



State-of-the-art 20 Mpox Symposium 25

3 - 5 December • Kinshasa • DRC

Lessons learned from Mpox research response

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CEPI's plan to prepare for future pandemics

CEPI

2.0

Vision statement

A world in which epidemics and pandemics are no longer a threat to humanity

Mission statement

Accelerate the development of vaccines and other biologic countermeasures against epidemic and pandemic threats so they can be accessible to all people in need

100
Days
Mission

'Vaccines should be ready for initial authorisation and manufacturing at scale within 100 days of recognition of a pandemic pathogen, when appropriate.'



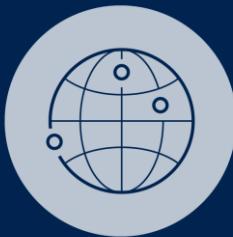
Prepare

for known epidemic and pandemic threats



Transform

the response to the next novel threat



Connect

to enhance and expand global collaboration

CEPI

Sensitivity: CEPI Internal

Equitable access is core to CEPI's vision

What are distinguishing features of research response?

- Requires rapid initiation & execution
- Driven by outbreak goals
- Actionable insights
- Focus on affected population
- Endpoints depend on an active outbreak
- Leverages existing, trusted relationships
- Preparedness is essential



Research strategies change during phases of outbreak

Acute phase of outbreak
(inform response decisions)

Synthesis of existing scientific evidence

Leverage existing networks and relationships

Launch operational, observational and clinical studies

Modelling vaccination strategies

Implement available tools and harmonize (e.g. assays, Dx, SOP)

During national or regional response
(real-world evidence)

Incorporate evidence into practice

Assessing vaccine effectiveness (prospective or retrospective)

Cohort event monitoring for safety

Observational studies, natural history & modelling

Mpox control strategy
(longer-term)

Understand available manufacturing capacity and opportunities to scale up; as needed

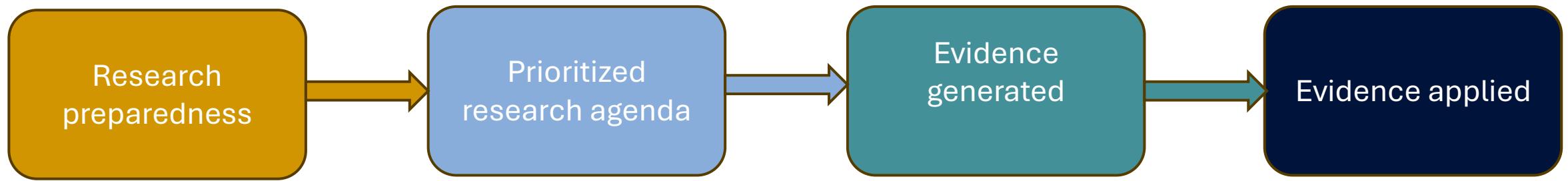
R&D regulatory and policy gaps

Optimization of licensed vaccines for the future

Support next generation medical countermeasures

Strengthen capabilities and capacity for future outbreak research

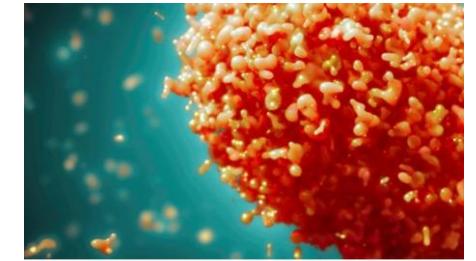
Key elements for effective research response



Enablers	Legal frameworks	Adequate funding	Access to product	Supportive systems	Site readiness
	e.g. for rapid contracting	e.g. to achieve actionable findings	e.g. Expedited import permits	e.g. Rapid protocol approval REC	e.g. infrastructure and experience

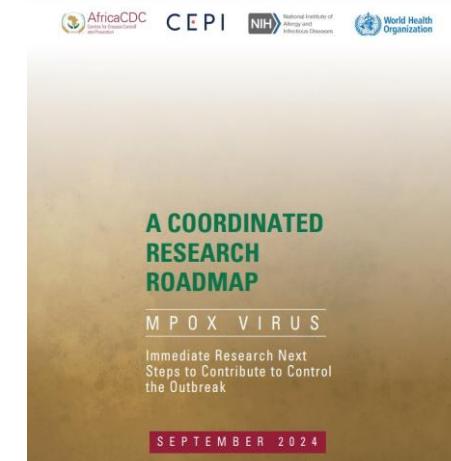
International coordination/prioritization challenges

- Coordination and research prioritization was too late
 - Research needs to be triggered prior to a PHEIC or PHECS
- Host countries lacked a sufficient role
 - Insufficient understanding of priorities and capacity
- Uncoordinated funding decisions
 - Duplication, underfunded priorities, delayed study start
 - Small underpowered studies unable address key gaps
- Infrastructure fragmented
 - Parallel capabilities built vs leveraging existing resource



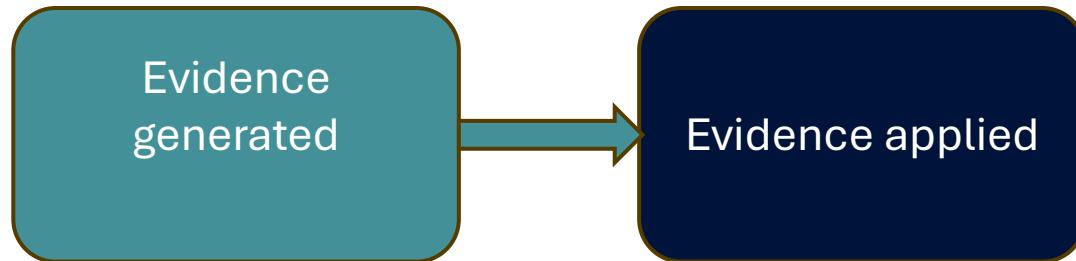
WHO Mpox (monkeypox)
Research: What are the
knowledge gaps and priority
research questions?

June 2022



Sept 2024

Evidence to Implementation Gap



- Unclear mechanism for sharing critical evidence with decision-makers
 - Evidence to reinforce or adjust Vx strategy, policies, EUL
- Slow adoption of evidence into application & policy
 - National laws and governing bodies differ
- Incorporation of best practices within the research community
 - Standard of care, community engagement, harmonized approaches to enable data interpretation

Research Preparedness is Essential

- Relationships established & roles and responsibilities agreed
- Site capacity ready, protocols pre-reviewed by REC
- Legal preparedness important
- **Systems to support rapid initiation**
 - Financing, MCM importation, reg/ethics review, etc
- Country response plan incorporates research objectives

CEPI-hosted Legal Summit – October 2025

“Navigating Legal Challenges and Solutions for Pandemic Preparedness and Response”

Solid Common Ground

- Legal preparedness is public health preparedness
- Legal clarity accelerates trust
- Predictability enables cooperation
- Equity, embedded in contracts from the start, transforms science into shared security

Shared Challenges

- **Fragmented legal frameworks:** differing national laws and emergency powers
- **Uneven Access Provisions:** upstream v. downstream; contracts and regulatory pathways
- **Liability & indemnification gaps:** limited mechanisms for indemnity, no-fault compensation, and risk sharing

Questions for further discussion

- Which **systems should be improved** to support early initiation of research?
- How could investigators be better-positioned for **timely execution** of the studies?
- How are **impacted countries and communities engaged** in setting priorities?
- What mechanisms can improve **harmonized data collection methods**?
- What more can be done to ensure research supports **equity in access to MCM and systems strengthening** aligned with country and regional goals?