use of interoperable digital innovations in clinical trials.
- Develop certification programs for digital infrastructure and training programs to build capacity across all phases of clinical research, and join AU-WHO accreditation framework for clinical trials, research pharmacies and labs, and CROs.
- Endorse a framework for harmonized ethics standards and joint review mechanisms specific to African clinical trials.
- Expand and optimize AVAREF clinical trial oversight functions.
- Develop and align country and continental legislative frameworks for clinical trials in emergency contexts and for emergency use.
- Harmonize country, regional, and continental policies for incentivizing local clinical trials and pharmacovigilance studies.
- Establish an African-focused framework, standards, and accountability measures for community and public engagement and begin an AU community of practice.

THE OUTCOMES

- Governance and coordinating mechanisms established and coordinating service partner based in Africa identified to support implementation.
- Research approaches and tools harmonized; EC/IRB applications, DAC, joint review mechanisms, and technology adoption across the ecosystem (e.g., eCRF, eCTD, eConsent) streamlined.
- Pilot-testing completed of 2-3 high-impact, multi-country clinical trials at 5 identified and capacitated clinical research centers; hub-and-spoke model tested through the new networked model with harmonized tools and approaches.
- At least two identified priority data repositories and a digital health/AI, cloud-based mechanism developed, pilot-tested or strengthened.
- At least 1-2 continental priority policies adopted to advance pandemic and non-pandemic research (e.g., for clinical trial data sharing).
- Human resource plan developed to support development and retention of adequate workforce capacity.
- Transparent and accessible evaluation approach to measure interim impact in place, results shared, and any needed adjustments identified.
- Sustainable strategic 3–5-year business model in place to clarify opportunities for revenue generation and develop new business models to sustain network model beyond initial seed funding.

SCALE
2027-2033

THE SOLUTIONS

During the final stage of implementation, the proposed solutions will be scaled to full impact. A fully resourced coordination mechanism housed at Africa CDC and implemented in partnership with AUDA-NEPAD will drive strategic investment, track and evaluate overall ecosystem progress and impact, and engage key stakeholders.

An implementation partner will provide expanded technical support, and a full capacity hub-and-spoke model will operate at scale. Investments by multiple funders/sponsors will support implementation of this stage.

THE OUTCOMES

- Initial pipeline expansion to an additional 5 multi-country clinical trials in line with African research priorities for infectious diseases, non-communicable diseases, and / pandemic preparedness, and 5 additional clinical research centers/hub and spokes.
- Further expansion to an additional 10+ clinical trials.
- Continental and/or subregional connection fostered between clinical research centers, public health institutions, and vaccine/ pharmaceutical manufacturing centers to ensure alignment across research, public health, and production priorities.
- Adoption of harmonized policies, tools, and practices for multi- country clinical trials by additional research centers and governments.
- Execution of prioritized data repositories and digital health initiatives.
- Human resource plan implemented to support development and retention of a human workforce capacity.
- Impact assessment study disseminated, including recommendations for long-term sustainability of African clinical trials.
- Forward-looking report disseminated on sustainable business model for Africa clinical trials ecosystem with pathway for funders' exit strategy.

Conclusion of the meeting and next steps

Meeting participants strongly agreed to the need for an African coordination mechanism to help connect and coordinate across partners in the effort to streamline funding, policies and standards, and the implementation of research and in particular the clinical trial ecosystem. It was proposed that Africa CDC take on a stronger and more explicit coordinating role for the African clinical trial ecosystem, in partnership with AUDA-NEPAD, WHO and AVAREF.

Under this new model, Africa CDC and partners will:

- Coordinate actors across sectors within the clinical trial ecosystem to articulate a cohesive vision for success in strengthening African clinical trials.
- Harmonize research approaches, tools, standards, and policies and develop and facilitate the adoption of continental policy frameworks by key Member States to support harmonized, standardized clinical research practices.
- Facilitate communication across actors through a centralized and open-access data portal.
- Design and implement an impact evaluation framework, including regular monitoring of progress and coordination of course corrections as needed.

Africa CDC and AUDA-NEPAD will continue to engage with researchers, donors, partners and African Member States to shape and refine this role and the execution roadmap and to explore opportunities to leverage existing initiatives and programs to achieve desired outcomes.

Workshop Sessions

DRIVING EFFICIENCY, IMPACT AND SUSTAINABILITY OF THE AFRICAN CLINICAL TRIAL ECOSYSTEM

Representatives from the research and donor/research sponsor communities were asked to share their views on the top three issues facing the clinical trial ecosystem and the top three solutions that could be implemented or shifts that could be made to drive greater efficiency, impact, and sustainability.

Panelists

- **Dr Elizabeth Spooner**, South African Medical Research Council (SAMRC)
- **Dr Helen Demerest**, Medicines for Malaria Venture (MMV)
- **Dr Huub Gelderblom**, HIV Vaccine Trials Network (HVTN)
- **Ndeye Dieynaba Drame**, Institut de Pasteur de Dakar (IPD)
- **Prof. Collen Masimirembwa**, African Institute of Biomedical Science and Technology (AiBST)
- **Dr Carlo Giaquinto**, UNIPD/PENTA

Researcher perspectives

Researcher representatives highlighted the need to address such issues as unpredictable and lengthy ethics and regulatory review processes, a lack of equity in capacity strengthening partnerships, limited views into the roles that various actors are fulfilling, inability to sustain talent and capacity at clinical trial sites, mismatches between study design and programmatic feasibility, lack of inclusion of women and children in trial populations, lack of inclusion of the range of language needs—particularly in capacity building programming—and need for clearer understanding about the feasibility of harmonization across such a broadly diverse continent. See **Table 1** below for a full list of issues identified by panelists.

Among the solutions identified by research implementers were mechanisms for better and more streamlined information sharing, the use of electronic mechanisms to streamline processes such as consent, clearer strategies for engaging communities including dissemination of trial results, diversity of language offerings for training platforms, strengthened and harmonized ethical and regulatory practices, diversified use of trial sites to avoid redundancies, frameworks to consider the impact of genetic diversity on products' effectiveness, and mechanisms for co-creation amongst diverse ecosystem actors. See **Table 1** below for a full list of solutions identified by panelists.

Discussion among meeting participants highlighted additional solutions to be considered across a range of topics.

For **capacity strengthening** issues, participants recommended earlier education on clinical trials in clinician education programs to increase the understanding of the value of clinical research as well as efforts to build researchers' capacity to engage with policymakers and politicians to strengthen trusted partnerships between research communities and governments.

To **streamline trial efficiency**, participants suggested re-examining the need for 'paperless' or reduced paper transactions (e.g., for regulatory review submissions), examining potential efficiencies around trial site monitoring by having sites/site staff monitor each other's sites, designing clinical trials more intentionally from the beginning to minimize repetition, and reducing the carbon footprint of travel between global north and global south.

To strengthen **regional/continental relevance** for the African clinical trial ecosystem, suggestions included establishing regional (not continental) centers of excellence for technical expertise that are relevant within a particular region, developing African-established and African-led clinical trial consortiums instead of relying on those developed by donors, and requiring clinical trials to be conducted in countries where product registration will be sought.

To improve **financial incentives** for trial centers and researchers, participants discussed re-examining salary and reimbursement practices to incentivize good talent to stay and exploring opportunities for diverse income streams to support sites. Other solutions discussed included improved translation of research outcomes to clinical practice; examining the genetic diversity of pathogens causing disease, especially for vaccines; including access as an early criterion for the approval of clinical trial implementation; exploring alternate terminology to improve perception of ownership (i.e., instead of trial "sites", consider trial "centers"), and strengthening public health infrastructure.

Table 1. Clinical trial issues and solutions from the perspective of research implementers

Challenges	Solutions
▪ Lack of funding ▪ Lack of true collaboration ▪ Lack of streamlining between relevant products and suitable practices ▪ Unpredictable, unharmonized, lengthy and slow ethics and regulatory processes ▪ Poor movement of expertise and required commodities into and throughout the continent ▪ Lack of equitable partnerships for capacity building ▪ Limited clarity into which actors are fulfilling which roles and where ▪ Challenges in recruitment and retention of strong, dependable talent ▪ Limited representation and inclusion of diverse language needs, particularly for capacity building ▪ Lack of implementation of phase 1 clinical trials in settings where they are relevant to African populations ▪ Unclear expectations about integration that match the size, diversity, and harmonization across Africa ▪ Inadequate sustainability of trial sites once they are established ▪ Insufficient consideration of real-world implementation and accessibility of trial results when studies are being designed ▪ Limited consideration of the needs of women (including pregnant women) and children as part of research agendas and clinical trials ▪ Gaps in capacity building, including lack of community engagement	▪ Ask us don't "trial" us ▪ Leverage electronic solutions like data-free apps and a return to COVID-19-era electronic consenting ▪ Improve transparency and trust ▪ Ensure better connected networks - networks of networks ▪ Create mechanisms for better information and data sharing, such as dashboards that allow for tracking clinical trials in Africa and the corresponding funding associated with it. ▪ Accelerate investments in clinical trials particularly from the ground up ▪ Develop clear results dissemination strategies and good participatory practice ▪ Integrate diagnostics as part of clinical trials ▪ Make training platforms available in languages other than English ▪ Strengthen and harmonize ethical and regulatory processes. ▪ Link policies to financing (e.g., financing and conducting clinical trials in areas where diseases studied are endemic) ▪ Diversify the use of sites/clinical trial units to avoid redundancy, duplication, and overburdening ▪ Conduct Phase 1 trials in Africa ▪ Develop a TPP framework that aligns with genetic diversity, to ensure that the impact of genetic variations on products' effectiveness is explored and understood before product marketing begins ▪ Bring together "regulatory" and "strategic" study questions into a single trial design ▪ Bring a range of stakeholders together to co-create solutions – e.g., academia, industry, regulatory authorities, and patient organizations ▪ Strengthen data collection capacity for an effective and efficient ecosystem to ensure that the implementation is yielding the desired results.

A second panel featured perspectives from funders and research sponsors on both issues and solutions related to strengthening the impact, efficiency, and sustainability of the African clinical trial ecosystem.

Panelists

- **Dr Thomas Nyirenda**, European and Developing Countries Clinical Trial Partnership (EDCTP)
- **Prof Charles Wiysonge**, Global Research Collaboration for Infectious Disease Preparedness (GLoPID-R)
- **Dr Christof Vennemeier**, Coalition for Epidemic Preparedness Innovations (CEPI)
- **Dirk Gille**, Johnson and Johnson (J&J)
- **Dr Vasee Morthy**, World Health Organization (WHO)
- **Lindie Rothmann**, Novartis

Research funder perspectives

Funders highlighted challenges such as a lack of buy in from political figures in countries, limited coordination and collaboration across funders, excessive bureaucracy that results in longer timelines, a limited number of researchers relative to the size of the population across African Member States, a lack of workplace incentives and policies to support women researchers and scientists, and an aging population of research experts. See **Table 2** below for a full list of issues identified by panelists.

Additionally, research funders shared their views on potential solutions. They highlighted opportunities to build political champions, foster stronger connection and engagement among donors, accelerate investments in the clinical trial workforce including incentives to make workplaces more 'woman friendly' and encourage the next generation of researchers, support capacity at trial sites between epidemic research surges, and share lessons and best practices to minimize bureaucracy while maintaining the necessary due diligence and increasing efficiency. See **Table 2** below for a full list of solutions identified by panelists.

Participants discussed additional solutions to address the issues raised by research sponsors.

Table 2. Clinical trial issues and solutions from the perspective of research funders and sponsors

Challenges	Solutions
▪ Political will and buy-in from governments ▪ Capacity and number of researchers relative to size of the African population ▪ Policies and environments are not 'women friendly' ▪ Aging out of a significant cohort of researchers ▪ Prioritization and coordination of research funding ▪ Limited capacity means fewer clinical trials in resource-constrained settings ▪ Coordination and collaboration among funders ▪ Limited local ownership of research partnerships ▪ Unsustainable research processes and procedures ▪ Excessive complexity, bureaucracy, paperwork ▪ Long timelines to initiate clinical trials	▪ Develop more champions among heads of state and build more domestic financing for clinical research ▪ Build and strengthen a critical mass of researchers across the continent ▪ Examine the promotion of women in science and accelerate investments in women researchers and scientists ▪ Develop and strengthen the next generation of researchers ▪ Design simplified research protocols for ease of replication ▪ Encourage use and re-use of freely accessible protocols developed by large clinical trials networks (ISARIC, ALERRT) and deposited in the public domain ▪ Involve stakeholders from the national, regional, and global levels in research prioritization ▪ Put funding mechanisms in place for coordination in response to emerging outbreaks

Challenges	Solutions
	▪ Increased sharing from partners in all regions about effective research practices, processes and procedures ▪ Implement new practices as donors to support ecosystem shaping by bringing effective practices to research partners, finding creative ways to fund research when it is most needed, and advocate for/invest in sustaining research capacity in inter-epidemic periods ▪ Include assessment and resource mobilization tools and data about available funding for clinical trials in common platforms (e.g., ctc.Africa) ▪ Ensure we are considering laboratories and diagnostics when we address the clinical trial ecosystem ▪ Focus on key issues to ensure science and ethical issues are addressed while simplifying ▪ Address gaps in underserved populations (e.g., children) ▪ Improve clarity about the roles of different stakeholders (governments, private sector, etc.) and involve them from early stages ▪ Accelerate use cases for translational research, developing interventions, and evidence generation for decision making

To address **HR and capacity** issues, they suggested a need to develop human resource management plans as part of institutional plans (succession planning), offer opportunities for younger researchers to access funding to conduct clinical trials, and the importance of training the full team, and having full capacities like finance, human resources, project management.

To **strengthen community and public engagement**, donors and other stakeholders should support and fund engagement initiatives to ensure that patients and communities are meaningfully engaged in research – not just as participants but so that they understand the reason for participating, embed patient engagement to help build demand for research outcomes, and create more publicity and awareness of success stories.

To improve **center capacity and sustainability**, solutions include providing legal support to trial centers and supporting clinical trial centers to develop business cases to aid in their sustainability.

To **strengthen collaboration between research funders**, it was suggested that donors and others co-fund to avoid competition between sites and encourage collaboration between funders and industry, encourage funder collaboration that creates a 'community of practice'-type environment including sharing of tools and guidelines and plans, and look to large research centers to force coordination across the donors that fund them (e.g., the South African Medical Research Council has done this with research donors in South Africa).

REGULATORY HARMONIZATION AND THE AFRICA MEDICINES AGENCY

To provide insights into a related harmonization and coordination effort, **Chimwemwe Chamdimba of AUDA-NEPAD** offered an overview of efforts led by AUDA-NEPAD to harmonize regulatory approval processes and stand up a new African Medicines Agency (AMA). The journey towards harmonization began in 2008, and the vision of the AMA started taking shape around 3-4 years ago. The African

Medicines Regulatory Harmonization (AMRH) initiative has been implemented in several regional economic communities, focusing on improving regulatory capacity, creating an enabling environment for research and development, and promoting local production of pharmaceutical products that meet international standards. The AMRH has adopted a stepwise approach, starting with one regulatory function (generic products) and gradually expanding to address other areas.

Under the AMRH, continental technical committees have been established to develop guidelines and frameworks across 10 topics, facilitating discussions and collaboration across the continent. Centers of excellence on regulatory systems have also been developed, aiming to address the capacity challenges faced by national medicines regulatory authorities, researchers, and the pharmaceutical industry. These centers, known as Regional Centers of Regulatory Excellence (RCOREs), possess regulatory science expertise and training capabilities. Currently, there are 11 RCOREs spread across Africa, comprising five national regulatory authorities, five academic institutions, and one combination of both.

There remain ongoing efforts and opportunities for regulatory capacity strengthening. Harmonization efforts within regional economic communities, the designation of the AVAREF as the continental technical committee on clinical trial oversight, the RCOREs, the College for Regulatory Science Professionals, and the collaboration between regulators and ethics committees through PACTA are all contributing to the enhancement of regulatory systems in Africa. The establishment of the AMA is seen as a significant opportunity for further progress in harmonization and regulatory capacity building, with plans to include all WHO maturity level 3 (ML3)-certified countries in the agency's mandate.

PRIORITY SOLUTIONS FOR REALISING THE OPTIMAL AFRICAN CLINICAL TRIAL ECOSYSTEM

PARTNER PRESENTATIONS ON WORKING GROUP THEMATIC AREAS

To provide background for subsequent discussions, several content experts were asked to provide overviews of the key issues and considerations for priority thematic areas.

Adriaan Kruger of nuvoteQ.io provided a presentation of the ctc.Africa site to examine opportunities to best leverage data for clinical trial measurement and evaluation. The ctc.Africa online platform pulls data from PACTR and US National Institutes of Health databases and then cleans and standardizes this data. In addition to data about clinical trial centers, the platform houses information about national regulatory authorities and ethics review committees. The site can be expanded to include additional data needs in the future and function as a central repository of all clinical research sites across Africa.

Ntando Yola, Desmond Tutu Foundation spoke about the importance of strengthening community and public engagement in clinical research. There are many essential benefits of engaging the public and communities, including increased integrity, accountability, support, and public relevance of clinical trials. The goal is to break down barriers between research and a broad range of stakeholders, accelerate research outcomes into public policy, and ensure equitable access to products tested in Africa. There remains a need for tailored, systematic, and ethical engagement that empowers communities to inform research, to include building engagement mechanisms and structures from the local to the national level, considering regional processes, and involving multiple stakeholders such as researchers, ethics and regulatory bodies, funders, and policy makers.

Michael Landau, CTI-LifeHealth spoke about the potential for harnessing digital technologies to create more efficiencies for clinical trials, including providing a demonstration of the CTI-LifeHealth platform. Digital technologies can help by providing faster response times and can further support efforts to track, recruit, investigate and manage the process of clinical trials. Data visualization is another useful tool that can help promote better understanding of demographics, trial results, and other information.

Dr. Alambo Mssusa, WHO AVAREF spoke about the harmonization of policies and practices from AVAREF's perspective and experience. Created in 2006, AVAREF seeks to connect RECs and developers to expedite access to treatment and prevention of major illness in Africa. AVAREF has four areas of

work related to clinical trial applications: joint reviews of submissions, harmonization of policies and practices, collaboration across varied stakeholders, and support to all member states with a focus on building institutional / technical capacity to meet demand in Africa. The AVAREF Technical committee, in partnership with other stakeholders, developed guides and tools such as standardized model documents for clinical trials applications and GCP applications to harmonize and facilitate the review and monitoring of clinical trials on the continent. AVAREF also engaged institutional review boards and ethical review committees to identify areas of improvement for process optimization for assessments. AVAREF has embraced capacity development and digital platforms to support its initiatives.

Sue Bailey, IQVIA presented opportunities for reducing costs and time and increasing quality of clinical trials, including the importance of strengthening predictability to improve the overall clinical trial ecosystem. Factors such as regulatory efficiency, post-trial access, and managing the perception of the African clinical trial ecosystem—and effectively demonstrating its value proposition—are critical for success. IQVIA ran over 100 COVID-19 clinical trials and documented lessons learned to reduce costs and increase effectiveness, including the value of networking sites and technology-driven efficiencies, which IQVIA estimates can reduce timelines by 20% (based on global data). The importance of site delivery, engagement with regulatory frameworks, and the diverse country landscape are critical factors for sustainable capacity building.

Professor Souleymane Mboup, IRRESEF discussed the value of networks in building research capacity in Africa. EDCTP Networks of Excellence began in 2009 to spread EDCTP investments more equitably across the continent. WANETAM began with 14 institutions in 7 West Africa countries and was the only network to include three languages – French, English, and Portuguese. The objective of these networks was to build capacity to conduct clinical trials in line with international standards; promote professional collaboration, strengthen collaboration, strengthen South-South and North-South collaboration to support less established institutions to build capacity for high quality clinical research, and promote networking between researchers, communities, and policymakers. Despite the many successes of this model, there remain several challenges: lack of funding beyond international donor funding to sustain activities, language barriers, a low use of data that's available and a fear of sharing data, lack of equitable partnerships for win-win collaborative research, and financial management capacity.

Participants discussed the various thematic areas and raised the following additional points:
On the use of digital solutions, participants discussed the importance of allowing technology to adapt to changing science needs and use technology to digitize some solutions. However, stakeholders must recognize that the adoption of digital solutions carries risk, and that the management of data within the clinical trial ecosystem is highly regulated. Digital solutions must align with patient data confidentiality, data protection laws, and other regulations. African countries can adopt international data standards to help with uniformity and collaboration, and digital solutions must increasingly operate with interoperability and standardized quality in mind. There are insufficient metrics in place for measuring the impact of community and public engagement, which must go beyond measuring those who are trained to also address how well researchers and communities work together.

PARTICIPATORY WORKING GROUP DISCUSSIONS

Meeting participants worked in small groups to identify priority solutions across a set of seven themes: clinical trial design, capacity development, network issues, digital technologies, financing, harmonized policies and practices, and community and public engagement.

Innovative Clinical Trial Design

To improve the clinical trial landscape, several strategies can be considered.
Embracing ***innovative trial designs***, such as adaptive clinical trials and platform trials, along with the effective utilization of technology, is crucial. It is important to provide better training for all stakeholders to facilitate meaningful change. Progress made during the COVID-19 pandemic should not be disregarded, and there should be a ***commitment to not regress to pre-COVID-19 practices***. Implementing master protocols that test multiple compounds in the same phase of development can streamline processes.

Stakeholder alignment from the outset is vital for success. Simplifying protocols, including enrollment criteria, informed consent forms, and procedures, and adopting a standard protocol template, can enhance efficiency. It is essential to resist the temptation to revert to previous practices and instead explore decentralized clinical trials, mobile clinics, and technology-driven solutions.

Access and affordability should be regulatory requirements, with collaboration with local manufacturers being crucial. Lastly, the ***ubiquity of electronic health records*** is emphasized for reliable epidemiological data. Africa has the opportunity to advance health research methodology at a rapid pace. It is vital that we are not left behind or that changes are dictated to African researchers.

Priority solutions identified to strengthen innovative clinical trial design include:

1. Equip (e.g., training, policies) stakeholders to adopt innovative and streamlined clinical trial designs including:
    a. Clear questions with matching trial design
    b. Simple, efficient and only essential elements
    c. Early engagement with regulators, healthcare professionals and community
2. Advocate for increased adoption of innovative technology in clinical trials
3. Develop AU model of harmonization of tools including electronic health records and electronic clinical trials data tools

Capacity Development

Having agreed that there are ***minimal phase 1 clinical trials*** conducted in Africa overall, to increase the number of phase 1 clinical trials in Africa, there will be a need to develop an accreditation system for clinical trial centers that can map and assess capacity for ***first-in-human, bridging and bioequivalence studies that meet international standards***. Currently, those sites that are optimized for Phase 2 and 3 infectious disease clinical trials need to be enabled to support NCD-related research to align with African public health priorities. Additionally, ***labs for drug and genomic analysis*** to support the conduct of clinical trials are needed, but more information is needed about where this capacity exists. If leveraged effectively, ***ICT solutions hold strong potential*** to support and inform clinical studies. To support capacity building efforts, there is a need to ***catalog existing training, tools, and software*** and make these tools widely available across languages. Lastly, we must examine the sustainability of clinical centers and their supporting laboratories and ICT infrastructure.

Priority solutions identified to ensure sustainable capacity development is in place include:

1. Map and establish an accreditation system for phase 1 clinical trial centers across Africa with capacity for first-in-human, bridging and bioequivalence studies that meet international standards, to include mapping:
    a. Clinical trial unit infrastructure
    b. Accredited research pharmacies
    c. Registered clinical laboratories
2. Leverage existing infectious disease trial infrastructure to support diagnostics/monitoring of other therapeutic areas.
3. Scale up training to support development of lab capacity for other therapeutic areas.
4. Engage the private sector (pharmaceutical and biotech companies).
5. Develop laboratory infrastructure that can support clinical studies with bioanalysis and next generation sequencing and bioinformatics analyses.
6. Consolidate strategic fundraising to establish and/or upgrade accreditation of labs for drug and genomic analysis in support of clinical trials.
7. Digitalize the collection, processing, analysis, and ethical sharing of clinical and genomic data.
8. Standardize metadata and other data formats.
9. Establish ICT infrastructure to enable the efficient and reliable digitalization of clinical trials.
10. Enhance product development in Africa through the establishment of drug discovery centers.
11. Develop an African genetic diversity, targeted drug profile framework.
12. Develop a training curriculum to support discovery / preclinical before the start of first-in-human clinical trials.

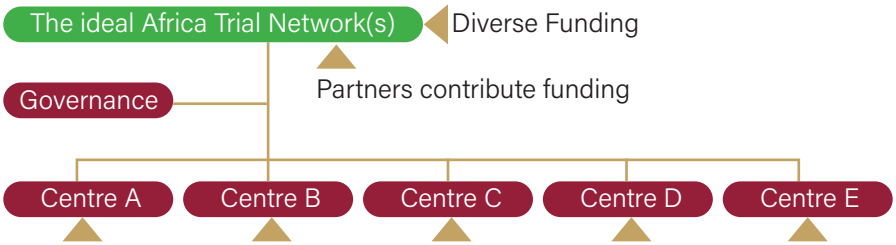
13. Develop and deploy a translational research model where grants can be used to initiate and de-risk projects to attract venture capital.
14. Train clinical trial leaders as part of succession planning.
15. Provide certification of training curriculum for clinical trial support staff.
16. Diversify source and funding of clinical trials to include grant funded public good with private sector commercial trials.
17. Mandate regulations that clinical studies have to be done in target populations.
18. Translate scientific knowledge in key local languages.
19. Find creative solutions to ensure that terminology for scientific processes is adapted and understood in local languages.

Network Issues

The current state of clinical trial networks in Africa is characterized by the presence of various networks at ***different levels of maturity*** and in different settings, including continental, regional, and local networks. However, there are several challenges and opportunities that need to be addressed. These include the need for ***better coordination***, ***prevention of duplication***, ***promotion of dialogue between relevant actors***, ***adequate funding***, limited ***brain drain***, improvement of ***infrastructure*** in certain areas, and development of sustainability plans that include succession plans. The responsibility for funding these networks lies with a combination of funders and governments, and it is important to define criteria for assessing the success and ***impact of these networks***. Close ***collaboration with the private sector*** is also crucial.

The establishment of networks is essential for ***achieving standardization, harmonization***, increased business opportunities, and setting the research agenda in Africa. A good network should be trustworthy, reliable, and have a pool of resources to draw from. The role of networks is to connect excellence and facilitate knowledge transfer, enhance collaboration, and the implementation of innovation to address significant health challenges in Africa. Adopting a ***business-oriented approach*** ensures a focus on sustainable solutions and economic growth, while African leadership guarantees relevance and contextual understanding. Networks that receive endorsement from governments are more likely to enjoy support and resources, enabling them to have a broader impact. Overall, clinical trial networks ***offer a unique value proposition by leveraging collective expertise, resources***, and networks to drive tangible and transformative outcomes in the African health ecosystem.

Figure 1. A model for an ideal clinical trial network in Africa



Priority solutions for clinical trial networks to take on to strengthen their impact include:

1. Supporting all forms of health research to enable strong research centers to undertake excellent clinical trials.
2. Strengthening research systems and delivery of faster and better clinical trials by sharing best-practice, research and data science tools, methods and systems to be taken up and used by others.
3. Developing and using quantifiable outcome measures (indicators) that are recognised and valued by stakeholders.
4. Delivering and supporting coordinated research skills training and career development that is work-place based, learning-by-doing to foster strong, diverse and lasting teams within programmes.

Digital technologies for clinical trials

The adoption of digital solutions in improving clinical trial activities in Africa encompasses various social, cultural, and economic aspects. While technology has the potential to ***streamline processes***, it is important to acknowledge that the adoption of technology can be slower than traditional paper-based methods, particularly among older generations. Factors such as job security—considering the perception that digital solutions may replace human functions—and trust play a role in the ***acceptance of digital solutions*** like ***e-consent***. To ensure the successful integration of digital solutions, it is crucial to have community representation and engagement throughout the process.

Education activities are needed to familiarize stakeholders with existing policies and regulations regarding the use of digital tools in clinical trials. ***Data security*** is a paramount concern, and robust measures must be implemented to protect digital data and maintain privacy. There is a need for regional/national discussions about how to practically advance the progression to ***digital clinical trials***. ***Harmonization of legislation*** between countries is also essential, considering the diverse perspectives and environments across Africa. In approaching the adoption of digital solutions, there should be a focus on addressing the specific challenges posed by the pandemic and leveraging technology to find solutions. By considering these factors and working towards a comprehensive approach, the adoption of digital solutions in clinical trials can be effectively implemented and contribute to improved research processes in Africa.

Priority solutions for stakeholders to maximize the use of digital technologies in clinical trials include:

1. Leverage practical solutions from a tech perspective (eRecruitment, eConsent, E-Feasibilities) and use enabling data sources (ICTRP, ctc.Africa, G-FINDER).
2. Implement legislation and policies that govern use of digital technologies and digital data (GDPR, POPIA, Global regulations).
3. Support infrastructure for digital technologies and data.

Financing

In the short term, it is crucial to ensure the ***viability*** of trial sites between major grants and studies. This can be achieved by identifying, profiling, and strengthening existing sites and leveraging them for new clinical trials through a coordinating mechanism at the continental level. Adopting a project-based approach to funding is recommended, as it allows for flexibility and minimizes the limitations imposed by co-funding requirements. However, there are structural and systemic challenges such as ***variances in indirect cost charges*** between North and South donors and institutions. To enhance sustainability, it is essential to ***link clinical trials to national priorities*** and conduct capacity and capability mapping to optimize sites, laboratories, and equipment.

In the medium and long term, a collaborative approach ***involving governments***, the ***private sector***, and ***public-private partnerships*** is crucial. Clinical trial centers should be ***government-funded*** and ***building investment and business cases*** for government financing of clinical trials can be achieved by highlighting the industrial policy sentiments of governments and emphasizing the life-saving impact of clinical research. Efficiency issues within the ecosystem need to be addressed (i.e., enable equipment use across trials even if purchased through funding from one trial), and opportunities arising from local manufacturing should be leveraged to drive research. ***Regional collaboration*** among institutions such as the Africa CDC, AUDA-NEPAD, AMA, African Continental Free Trade Area, and Africa Pharmaceutical Technology Fund is vital for strengthening institutional capacity, pooling resources, and addressing human resource needs. More sustainable financing can contribute to reducing brain drain and incentivizing students to consider a career in clinical research.

Equity, ***equitable access***, and ***excellence*** should be prioritized, considering funding attitudes and the capacity of the state to negotiate and engage with different stakeholders. Public-private partnerships, as exemplified by the COVID-19 experience, can be established to facilitate pool procurement approaches, with the role of development finance institutions, biotech companies, private capital, and venture capitalists being crucial. Developing a ***portfolio of financing options***, including dedicated funds such

as the Africa Epidemics Fund and the Africa Pharmaceutical Technology Fund, can ensure a steady commitment of resources to support research and clinical trials in Africa.

Priority solutions to strengthen the impact of financing for clinical trials include:
1. Establish a coordinating mechanism of networks to identify, profile, and strengthen existing sites and leverage them for new clinical trials.
2. Link clinical trials to national priorities.
3. Conduct capacity and capability mapping of clinical trials sites.
4. Build institutional capacity into funding for clinical trials.
5. Convene a political dialogue on health research as a health security agenda.
6. Build an investment case for government funding by AU member states.
7. Foster regional cooperation on research and clinical trials.
8. Facilitate public private partnerships.
9. Develop a portfolio of financing options for research and clinical trials.
10. Leverage Africa Epidemics Fund / Africa Pharmaceutical Technology Fund.

Harmonisation of Ethics and Regulatory Policies, Procedures and Guidelines

The biggest limitation in many countries is the ***lack of a strong legal framework for clinical trials***. ***Government commitment*** and ***political will*** are essential to address this challenge effectively. The role of AVAREF needs to be clarified, particularly in terms of capacity building and facilitating joint reviews. The main intention of AVAREF is to ensure timely processes while countries maintain accountability. Although AVAREF has put significant effort into creating templates, processes, inspection training, and capacity building initiatives, the implementation of these measures varies across different countries.

One significant bottleneck is the ***capacity of reviewers***, which needs to be addressed to expedite the review process. Several platforms have been established under the AMRH initiative, and once the AMA becomes functional, ***integration and leveraging of existing platforms*** will be easier. Providing funding incentives to encourage collaboration with AVAREF can help promote harmonious cooperation. Additional needs include a standardized protocol format, to include a summary page noting 'what is different' so that reviews may be streamlined and faster, review checklists, and training for reviewers to standardize their practices and reinforce predictability.

The ***accreditation of ethics committees*** is another area of concern, as different countries have varying acts and focus areas. There is a ***need for improved coordination*** between behavioral research, clinical trials, and ethical considerations. Enhancing communication and ***collaboration between ethics committees and national regulatory authorities*** is crucial for ***streamlining the review and approval processes***.

Priority solutions to improve policy harmonization include:
1. Align country legislative frameworks with continental recommendations.
2. Advocate for / discuss harmonization with governments (including ministries of health) to create political will.
3. Define legislation for member states to align ethics committees.
4. Utilise the AVAREF framework as best practices to strengthen regional expert working groups on clinical trial oversight.
5. Develop regional and country memorandums of understanding with AVAREF that ensure those who have access to tools that would benefit capacity building must utilize the tools, to maximize the effectiveness of joint reviews.
6. Expand guidance tools to include ethics committee guidance, particularly to address informed consent, recruitment practices, insurance, translations, material transfer, and data transfer agreements.
7. Anticipate continuous training needs to expand and replace capacity and develop career pathways.
8. Implement a post-review process.
9. Expand on potential efficiencies for clinical trials, linking other regulatory functions with clinical trial processes.
10. Re-invigorate the AVAREF forum, with the African Medicines Regulatory Authorities Conference convening a sideline meeting.

11. Clarify or (re)brand AVAREF in alignment with the launch and transition of AMA.
12. Invest in long-term sustainability of AVAREF structures beyond funding.

Community and Public Engagement

Funders often assume that if ethics committees approve clinical trial protocols, then community and public engagement (C/PE) has been adequately addressed. However, there is limited understanding of the degree and quality of Community Engagement. C/PE is often seen as following a "deficit" model, which is unidirectional and aimed at informing, recruiting, and retaining participants. In various contexts, C/PE is considered ***last in priority***, whether it be in presentations, budgeting, or agendas. Furthermore, it is often the ***first aspect to be reduced or dropped*** if there are budget cuts. There is a ***misconception that science communication fulfills the role of C/PE***, and public engagement is ***not always seen as important***. It is crucial to recognize that C/PE is distinct from science communication and should be delineated as separate fields of practice to facilitate better planning, budgeting, and implementation.

Additionally, there is a ***distinction between community engagement and public engagement***, which impacts the types, levels, magnitude, and outcomes of engagement (i.e., "Must Do" vs. "Smart to Do" vs. "Wise to Do"). To improve C/PE practices, there is a need for capacity strengthening among trialists, funders, and regulators. It is important to ensure the ***implementation of minimum standards for C/PE in clinical trials*** and track their progress, which can be done by medical monitors. We must also consider frameworks for good participatory practice that are disease and product agnostic, which can be tailored for any clinical trial (see **Figure 2**).

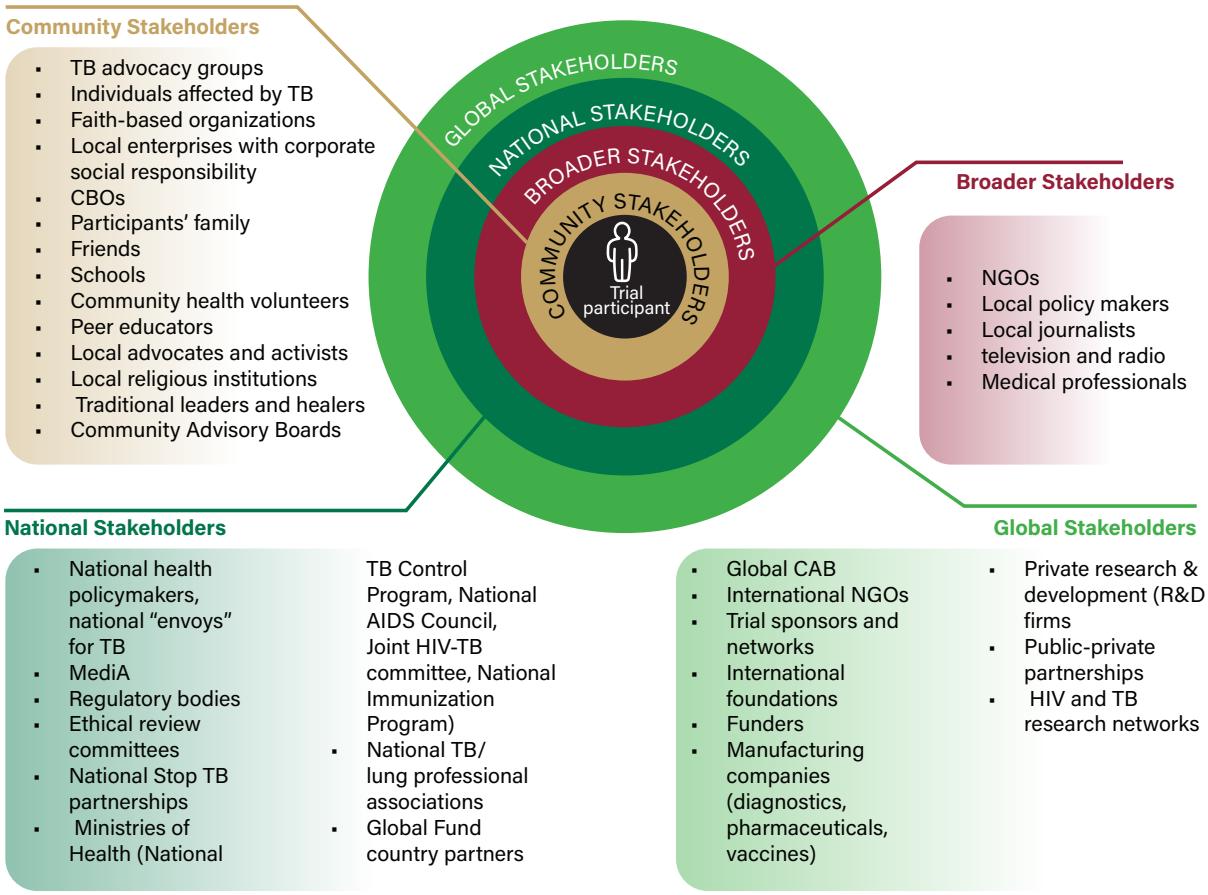
Priority solutions to improve community and public engagement include:

1. Develop a training curriculum to build capacity for C/PE among trialists, funders and regulators (and communities).
2. Identify and/or conduct a systematic literature review on effects of quality community engagement initiatives in clinical trials.
3. Implement funder requirement that trialists embed C/PE in funding proposals and reporting templates.
4. Create a glossary for C/PE.
5. Monitor and track C/PE by clinical trial medical monitors.
6. Link to C/PE minimum standards document and PACTR, which is the only Africa WHO primary registry in Africa, uploaded on funder and partner websites.
7. Scope and review existing C/PE guidelines to identify critical minimum standards for clinical trials that are not disease /condition specific.
8. Contribute to the ICH E-6 section to ensure C/PE is included, as well as contribute to the WHO guideline coming up for public consultation.

Figure 1: TB vaccine stakeholder layers.
The examples in each layer are generic and non-prescriptive. Research teams can use these categories as a framework for stakeholder identification and analysis.

Figure 2. The TB vaccine research framework for Good Participatory Practices

The examples in each layer are generic and non-prescriptive. Research teams can use these categories as a framework for stakeholder identification and analysis.



PLENARY SESSION: DONOR FINANCING AND PRIORITIES FOR CLINICAL TRIAL ECOSYSTEM STRENGTHENING

In a moderated discussion, clinical trial funders discussed funder priorities for strengthening the clinical trial ecosystem, including current investments, and opportunities for funder coordination and measuring impact for funding.

Stronger collaboration across funders and other stakeholders

There are various funding-related issues that need to be considered, particularly in relation to ethics. One aspect involves determining what costs are allowable and non-allowable within the context of clinical trials. Additionally, there are ethical considerations regarding donor transparency. While some donors may prefer to disclose their identity, others may wish to remain anonymous, posing challenges in maintaining transparency. Another aspect to address is the exclusion of certain donors, such as the sugar and tobacco industries, from contributing to clinical trials due to ethical concerns. Managing situations where these excluded entities express a desire to donate while remaining anonymous raises further ethical considerations. Furthermore, it is important to establish mechanisms for sustaining clinical trial sites during periods of peace or between pandemics. This may involve funding non-permanent staff and infrastructure to maintain capacity and deliver, ensuring that these resources can be leveraged in the event of another pandemic.

Measuring and evaluating the impact of funders' contributions and investments

The evaluation of impact extends beyond the number of publications and must focus on the quality of science, public health outcomes, ethical standards, local leadership and community support, and investments in human and laboratory capacity. The objective is to connect all these elements with other partners to maximize impact. Government commitment is crucial for long-term success, and funders engage by working with researchers to establish partnerships beyond crisis situations. To measure and enhance impact, it is essential to unite researchers, harness existing capacity, and involve those with lower capacity in collaborative efforts.

Strategies to increase public financing of research in Africa

It is crucial to challenge African countries to recognize that clinical trials are not just a health security issue but also a broader security concern, requiring a change in narrative and effective communication with leaders. Highlighting the job creation and career pathways potential and potential for reducing brain drain/increasing retention and emphasizing the importance of clinical trials for economic growth can help in persuading countries to allocate increased budgets for R&D. Additionally, engagement with influential individuals in the private sector who have a background in R&D is essential. Exploring opportunities for collaboration with these stakeholders can bring significant support and investment to the clinical trial ecosystem. Innovative financing vehicles, including community contributions and initiatives like the proposed airline tax, can also play a significant role in generating funds to support clinical trials, with potential support from donors and funders such as the EU, Gates Foundation, and the US. Ensuring efficiency and accountability is crucial.

Reducing duplication and costs related to "switch on and switch off" and "un-informativeness" of clinical trials

The World Health Assembly resolution on global clinical trials highlighted that the majority of the 18,000 COVID-19 clinical trials conducted were deemed ineffective, while a few had transformative outcomes. The clinical trials that successfully changed the dialogue involved key stakeholders, including delivery teams, governments, communities, and private sectors. It is essential for everyone to recognize the importance of clinical trials in identifying implementable interventions. Taking a collaborative and integrative approach is crucial for driving meaningful initiatives forward, such as the advancements in genomics in Africa. However, it is important to note that the involvement and support of African research institutions have been lacking in some discussions. Without genuine community engagement, we will miss out on the impact we aim to achieve.

Best capacity development strategy investments to leverage existing capacity

Efforts to build capacity on the African continent can have long-term sustainability and be utilized by other funders, as exemplified by IAVI's collaboration with the Partnership for Research on Ebola Vaccines in Liberia (PREVAIL) bioresearch center in Liberia for a Lassa vaccine trial. However, it is crucial for funders to collaborate and optimize the efficient use of committed and invested funds; there is currently a tendency for each funder to work in isolation. Taking the COVID-19 pandemic as a reference point, there is a pressing need to establish baseline capacity building for clinical research, which will enable Africa to take the lead in driving and sustaining clinical trials. Envisioning a future where Africa leads in this field and drives business to achieve sustainability is a key objective.

Lessons to derive from the EU's integrated science and innovation initiatives across many nations

The European Commission plays a dual role as a regulator and funder of clinical research, aiming to promote clinical excellence and collaboration across EU member states. The EU faces the challenge of maintaining its position as an attractive candidate for clinical trials, especially in emergencies. To address this, efforts are being made to establish multi-country clinical trials through networks, leverage innovative trial designs, foster a favorable regulatory environment, and coordinate funding and support for epidemic sponsors. The EU's research budget, though relatively small compared to individual countries' budgets, dedicates half of its funding to collaborative research, with a focus on encouraging international participation, particularly from low- and middle-income countries. In areas of common interest, such as rare diseases, the EU forms partnerships with member states. The EC also engages in formal partnerships with industry, promoting competitive research on diseases of significance. EDCTP operates on similar principles, aiming to create network clinical trials and enhance collaboration within Europe. The new

Global Health EDCTP3[1] program, with a budget of 1.6 billion Euros, is funded with contributions from the EU, participating countries, and other stakeholders such as industry and philanthropy. Through these initiatives, the EU aims not only to strengthen collaboration but also to learn from other regions to improve its own practices.

The potential for aggregated funding and joint execution model to strengthen impact and efficiency

There is a vision for a future where Africa CDC takes the lead rather than relying solely on funders. The power of public-private partnerships is widely recognized, particularly with the private sector in Africa. However, there are challenges to address, such as optimizing networks of networks and developing pipelines for all clinical trials, with Africa CDC and AU-NEPAD leading efforts to strengthen capacity. It is crucial to consider the execution model of clinical trials, prioritizing different levels and cost considerations. Donors must be committed to collaborating with other funders, listening to the leadership and coordination of the continent, and remaining flexible with their funding mechanisms. The aim is to shift the dynamics, with Africa taking the lead and all funders actively listening and driving the necessary change.

Donor co-funding of clinical trials

Funding should not be considered limited to money; other resources (such as the 'offering' of clinical trial sites and their in-house expertise and capacity) should be considered co-funding. There is a need to engage African member states in decisions of co-funding to ensure this addresses their needs and public health priorities. When there is clarity on the health research agenda, this will guide how partners and domestic funding can be used in a collective way that includes all stakeholders.

1 The Global Health EDCTP3 Joint Undertaking (Global Health EDCTP3)

Appendices

APPENDIX 1. MEETING AGENDA

Optimizing Efficiency and Impact in the African Clinical Trial Ecosystem

16-18 May, 2023
Radisson RED Cape Town

Meeting objectives

- Diagnose and develop a collective vision for strengthening the African clinical trial ecosystem to drive more impact.
- Co-design a roadmap to drive efficiency and optimal impact for clinical trial pipelines in line with global initiatives on clinical trials.
- Identify priority funding, areas of harmonization in policy and practices, and opportunities for meeting participants to contribute to strengthening the ecosystem.

Meeting agenda

	Monday, 15th May
18:00 - 20:00	Optional opening reception at Radisson Red Hotel
08:00 - 17:00	**Tuesday, 16th May**
08:00 - 08:30	**Registration**
08:30 - 09:00	**Introductions by all participants**
09:00 - 09:30	**Opening remarks: A vision for the future of the African clinical trial ecosystem**
	Shingai Machingaidze, Senior Science Officer, Africa CDC **Chimwemwe Chamdimba**, Principal Policy Specialist, AUDA NEPAD
09:30 - 11:00	**Plenary session: Framing the future of clinical trials to meet the needs of the African continent**
	Shingai Machingaidze, Africa CDC - Where are we and where do we want to go in Africa with clinical trials? **Dr Nick Chapman, Policy Cures** - Anticipated trials over the coming 5-10 years and examine how they align with African health priorities **Prof. Collet Dandara, University of Cape Town** - Suitability of the clinical trial pipeline and diversity to drive African R&D priorities **Thy Pham, Bill & Melinda Gates Foundation** - Efficiency, optimization, and sustainable impact in clinical trials Moderator: **Chimwemwe Chamdimba**, AUDA-NEPAD
11:00 - 11:30	**Tea Break**
11:30 - 13:00	**Plenary panel discussion: driving efficiency, impact and sustainability of the African clinical trial ecosystem - Perspectives from researchers**

	Prof. Francine Ntoumi, Congolese Foundation for Medical Research **Dr Elizabeth Spooner**, South African Medical Research Council (SAMRC) **Dr Helen Demerest**, Medicines for Malaria Venture (MMV) **Dr Huub Gelderbon**, HIV Vaccine Trials Network (HVTN) **Ndeye Dieynaba Drame**, Institut de Pasteur de Dakar (IPD) **Prof. Collen Masimirembwa**, African Institute of Biomedical Science and Technology (AiBST) **Prof. Carlo Giaquento,** UNIPD, PENTA **Moderator: Shingai Machingaidze**, Africa CDC
13:00 - 14:00	**Lunch**
14:00 - 14:10	**Group Photo**
14:10 - 14:30	**Keynote Address** **Africa CDC's vision for the future of the African clinical trial ecosystem** **H.E. Dr Jean Kaseya, Director General, Africa CDC**
14:30 - 15:45	**Plenary panel discussion: driving efficiency, impact and sustainability of the African clinical trial ecosystem - Perspectives from funders/sponsors**
	Dr Thomas Nyirenda, European and Developing Countries Clinical Trial Partnership (EDCTP) **Dr Mongezi Mdhuli**, South african Medical Research Council (SAMRC) **Prof Charles Wiysonge**, Global Research Collaboration for Infectious Disease Preparedness (GLoPID-R) **Dr Christof Vennemeier**, Coalition for Epidemic Preparedness Innovations (CEPI) **Dirk Gille**, Johnson and Johnson (J&J) (TBC) **Dr Vasee Morthy**, World Health Organization (WHO) **Lindie Rothmann**, Novartis (TBC) **Moderator: Jens Pedersen**, Africa First Advisory
15:45 - 16:00	**Tea Break**
16:00 - 16:45	**Plenary discussion:** Proposed solutions for driving efficiency, impact and sustainability
	Faith Nfii, Africa CDC - Summary of challenges and solutions for driving efficiency, impact and sustainability of the African clinical trial ecosystem **Moderator: Shingai Machingaidze**, Africa CDC
16:45 - 17:00	**Closing remarks** **Dr Jean Kaseya**, Africa CDC
08:30 – 16:00	**Wednesday, 17th May**
08:30 - 09:00	**Recap of Day 1** **Chimwemwe Chamndimba, AUDA NEPAD**
09:00 - 11:00	**Plenary session: Partner presentations on Working Group Thematic Areas**

	Adriaan Kruger, nuvoteQ.io - Data for clinical trial measurement and evaluation **Sue Bailey, IQVIA** - Opportunities for reducing costs and time and increasing quality of clinical trials **Michael Landau, CTI-LifeHealth** - Harnessing digital technologies for clinical trial efficiencies **Dr Alambo Mssusa, WHO AVAREF** - Harmonization of clinical research policies and practices **Prof. Souleyman Mboup, IRRESEF** - The value of networks in building research capacity in Africa **Ntando Yola, Desmond Tutu Foundation** - Strengthening community and public engagement in clinical research (TBC) **Moderator: Thy Pham**, BMGF
11:00 - 11:30	**Tea break**
11:30 - 13:00	**Working Groups: Align on future vision for thematic areas and develop proposed solutions, actions, and measurable achievements**

1. **Clinical trial design**. What innovations in clinical trial design are needed (e.g., novel design, new techniques for gathering data, etc.)? How can clinical trial networks/research centers be prepared to adopt new approaches to clinical trial design?
   Working Group Leads: Dr Elizabeth Spooner, SAMRC
   Marisa Russell, IAVI
   Facilitator: **Thy Pham**, BMGF

2. **Capacity development**. What capacity development issues are not addressed by current initiatives? How can we retain clinical trial capacity at research centers in between grants/major trials?
   Working Group Leads: Prof Collen Misimirembwa, AIBST
   Prof Fred Binka, MCTA
   Facilitator: **Faith Nfii**, Africa CDC

3. **Network issues.** How are network members working together effectively, and where are there challenges? How do distinct networks connect with each other?
   Working Group Leads: Dr Duncan Chanda, TESA Network
   Prof Trudie Lang, TGHN
   Facilitator: **Michelle Nderu**, EDCTP

4. **Digital technologies for clinical trials**. How can digital technologies be utilised to harmonize clinical trial activities better?
   Working Group Lead: Caxton Murira,Science for Africa Foundation
   Facilitator: **Dr Elvis Temfack**, Africa CDC

5. **Financing**. What financing models can be employed to retain trial site viability in between major grants/trials?
   Working Group Lead: Dr Abebe Genetu, Africa CDC
   Facilitator: **Bahati Ngongo**, BMGF

6. **Harmonization of ethics and regulatory policies, procedures, and guidelines**. What policies need to be harmonized?
   Working Group Lead: Dr Alambo Mssusa, AVAREF/WHO AFRO
   Facilitators: **Nuraan Fakier**, EDCTP
   Boitumelo Mokgatla, AUDA NEPAD, GIZ
7. **Community and public engagement**. How do we ensure that patients' and communities' needs are central to clinical trial design and implementation?
   Working Groups Leads: Lillian Mutengu, Science for Africa Foundation
   Maimouna Diop Ly, Speak Up Africa
   Facilitator: **Dr Duduzile Ndwandwe**, PACTR, SAMRC

13:00 - 14:00	**Lunch**
14:00 - 15:30	**Working Groups *continued***
15:30 - 16:00	**Tea break and Networking**

08:30 – 17:00	**Thursday, 18th May**
08:30 - 11:00	**Plenary session: Presentations from working groups** ▪ Presentations by each thematic working group **Moderator: Chimwemwe Chamdimba**, AUDA NEPAD
11:00 - 11:30	**Tea Break**
11:30 - 13:00	**Plenary session: Donor financing and priorities for clinical trial ecosystem strengthening** ▪ Funder priorities for strengthening the clinical trial ecosystem, including current investments ▪ Opportunities for funder coordination and measuring impact for funding **Dr Mongezi Mdhuli**, South African Medical Research Council (SAMRC) **Dr Vasee Morthy**, World Health Organization (WHO) **Marisa Russell**, IAVI (TBC) **Sophia Siddiqui**, Embassy of the United States/ NIH **Jan Paehler**, European Commission/ EDCTP 3 Global Health **Bahati Ngongo**, Bill & Melinda Gates Foundation (BMGF) **H.E. Dr Jean Kaseya**, Africa CDC **Moderator: Dr Thomas Nyirenda**, EDCTP
13:00 - 14:00	**Lunch**
14:00 - 15:30	**Plenary session: Streamline and prioritize solutions developed by working groups** Working session to streamline recommendations for each thematic area **Moderator: Shingai Machingaidze**, Africa CDC
15:30 - 16:00	**Tea Break**
16:00 - 16:45	**Feedback on the workshop and proposed approach to improving the African clinical trials ecosystem** All participants
16:45 - 17:00	**Closing Remarks** **Chimwemwe Chamdimba**, AUDA NEPAD **Shingai Machingaidze**, Africa CDC

APPENDIX 2. MEETING PARTICIPANTS

Name	Organization
Abebe Genetu	Africa CDC
Adriaan Kruger	nuvoteQ.io
Akhona Tshangela	Africa CDC
Alambo Mssusa	WHO AVAREF
Bahati Ngongo	Bill & Melinda Gates Foundation
Bernard Kikaire	East Africa Consortium for Clinical Research
Boitumelo Mokgatla	GIZ/AUDA-NEPAD
Carlo Giaquinto	UNIPD
Caroline Forkin	CEPI
Caxton Murira	Science for Africa Foundation
Charles Wiysonge	South Africa Medical Research Council
Chimwemwe Chamdimba	AUDA-NEPAD
Chris Obwanga	IQVIA
Christof Vinnemeier	CEPI
Collen Masimirembwa	African Institute of Biomedical Science and Technology
Collet Dandara	University of Cape Town
Dirk Gille	Johnson and Johnson
Dudu Ndwandwe	South Africa Medical Research Council
Duncan Chanda	University Teaching Hospital, HIV/AIDS Program
Elizabeth Spooner	South Africa Medical Research Council
Elvis Temfack	Africa CDC
Faith Kiyuka	Science for Africa Foundation
Faith Nfii	Africa CDC
Fred Binka	University of Health and Allied Sciences
Funda Celikel-Esser	European Union
Glenda Gray	South Africa Medical Research Council
Hassen Ghannem	University of Sousse, Tunisia
Helen Demarest	Medicines for Malaria Venture
Huub Gelderblom	HIV Vaccine Trials Network
Ibraheem Sanusi	GIZ Office to the African Union
Jan Paehler	European Commission
Jens Pedersen	Africa CDC
Kaitlin Christenson	Global Health Visions (supporting Gates Foundation)
Kirsten Stevenson	Bill & Melinda Gates Foundation

Name	Organization
Lillian Mutengu	Science for Africa Foundation
Lindie Rothmann	Novartis
Maimouna Diop Ly	Speak Up Africa
Marisa Russell	IAVI
Mariska Louw	EDCTP
Matshidiso Masire	Bill & Melinda Gates Foundation
Michael Landau	CTI-LifeHealth
Michelle Nderu	EDCTP
Mongezi Mdhluli	South Africa Medical Research Council
Nandi Siegfried	South Africa Medical Research Council
Ndeye Dieynaba Drame	Institut Pasteur of Dakar
Nick Chapman	Policy Cures Research
Ntando Yola	Desmond Tutu Foundation
Nuraan Fakier	EDCTP
Shingai Machingaidze	Africa CDC
Sibusiso Hlatjwako	PATH
Sophia Siddiqui	Embassy of the United States/National Institutes of Health
Souleymane Mboup	Institute of Health Research Epidemiological Surveillance and Trainings
Sue Bailey	IQVIA
Tadesse Mikonen	Avacare Global
Thy Pham	Bill & Melinda Gates Foundation
Tom Nyirenda	EDCTP
Trudie Lang	The Global Health Network
Vasee Morthy	WHO
Vidette Zeeman	Novartis

APPENDIX 3. COMPENDIUM OF PROPOSED SOLUTIONS

Theme	Solutions/actions	Lead	Rationale	Metrics
Innovative Clinical Trial Design	Equipping (e.g., training, policies) stakeholders to adopt innovative and streamlined clinical trial designs including: - Clear questions with matching trial design - Simple, efficient and only essential elements - Early engagement with regulators, healthcare professionals and community	Investigators and institutions to implement. governing public health authority (e.g., WHO, Africa-CDC, AMA, national MoHs) to enable and facilitate	Faster product development; Avoid unclear objectives, unnecessary complexity and unfeasible implementation	- Number of trainings conducted / policy papers / guidelines on the topic - Delayed timeline trends - Completed clinical trials with no results reported in clinical trials registries
Innovative Clinical Trial Design	Advocate for increased adoption of technology in clinical trials Implementation and use of adaptive clinical trials platforms	- Investigators and institutions - Funders and Sponsors promote - Sponsor & investigators adopt - Regulatory acceptance - Funders (to support cost-effective study design)	Adoption of technology for speed, efficiency, quality and cost of clinical trials Need for timely decision on promising vs failing candidates in trials	Trend in type of technology used in clinical trials over time
Innovative Clinical Trial Design	Implementation of Electronic Health Records	Africa CDC (continental) national MoH's (country) AUDA-NEPAD	Access to epidemiology data to enable better informed trial design	Number of health centers adopting EHRs by country and continent
Capacity Development	Clinical Unit infrastructure	Africa CDC - AMA	Established sites are not known/recognized contributing to underutilization	1.Number of phase 1 studies/ year 2. Diversity of phase 1 studies (First in man, BE, bridging, etc.)
Capacity Development	Accredited Research pharmacies	African CDC	Required in association with Clinical Unit	

Theme	Solutions/actions	Lead	Rationale	Metrics
Capacity Development	Registered Clinical laboratories	African CDC	Leverage registered clinical laboratory Clinical units can access	
Capacity Development	Leverage existing infrastructure to support (diagnostic/monitoring) in other therapeutic areas	Africa CDC	Africa increasing clinical trial pipeline beyond infectious diseases	1.Number of phase 2/3 studies/year on NCD interventions 2. Ratio of infectious diseases to NCD clinical trials done
Capacity Development	Training to support other lab capacity in other therapeutic areas		Current workforce mostly focused Infectious Diseases	
Capacity Development	Engaging private sector (pharmaceutical and biotech companies)			
Capacity Development	Laboratory Infrastructure that can support clinical studies with bioanalysis and next generation sequencing and bioinformatics analysis	Africa CDC	Pharmacokinetic / pharmacodynamic endpoints depend on measuring clinical and drug exposure. Most studies currently sent sample abroad for bioanalysis Host and pathogen genomics have gained increased value in the design and conduct of clinical studies. Currently they are most done outside Africa.	Reduction in # of exported samples
Capacity Development	Consolidated fund raising (Strategic) to establish and/or upgrade for accreditation	Africa CDC	Cost of establishing and maintaining bioanalytic and genomic laboratories is very high. Need to establish Centers of Excellence	Capacity building to reduce burden on individual researchers/institution
Capacity Development	Digitalizing the collection, processing, analyses and sharing of clinical and genomic data	Africa CDC – AMA AUDA-NEPAD	Information from these data allows us to capture the target populations & subgroups. Such databases will inform the safety and efficacy of medical interventions in African populations	1.ML/AI solutions
Capacity Development	Standardized data formats	AUDA-NEPAD	Allow ease of collaboration	1. Standardised data formats
Capacity Development	ICT infrastructure		To enable the efficient and reliable digitalization of clinical trials	1.Security 2.Storage conclaves

Theme	Solutions/actions	Lead	Rationale	Metrics
Capacity Development	Enhance product development in Africa through the establishment drug discovery centers	Africa CDC	Clinical development needs input of product to test for efficacy and safety so developing Clinical Trial capacity without a supply of products to test is not viable. As long as the Clinical trial ecosystem depends on external products, it's not possible to guarantee its viability.	In the short term, more diagnostic tests and medical devices and in the long term, more drugs and vaccines discovered and developed in Africa
Capacity Development	Developing of an African genetic diversity, targeted drug profile framework	Africa CDC AUDA-NEPAD	Genomics is now a recognized key player in product discovery where population variability translates to different product safety and efficacies. African genomic diversity has been established to be the greatest among human populations and there is increasing evidence that this is associated with clinically significant differences in drug responses with respect to safety and efficacy. It is therefore urgent that we harness African populations genomic diversity in the formulation of a TPP framework for the discovery and development of medical interventions	Increase Medical products with clinical use information informed by genetic variation at individual and population level
Capacity Development	Training curriculum to support discovery – preclinical before the start of first in human	Africa CDC	There is currently very low capacity for medical product discovery and development in Africa. This means that Africa cannot determine its capacity in both time and extent to address its healthcare burden as this is left to the planning and prioritization of the Global North. This is clearly unacceptable. The development and deployment of product discovery and development training program is needed	Increased number of scientists in pharmaceutical and health products discovery and development

Theme	Solutions/actions	Lead	Rationale	Metrics
Capacity Development	Funding for product discovery and development		Limited funders in product discovery and development given its high risk. A translational research model where grants can be used to initiate and de-risk projects for them to attract venture capital needs to be developed and deployed.	Product R&D ecosystem established
Capacity Development	Training of Clinical Trial leaders		Most sites have one or few dominant leaders with no alternative or succession plan. Succession plans required to make Clinical Centers sustainable	More Clinical study PI to both ensure sustainability and in response to the anticipated increase in clinical trials due to built capacity
Capacity Development	Certification of training curriculum of clinical trial support stuff such as data captures, nurses, etc.		There currently is no official training besides the short few days GCP training for personnel	Increased number of clinical personnel undertaking accredited training
Capacity Development	Diversify source and funding of clinical trials to include grant funded public good with private sector commercial trials	Africa CDC	Grants funded clinical trials are driven by public good of funders whereas private sector funded studies are business driven, thus a good balance likely to make clinical centers sustainable	Financial viability of clinical trial centers established
Capacity Development	Regulation such that Clinical studies have to be done in target populations		Clinical development of most drugs on the market was done in European populations and their safety and efficacy extrapolated to African populations. Studies and subsequent regulation developed in Japan and China showed that for many drugs such generalizations cannot be done hence the requirement by Japanese and Chinese authorities to have clinical studies done in their populations as well. It is not acceptable that safety and efficacy is not established before registration and use of medicines in Africa.	Increased number of clinical studies in Africa associated with better utilization of centers and increased profitability and viability

Theme	Solutions/actions	Lead	Rationale	Metrics
Capacity Development	Translations of scientific knowledge in key local languages		Many non-English speaking countries still use English as the scientific medium but make significant effort to translate most scientific literature into their languages to better understand the science and to effectively share it with their populations. Lack of such practice potentially compromises the understanding of science by African sciences and by general public in Africa	Number of translations and/or original scientific writing in African languages
Capacity Development			It is not for African to keep fighting over which colonial language to use. English just happens to be the colonial language even the `Europeans tend to use among themselves for scientific publication	
Capacity Development	Support of creative works that seek to 'invent' local language terminology for scientific processes		Most African languages had not formalized their languages to match advances in science and technology hence lack words for many items and processes.	Creation of new words, expressions and processes
Network issues	Networks supporting all forms of health research to enable strong research centers to undertake excellent clinical trials	Africa CDC / AFRO? Pan continent	Builds whole ecosystems and generates data to guide clinical trials AND tackle diseases = Benefits community and addresses the Sustainable Development Goals	Functioning networks with terms of reference & business plan for incremental growth
Network issues	Networks serve to strengthen research systems and delivery of faster and better clinical trials by sharing best-practice, research and data science tools, methods and systems to be taken up and used by others	All the partners: needs to be open, democratic, decentralized with a governance structure that is supported by stakeholders including governments	Reduce duplication, drive production of better evidence, prove ability for delivering quality data. Internationally competitive	New evidence Stronger teams = diverse income

Theme	Solutions/actions	Lead	Rationale	Metrics
Network issues	Networks should have quantifiable outcome measures (indicators) that are recognised and valued by stakeholders	Working group that includes various funders experts (CEPI/ BMGF/ EDCTP/GH EDCTP3 NIH/ EU)	Most funders are set up for supporting primary research. Need to quantify the value of enabling research systems - taking up new methods	Agreed outcomes measures for networks and projects that are research enabling activities
Network issues	Networks delivering and supporting coordinated research skills training and career development that is work-place based, learning-by-doing to foster strong, diverse and lasting teams within programmes	The Global Health Network Africa = Africa CDC and WHO /AFRO/ TDR	Need to develop research systems in health systems and this needs teams comprising all the required skills and able to lead and responsibly manage complex programs	The TDR professional development scheme that measures research skills competencies and change over time and TDR essential curriculum
Network issues	Networks should support evolution towards the development and adoption of standards of African accreditation or certification systems that are recognised by International regulatory bodies	African Organisation for Standardisation – standardization, research ecosystem management AMA – regulatory bodies	Trusted and recognized globally for quality research	New Africa standards for areas where these are needed – labs, trial centers, data services?
Digital technologies for clinical trials	Practical solutions from a tech perspective (eRecruitment, eConsent, eFeasibilities) Use of enabling data sources: ICTRP, ctc.Africa , World Health, G-FINDER	Tech companies, Technology Vendors, Service Providers (CROs, Clinics, Logistics, etc.) AUDA-NEPAD	Need for efficiency for activities under the clinical trials process	Adoption of standardized / harmonized approaches to building digital tech solutions Use of tech to drive cost of clinical trials – use of open software (RedCap)

Theme	Solutions/actions	Lead	Rationale	Metrics
Digital technologies for clinical trials	Legislations and Policies that govern use of digital technologies, data (GDPR, POPIA, Global regulations)	WHO, Africa CDC, NGOs, Community and Public	Health emergency considerations Industry Standards Digital use regulations Legal considerations Frameworks	Harmonized in country and continental Legislations on digital technologies for conducting clinical trials. Standardization of data frameworks for access, storage, use and reuse
Digital technologies for clinical trials	Supporting Infrastructure to support the digital technologies and data	Tech companies, Technology Vendors, governments, Africa CDC	Data storage infrastructure Hosting infrastructure Interoperability of digital technology	Interoperability and harmonized outputs from digital health solutions Accommodative Data Management and data Sharing Plans Having digital evidence that can influence policy change
Financing	Coordinating Mechanism of Networks - Identify, profile, and strengthen existing sites and leverage them for new clinical trials	Africa CDC	Reduce duplication and increase synergies within the ecosystem	Comprehensive Mapping or a Clinical Trial Observatory
Financing	Linking clinical trials to national priorities	Networks, National Research Institutes, Africa CDC	Ensure visibility of product pipeline, research relevance and build in sustainability for clinical trials sites etc.	Visibility of Product Pipelines at National, Regional and Continental levels
Financing	Capacity and Capability Mapping of clinical trials sites	Africa CDC, RECs, Networks	Optimal usage of sites, resources and reducing wastes. The need for sites designed for multiple research potentials	Comprehensive Mapping or a Clinical Trial Capabilities in Africa
Financing	Building Institutional Capacity into funding for clinical trials	Funders	Variances in the indirect cost percentages in the North/South as well as challenges with currency variations etc.	Increase in core institutional funding for clinical trials networks and sites

Theme	Solutions/actions	Lead	Rationale	Metrics
Financing	Political Dialogue on Health Research as a Health Security Agenda	Africa CDC	Sustainable financing for science and clinical trials and Research in Africa	AU Assembly Decision on Africa Research Priorities and dedicated funding from the Africa Epidemics Fund
Financing	Building an investment case for Government Funding in AU Member States	Africa CDC, AMA, AUDA-NEPAD, African Pharmaceutical Technology Foundation, AU Member States	Leveraging Industrial Policy sentiments and the local vaccine and medical product manufacturing	Business Case Model for Clinical Trials in Africa
Financing	Fostering Regional Cooperation on Research and clinical trials	Africa CDC, AUDA-NEPAD, AMA, African Continental Free Trade Area , African Pharmaceutical Technology Foundation	The need for pooled approaches and Multi-Country Mechanisms for collaboration on Human Resources (Clinical Trial Monitors etc.), Funding	Number of Multi-Country Research and Clinical trials
Financing	Facilitating Public Private Partnerships	Africa CDC	Leveraging private capital for research and clinical trials	Africa CDC / Private Sector Coalition for Health Research and Clinical Trials
Financing	Developing a portfolio of financing options for research and clinical trials	Africa CDC, AUDA-NEPAD	Providing guidance to National Research Institutes and CTCs	Guidance Note on Financing Options for Research and clinical trials in Africa
Financing	Leveraging Africa Epidemics Fund / Africa Pharmaceutical Technology Fund	Africa CDC / African Pharmaceutical Technology Foundation	Building homegrown capacity to fund research and clinical trials in Africa	AU Assembly Decision on Africa Research Priorities and dedicated funding from the Africa Epidemics Fund

Theme	Solutions/actions	Lead	Rationale	Metrics
Harmonization of ethics and regulatory policies, procedures, and guidelines	Align country legislation framework with continental recommendations. Advocacy / Dialogue with governments/ MOH to create political will	AMRH/AMA – Technical committee on medicines policy and regulatory reforms	Need policies, acts and regulations so the inclination doesn't change with personnel changes Utilize the update opportunity to incorporate pandemic preparedness/ emergency authorization/ reliance legislation	WHO Global benchmarking tool – maturity levels. 5/55 countries currently have maturity level 3 for the clinical trial function. AU model law implementation. Currently 13/55 countries.
Harmonization of ethics and regulatory policies, procedures, and guidelines	Define legislation for member states to align ethics committees	AMRH/AMA – Technical committee on medicines policy and regulatory reforms	Build on existing structures to close the gap in ethics structures governance in member states	To be defined in the model that needs to be adopted. Possibly the WHO Global Benchmarking Tool to be utilised.
Harmonization of ethics and regulatory policies, procedures, and guidelines	Utilise the framework that AVAREF have created as best practices to strengthen regional expert working groups on clinical trial oversight. Agree regional and country memorandums of understanding with AVAREF that those who benefit from capacity building must utilise the tools.	AMRH/ AMA/ AVAREF	Uptake of tools and implementation in practice is happening inconsistently. Already established effort with successful case studies to convince. Respond to financial concerns of review bodies.	Increase the number of participating countries in joint review activities. Currently 24 countries. Adherence of countries to the agreed timelines. Track the timelines, currently manually collated in excel with country feedback. Potential to automate to a dashboard.
Harmonization of ethics and regulatory policies, procedures, and guidelines	Expand guidance tools to include Ethics committee guidance. Particularly to address informed consent, recruitment practices, insurance, translations, material transfer, data transfer agreements	AVAREF and multi-regional clinical trial working group	Availability and uptake of the tools	Availability and uptake of the tools

Theme	Solutions/actions	Lead	Rationale	Metrics
Harmonization of ethics and regulatory policies, procedures, and guidelines	Anticipate continuous training needs to expand and replace capacity and develop career pathways	AVAREF. Connect/ embed with RCOREs, AMRH platform (Need to ensure training from RCOREs is appropriately priced) Development/ Utilise more mature countries to capacity build in less mature countries	To have a good workforce management and training plan.	Systematic approach to who is training, who is trained and what the outcome is. Improve reviewer availability
Harmonization of ethics and regulatory policies, procedures, and guidelines	Post review process to be implemented.	AVAREF May collaborate with African Union Smart Safety Surveillance safety monitoring.	Oversight is critical for patient safety. Amendments to be included in joint review. Recent guidance on safety reporting has been established. Needs to be done at country level and reported jointly within the timelines.	Utilise the PACTR to update the outcome – very NB for funders, participants and driving outcomes.
Harmonization of ethics and regulatory policies, procedures, and guidelines	Expand on potential efficiencies for clinical trials, linking other regulatory functions with clinical trial processes.	AVAREF	Challenges with additional departments for trial approvals can be significant delays. Import/Export logistics a challenge Advocate for simplification and technical support for some countries	Timelines for import/export licenses for IMPs
Harmonization of ethics and regulatory policies, procedures, and guidelines	Re-invigorate forum. African Medicines Regulatory Authorities Conference (AMRAC) convening sideline meeting	AVAREF/ AMRAC	Forum for sharing successes, process improvement pan continental	Number of forums annually/ biannual
Harmonization of ethics and regulatory policies, procedures, and guidelines	Clarify or (Re)brand AVAREF, aligned with transition to AMA	AVAREF / AMA	Vaccine nomenclature is misleading	

Theme	Solutions/actions	Lead	Rationale	Metrics
Harmonization of ethics and regulatory policies, procedures, and guidelines	Long-term sustainability of AVAREF structures beyond funding	WHO/ AVAREF/ AMA		
Community and public engagement	Developing a training curriculum to build capacity for C/PE among trialists, funders and regulators (and communities)	Africa CDC to conduct partner assessment to identify key task lead	C/PE is poorly understood, hence not prioritized, budgeted for or delivered in a meaningful manner. A curriculum will help trialists, funders and regulators address confusion, fund, plan and deliver better	Training curriculum developed
Community and public engagement	Identify and/or conduct a systematic literature review on effects of quality CEI in CTs	Africa CDC to conduct partner assessment to identify key task lead	There is dismal evidence based on C/PE. There is a need to begin to deliberately build this to inform policy, funding gaps, minimum standards. A quick search of the literature reveals 2 relevant systematic reviews on C/PE	# of publications on C/PE identified, research areas covered
Community and public engagement	Funders should require trialists to embed C/PE in funding proposals and reporting templates	Africa CDC to conduct partner assessment to identify key task lead	Majority of clinical trials are funded externally. Funders have an obligation to facilitate embedding C/PE by making it a requirement	# of funders requiring C/PE as part of application submission and reporting
Community and public engagement	Create a glossary for C/PE	Africa CDC to conduct partner assessment to identify key task lead	To facilitate meaningful discussion, we need to have common understanding of terminology regarding C/PE	Glossary developed A link to partner and funder websites and knowledge transfer platforms
Community and public engagement	Clinical trial medical monitors to track C/PE	Africa CDC to conduct partner assessment to identify key task lead	Share resources based on the AVAREF Model of reciprocal clinical trial monitoring	Number of medical monitor groups that include C/PE as an indicator in their tracking forms

Theme	Solutions/actions	Lead	Rationale	Metrics
Community and public engagement	Link for C/PE minimum standards document and the Pan African Clinical Trial Registry (PACTR), which is the only Africa WHO primary registry in Africa, uploaded on funder and partner websites	Africa CDC to conduct partner assessment to identify key task lead		C/PE minimum standards document link developed and shared Link to PACTR clinical trial registry developed and shared # of partners and funders with links on their websites/platforms
Community and public engagement	Scoping and review of existing C/PE guidelines to identify critical minimum standards for CT that are not disease specific, situation specific	Africa CDC to conduct partner assessment to identify key task lead	The key principles and tenets for meaningful C/PE are the same, yet we have numerous and bulky guidelines that are disease specific or situation specific, creating confusion and fatigue for trialists	A Minimum standards document for trialists developed and adopted by trialists, funders, regulators.
Community and public engagement	How to contribute to the ICH E-6 section to ensure C/PE is included, as well as contribute to the WHO guideline coming up for public consultation.	Africa CDC to conduct partner assessment to identify key task lead	This is critical in including community engagement in these accepted guidelines for the conduct of clinical research	Community expert's involvement in the discussions

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