

CEPI

CEPI

New vaccines for a safer world

John-Arne Røttingen, CEO
September 29, 2016



Norwegian Ministry
of Foreign Affairs

BILL & MELINDA
GATES *foundation*



WORLD
ECONOMIC
FORUM



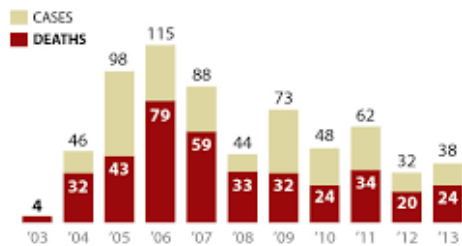
DEPARTMENT OF BIOTECHNOLOGY
Ministry of Science & Technology

The challenge of epidemics



H5N1 AVIAN FLU CASES

Annual confirmed human cases for avian influenza A(H5N1) and deaths reported to the World Health Organization as of Dec. 10, 2013:



SOURCE: WORLD HEALTH ORGANIZATION

THE CANADIAN PRESS



Calls for global action

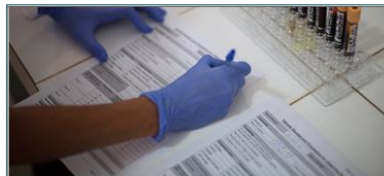
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Protecting Humanity from Future Health Crises

Report of the
High-level Panel on the Global Response to Health Crises

25 January 2016

Report of the Ebola Interim Assessment Panel



AN R&D BLUEPRINT FOR ACTION TO PREVENT EPIDEMICS PLAN OF ACTION MAY 2016



Outcome document
Financing of R&D Preparedness and Response to Epidemic
Emergencies
October 29-30, 2015
Oslo, Norway

Background

This Outcome document summarizes discussions that took place during the Oslo consultation on *Financing of R&D Preparedness and Response to Epidemic Emergencies* (October 29-30, 2015). It reflects views expressed and the discussion that took place, but does not necessarily reflect all interventions. Names of representatives of countries and organizations participating in the Oslo consultation on Financing can be found on the webpage of the Norwegian Institute of Public Health. Stakeholders represented included government, industry, NGOs and academia as well as charitable foundations and other relevant actors. The consultation was jointly organized by WHO and the Norwegian Institute of Public Health and hosted by the Norwegian Institute of Public Health.

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Health Policy

Will Ebola change the game? Ten essential reforms before the next pandemic. The report of the Harvard-LSHTM Independent Panel on the Global Response to Ebola

Dr Suerie Moon, PhD, DPhil, Sophie Delaunay, MSc, Prof Eric Goosby, MD, Prof Leung, MD, J Stephen Morrison, Benjamin Hawkins, PhD, Li
Published Online: 22 November 2015

NATIONAL ACADEMY OF MEDICINE

ABOUT THE NAM PROGRAMS INITIATIVES PERSPECTIVES NEWS SUPPORT MEMBER RESOURCES

Global Health Risk Framework

The Neglected Dimension of Global Security: A Framework to Counter Infectious Disease Crises

Download the Report



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Perspective

Establishing a Global Vaccine-Development Fund

Stanley A. Plotkin, M.D., Adel A.F. Mahmoud, M.D., Ph.D., and Jeremy Farrar, M.D., Ph.D.
N Engl J Med 2015; 373:297-300 | July 23, 2015 | DOI: 10.1056/NEJMp1506020

Comments open through July 29, 2015

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Article References Citing Articles (8) Comments (2) Metrics

CEPI-actions January - June



**High Level Meeting
Davos
21 January**



**Task Team Meeting
Meeting, Oslo
6-7 April**



Task Team Tele-conferences



**Leadership Group Meeting
Washington DC
17 May**



**Interim CEO appointed
Interim board constituted
Business Plan presented to stakeholders**

CEPI-actions July - September



**Core Group
and
Leadership
Group Tele-
conferences**



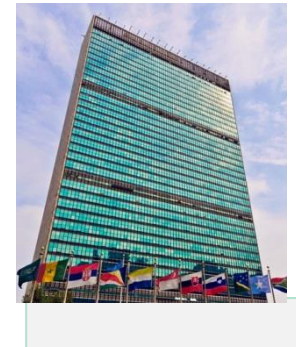
**First CEPI
interim board
meeting
London,
31 August**



**CEPI soft
launch
Media
coverage**



**G7 Health
ministers' side
event,
Kobe,
10 September**



**UNGA side
event on health
emergencies,
NY,
19 September**

Challenges

1

The pipeline is weak for most emerging infectious diseases characterized by lack of market incentives

2

Unilateral, uncoordinated government efforts to fund R&D preparedness are inefficient and unsustainable in addressing global epidemic risks

3

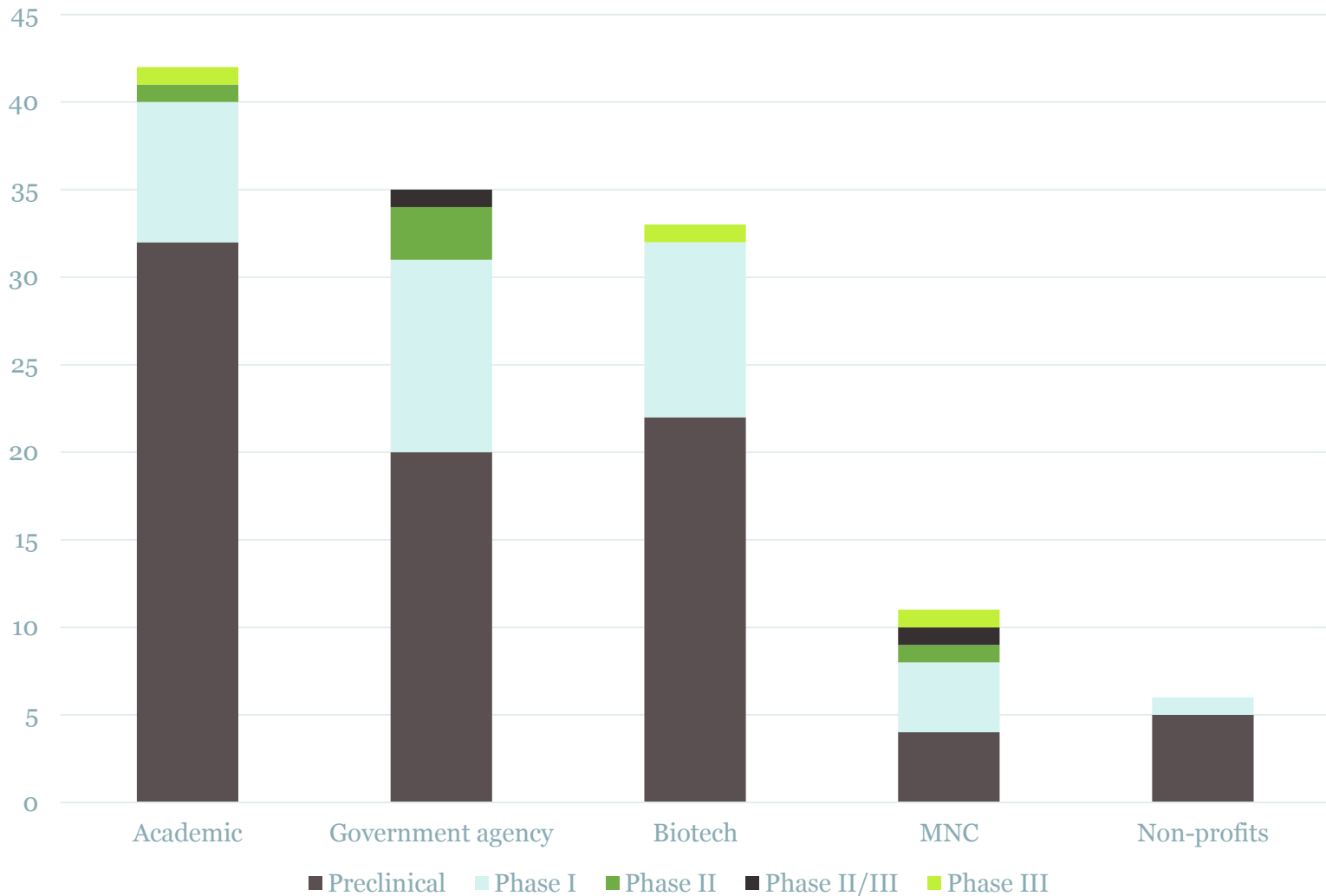
Clinical & regulatory pathways are not easily adaptable to epidemic contexts

4

Incentives are lacking to motivate greater industry engagement

Vaccine pipelines

FIGURE: VACCINE PIPELINES FOR PRIORITY PATHOGENS INCLUDED IN THE WHO R&D BLUEPRINT LIST AS AT MID- 2016



Opportunities

1

The Ebola momentum: vaccines are feasible despite a risky development pathway

2

The Ebola momentum: it is possible to advance the clinical development of safe and effective vaccines against EIDs in an emergency

3

R&D actors supporting EID vaccine pipelines: government health research agencies, academic research institutions, biotechs, multinational vaccine manufacturers, and non-profits

4

Manufacturing capability and capacity for vaccines has always been a critical bottle-neck in epidemic events. Major vaccine manufacturers can drive pipelines forward

The CEPI response

**Rationalize
&
accelerate**

Rationalize and **accelerate** research and development responses to new outbreaks



Coordinate

Coordinate resources of industry, academia, governments, philanthropies, and NGOs



**Prioritize
& facilitate**

Prioritize platform technology and vaccine targets and **facilitate** the advanced development of vaccines for emerging infectious diseases

Vision

*Vaccines contributing
to preventing outbreaks
from becoming
humanitarian crises*

Mission

To stimulate, finance and co-ordinate vaccine development against emerging infections with epidemic potential, especially in cases where market incentives alone do not achieve this

Approach

End-to-end approach

1. Move new vaccines through late preclinical studies to proof of concept and safety in humans, and
2. Develop platforms that can be rapidly deployed against known and unknown pathogens.

Strategic objectives

1

Preparedness

2

Response speed

3

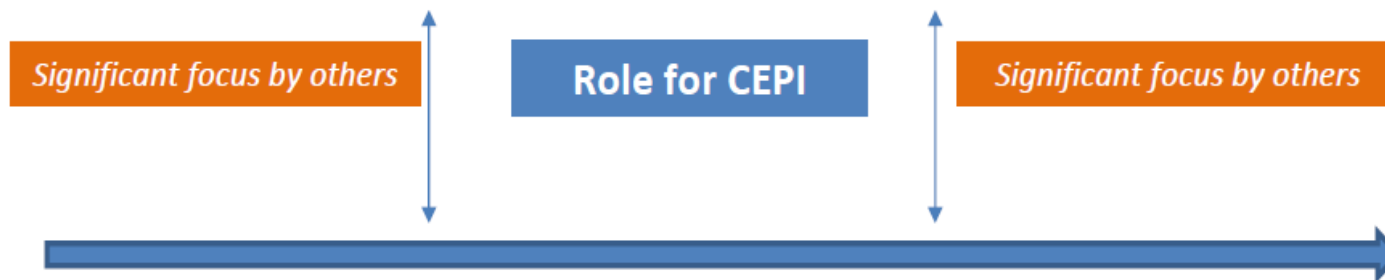
Predictability

4

Equity

CEPI fit along the end-to-end spectrum

CEPI Scope and Fit with other Initiatives

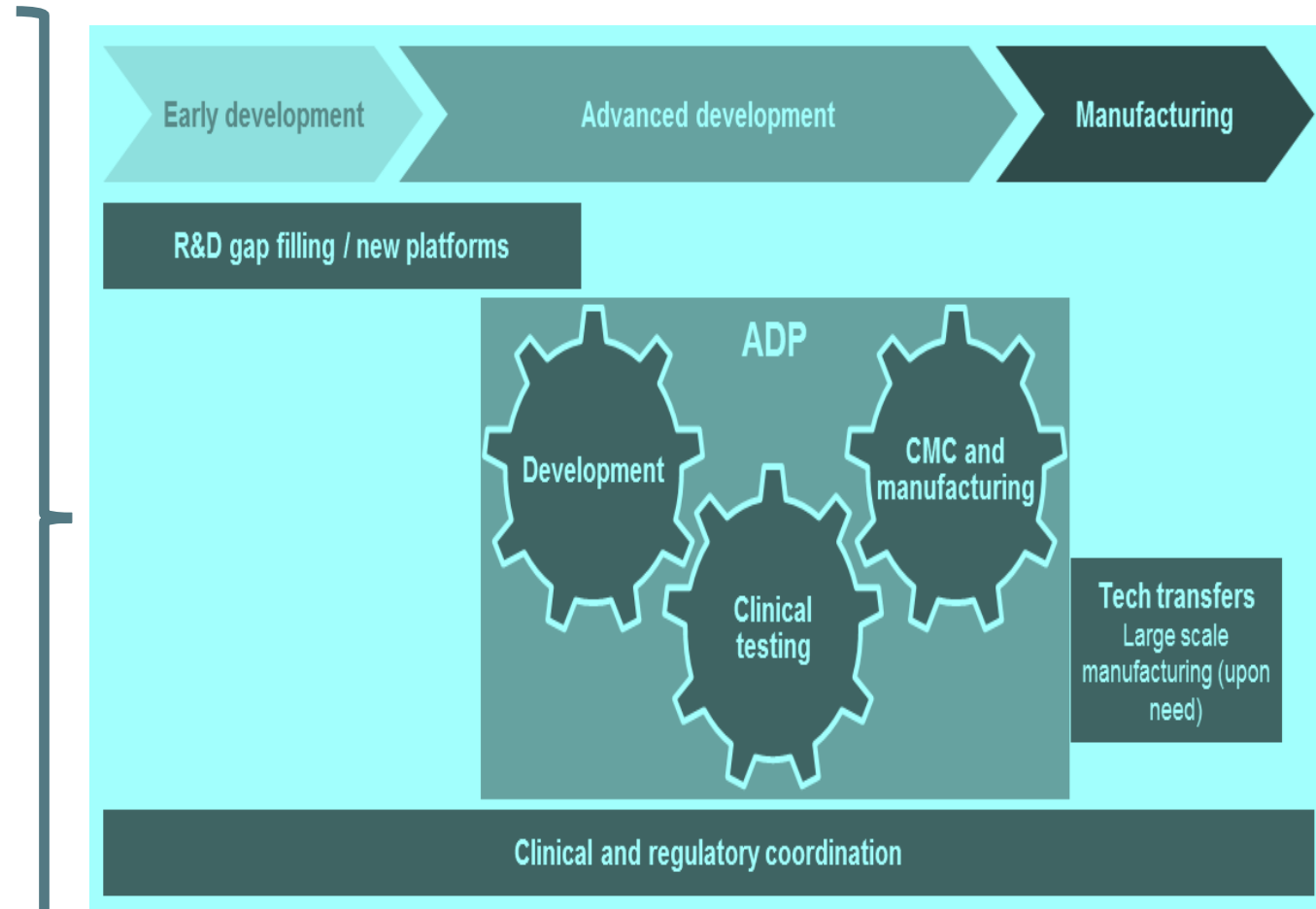


Phase	1 Discovery	2 Development/ Licensure	3 Manufacturing	4 Delivery/ Stockpiling
Current Stakeholders	<ul style="list-style-type: none"> • Academia • Governments • WT/NIH • GLOPID-R • Industry • Regulators • Biotech 	<ul style="list-style-type: none"> • Industry • National Governments • Regulators • Gates • BARDA/DTRA etc. • WHO • Biotech • PDPs 	<ul style="list-style-type: none"> • Industry • BARDA • CMOs • Regulators • National Governments • WHO 	<ul style="list-style-type: none"> • GAVI • UNICEF • PAHO • National Governments • WHO • Industry • Pandemic Emergency Facility (World Bank)

The CEPI partnership model

CEPI is building capabilities through a mix of partnership models:

1. Advanced Development Partnership (ADP)
2. Targeted investments for filling additional R&D gaps
3. Clinical and regulatory coordination network
4. Complementary coordination initiatives



CEPI's operating principles

1

Equitable access

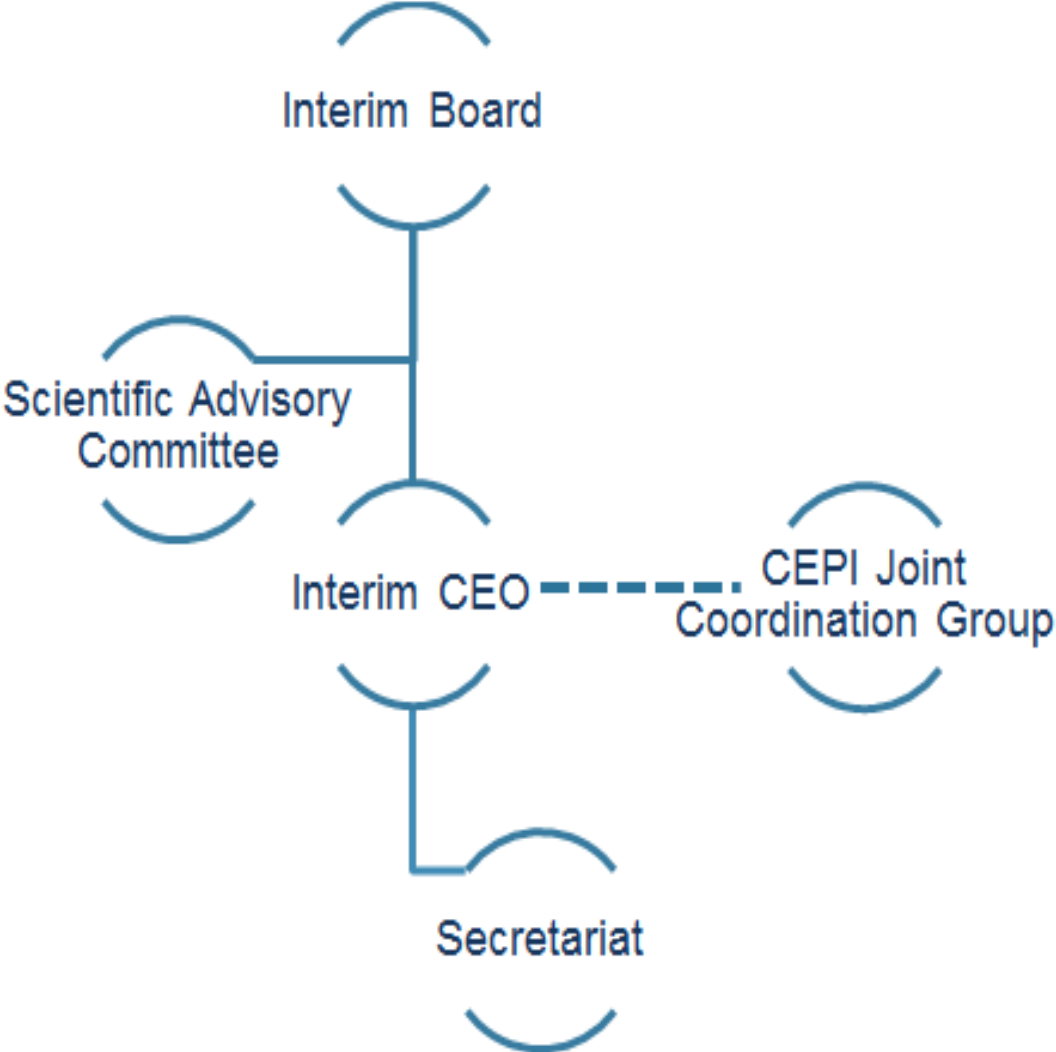
2

Cost coverage

3

Shared benefits

Organizational setup: startup phase



CEPI Interim Board

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Ministry of Science and
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Arnaud Bernaert

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DG RTD,
European Commission

Yah Zolia

Deputy Minister of Health and
Social Welfare
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David Wood
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Chinese Center for Disease Control
and Prevention

Gunnstein Norheim
Norwegian Institute of Public Health

Heinrich Feldman
NIH National Institute of Allergy and
Infectious Diseases

Helen Rees
Wits Reproductive Health and HIV
Institute

Jesse Goodman
Georgetown University

Kathleen Neuzil
University of Maryland

James Robinson
James Robinson Biologics
Consulting

Maharaj Kishan Bhan
JIPMER

Peter Smith
London School of Hygiene and
Tropical Medicine

Rick Bright
Biomedical Advanced Research
and Development Authority
(BARDA)

Stanley Plotkin
VaxConsult

Subhash Kapre
Inventprise

CEPI financing needs

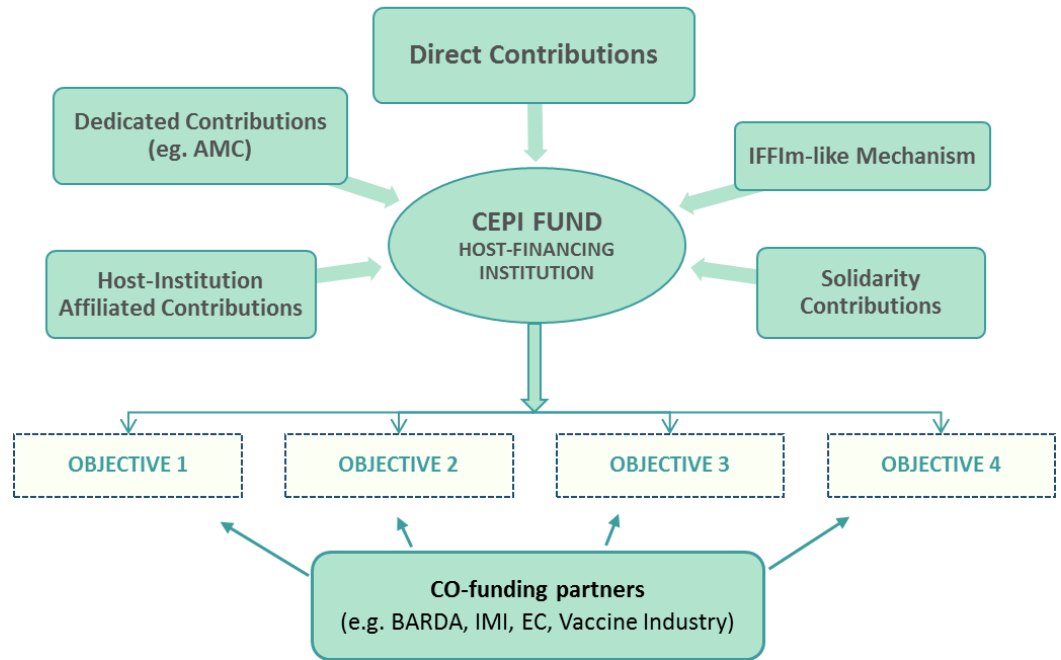
CEPI raising USD 1 billion to support a five year portfolio strategy of two to three prioritized pathogens and two to three phase IIa vaccine candidate targets per prioritized pathogen by the end of this period.

Financing Model

CEPI seeks multi-year donor commitments to satisfy its core financing needs, as well as targets through a multi-source financing model.

Four key financing principles

1. Broad-based financing
2. Long term, predictable financing
3. Complementary and new financing
4. Fit-for purpose financing



Next steps

Sept → Oct → Nov → Dec → Jan 2017

Start Up Phase

Formalize Commitments

Launch Partnership



Scientific Advisory Committee Meeting, 20 and 21 October



Joint Coordination Group Meeting, 18 November 2016



Secure initial commitments of CEPI participation and contribution

2nd Interim Board Meeting in India 16 December 2016



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