Covid-19 VACCINE DEVELOPMENT PLATFORMS

ADVAC ALUMNI MEETING

02 APRIL, 2020
Our mission

CEPI accelerates development of vaccines against emerging infectious diseases and enables equitable access to these vaccines for affected populations during outbreaks.
Our Strategic Objectives

**Preparedness**
Advance access to safe and effective vaccines against emerging infectious diseases

**Response**
Accelerate the research, development and use of vaccines during outbreaks

**Sustainability**
Create durable and equitable solutions for outbreak response capacity
A sustainable partnership

CEPI role as a facilitator

CEPI role as a funder

1. DISCOVERY
   - Academia
   - Governments
   - Wellcome Trust
   - NIH
   - IMI
   - GLOPID-R
   - Industry
   - Regulators
   - Biotech

2. DEVELOPMENT / LICENSURE
   - Industry
   - Governments
   - Regulators
   - Wellcome Trust
   - NIH
   - EC
   - IMI
   - BMGF
   - BARDA/DTRA etc.
   - WHO
   - Biotech
   - PDPs

3. MANUFACTURE
   - Industry
   - BARDA
   - CMOs
   - Regulators
   - Governments
   - WHO
   - GHIF

4. DELIVERY / STOCKPILING
   - GAVI
   - UNICEF
   - PAHO
   - Governments
   - WHO
   - Industry
   - Pandemic Emergency Facility (World Bank)
   - WHO Contingency Fund

5. LAST MILE
   - Countries
   - WHO
   - UNICEF
   - Responding Organisations (eg, MSF)
CEPI’s strategic portfolio targets

- **Lassa**
- **MERS-CoV**
- **Nipah**
- **Rift Valley Fever**
- **Chikungunya**
- **Disease X**

**Lassa, MERS-CoV, Nipah, Rift Valley Fever, Chikungunya:**
- Advance at least one vaccine for each pathogen through phase IIA and stockpile within five years of funding.
- Support activities enabling late stage development, prequalification and access.

**Disease X:**
- Advance through phase I multiple rapid response platforms with potential to significantly improve speed of vaccine development against multiple pathogens.
CEPI’s enabling sciences portfolio support advancement of vaccine candidates

<table>
<thead>
<tr>
<th>Cross-cutting activities</th>
<th>Task Forces</th>
<th>Landscape analyses</th>
<th>Regulatory workshops</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antigen</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pathogen</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Lines show timelines for ongoing (filled line) and planned (dotted line) projects; diamond show deliverable deadlines

* Funding not yet allocated
CEPI will accelerate development by use of vaccine technology platforms

**Aspirational goals**
- 16 weeks from identification of pathogen to product for clinical trial
- 6 weeks from first dose to clinical benefit
- 8 weeks to manufacture 100,000 doses

**CEPI funding approach**
- Test platform versatility on three pathogens, two into phase I
- Characterize the safety and immunology profile
- Live fire exercise – for disease X

**Platforms**
- mRNA - Curevac
- SA RNA - Imperial
- Recombinant proteins – molecular clamp
Disease X: COVID-19

As of 01 April:
CONFIRMED CASES: > 750,000
DEATHS: >36,000

The rapid global spread and unique epidemiological characteristics of the novel coronavirus disease, COVID-19, is deeply concerning.

CEPI has moved with great urgency and in coordination with WHO, who is leading the development of a coordinated international response.

We have initiated several programmes which will leverage our work on MERS and innovative new technologies to speed up vaccine development against COVID-19.
CEPI’s response to COVID-19

speed, scalability and access

- Rapid response platforms
- More proven vaccine technology already at scale
- Adjuvants
- Enabling sciences
- Global manufacturing capacity
## Current CEPI COVID-19 portfolio

<table>
<thead>
<tr>
<th></th>
<th>Technology platform</th>
<th>Antigen</th>
<th>Partner type</th>
<th>Geo allocation</th>
<th>Manufacturing scalability (High/medium/low)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inovio</td>
<td>DNA</td>
<td>Spike</td>
<td>Biotech</td>
<td>US</td>
<td>Medium/Low</td>
</tr>
<tr>
<td>Moderna</td>
<td>mRNA</td>
<td>Spike</td>
<td>Biotech</td>
<td>US</td>
<td>High</td>
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<tr>
<td>CureVac</td>
<td>RNA</td>
<td>Spike</td>
<td>Biotech</td>
<td>EU</td>
<td>Proprietary</td>
</tr>
<tr>
<td>Queensland</td>
<td>Subunit</td>
<td>Spike</td>
<td>Academic</td>
<td>Australia</td>
<td>High</td>
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<tr>
<td>Novavax</td>
<td>VLP</td>
<td>Spike</td>
<td>Biotech</td>
<td>USA</td>
<td>High</td>
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<tr>
<td>University of Oxford</td>
<td>ChadOX</td>
<td>Spike</td>
<td>Academic</td>
<td>UK</td>
<td>Low</td>
</tr>
<tr>
<td>University of HongKong</td>
<td>Viral vector</td>
<td>Spike RBD</td>
<td>Academic</td>
<td>Hong Kong</td>
<td>High</td>
</tr>
<tr>
<td>IP Themis</td>
<td>Viral vector</td>
<td>Spike</td>
<td>Academic/Industry</td>
<td>France/Germany/India</td>
<td>High</td>
</tr>
</tbody>
</table>

Moderna already in first in human clinical trial – in just 63 days
### Platform attributes

<table>
<thead>
<tr>
<th>Vaccine Platform Type</th>
<th>Attributes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Single dose</td>
</tr>
<tr>
<td>Inactivated</td>
<td>No</td>
</tr>
<tr>
<td>Recombinant protein</td>
<td>No</td>
</tr>
<tr>
<td>Live attenuated</td>
<td>Yes</td>
</tr>
<tr>
<td>DNA</td>
<td>No</td>
</tr>
<tr>
<td>RNA</td>
<td>No</td>
</tr>
<tr>
<td>Vector based</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Only a fundamental paradigm shift provides potential of rapid vaccine development with appropriate safety standards.

**Major shifts**

- **Speed:** Accelerate and advance development stages in parallel with continuous risk-benefit monitoring; quickly raise and deploy funds.
- **Scale:** Adaptive versus rigid development process and earlier launch of scale-up.
- **Access:** Geographic spread of manufacturing and development sites and pursuit of emergency authorization before licensure.

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**Traditional paradigm**

- **6 - 11.5 years**
  - **Target ID, development partner selection, and pre-clinical**
    - 6 - 24 months
  - **Phase I**
    - 12 months
  - **Phase IIa**
    - 12 - 18 months
  - **Phase IIb**
    - 18 - 36 months
  - **Phase III**
    - 18 - 36 months
  - **Licensure**
    - 12 - 36 months

**Outbreak paradigm**

- **12 - 18 months**
  - **Target ID, development partner selection, and pre-clinical**
    - 4 - 8 months
  - **Clinical development**
    - **Early stage**
      - 3 - 4 months
      - **First in human**
    - **Late stage**
      - 6 - 8 months
      - **Scale from n=10s to n=100s**
      - **Emergency authorization**
  - **Go/no-go decision to invest in candidates**