Research Preparedness Program in East and Central Africa (RPECA)

Initial Foundational Technical Workshop Report

10-11 December 2025

Nairobi, Kenya

AfricaCDC
Centres for Disease Control and Prevention

PATH

CEPI

Contents

Abbreviations

Africa CDC	Africa Centers for Disease Control and Prevention
AfDB	African Development Bank
AMA	African Medicines Agency
ARC-WA	Advancing Research Capacity in West Africa
ASLM	African Society for Laboratory Medicine
AUC	African Union Commission
AUDA-NEPAD	African Union Development Agency - New Partnerships for Africa Development
AVAREF	African Vaccine Regulatory Forum
BARDA	Biomedical Advanced Research Development Authority
CANTAM	Central Africa Network on Tuberculosis, HIV/AIDS and Malaria
CEM	Cohort event monitoring
CEPI	Coalition for Epidemic Preparedness Innovations
CERMEL	Centre de Recherches Médicales de Lambaréné
COVAX	COVID-19 Vaccines Global Access Facility
C4IR	The Centre for the Fourth Industrial Revolution
DHIS2	District Health Information Software 2
DRC	Democratic Republic of Congo
EAHRC	East African Health Research Commission
ECSA-HC	The East, Central and Southern Africa Health Community
EDCTP	European and Developing Countries Clinical Trials Partnership
EVD	Ebola virus disease
GCP	Good Clinical Practice
INRB	Institut National de Recherche Biomédicale
ICH-GCP	International Conference on Harmonisation - Good Clinical Practice
IVI	International Vaccine Institute
MOH	Ministry of Health
MRCG	Medical Research Council Unit The Gambia, London School of Hygiene & Tropical Medicine
NIH	National Institutes of Health
NPHI	National Public Health Institute
OCEAC	Organisation de Coordination pour la lutte contre les Endémies en Afrique Centrale
PABIN	Pan-African Bioethics Initiative
PANTHER	PANdemic preparedness plaTform for Health and Emerging infections Response

mRNA	Messenger ribonucleic acid
MSF	Médecins Sans Frontières
R&D	Research and development
RPECA	Research Preparedness Program in East and Central Africa
RBC	Rwanda Biomedical Centre
RCC-CA	Africa CDC-Central Africa Regional Coordination Centre
RWE	Real-world evidence
SOP	Standard operating procedures
SPEAC	Safety Platform for Emergency Vaccines
TCP	Technical Coordinating Partner
UVRI	Uganda Virus Research Institute
VIBRI	Victoria Biomedical Research Institute
WAHO	West African Health Organization
WHO	World Health Organization

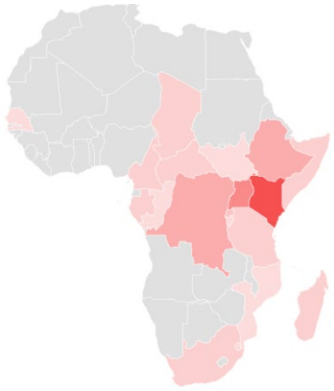
Executive Summary

On 10 and 11 December 2025, the Africa Centers for Disease Control and Prevention (Africa CDC), the Coalition for Epidemic Preparedness Innovations (CEPI), and PATH hosted an initial foundational technical workshop for the Research Preparedness Program in East and Central Africa (RPECA) in Nairobi, Kenya. This bilingual (English and French) foundational technical engagement aimed to initiate the development of a roadmap and consortium structure for strengthening research preparedness in East and Central Africa and enabling the rapid generation of emergency evidence during outbreaks.

Initiated in March 2025, RPECA is a multi-region, multi-country initiative led by PATH as the initial Technical Coordinating Partner (TCP), funded by CEPI and in collaboration with the Africa CDC and regional stakeholders. Building from Africa CDC's continental initiatives and other regional activities, RPECA's work intends to leverage existing entities, networks, and programs in the region to ensure readiness of a regional vaccine research platform for conducting real-world evidence (RWE) and clinical studies.

The workshop convened approximately 80 stakeholders from more than 30 countries, including representatives from 20 countries in East and Central Africa (Figure 1), focused on research preparedness and emergency response. Participants included a broad array of stakeholders representing diverse perspectives, including research institutions, clinical trial sites, ministries of health, national public health institutes, nongovernmental organizations, laboratory networks, manufacturers, economic communities, and funders.

Figure 1. Workshop participants attended from the countries in Africa shaded in pink; darker shading represents a higher number of attendees.



Via plenary presentations and discussions, live polls, and breakout sessions, the workshop targeted the collection of several key outputs, including: a summary of country research priorities and regional differences; the identification of research ecosystem gaps/barriers and solutions toward developing a rapid emergency evidence generation platform; preferred criteria for establishing regional research preparedness partners and coordination frameworks; and expanding of the network of stakeholders for building RPECA. This report summarizes the outcomes of the workshop, which will inform the development of a roadmap for regional research preparedness and the future structure and operation of RPECA.

Important takeaways from the workshop include:

- **Several gaps/barriers to emergency evidence generation exist and potential solutions should be built into the RPECA roadmap.** Identified issues were related to regulatory and ethics approvals, data systems and interoperability, laboratory capacity, decision-making processes, workforce readiness, pharmacovigilance, and rapid study start-up. Participants proposed several solutions, as well as existing networks, entities, and programs that could help address these gaps/barriers.
- **Optimizing partner coordination is critical.** Effective emergency evidence generation requires collaboration among ministries of health, ethics committees, regulatory bodies, research institutions, and continental agencies like African Medicines Agency, Africa CDC, and the World Health Organization African Region. Country-specific mechanisms and international organizations also play critical roles, especially for cross-border outbreaks.

Ongoing engagement with these stakeholders will refine the RPECA roadmap and ensure sustainability in addressing future outbreaks.

- **A clear and robust methodology needs to be established for selecting regional technical coordinating and consortium partners to enable research preparedness in East and Central Africa.** Participants noted the importance of selecting partners with strong reputations, robust administrative structures, multi-country trial experience, capacity for rapid resource mobilization, and proven surveillance and diagnostic capabilities.

This workshop marked an important first step toward building a regionally owned research preparedness system in East and Central Africa. By discussing gaps and barriers, proposing solutions, and emphasizing inclusive partnerships, the workshop laid the groundwork for the forthcoming structure of RPECA and ensuring rapid, high-quality emergency evidence generation during future outbreaks. Continued engagement and collaboration among Africa CDC, CEPI, PATH, and regional stakeholders will be essential to establishing a sustainable, prepared research ecosystem that can be activated rapidly in an outbreak.

A collection of photos from the RPECA Initial Foundational Technical Workshop.

Introduction

Background

The Research Preparedness Program in East and Central Africa (RPECA) is a multi-region, multi-country initiative led by PATH as the initial Technical Coordinating Partner (TCP), funded by the Coalition for Epidemic Preparedness Innovations (CEPI) and in collaboration with the Africa Centers for Disease Control and Prevention (Africa CDC) and regional stakeholders. The initiative is part of CEPI's Research Preparedness Program, a multi-regional approach to leveraging investments for advanced-stage clinical development of CEPI's portfolio vaccines and supporting countries in key regions across the globe to generate emergency evidence in future outbreaks (Figure 2). CEPI's Research Preparedness Program in Africa also includes the Advancing Research Capacity in West Africa (ARC-WA) Program, coordinated by the International Vaccine Institute (IVI) and Medical Research Council Unit Gambia (MRCG).

Figure 2. To account for both routine clinical development of vaccines in inter-epidemic periods and evidence generation in emergencies, CEPI's Research Preparedness Program is split into two tracks that mutually inform and complement each other. While work under Track A focuses on specific priority diseases for each region, the approach for Track B is broader and focused on the generation of emergency evidence and is disease-agnostic.

TRACK	A *‚Interepidemic period'* Routine Clinical Research Preparedness	B *‚Outbreak'* Emergency Evidence Generation Readiness
Focus	CEPI priority diseases portfolio vaccines (e.g. Lassa fever in West Africa)	Any pathogen with epidemic / pandemic potential in respective region
Ambition	To identify clinical trial sites / research institutions, strengthen their capacity to enable them to conduct a GCP-compliant Phase 2b / Phase 3 trial	Support countries in the respective region in their ability to generate emergency evidence in future outbreaks (incl. real world evidence)
Goal	Operational site readiness to support advanced-stage clinical development of CEPI portfolio vaccine candidates	Support CEPI's 100 days mission by promoting universal access to self-sustained, independent clinical trial sites

RPECA was initiated in March 2025 and is designed to strengthen regional clinical research ecosystems to catalyze the ability to efficiently and effectively conduct Good Clinical Practice (GCP)-compliant late-stage vaccine trials and to support the rapid generation of emergency evidence in the context of infectious disease outbreaks. As part of establishing RPECA as a longer-term research preparedness program and in alignment with key stakeholder goals and country priorities, PATH will be leading the development of a leadership and coordination consortium mechanism ensuring regional ownership and sustainability.

East and Central Africa face a high risk of emerging and re-emerging infectious diseases such as mpox, Rift Valley fever, chikungunya virus, and filoviruses. Despite past investments in vaccine development that were mainly focused on specific projects that developed capacity to address specific objectives, many clinical research entities lack legacy and sustained readiness capacity for generating emergency evidence (including clinical trials and real-world evidence [RWE] studies) during infectious disease outbreaks. RPECA addresses this gap by strengthening institutional preparedness for outbreak-response research while sustaining a ready and durable network for both emergency and routine vaccine research.

On 10 and 11 December 2025, Africa CDC, CEPI, and PATH hosted a bilingual initial foundational technical workshop for RPECA in Nairobi, Kenya. Of the approximately 80 stakeholders in attendance, there were representatives from 11 countries in East Africa and from 9 countries in Central Africa, about one-third of whom were francophone participants. This foundational technical engagement aimed to initiate the development of a roadmap and consortium structure to strengthen research preparedness in East and Central Africa and to enable rapid generation of evidence during outbreaks. Building from Africa CDC's continental initiatives of strengthening and optimizing the health research ecosystem and other regional activities, RPECA's work intends to build on and leverage existing entities, networks, programs, and projects in the region thereby contributing readiness of a regional vaccine research platform for conducting GCP-compliant trials and RWE studies aligned with Africa CDC and CEPI priorities.

Workshop objectives and targeted key outputs

The workshop aimed to:

- Obtain an understanding of country research priorities (with a focus on outbreak-prone diseases) and their alignment with CEPI and Africa CDC priorities.
- Provide a status update on Africa CDC's ongoing regional stakeholder mapping and next steps for a gap assessment.
- Gain a better understanding of evidence-generation pathways for outbreak response and mechanisms for optimizing coordination.
- Foster collaboration across clinical research and outbreak-response networks in East and Central Africa.

Expected key outputs included:

- A summary of country research priorities and regional differences.
- Identification of gaps in the research ecosystem for rapid emergency evidence generation.
- Criteria for regional research preparedness and coordination frameworks.
- Stakeholder identification for building RPECA.

Identifying stakeholders to attend the workshop

The workshop, which was conducted in both English and French, engaged a wide range of stakeholders focused on research preparedness and emergency response ecosystems. The participants were from research institutions, clinical trial sites, ministries of health, national public health institutes, nongovernmental organizations, laboratory networks, manufacturers, economic communities, and funders.

PATH carried out a comprehensive mapping exercise across East and Central Africa to identify key regional entities and stakeholders to invite to the workshop. Individual stakeholders from each of the entities were identified by in-country and regional staff as well in consultation with CEPI and Africa CDC. In instances where there were no individuals identified from a country, Africa CDC sent a Note Verbale to the Member States through their embassies, requesting the nomination of participants. It is important to note that the stakeholders who attended this workshop only represent a preliminary group identified through the stakeholder mapping exercise, and some were unable to attend. Stakeholder engagement as a key activity of RPECA will be a continuous process throughout the establishment of the consortium.

Workshop agenda and engagement methodology

The workshop agenda featured a combination of plenary presentations, live participant polls on key issues, question and answer sessions, and breakout group discussions to identify priorities, gaps, proposed solutions, key partner and consortium characteristics, and operational lessons. Prior to the workshop, participants were equipped with big-picture questions designed to inspire reflection in advance. Initial presentations were focused on establishing a shared understanding of key concepts, such as the differences between outbreak response and research conducted during outbreak response, as well as case studies of research implemented during disease outbreaks and under emergency conditions. These strategies created the momentum for meaningful polls and rich dialogue during the workshop.

PATH conducted live polling during the workshop with Mentimeter, an interactive, web-based audience engagement tool that easily gathers insights from a group and visualizes the results in real time. The facilitated plenary and breakout sessions used Mentimeter to capture individual stakeholder opinions, which were collated and organized to guide further discussions. The Mentimeter polling questions for the plenary and breakout sessions were rooted in topic areas relevant to achieving the aims of the workshop. To ensure a common understanding of the questions, all polling sessions were either bilingual or completed in the preferred participant language.

To understand country and regional differences, the workshop organizers grouped the stakeholders for breakout sessions based on geography and language (e.g., Kenya, Uganda, Tanzania in one group; francophone countries in another group; smaller and larger countries together). Cross-cutting stakeholders (e.g., representatives from funders and networks) were spread across the breakout groups. The facilitators of the breakout groups were PATH staff from the region with research experience who were trained to utilize a standard facilitator topic guide and process.

Workshop structure

Figure 3. The four sessions that shaped the agenda of the RPECA Initial Foundational Technical Workshop.

The workshop was organized into four overarching sessions (Figure 3). Day 1 covered sessions one and two, including both plenary and breakout session formats. The plenary session focused on distinguishing outbreak response from emergency evidence generation, CEPI's 100 Days Mission, Africa CDC's preparedness strategies and initiatives, PATH's role as TCP, and case studies on chikungunya, COVID-19, Ebola, malaria, Marburg, and mpox outbreaks. The breakout sessions aimed at identifying key gaps/barriers impeding rapid generation of emergency evidence. Day 2, which covered sessions three and four, continued the use of breakout sessions and small-group discussions. Discussion topics focused on identifying solutions and recommendations for preparing and implementing rapid emergency evidence generation for the gaps identified on Day 1. Day 2 also included exploratory exercises in the plenary session to discuss how to optimize coordination of emergency evidence generation and considerations for identifying key partners during an outbreak. Appendix 1 provides a complete list of the institutions participating in the workshop, and Appendix 2 shares a detailed agenda from the workshop.

Session 1: Continental and Regional Initiatives for Emergency Evidence Generation

Session 1 opened the workshop by highlighting the importance of coordinated research preparedness across East and Central Africa. The speakers presented continental and regional initiatives, emphasizing the need to align country research priorities with broader organizational goals. This session also set the stage for collaborative efforts to strengthen emergency evidence generation during outbreaks, introducing the RPECA initiative and its alignment with Africa CDC and CEPI priorities.

Opening ceremony

The workshop began with welcoming remarks by leaders from Africa CDC, CEPI, PATH, the Kenya National Public Health Institute (NPHI), and the Kenya Ministry of Health. The speakers reinforced the critical importance of research preparedness and enabling data and evidence generation for ongoing and future disease outbreaks. While Africa's public health architecture, led by Africa CDC, is advancing, research preparedness systems must keep pace—technically, ethically, operationally, and collaboratively. Arguably, no single entity can deliver emergency evidence alone, so multi-sectoral partnerships like RPECA (and the similar ARC-WA initiative) will be critical in future outbreaks.

Photos from the workshop's opening remarks.

CEPI emphasized their flagship initiative, the 100 Days Mission, which aims to enable vaccine development within 100 days of declaration of an outbreak. This ambitious goal requires preparatory investments across the ecosystem, including robust surveillance, rapid identification of immune markers, vaccine libraries, clinical and laboratory networks, global manufacturing capacity, and strong regulatory and financing frameworks.

The remarks from Kenya's NPHI and Ministry of Health drew parallels between the workshop and RPECA's goals and Kenya's priorities and national guidelines on research and emergency response. For instance, NPHI's work aims to strengthen research systems, including research prioritization and capacity mapping conducted with support from Africa CDC. They highlighted that gaps in research preparedness have historically delayed critical decisions on deploying medical countermeasures, while coordinated research supported by strong regulatory systems, efficient surveillance, robust laboratories, and community engagement has saved lives. Finally, the Kenya representatives' remarks noted the country's commitment to contributing to a regional framework that leverages existing networks while addressing gaps and identifying practical solutions rooted in three principles:

- Regional solidarity: Outbreaks do not respect borders, and neither should research systems.
- Scientific rigor and ethics: Speed is important, but quality and community trust are non-negotiable.
- Sustainability: Solutions must build long-term capacity, not temporary fixes.

Following the opening remarks, PATH facilitated an icebreaker session that aimed to help the stakeholders get to know each other, while also identifying regional and country regional research priorities. During this session, more than half of workshop participants (n=46) noted that their institution is part of an existing research network. In addition, approximately half of the workshop participants (n=38) noted that their country or region has defined research priorities, with infectious diseases, non-communicable diseases, capacity development, outbreak response and surveillance, maternal and child health, research and innovation, and One Health noted as the leading priorities.

Participants greet each other during the icebreaker session.

Overview of research preparedness in African region

Plenary presentations from Africa CDC, CEPI, and PATH delved into the design of RPECA and its expected interplay with other research preparedness activities in the African region.

Dr. Mosoka Fallah, Acting Director of Science and Innovation at Africa CDC, provided an overview of Africa CDC's mandate, structure, and strategies for strengthening research preparedness and outbreak response across the continent. He emphasized the urgent need for improved outbreak preparedness, noting that Africa faces increasing health threats while lacking vaccines and therapeutics for major diseases such as Ebola, Marburg, mpox, Lassa fever, and chikungunya. Dr. Fallah also shared Africa CDC's efforts to foster collaboration among African scientists through thematic networks, develop a sovereign research and development (R&D) fund, and secure sustainable financing for research and innovation. He concluded by stressing that Africa must establish its own continental priorities and lead its own preparedness and response agenda.

Ms. Jennifer Kealy, Clinical Development Operations Lead for East and Central Africa at CEPI, shared an overview of CEPI's research preparedness program and its role in advancing vaccine development and emergency evidence generation. She emphasized the need for a paradigm shift in clinical research preparedness, moving away from fragmented, project-specific funding toward sustainable, locally owned models. Ms. Kealy also introduced the hub-and-spoke model for clinical trial networks, designed to leverage existing infrastructure while enabling flexible mobile units for remote outbreak settings. Hubs would provide strategic oversight and technical expertise, while spokes would connect subnational facilities to ensure localized implementation.

An overview of research preparedness from (clockwise from top left) Dr. Mosoka Fallah of AfCDC, Dr. Kristen Lewis of PATH, and Ms. Jennifer Kealy of CEPI.

Dr. Kristen Lewis, RPECA Director at PATH, explained that the initiative is designed to support CEPI and Africa CDC's strategic vision, focusing on enabling rapid generation of emergency evidence during outbreaks while maintaining routine research as a foundation for

ensuring a sustainable preparedness mechanism. She noted that RPECA builds on lessons from the ARC-WA initiative and is anchored in stakeholder engagement at continental, regional, and local levels. Dr. Lewis reinforced that RPECA aims to create sustainable research infrastructure capable of responding rapidly to outbreaks, while promoting collaboration and local ownership. She concluded by reaffirming PATH's commitment to co-developing solutions with countries, building a regionally owned program, and leveraging partnerships to strengthen preparedness across East and Central Africa.

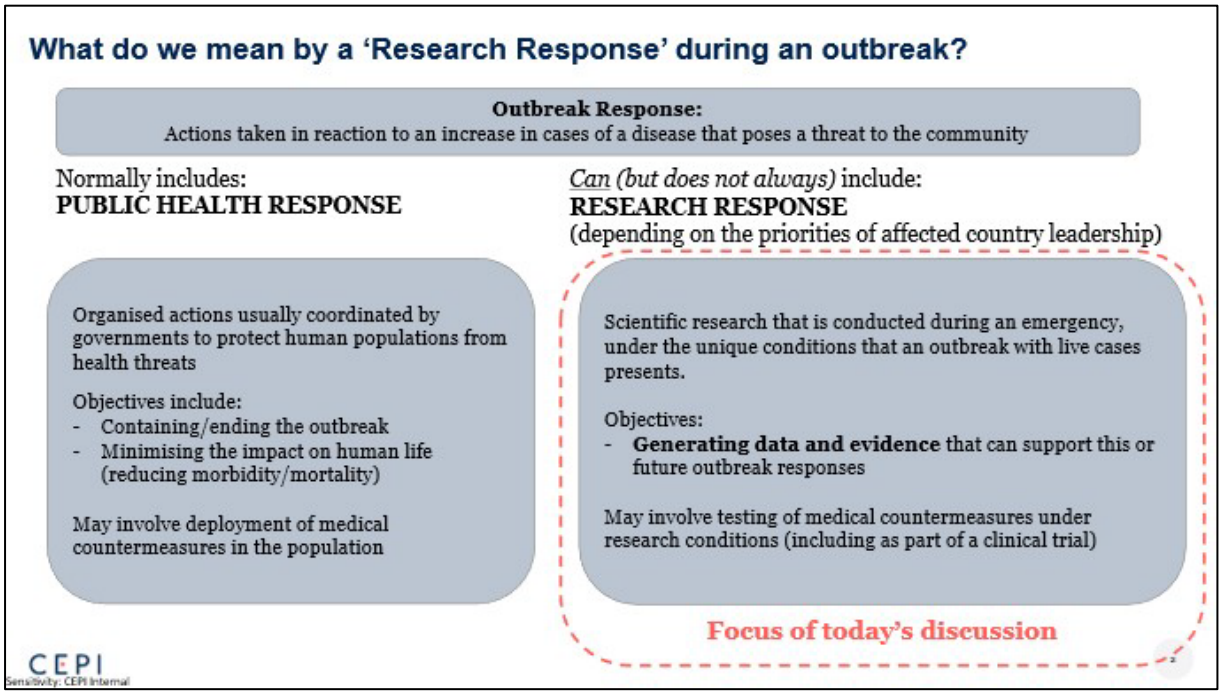
Session 2: Emergency Evidence Generation—What Does It Take?

Session 2 explored the practical requirements for generating emergency evidence during outbreaks. A series of plenary presentations addressed the distinction between outbreak response and research activities, sharing recent examples of RWE studies and clinical trials. Key topics included pharmacovigilance, community engagement, and institutional, site, and developer experiences. Within these topics, challenges and successes in implementing research during outbreaks were highlighted. The session also featured breakout discussions to identify regional, sub-regional, and country-level gaps and barriers to effective emergency evidence generation, with a focus on enabling seamless collaboration across functions.

Generating emergency evidence during an outbreak: Overview

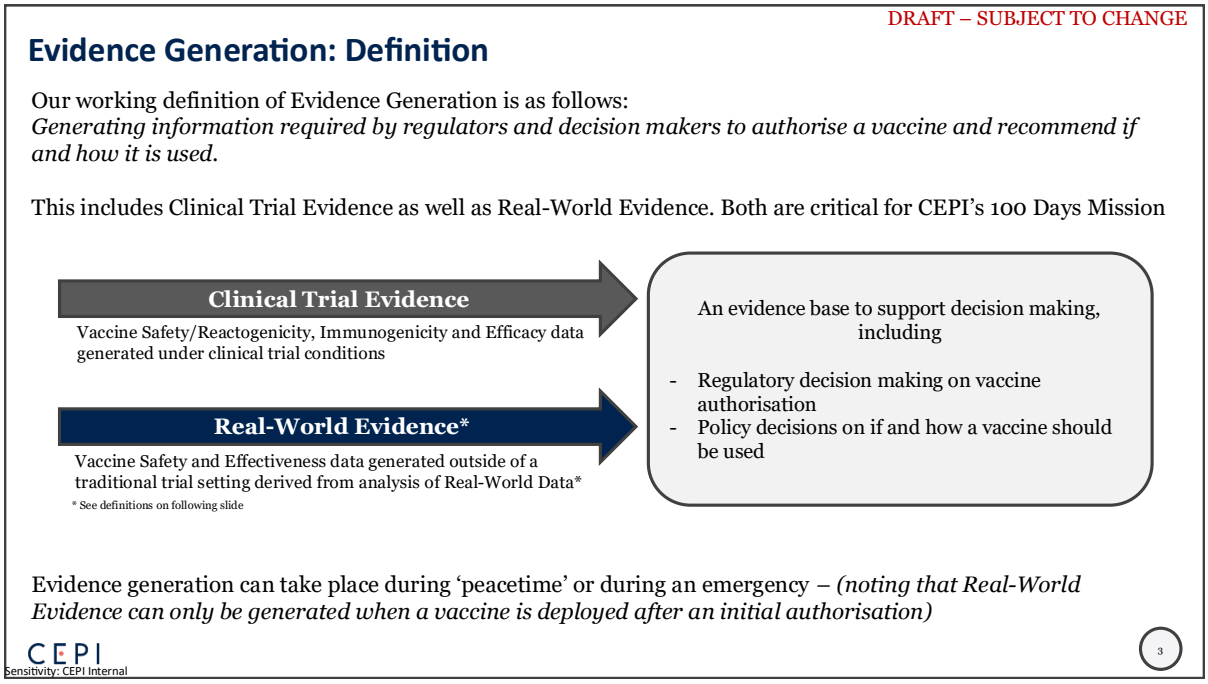
Dr. Roshni Best, Senior Manager of Emergency Response at CEPI, gave a plenary presentation on how CEPI's preparedness and response division focuses on planning for emergencies and enabling rapid vaccine research during outbreaks. Dr. Best's presentation clarified the distinction between public health response and research response during an outbreak (Figure 4). While public health actions aim to contain and end the outbreak using licensed medical countermeasures, research responses focus on generating scientific evidence under emergency conditions, often through clinical trials or RWE studies. She reiterated CEPI's vision for achieving vaccine authorization within 100 days of an outbreak alert, highlighting the need for pre-positioned evidence, rapid trials, and continued data collection post-authorization. Evidence-generation strategies must align with national vaccination plans and consider factors such as vaccine development stage, epidemiological context, benefit-risk assessments, infrastructure readiness, and country leadership priorities.

Figure 4. Slide from Dr. Best's presentation focused on the distinction between public health and research responses during an outbreak.



Dr. Best also differentiated types of emergency research and identified key building blocks for generating emergency evidence via clinical trials and RWE studies, including access to investigational doses, approved protocols, laboratory and surveillance capacity, safety monitoring systems, and regulatory support (Figure 5). For RWE studies, additional requirements include robust interoperable data systems and analytics capabilities to link vaccination records with health outcomes. She stressed that CEPI's enabling activities—such as research preparedness networks and infrastructure mapping—aim to strengthen these capabilities across high-risk countries.

Figure 5. Slide from Dr. Best's presentation with an overview of the types of evidence generation.



In conclusion, Dr. Best called for collaboration to assess readiness against these building blocks, to identify gaps, and to explore opportunities for testing systems through exercises and live outbreak responses. She also reiterated CEPI's commitment to supporting countries in building sustainable research ecosystems that can respond rapidly and effectively during emergencies.

Examples from RWE studies, community engagement research, and clinical trials

Following Dr. Best's overview presentation, a panel of presenters shared case studies about past examples of emergency evidence generation during outbreaks in East and Central Africa.

Africa CDC shared insights from a cohort event monitoring (CEM) vaccine safety surveillance study conducted in the Democratic Republic of Congo (DRC) that aimed to generate safety evidence for two vaccines during the early days of the mpox outbreak. Africa CDC collaborated with multiple organizations, including the National Pharmacovigilance Center, the DRC Ministry of Health, CEPI, PATH, WHO, and the Safety Platform for Emergency Vaccines (SPEAC) project, to co-develop protocols and study implementation tools. The CEM study achieved enrollment of approximately 24,000 participants (making it one of the largest safety studies in the DRC), with high follow-up completion and robust documentation of adverse and serious adverse events. With PATH's support, Africa CDC also developed standardized operational, data management, and statistical analysis plans, supporting standardized study implementation across multiple health facilities, the use of a central data management system, and the use of centralized dashboards for real-time monitoring, and

strengthened local capacity for future pharmacovigilance studies. This example demonstrated the value of multi-stakeholder collaboration, which not only enabled rapid study implementation but also created protocols, tools, and networks that can be leveraged for future outbreak research. Lessons learned included the need for early training of trainers, planning for sustainability from the outset, and adopting a unified digital ecosystem for data collection.

Africa CDC also presented findings from a multi-country malaria operational research study, which applied a harmonized approach across Lesotho, Namibia, and Zimbabwe to integrate findings on entomology, vector control, and health system readiness. The results confirmed that the study areas had low mosquito net coverage and delayed diagnosis and treatment of malaria. In addition, cross-border mobility was a major transmission driver, and COVID-19 disruptions resulted in weakened supply chains and delayed interventions. This example reinforced that operational research can be an effective preparedness tool. It enables early detection of emerging threats, strengthens health systems, and informs rapid, evidence-based action.

Various speakers presenting examples of studies that generated emergency evidence.

The Institut National de Recherche Biomédicale (INRB) shared a historical perspective about groundbreaking achievements in Ebola virus disease (EVD) research and treatment in the DRC. Research conducted during the 1995 and 2018-2019 Ebola outbreaks enabled INRB's work on the development and testing of innovative strategies, including vaccines, diagnostics, and therapeutics. The results of these studies led to the regulatory approval of two drugs to treat EVD, transforming Ebola from an untreatable disease to one with effective therapies. Despite these advances, ongoing challenges include improving access to drugs in resource-limited settings, strengthening supportive care, and addressing late presentation of patients with high viral loads, which correlates with poor outcomes. Continued research is needed to develop new therapeutics, clear viral reservoirs, and sustain infrastructure improvements initiated under the earlier studies. There is also a need for sustainable funding and partnerships to maintain clinical research capacity and expand innovative studies beyond Ebola to other emerging infectious diseases. This presentation concluded by reaffirming the importance of high-quality randomized, controlled trials as an integral component of outbreak response and emphasizing the importance of partners joining efforts in advancing Africa-led research preparedness and response.

BioNTech presented on the company's rapid development of COVID-19 mRNA vaccines that involved multiple stakeholders—including academia, industry, regulators, and governments—collaborating intensively. Strong leadership commitment, early partnerships with other vaccine developers, and careful regulatory planning were critical to success. During this time, clinical trials faced challenges such as patient recruitment during lockdowns, evolving disease incidence, and data pipeline constraints. Best practices included decentralizing trial structures, adopting adaptive designs, and leveraging automation for real-time data monitoring. BioNTech also noted the importance of involving

regulators as active partners with frequent communication to offer expedited pathways like Emergency Use Authorization, rolling reviews, and pre-approval of key dossier sections. In addition, WHO's role in global coordination, emergency listings, and equitable vaccine access through COVAX were critical to BioNTech's success, as well as distributed clinical networks, integrated development and manufacturing strategies, and rigorous decision gates.

Valneva shared details on a Phase 3b trial of its chikungunya vaccine, IXCHIQ®, in Kenya, which aims to confirm vaccine safety and effectiveness in endemic countries. Rising chikungunya cases in Kenya prompted Valneva, with CEPI and PATH support, to evaluate trial feasibility there. Challenges in setting up the trial in Kenya included complex, resource-intensive approval processes, decentralized submissions, and limited surveillance data, which made site-specific adaptations time-consuming. Valneva found that Kenya's strengths, including excellent clinical research expertise, motivated trial sites, strong English proficiency, and established community engagement strategies, as well as regulatory flexibility, such as parallel submissions and the acceptance of draft documents, facilitated progress. Valneva concluded that including African populations in research is vital to confirm vaccine safety and effectiveness in at-risk populations, especially given the high local chikungunya risk and the need for diverse data.

The University of Kinshasa presented on its experience from an Ebola vaccine trial conducted in Tshuapa Province, DRC, during overlapping outbreaks of measles, Ebola, and COVID-19. Political instability, limited regulatory resources, and economic constraints were major challenges, which were mitigated through proactive engagement with focal people and securing funding from organizations such as the European and Developing Countries Clinical Trials Partnership (EDCTP) and CEPI. Building skilled local trial staff required robust training plans, dry runs, and reinforcement from experienced teams in Kinshasa. In addition, community engagement was critical to overcoming fear and mistrust, achieved through involvement of local authorities, medical anthropologists, and continuous dialogue with opinion leaders. Logistical hurdles—such as lack of infrastructure, cold chain, and connectivity—were addressed by providing sites with new equipment, while remoteness and poor transport required chartered flights and alternative money transfer systems. Biometric tools also helped prevent fraud and improve participant follow-up. Lessons from an mpox vaccine trial reinforced the importance of collaboration with health zones, contract research organizations, and community leaders, as well as tailored communication in local languages and continuous protocol training.

The Uganda Virus Research Institute (UVRI) shared its experience in implementing an intra-outbreak Ebola Sudan ring vaccination trial. Lessons from a 2022 outbreak in Uganda enabled swift action during another outbreak in 2025. The pre-approved protocol was kept active through annual renewals, and a vaccine was already stockpiled in-country. The trial was launched within four days of the outbreak declaration, thanks to stewardship from WHO and the Uganda Ministry of Health, pre-financing by implementing institutions, and strong collaboration between Makerere University and UVRI. South-South collaboration, supportive ethics and regulatory systems, and research capacity built during previous outbreaks were key enablers to the study's success. Challenges included vaccine hesitancy among health workers, logistical hurdles in transporting samples, and fear about the high blood volumes collected. Strong collaborations, agile ethical approvals, and mobile laboratories for on-site testing were critical for conducting timely outbreak research. Uganda's experience demonstrates the value of preparedness and sustained investment to enable rapid evidence generation during epidemics.

The Rwanda Biomedical Centre presented on how it successfully managed the 2024 Marburg virus disease outbreak through rapid coordination, strong partnerships, and evidence-based interventions. Within days of the Marburg outbreak being declared, Rwanda prioritized ring vaccination for frontline healthcare workers. This was achieved through close collaboration with CEPI, Sabin Vaccine Institute, WHO, and regulatory authorities, enabling shipment of vaccine doses and approval of a clinical

protocol in record time. Rwanda vaccinated frontline workers under an open-label Phase 2 protocol while simultaneously strengthening surveillance, contact tracing, and care systems. The case fatality rate, which typically averages around 50 percent, was reduced to less than 24 percent through early supportive care and rapid response measures. Lessons learned included the importance of early symptom recognition and the need for robust community engagement and scientific collaboration. This presentation also noted Rwanda's reaffirmed commitment to epidemic and pandemic preparedness through its 2026–2040 strategic plan.

IQVIA shared lessons learned from its role as CEPI's research preparedness partner, supporting epidemic and pandemic responses through surge capacity and rapid mobilization of staff. The presentation cited the importance of scientific, operational, and logistical preparedness, including adaptive trial designs, governance clarity, harmonized standard operating procedures (SOPs), and robust supply chain management. Building trust with communities and maintaining open communication were also identified as critical success factors. IQVIA illustrated these principles through the Marburg outbreak response in Rwanda, where they supported initiation of a vaccine trial within ten days of the public health emergency declaration. This rapid timeline was achieved through collaborative partnerships with the Rwandan government, regulatory authorities, and organizations such as CEPI and the Biomedical Advanced Research Development Authority (BARDA). Key strategies included rapid staff deployment, training in International Conference on Harmonisation - Good Clinical Practice (ICH-GCP) to ensure compliance and data integrity, and the use of innovative tools like dashboards and protocol chatbots for real-time coordination. Effective outbreak response also requires strong local partnerships, harmonized processes, and strategic alignment across stakeholders, combined with flexibility and technology-driven solutions to accelerate evidence generation without compromising quality.

Session 3: Preparing for Emergency Evidence Generation

Focusing on gaps or barriers to achieving optimal research preparedness and identification of potential solutions, Session 3 examined challenges and solutions to rapidly generate emergency evidence in the context of an outbreak. To facilitate focused discussions on the most important factors for preparing and implementing clinical trials and RWE studies, participants were divided into four groups—three held discussions in English and one in French. As described earlier, the groups used a web-based polling tool (Mentimeter) to capture individual opinions and rapidly collate and organize these inputs to guide further discussion within each group.

Gaps/barriers and potential solutions

The participants were first tasked with identifying the most significant gaps and barriers hindering the ability to generate evidence during an outbreak and to collaboratively develop actionable solutions to address these challenges. Using the Mentimeter polling tool, each group examined the readiness of 13 key elements required to conduct a trial or study in the context of an outbreak (Figure 6).

Figure 6. The 13 key readiness elements included in the Mentimeter poll.

These elements were rated on a scale of one to five from “not in place” to “ready to go,” and then the participants used Mentimeter to vote on the three most important gaps. These Mentimeter ratings and rankings were utilized in a facilitated discussion to identify any key elements not yet represented, prioritize gaps, explore underlying causes for the gaps, and propose solutions and practical steps to strengthen emergency research systems across the East and Central Africa region. Across the groups, several common themes emerged, with eight key gaps/barriers prioritized and potential solutions identified. These are listed below by order of group consensus, including the rationale for identifying each gap/barrier and proposed next steps (if any).

Gaps/barriers prioritized by <u>all groups</u>

1. Rapid regulatory approval

Rationale for identifying gap/barrier	Potential solutions for addressing gap/barrier
• Slow and inconsistent approvals • Limited capacity for joint/parallel reviews • Absence of fast-track pathways • Inadequate reviewer expertise and human resources	• Establish clear, expedited approval procedures and fast-track pathways for emergencies • Develop and harmonize regulatory frameworks, SOPs, and standardized templates across countries • Form expert teams and provide training for regulators on emergency procedures • Engage policymakers and ensure strong government commitment • Promote joint reviews with ethics, parallel submissions, and digital platforms for regulatory review • Define regulatory criteria and conditions by law/decree; ensure collaboration between regulatory committees

Proposed next steps: Active communication to break silos; understand regulatory initiatives on the continent (e.g., EDCTP, WHO, CEPI); consultation with the African Medicines Agency (AMA) to understand how to integrate; dissemination of workshop report; debrief with relevant government departments; dissemination of publicly available existing tools; and identification of relevant stakeholders to support the work.

Gaps/barriers prioritized by <u>three groups</u>

2. Rapid ethics approval

Rationale for identifying gap/barrier	Potential solutions for addressing gap/barrier
• Multiple uncoordinated ethics committees • Heavy workloads and brain drain • External funding impacting sustainability • Inconsistent procedures prolong approvals	• Build capacity and provide regular training for ethics committee members on emergency procedures • Develop clear SOPs and templates for emergency protocol review • Streamline and digitize ethics review processes; enable fast-track mechanisms • Ensure committees are well resourced, compensated, and have administrative support • Foster collaboration between ethics committees, ministries of health, and research institutions • Encourage regional/continental ethics committees and harmonization • Consider adopting a fee-model for ethics committees (e.g., private institutional review boards used in the United States) to conduct urgent reviews and consider mutual recognition mechanisms (e.g., one ethics committee could provide an approval for multiple sites)

Proposed next steps: Integration with AMA and Africa CDC mechanisms; active communication to break silos; dissemination of workshop report; debrief with relevant government departments; dissemination of publicly available existing tools; and identification of relevant stakeholders to support the work.

Gaps/barriers prioritized by <u>two groups</u>

3. Data systems and interoperability

Rationale for identifying gap/barrier	Potential solutions for addressing gap/barrier
• Fragmented, non-interoperable systems • Lack of national guidance and monitoring • Data quality issues • Limited triangulation across platforms—hindering rapid evidence generation and coordination	• Harmonize data systems and platforms nationally and regionally; develop interoperable digital repositories • Establish national legal frameworks for data sharing and governance • Train data managers and strengthen data analytics capacity • Develop common dashboards, integrate District Health Information Software 2 (DHIS2), and promote digitalization • Ensure confidentiality and quality of data; create monitoring teams • Engage private sector and IT companies for technical support

Proposed next steps: Mapping of key stakeholders (including technology companies and laws); and regional and country convening of technical data managers, data scientists, researchers, and government decision-makers.

4. Laboratory capacity

Rationale for identifying gap/barrier	Potential solutions for addressing gap/barrier
• Limited technical capacity for molecular assays/genomics • Project-specific funding undermines sustainability • Insufficient specialized resources	• Establish and strengthen hub-and-spoke laboratory networks • Equip labs to international standards • Build capacity in human resources, equipment maintenance, and supply chains • Decentralize laboratories and promote networking between national and regional laboratories • Encourage countries to allocate budget for laboratory equipment and maintenance • Foster collaboration with public health institutions and research centers

5. Clear and rapid decision-making

Rationale for identifying gap/barrier	Potential solutions for addressing gap/barrier
• Weak coordination among institutions • Unclear mandates and leadership • Insufficient legal frameworks or awareness • Competition and duplicated efforts delay action	• Establish national and regional coordination mechanisms with clear stakeholder roles • Create single coordinating bodies or task forces • Develop mapped structures and frameworks for transparent coordination • Pilot decision-making frameworks around priority diseases

Proposed next steps: Pilot convening around priority disease(s) to develop decision-making framework with relevant stakeholders.

Gaps/barriers prioritized by <u>one group</u>

6. Workforce readiness

Rationale for identifying gap/barrier	Potential solutions for addressing gap/barrier
• Lack of a sufficient trained, deployable core workforce • Reliance on ad hoc surge training • Limited sustained funding for readiness	• Maintain sustainable funding for a trained core workforce • Incorporate research capacity into surge training programs • Prepare staff for emergencies, involve community health workers, and promote task-shifting • Establish regional databases of specialists and active national repositories • Foster public-private partnerships and retain subject matter experts • Establish mobile mentoring programs where more experienced researchers could be called upon to assist less experienced investigators across regions

7. Pharmacovigilance

Rationale for identifying gap/barrier	Potential solutions for addressing gap/barrier
• Weak national procedures and platforms for monitoring safety of vaccines/ medicines during routine and emergency use	• Develop standard procedures and SOPs for pharmacovigilance, including emergency-specific protocols • Establish platforms for reporting adverse events and promote digital tools for surveillance • Train health workers on pharmacovigilance and promote post-marketing and post-trial surveillance • Allocate budget and create secure databases for pharmacovigilance data

8. Rapid research startup

Rationale for identifying gap/barrier	Potential solutions for addressing gap/barrier
• No rationale provided	• Identify dedicated emergency research funds • Rely on existing site readiness assessments, fast-tracked contracting processes, digital infrastructure, and existing community engagement mechanisms • Provide on-call rapid response support to ensure necessary logistical support, including resources and expertise

Considering the potential for differences between ecosystems and infrastructure across East and Central Africa, following the meeting, the Mentimeter results were combined across the three anglophone groups and compared to the francophone group, which generally had more Central Africa representation. While conclusions should not be drawn from these observations, a few key differences and insights within and across these groupings emerged for consideration:

- The francophone group was the only group that identified pharmacovigilance as one of the top four to five key gaps. Interestingly, pharmacovigilance also scored relatively low among anglophone groups when combined.

- Across both francophone and anglophone groups, community engagement was identified as a gap that scored relatively lower compared to other elements. However, community engagement did not rise to the top-prioritized gaps for any of the groups.
- Public health and research laboratories were identified as key gaps in the francophone group, with research laboratories scoring lower than public health laboratories in the anglophone groups.
- Diagnostic capabilities scored higher in the francophone group than in the anglophone groups.

Existing networks, entities, and programs

The breakout groups were then tasked with identifying existing networks, entities, and programs that could serve as resources to build readiness for a regional vaccine research platform capable of conducting GCP-compliant trials and RWE studies to help address the identified gaps/barriers. These included the following:

- Key continental and regional organizations such as Africa CDC, WHO, African Vaccine Regulatory Forum (AVAREF), AMA, CEPI, and EDCTP offer technical expertise, regulatory harmonization, and coordination frameworks for rapid evidence generation.
- National ministries of health, public health institutes, and research councils play a critical role in prioritizing research activities, providing political commitment, and ensuring relevant laws and policies are in place.
- Academia, research institutes, and centers contribute to identifying research priorities and gaps, while civil society and research funders can support decision-making and data system improvements.
- Specialized entities such as the African Society for Laboratory Medicine (ASLM), the East African Health Research Commission (EAHRC), the East, Central and Southern Africa Health Community (ECSA-HC), and Pan-African Bioethics Initiative (PABIN) provide support such as laboratory capacity building and ethical review strengthening, as well as human resource deployment.
- Foundations and sponsors, including the Mastercard Foundation and US National Institutes of Health (NIH), offer funding and training for ethics and data systems.

These networks and entities, through their convening power, technical support, and advocacy, are well positioned to help implement the actionable solutions identified during the breakout sessions and drive progress toward a more coordinated and effective emergency research response across the region. The table below provides a summary of the specific organizations, networks, and programs identified by workshop participants. (Note that all programs/entities are listed in alphabetical order.)

Gap/theme	Supporting programs/entities
1. Rapid regulatory approval	Africa CDC, AMA, AVAREF, civil society, ministries of health, national assemblies, WHO
2. Rapid ethics approval	Academia, AfCDC, African Union Development Agency - New Partnerships for Africa Development (AUDA-NEPAD), EDCTP, Gates Foundation, Mastercard Foundation, ministries of health, national councils (e.g., NACOSTI/Kenya), national research institutes, PABIN, PANdemic preparedness plaTform for Health and Emerging infections Response (PANTHER), WHO
3. Data systems and interoperability	Academia, AfCDC, the Centre for the Fourth Industrial Revolution (C4IR), DHIS2, Mastercard Foundation, national councils (e.g., NACOSTI/Kenya),

	NIH, private sector, Sand Technologies, study sponsors, ministries of health, WHO
4. Laboratory capacity	Africa CDC, AFROSCREEN, ASLM, EDCTP, Institut Pasteur, national laboratories, WHO
5. Clear and rapid decision-making	Africa CDC, civil society, medical research councils, ministries of health, regulatory authorities, WHO
6. Workforce readiness	Academia, Africa CDC, Amref, CDT Africa, ministries of health, Red Cross/NGOs, Wellcome Trust, World Bank
7. Pharmacovigilance	Africa CDC, AMA, International Vaccine Safety Network, national drug agencies, national health programs, WHO
8. Rapid research startup	Africa CDC

Additional issues raised during plenary discussion

After read outs from each of the breakout groups, the workshop participants engaged in a plenary discussion. Several issues were raised by the participants, including:

- Questions about how routine vaccine development and emergency vaccine generation can be operationalized in East and Central Africa given regional nuances.
- The need for routine research capacity strengthening and the ability to pivot to emergency readiness.
- Concerns about the cyclical nature of research funding (noting that outbreaks often strike irrespective of whether systems are resourced or not), the challenges of conducting research during civil unrest, the need to reinvigorate and maintain existing structures, and the critical nature of political will.
- A need for sustainable models, stronger coordination at national, regional, and continental levels, and practical strategies to align group findings with RPECA's overarching goal of strengthening research preparedness in the region.
- A request for the workshop organizers to examine the detailed findings from the breakout group discussions, rather than solely focusing on broader theme areas, as there was other important feedback noted during these sessions.

Workshop participants engage and reflect during plenary session discussions.

Session 4: Regional Partners and Coordination

This plenary session consisted of two “exploratory exercises” that began with introductory presentations to set the stage for the interactive parts of the session. The sessions aimed at understanding key decision-makers, coordination mechanisms, and important lead partner characteristics and considerations. As in Session 3, the web-based polling tool (Mentimeter) was used to gather input from the participants and enable rapid sharing with the full group to guide further discussion.

Optimizing coordination of emergency evidence generation during an outbreak

To introduce the first exercise, CEPI presented the “hub and spoke” model (Figure 7). Hubs serve as central facilities providing strategic oversight, technical expertise, and resource coordination across multiple countries, while spokes are sub-national facilities that connect to hubs and enable localized implementation of clinical trials. Mobile units, attached to spokes or hubs, offer flexible coverage across wide geographic areas without requiring substantial infrastructure investment. This exercise aimed to emphasize how successful implementation requires collaboration with regional institutions, Africa CDC, and local experts to ensure the development of a strong consortium supporting RPECA in addressing regional and national priorities.

Figure 7. Slide outlining the hub and spoke model from CEPI’s presentation.

Polling and discussion

The participants used Mentimeter to respond to polling prompts to identify key regional decision-makers and how coordination works in the region. Polling revealed that effective coordination relies on a diverse array of decision-makers, including ministries of health, national public health institutions, national ethics councils, biosafety committees, regulatory bodies, research institutions, universities, and continental and global agencies such as Africa CDC and WHO. Participants emphasized the importance of country-specific mechanisms—like joint review committees and national public health

institutes—and highlighted the critical role of international organizations in supporting rapid research, especially for cross-border outbreaks. Coordination mechanisms and organizations most identified by participants for facilitating within-country rapid conduct of emergency evidence research included ministries of health, NPHIs, and the WHO (in that order). For cross-border outbreaks, this shifted to the WHO, Africa CDC, ministries of health, CEPI, and ECSA-HC/Médecins Sans Frontières (MSF), (in that order).

Participants also highlighted some persistent challenges, such as breakdowns in communication within and between organizations, political interference, fragmented information sharing, and the absence of regular stakeholder meetings. Community advisory boards, civil society, and private sector entities were recognized as vital contributors to bridge gaps between government and local communities. Additionally, issues such as power dynamics and attempts to retain control or funding were identified as obstacles to effective coordination. Inclusive, multi-sectoral collaboration, robust communication systems, and strong international partnerships were noted as critical for optimizing emergency evidence generation during health crises.

In the discussion that ensued, the participants broadened the earlier brainstorming on communication and coordination by emphasizing regulatory readiness and multi-level structures for East and Central Africa. A key concern was the omission of the AMA from the Mentimeter polling results, with several noting that regulatory clarity and speed—especially for unlicensed products and emergency use licensure—often determine how quickly evidence generation can begin. Participants further recommended strengthening country-level coordination first: formally integrating research institutions into outbreak response so ministries of health are not simultaneously burdened with service delivery and research and then building outward to regional alignment. They urged a hybrid model that balances centralized, harmonized standards with decentralized implementation to preserve national sovereignty, expand capacity across institutions, and ensure interoperable, decision-grade data. Participants also questioned whether national task forces are truly functional at subnational levels, proposing clearer mapping of performance to ensure actions “trickle down” to where epidemics occur. Finally, reflecting on the high concentration of emergencies in fragile, conflict-affected, and vulnerable countries, participants called for resilient research networks and regulatory pathways tailored to conflict contexts, noting evidence of attacks on healthcare that reduce access during crises and suggesting engagement with partners experienced in such settings and use of WHO dashboards to guide preparedness and protection.

Informing the methodology to identify and select regional research preparedness partners

CEPI, IVI, and PATH provided brief presentations to introduce the second exercise. First, CEPI highlighted the need for participants to reflect on the importance of coordinating the many teams working on research preparedness and outbreak response across Africa, highlighting the value of regionally anchored TCPs, with a focus on building capacity, fostering sustainability, and ensuring rapid response capabilities through collaboration with local health authorities, research institutions, government ministries, and communities. Then, IVI and PATH presented on the role of TCPs in advancing research preparedness in Africa under ARC-WA and RPECA, respectively.

ARC-WA began with establishing routine operational site readiness for Lassa fever vaccine trials. A structured baseline readiness assessment identified priority gaps in infrastructure, clinical operations, laboratories, data systems, finance, community engagement, and regulatory processes. IVI and MRCG jointly led the TCP function, combining IVI’s scientific leadership with MRCG’s operational capabilities, and they worked closely with Africa CDC to align with continental priorities and regulatory harmonization. The TCP served as the technical, operational, and coordination backbone, providing leadership across workstreams such as SOP harmonization, workforce development, and

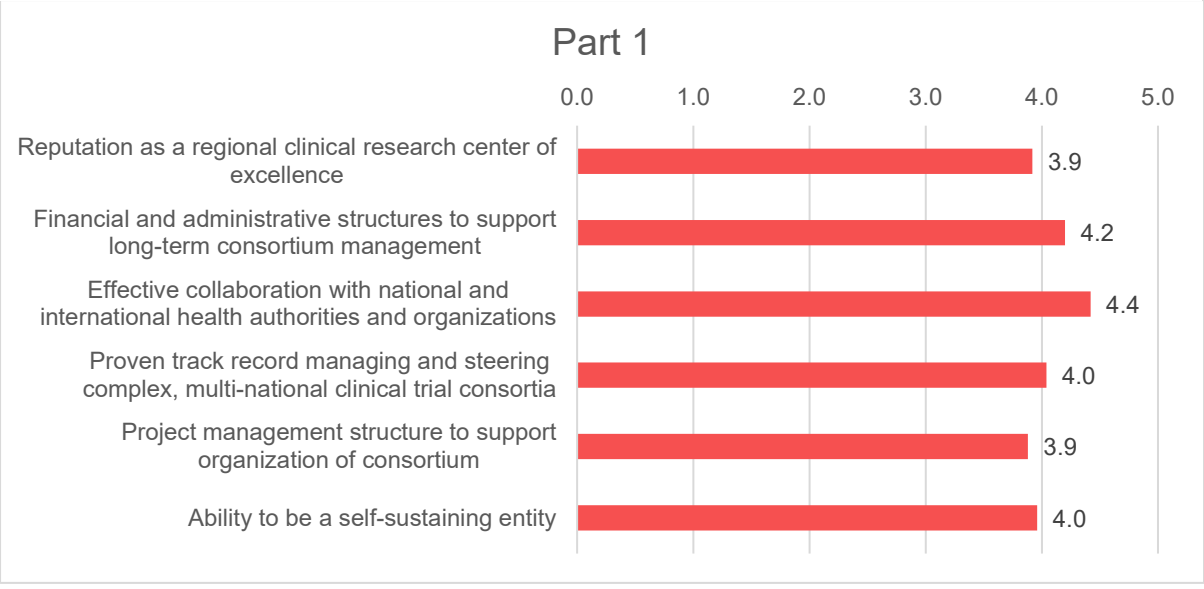
governance. IVI noted that local leadership was essential for rapid progress, complementary institutional strengths amplified impact, and structured technical coordination accelerated readiness. Sustainability requires long-term capacity building rather than one-off activities, and transition planning should start early to ensure continuity when TCP roles shift to lighter-touch advisory functions. Looking ahead for ARC-WA, IVI will be placing clinical research sites at the center of the ecosystem, strengthening the preparedness network through coordinated hub-and-spoke structures, and defining a sustainable advisory role for TCPs that complements local and regional responsibilities without duplication.

The RPECA initiative is starting with a focus on emergency evidence generation rather than with a predefined disease, as was the case for ARC-WA. CEPI selected PATH as the initial TCP for RPECA to help establish a sustainable research preparedness platform capable of rapid deployment during outbreaks. The mandate includes identifying one or more regionally based partners who will co-develop the consortium model with PATH and eventually assume full leadership and governance responsibilities. The lead partner will need to sustain an “at-the-ready” emergency evidence preparedness ecosystem, coordinate a consortium that can respond rapidly during outbreaks, and lead capacity-building efforts for other regional institutions using a hub-and-spoke model. The identified partner must combine scientific and administrative expertise, have strong regional presence, and be able to conduct routine research outside outbreak periods to maintain readiness.

Polling and discussion

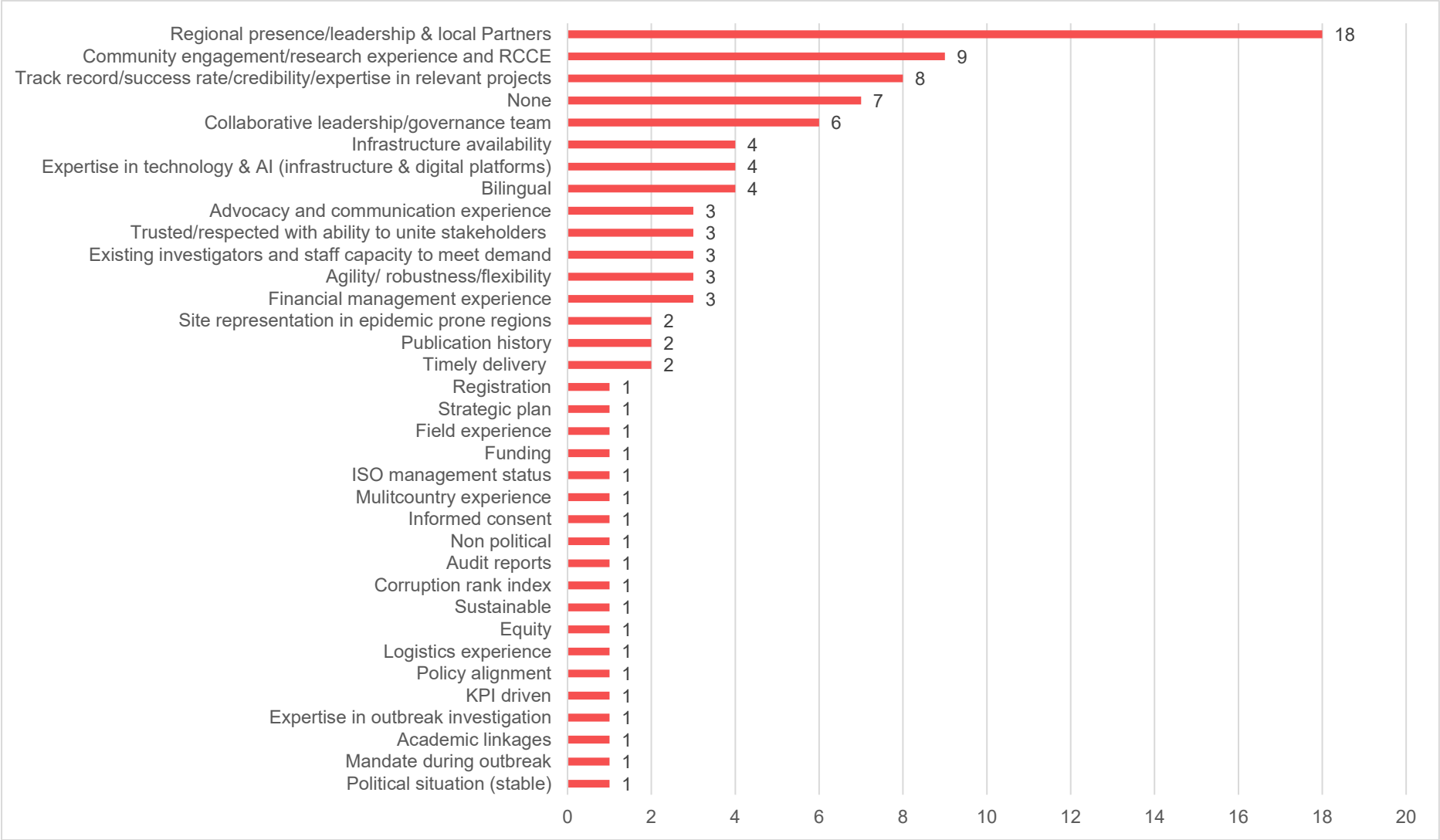
Participants used Mentimeter polling to inform the methodology for identifying and selecting TCPs in East and Central Africa. The polls were conducted in English and French and utilized a scale of 1 (not important) to 5 (essential). Participants from both language groups emphasized the importance of selecting lead partners with strong reputations as centers of clinical research excellence, robust financial and administrative structures, and proven experience managing complex, multi-country clinical trial consortia (Figure 8). Effective collaboration with national and international health authorities, the ability to mobilize human and technical resources rapidly, and a track record in capacity building and operationalizing clinical trials were also consistently rated as essential characteristics. Additionally, the francophone group emphasized the need for bilingual/francophone coordination.

Figure 8. Mentimeter responses to rating the most important TCP characteristics for long-term success.



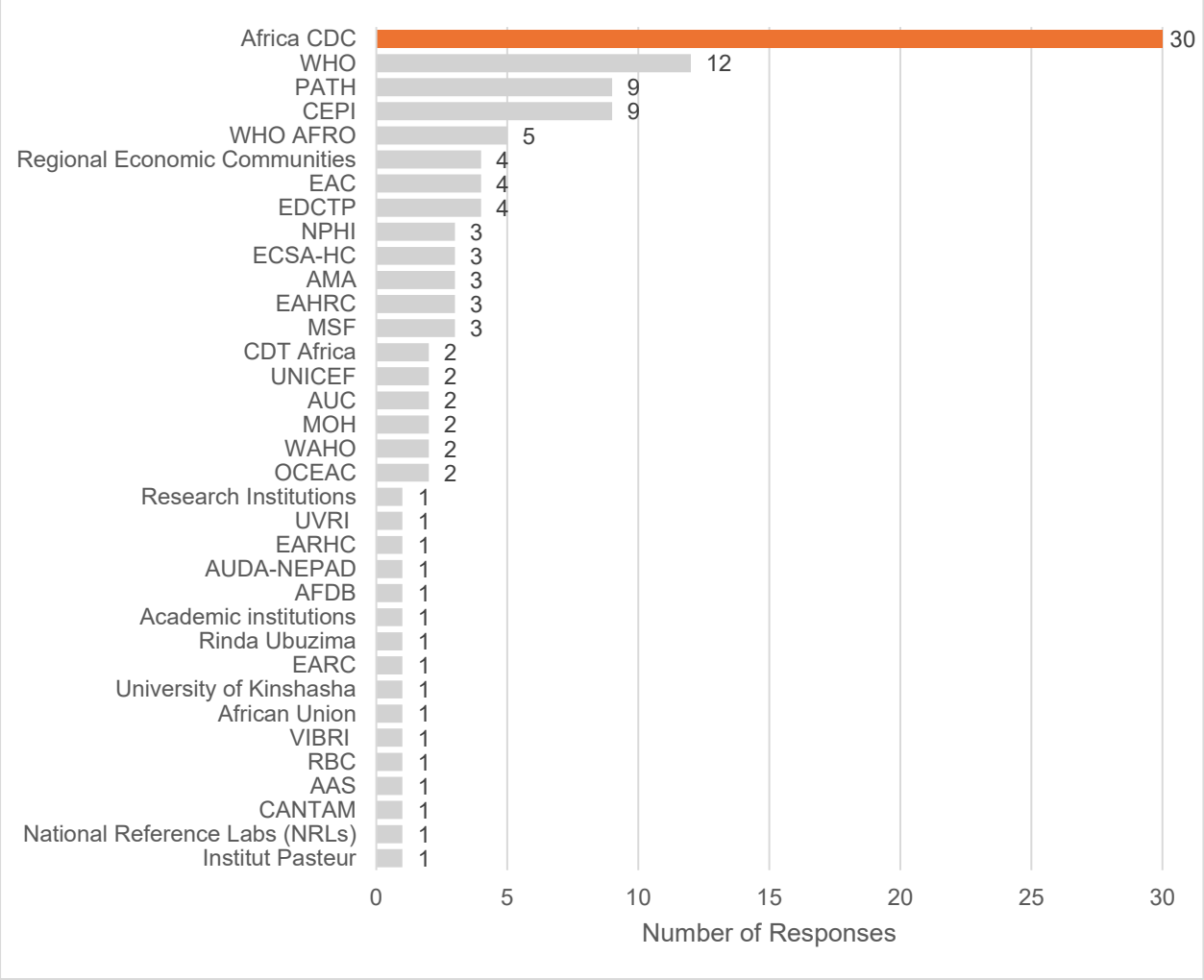
Approximately two-thirds of workshop participants across and within francophone and anglophone speakers indicated consensus for separate regional consortium leads, one in East and one in Central Africa. Participants also noted that, to address region-specific needs and ensure effective coordination, it is important for consortium leads be local East and/or Central Africa entities. There was openness to partnerships between multiple organizations. Additional criteria noted as important for consortium leads included collaborative and regional leadership, local partners, credibility, technological expertise, communication skills, staff capacity, autonomy, bilingual capacity, community engagement, and financial management. The importance of credibility and the ability to unite stakeholders was also noted (Figure 9).

Figure 9. Mentimeter responses to the prompt for participants to identify other important TCP characteristics.



Key regional entities identified for inclusion in the TCP selection process included Africa CDC, WHO AFRO, PATH, CEPI, EAHRC, EDCTP, national public health institutes, academic institutions, regional economic communities, AMA, and MSF (Figure 10).

Figure 10. Mentimeter responses on regional entities considered important to include in the process for selecting consortium leads/TCPs.



Participants also raised important considerations for TCP selection methodology: the need for political commitment, equity in partnerships, transparency, community involvement, and alignment with national priorities. Challenges such as linguistic barriers, corruption, lack of alignment, and competition over mandates were acknowledged, with calls for standardized procedures, sustainability plans, and active involvement of both public and private sectors.

Overall, this collective output underscores the value of inclusive, regionally anchored, and well-coordinated partnerships, supported by strong governance, stakeholder engagement, and commitment to capacity building and equitable collaboration. These insights will inform the development of a robust methodology for selecting and supporting regional research preparedness partners in Africa.

Closing Remarks

The final session of the workshop featured closing remarks from PATH, CEPI, and Africa CDC to briefly reflect on the discussions that had taken place and thank the presenters and participants for their invaluable contributions to the workshop.

Dr. Kristen Lewis, RPECA Director at PATH, noted that the workshop participants had surfaced real barriers to rapid and rigorous evidence generation during outbreaks, while also identifying solutions, consortium models, and partner characteristics to inform the basis of a locally led and regionally aligned roadmap. She emphasized that this foundational workshop was only the first step in developing a research preparedness roadmap for emergency evidence generation in East and Central Africa.

Dr. Gabrielle Breugelmans, Director of Epidemiology and Data Science at CEPI, observed that the workshop had covered a tremendous amount of ground and generated many invaluable insights, bringing us closer to a collective understanding of what it truly takes to conduct clinical research for investigational vaccines during public health emergencies. Dr. Breugelmans stressed that CEPI's 100 Days Mission could not be accomplished alone, and that partnerships with researchers, policymakers, implementers, and community leaders were essential. She described the workshop as the beginning of an important journey and expressed CEPI's eagerness to move forward together with the participants and PATH as the TCP, building on successful collaborations in West Africa.

Dr. Elvis Temfack, Head of R&D and Clinical Trials Coordination at Africa CDC, emphasized the importance of building a robust ecosystem with pillars such as ethics, regulation, and strengthening capacity. He also discussed the need to involve both the general community and political stakeholders in research preparedness, advocating for effective communication with politicians to secure resources and reduce barriers to public health initiatives. In addition, he addressed the importance of leveraging modern technology, such as artificial intelligence and simulations, to enhance capacity building and preparedness for research and emergency response. Finally, Dr. Temfack concluded the meeting by thanking participants, national authorities, and partners such as CEPI, PATH, and Africa CDC, and encouraged their ongoing collaboration to advance the research preparedness ecosystem.

Next steps

Based on the outcomes of these discussions, CEPI, PATH, and Africa CDC will continue consultations toward achieving the following in 2026:

- Development of a Research Preparedness Roadmap for East and Central Africa focusing on the priority gaps and solutions identified in this workshop.
- Development of a methodology for co-TCP(s) identification and selection, as well as a related consortium structure.
- Development of a regional "hub and spoke" model methodology for CEPI priority diseases.
- Conduct of additional workshops, convenings, and/or tabletop exercises to gather iterative input and feedback into the planning of these activities.

These activities will be followed by partner selection and piloting the roadmap.

Appendices

Appendix 1. Institutions that participated in the workshop

Institutions are listed in alphabetical order and then alphabetically by country name (if relevant).

Organization	Title	Country
Africa CDC	Consultant	Ethiopia
Africa CDC	Regional Program Lead	Ethiopia
Africa CDC	Pharmacovigilance Unit Lead	Ethiopia
Africa CDC	Director	Ethiopia
Africa CDC	Technical Officer Pharmacovigilance	Ethiopia
Africa CDC	Senior Technical Officer-Regulatory Solutions	Ethiopia
Africa CDC	Regional Program Lead	Ethiopia
Africa CDC	Senior Technical Officer (Lead, Climate Change And Health Programme & Eastern Africa RISLNET)	Ethiopia
Africa CDC	Head, R&D and Clinical Trials	Ethiopia
Africa CDC-Central Africa Regional Coordination Centre (RCC-CA)	Senior Technical Officer for Pathogen Genomics	Gabon
Africa Clinical Research Network	Chief of Staff	South Africa
Akagera Medicines	Project Coordinator	Rwanda
Amref Health Africa	Advocacy and Communications Advisor (Health Research, Development and Innovation)	Uganda
ANRS EID (Inserm)	Head, Outbreak Research Response and International Partnerships	France
Armauer Hansen Research Institute of MOH in Ethiopia	Researcher, Director	Ethiopia
ASLM	Project Manager	Kenya
AUDA-NEPAD	Senior Programme Officer	South Africa
BioNtech	Senior Director Global Health Office	Spain
Centre de Recherches Médicales de Lambarene (CERMEL)	Director	Gabon
Centre for Tropical Diseases and Global Health, Catholic University of Bukavu	Director, Research and Innovation, and Head, Ubuntu Clinical Trial and Pandemic Preparedness	Democratic Republic of Congo
Centre national des maladies endémiques	Médecin au Programme national de lutte contre la tuberculose et le VIH/SIDA	São Tomé and Princípe
CEPI	Director of Epidemiology and Data Science	The Netherlands
CEPI	Director Clinical Development	United Kingdom
CEPI	Head of Africa Strategy and Engagement	United Kingdom
CEPI	Senior Clinical Development Lead	United Kingdom
Department of Tropical Medicine, UNIKIN	Professor	Democratic Republic of Congo
Director of National Public Health Laboratory	Ministry of Health / National Public Health Laboratory	Gabon
East African Community	Statistician	Uganda
East Central and Southern Africa Health Community	Manager for Knowledge Management Monitoring and Evaluation	Eswatini

Eduardo Mondlane University, Faculty of Medicine	Associate Professor	Mozambique
Ifakara Health Institute	Director Of Science	Tanzania
INRB, Ministère de la Santé	Head of Epidemiology and Global Health, and Director of Clinical Research Center of INRB	Democratic Republic of Congo
Institut Pasteur De Bangui	Directeur	Central African Republic
Institut Santé Publique du Tchad (INSAPT)	Directrice de la communication, des statistiques et des Archives de l'INSAPT	Chad
Institution - Medical and Epidemiological Research	Laboratory Director	Uganda
IVI	Deputy Director General EPIC	Korea
Kavi-Institute of Clinical Research, University of Nairobi	Professor And Senior Research Leader	Kenya
Kenya Medical Research Institute	Director Centre for Virus Research and Head of Outbreak and Surveillance Program in KEMRI	Kenya
Kenya Medical Research Institute	Senior Principal clinical research scientist	Kenya
Kenya Ministry of Health	Director of Public Health and Sanitation	Kenya
Kenya National Public Health Institute	Ag. Director, Public Health Research and Informatics	Kenya
Laboratoire de recherche en santé publique Baney	Biologiste médical	Equatorial Guinea
Makerere University Lung Institute	Trial coordinator / Physician	Uganda
Ministère de la Santé	Chargé de la Recherche et des Investigations	Republic of Congo
Ministère de la Santé et de la Protection Sociale	Epidémiologiste, Santé Publique, MTN, Lèpre -tuberculose	Comoros
Ministère de l'Enseignement supérieur, de la recherche scientifique et de la formation professionnelle	Vice-président du Président du Comité de Bioéthique du Tchad Directeur général de l'enseignement supérieur	Chad
Ministère Santé et Protection Sociale	Directrice Planification Etudes et Recherche	Comoros
Ministério da Educação	Vice-Presidente/ Diretora Pedagógica, Professora do Instituto Superior de Ciências da Saúde Victor Sá Machado da Universidade de São Tomé e Príncipe	São Tomé and Princípe
Ministry of Health and Wellness Community	Physician, Communicable Disease Control Unit	Mauritius
Ministry of Health, Ethiopia	Analyst and Coordinator for Policy, Strategy and Research LEO-Ministry of Health	Ethiopia
Ministry of Health, Madagascar	Director of Training and Research	Madagascar
Ministry of Health, National Public Health Institute, South Sudan	Researcher	United States
Ministry of Health, Seychelles	Policy Analyst	Seychelles
Ministry of Health/Makerere University	Associate Professor	Uganda
Ministry of Public Health, Cameroon	Research Executive	Cameroon
National Institute for Medical Research (NIMR)	Senior Research scientist	Tanzania
National Institute for Public Health - Burundi	Lecturer - Researcher	Burundi

National Institute of Health, Somalia	Research Officer	Somalia
National Institute of Health, Somalia	Director of Health Research Department	Somalia
National Public Health Institute	Expert at the Research and Training in Public Health Department	Democratic Republic of Congo
PANTHER Africa	Chair, Scientific Advisory Board, PANTHER & Board Member, PANTHER Africa	Kenya
PATH	Senior Technical Program Manager Malaria and Neglected Tropical Diseases	Central African Republic
PATH	Strategic Communications Officer	Kenya
PATH	Head of PATH Kenya	Kenya
PATH	Senior Medical Officer	Kenya
PATH	Vaccines and Immunization Lead- Kenya	Kenya
PATH	Senior Technical Officer	Senegal
PATH	Director of Strategic Alliances	USA
PATH	Director, RPECA	USA
Post-doc Researcher	Fondation Congolaise pour la Recherche Médicale	Republic of Congo
Public Health Authority Ministry of Health	Director of Research	Seychelles
Rinda Ubuzima	Executive Director	Rwanda
Rwanda Biomedical Centre (RBC)	Epidemiologist	Rwanda
Science for Africa Foundation	Senior Programme Manager	Kenya
Uganda National Institute of Public Health, Ministry of Health	Senior Epidemiologist	Uganda
Uganda Virus Research Institute	Director	Uganda
Uganda Virus Research Institute, Ministry of Health	Assistant Director of Research, Immunology	Uganda
Université de Bangui	Enseignant chercheur	Central African Republic
University of Antananarivo Madagascar Institute for Vaccine Research	President Of Madagascar Institute For Vaccine Research	Madagascar
University of Dschang / Cameroon Ministry of Public Health	Head of the Clinical Research Unit at the Division of Health Operations Research	Cameroon
University of Juba	Dean, College of Medicine	South Sudan
University of Kinshasa	Professor and Head of the Department of tropical medicine	Democratic Republic of Congo
Valneva	VP Clinical Development	Austria
Victoria Biomedical Research Institute	Principal Investigator/ CEO	Kenya

Appendix 2. Workshop agenda

Day 1 (Wednesday, 10 December 2025)		
Time	**Topic**	**Presenter/moderator**
8:00 – 9:00	**Registration**	All
Session 1: Continental and Regional Initiatives for Emergency Evidence Generation		
9:00 – 9:30	**Opening ceremony**	• Dr. Mosoka Fallah, Ag. Director of Science & Innovation, Africa CDC • Ms. Shingai Machingaidze, Head of Africa Strategy and Engagement, CEPI • Ms. Carolyne Njuguna, Kenya Country Director, PATH • Dr. Fred Ouma, Ag. Director, Public Health Research and Informatics, Kenya National Public Health Institute • Dr. Stephen Muleshe, Director of Public Health and Sanitation, Kenya Ministry of Health
9:30 – 9:45	**Icebreaker**	Ms. Carla Botting, Director, Strategic Alliances, CVIA, PATH
9:45 – 11:00	**Overview of research preparedness in African Region – Africa CDC, CEPI, PATH** Overview of the following: • Africa CDC's related initiatives and priorities • Background of CEPI program and regional research priorities • Introduction to RPECA	• Dr. Mosoka Fallah, Ag. Director Science & Innovation, Africa CDC • Ms. Jennifer Kealy, Clinical Development Operations Lead for East and Central Africa, CEPI • Dr. Kristen Lewis, Director Research Preparedness East/Central Africa, PATH
11:00 – 11:30	**Break and group photo**	All
Session 2: Emergency Evidence Generation—What Does It Take?		

11:30 – 12:30	**Generating emergency evidence during an outbreak (Part 1): Overview and real-world evidence (RWE)**
	• Distinguishing outbreak response from research activities: What does it take to generate emergency evidence during an outbreak?
	• Recent examples of RWE studies (and clinical trials): What worked? What needs to change?
	  ○ Pharmacovigilance
	  ○ Community engagement
	  ○ Institutions
		• Dr. Roshni Best, Senior Manager, Emergency Response, CEPI
		• Panel presentations/discussion
		  ○ Dr. Alemayehu Duga, Pharmacovigilance Unit Lead, Africa CDC
		  ○ Dr. Manar Keshk, Senior Technical Expert, Africa CDC
		  ○ Prof. Placide Mbala, Head of Epidemiology and Global Health and Director of Clinical Research Center of Institut National de Recherche Biomédicale (INRB)

12:30 – 13:30	**Lunch break**	All

13:30 – 14:30	**Generating emergency evidence in an outbreak (Part 2): Clinical trials**
	• Recent examples of clinical trials: What worked? What needs to change?
	  ○ Developers
	  ○ Researchers
	  ○ Operations
		Panel presentations/discussion
		• Ms. Erin Shutes, Senior Director, Global Health Office, BioNTech
		• Dr. Susanne Eder-Lingelbach, Vice President, Clinical Development, Valneva
		• Prof. Hypolite Muhindo Mavoko, Head of the Department of Tropical Medicine, University of Kinshasa
		• Prof. Pontiano Kaleebu, Director, Uganda Virus Research Institute

		• Mr. Olivier Nsekuye, Epidemiologist, Rwanda Biomedical Centre • Dr. Ayub Mpoya, Assoc. Director Site Networks, IQVIA
14:30 – 15:30	**Breakout session: Regional, sub-regional, and country gaps with respect to emergency evidence generation** • Review status quo for key pillars/functions (e.g., epidemiology/surveillance, regulatory, laboratory, pharmacovigilance, community engagement, qualitative research, quality, etc.). • Identify the most critical barriers/gaps that exist to enable emergency evidence generation for vaccines in the context of an outbreak, including gaps to enable seamless collaboration across functions.	• Introduction: Dr. Kristen Lewis, Director Research Preparedness East/Central Africa, PATH • Breakout groups: All
15:30 – 15:50	**Break**	All
15:50 – 17:00	**Breakout session (continued): Regional, sub-regional, and country gaps with respect to emergency evidence generation**	Breakout groups (continued)
18:30	**Networking dinner**	

Day 2 (Thursday, 11 December 2025)		
Time	**Topic**	**Presenter/moderator**
Session 3: Preparing for Emergency Evidence Generation		

9:00 – 12:30	**Breakout session: Opportunities to prepare for rapid emergency evidence generation**
	• Considering gaps and recommendations, what are the most important factors for:
	  ○ Preparing each pillar/function.
	  ○ Ensuring seamless cross-institutional and cross-border collaboration in rapid research implementation.
	  ○ Supporting research centers in completing clinical trials and RWE studies.
	• Recommendations for building off existing ecosystem (i.e., entities, networks, programs, and projects) in the region, thereby contributing readiness of a regional vaccine research platform for conducting GCP-compliant trials and RWE studies.
		Breakout groups

12:30 – 13:30	**Lunch**	All
13:30 – 14:30	**Session 3: Breakout group readout** Focus on top three recommendations/gaps for each point discussed.	Breakout groups
Session 4: Regional Partners and Coordination		
14:30 – 15:30	**Exploratory exercise: Optimizing coordination of emergency evidence generation during an outbreak**	• Ms. Shingai Machingaidze, Head of Africa Strategy and Engagement, CEPI • Carla Botting, Director, Strategic Alliances, PATH

	• Identify decision-makers who can support rapid emergency evidence generation. • Incorporate considerations related to building off existing networks and platforms. • Identify recommendations for shorter-term coordination with the goal of longer-term sustainable coordination.	
15:30 – 15:50	**Break**	All
15:50 – 16:50	**Exploratory exercise: Informing the methodology for identification and selection of regional research preparedness partners** • Explore preferred partner characteristics • Next steps	• Dr. Paul Ndaya Oloo, Senior Clinical Development Lead, CEPI • Dr. Florian Marks, Deputy Director General EPIC, International Vaccine Institute • Dr. Kristen Lewis, Director Research Preparedness East/Central Africa, PATH
16:50 – 17:00	**End of meeting: Summary and next steps**	• Dr. Kristen Lewis, Director Research Preparedness East/Central Africa, PATH • Dr. Gabrielle Breugelmans, Director of Epidemiology and Data Science, CEPI • Dr. Elvis Temfack, Head of R&D and Clinical Trials, Africa CDC
17:00	**Adjourn**	