CEPI

Epidemic preparedness:
Towards analytical standardization for rapid response vaccine delivery

USP open forum

Franz Schnetzinger / 28-29 Feb 2024

A global partnership

Vision

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

Mission

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

CEPI’s vaccine portfolio

Investments in vaccine candidates or platform technologies

3

Chikungunya
2 active

6

Lassa Fever
3 active

4

MERS-CoV
2 active

4

Nipah Virus
3 active

14

SARS-CoV-2
*4 WHO EUL. 3 approved for domestic use. 1 active.

13

Broadly protective CoV vaccines
10 active

2

Rift Valley Fever

5

Disease X platforms

Compressing timelines further will require a fundamental shift towards preparedness

ILLUSTRATIVE

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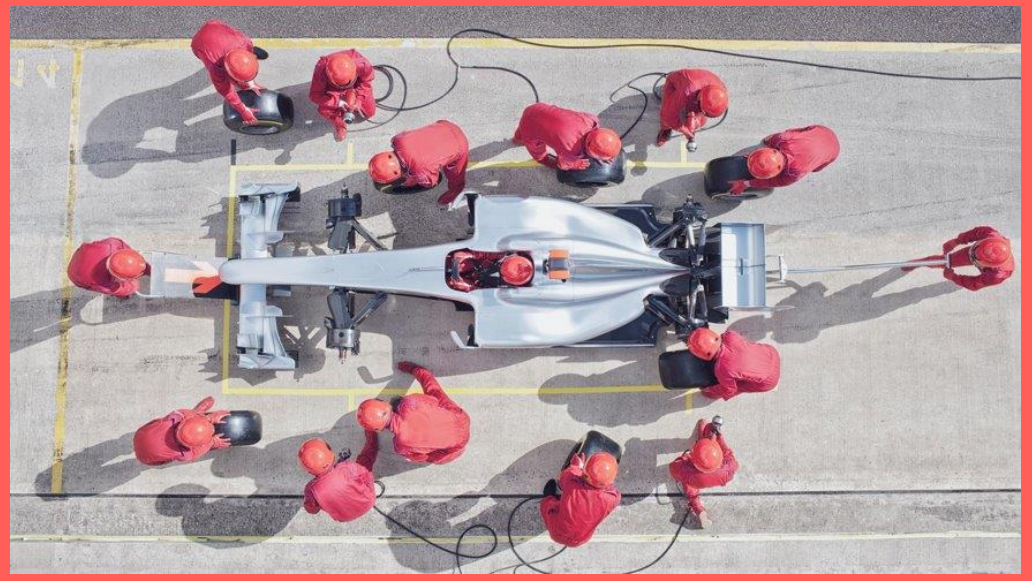
97% reduction

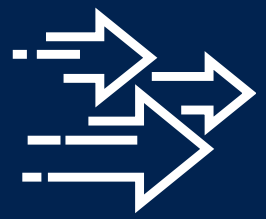
in elapsed time

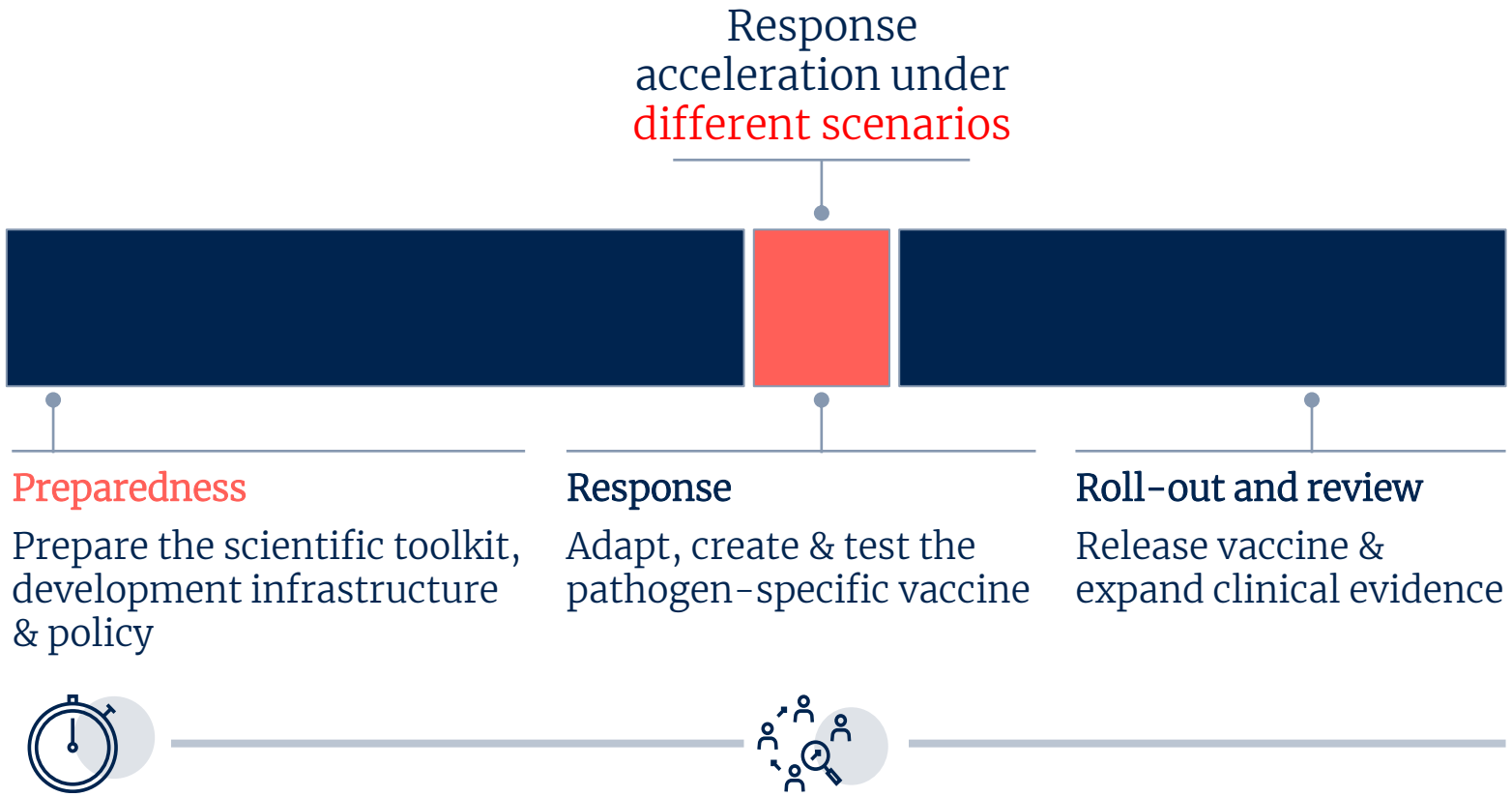
1 minute



2 seconds

Achieving the 100 Days Mission will require a paradigm shift





Paradigm shift: significant front-loading in preparedness, and breaking the firewall between development and intervention

Access lies at the heart of our plan

Achieving the 100 Days Mission would give the world a fighting chance of tackling and containing outbreaks close to the source, before they spread around the world and become pandemics.

But that only works if the vaccines are deployed in the country or region affected by the outbreak – regardless of where that may be.

That requires a fundamental shift in international collaboration and cooperation towards a system founded on the principle of equitable access.

#100DaysMission

What will it take?

(1) Strengthening disease surveillance and global early-warning systems

(2) Speeding up identification of immune response markers

(3) Creating vaccine libraries against representative pathogens from virus families with greatest pandemic potential

(4) Establishing global manufacturing capacity to make top-quality, safe, and effective new vaccines quickly

(5) Getting clinical trial and laboratory networks at the ready

Supported by enabling regulatory, policy and financing architecture

Vx Manufacturing Facility Partners established, to optimize geodiversification of MSC capacity/capability in Global South

Manufacturing & Supply Chain

Prioritized areas

- Enhance DS, DP, F/F capabilities and capacity access to Vx in Global South
- Strengthen rapid outbreak response vaccine manufacturing platform capabilities

INSTITUT PASTEUR de Dakar

aspen PHARMACARE

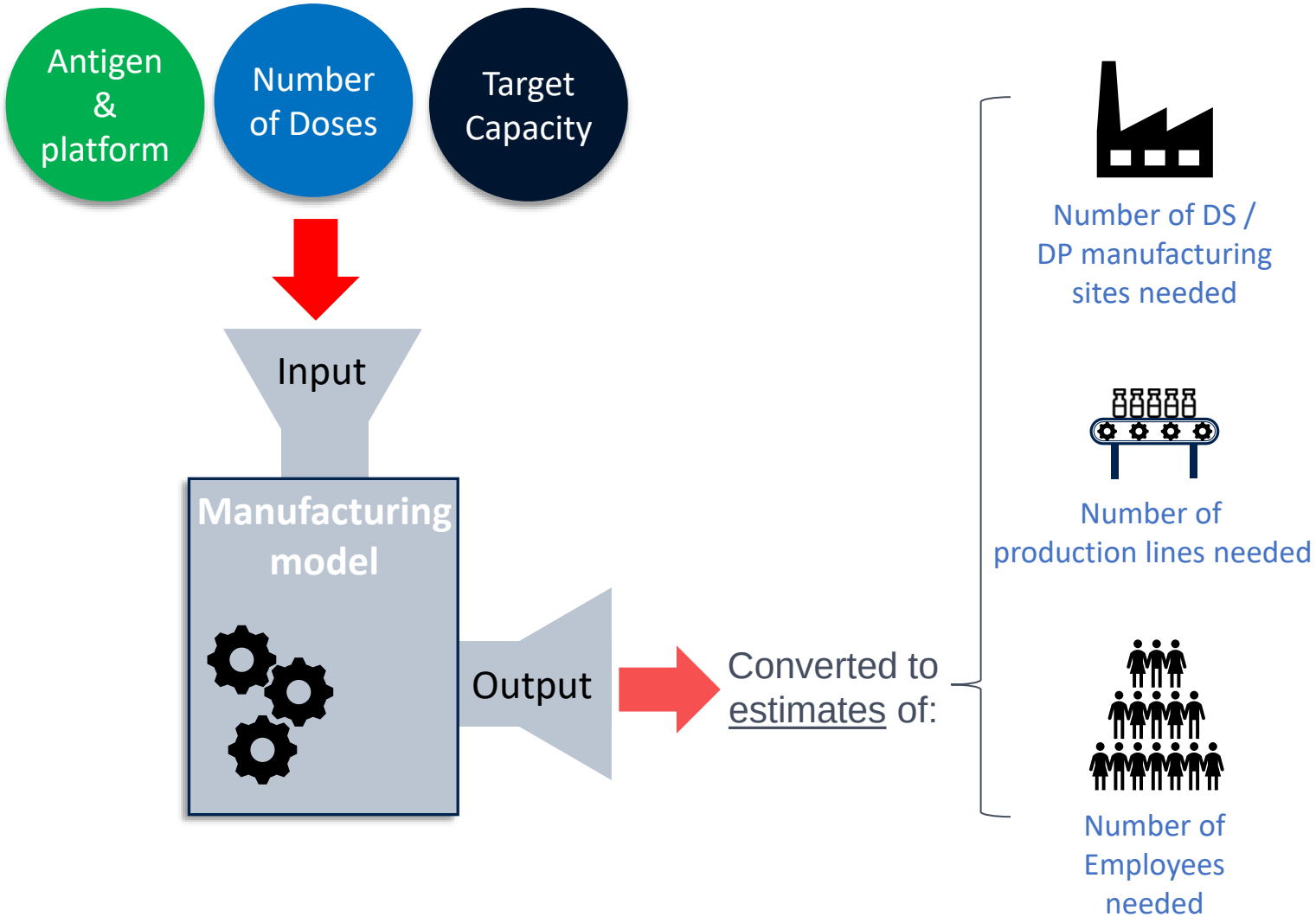
bioFarma

SERUM INSTITUTE OF INDIA

SC Modelling

SC modelling estimates the manufacturing capacity and capabilities needed to produce enough doses of a given vaccine to meet future target demand.

- *For example:* If African vaccine manufacturers are currently producing 5 million doses of pneumococcal vaccine annually but need to produce 140 million doses annually to meet the PAVM target, our model estimates the number of DS and DP production sites, production lines, and employees needed to meet that goal.



CEPI KU LEUVEN ACCESS-TO-MEDICINES

CMC Tech Transfer Framework

❑ *Objective*

To support and facilitate the CMC tech transfer at CEPI awardees and manufacturing partners –DS, FFP and analytical methods

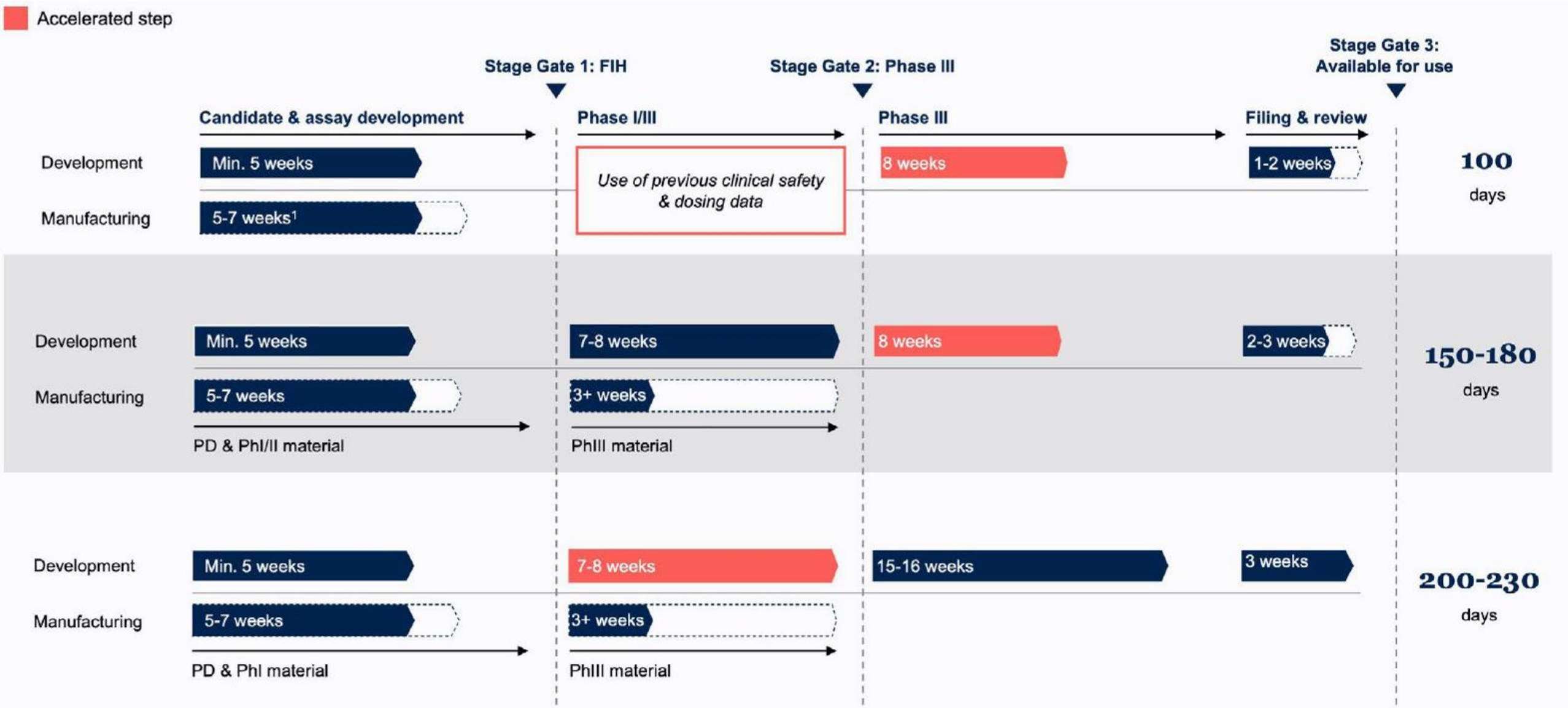
❑ Tech transfer Scenarios

Development stage	Sending unit	Receiving unit
Development → GMP manufacturing	Awardee vaccine development	Awardee GMP manufacturing site
	Awardee vaccine development	Third-party GMP manufacturing site (CMO)
	A third-party development site (CDMO)	Awardee GMP manufacturing site
Early stage → late-stage development	Vaccine development (small scale)	Scale up / large scale development

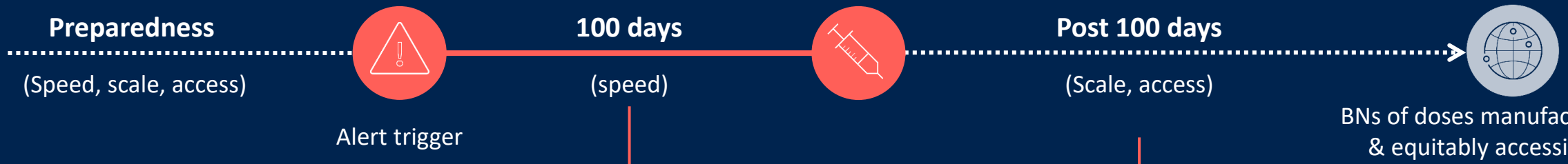
*Technology Transfer in Pharmaceutical Product Life Cycle **

** Adapted from ICH Q10 Pharmaceutical Quality System (PQS) and pharmaceutical product life cycle*

Three scenarios for response to an outbreak of a novel pathogen



CMC Innovations contribute to the mission



Alert trigger

Vaccine available for use

- LenioBio will test if their cell-free technology can produce vaccine proteins in as little as 20 days
- Algenex will utilize baculovirus expression vector and insect cells to quickly generate large quantities of viral antigens

- Implementation of CMC innovations with manufacturing networks and R&D

- Developed by Jurata Thin Film, vaccine-loaded thin films administered under the tongue could help avoid complexities that can come with standard needle-and-syringe administration

- Monitoring of innovation landscape and CEPI portfolio, for opportunities and gaps, to prioritize areas for future investment
- Assays, standards and reagents initiative to supply critical materials to portfolio projects and Disease X

Thermostability prioritized as first CMC innovation area to invest in

- To enable equitable access, increase vaccine coverage, and reduce wastage
- Call for Proposals was open from Jan ’22 – Jan ‘23
- Projects currently in execution (4), and negotiations (1)

Platform analytics in support of manufacturing platforms

ICH Q14 highlights

- Changes to product and/or control strategy may trigger method changes
- Extent of studies is defined by knowledge and risk
- Definition of established conditions (see ICH Q12 lifecycle management)
- Real time release testing
- Platform analytical method
- Analytical procedure control strategy
- Ongoing monitoring

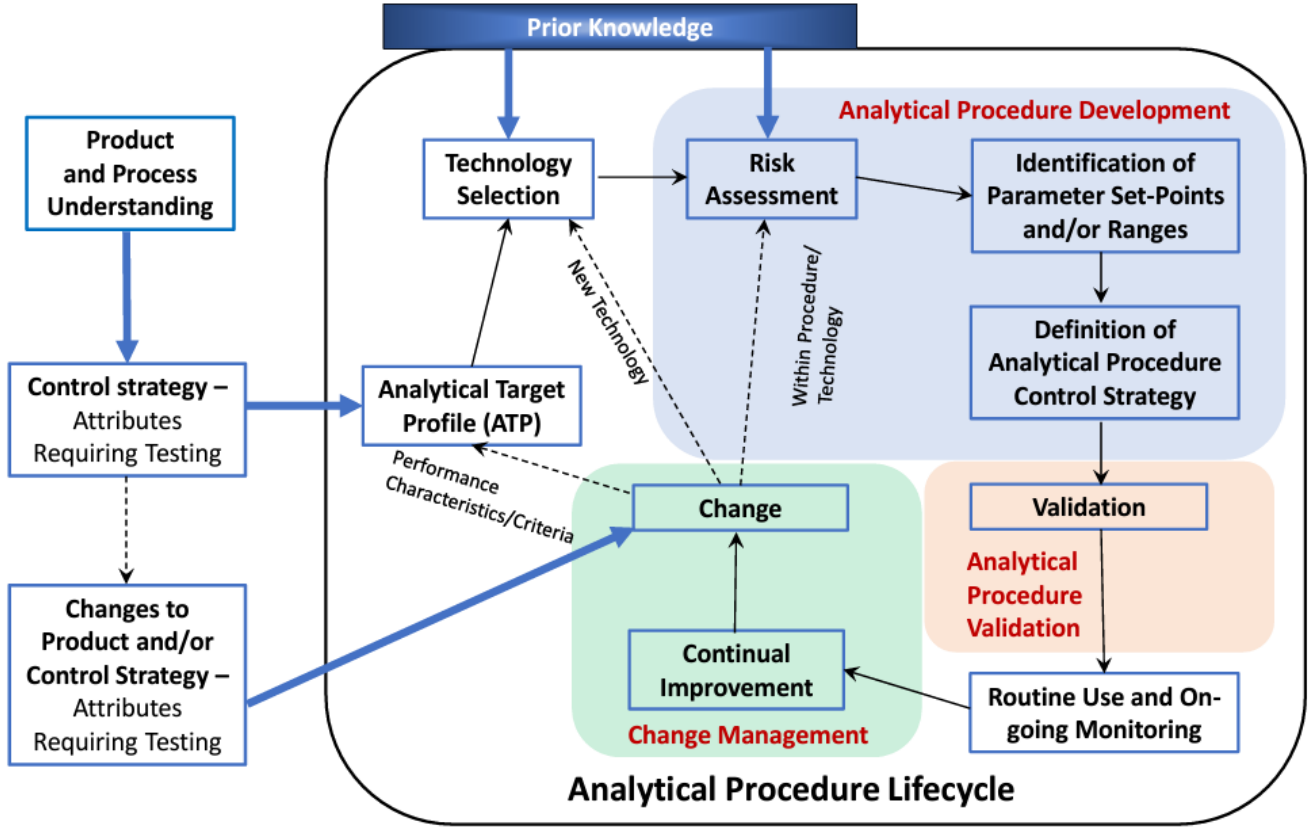


Figure from ICH Q14 draft for public consultation

Assay innovations & reagent support

Reduce product release timeline

- Process Analytical Technologies (PAT) for in-/at-line testing, rapid methods for real-time QC release, standardized analytical toolbox
- Focus Area 2 in speed call on analytical technologies to accelerate batch release (open May – Dec'23)

mAb standards suitable for pre-clinical and CMC assay development

- Wuhan/Delta/Omicron specific SARS-2 antibodies manufactured through PATH partnership; available at MHRA
- Generation and stability confirmation of SARS-1 antibody Broadly protective Coronavirus Vaccine (BPCV) development candidate mAbs require neutralising capability but minimal SARS-2 cross-reactivity
- Identify need and create roadmap for reagent sourcing in support of Disease X project

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CEPI CfP: Innovations for vaccine manufacturability focused on speed

- **Focus Area 1:** Platform process development, optimization, standardization and acceleration
  - mRNA, viral vectors, proteins or other novel platforms in batch or continuous processing modes to be considered
- **Focus Area 2:** Analytical technologies to accelerate drug substance/product batch release and availability of master cell bank (MCB) / master viral stock (MVS)
  - Deployment of existing rapid technologies, and new technologies, including implementation
- **Focus Area 3:** Innovations to accelerate cell-based manufacturing steps, including synthetic approaches
  - Implementation of cell-free manufacturing innovations to improve vaccine production
- **Focus Area 4:** Any other manufacturing-related innovations that can accelerate clinical trial material availability
  - Use of Artificial Intelligence (AI) in developing and controlling the manufacturing process to aid in post-approval rapid vaccine deployment

CfP open May – Dec 2023
Two projects currently in due diligence

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CEPI CfP: Innovative manufacturing technologies to improve vaccine scalability and equitable access

- Technologies that accelerate and support scale-up, scale-out and technology transfer, to make vaccines available at the right commercial **scale** in response to an outbreak
- Technologies that can reduce **cost of goods**
- Technologies that facilitate **equitable access**, distribution and delivery in all regions, especially the Global South
- Focus Area 3 of Vaccines & Biologics Innovations Initiative, published October 2023

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