Advancing the clinical research ecosystem in Africa: inclusive, innovative and impact-driven approaches

AFRICA REGULATORY CONFERENCE 2025

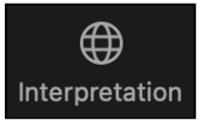
4-PART SERIES

PATIENT AND COMMUNITY ENGAGEMENT IN CLINICAL TRIALS

16 September 2025

13H00 – 16H00 CET & SAST

PARTICIPANT GUIDE

- The conference is held in **English**. Interpretation in **French** is available.
- Click on the interpretation icon in Zoom to enable this. 

- All participants are muted. We encourage you to **use the Q&A box** to raise questions to the speakers. If a question you would like to ask has already been raised, **you can also "like" that question**.
- For some sessions, participants will have the opportunity to also engage with speakers through Zoom polls.
- We encourage you to join all webinars in the series. You can sign up to the rest of the sessions on https://africaregulatoryconference.ifpma.org/.
- All **sessions are recorded**. All speaker presentations and videos will be **made available** on the https://africaregulatoryconference.ifpma.org/website after the conference.

AFRICA REGULATORY CONFERENCE 2025

SESSION 1: WHY IS IT IMPORTANT TO ENGAGE PATIENTS AND COMMUNITIES IN CLINICAL RESEARCH?

PANEL DISCUSSION

Luke Kanyangareng, Nurse

Tariro Makadzange, Africa Clinical Research Network

Norest Beta, Africa Clinical Research Network

Waila Mukulu, Science for Africa Foundation

AFRICA REGULATORY CONFERENCE 2025

Please use the “Q&A” function in Zoom to type in your question for the panel.

You can also “like” or “upvote” a question asked by another audience member.

Q&A

KEYNOTE PRESENTATION

Dr. Mosoka Fallah,
Africa CDC

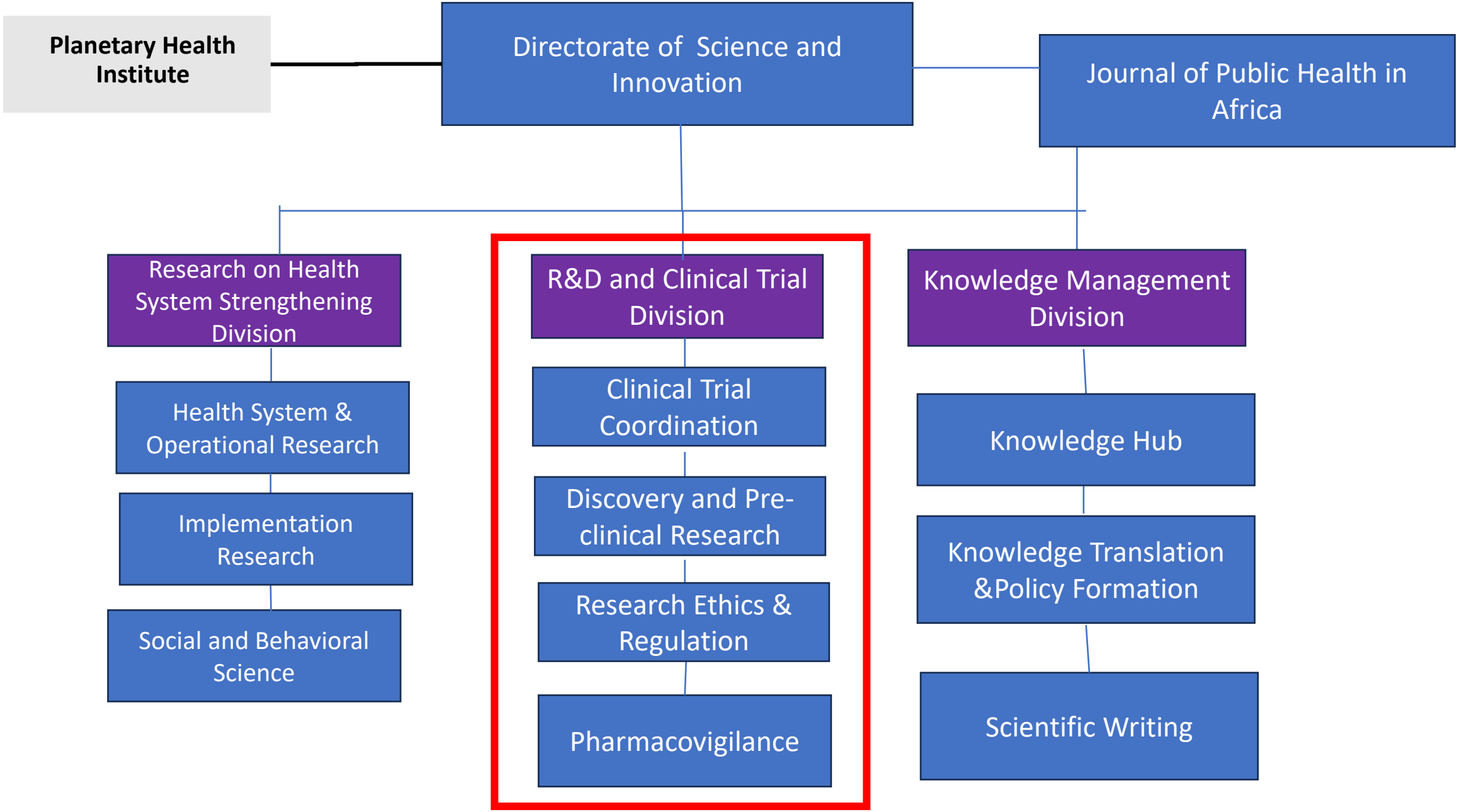
Safeguarding Africa's health

"Achievements in R&D & Opportunities of South-South and North-South collaboration of private companies on R&D"

Dr. Mosoka P. Fallah
Ag. Director Science and Innovation Directorate

THE BACKGROUND AND CONTEXT

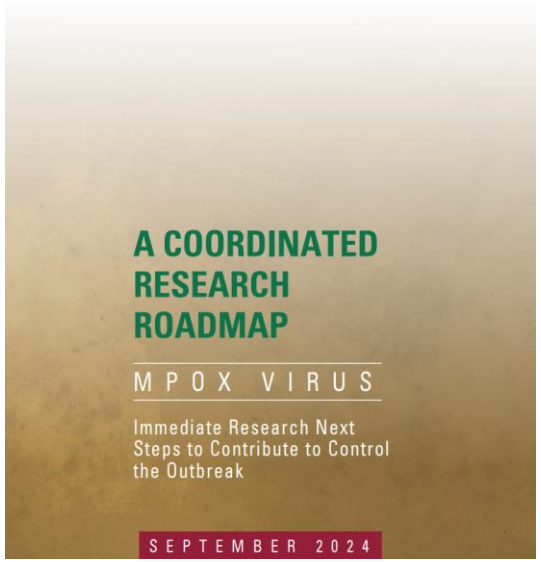
The Directorate of Science and Innovation



Directorate of Science and Innovation

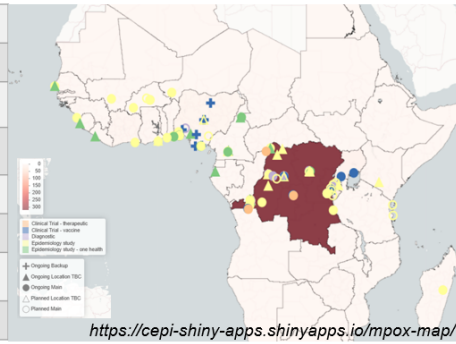
- R&D and Clinical Trial Division
- Clinical Trial Coordination
- Discovery and Pre-clinical Research
- Research Ethics & Regulation
- Pharmacovigilance

R&D to Enhance outbreak Response



Continental coordination of Mpox research

Study area	#
Socio-behavioral study	1
Therapeutic trial/study	4
Vaccine trial/study	6
Diagnostics trial/study	2
Epidemiological one health	3
Epidemiological study	32
Total	**48**

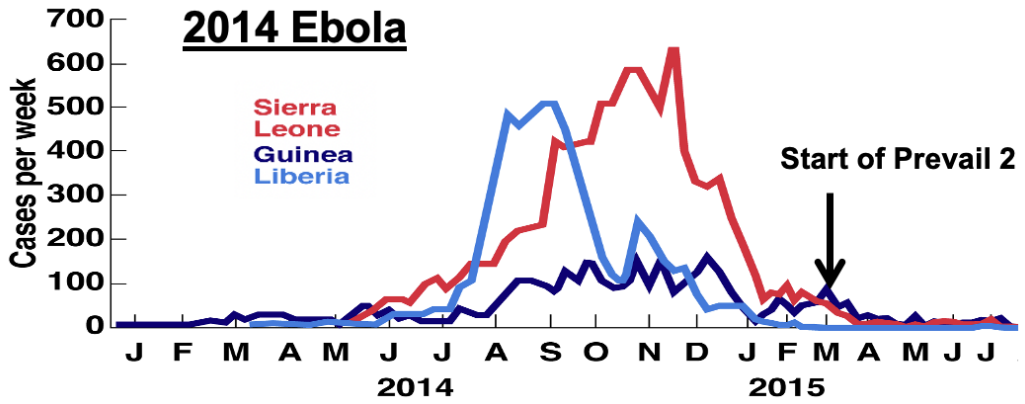


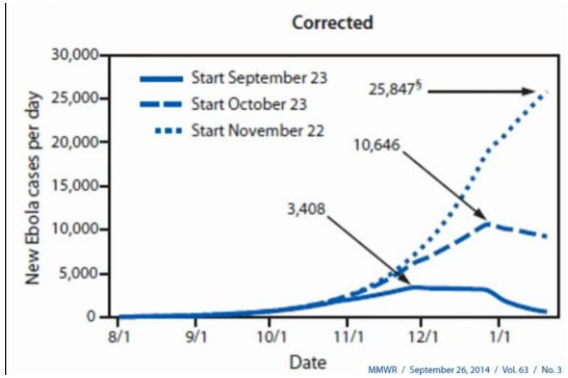
Use R&D to Enhance and support the Local manufacturing Vax, Dx & Therapeutic

Lack of R&D Investment has consequences

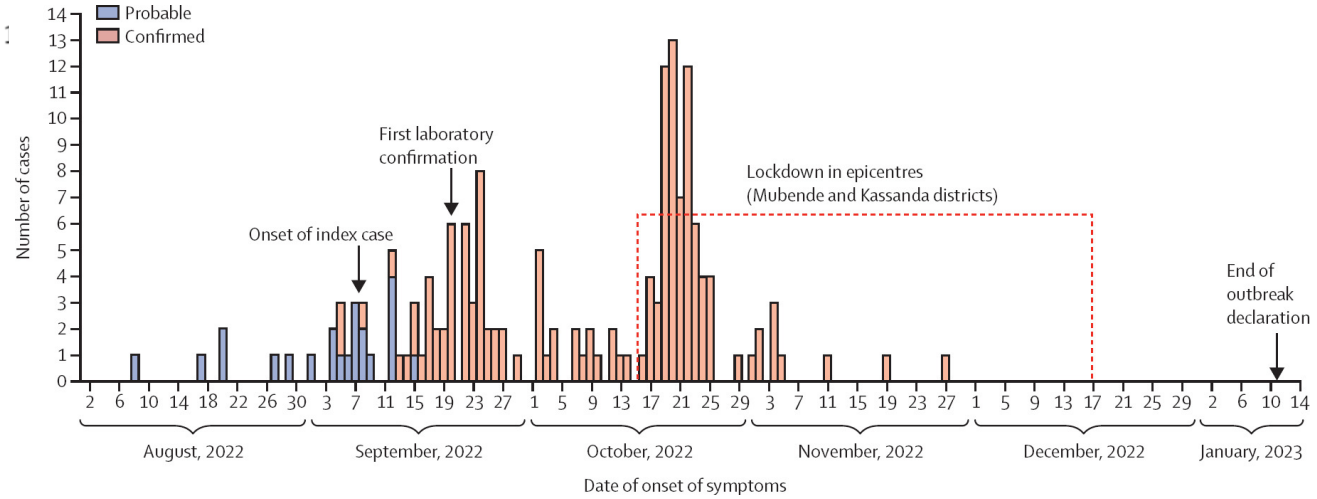
(CFR)- Guinea (70.7%),
Liberia (72.3%),
Sierra Leone (69.0%)
MORTALITY- 11,380

Ebola Zaire





2022 Ebola Sudan in Uganda



Dynamic of mpox 2024 - 2025

January - April 2024	May - August 2024	September - December 2024	January - April (2025)
Weekly average (susp): 376	Weekly average (susp): 909	Weekly average (susp): 2777	Weekly average (susp): 2874
Weekly average (conf): 55	Weekly average (conf): 186	Weekly average (conf): 488	Weekly average (conf): 672
CFR: 5.6%	CFR: 1.6%	CFR:1.3%	CFR: 1.0%
MS: 6	MS: 13 (+7)	MS: 20 (+7)	MS: 24 (+4)
January – April 2024: MS affected: 6	January – August 2024: MS affected: 13 (+7)	January – Dec 2024: MS affected: 20 (+7)	Jan 2024 – April 2025: MS affected: 24 (+4)
No Cases reported	Sweden and Thailand.	Germany, Belgium, UK*, US, Canada, India, Oman, Pakistan,	China, United Arab Emirates, Switzerland,

Dx of Epidemics	Treatment and Vx Status
Ebola Sudan	No Treatment/Exp vx
Chikungunya	No Treatment/Exp. Vx
mpox	No Treatment/Repurpose Vx
RFV	No Treatment/Exp Vx
Lassa fever	No Treatment/Exp Vx

After 50 Years of consistent outbreaks in Africa- there is no vaccine or therapeutics for mpox

Concurrent Clade I and Clade II Monkeypox Virus Circulation, Cameroon, 1979–2022

Delia D. Djuicy, Serge A. Sadeuh-Mba,[1] Chanceline N. Bilounga, Martial G. Yonga, Jules B. Tchatchueng-Mbougua, Gael D. Essima, Linda Esso, Inès M.E. Nguidjol, Steve F. Metomb, Cornelius Chebo, Samuel M. Agwe, Placide A. Ankone, Firmin N.N. Ngonla, Hans M. Mossi, Alain G.M. Etoundi, Sara I. Eyangoh, Mirdad Kazanji, Richard Njouom

During 1979–2022, Cameroon recorded 32 laboratory-confirmed mpox cases among 137 suspected mpox cases identified by the national surveillance network. The highest positivity rate occurred in 2022, indicating potential mpox re-emergence in Cameroon. Both clade I (n = 12) and clade II (n = 18) monkeypox virus (MPXV) were reported, a unique feature of mpox in Cameroon. The overall case-fatality ratio of 2.2% was associated with clade II. We found mpox occurred only in the forested southern part of the country, and MPXV phylogeographic structure revealed a clear geographic separation among concurrent circulating clades. Clade I originated from eastern regions close to neighboring mpox-endemic countries in Central Africa; clade II was prevalent in western regions close to West Africa. Our findings suggest that MPXV re-emerged after a 30-year lapse and might arise from different viral reservoirs unique to ecosystems in eastern and western rainforests of Cameroon.

Monkeypox virus (MPXV) is an emerging zoonotic *Orthopoxvirus* causing mpox in humans, a disease similar to the eradicated smallpox (*1*). Since identification in a monkey in 1958 (*2*) and a human in 1970 (*3*), MPXV-associated outbreaks have occurred primarily in rural rainforests in countries of Central and West Africa (*4–6*).

Author affiliations: Centre Pasteur of Cameroon, Yaounde, Cameroon (D.D. Djuicy, S.A. Sadeuh-Mba, M.G. Yonga, J.B. Tchatchueng-Mbougua, G.D. Essima, S.I. Eyangoh, M. Kazanji, R. Njouom); Ministry of Public Health, Yaounde (C.N. Bilounga, L. Esso, I.M.E. Nguidjol, S.F. Metomb, C. Chebo, S.M. Agwe, P.A. Ankone, F.N.N. Ngonla, H.M. Mossi, A.G.M. Etoundi); University of Douala, Cameroon (C.N. Bilounga); University of Bamenda, Cameroon (L. Esso)

DOI: https://doi.org/10.3201/eid3003.230861

Mpox is characterized by an influenza-like syndrome accompanied by adenopathy and maculopapular rashes typically developing on the palms of the hands and soles of the feet (*4,7*). For infected persons, supportive care and antiviral treatments, including cidofovir and tecovirimat, are provided (*4*). Cross-immunity with smallpox vaccination and a new generation of smallpox vaccines equally offer some protection (*8–10*). However, after smallpox vaccination was discontinued in the early 1980s, herd immunity gradually declined, enabling re-emergence of mpox, which is highlighted by the increased number of cases in Africa during the past 3 decades (*4,8,11–13*). Since early 2022, case counts have surged, and ≈1,215 confirmed mpox cases and 219 deaths were reported in Africa by December 28, 2022 (*14*). Before April 2022, mpox cases in the Western Hemisphere were typically reported from exposure to the exotic pet trade and international travel (*15–20*). Since then, MPXV-associated outbreaks have occurred worldwide, affecting >100 countries outside Africa (*4,21*) and becoming a global public health concern.

Primary MPXV transmission can occur through direct contact with body fluids or skin lesions of infected animals or indirectly via contaminated fomites. Similar contact with an infected person or with infected respiratory droplets might also lead to human-to-human secondary transmission, the main transmission mode of the 2022 global outbreak (*4,22*). Historically, primary zoonotic transmission was more common and mostly involved an at-risk population of hunters, butchers, and bushmeat handlers; secondary transmission was rare, but nosocomial and household transmission have been described (*3,13,23–25*).

[1]Current affiliation: Maryland Department of Agriculture, Salisbury, Maryland, USA.

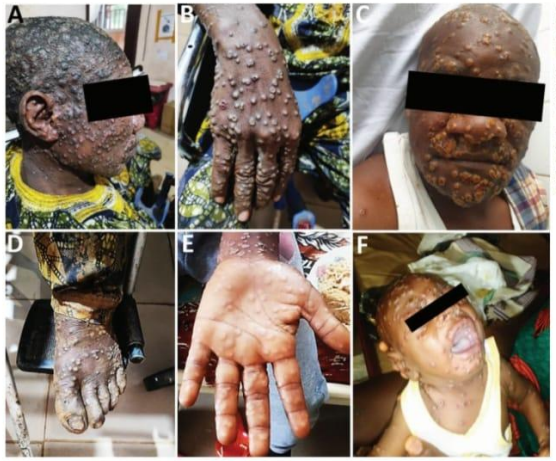


Figure 2. Maculopapular lesions in mpox patients from a study of concurrent clade I and clade II monkeypox virus circulation, Cameroon, 1979–2022. A–E) Deep maculopapular lesions of different sizes spread from the head (A, C) to hands (B) and diffuse to the soles of the feet (D) the palm of the hand (E). F) Lesions, including oral lesions and mouth ulcers, in a 3-month-old male baby.

confirmed in patients from the Centre, South, and East regions; all but 1 of clade II MPXV samples were recovered from patients from the Littoral, Northwest, and Southwest regions. Indeed, a clade II MPXV detected in the Centre region was an internally displaced person (IDP) originally from the Northwest region (Table 1; Appendix Table 3). The distribution of mpox cases points toward geographic segregation of the 2 viral clades in Cameroon. Those findings indicate a strong geographic association of MPXV genotypes in southern Cameroon, and that MPXV clade II is associated with the western part and the clade I with the eastern part of the country.

We obtained partial MPXV *ATI* gene sequences from 8 mpox-confirmed cases from 4 regions of Cameroon. We derived the newly determined sequences from samples collected in the Northwest (CPC code 22V-0972), Southwest (CPC codes 22V-07739, 22V-07911, 22V-07968), Centre (CPC codes 22V-05210, 22V-04865, 22V-4639), and South (CPC code 22V-6957) regions. Maximum-likelihood phylogenetic analysis of the 942 nt consensus sequences, including reference sequences (Appendix Tables 1–3), revealed that the 8 MPXV genomes from Cameroon segregated into clade I and clade II. As expected from the geographic association of MPXV isolates we report, MPXV clade I from the Centre and South regions grouped reliably with reference counterparts previously reported from countries in Central Africa, and clade II sequences from the Northwest and Southwest regions grouped consistently with strains from West Africa (Figure 4). Clade II strains from Cameroon clustered reliably within subclade IIb with 83% bootstrap support (Figure 4). Altogether, genotypic and phylogenetic analysis confirmed the concurrent circulation of both MPXV clades I and II in Cameroon with a striking geographic segregation.

Discussion

We examined the clinical, epidemiologic, and molecular patterns of MPXV infection in Cameroon over a 44-year period (1979–2022) as part of mpox surveillance in the country. During 1979–2022, a total of 137 persons were suspected of having mpox, and 32 were confirmed to be MPXV infected. Three persons died (CFR 2.2%) and death was associated with MPXV clade II. That CRF is much lower than those reported in previous studies of MPXV clade I that showed CFRs of 7%–10% (*13,43*). Overall, CFRs are lower among patients infected with clade II, including in the 2022 global outbreak settings (*4,25*). We were not able to collect information on potential underlying conditions of case-patients to determine whether

INVESTMENT IN R&D AND LOCAL MANUFACTURING HAS BOTH SECURITY & ECONOMIC IMPERATIVES

INVESTMENT IN R&D ACCELERATE MANUFACTURING WITH TRANSFORMATIVE ECONOMIC VALUE TO AFRICA

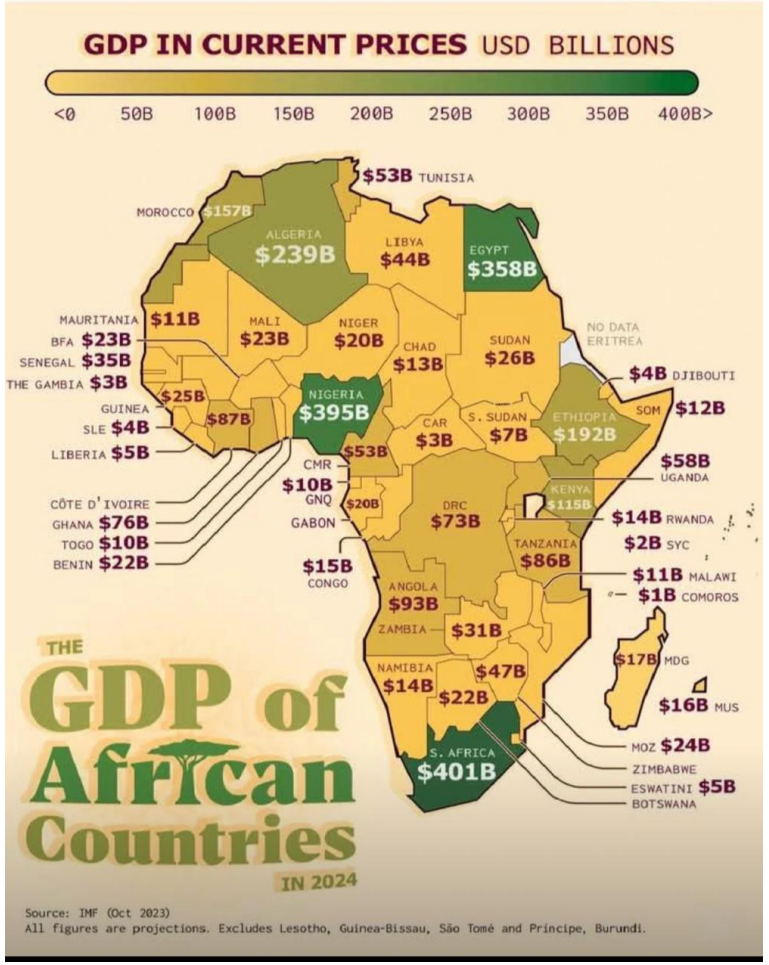
Annual revenue of Indian pharmaceutical market 2015-2047

Published by A. Minhas, Oct 25, 2024

India's domestic pharmaceutical industry's annual turnover reached around 50 billion U.S. dollars in 2023.

In 2018, the India pharmaceutical market was valued at 18 billion U.S. dollars.

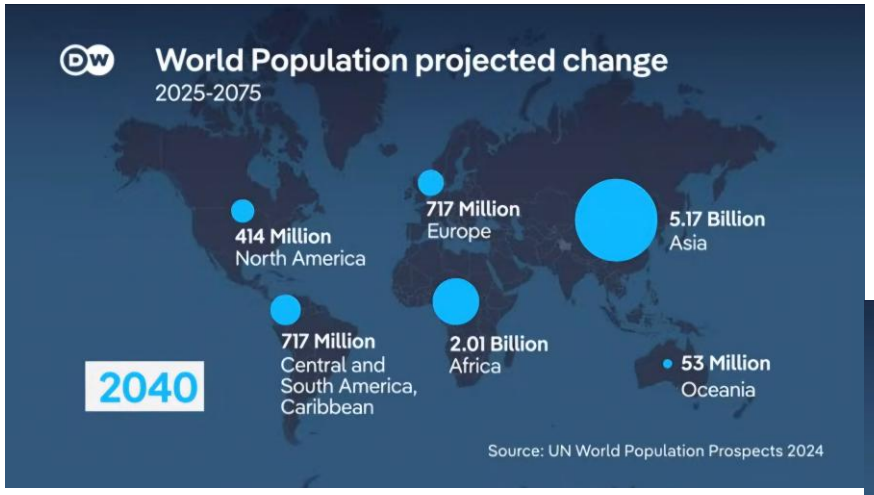
There was a **9.8 percent year-on-year growth rate** recorded in the market in 2019 compared to 2018.

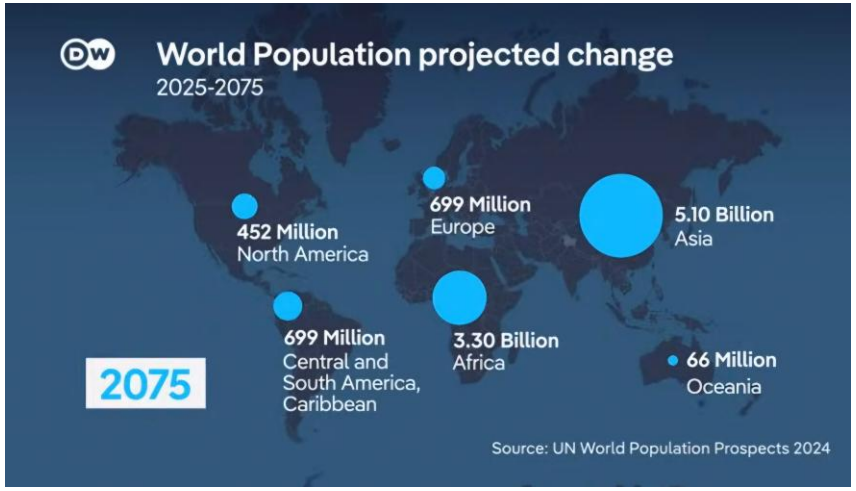


AFRICA GROWTH POTENTIAL IS A GREAT MARKET OPPORTUNITY

The total market size of the Indian Pharma Industry is expected to reach **US$ 130 billion by 2030** and **US$ 450 billion market by 2047**.

* Indian pharmaceutical companies are projected to achieve a revenue growth of 9-11% in FY25.





Overview of Key Activities, future vision, collaboration, Partnerships, etc. to strengthen Clinical Research/Clinical Trial Ecosystem from a Continental Perspective

AFRICA-LED CONTINENTAL COORDINATION OF RESEARCH RESPONSE IN OUTBREAKS

1.

Research Pillar:

Strategic Partnership for Continental mpox Research Coordination

AFRICA CDC
US NIH
CEPI
WHO

GLOBAL & CONTINENTAL MPOX RESEARCH MTG- AUG. 29/30 AFRICAN SCIENTISTS

OUTPUTS

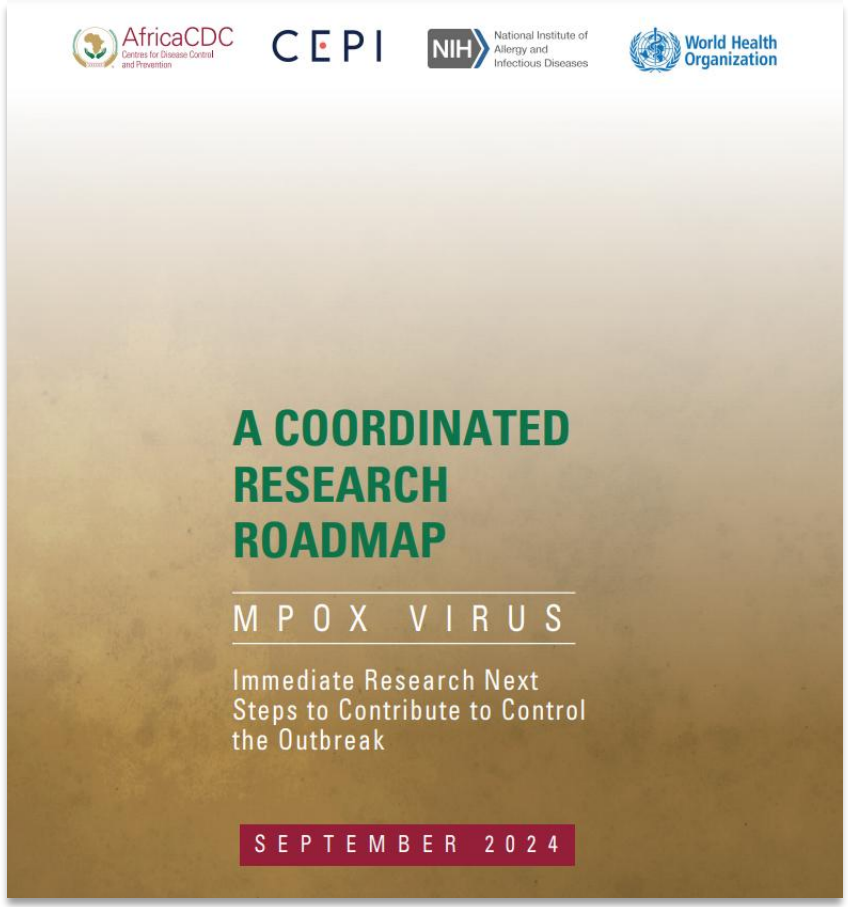
A COORDINATED RESEARCH ROADMAP Monkeypox virus

Immediate research next steps to contribute to control the outbreak

2.

A DASH BOARD To Track ALL mpox Clinical Trials & Research
https://cepi-shiny-apps.shinyapps.io/mpox-map/

Prioritization and coordination of research for mpox virus



10 immediate next steps for a coordinated Mpox Research Roadmap

- Obtain additional data on Mpox transmission and epidemiology, including clinical outcomes and risk factors for severe disease.
- Conduct research on animal models and use animal models towards the determination of correlates of protection, and support research on immunoassays
- Evaluate and deploy new rapid and sensitive diagnostic tests (including unbiased tests) that detect all MPXV clades and help differential diagnosis of diseases that can mimic mpox.
- Define regulatory pathway for "next generation" of medical countermeasures
- Define and implement all elements of optimized clinical standard of care for all MPXV infected patients
- Use existing tools to incorporate Good Participatory Practices and community engagement in research including public health research.
- Promote the development of new therapeutics and the evaluation of safety and efficacy of prioritized candidate therapeutics for mpox, in coordinated collaborative multicenter trials.
- Integrate research into the outbreak response activities.
- Facilitate availability of vaccines in areas with sustained human to human transmission, as part of an integrated response, and promote generation of critical data regarding vaccines safety, effects, and delivery strategies.
- Embrace and expand opportunities for coordination and collaboration of all research initiatives with local authorities and research institutions, with researchers from affected countries and the MoH at the centre of the response.

[Link to roadmap]

CEPI

NORTH-SOUTH-SOUTH COLLABORATION BEFORE-DURING AND AFTER OUTBREAKS

Research Response to Marburg Virus Disease in Rwanda - REMDESIVIR

News / Press Releases

Gilead Sciences, Rwanda's Ministry of Health and Africa CDC Collaborate to Support Rwanda's Marburg Virus Disease Response with Antiviral Therapeutic Donation-

8 DAYS FROM REQUEST TO DELIVERY

Addis Ababa, ETHIOPIA, October 8, 2024 – Gilead Sciences, Inc., in collaboration with Africa CDC and Rwanda's Ministry of Health, has donated 5,100 vials of remdesivir to support Rwanda's response to the Marburg Virus Disease (MVD). This emergency donation aims to provide treatment to those affected by the virus following negotiations led by Africa CDC.

Upon declaration of the outbreak on September 27, 2024, by the Ministry of Health of Rwanda, Africa CDC deployed senior response leaders to Kigali to assist with surveillance, lab testing, and research. While there is no approved cure for MVD, remdesivir is being supplied for emergency use as global vaccine and therapeutic trials, led by WHO, are underway. Gilead is now coordinating directly with the Ministry of Health of Rwanda to enable getting treatment courses of remdesivir to patients in need across the affected regions.

PANTHER:

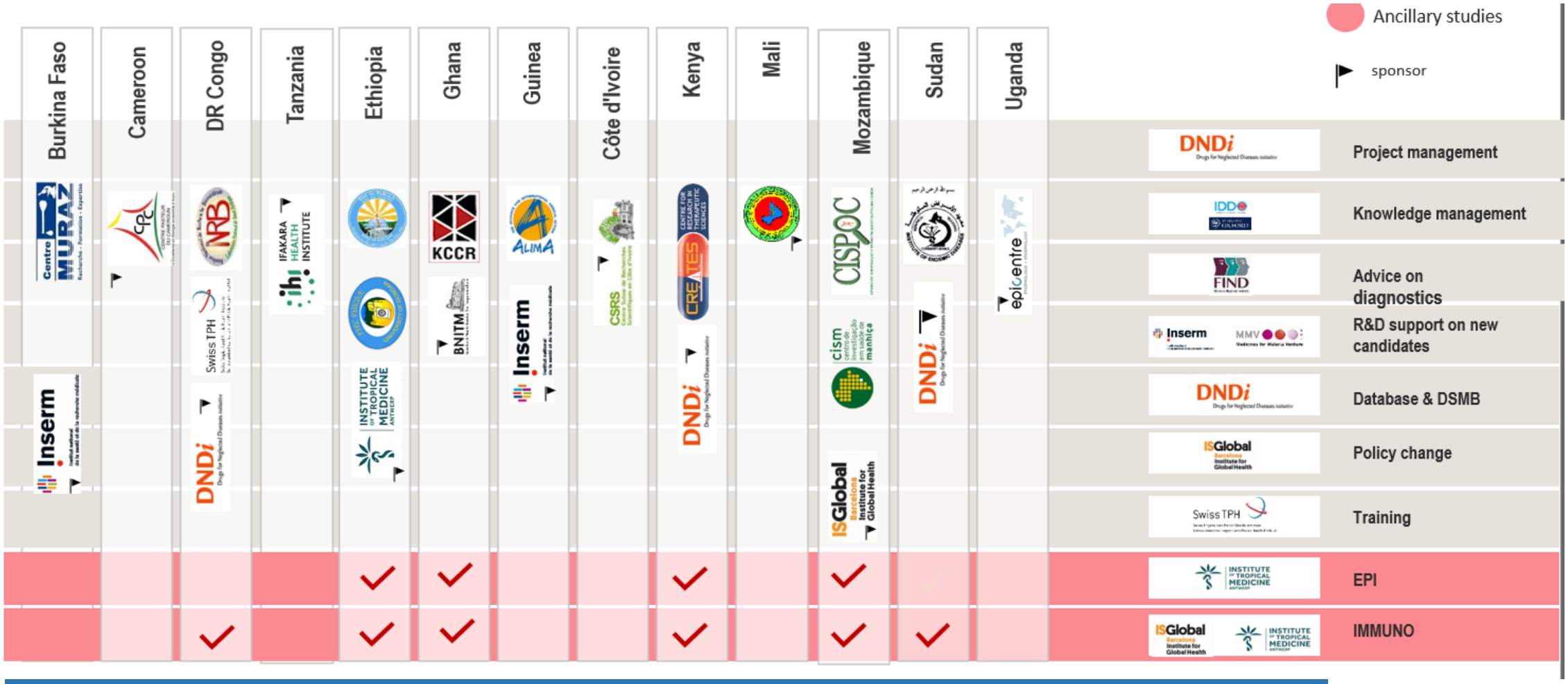
a collaborative African-led initiative

September 2025

PANTHER

Pandemic preparedness platform for health and emerging infections response

ANTICOV consortium : the example of a North, South collaborative, coordinated, multi-sponsor platform adaptive trial testing treatments for COVID outpatients in Africa*– www.anticov.org



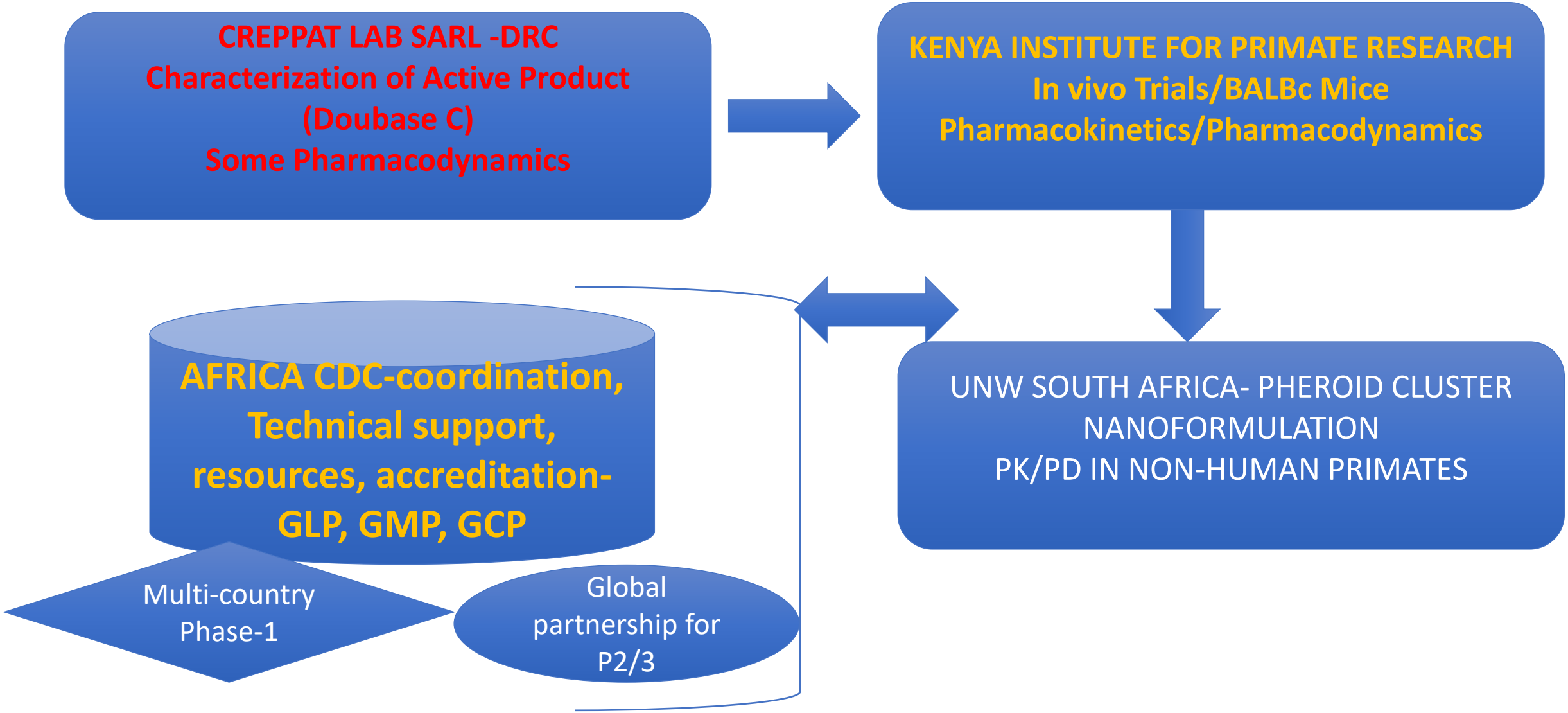
Leveraging expertise, needs and funding opportunities from a diverse group
Aligned around the same vision

PANTHER’s VISION

Contribute to a future where clinical research is firmly rooted in communities, working at the epicenter of outbreaks. Where priorities are set close to country needs

Where governance is African

SOUTH-SOUTH COLLABORATION: PRIVATE AFRICAN COMPANY-UNIVERSITIES



A DISAPORA NORTH-SOUTH-SOUTH COLLABORATION: BROAD-BASED ANTI-VIRAL FROM MATURAL PRODUCT

METRAF Canada Inc.

Leveraging endogenous, ancient and millennial African medicine for infectious diseases

metraf.com

METRAF Canada History

METRAF Canada took its roots at PROMETRA, an organization for cultural research, medical practice and scientific diffusion

A pan-African instrument of integration & international relations through the revaluation of African medicines and traditions, endogenous knowledge, and universal empiric science

Founded and led more than 40 years ago by **Dr. Érick Gbodossou, MD**, CEO PROMETRA International & METRAF Company SA

Canadian team formed in 2023 with **Dr. Jean-Pierre Metabanzoulou, PhD, MBA** and **Dr. Hugues Loemba, MD, PhD**

METRAF Canada was incorporated in Quebec in August 2025

METRAF Lead drug candidate: MoMo30 discovery

This protein derived from plants has been discovered by African traditional medicine healers affiliated to PROMETRA in collaboration with US-based scientists

MoMo30 represents a bio-active compound, a protein approximately 30 kDa weight isolated from *Mormodica Balsamina* herbal extract

Preliminary findings on MoMo30 antiviral inhibitory activities have shown that its mechanism of action relies on targeting specific structure of several virus envelopes and prevent their entry into the target cells

MoMo30 could be potentially active against many viruses, including, HIV, SARS-Cov-2, Influenza, Ebola, Herpes Simplex

MoMo30 potentially could be a large spectrum antiviral agent

OTHER NORTH-SOUTH AND SOUTH-SOUTH COLLABORATION-

- ON QUININE FROM NATURAL PLANTS IN THE DRC
- PHARMAKINA- 30 YEARS IN THE DRC: EXTRACTION TO API
- AFRICA CDC PARTNERSHIP TO EXPAND TO OTHER PRODUCTS
- EMORY UNIVERSITY- UNIVERSITY OF KWAZULU NATAL- REPURPOSE MOLECULE, IDRC, CANADA,
- AFRICA CDC-PAHO- LATIN AMERICAN COUNTRIES AND CARRIBEAN

The Africa CDC-AUDA NEPA R&D Blueprint

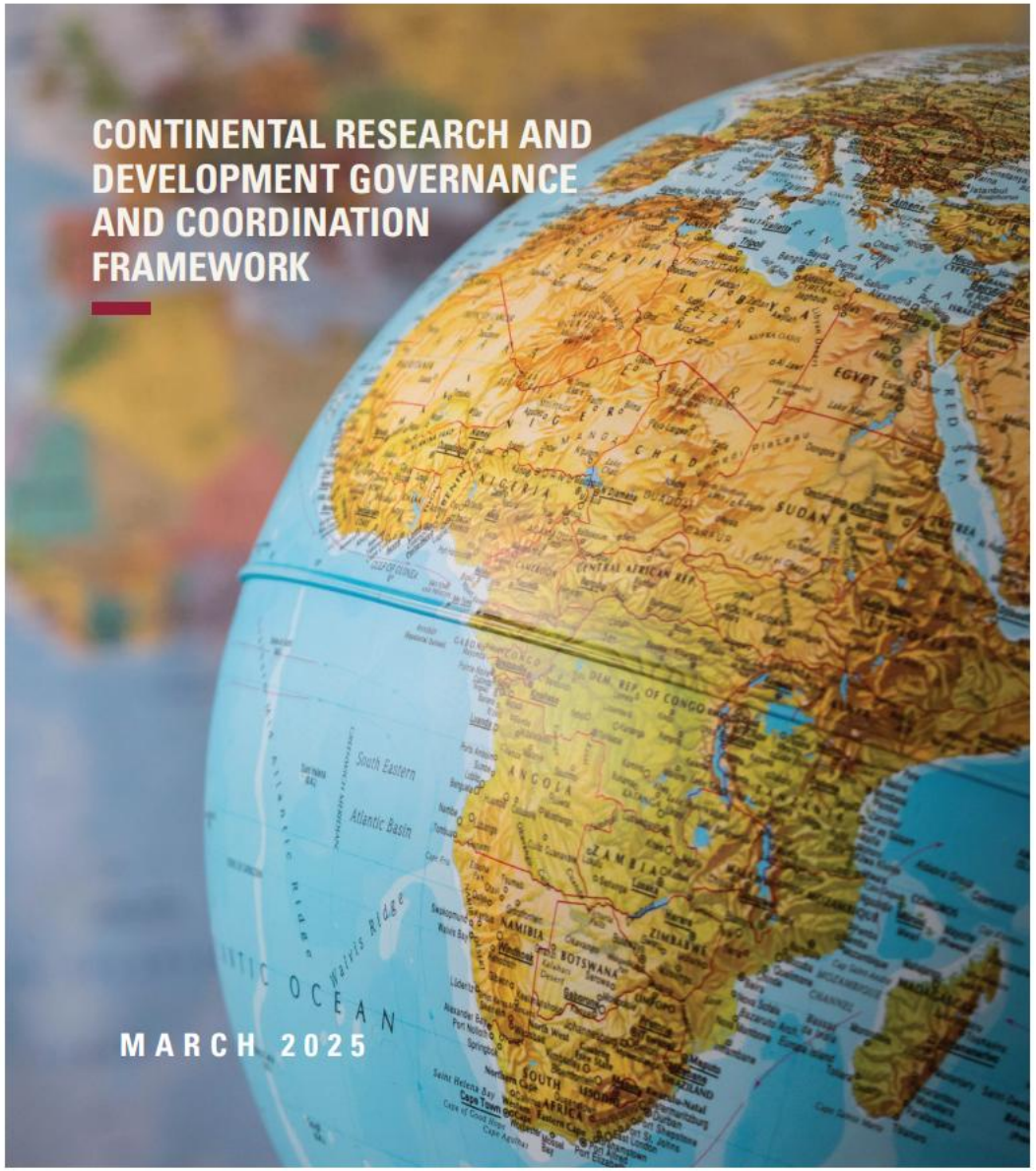
In May 2023, AUDA-NEPAD, Africa CDC &African Union had a meeting on “Optimizing Efficiency and Impact in the African Clinical Trial Ecosystem”

What are the tangible ACHIEVEMENTS

Bringing Africa Scientists together for coordinated Strategy : Co-creating a Solution:

November 19-21, 2024 in Addis Ababa, Ethiopia

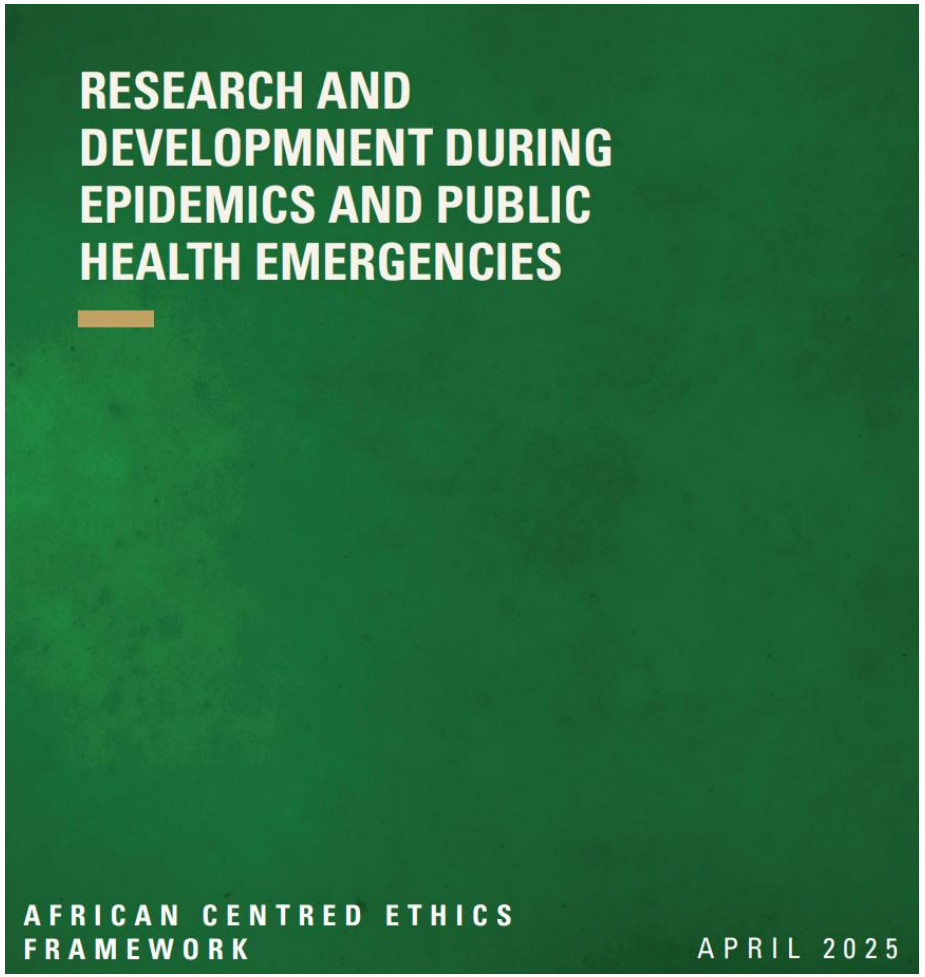
- More than 130 scientists, regulators, and research partners from 47 member states attended a three-day continental workshop in Addis Ababa, Ethiopia in November 2024.



AFRICAN HEALTH RESEARCH AND DEVELOPMENT AGENDA

PRIORITISATION FRAMEWORK

APRIL 2025



A call for an Africa-centric health research ethics framework: a way forward for shaping global health research

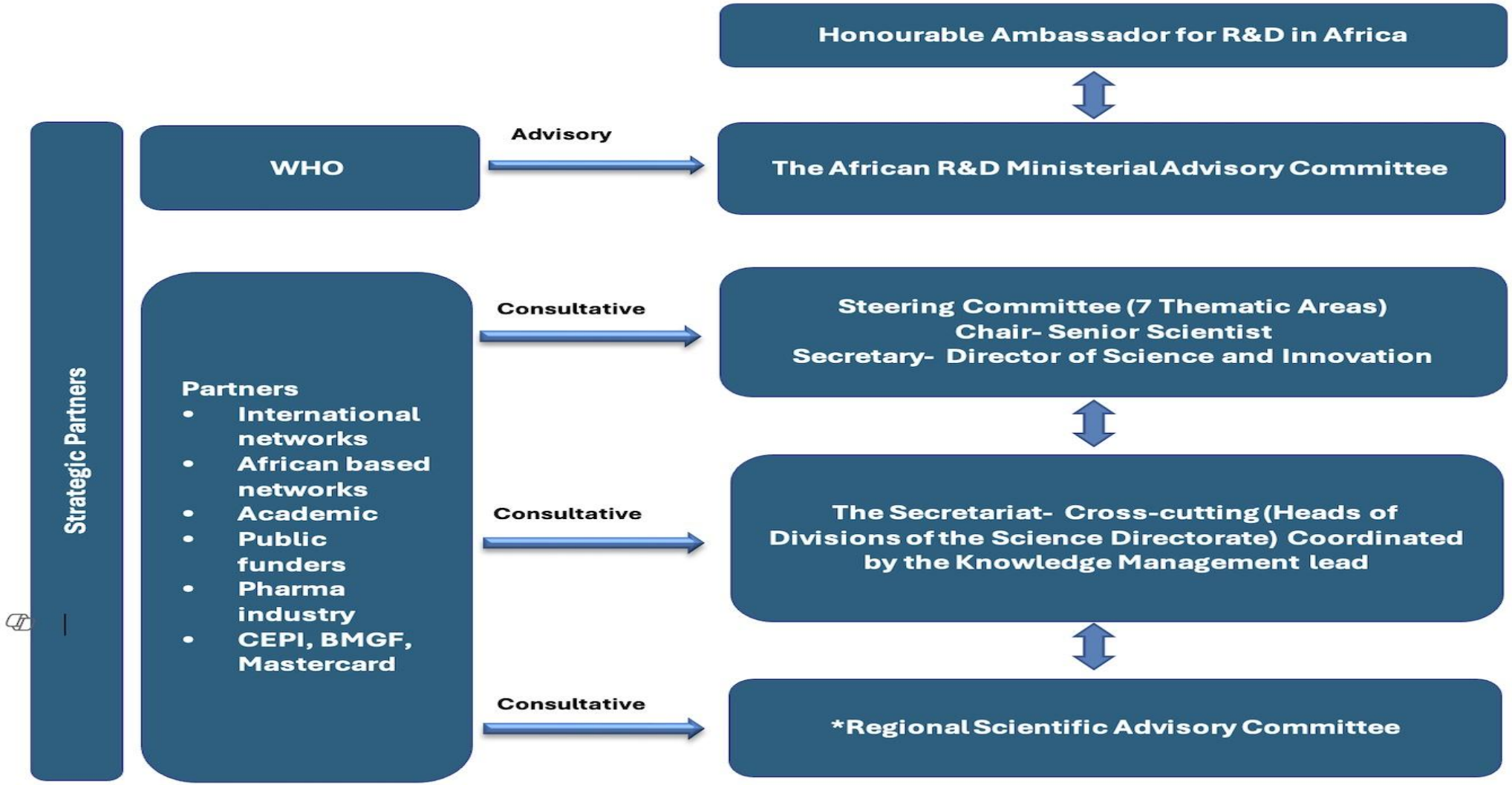
Lancet Glob Health 2025
Published Online
February 28, 2025
https://doi.org/10.1016/S2214-109X(25)00097-X

Health research emanating from Africa is scarce, despite the continent's share of 18% of the world population and 25% of the disease burden.[1] This situation in part stems from the poor research ethics framework and failure of international research ethics principles to protect African research participants optimally.[2] African populations have unique cultures, values, belief systems, and virtues that need to be explored and understood to conduct ethical research. For example, a study in an African setting reported that informing patients of diagnoses such as cancer while seeking consent for treatment has been indicated as unfavourable, which can alter the treatment and care outcome of the patients.[3] In African settings, unlike high-income countries, more emphasis is placed on community-level

the timely research and response efforts to mitigate the outbreak.

To address these challenges, the Africa Centres for Disease Control and Prevention (Africa CDC), in consultation with heads of national ethics committees of African Union member states, proposed developing a continent-wide Africa-centric research ethics framework that is based on a contextual understanding of the African settings, values, virtues, cultures, and socioeconomic profiles. An Africa-centric framework for ethical research practices that ensure optimal protection of participants in complex and diverse cultural and socioeconomic settings of Africa is urgently required. This framework must delve into the context-specific realities, nuances, and challenges experienced by

Supporting the R&D Governance and Coordination



Supporting the R&D Governance and Coordination

THE LANCET

CORRESPONDENCE · Volume 405, Issue 10482, P889-890, March 15, 2025

A call for health R&D prioritisation and governance mechanisms in Africa

Mosoka Papa Fallah [a] · Nebiyu Dereje [a] · Elvis Temfack [a] · Dathan M Byonanebye [b] · Jacqueline Weyer [c,d,e] · Polydor Ngoy Mutombo [f] · et al. Show more

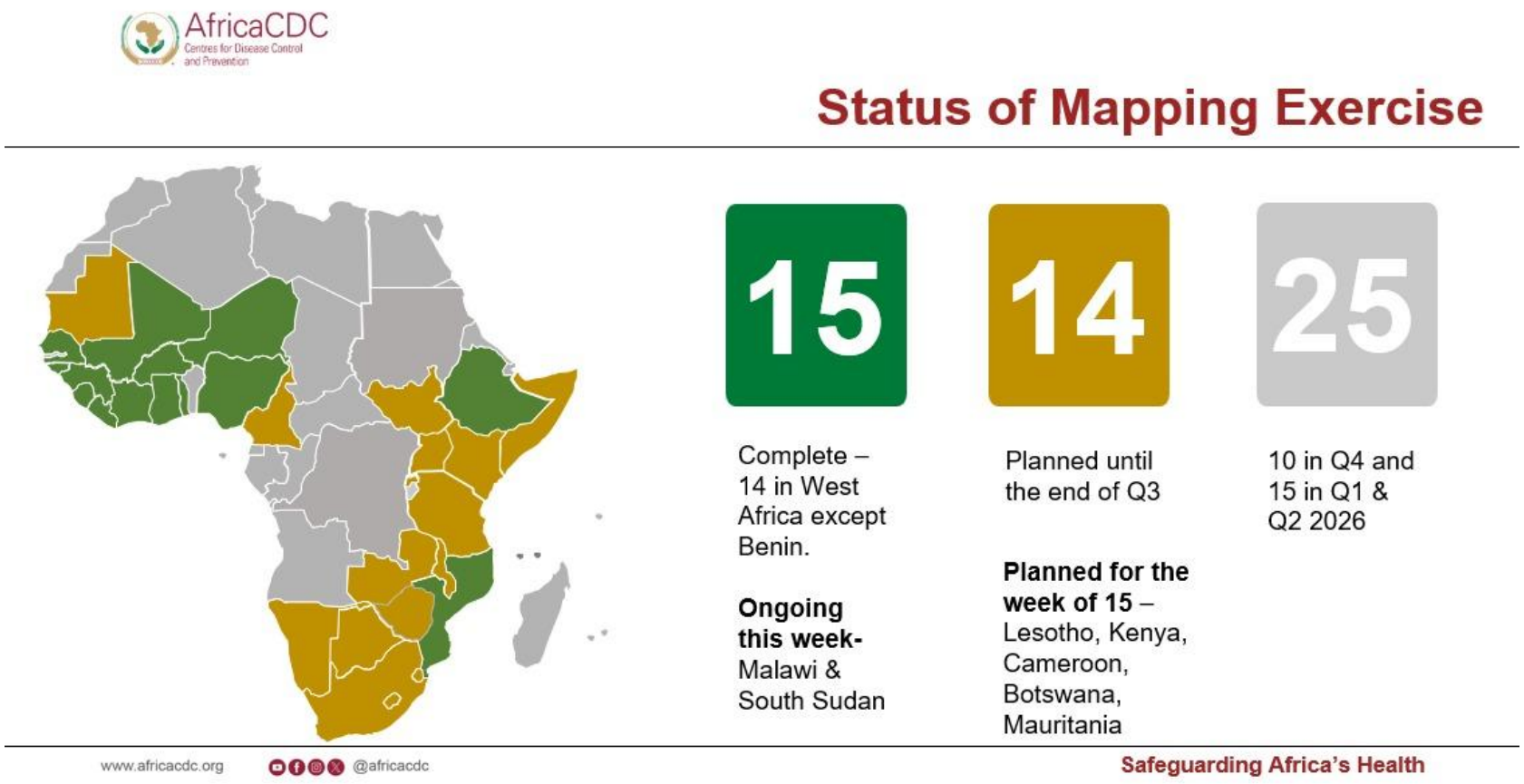
Affiliations & Notes Article Info

Africa accounts for only 3% of all medicine production globally, and more than 90% of drugs and 99% of vaccines consumed are imported.[1] The continent has not been well positioned to address these gaps due to capacity challenges related to limited research and development (R&D) infrastructure and skilled researchers, the absence of a well defined continental health research governance framework, and scarcity of sustainable financing for R&D.[2] Moreover, there is inadequate local funding, and

Developed and launched tools for of Pre-clinical and Clinical Trial sites

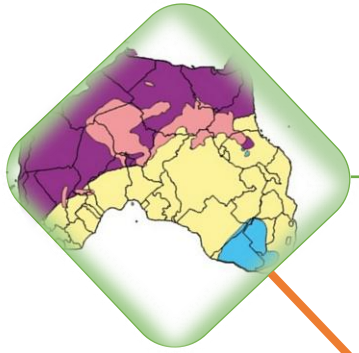
BASIC- 97

PHASE 3----18
PHASE 2----33
PHASE 1---20



"African Health Research Capacity Strengthening: Member States Stakeholders' Consultation on the Hub-and-Spoke Model"Abidjan, Côte d'Ivoire CI, from 27-29 August 2025.

Network Architecture



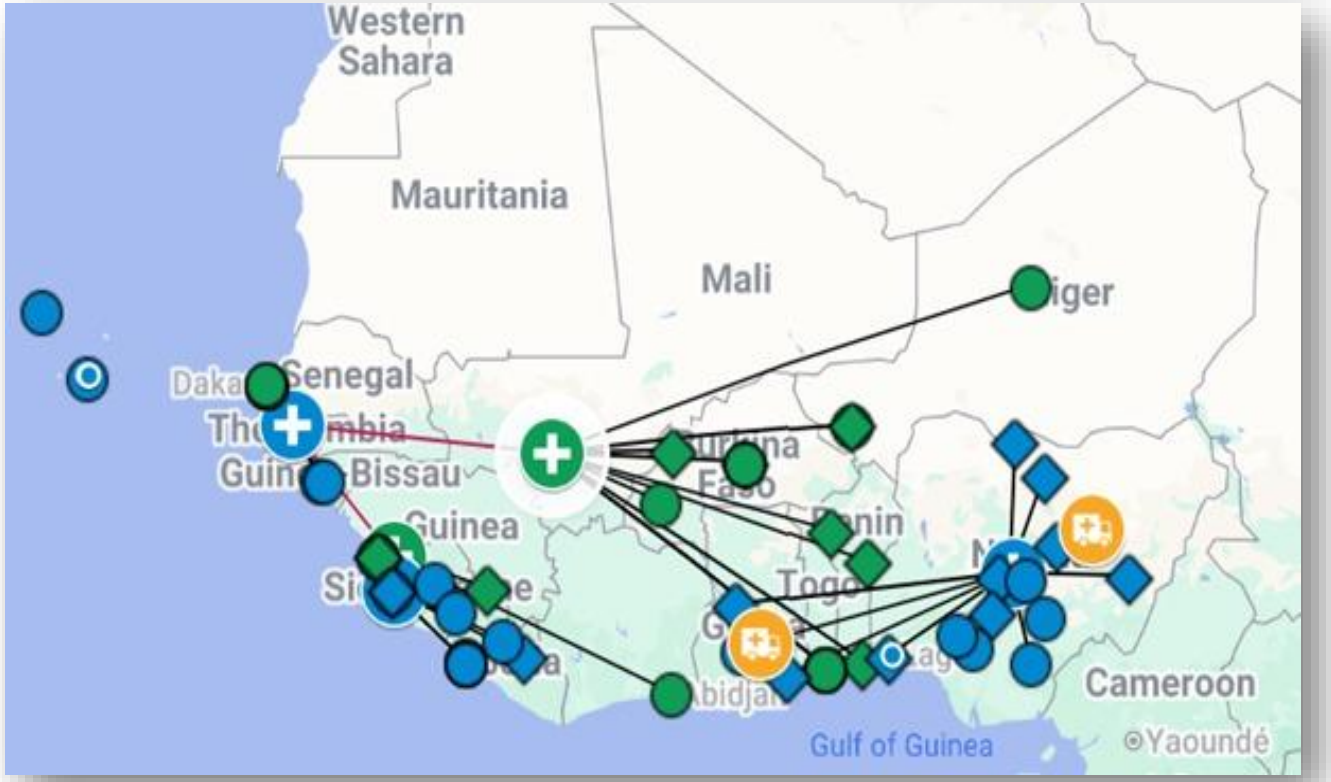
Flexible design, adaptable to **geographic & linguistic contexts**

Each hub supports **8–10 spokes**

Functions

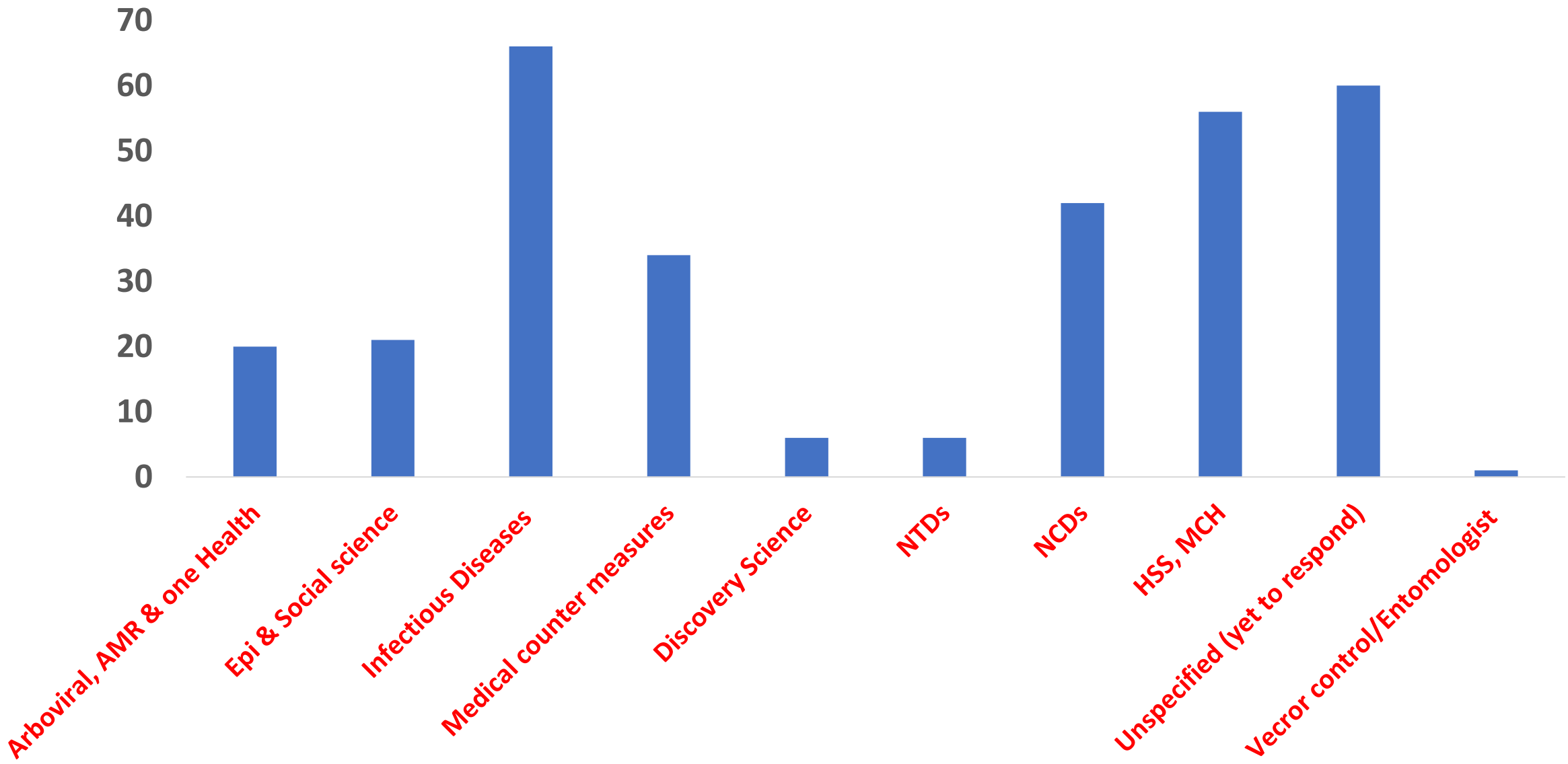
- Mentorship & training
- Joint research implementation
- Coordination of regulatory processes

Example of Flexible Hubs-and-Spokes Model



- Network architecture refers to how hubs, spokes, and mobile units are linked -across regions, languages, and functions
- There could be different clusters of networks (e.g., English-speaking cluster, French-speaking cluster)
- Hubs and spokes will be selected based on
  - Research capacity
  - Regional relevance
  - Potential for collaboration

Linking African Scientists into Major Disease Group to Drive R&D



Safeguarding Africa's health

Home in on Specific Work Featuring patients and Community

Part I: Diverse Clinical Trials with patients durinf the mpox and Marburg Response

March 2025

Ongoing Studies coordinated to enhance the response to mpox

Studies that have approved protocol that are ongoing across Africa on mpox.

- Epidemiology studies- 1 ongoing study in the DRC and 1 in South Africa
- Diagnostics Studies- 2 completed studies (1 in DRC and 1 in Uganda)
- Therapeutic Study- 1 ongoing study (Brincidofovir)- 40 participants recruited and awaiting 10 new participants for safety and then move to 100 for efficacy
- Vaccine studies- 1 study completed in the DRC and 2 ongoing in the DRC
- Socio-behavioral study- 9 ongoing studies in 9 African Countries- 17,000 data collected.

Study to start soon-

Vaccine effectiveness study and Dose reduction in the DRC and Uganda

Link to roadmap

Safeguarding Africa's health

Pilot Study in Kinshasa, DRC for Epidemiology of mpox infection: Magnitude, Risk Factors, Clinical Outcomes and evaluation of AI-powered diagnostic tool

March 2025

Home in on Specific Work Featuring patients and Community

Part II: Community Engagement with Socio-behavioral Research during outbreak to inform the Response

March 2025

Figure 1: Trust in Modalities and Sources of Information on MPox

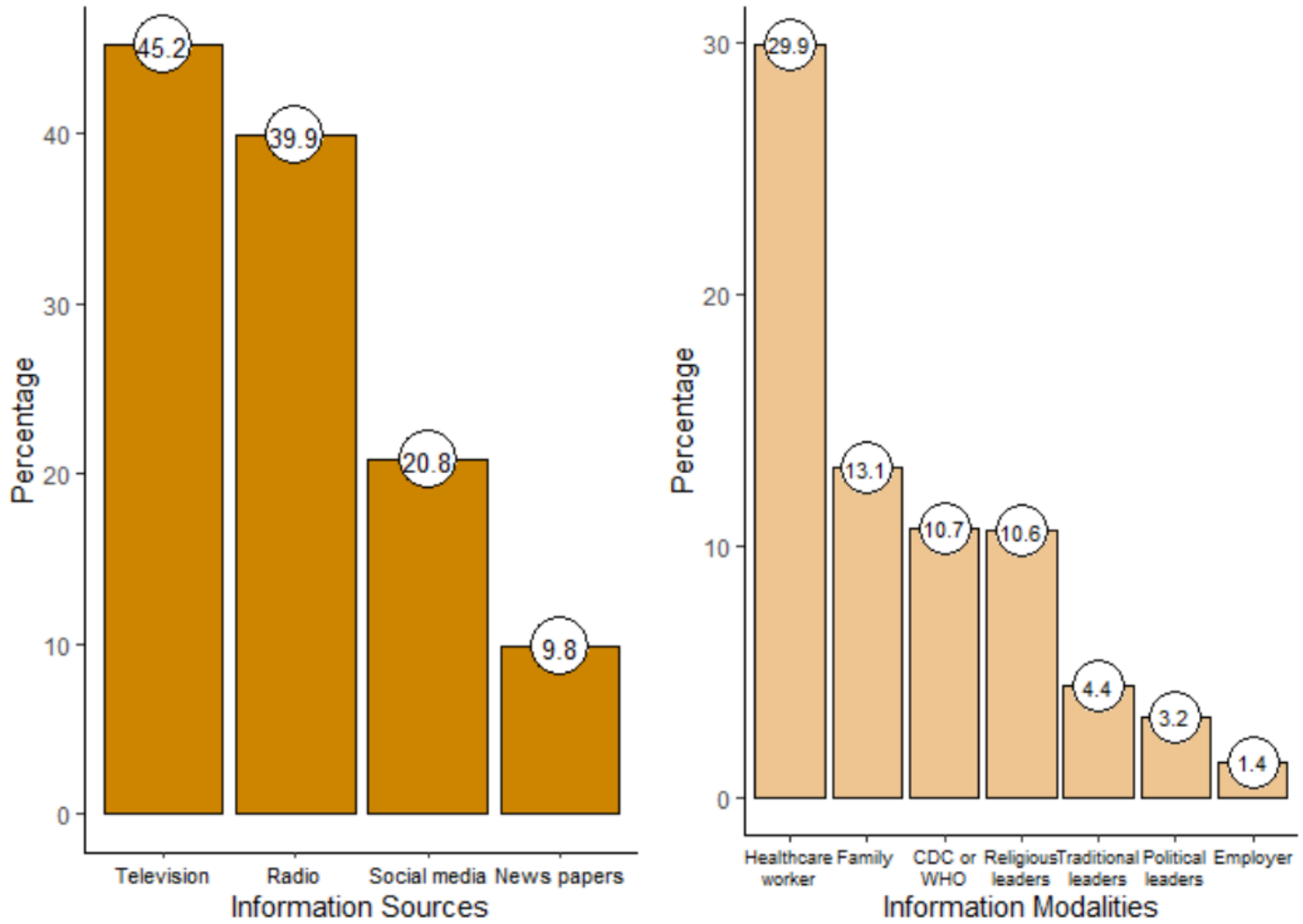


Figure 2: Participant Concerns about contracting MPox

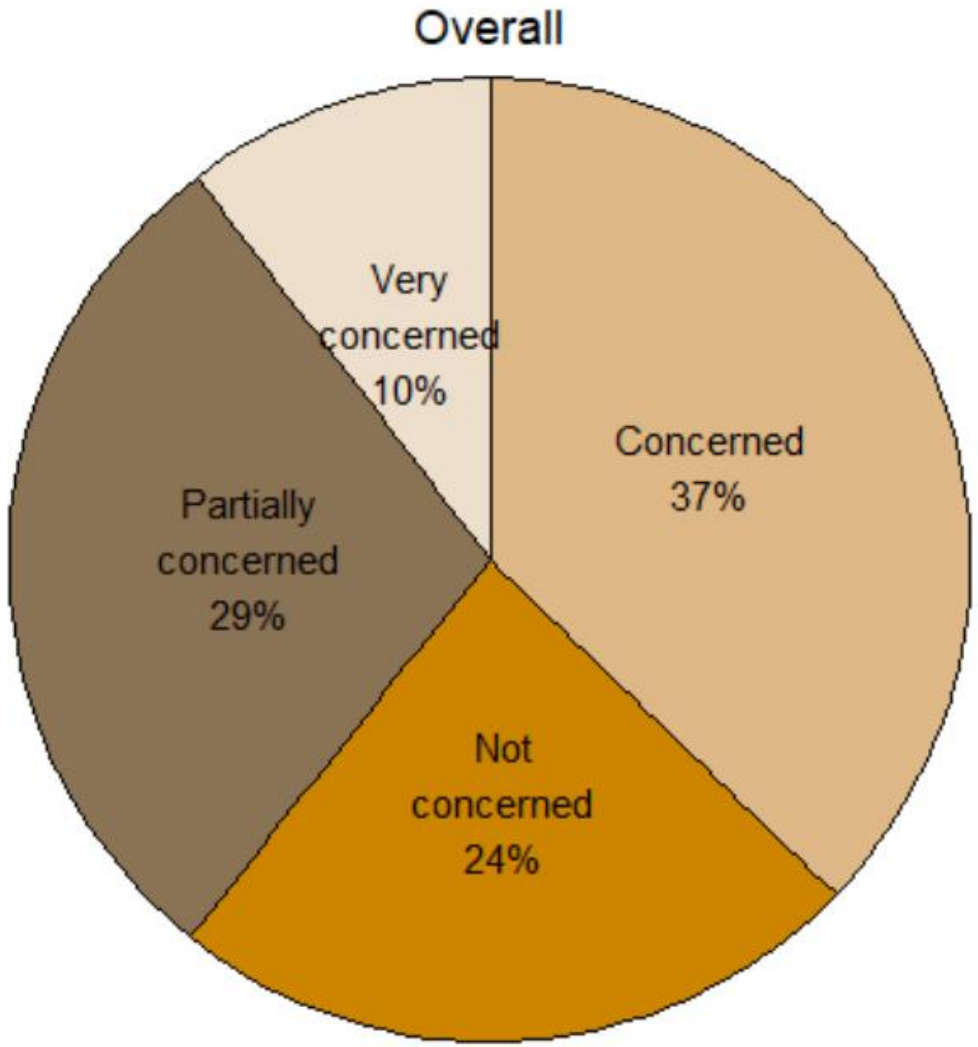
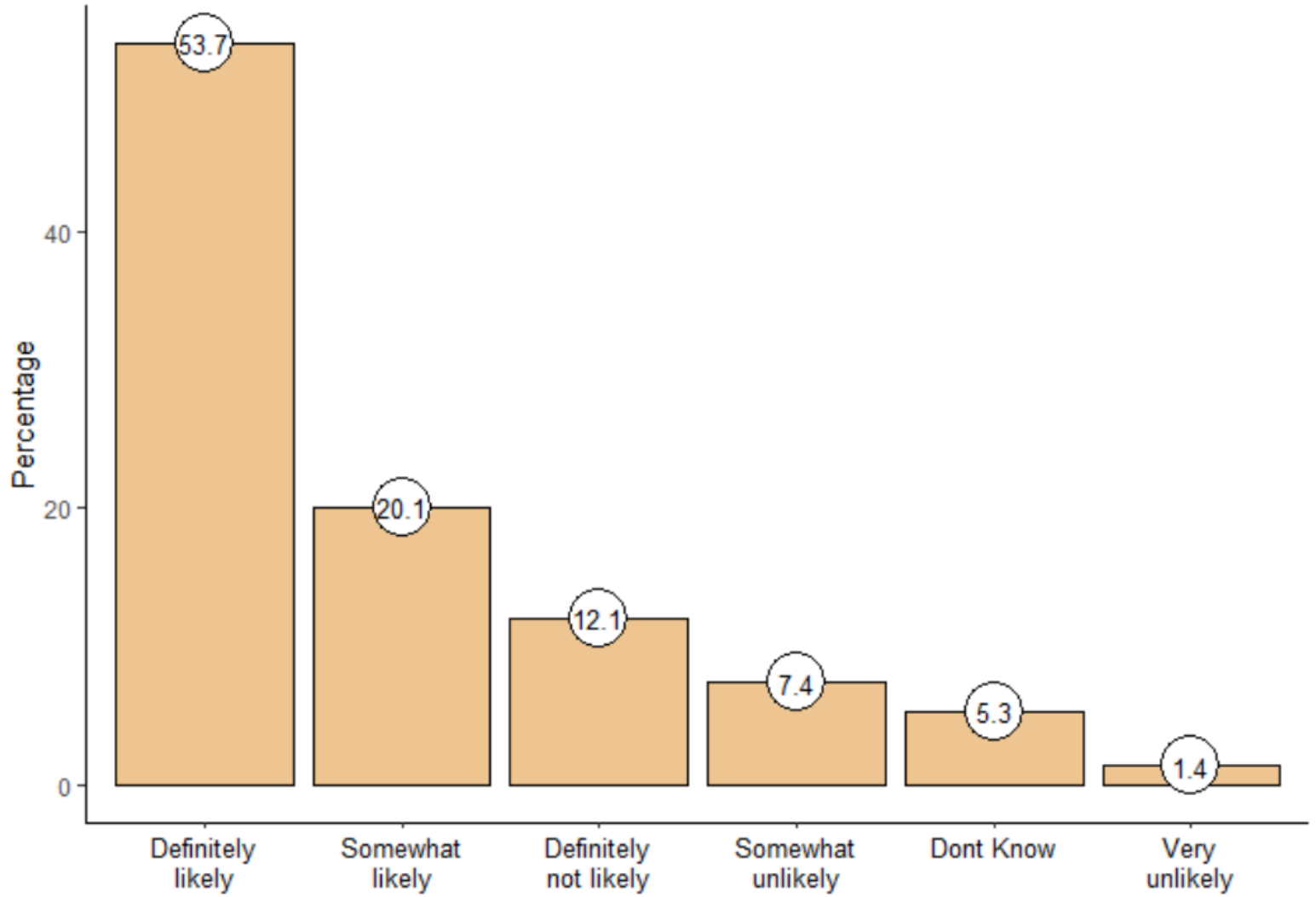


Figure 3: Participant's perception on willingness to accept MPox vaccine



Participant Characteristics

Country/Site	Overall	DRC	Congo	KENYA
Number of Transcripts	38	4	24	10
Interview category				
Key Informant (KII)	27	2	20	5
Individual in-depth interviews (IDI)	11	2	4	5
Sex				
Male	13	3	7	3
Female	25	1	17	7

THEME 1: KNOWLEDGE AND ATTITUDE ON MPOX

Sources of information

- Health talks in hospitals
- Mobile drive or public address system in the community, by community health workers.
- Television
- Social networks or colleagues
- Social Media
- Radio
- Posters and other IEC materials

Knowledge gaps on Mpox

- Lack of Mpox basic knowledge

They lacked basic knowledge of transmission and often confused it with chicken pox.

> *"I have no information about it. We first thought it was chickenpox…So I went to the market to buy some cassava leaves, I prepared a mixture of these leaves and applied it on him. Despite my applications, there was no change"*
> –27 year old female, 27_Contact_DRC

- Scepticism towards vaccination, speculating it would cause side effects.

Demonstrated a strong understanding of risk factors

Perceived risks factors for Mpox

- Sexual intercourse
- Contact with infected people
- Trans highway cities
- Transaction sex area
- Spread from sharing clothes or contact with clothes of the sick
- Sanitation challenges
- Low immunity e.g PLHA
- Bestiality
- Living in highly crowded places

- *Sexual intercourse and contact with infected people*

"We already know that the disease can be transmitted by contact, through scabs, or even the liquid that the disease presents, or even more sexually transmitted."
-IDI_18_Clinician_Brazaville

Quotes for perceived risk factors…

- Transaction sex

“Most of our clients who stay within town—they do a lot of sex work around and they don't hide it,” -49-year-old, female_Health worker_Kenya

- Low immunity

“Maybe their immune system is weaker. As they say in Lingala, *"Makila naye eza pete"* , that is to say, their immune defenses are weak, and that is why they get sick.” –27 year old female, DRC

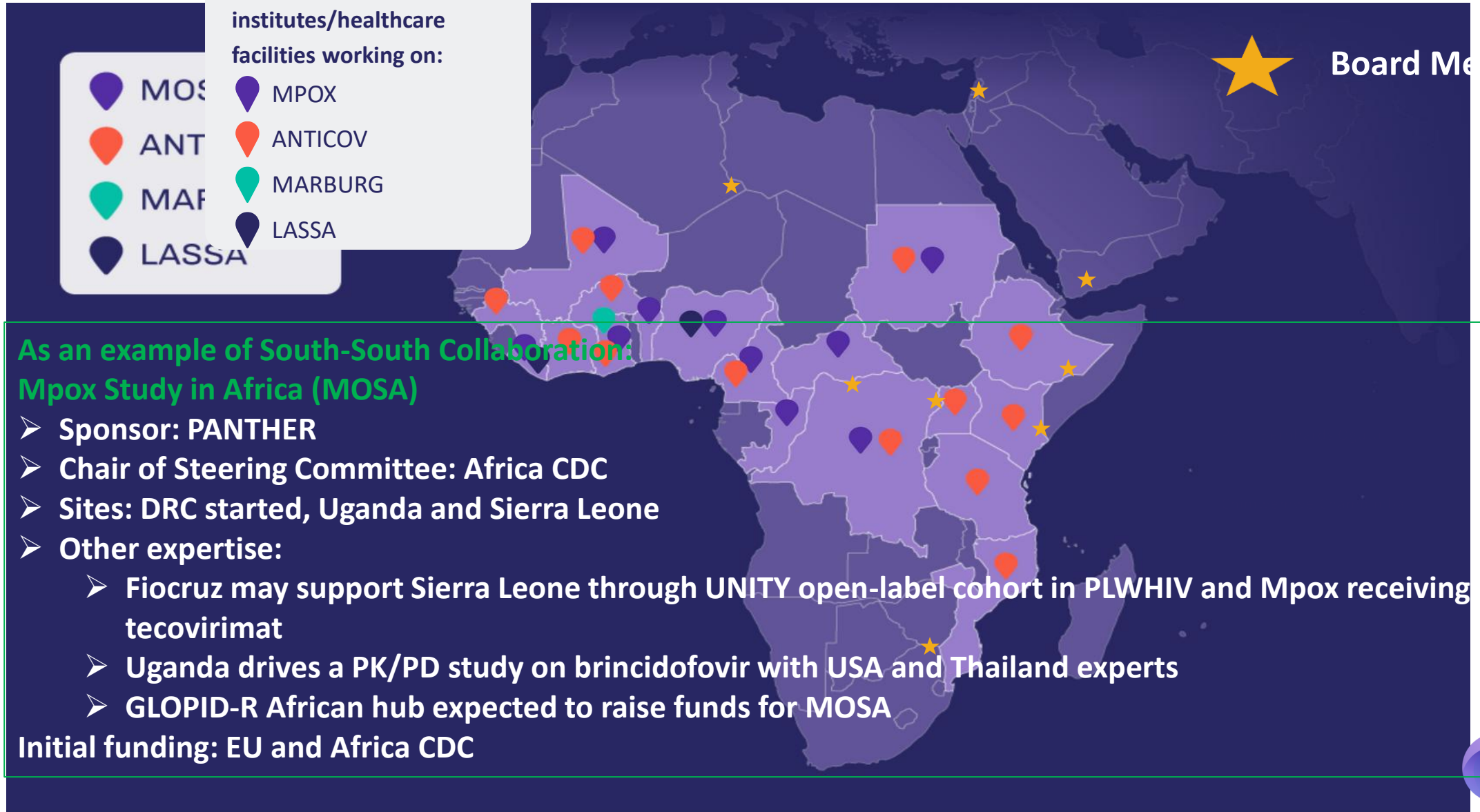
- Sharing clothes

"T*he most common thing is the use of goods together, common goods like utensils, clothes, everything domestic*." -- KII_20_Health authority_Brazaville

- Living in crowded cities

“For example, in a city like ours, with crowded public transport, we cannot always know who is infected.”—38- year old, male, contact_DRC

South-South collaboration



As an example of South-South Collaboration:
Mpox Study in Africa (MOSA)

- **Sponsor: PANTHER**
- **Chair of Steering Committee: Africa CDC**
- **Sites: DRC started, Uganda and Sierra Leone**
- **Other expertise:**
  - **Fiocruz may support Sierra Leone through UNITY open-label cohort in PLWHIV and Mpox receiving tecovirimat**
  - **Uganda drives a PK/PD study on brincidofovir with USA and Thailand experts**
  - **GLOPID-R African hub expected to raise funds for MOSA**

Initial funding: EU and Africa CDC

PANTHER

THANK YOU

Africa Centres for Disease Control and Prevention (Africa CDC),
P.O. Box 3243, Addis Ababa, Ethiopia, Ring Road, 16/17,
Tel: +251 (0) 11 551 77 00, Fax:+251 (0) 11 551 78 44

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SESSION 2: WHAT ARE THE ENABLERS OR BEST PRACTICES THAT CAN IMPROVE COMMUNITY AND PATIENT ENGAGEMENT IN CLINICAL RESEARCH?

CASE STUDIES

Joy Malongo,
DND*i*

Enhancing Community and Patient Engagement in Research

Africa Regulatory Conference 2025

Joy Malongo, DNDi Access Manager

Tuesday 16 September 2025

DNDi

Best Science
for the Most Neglected

BEST SCIENCE FOR THE MOST NEGLECTED

We discover, develop, and accelerate access to urgently needed treatments for neglected patients focusing on gaps for infectious diseases that fuel cycles of poverty and disease in resource-constrained settings.

DNDi

Introduction and Vision

- DNDi core value of caring “about the well-being and needs of the neglected patients and communities we serve”
- Involvement of patients and communities in planning and decision making is an increasingly essential component of R&D and access projects
- DNDi has a strong history of patient and community engagement. Now working to institutionalize this approach across all teams, ensuring alignment with established guidance and best practices (e.g., Helsinki Declaration, WHO guidelines).
- In 2022, DNDi joined Patient Focused Medicines Development (PFMD)
- In 2023, a working group was formed to propose guiding principles and best practices for engaging patients within all phases of our R&D work, including access

PCE Working Group objectives

1. Create a **systematic** and **comprehensive** process for patient centricity in all stages of the R&D process and in DNDi’s access/implementation program and policy/advocacy activities
2. Provide project teams with the advice and materials needed to facilitate good patient engagement
3. Integrate relevant external resources and materials into PCE at DNDi

Why do we need patient and community engagement?

- Inclusive decision making
- Addressing health inequality
- Promoting accountability, transparency and trust
- Strengthening R&D
- Promoting ethical and responsible research
- Address real needs and priorities of the people affected

The three pillars of patient and community engagement at DNDi

Values & Governance

- Putting people and patients at the heart of our organisation
- Patient and public representation and communication
- Measuring delivery of our commitment to patient centricity

Language

- Being people and patient-centered in the language we use internally and externally

R&D and Access

- Ensuring that we are developing medicine that people want
- Conducting research with and for people with diseases
- Working with people and communities to provide access

EMPOWERMENT

Provide resources to help patients make informed decisions

OPEN DIALOGUE

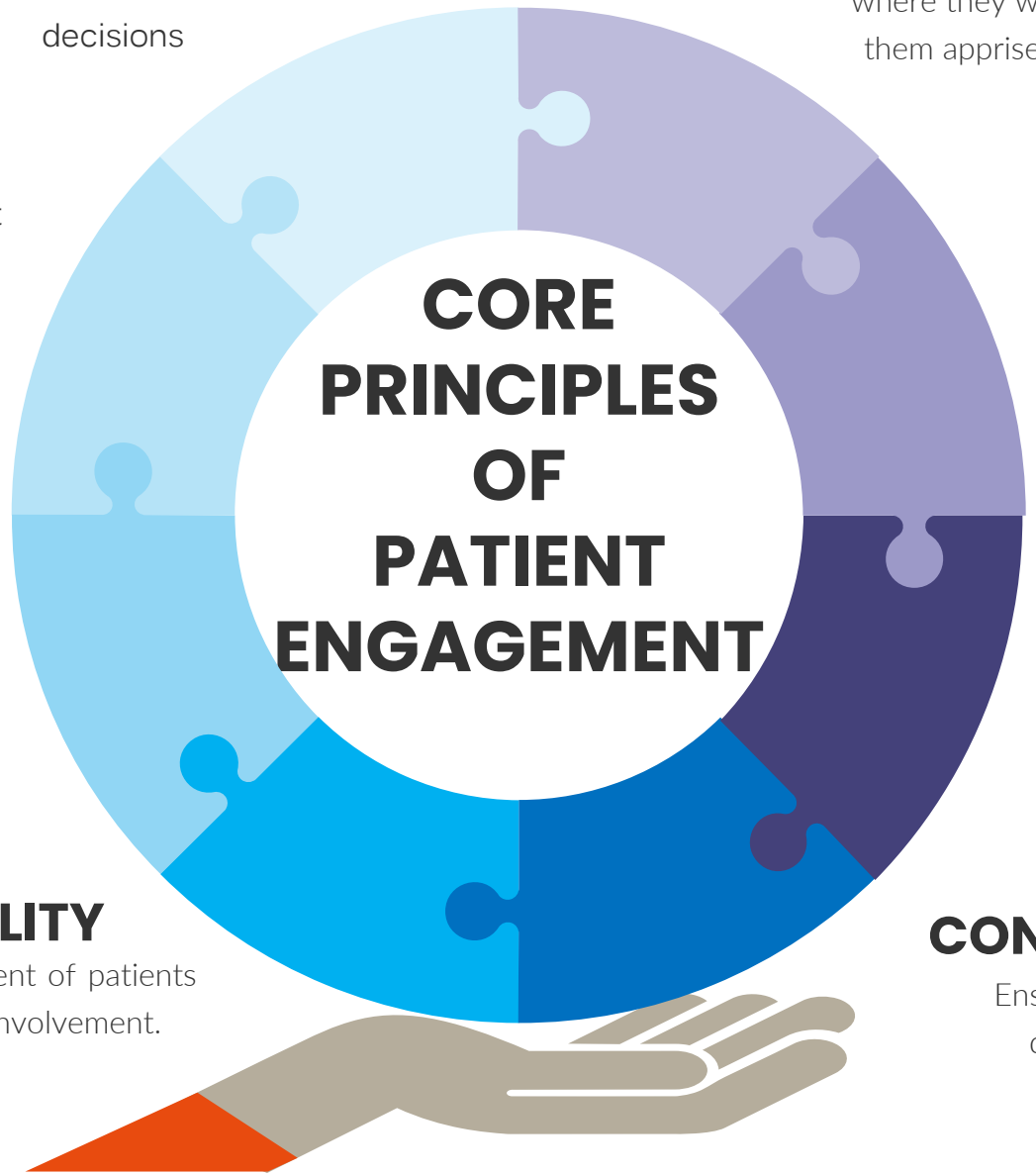
Provide feedback to patients on issues where they were consulted and keep them apprised of potential impacts.

FAIRNESS

Compensate fairly for time spent (neither too much, nor too little) and respect patients' independence.

DIVERSITY

Ensure appropriate diversity in patients' profiles, considering age, gender, race/ethnicity, gender, sexuality, and other factors relevant to each disease context.



RESPECT

Respect patients' opinions and worldviews, conduct yourself respectfully, acknowledge & accept cultural differences. Patients have their own opinions which are equally valid to those of other stakeholders.

TRANSPARENCY

Be transparent throughout the process - be clear about our objectives, our motivations; explain why we may retain some ideas and not others; keep and share written records.

SUSTAINABILITY

Ensure sustained involvement of patients over time-not just one-off involvement.

CONFIDENTIALITY

Ensure confidentiality as a default best practice.

DNDi

Current activities

DNDi

How DNDi approaches PCE

Activities undertaken at DNDi

- Mapping our current activity and gaps across diseases
- NTD-Person-first language (NTD PFL)
- Disease strategy updates
- PMFD engagement
- SharePoint and guidance developed
- Launch of Regional CACs (India and LATAM already in place). Africa (early 2026)
- PR on DNDi Board of Directors
- PCE metrics defined

Vision in R&D

- TMP development to include patients and community
- PROs to be implemented where appropriate (feel, function, survive)
- Study designs and materials co-designed
- Gender-balanced engagement
- Results disseminated to patients and the community

Vision in access

- TMPs co-designed
- Packaging, PILs, educational materials etc co-designed
- Incorporating qualitative and social sciences implementation research

Regional Community Advisory Committees

Objectives

- Provide **strategic guidance and feedback** on prioritized aspects of our R&D activity for a project, including implementation, ensuring they align with community priorities, values, and expectations
- Foster **collaboration and engagement** between DNDi and the community, promoting mutual understanding and trust
- Ensure that the perspectives, needs, and concerns of the community, particularly marginalized or vulnerable populations, are **part of the decision-making process and represented** in the R&D and access activities

Key activities

- **Share perspectives** on patient and community needs and priorities that should be addressed in the research agenda
- Targeted **reviews** of proposed R&D projects and providing **feedback** on their potential impact, feasibility, and relevance to the community
- Provide **inputs** on aspects of study design, including recruitment and retention strategies, study procedures and protocols, informed consent processes & language, and outcome measures

Composition and structure

- 6-8 members including people living with, or previously affected by our diseases; advocates from other diseases, and (as needed) community activists or social scientists
- Regular in-person meetings (minimum biannual), with ad hoc meetings and training as needed online

Promoting "People First" Language in Our Scientific Communications

- There is a long history of stigmatization in NTDs, intimately linked to the language that is used to talk about the diseases and the people they impact
- Several organizations have developed guidance and recommendations on use of language that is respectful to the people we serve (Oxfam, PATH, UNAIDS)
- There is a complete section on Respectful Word Choice in the DNDi Style Guide available on SharePoint/Comms Resources

People First Charter

- *People First Charter* – a living document which provides recommendations for person-friendly, non-stigmatizing language for HIV-related scientific communications
- The People First Charter was presented by its founder, Laura Waters, during a Learning Lunch session last year
- As another action the PCE working group is drafting an "People First Charter for NTDs"

BEST PRACTICES AND STRATEGIES FOR ENGAGEMENT

Build trust through early and ongoing engagement:

- Involve community members and patients from the start – during the problem identification, study design, and protocol and donor proposal development
- Maintain transparent communication throughout the research lifecyle

Co-design research with communities:

- Involvement in developing study designs, consent forms, and data collection methods to ensure relevance and respect
- Community sensitization and active case finding through a community mobilizer
- Include community partners in governance roles (e.g., patient advisory boards, co-investigators, PR on BoD, RCACs)

Address barriers to participation:

- Identify and mitigate logistical, cultural, and social economic barriers to access
- Use culturally sensitive communication e.g. tailor research messaging to local languages, beliefs, and values; use of plain language and culturally appropriate materials (People First Language)

Support capacity Building (e.g, train patients and communities to actively participate in decision-making, advocacy and health system improvement

Feedback loops to share study progress and results with participants and communities

- Use community forums, local radio to disseminate results, social media campaigns etc

Operational research together with partners

- Recognize and celebrate community contributions publicly.
  - Articles about R&D, access in different local and international media
- Invest in long-term partnerships that span multiple projects
- Sustained engagement with patients, communities and primary healthcare professionals enabled the identification of the most suitable RCAC representatives (LATAM and India)
- Evaluate and improve engagement.
  - Collect feedback from community partners to refine future approaches

DNDi

Patients and community are at the heart of what we do

Arkokeya community, Uganda conducts a gap assessment to inform donor proposal development

Workshops, bringing together frontline health workers, and community members to understand their needs

DNDi

Challenges and Mitigation

Challenge	Impact	Mitigation Strategy
Power imbalances	Unequal decision-making authority and lack of representation	Shared governance models, transparent communication, capacity building
Resource Limitations	Limited funding and logistical support for engagement	Fair compensation, partnerships, low-cost tools
Cultural Barriers	Misalignment with local customs, language, and values	Culturally sensitive communication, community-led messaging, respectful practices

Sustainability of DNDi PCE strategy through the active functioning of RCACs, funding approvals and relationship with other global PCE initiatives

RCACs established in the remaining regions

Template Informed Consent Forms revised following engagement with patients and communities

Study protocol and associated patient information and consent forms co-developed with patients and communities (target 50% of interventional phase II/III trials)

First project team consults RCACs on issues related with end-users' perspectives that will impact development plans, and on qualitative and social science research projects.

Study protocols and associated patient information and informed consent forms co-developed with patients and communities (target >70% or phase II/III interventional trials)

Phase II/III trial results disseminated to patients and communities (target 50%)

More project teams consult, as needed RCACs on issues related with end-users' perspectives that will impact development plans, and on qualitative and social science research projects

Thank you

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for the Most Neglected

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PANEL DISCUSSION

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Alun Davies,
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Huwaida Bulhan,
Roche, IFPMA

AFRICA REGULATORY CONFERENCE 2025

KEY TAKEAWAYS

WEBINAR #2: UNDER-REPRESENTED POPULATIONS IN CLINICAL TRIALS

Scan to register

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THANK YOU

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