

# DEMOCRACY AND PANDEMIC



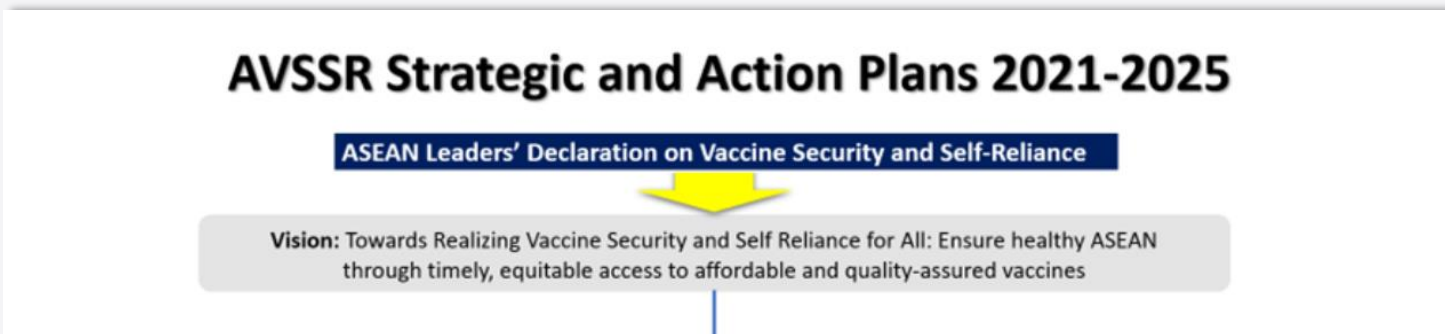
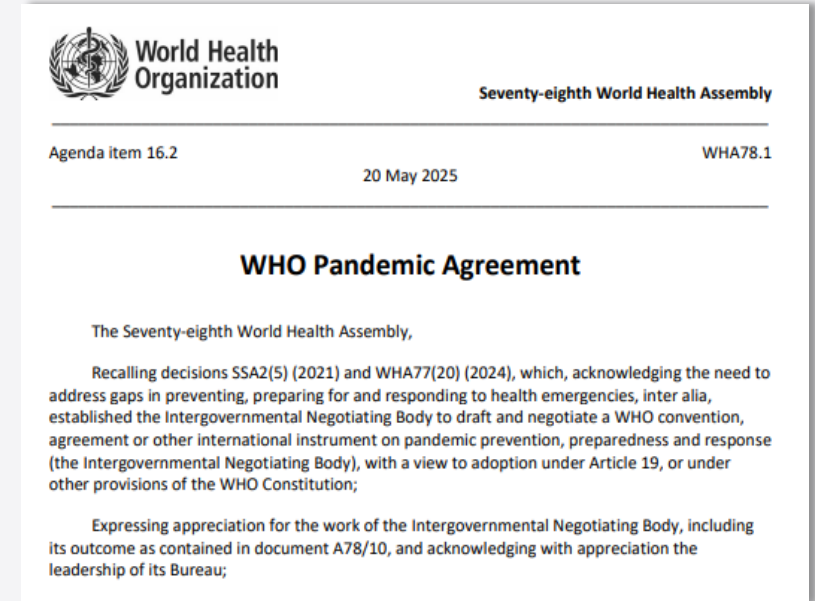
13 — 15.11.25

Fondazione Giorgio Cini, Venezia

# Investing in partnerships: readiness to go fast and far together

Saul Walker  
Director Public Partnerships, CEPI

# Shared goals for epidemic and pandemic readiness



# Prepare & partner for speed and equity

## Covid-19 lessons

- **Head start** on viral family and vaccine platforms R&D
- **Regulators innovated:** rolling review, EULs and immuno-bridging for VSVs
- **Clinical trials:** highly variable quality, speed and distribution
- **Concentrated vaccine manufacturing capacity** and **purchasing power** delayed LIC and MIC access
- **Demand and delivery capacity** delayed and limited coverage in LICs

ILLUSTRATIVE

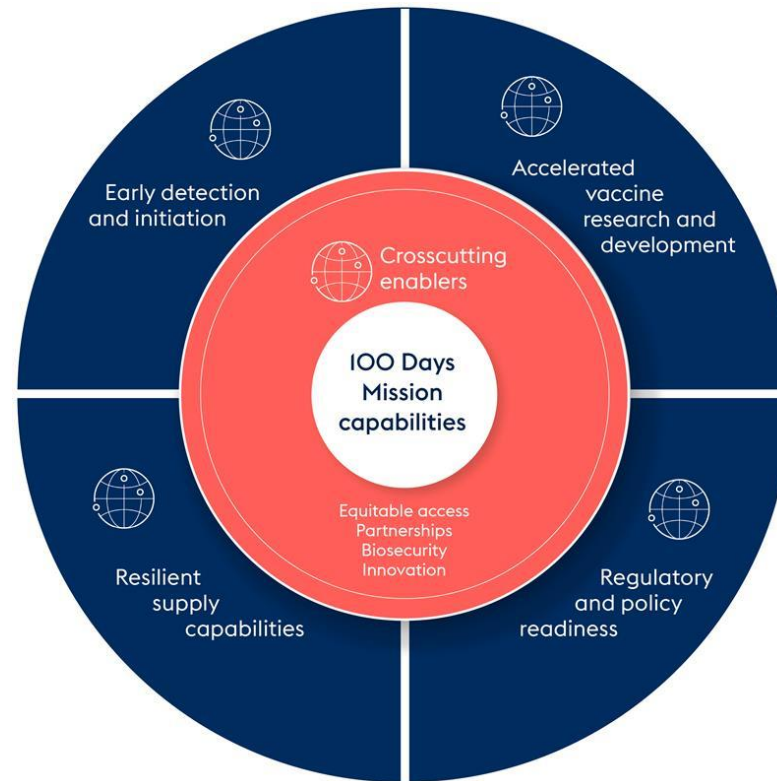
## Vaccine development timeline



# Capabilities For The 100 Days Mission

- Rapidly interpret early alerts and trigger safe, coordinated, locally led R&D&M responses.
- Epi data and modelling informs Vx development and manufacturing plans earlier.

- Geo-diversified and economically viable manufacturing ecosystem.
- Business models to address commercial and access barriers for Vx and innovations.



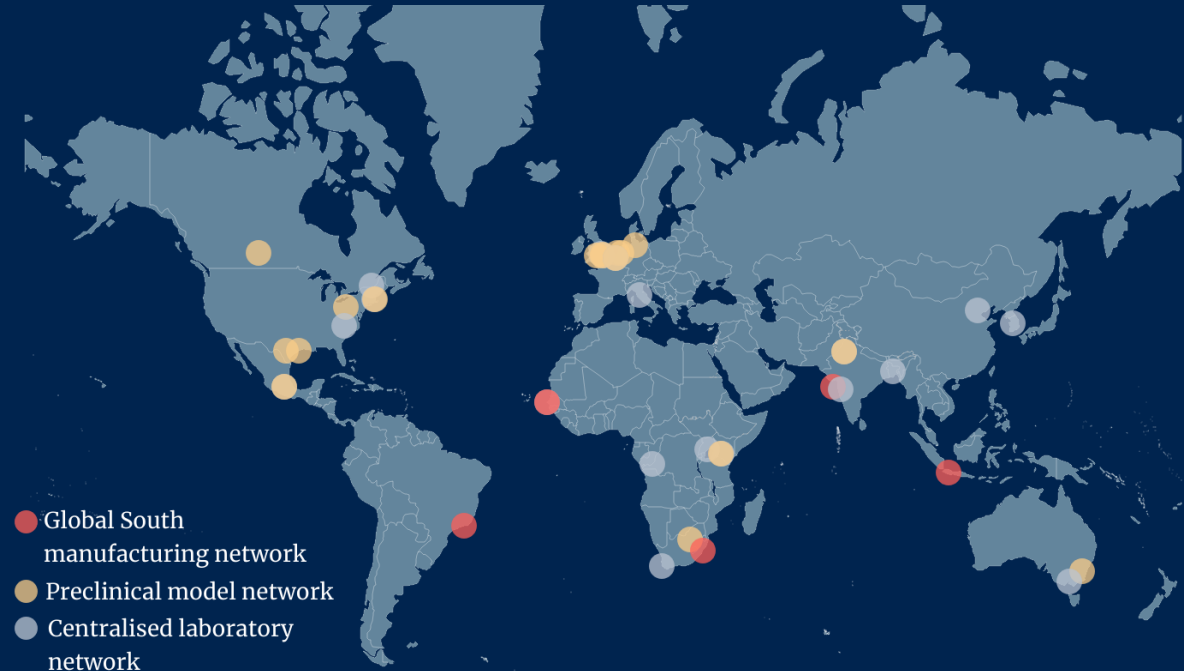
- Networked R&D&M partners accelerate design and testing of safe, effective and accessible Vx
- Prototype Vx for priority pathogen families.
- Established, flexible platforms.

- Global regulatory systems support accelerated and safe outbreak Vx authorization.
- Country adoption of regulatory and policy mechanisms

Innovation partnerships that increase effectiveness and speed, reduce costs, maintain safety and support equity

# An R&D and Manufacturing Base

- **Viral families:** build scientific base for known pathogens and viral families to respond quickly to epidemic and pandemic threats
- **Networked Partners:** interoperable clinical trial networks ready to conduct outbreak trials
- **Vaccine Platforms:** promising/proven and appropriate platforms that accelerate development and manufacturing
- **Enabling Sciences:** accelerate development and make collaboration possible (e.g AI enabled design, standardised assays)



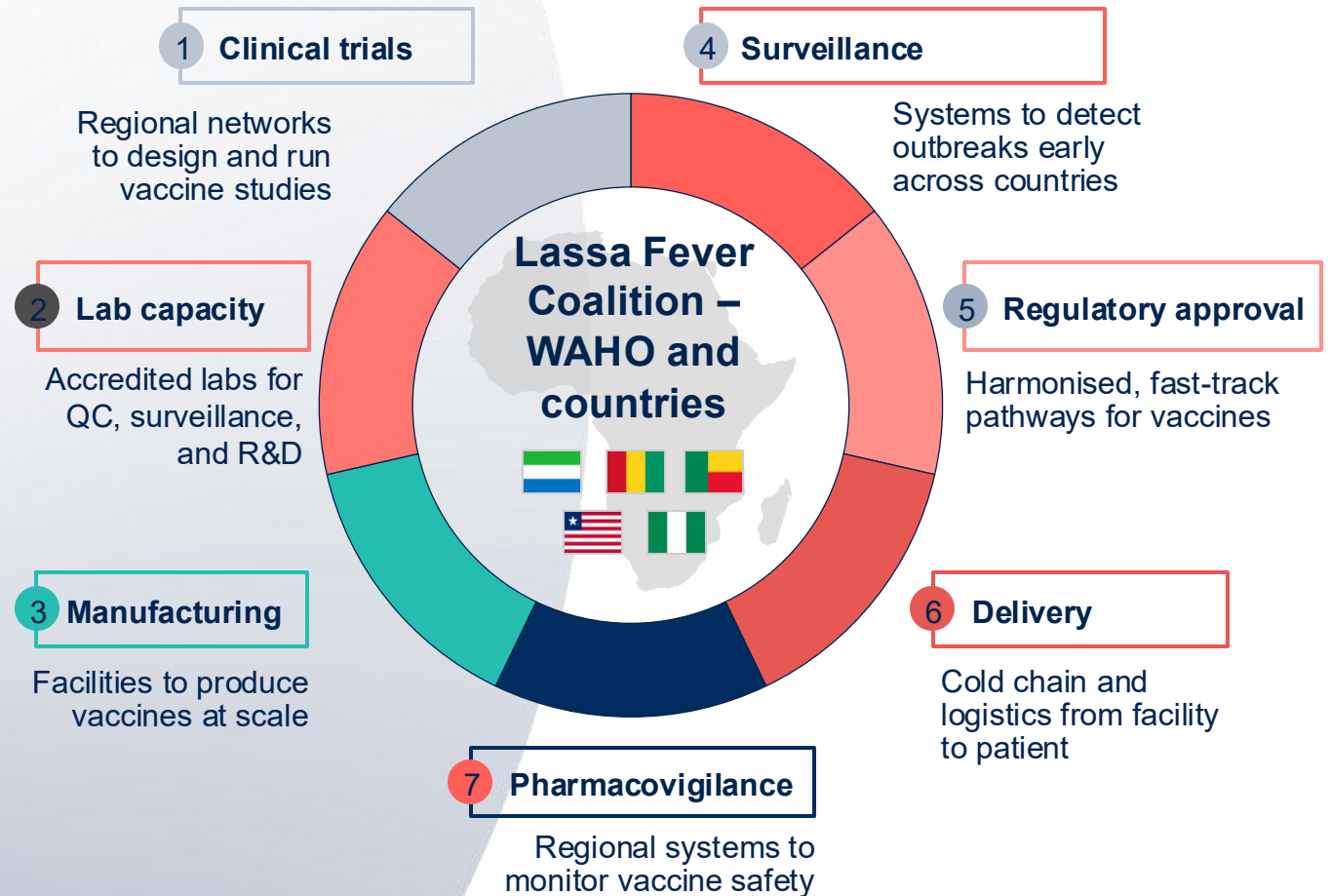
# WAHO Coalition: Lassa and Epidemic Readiness

West African leaders committed to advance Lassa Fever vaccine development for the Region, at the ECOWAS Lassa Fever International Conference this year.



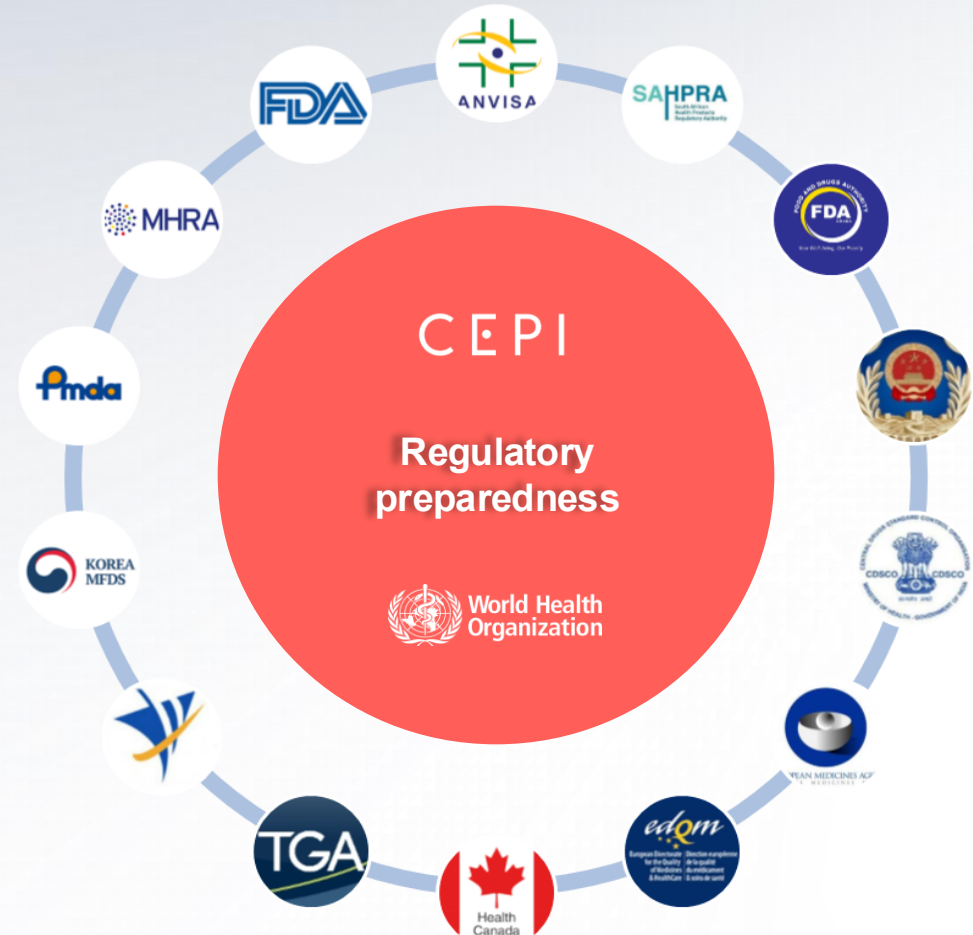
# WAHO Coalition: Core Capabilities

**Seven core capabilities** that enable West Africa to respond to future outbreaks and enable regional vaccine readiness



# Regulatory Science Innovation: Regulatory Advisory Group

- Co-chaired by CEPI and WHO
- Including 13 regulatory authorities



# Regulatory Science Innovation: Regulatory Innovations Consortium



**Launched October 2023.**  
Includes regulatory agencies  
from all WHO regions.



Goal to **support accelerated regulatory processes for epidemic and pandemic preparedness vaccines or other biological countermeasures** for high-risk populations as soon as evidence supports, including local determination of benefit risk.



Proactive **consolidation of available data, information and expectations** to facilitate regulatory documentation preparation, submission, review and authorization for vaccine use, targeting the potential for simultaneous access for high-risk populations in whichever countries they reside.



The Consortium will also **identify, prioritize and advocate for regulatory innovations** needed for further acceleration.

# CEPI Vaccine Manufacturing Partners (Oct 2025)



# Networking Capabilities for H5N1 Vaccine Development

## First demonstration of interoperability:

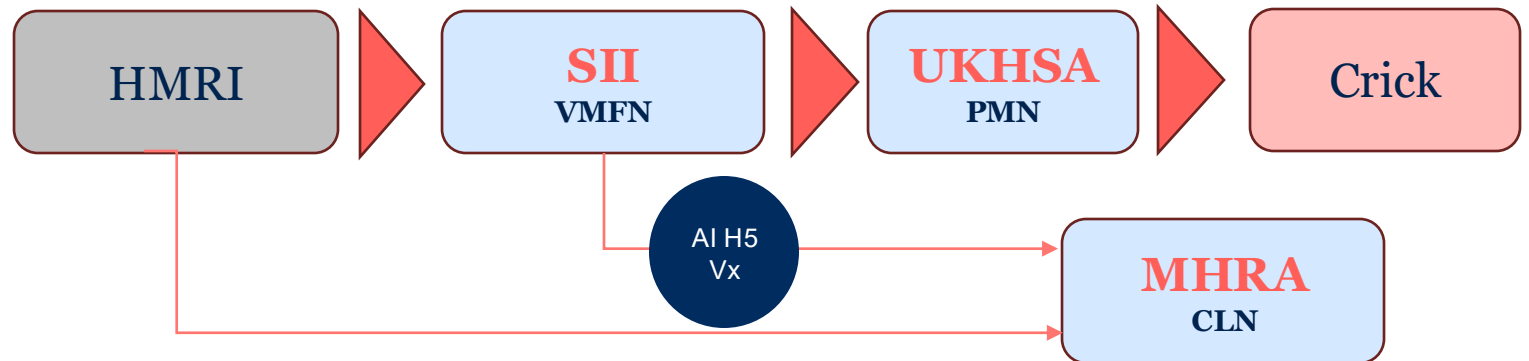
CEPI Network partners with **SII**, **UKHSA**, Crick and **MHRA** to pressure-test E2E outbreak supply response using wild-type and AI-designed H5 antigens, simulating a future pandemic threat

<https://cepi.net/serum-institute-india-and-cepi-supercharge-pandemic-response-preparedness-targeting-h5n1>

**HMRI:** design an AI-optimized, broad-spectrum H5 antigen and produce critical reagents

**SII:** use validated baculovirus-recProtein Vx platform to produce wt and AI-designed H5 vaccines

**UKHSA:** perform immunogenicity and wt H5 challenge efficacy studies in animals



**MHRA:** confirm the SII AI-H5 vaccine using HMRI critical reagents in a validated potency release test

# The Role of International Organisations



Innovation as a public good:  
generate and share knowledge



Mobilising and aligning financial  
and other resources



Collaborative thought leadership:  
convening, shared goals and  
regional leadership



Standards and tools for  
networking and collaboration



Linking across regions and sectors



Aligning with and for response

CEPI