Coalition for Epidemic Preparedness Innovations (CEPI)

Presentation to the WHO

21 July, 2017

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wellcome trust

WORLD ECONOMIC FORUM

DEPARTMENT OF BIOTECHNOLOGY
Ministry of Science & Technology

Why CEPI?

1

Global consensus that new and sustainable partnership models are needed for product development (vaccines, diagnostics, therapeutics) to contain outbreaks of EIDs

2

Recent outbreaks – SARS, Ebola and Zika - reveal gaps such partnerships should fill

- need for coordinated and proactive R&D and increased funding
- stronger advanced development and manufacturing capabilities
- regulatory innovations and harmonization of regulatory requirements

3

Comprehensive policy ecosystem required with a collective end-to-end vision

- Ebola response reviews/panels suggest lack of mechanisms to unite funders, developers, regulators
- Effective coordination will require dedicated mechanisms and resources, as well as end-to-end coordination of R&D and access

CEPI vision and approach

Vision

Epidemic outbreaks of infectious diseases will be managed at an early stage to prevent them from becoming public health emergencies that result in loss of life, undermine social and economic development and emerge into humanitarian crises.

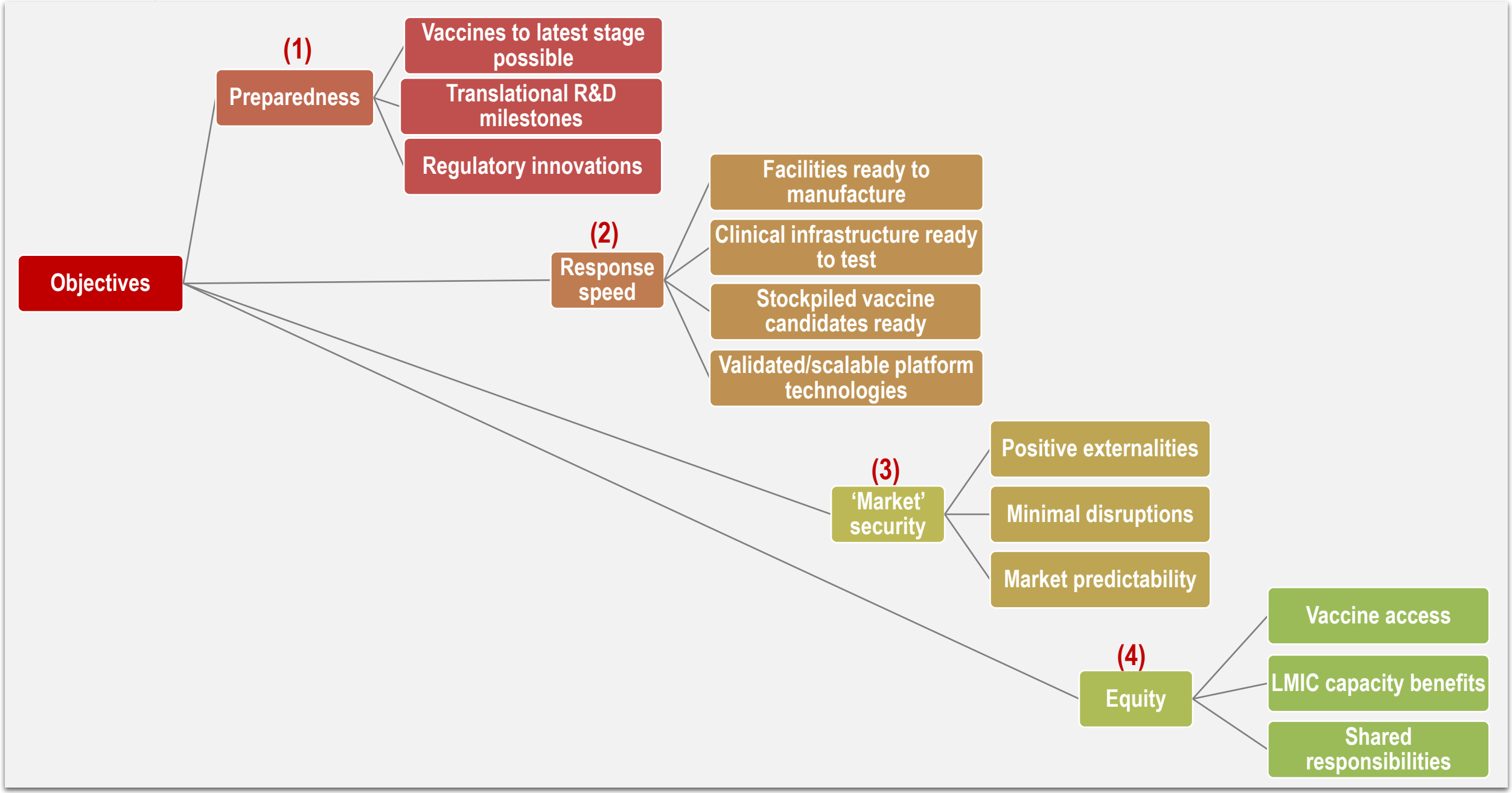
Building on the WHO R&D blueprint

- Need for improved R&D preparedness for diseases of epidemic potential
- Need for improved ability to conduct responsive R&D in emergencies
- Prioritization of pathogens
- Identification of R&D priorities
- Exploration of funding models for R&D preparedness and response

Approach

An end-to-end approach to vaccine development to application, CEPI will focus on essential gaps in product development due to market failure. The initial focus will be to move new vaccines through development from preclinical to proof of principle in humans and the development of platforms that can be used for rapid vaccine development against unknown pathogens.

CEPI objectives



CEPI fit in the end-to-end spectrum of vaccine preparedness

Phase	1 Discovery	2 Development/ Licensure	3 Manufacturing	4 Delivery/ Stockpiling
Current Stakeholders	• Academia • Governments • WT/NIH • GLOPID-R • Industry • Regulators • Biotech	• Industry • National Governments • Regulators • Gates • BARDA/DTRA etc. • WHO • Biotech • PDPs	• Industry • BARDA • CMOs • Regulators • National Governments • WHO	• GAVI • UNICEF • PAHO • National Governments • WHO • Industry • Pandemic Emergency Facility (World Bank)

CEPI principles

GOVERNANCE

- Accountability
- Public trust
- Political legitimacy
- No conflict-of-interest
- Transparency
- Independence / neutrality
- Public interest representation
- Flexibility / nimbleness
- Global health responsibility

OPERATING

- **No loss**: vaccine developers should be reimbursed for their direct and indirect costs
- **Shared benefits:** Rewards to vaccine developers should be proportional to levels of risk, R&D, infrastructural or other types of commitments. If a CEPI-sponsored vaccine should develop economic value above and beyond a pre-agreed set point, vaccine developers should reap these rewards and pay back CEPI funding
- **Equitable access**: global access agreements should be negotiated between CEPI and vaccine developers to encourage affordability and availability in Low Income Countries (LICs). Contracts should include reasonable royalty payment provisos for products or patents

Process to date

CEPI initiation & preparatory phase: January 2016 – June 2016

- ✓ High Level Meeting WEF Davos 21 January 2016;
- ✓ Formed Leadership Group and Chairs Group
- ✓ Three task teams set up on 'science and regulation', 'partnership models' and 'financing mechanisms' with final recommendations for integration in the strategic and business plans expected by end July 2017;
- ✓ Refined the scope of CEPI and the selection criteria for pathogens;
- ✓ Identified an appropriate partnership model;
- ✓ Advanced financing considerations;
- ✓ Defined rules of engagement for media and communications;

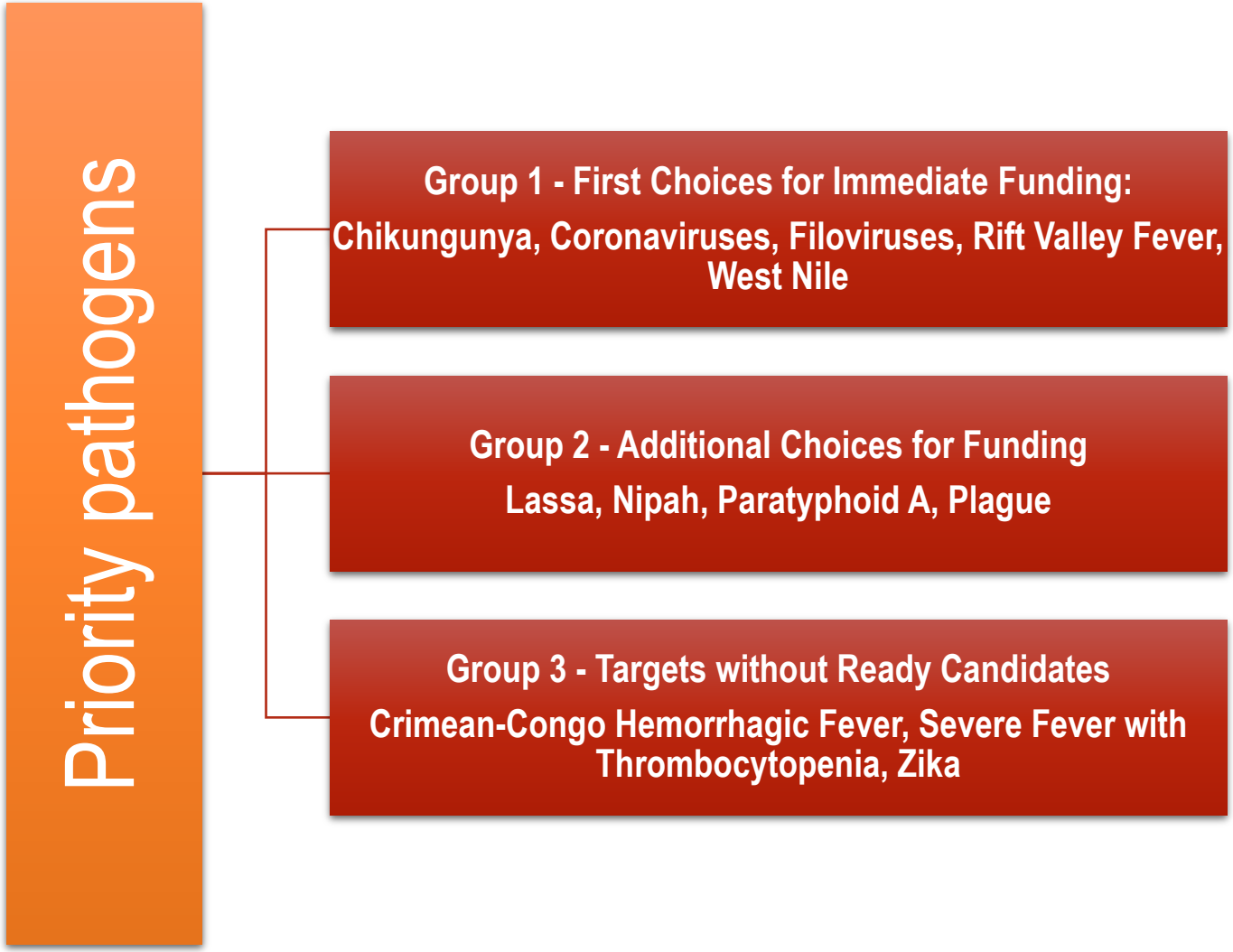
CEPI startup phase: June 2016 – December 2017

- ✓ Adopted interim entity, CEO and secretariat
- ✓ Finalized strategic plan
- ✓ Established a cross task teams cost modeling group
- ✓ Nominated candidates for interim BoD and SAC
- ❑ Finalizing interim governance arrangements, including selection of BoD and SAC members
- ❑ Drafting CEPI business plan for first five years of operation

Task Team 1 Output, Science and Regulation

- Developed prioritization criteria and ranked select pathogens for first one to two years of operation (interim, to be ratified by SAC)
- Exploring clinical development pathways for Phase I and II
- Landscaping of global capabilities for CMC/mfg
- Costings for developing/manufacturing vaccines
- Analysed legal and regulatory gaps to vaccine development

Priority pathogens (interim)



Criteria	Comment to interpretation
Protection in a relevant animal model	Protection in mice also scored but rated lower than protection in models closer to humans.
Evidence for a correlate of protection	Preferably inferred from data in humans, but also counted if inferred from animal or natural history data.
A viable platform for vaccine manufacture exists	Preferably more than one. If the proposed vaccine was accomplished by an important technological advance in vaccinology that could be applied to other vaccines its score was increased.

Task Team 2 Output, Partnership Model

A hybrid **Advanced Development Partnership (ADP)** model that can accommodate both permanently dedicated and project-based capabilities, providing a mixture of warm base funding and project-based funding, through RFPs that can ensure the best science and capabilities can be enabled to develop the vaccines of need

A **clinical and regulatory coordination network** that can: provide advice and negotiate on regulatory & ethical pathways for EID vaccines in epidemics; develop model protocols / agreements for liability protection, data & sample sharing; identify, evaluate and prepare competent clinical trial centers worldwide for large scale clinical testing of vaccines in EID outbreak situations

Task Team 3 Output, Financing Consideration

- **Seed Funding will be sought to commence operations, to be augmented with longer term funding**
- **Precise scale will depend on cost modeling and budget, we assume $1-2bn over 10 years**

Core Funding anticipated to require a blend of traditional and innovative capital raising

- Large upfront investments through grants by governments and foundations with 10-year commitments
- Funds granted ahead of need would be invested, to increase their spending power in later years, e.g. through IFFIm
- Returnable capital options for smaller funders through investments in a special purpose vehicle, the yields from which would generate additional funding for CEPI

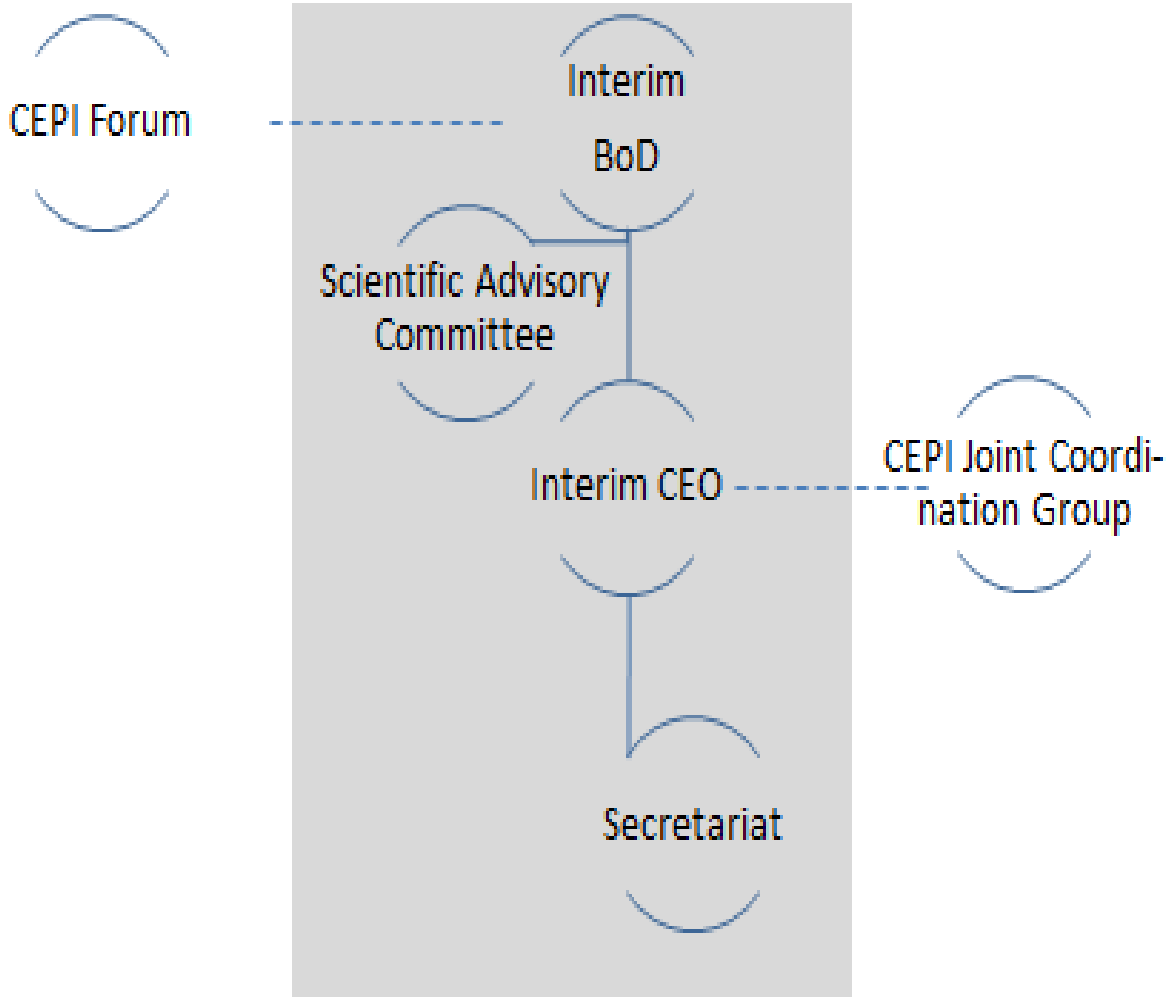
Ideas to support scale up and rollout in the event of an outbreak (to further explore)

- No displacement of existing "pull mechanisms", but coordination with these for post licensure
- CEPI could offer R&D milestone prizes
- Advance Market Commitments or Volume Guarantees for manufacturing scale up, potentially structured through GHIF or InnovFin, conditional pledges to Gavi or IFFIm, etc.
- Priority review vouchers (country-specific)

Organizational setup: Interim establishment

- Independent legal entity, existing as an international non-profit association under Norwegian law
- Hosted by the Norwegian Institute of Public Health under a service agreement
- Founding members of the association: Gates Foundation, the World Economic Forum, the Wellcome Trust, India's Department of Biotechnology, and the Government of Norway
- Flexible arrangement, can transition into other institutional and governance arrangements
- Decisions about its permanent organizational structure and governance made by the CEPI Board during the interim phase

Organizational setup: Decision making and coordination (interim)



Two prime institutional bodies

CEPI Board: Exercise supreme decision-making authority

CEPI Secretariat: Led by CEPI CEO, Manage day-to-day affairs, execute Board decisions

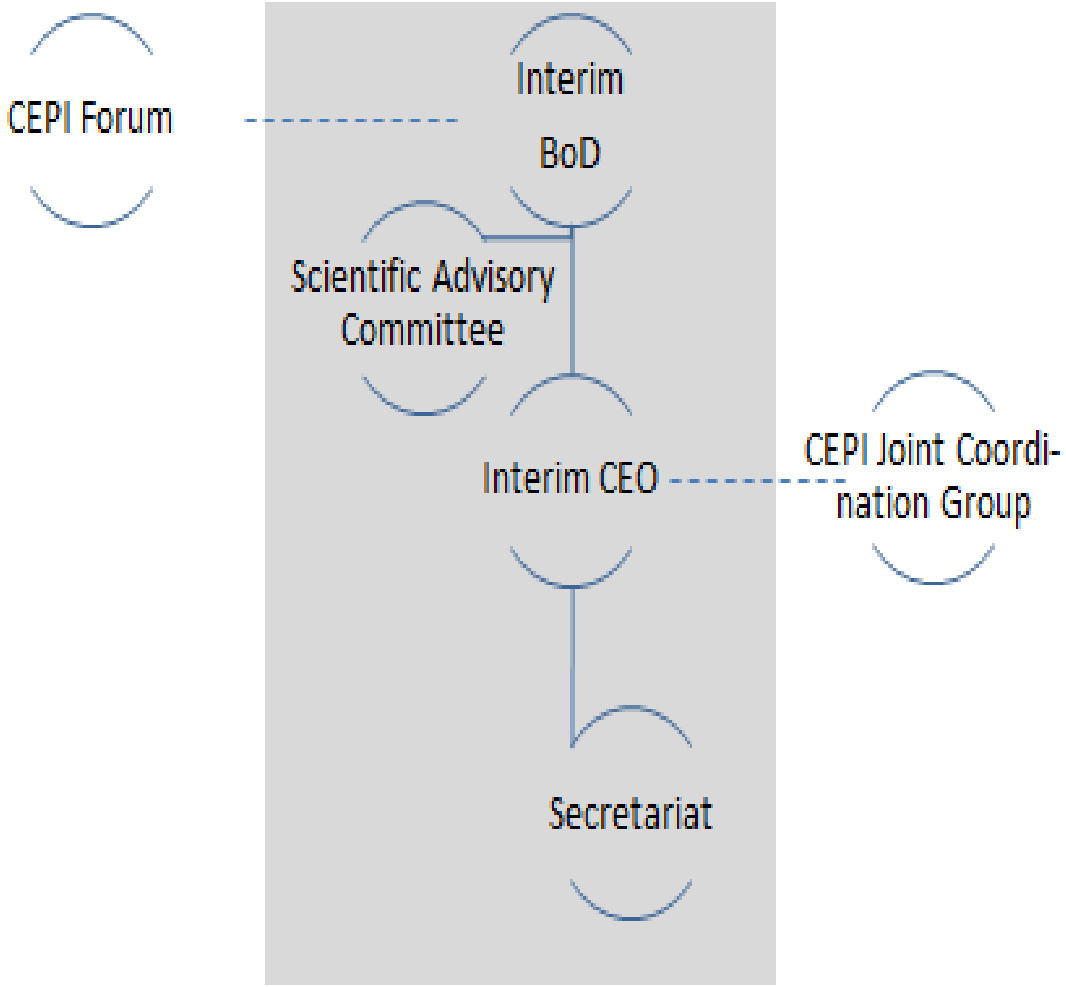
One advisory body

CEPI Scientific Advisory Committee: Principal advisory group on scientific matters important to the operations of CEPI, including recommending RfPs

One body with advisory and coordination function

CEPI Joint Coordination Group: composed of coalition partners committed to CEPI's mission and vision through a MoU

Organizational setup: Advisory and advocacy (interim)



One informal advocacy group

CEPI forum: serving as a group of ambassadors of and champions for CEPI's vision, and aiming to contribute to the mobilization of political and financial capital

Committees or advisory working groups established by CEPI Board based on needs

Joint Steering Committee: oversee programs or projects for which CEPI have used core funding to co-fund together with other co-funders

Ad hoc advisory groups: three task teams that have informed the development of CEPI is proposed transitioned into ad hoc advisory groups during the interim phase

- Science and Regulation
- Partnership Models
- Incentives and Innovative Financing

Organizational setup: CEPI Board

- **Composition**

(1) 3-5 HIC government representatives;
(2) 3-5 LMIC government representatives;
(3) 2-3 philanthropic funder representatives;
(4) 3-4 private sector representatives, of which 2 will constitute MNCs who have signed a Memorandum of Understanding with CEPI;
(5) 1-2 representatives from civil society/NGOs/patient organizations;
(6) 1-3 members in their individual capacity.

- All CEPI stakeholders invited to nominate experts
- The Chairs Group will select the Interim CEPI Board

Organizational setup:
CEPI Scientific Advisory Committee (SAC)

- 12-16 qualified individuals, representing core areas of scientific expertise
  - **V**: Virology and Vaccine Development; **I**: Immunology; **B**: Biochemical/biotech background; **P**: Pathogen expertise; **R**: Regulatory; **E**: Epidemiology
- Representing in their individual capacity as independent experts
- Declaration of Interests form required, potential conflict of interest managed in accordance with CEPI's conflict of interest policy
- The Chairs Group will select the Interim CEPI Scientific Advisory Committee

Organizational setup:
CEPI Joint Coordination Group (JCG)

Composition

- Representatives of all coalition partner organizations: the WHO; core funders (e.g. Wellcome Trust, Gates Foundation, Govt of Norway) and co-funders (e.g., BARDA, EC, IMI, and NIH); public and private sector implementers/innovators (e.g. MNCs, research institutes, PDPs); regulators and normative bodies (e.g. US FDA, EMA, WHO PQ, AVAREF, national academies of medicine or science), procurement and distribution partners (e.g. Gavi)

Function

- Forum for aligning activities across the end-to-end spectrum of vaccine preparedness
- Facilitate the involvement of CEPI partners in the strategic direction and policy oversight for CEPI's operations
- Serve a joint advisory function to the CEPI Board

Organizational setup: Progress

- Founding documents and Articles of Associations for the establishment of CEPI prepared
- CEPI Board
  - Nomination open until July 25th, >20 nominations received, to be selected on July 29
- CEPI Scientific Advisory Committee
  - Nominations closed, >70 nominations received, shortlist in preparation, 15 experts to be selected on July 29
- CEPI Joint Coordination Group
  - MoU for coalition partners to sign prepared in collaboration with founding members

Collaborating with WHO

- In the process of developing an MoU between WHO and CEPI
- CEPI will rely on WHO as the global normative lead agency on health
- Guiding principles
  - To respond to vaccine R&D needs for emerging infectious diseases, and ensure that the developed vaccines will be available to all in need, in order to achieve the highest possible public health impact
  - To focus on diseases on which the market fails to provide adequate incentives
  - To strategically leverage the existing diverse set of national and international mechanisms that support vaccine R&D, avoid duplication, and maximize synergies

Collaborating with WHO - Objectives

- Meet public health needs through acceleration of vaccine R&D processes, without sacrificing scientific rigor or public safety for pathogens with epidemic potential for which the market does not provide adequate incentives
- Improve global coordination, investment, and incentives for advanced vaccine R&D
- Ensuring global regulatory optimization and alignment, and strengthen global scientific advice on vaccine development for emerging infections
- Development and implementation of new norms and standards adapted to and appropriate for an epidemic context

Next steps

June 2016 → July → Aug → Sept → Oct → Nov → Dec → Jan 2017

Preparatory Phase | **Start Up Phase**

Finalize Strategic Plan > Initiate Business Plan | **Adopt Interim Entity** | **Formalize Commitments** | **Launch Partnership**

Align CEPI partners on objectives and KPIs; strategic plan and **governance arrangements**.

Set up cost modeling group and design **cost model for business plan,** teleconference on 15 July.

Constitute Interim Board, 29 July, appoint CEO finalize business and communication plan

Present Strategic/ Business Plan at the **Leadership Group meeting 30 August in London**

Interim board face- to- face meeting 31 August

Scientific Advisory Committee Meeting, 1 September

Submit Strategic/ Business plans and hold consultations with **G7** Sherpas ahead of the **Health Ministers Meeting in Japan, 11-12 September**

Secure initial commitments of CEPI participation and contribution

Interim Board Meeting in India, 10 November

Lead funders to launch CEPI and call for additional participation at the Annual Meeting at Davos 2017