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Pandemic Preparedness

CEPI's Lessons learnt from COVID-19 pandemic response, and the 100 day mission for pandemic preparedness

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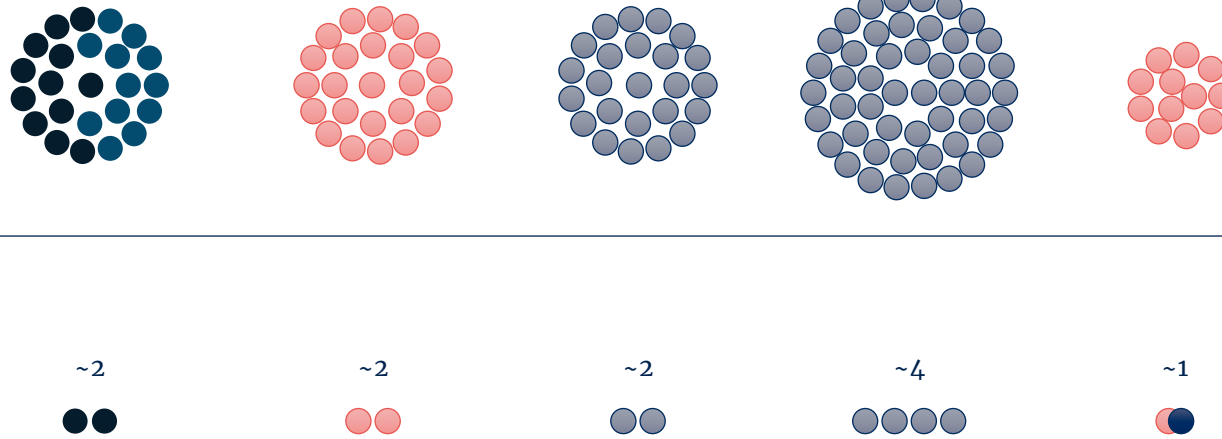
Global Vaccine and Immunization Research Forum 2023

Plenary Session 2

During COVID-19, it took 326 days for development to EUA by stringent regulatory authority

Vaccine development then and now, months

	Preclinical, including toxicity, technology development	Phase I: Safety and immunology	Phase II: Proof-of-concept study	Phase III: Large-scale safety and efficacy trials	Filing	Registration	
Sample baseline scenario[1], (after multiple years of research)	~12–24	~12–24	~24	~36–48	~12	~12	**~10 years**
Sample accelerated timeline[2], (based on previous SARS/MERS research) *Development was simultaneous rather than sequential. Clinical phases were continued after subsequent steps were initiated*	~2	~2	~2	~4	~1	Authorization (EUA by stringent regulatory authority)	**326 days**



1. Timelines can vary widely based on disease and trial designs
2. Patient safety was paramount despite the condensed timeline

Existing investments in priority pathogens and end-to-end collaboration made speedy vaccine development and deployment possible

We were able to respond quickly to COVID-19 due to:

1. **Prior research and development in two closely related coronaviruses, SARS and MERS**, including early funding from CEPI to support Oxford's **ChAdOx platform**.
2. Decades of development of **the mRNA platform**, allowing for fast, adaptable and highly scalable vaccine development —a step change from traditional biological manufacturing.

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145+ countries accessed the CEPI-funded vaccine portfolio thanks to the collaboration of COVAX partners to enable fair and equitable access

11 Vaccines

CEPI-led R&D support enabled access to a portfolio of **11** vaccines/candidates across **4** technology platforms

1.8b doses

COVAX has shipped over **1.8b** vaccine doses, out of which **1.5B**1 to AMC countries (92 LMICs)

39 Days

COVAX made it possible for the first vaccine deliveries in LMICs to take place within **39** days from introduction in the first few high-income countries

COVAX

ONE WORLD PROTECTED

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Gavi The Vaccine Alliance

unicef

World Health Organization

>100 countries

COVAX assessed and supported the roll-out planning process in **>100** countries with the development of National Deployment and Vaccination Plans (NDVP)

Global allocation

The fair and equitable allocation mechanism was established across partners, ready in time to allocate doses globally

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CEPI's plan to prepare for future pandemics

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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 day mission

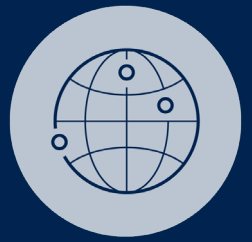
To develop a safe and effective vaccine in 100 days from the moment that a pathogen is sequenced and/or the need for a vaccine is recognised to initial availability for use.

Prepare

for known epidemic and pandemic threats

Transform

the response to the next novel threat



Connect

to enhance and expand global collaboration

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Compressing timelines further will require a fundamental shift towards preparedness

ILLUSTRATIVE

The NEW ENGLAND JOURNAL of MEDICINE

Delivering Pandemic Vaccines in 100 Days — What Will It Take?

Melanie Saville, M.B., B.S., Jakob P. Cramer, M.D., Matthew Downham, Ph.D., Adam Hacker, Ph.D., Nicole Lurie, M.D., M.S.P.H., Lieven Van der Veken, M.D., Mike Whelan, Ph.D., and Richard Hatchett, M.D.

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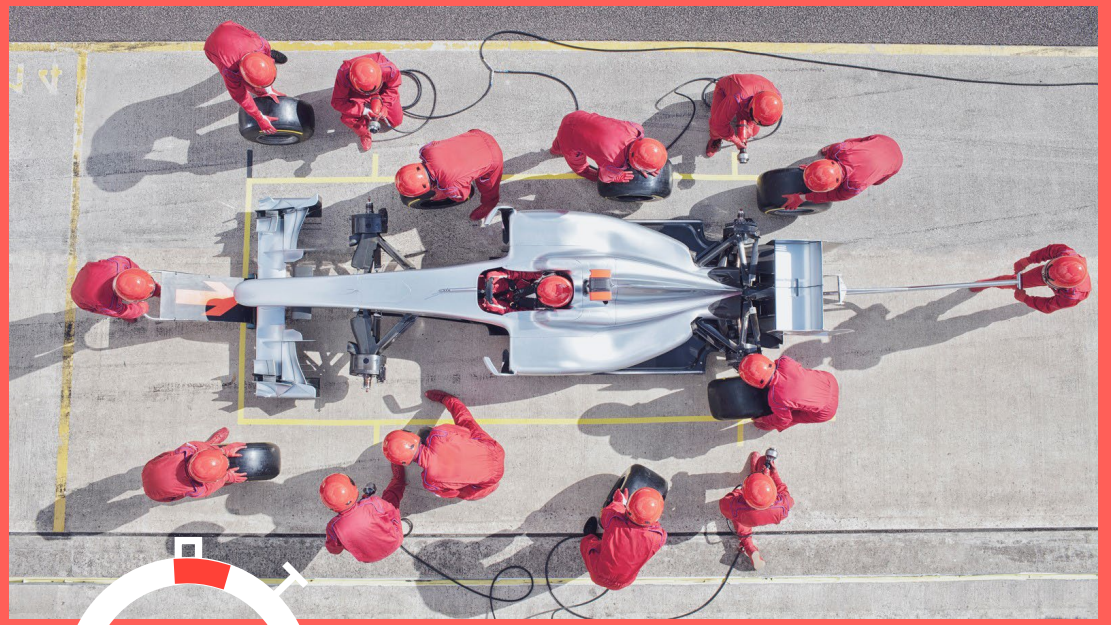
1
min



2
sec

in elapsed time

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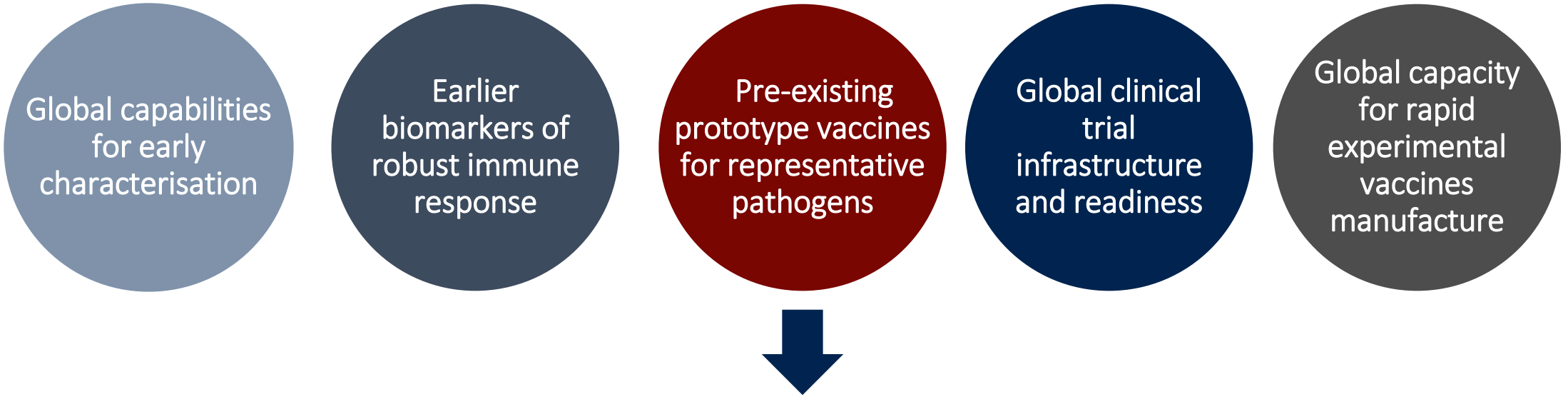
3 R&D&M focus areas for pandemic preparedness



As part of the 100 day mission, CEPI invests in developing a **library of 'prototype vaccines' against representative viruses** with spill over potential so that they can be swiftly pulled off the shelf and adapted the second a new virus emerges, and we don't lose valuable time creating a new vaccine from scratch.

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What does a virus family vaccine library look like?

Extensive knowledge base

viruses, receptors, Phylogenetics

Immunogen design

Human Zoonotic spill-over genera

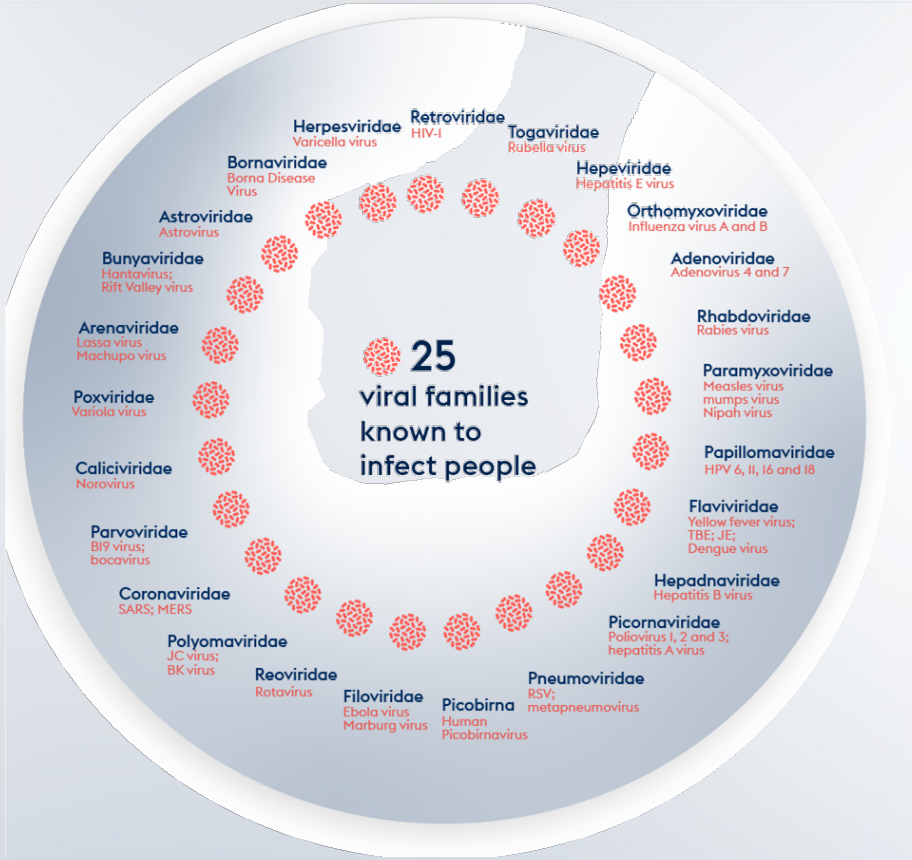
Subset put in **cDNA plasmid** Conformational verification

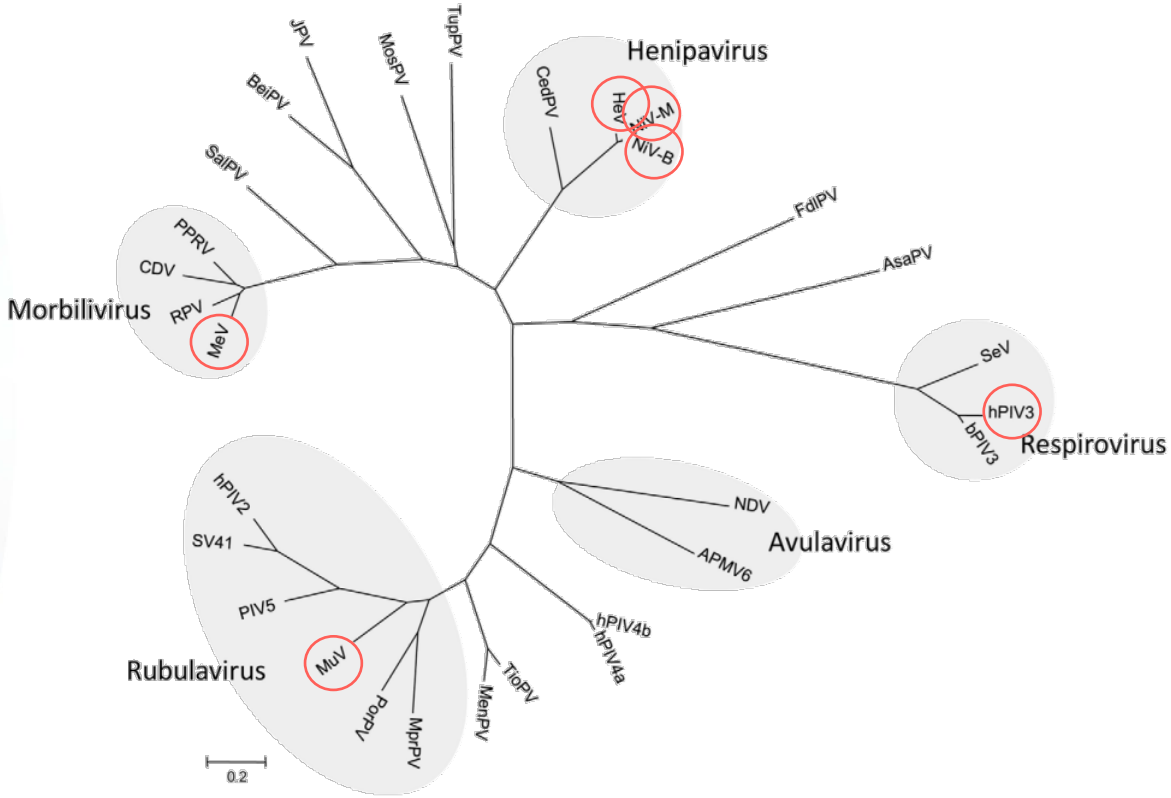
Immunogen design **tested in different platforms** e.g. mRNA, ChadOx, other Preclinical safety and efficacy

Exemplar vaccine candidates clinical testing for safety and immunogenicity and stockpiled

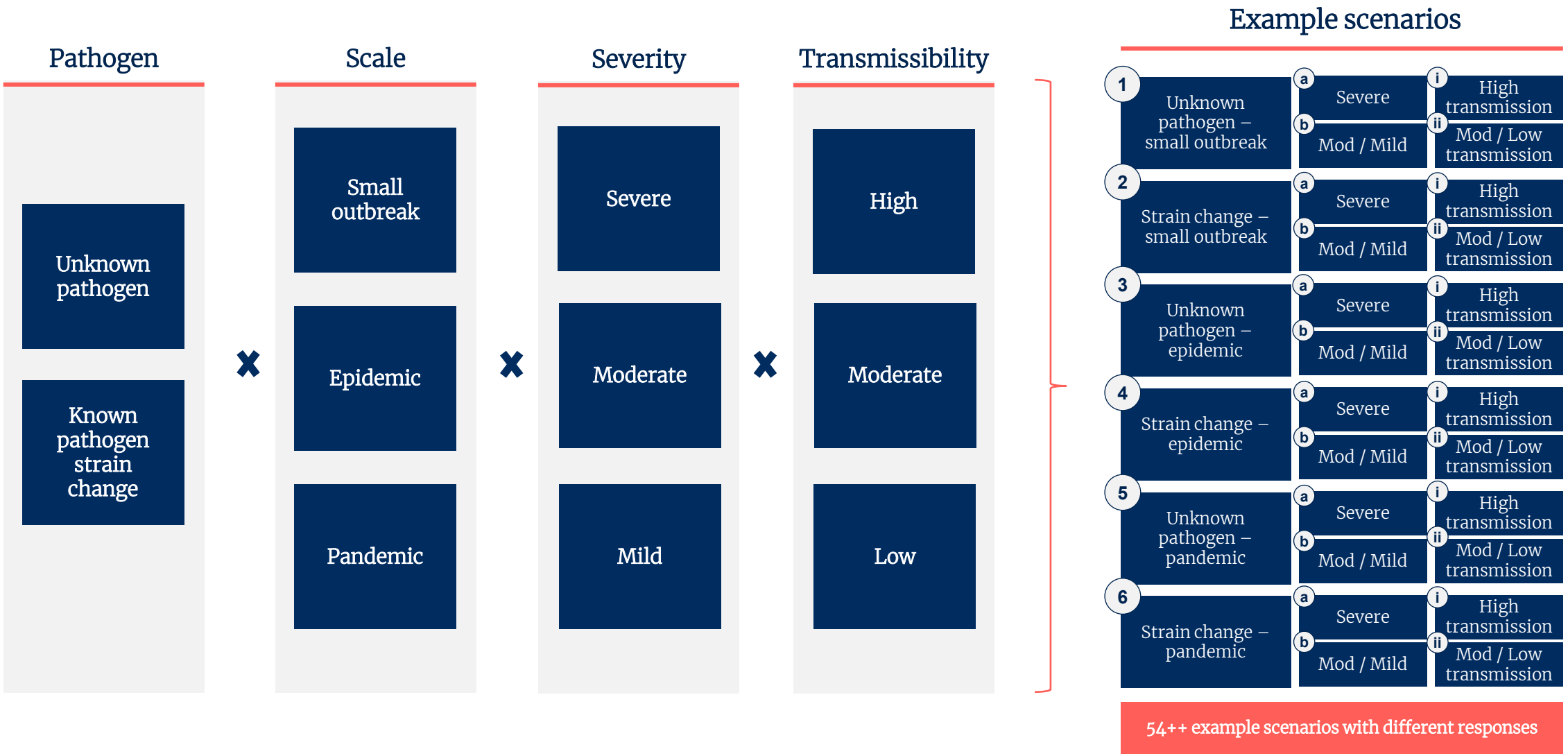
Access to data, materials and vaccine candidates through our equitable access provisions

Prototype pathogen approach - Paramyxoviridae





Different outbreak scenarios may have different potential response timelines



E.g., “SARS-CoV-3” vs “Pathogen X”

CEPI’s work on priority pathogens helps the world also prepare for Disease X

Scenario 1: SARS-CoV-3 — Similar to SARS-CoV-2 in terms of virology, clinical severity, transmissibility, etc.

- Ability to use previous safety and dosing clinical data, reduce efficacy assessment requirements, & leverage networks (clinical, epi, labs, manufacturing, etc.)

Scenario 2: Pathogen X — Unknown pathogen with high pandemic potential, severe disease, high transmissibility

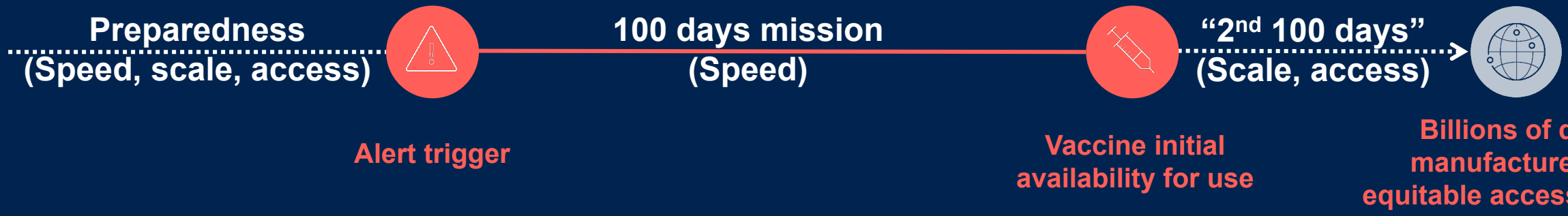
- Candidate development and assay development take longer
- Ability to leverage existing enabling networks, but trial design difficult because of lack of familiarity with the virus
- Evidence generation in clinical trials important to pave the way for future outbreaks

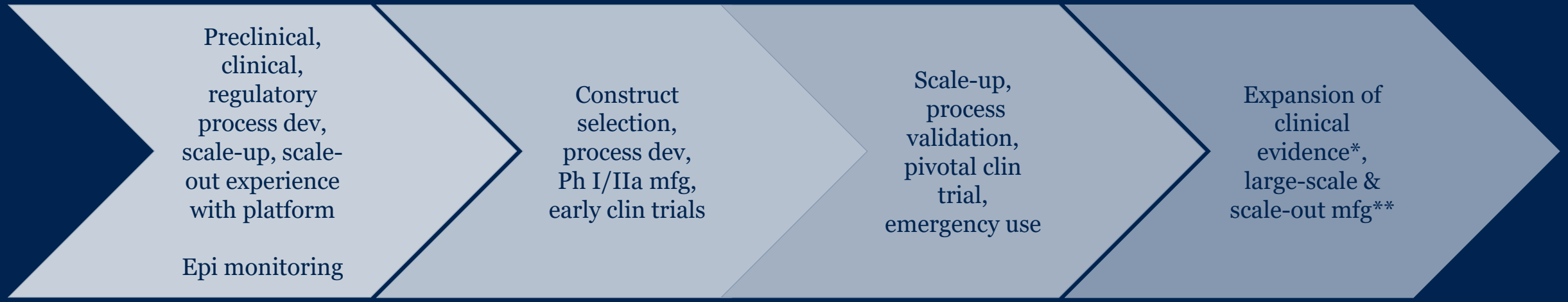
Additional scenarios — Additional outbreak scenarios can be considered to evaluate innovations / response time

Response acceleration **depends on the details of the outbreak and decisions on the development path.**

Even with maximal preparedness, the **response path will vary** under different scenarios.

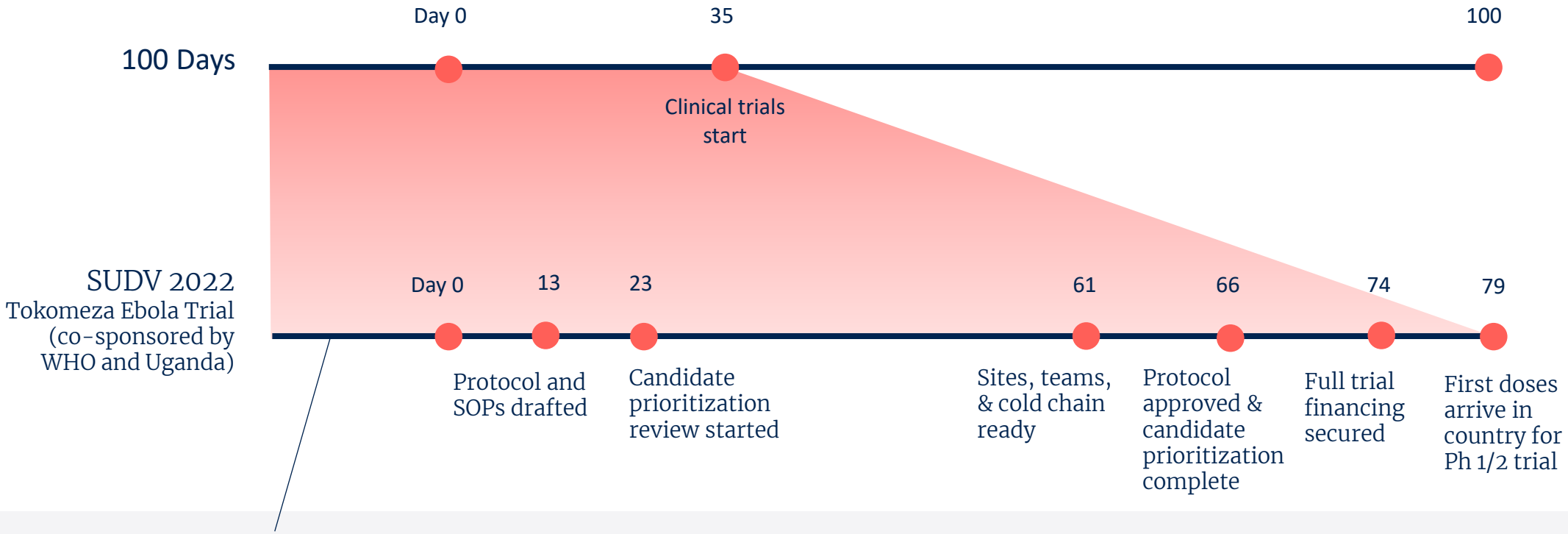
Pathway towards vaccine availability for use and equitable access (100DM + "2nd 100 days)





* Geo-diversified clinical, laboratory and regulatory capacity established during preparatory stage is critical for 100DM + "2nd 100 days"
** Geo-diversified large-scale and scale-out manufacturing capacity is critical to ensure global equitable access

Sudan Ebola live-fire exercise helped identify areas for improvement



Some preparedness gave a head start:

- Well-known viral family
- A few candidates with some Phase 1 data and proven platforms
- Bulk supply
- Strong country capacity for research
- Insurance & liability agreements in place
- Clinical stockpiles of exemplar vaccines

To achieve the 100 days mission we need to

- Work in preparedness mode
- Have sustainable geo-diversified manufacturing
- Have regulatory mechanisms
- Take every outbreak as an opportunity to practice
- Have much improvement towards equitable access

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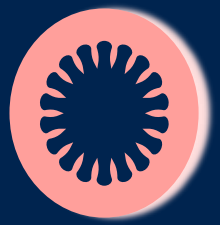
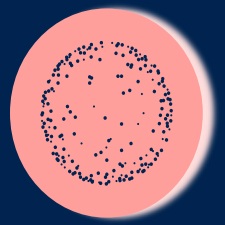
CEPI's active vaccine portfolio for outbreak preparedness and response



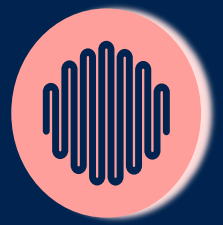
MERS

2 Vaccine Candidates



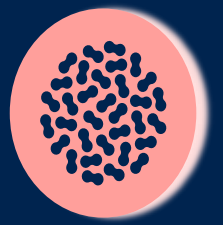
Lassa

4 Vaccine Candidates



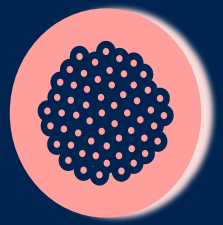
Nipah

3 Vaccine Candidates



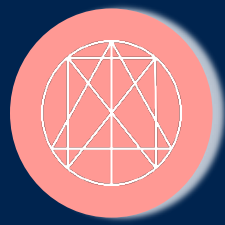
Chikungunya

3 Vaccine Candidates



Rift Valley fever

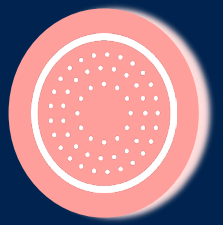
2 vaccine Candidates



COVID-19 / broadly protective

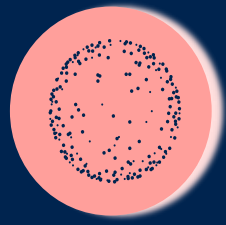
7 COVID-19 Vaccine Candidates

12 Broadly Protective[1] Vaccine Candidates



Disease X

3 Platform Technologies



Ebola[2]

8 Clinical Projects for 2 Vaccine Candidates

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[1] includes broadly protective SAR-CoV-2 and broadly protective betacoronavirus.
[2] *Finishing Ebola* : CEPI is funding 8 Ebola clinical projects for Merck and Janssen vaccines. In addition, CEPI is in dialogue with WHO to potentially support Ebola Sudan ring vaccination.