

CEPI

# Coalition for Epidemic Preparedness Innovations

*New vaccines for a safer world*

*Frederik Kristensen*

*DCVMN Annual Meeting*

*25 October 2016*

## FOUNDING PARTNERS



Norwegian Ministry  
of Foreign Affairs



DEPARTMENT OF BIOTECHNOLOGY  
Ministry of Science & Technology



BILL & MELINDA  
GATES foundation

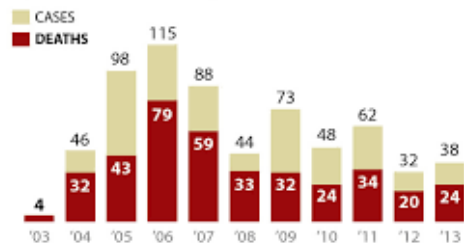


# The challenge of epidemics



## 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

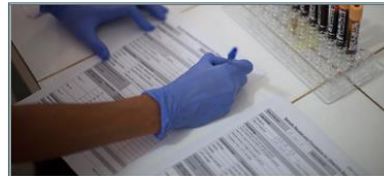
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## Protecting Humanity from Future Health Crises

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.

## THE LANCET

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< Previous Article Volume 386, No. 10009, p2204-2221, 28 November 2015 Next Article >

### 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 Sue-ri Moon, PhD, DPhil, Sophie Delaunay, MSc, Prof Eric Goosby, MD, Prof Leung, MD, J Stephen Morris, 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

## The NEW ENGLAND JOURNAL of MEDICINE

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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

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

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# CEPI - January - June



**High Level  
Meeting  
Davos  
21 January**



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



**Task Team  
Tele-  
conferences**



**Leadership  
Group Meeting  
Washington DC  
17 May**



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

# CEPI - July - September



**Core Group and Leadership Group Teleconferences**



**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

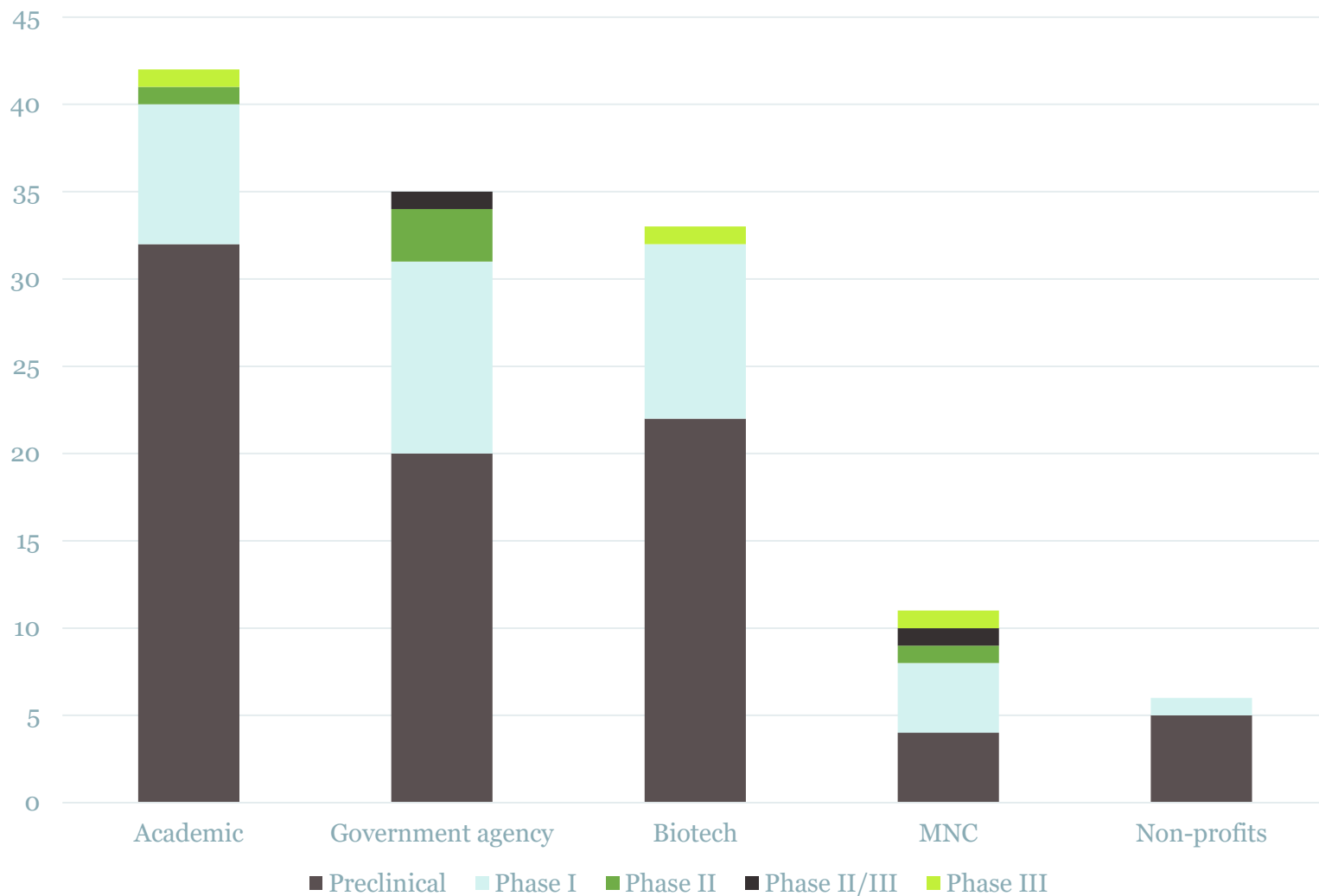
Clinical & regulatory pathways are not easily adaptable to epidemic contexts

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 a feasible strategy, 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, vaccine manufacturers, and non-profits

4

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



# CEPI's Approach

## Vision

Vaccines can **prevent outbreaks from becoming health, economic and humanitarian** crises.

## Mission

**Prioritize, stimulate, finance and coordinate** vaccine development against EIDs with epidemic potential, especially in cases where market incentives alone do not achieve this.

## Scope

End-to-end approach to vaccine development

- 1. Advance EID 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 2017-'21

1

Improved Preparedness

2

Accelerated Response

3

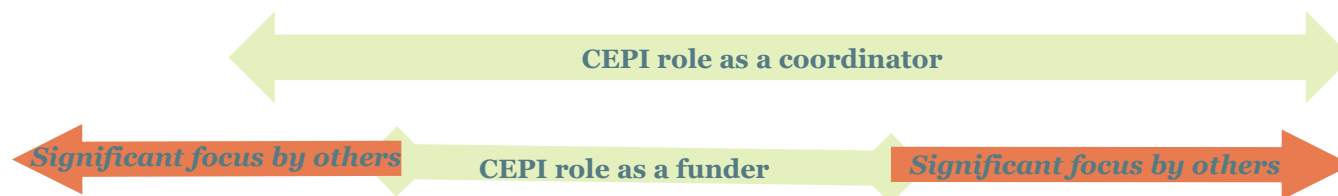
Market predictability

4

Equity

# CEPI's Roles

## Funder and Coordinator



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

# CEPI's operating principles

1

Equitable access

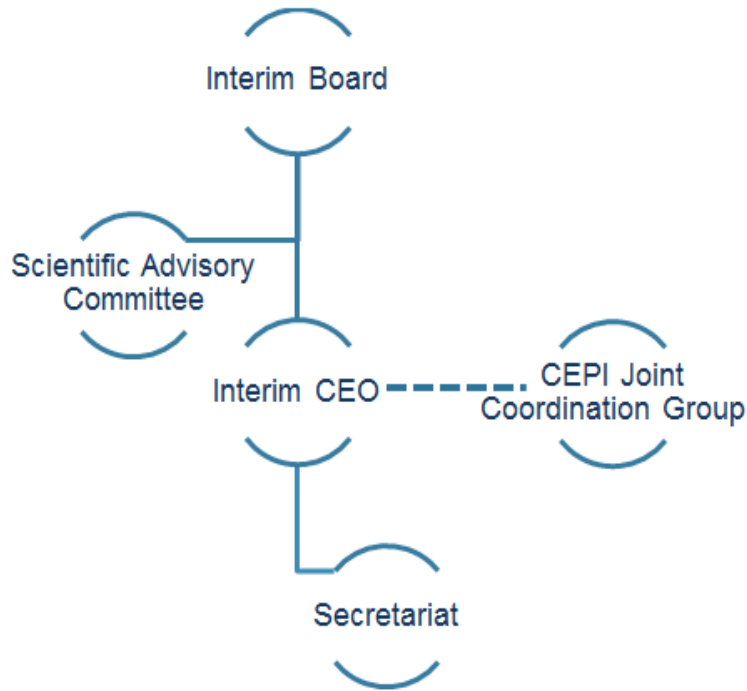
2

Cost coverage

3

Shared risks and  
benefits

# Organizational Setup: Startup Phase



- Founding Partners are the Gates Foundation, Wellcome Trust, Department of Biotechnology of India, Government of Norway, and World Economic Forum
- Independent legal entity; an international non-profit association under Norwegian law
- Interim Secretariat is hosted by the Norwegian Institute of Public Health under a service agreement
- Flexible arrangement, can transition into other institutional and governance arrangements
- The permanent organizational structure and governance will be made by the CEPI Interim Board prior to launch
- SAC advises on scientific matters and JCG coordinates CEPI's activities with other stakeholders

# CEPI Interim Board

**K. Vijay Raghavan, *chair***

Secretary, Department of  
Biotechnology  
Ministry of Science and  
Technology, India

**Peter Piot, *vice chair***

Director of the LSHTM

**Jane Halton**

Permanent Secretary  
Department of Finance, Australia

**Tore Godal**

Special Adviser on Global Health  
MFA, Norway

**Christopher Whitty**

Chief Scientific Adviser  
Department of Health, UK

**Kesetebirhan Admasu**

Minister of Health, Ethiopia

**Jeremy Farrar**

Director, Wellcome Trust

**Trevor Mundel**

President Global Health  
Division  
The Bill & Melinda Gates  
Foundation

**Adar Poonawalla**

CEO and Executive Director  
Serum Institute of India

**Nima Farzan**

President and CEO  
PAXVAX INC.

**Julie Gerberding**

Executive Vice President  
Merck

**Moncef Slaoui**

Chairman of vaccines  
GSK

**Joanne Liu**

International President  
Medecins sans Frontieres

**Victor Dzau**

President of the Institute of  
Medicine  
National Academy of  
Sciences

**Arnaud Bernaert**

Head of Global Health and  
Healthcare Industries  
World Economic Forum

**Ruxandra Draghia-Akli**

Deputy director-general of  
DG RTD, EC

**Eduardo de Azeredo**

**Costa**, Technical Advisor,  
Center for International  
Affairs in Health, Fiocruz

**Yah Zolia**

Deputy Minister of Health and  
Social Welfare, Liberia

**Observers****Marie-Paule Kieny**

Assistant Director-General  
World Health Organization

**Mark Feinberg (Chair of SAC)**

President & Chief Executive  
Officer, IAVI

**Peggy Hamburg (Chair of JCG)**

Foreign Secretary of the Institute  
of Medicine  
National Academy of Sciences

**John-Arne Røttingen**

Interim CEPI CEO

**Nicole Lurie**

Assistant Secretary,  
Department of HHS, US (serving  
in a liaison position)

# CEPI interim SAC

**Mark Feinberg (Chair)**  
International AIDS Vaccine Initiative

**Alan D. Barrett**  
University of Texas Medical Branch

**Amadou Sall**  
Institute Pasteur Dakar

**Bernard Fanget**  
Abivax, Neovacs

**Chery Gagandeep Kang**  
Christian Medical College Vellore

**Connie Schmaljohn**  
University of Maryland

**Daniel Brasseur**  
European Commission

**David Kaslow**  
PATH/CIVA

**David Wood**  
World Health Organization

**George Fu Gao**  
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)

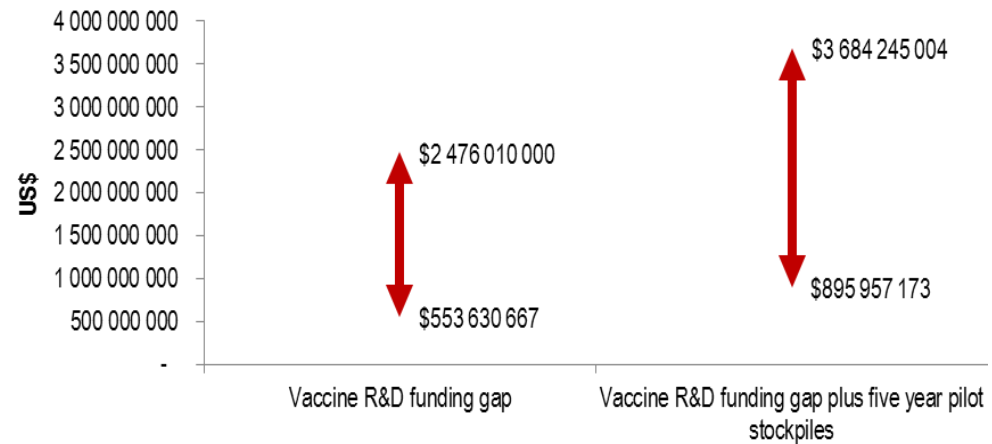
**Stanley Plotkin**  
VaxConsult

**Subhash Kapre**  
Inventprise



# CEPI's Funding Needs

Preliminary cost-modeling estimates\*  
5-year costs for advancement of **10 WHO Blueprint EID vaccine candidates** to the end of clinical phase IIa development at between **US\$600M and US\$3.7B**, depending on the complexity of the technology used, pilot manufacturing requirements and other manufacturing cost variants, and stockpiling needs.



CEPI is seeking multi-year donor contributions to an **initial investment pool of US\$1B** (2017-21) to advance **late-stage development of 4 to 6 vaccine candidates** against 2 to 3 priority EIDs to the end of clinical phase II development, and save countless lives and billions of dollars.

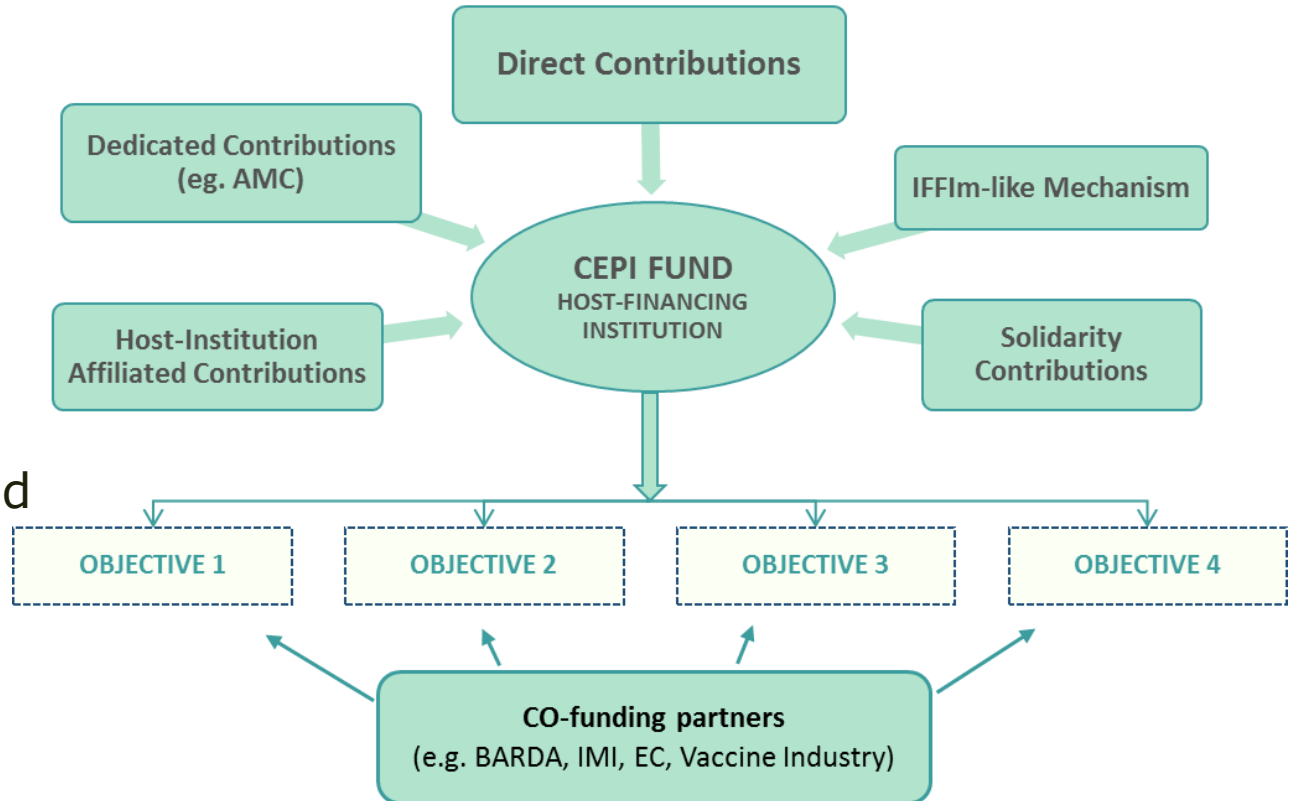
\* Details on cost estimates and assumptions are available upon request.

# CEPI Financing Model

CEPI will use a multi-source financing model to satisfy its core resource needs.

## Four financing principles

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



# Next Steps

Sept → Oct → Nov → Dec → Jan 2017

Start Up Phase

Formalize Commitments

Launch Partnership



**Scientific Advisory Committee Meeting,**  
20 and 21 October  
(NY)



**Joint Coordination Group Meeting,**  
18 November 2016  
(GENEVA)



**Secure initial funding and other partnership commitments**

**2<sup>nd</sup> Interim Board Meeting**  
16 December 2016  
(DELHI)



Announce CEPI initial investment priorities and partner commitments at formal CEPI launch at annual **World Economic Forum** meeting  
January 2017  
(DAVOS)