



Research Preparedness Ecosystem Engagement Workshop Report

Advancing Research Capacity in West Africa (ARC-WA)

25th – 27th June 2024

Pullman Dakar Teranga Hotel, Senegal

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LIST OF ABBREVIATIONS

Africa CDC	Africa Centres for Disease Control and Prevention
ARC-WA	Advancing Research Capacity in West Africa
AFENET	African Field Epidemiology Network
AVAREF	African Vaccine Regulatory Forum
BMGF	The Bill & Melinda Gates Foundation
BNITM	Bernhard Nocht Institute for Tropical Medicine
CEPI	The Coalition for Epidemic Preparedness Innovations
COVID-19	Coronavirus disease 2019
ECOWAS	Economic Community of West African States
EDCTP	The European and Developing Countries Clinical Trials Partnership
GAVI	Global Alliance for Vaccines and Immunization
GIZ	The Deutsche Gesellschaft für Internationale Zusammenarbeit
IPD	Institut Pasteur de Dakar
IVI	International Vaccine Institute
MRCG	Medical Research Council Unit The Gambia at the London School of Hygiene and Tropical Medicine
MSF	Médecins Sans Frontières
NGO	Non-governmental organisation
NCDC	Nigeria Centre for Disease Control and Prevention
PREVAIL	Partnership for Research on Vaccines and Infectious Diseases in Liberia
RCSDC	Regional Centre for Surveillance and Disease Control
TCP	Technical Coordinating Partner
TWG	Technical Working Group
UNDP	United Nations Development Programme
UNICEF	United Nations Children's Fund
US CDC	United States Centers for Disease Control and Prevention
USAID	United States Agency for International Development
WAHO	West African Health Organization
WANETAM	West African Network for Tuberculosis, AIDS and Malaria
WHO AFRO	World Health Organization Regional Office for Africa

1. BACKGROUND

The Ebola epidemic and COVID-19 pandemic in West Africa exposed significant weaknesses in the region's health systems, particularly in disease surveillance, preparedness, and response to public health emergencies. These crises also highlighted the critical need for collaboration among various sectors, including government agencies, healthcare systems, NGOs, academia, and the private sector, to ensure that countries in the region can respond effectively to such emergencies.

The Advancing Research Capacity in West Africa (ARC-WA) project aims to strengthen clinical research capacity for rapid outbreak response, addressing the growing threat of emerging and re-emerging diseases with epidemic potential. This initiative, funded by the Coalition for Emergency Preparedness Innovations (CEPI) and facilitated by the International Vaccine Institute (IVI) and the Medical Research Council Unit The Gambia (MRCG) as the Technical Coordinating Partner (TCP), seeks to improve the readiness of research systems for the rapid generation of clinical evidence for routine and emergency vaccine development and use, in alignment with CEPI's 100-day mission. This mission is "to respond to the next Disease X by compressing the development of safe, effective, globally accessible vaccines to as little as 100 days".¹

To develop the plans for a locally relevant and effective research preparedness and response programme, a workshop was held, which aimed to gather diverse stakeholders from West Africa to discuss challenges and strategies for outbreak preparedness and evidence-generation readiness across the region. Due to the diversity of stakeholders and the geographic scope of the project, the invitee list was not intended to be comprehensive but rather to gather individuals from different sectors and locations with a focus on the countries involved in the initial work of ARC-WA related to Lassa fever trial preparedness. A second workshop will build on these findings.

Workshop Objectives

The workshop aimed to:

- a) Further understand the research preparedness landscape to develop effective and comprehensive strategies to:
 - Identify key stakeholders (clinical trial facilities, academic institutions, pre-existing clinical trial networks and initiatives, local, national, and regional authorities).
 - Understand existing capacities and gaps.
 - Understand national and regional coordination mechanisms and networks that advance health emergency preparedness and response efforts.
 - Understand national policies/programs/priorities that drive decision-making processes.
- b) Validate and complement emerging stakeholder and landscape analysis findings.
- c) Test ideas and develop new strategies for an engagement plan and future meetings required to move this forward.

2. OVERVIEW OF WORKSHOP

The three-day workshop took place from 25-27 June 2024, at the Pullman Dakar Teranga Hotel in Dakar, Senegal. It was attended by 54 participants, including public health researchers and practitioners from nine West African countries and representatives from CEPI and the TCP (IVI and MRCG) (see Appendix A for the full list of participants).

¹ <https://cepi.net/cepi-20-and-100-days-mission> (Accessed 08 August 2024)

Breakout sessions were used to facilitate brainstorming, maximize participant engagement, and elicit inputs from participating stakeholders. The workshop agenda is provided in Appendix B. Participants discussed the key stakeholders and systems required for emergency evidence generation preparedness and response across the region, effective strategies for engaging in-country and regional stakeholders to strengthen existing systems, and prerequisites for rapidly implementing clinical trials in case of an outbreak. The workshop outputs validated and complemented data gathered from an initial stakeholder and landscape analysis conducted by the TCP.

3. OPENING AND INTRODUCTION TO THE RESEARCH PREPAREDNESS PROGRAMME

Participants were welcomed by the TCP team, who shared the objectives of the workshop. Dr. Christoff Vinnemeier from CEPI then shared the vision of the Research Preparedness Programme. He emphasized that evidence generation readiness is critical for catalyzing rapid implementation of clinical research during an outbreak to achieve CEPI's 100-days mission. He explained that the Research Preparedness Programme is a multi-regional programme, with an initial focus on West Africa comprising two tracks:

- Track A: Strengthening routine clinical research preparedness during inter-epidemic period, with an initial focus on Lassa fever.
- Track B: Strengthening emergency evidence generation preparedness for any future outbreak.

The programme aims to leverage regional guidance, local ownership, alignment with national priorities, and long-term strategies to strengthen research systems that will support rapid clinical trials towards achieving CEPI's 100-day mission.

Dr. Elvis Temfack, a Senior Research Officer at the Africa CDC, in a virtual presentation, reiterated the Africa CDC's commitment to strengthening Africa's public health systems to ensure timely detection and response to outbreaks. He reported that 166 public health outbreaks were reported to the Africa CDC in 2023 (an average of three events per week), giving a clear picture of the health emergency situation on the continent. He emphasized that Africa CDC is willing to partner with organisations on initiatives that will enable an effective response to diseases. Dr. Temfack highlighted that the Research Preparedness Programme will significantly support Africa CDC's plans to implement a three-tier "hub-and-spoke" model for clinical trial sites across the continent.

4. RESEARCH PREPAREDNESS LANDSCAPE IN WEST AFRICA

Workshop participants shared insights during group discussions, on the existing structures, systems, infrastructure and mechanisms for coordinating outbreak preparedness and response in their countries. The key points included:

- a) **Governance:** In most countries, the Ministry of Health (or equivalent) oversees emergency preparedness and response coordination. The Ministries often execute this oversight through a national public health agency, national technical coordinating committee, disease control agency, 'One Health' platform, or emergency response operations centre to coordinate response to outbreaks. One of the challenges highlighted was that many of these committees and platforms are inactive during interepidemic periods.

- b) **Regulatory framework:** Although the regulatory frameworks in several countries require strengthening, ethical review boards and drugs or pharmaceutical regulatory authorities exist in many countries to ensure the safety of medicines, vaccines, biological products, medical devices, and clinical trials.
- c) **Infrastructure and clinical research systems:** Several countries have clinical trial sites and laboratories with varying levels of resources, some of which are government-funded, while others derive their resources from external means, including reference laboratories with diagnostic and sequencing capacity such as Institute Pasteur de Dakar. Despite these resources, clinical trial infrastructure and services are often inadequate with poor geographic coverage. Representatives from several countries also reported a shortage of personnel with specialist skills for clinical trials, limited diagnostic and genomic sequencing capacity, and an inadequate number of sentinel surveillance sites. Key gaps include limited pre-clinical and discovery research and insufficient capacity for product development and manufacturing capacity for diagnostics, vaccines, and therapeutics. Clinical trial networks (e.g. PREVAIL and WANETAM) help strengthen clinical research capacity in the region, but there is a lack of networking among clinical researchers and those in policy or emergency response within and across countries.
- d) **Community engagement:** Some countries have effective community engagement structures that support local mobilization for clinical research, while other countries reported weak systems that required strengthening to support rapid evidence generation.

The TCP team presented findings from an initial stakeholder and landscape analysis on research preparedness in West Africa. These findings on key stakeholders involved in outbreak preparedness and response, clinical trials, product development, existing capacity, and gaps in several countries, were similar to the output of the participants' discussions as outlined above. Workshop participants provided additional information to refine the findings further.

5. RAPID IMPLEMENTATION OF CLINICAL TRIALS

To understand the requirements for rapid evidence generation in response to a future outbreak, participants were tasked to identify prerequisites and strategies for successful coordination of clinical trials for a vaccine or other medical countermeasures along with potential challenges to be addressed.

a) **Pre-requisites and strategies for successful evidence generation**

Participants proposed the following structures and measures required in all countries to facilitate the successful coordination and operationalisation of rapid evidence generation in case of an outbreak:

- i) Political commitment at the highest level of government (e.g. Presidency/Inter-ministerial Committee).
- ii) Oversight by a National Coordination Committee led by the Ministry of Health or government-mandated institution.
- iii) Comprehensive outbreak preparedness and response plans including risk assessment, mitigation, and communication strategies.
- iv) Active network of relevant stakeholders from both within and outside the health system (including governance, researchers, regulators, and healthcare providers) with consistent engagement mechanisms even during inter-epidemic periods.

- v) Clinical trial sites with surge capacity for rapid activation during an outbreak.
- vi) Effective surveillance and incident management systems.
- vii) Strong systems for public and community engagement.
- viii) Funding support from both government and external partners channelled through established national and regional structures.

b) Sustaining clinical trial sites for research preparedness

A critical contributor to rapid evidence generation during an outbreak is having a network of warm base clinical trial sites across the region. A team from IQVIA, a partner in the Research Preparedness initiative, led discussions on developing a sustainability framework for clinical trial sites that considered suitable criteria and drivers of sustainability.

Although "sustainability" was interpreted in various ways, a common understanding emerged: a site's ability to continuously operate and maintain essential resources. Some participants also proposed utilizing the "hub-and-spoke" model for networking clinical trial facilities. In this model, hubs would serve as coordinating and support centres for multiple satellite sites to ensure broader geographical coverage, as previously mentioned by Dr. Temfack. Some participants also stressed the importance of securing core funding to maintain trial sites with appropriate infrastructural and human capacity during inter-epidemic periods to ensure their preparedness and long-term sustainability.

c) Facilitating cross-border evidence generation

Participants highlighted the importance of regional coordination during an outbreak and proposed the following strategies for effective cross-border initiatives and evidence generation during an epidemic or pandemic.

- i) Africa CDC and WAHO should lead the coordination of funding, technical support, and procurement of vaccines and other products in collaboration with other regional stakeholders.
- ii) Establish regular meetings among country representatives to discuss outbreak preparedness and response.
- iii) Establish collaboration for data and experience sharing, under a mutually cooperative framework among countries.
- iv) Harmonise regulatory and ethical review processes, standard operating procedures, and adaptable protocols for clinical trials across countries.
- v) Create a platform for information sharing among countries (an example is the information sharing mechanism between National Health Security Agency in Guinea and National Public Health Institute in Liberia on Lassa fever cases).
- vi) Leverage existing networks and platforms, such as the West African Research Preparedness Clinical Trials Network established after the Ebola outbreak.

d) Challenges to effective evidence generation coordination

The following obstacles were identified as hindrances to effective national and cross-border coordination of evidence generation during an outbreak:

- i) Geo-political challenges and governance instability in some countries.
- ii) Nationalist tendencies fuelled by limited resources and closed borders during outbreaks.

- iii) Different priorities and conflicts of interest among countries and stakeholders within countries.
- iv) Limited infrastructure, technical capacity, and logistics supply chain challenges.
- v) Lack of dedicated national emergency funds to respond to health threats.
- vi) Lack of core funding for clinical trial activities including staff & operations, during inter-epidemic periods.
- vii) Prolonged timelines for in-country ethics and regulatory approvals.

6. STAKEHOLDER ENGAGEMENT

Stakeholder engagement is an integral part of the Research Preparedness Programme aimed at operationalizing CEPI's commitment to regional guidance, alignment with national priorities, and local ownership. Breakout groups, organised for nine of the West African countries, were held in order to identify key stakeholders in outbreak preparedness and response at regional, national and community levels.

Below are examples of stakeholders identified by workshop participants (please note that this list is not exhaustive):

- a) **Regional level:** Africa CDC, WAHO RCSDC, WHO AFRO, Gavi, UN agencies (e.g. UNDP, UNICEF), US CDC, NGOs (e.g. MSF), funders (e.g. CEPI, EDCTP, BMGF), regional regulatory bodies (e.g. African Vaccine Regulatory Forum (AVAREF) and Africa Medicines Agency), regional networks (e.g. AFENET), international research institutions (e.g. IVI, BNITM).
- b) **National level:** Ministry of Health, Ministry of Finance, public health/disease control agencies (e.g. NCDC in Nigeria), emergency operations centres, ethics committees, national regulatory authorities, healthcare providers, academic and research institutions, clinical trial sites, private laboratories, surveillance systems, vaccine development agencies (e.g. National Vaccine Institute in Ghana), vaccine development and production partners, (e.g. Institute Pasteur de Dakar in Senegal), civil society/NGOs, WHO Country Offices, development partners (e.g. UNICEF, US CDC, USAID, GIZ), procurement agencies, communication experts and the media, and parliamentary health committees.
- c) **Community level:** Community health structures for surveillance, community health workers, community advisory boards, key opinion leaders (religious, political, administrative, traditional), community radios and independent practitioners, social media influencers.

Summary of proposed strategies for effective stakeholder engagement:

It was generally agreed from the deliberations that multi-sectoral and multi-level collaborations are crucial for effective epidemic/pandemic preparedness and response. Participants therefore proposed several actions and strategies for engaging identified stakeholders.

- a) **National-level engagement:**
 - i) Engage the Ministry of Health or relevant national public health agency to lead advocacy and facilitate buy-in and in-country stakeholder engagement.
 - ii) Tailor engagement strategies to the different stakeholders based on their roles and responsibilities.

- iii) Seek to understand the existing outbreak preparedness and response structures, coordination pathways, decision-making processes, and communication mechanisms within each country. Beyond mapping the stakeholders, this should include reviewing national health emergency preparedness and response plans where these exist.
- iv) Utilize existing platforms that provide opportunity for regular interaction among stakeholders such as steering committees, emergency response groups, or technical working groups.
- v) Assess the varying needs of different stakeholders during engagement, ranging from the national-level platforms to the clinical trial sites themselves, including the need for community engagement plans.

b) Regional-level engagement:

- i) Liaise with Africa CDC and WAHO RCSDC to provide regional leadership and legitimacy, and to lead advocacy, planning, and implementation of regional research preparedness activities.
- ii) Establish a regional network with communication mechanisms linked to national structures/networks if they do not already exist.
- iii) Collaborate with regional institutions to develop a regional emergency research preparedness plan that aligns with national plans if they do not already exist.
- iv) Leverage existing regional clinical trials and research networks, such as AVAREF, WANETAM, PREVAIL and Enable to facilitate access to stakeholders across the region.

7. KEY RECOMMENDATIONS AND NEXT STEPS

Drawing on the group discussions, deliberations during plenary and their experiences in diverse contexts within the region, participants proposed several recommendations for strengthening the implementation of the Research Preparedness initiative.

Overall, a summary of the key recommendations from the workshop included the following:

- a) Endeavour to understand the existing structures and processes for emergency response and the organisational and political dynamics within each country.
- b) Entrust MoH and/or designated agencies to lead advocacy efforts and facilitate engagement with other stakeholders at the national level.
- c) Hold discussions with Africa CDC, WAHO and other regional actors to play a leading role in the coordination of research preparedness in West Africa.
- d) Plan the next workshop in collaboration with Africa CDC for broader regional involvement.
- e) Develop an appropriate regional emergency research preparedness plan that builds on (rather than replicates) national plans.
- f) Appoint national ambassadors to act as representatives, enhance engagement, and champion in-country communication.
- g) Incorporate the role of social scientists in the assessment of the local community perception, attitudes and practices toward Disease X and vaccine hesitancy
- h) Widen the range of stakeholders and include actors such as laboratory networks, hospitals, grassroots organizations and the media in engagement activities and subsequent meetings
- i) Recognize the need for flexibility in engagement strategies as stakeholder dynamics evolve
- j) Invest in core funding to support trial sites during inter-epidemic periods and human resource/career path development as these are crucial to ensure rapid activation during an outbreak.

- k) Ensure adequate representation from national-level institutions (e.g. representatives from Ministries of Health and other key decision-makers)
- l) Share the outputs of the current meeting with participants and key stakeholders as part of engagement efforts.

8. CONCLUSION

The workshop successfully engaged key partners and stakeholders from across West Africa to discuss strategies for outbreak preparedness and evidence generation readiness across the region.

Through the discussions, participants gained a clearer understanding of the project's goals and the steps needed to achieve them. The discussions offered valuable insights into the pandemic preparedness and product development landscape in several countries across the region. Breakout group sessions addressed critical areas such as identifying stakeholders, understanding the research environment, coordinating evidence generation during an outbreak, and strategies for engaging stakeholders at the country and regional levels.

The workshop's outcomes complemented and expanded upon the initial findings from the TCP's stakeholder and landscape analysis. These insights will serve as a crucial resource for developing a comprehensive stakeholder engagement plan, which will be further reviewed and refined in the upcoming workshop planned for October 2024.

9. APPENDICES

A. List of participants

Name	Job Title	Affiliation
Dr. Elvis Temfack	Senior Research Officer, Center for Science and Innovation	Africa Centres for Disease Control and Prevention (Africa CDC)
Dr. Dossou Ange	Deputy Director of Medicine and Hospitals	Ministry of Health, Benin
Dr. Sikiru Badaru	Director of Planning, Research and Statistics	Nigeria Centre for Disease Control and Prevention (NCDC)
Dr. Elsie Illori	Project Coordinator	Nigeria Centre for Disease Control and Prevention (NCDC)
Prof. Christian Happi	Director	African Centre of Excellence for Genomics of Infectious Diseases (ACEGID), Nigeria
Dr. Bode Shobayo	Director of the Division of Public Health and Medical Research	National Public Health Institute, Liberia
Prof. Seth Owusu-Agyei	Pro-Vice Chancellor	University of Health and Allied Sciences, Ghana
Dr. Ahmed Liasu Adeagbo	Chief Medical Director	Federal Medical Centre (FMC), Owo, Nigeria
Dr. Femi Ayodeji	Head of Infection Control and Research	Federal Medical Centre (FMC), Owo, Nigeria
Prof. Yusuf Bara Jibrin	Chief Medical Director	Abubakar Tafawa Balewa University, Bauchi, Nigeria
Prof. David Wohl	Professor, Institute of Global Health and Infectious Diseases	University of North Carolina, USA
Prof. Benedict Azuogu	Professor of Epidemiology, Director of Grants, Research and Partnership	Alex Ekwueme Federal University Teaching Hospital (AEFUTH), Abakaliki, Nigeria
Dr. Donald Grant	Chief Physician, Lassa Fever Program	Kenema Government Hospital (KGH), Sierra Leone
Prof. Danny Asogun	Consultant Public Health Physician	Irrua Specialist Teaching Hospital (ISTH), Nigeria
Dr. Minnie Sankawulo-Ricks	Medical Director/CEO	Phebe Hospital and School of Nursing, Liberia
Prof. Yaw Adu-Sarkodie	Professor	Kwame Nkrumah University of Science and Technology (KNUST), Ghana
Dr. Moussa Douno	Doctoral Researcher	CEA-PCMT, UGANC, Guinée
Prof. Ifedayo Adetifa	Independent Researcher/Consultant	Independent
Dr. Abdourahmane Sow	Director of Public Health	Institut Pasteur de Dakar (IPD), Senegal
Dr. Billo Tall	Clinical Trial Operations	Institut Pasteur de Dakar (IPD), Senegal
Prof. Sylvanus Okogbenin	Consultant	ARC-WA Consortium Management Group (CMG)
Prof. Ellis Owusu-Dabo	Pro-Vice Chancellor	Kwame Nkrumah University of Science and Technology (KNUST),
Prof. Yazdan Yazdanpanah	Director	ANRS Emerging Infectious Diseases Agency, France
Prof. Halidou Tinto	Regional Director	Institut de Recherche en Sciences de la Sante (IRSS), Nanoro, Burkina Faso
Dr. Yvonne Ayongo Adu Boahen	Director, Department of Clinical Trials	Ghana Food and Drugs Authority
Dr. Andy Stergachis	Professor of Pharmacy & Global Health	University of Washington, USA
Margaret Williams	Chief Executive Officer	Margan Clinical Research Organization (MMARCRO)
Julius Williams	Chief Operating Officer	Margan Clinical Research Organization (MMARCRO)
Dr. Michael Ntiri	Clinical Operations Lead	Margan Clinical Research Organization (MMARCRO)
Prof. Stephen Gunther	Head of Department of Virology	Bernhard-Nocht-Institut für Tropenmedizin (BNITM)
Dr. Nathalie Jane Vielle	Scientist/ Laboratory Expert	Bernhard-Nocht-Institut für Tropenmedizin (BNITM)
Sue Bailey	VP, Site Management, Sub-Saharan Africa	IQVIA
Ayub Mpoya	Strategic Site Solutions Manager, Sub-Saharan Africa	IQVIA

Dr. Jakob Cramer	Director of Clinical Development	Coalition for Epidemic Preparedness Innovations (CEPI)
Dr. Christof Vinnemeier	Clinical Development Operations Lead	Coalition for Epidemic Preparedness Innovations (CEPI)
Dr. Caroline Forkin	Head of Clinical Development Programmes and Operations	Coalition for Epidemic Preparedness Innovations (CEPI)
Dr. Paul Oloo	Clinical Development Lead	Coalition for Epidemic Preparedness Innovations (CEPI)
Dr. Gabrielle Breugelmans	Director of Epidemiology	Coalition for Epidemic Preparedness Innovations (CEPI)
Dr. Mandi Henshaw	Senior Epidemiology Head, ENABLE Lassa Research Programme	Coalition for Epidemic Preparedness Innovations (CEPI)
Roice Fulton	Consultant, ENABLE Lassa Research Programme	Coalition for Epidemic Preparedness Innovations (CEPI)
Dr. Florian Marks	Deputy Director General, EPIC	International Vaccine Institute (IVI)
Dr. Birkneh Tadesse	Associate Director General, EPIC	International Vaccine Institute (IVI)
Dr. Anthony Huszar	Program Director, EPIC	International Vaccine Institute (IVI)
Wan Jun Lim	Project Manager	International Vaccine Institute (IVI)
Dr. Mohammadou Siribie	Research Scientist	International Vaccine Institute (IVI)
Dr. Derick Kimathi	Research Scientist	International Vaccine Institute (IVI)
Dr. Nadia Tagoe	Consultant	International Vaccine Institute (IVI)
Ritu Poudyal	Project Administrator	International Vaccine Institute (IVI)
Prof. Ed Clarke	Professor, Vaccines and Immunity Theme Lead	MRC Unit The Gambia at LSHTM
Dr. Armel Zemsi	Head of Clinical Trial Unit	MRC Unit The Gambia at LSHTM
Dr. Ahmed Futa	Clinical Trial Coordinator	MRC Unit The Gambia at LSHTM
Isatou Njai Cham	Head of Communications and Engagement	MRC Unit The Gambia at LSHTM
Bai Lamin Dondeh	Head of Data Management & Architecture	MRC Unit The Gambia at LSHTM
Elizabeth Batchilly	Head of Research Governance and Research Support Services	MRC Unit The Gambia at LSHTM

B. Workshop agenda

Day 1: Tues, 25 June 2024 – “understanding the challenge”

0900-0920	<i>Registration</i>
0920-1040	<ul style="list-style-type: none"> Welcome + ‘housekeeping’ (10 mins – TCP: Florian Marks, Ed Clarke, Anthony Huszar) Roundtable introductions (30 mins – All, 2-3 sentences each): <ul style="list-style-type: none"> name, organization, role, country what role do you and your institution play in outbreak response CEPI: Vision, Research Preparedness (20 mins – CEPI: Christof Vinnemeier) TCP ‘ARC-WA’ – current activities and plans (20 mins – Anthony Huszar, Armel Zemsi)
1040-1100	<i>Group photo + Coffee break</i>
1100-1200	<ul style="list-style-type: none"> Africa CDC: Vision and wider plans (20 mins – Africa CDC: Elvis Temfack) Q&A for CEPI, TCP, Africa CDC – 20 mins Slido (interactive): ideas, concerns, expectations (20 mins – TCP)
1200-1300	<i>Lunch</i>
1300-1500	<p>Session Chair: Dr Paul Oloo</p> <ul style="list-style-type: none"> Case study: rapidly implementing clinical trials for Disease X in West Africa. (20 mins to introduce) Breakout groups (100 mins): <ul style="list-style-type: none"> Who are the key stakeholders nationally and regionally in an outbreak and in pandemic preparedness? In the context of evidence generation and product development, who are the key players? – and what are the pre-requisites for their successful coordination? What other national/regional policies/programs/priorities affect coordination or decision-making? What capacities exist for evidence generation and product development? – and what’s missing? What are the practical challenges in starting and operationalizing clinical trials in an outbreak response? How can we work across borders?
1500-1530	<i>Coffee break</i>
1530-1700	<p>Session Chair: Dr Paul Oloo</p> <ul style="list-style-type: none"> Feedback session, 20 mins per group – on slides/short notes
1830-2030	<i>Dinner</i>

Day 2: Weds, 26 June 2024 – “sustainability and understanding the stakeholders”

0900-0915	Re-cap of Day 1 (15 mins – TCP)
0915-1040	<p>Session Chair: Prof Halidou Tinto</p> <ul style="list-style-type: none"> Sustainability of clinical trial sites: a framework (70 mins – IQVIA) Q&A (15 mins)
1040-1100	<i>Coffee break</i>
1100-1200	<ul style="list-style-type: none"> Sustainability feedback – continued (30 mins – IQVIA) TCP stakeholder analysis – (30 mins – TCP)
1200-1300	<i>Lunch</i>
1300-1430	<p>Session Chair: Prof Sylvanus Okogbenin, facilitated by TCP</p> <ul style="list-style-type: none"> Breakout groups: (90 mins) <ul style="list-style-type: none"> Review the stakeholder list provided <ul style="list-style-type: none"> Which key groups are not represented and what would be their roles? Which stakeholders need more attention? What relationships exist between groups? How would each group want to be involved? How should we engage them?

	<ul style="list-style-type: none"> ○ What mechanisms and stakeholder communication channels exist for emergency evidence generation and product development? ○ How can we fully understand the research preparedness landscape in-country? ○ What clinical research networks exist or can be established for a well coordinated response to outbreaks (in-country and cross-border)?
1430-1445	<i>Coffee break</i>
1445-1600	Session Chair: Prof Sylvanus Okogbenin, facilitated by TCP <ul style="list-style-type: none"> • Feedback from groups (15 mins x4) + 15 mins for additional discussion

Day 3: Thurs, 27 June 2024 – “what can we do?”

0900-0915	Re-cap of Day 2 (15 mins – TCP)
0915-1030	Session Chair: Prof Ellis Owusu-Dabo <ul style="list-style-type: none"> • Breakout groups: (75 mins): If we want to create clinical research and development ecosystem that can respond to Disease X in West Africa, what should the engagement plan look like?: <ul style="list-style-type: none"> ○ How best to develop/structure an Engagement Plan for the regional research preparedness network? ○ How should each stakeholder group be engaged? ○ What other ideas should we test in the follow-up workshop?
1030-1050	<i>Coffee break</i>
1050-1150	Session Chair: Prof Ellis Owusu-Dabo <ul style="list-style-type: none"> • Each group to pitch their ideas (4x10 mins) • Discussion (20 mins)
1150-1200	<ul style="list-style-type: none"> • Debrief, next steps, thanks (10 mins – TCP)
1200-1300	<i>Lunch</i>