CEPI – Coalition for Epidemic Preparedness Innovations

CEPI – a model for funding other initiatives and areas
Testing of an Ebola vaccine – a successful but suboptimal story

Start:
- 1 Jan: Start stability study

9 months:
- 9 months
- 90 rings

6 months:
- 6 months

WHO level meeting:
- Guinea working group formed

WHO high level meeting:

Extension to Sierra Leone:
- 1 Sept

Guinea working group formed:

WHO level meeting:

WHO Consultation on Ebola Vaccines:
- 29-30 Sept

Protocols / Financing:
- Dec-Jan

Vaccine choice:
- 5 Feb

Vaccination initiated:
- 23 Mar

WHO Ethics Report:
- 11 Aug

Ring design decided:
- 5 Nov

Last randomized ring vaccinated:
- 7 Aug

Interim analysis:
- 20 Jul

Preliminary results:
- 31 Jul

Interim analysis:
- 20 Jul
The start: A need for global solutions
In addition: EC plans to co-fund with up to €250 mill
What is CEPI?

• CEPI is a partnership of public, private, philanthropic and civil society organisations

• CEPI will *stimulate, finance and coordinate* vaccine development
  • against priority threats,
  • particularly when development is unlikely to occur through market incentives alone.
Strategic objectives

1. Preparedness
2. Response speed
3. Predictability
4. Equity
CEPI’s end-to-end gap-filling role: a sustainable partnership approach

<table>
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<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>Governments</td>
<td>BARDA</td>
<td>UNICEF</td>
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<td>WT/NIH</td>
<td>Regulators</td>
<td>CMOs</td>
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<td>GLOPID-R</td>
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<td>Industry</td>
<td>Bill and Melinda Gates Foundation</td>
<td>WHO</td>
<td>Industry</td>
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<td>Regulators</td>
<td>BARDA/DTRA etc.</td>
<td>GHIF</td>
<td>Pandemic Emergency Facility</td>
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<td>Biotech</td>
<td>WHO</td>
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<td>(World Bank)</td>
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<td>Biotech</td>
<td>Biotech</td>
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<td>WHO Contingency Fund</td>
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CEPI’s operating principles conceptualized in Business Plan

• Adhering to equitable access principles of affordable pricing and availability of vaccines by priority populations in emergencies

• Securing industry participation through predictable pathways and risk/benefit sharing arrangements and handling of liability through indemnification

• Supporting data sharing and sample sharing mechanisms, and long-term development of regional capabilities for epidemic vaccine preparedness
How will CEPI work?

• CEPI will move vaccine candidates through late preclinical studies to proof of concept and safety in humans before epidemics begin
  • larger effectiveness trials can begin swiftly in an outbreak
  • small stockpiles are ready for potential emergency use

• CEPI will build technical platforms and institutional capacities that can be rapidly deployed against new and unknown pathogens
CEPI’s Initial Target Diseases

- MERS
- Lassa
- Nipah

Starting point: WHO’s list of priority pathogens defined by the WHO R&D Blueprint

CEPI’s SAC chose three initial diseases based expected
- public health impact
- risk of an outbreak occurring
- feasibility of vaccine development
CEPI’s Calls for Proposals for Vaccine Development

1. MERS, Lassa-fever and Nipah virus
   Step 1: Deadline 8 March 2017
   Step 2: July 2017

2. Vaccine platform technology
   Deadline 17 October 2017

3. Ebola
   Pending dialogue with scientific groups to define specific need
   Autumn 2017
## Regulatory scientific challenges – Working Group

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<th>Basic Research</th>
<th>Preclinical development</th>
<th>Clinical / Non-clinical development (Phase I and II)</th>
<th>Stockpiling Investigational vaccine</th>
<th>EUA/EUAL</th>
<th>Phase III</th>
<th>Readiness / Stockpiling</th>
<th>Emergency Use</th>
<th>Distribution &amp; Administration</th>
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### Quality, efficacy and safety

- Data requirements and regulatory vehicles in the absence of an outbreak
- The regulatory issues around stockpiling
- Regulatory and ethical issues surrounding the use of stockpiled product during outbreaks

### CEPI

- Clarify current gaps in scientific knowledge that makes it challenging to use non-traditional regulatory pathways for the approval of CEPI and Ebola vaccines in the absence of clinical efficacy data.
- Need a process to allow regulators and vaccine developers discuss what could be attempted to overcome these issues.
G20 - calling for an international collaboration hub for AMR R&D

• The Global Antimicrobial Resistance (AMR) Collaboration Hub
  - co-ordinate efforts to invigorate antimicrobial research
  - encourage global involvement and investment

• The scope of work
  - all stages of the antimicrobial development pipeline
  - vaccines, alternative therapies and new diagnostic tools
Suggested international AMR policy actions

- Strengthening surveillance and monitoring systems in the community and hospitals
- Fostering research and development of new antimicrobial therapies, including improved biosecurity measures in agriculture
- Need for both “push” and “pull” mechanisms
- Access and sustainable use are integral
- Global collaboration and financing necessary
- Enhancing coordination between countries to develop a true global action plan to tackle AMR
- Adopt a broader ‘one-health’ approach covering human health, agriculture and the environment
Significant “push” progress – R&D development

Basic Science
- JPIAMR
- IMI/ND4BB
- Wellcome Trust
- National Science Research Agencies
  - CARB-X
  - GARD-P
- UK/China Global Innovation Fund

Preclinical
- BARDA
- NIH/NIAID

Phase I
- NIH/NIAID

Phase II
- Wellcome Trust
- National Science Research Agencies
- GARD-P

Phase III
- EIB’s InnovFin

Market
- Existed prior to 2016
- Recently launched
“Pull” is missing – to obtain a sustainable market

Basic Science

Preclinical

Phase I

Phase II

Phase III

Market

JPIAMR

IMI/ND4BB

BARDA

NIH/NIAID

Wellcome Trust

National Science Research Agencies

CARB-X

GARD-P

EIB’s InnovFin

UK/China Global Innovation Fund

Existed prior to 2016

Recently launched

Norwegian Institute of Public Health
Neglected Tropical Diseases

- Historically overlooked diseases
- Neglected at the community, national, and international levels
- Endemic in many resource-poor populations and developing countries
- WHO has specifically identified 20 core NTDs
- Poverty in particular is a key social determinant of uncontrolled NTD spread
- Regulatory scientific challenges
- Clinical trial capacity in endemic setting
DNDi - non-profit drug research and development (R&D) organization

Develop treatments for people suffering from neglected diseases

Strengthen research capacity
DNDi enables R&D networks while harnessing existing support capacities in low- and middle-income
«CEPI is an extremely important contribution to global health.»

German Chancellor Angela Merkel
“THANK YOU SCIENCE!”