Coalition for Epidemic Preparedness Innovations

New vaccines for a safer world

Frederik Kristensen

DCVMN Annual Meeting

25 October 2016
The challenge of epidemics
Calls for global action
CEPI - January - June

- High Level Meeting Davos 21 January
- Task Team Meeting, Oslo 6-7 April
- Task Team Teleconferences
- 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

Academic
Government agency
Biotech
MNC
Non-profits

Preclinical  Phase I  Phase II  Phase II/III  Phase III
The Ebola momentum: vaccines are a feasible strategy, despite a risky development pathway.

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

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

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

<table>
<thead>
<tr>
<th>Vision</th>
<th>Vaccines can <strong>prevent outbreaks from becoming health, economic and humanitarian crises.</strong></th>
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<tbody>
<tr>
<td>Mission</td>
<td><strong>Prioritize, stimulate, finance and coordinate</strong> vaccine development against EIDs with epidemic potential, especially in cases where market incentives alone do not achieve this.</td>
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| 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

<table>
<thead>
<tr>
<th>Phase</th>
<th>1 Discovery</th>
<th>2 Development/Licensure</th>
<th>3 Manufacturing</th>
<th>4 Delivery/Stockpiling</th>
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<tbody>
<tr>
<td>Current Stakeholders</td>
<td>Academia</td>
<td>Industry</td>
<td>Industry</td>
<td>GAVI</td>
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<td></td>
<td>Governments</td>
<td>National Governments</td>
<td>BARDA</td>
<td>UNICEF</td>
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<td>WT/NIH</td>
<td>Regulators</td>
<td>CMOs</td>
<td>PAHO</td>
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<td>GLOPID-R</td>
<td>Bill and Melinda Gates Foundation</td>
<td>Regulators</td>
<td>National Governments</td>
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<td></td>
<td>Industry</td>
<td>BARDA/DTRA etc.</td>
<td>National</td>
<td>WHO</td>
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<td></td>
<td>Biotech</td>
<td>WHO</td>
<td>Governments</td>
<td>Industry</td>
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<tr>
<td></td>
<td>PDPs</td>
<td>Biotech</td>
<td>WHO</td>
<td>Pandemic Emergency Facility</td>
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<td>PDPs</td>
<td>GHIF</td>
<td>(World Bank)</td>
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<td>WHO Contingency Fund</td>
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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

**Start Up Phase**

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

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

**Nov**
- Secure **initial funding and other partnership commitments**
  - 2nd Interim Board Meeting, 16 December 2016 (DELHI)

**Dec**
- Launch Partnership

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