



# Accelerating Vaccine Development for Epidemic Preparedness: New Vaccines for a Safer World

Richard Hatchett, MD  
CEO, CEPI



Norwegian Ministry  
of Foreign Affairs

BILL & MELINDA  
GATES *foundation*

wellcome**trust**



DEPARTMENT OF BIOTECHNOLOGY  
Ministry of Science & Technology



Photo: Daniel Berehulak, The New York Times

# CEPI's Gestation (1)

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February 2016 to June 2016, three expert Task Teams convened:

1. Challenges and potential solutions for **pathogen prioritization, R&D/ CMC capacity** and **regulatory pathways**
2. Relevant **partnership models**
3. Promising **funding strategies**

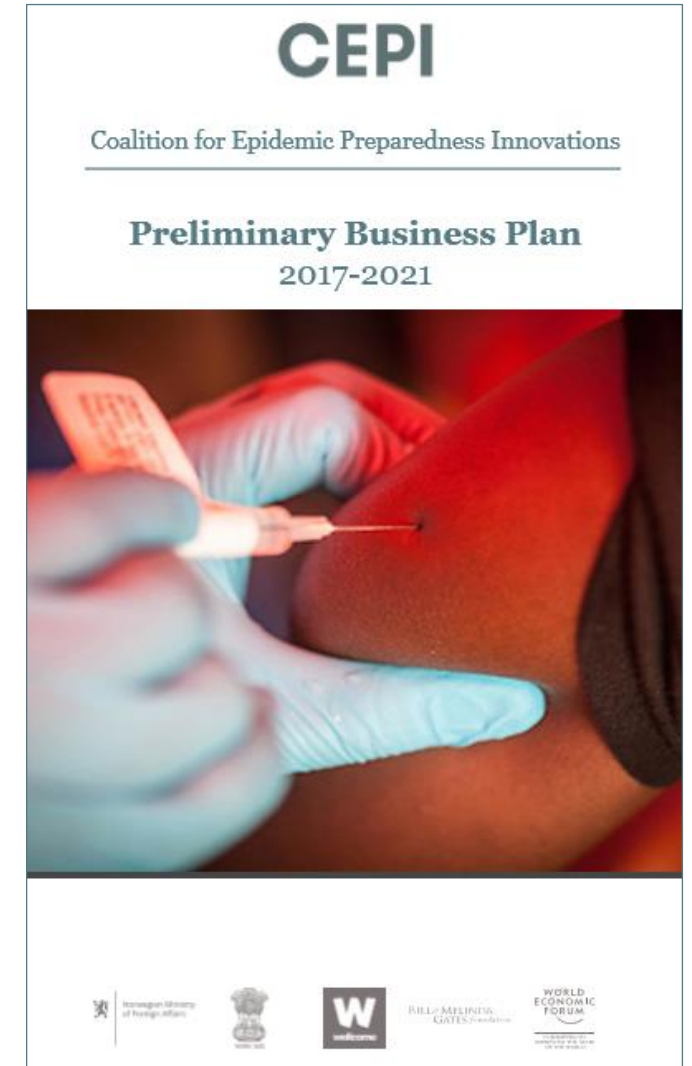
# CEPI's Gestation (2)

Task Teams made select recommendations:

- **Make vaccine R&D investments on advanced development phases** - from late preclinical to proof of concept in humans (phase II trials)
- Support **technical and institutional platforms** that can be used for rapid vaccine development against known and unknown pathogens in the event of a new epidemic
- Develop policies on principles of **equitable access, cost coverage, risk-benefit sharing, and IP management**
- Explore risk sharing arrangements such as **milestone payments**



# CEPI Launched at Davos



# CEPI

## 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 market forces fail to drive needed development
  - By supporting the development of rapid response vaccine development and manufacturing platforms

## How will CEPI work?

- CEPI will move vaccine candidates through late preclinical studies to proof of concept and safety in humans before epidemics begin
  - Effectiveness trials can begin swiftly in an outbreak
  - 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

*New vaccines for a safer world*  
<http://cepi.net/>

# Strategic objectives

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1

## **Preparedness**

Advance late-stage EID vaccine development to enable testing in the initial stages of an outbreak

3

## **Market predictability**

Secure industry participation through partnerships that share the risks and benefits of vaccine development

2

## **Response speed**

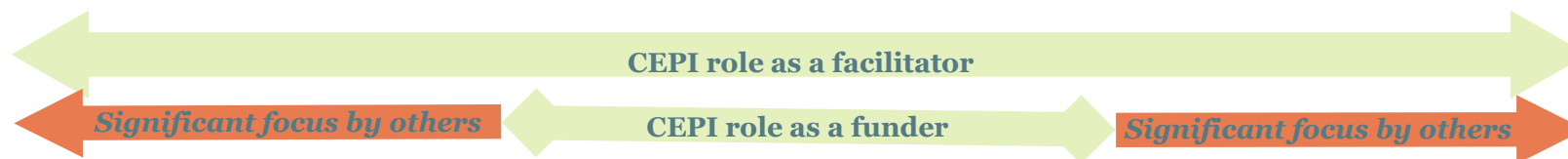
Build technical and institutional platforms to accelerate research, development, manufacturing, and clinical evaluation in an outbreak

4

## **Equity**

Support the long-term development of regional capabilities for EID vaccine preparedness

# CEPI fills a critical gap and depends on long-term partnerships



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>• EC/IMI</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>• Governments</li> <li>• Regulators</li> <li>• WT/NIH</li> <li>• EC/IMI</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>• 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>• Governments</li> <li>• WHO</li> <li>• Industry</li> <li>• Pandemic Emergency Facility (World Bank)</li> <li>• WHO Contingency Fund</li> </ul>



# What we're doing

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**Calls for Proposals**

1: Lassa, Nipah, MERS  
*2: Platform technologies*

**Working groups**

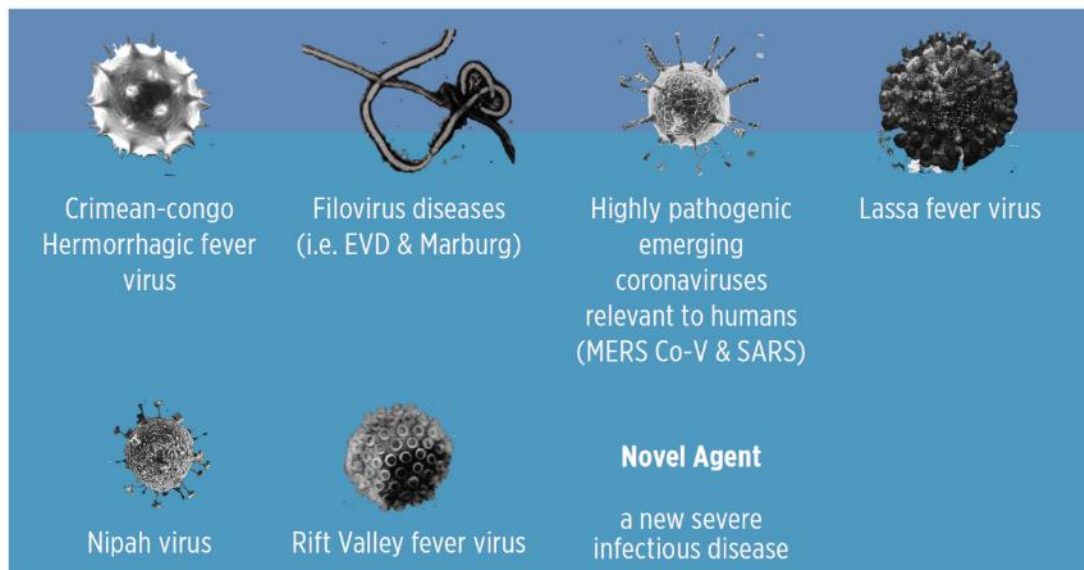
**Partnerships/meetings**

**Resource mobilization**

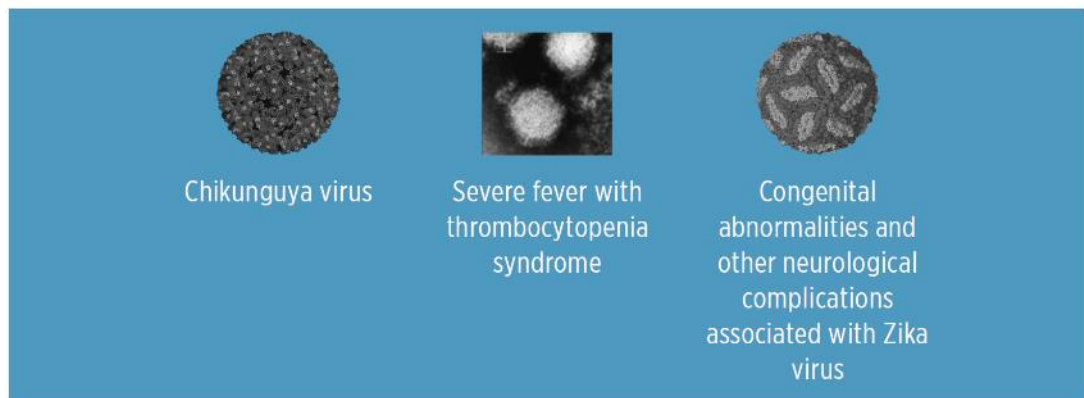
**Setting up the organization**

# WHO priority pathogens and CfP1

DISEASES TO BE URGENTLY ADDRESSED UNDER THE R&D BLUEPRINT, AS OF MAY 2016



SERIOUS DISEASES NECESSITATING FURTHER ACTION AS SOON AS POSSIBLE, AS OF MAY 2016



Pathogens chosen for vaccine development  
by the CEPI SAC, November 2016

Pathogen	No. of votes	Percent of members voting for this pathogen
<b>MERS</b>	20	100%
<b>Lassa</b>	15	75%
<b>Nipah</b>	11	55%
Chikungunya	9	45%
Rift Valley	5	25%
Total votes	60	(3 votes, 20 people)

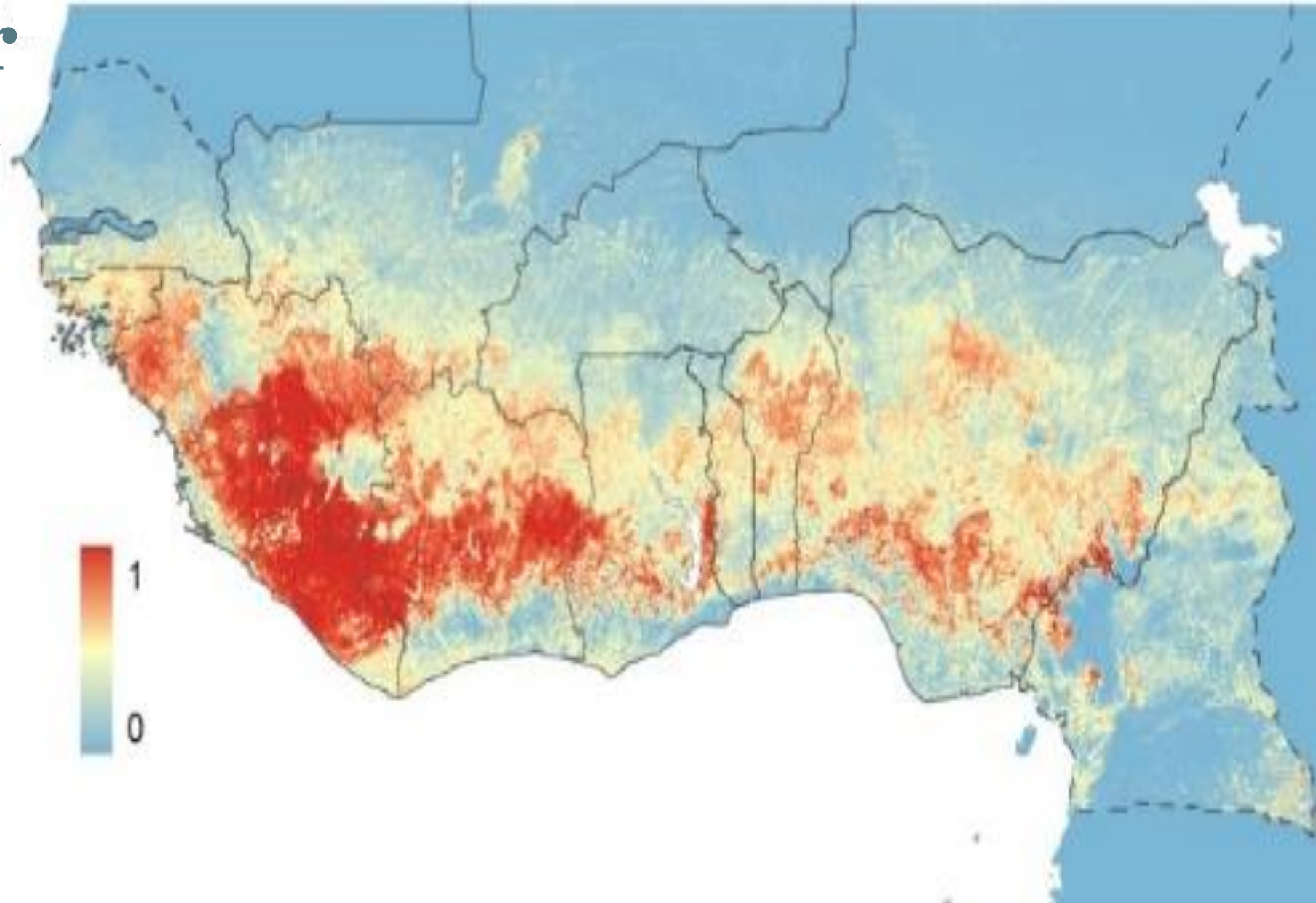
# Lassa fever

## Disease burden

- Endemic, annual outbreaks
- Estimated 300,000 cases/year
- 80% asymptomatic;
- ~30% CFR among symptomatic

## Key countries

- Sierra Leone
- Liberia
- Ivory coast
- Nigeria



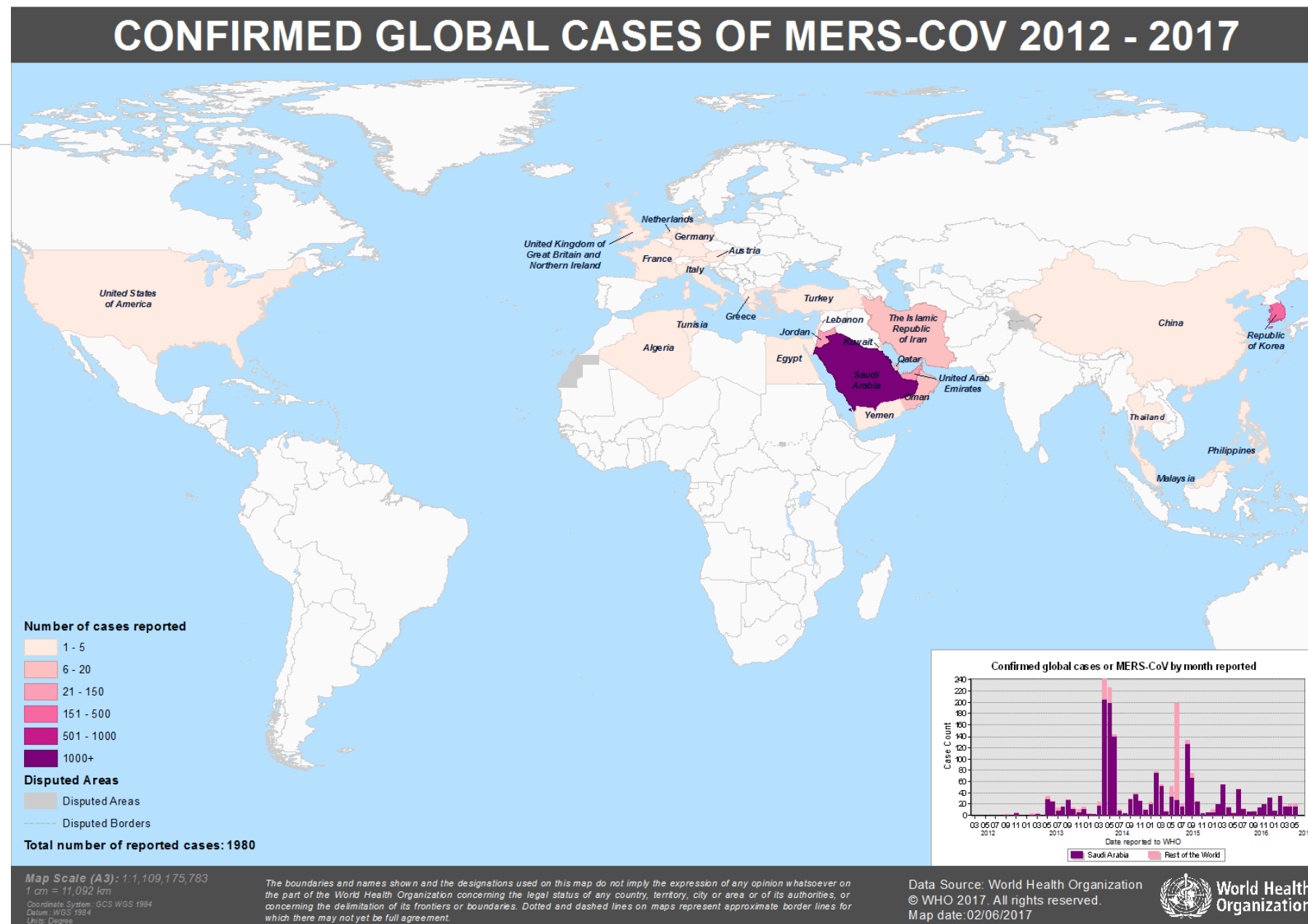
# MERS

## Disease burden

- Total 2 040 cases
- Endemic cases, outbreaks
- Transmission via camels and human-to-human infections in health care
- ~35% CFR among those diagnosed

## Key countries

- Middle East; especially Saudi Arabia (80% cases)
- At risk: Jordan, UAE, Egypt, Somalia, Ethiopia, Sudan





# Nipah

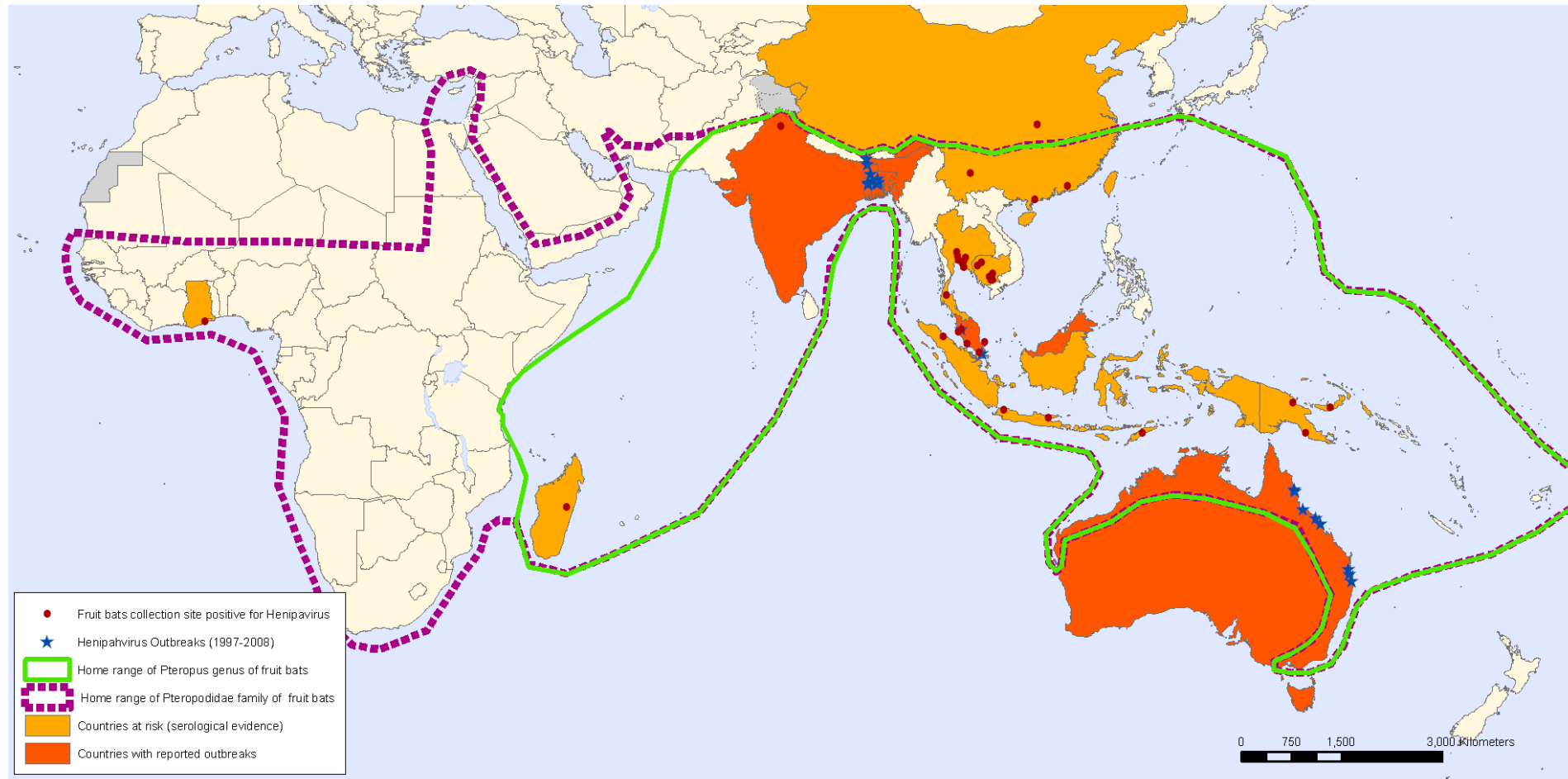
## Disease burden

- Annual outbreaks in Bangladesh/India
- Up to 80% CFR
- Human-human transmission and via intermediate hosts (pigs)

## Key countries

- Bangladesh
- India
- Malaysia

## Geographic distribution of Henipavirus outbreaks and fruit bats of Pteropodidae Family



The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

Data Source: Global Alert and Response Department  
World Health Organization  
Map Production: Public Health Information  
and Geographic Information Systems (GIS)  
World Health Organization



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# Disease specific considerations

## Lassa

### WHO TPP

- Preventive use
- (Reactive use)

### Protective immunity profile needed

- Both humoral and cellular immune responses against G protein contribute to protection against disease
- Cellular immunity is likely critical to provide protection

## MERS-CoV

### WHO TPP

- Preventive use
- Reactive use

### Protective immunity profile needed

- Neutralizing antibodies against Spike protein given prophylactically were protective in animal models.
- Cellular immunity may contribute to protection.

## Nipah

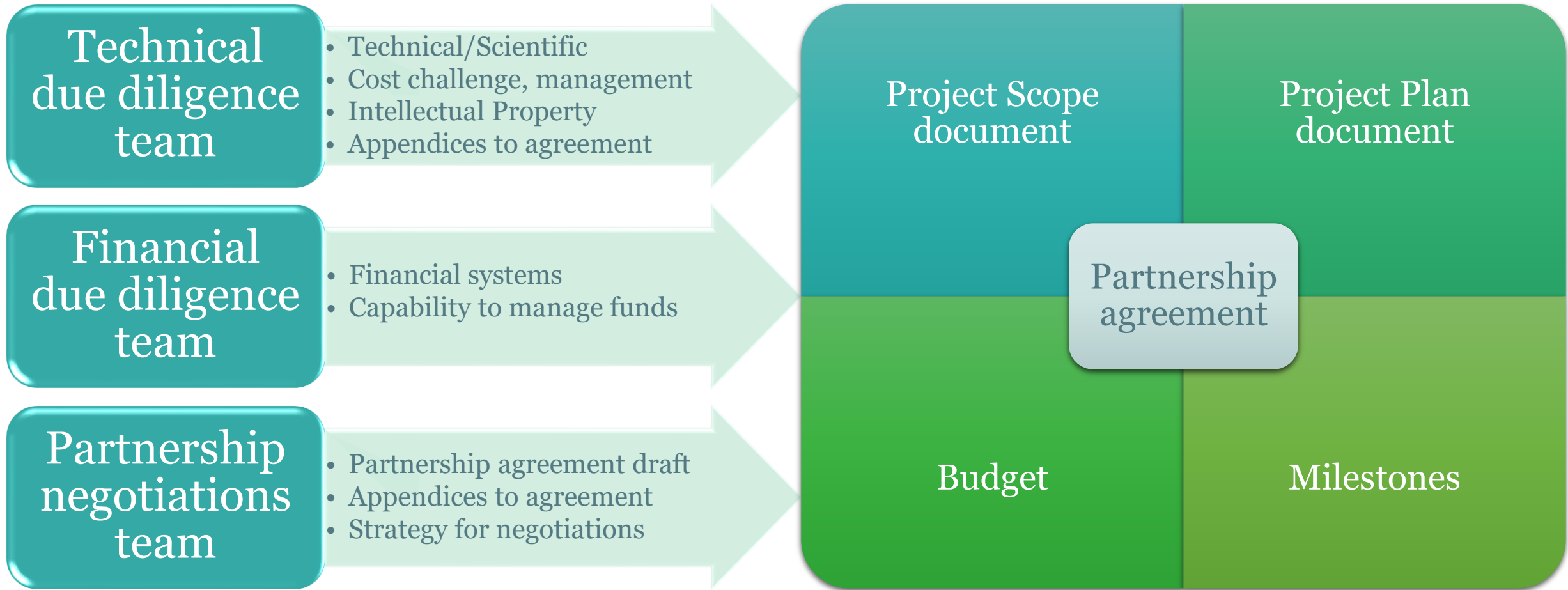
### WHO TPP

- Reactive use

### Protective immunity profile needed

- Neutralizing antibodies against the Nipah G protein correlate with protection

# Next steps following Board approval



Drafting of legal framework ongoing since June 2017  
Partnership agreement draft ready Sept 2017

# CfP-2: “Just in Time” vaccines

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1. Target a 16-week timeframe from identification of antigen to product release for clinical trials
2. Target a 6-week timeframe from administration of first dose to achievement of clinical benefit (i.e. immune response likely to result in clinical benefit)
3. Produce 100,000 vaccine doses within 8 weeks to impact an emerging outbreak (i.e. from Go-decision to scale-up to production, fill, finish, and release)

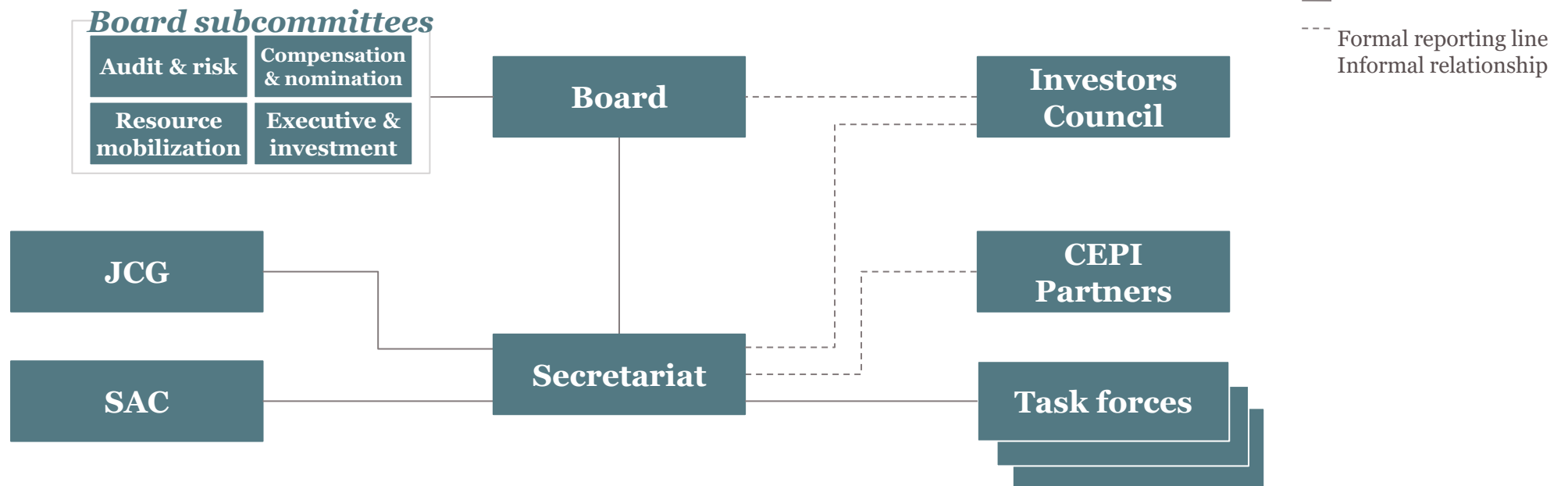
**Deadline for submission of preliminary proposals:  
4 p.m. CEST 17 October 2017**



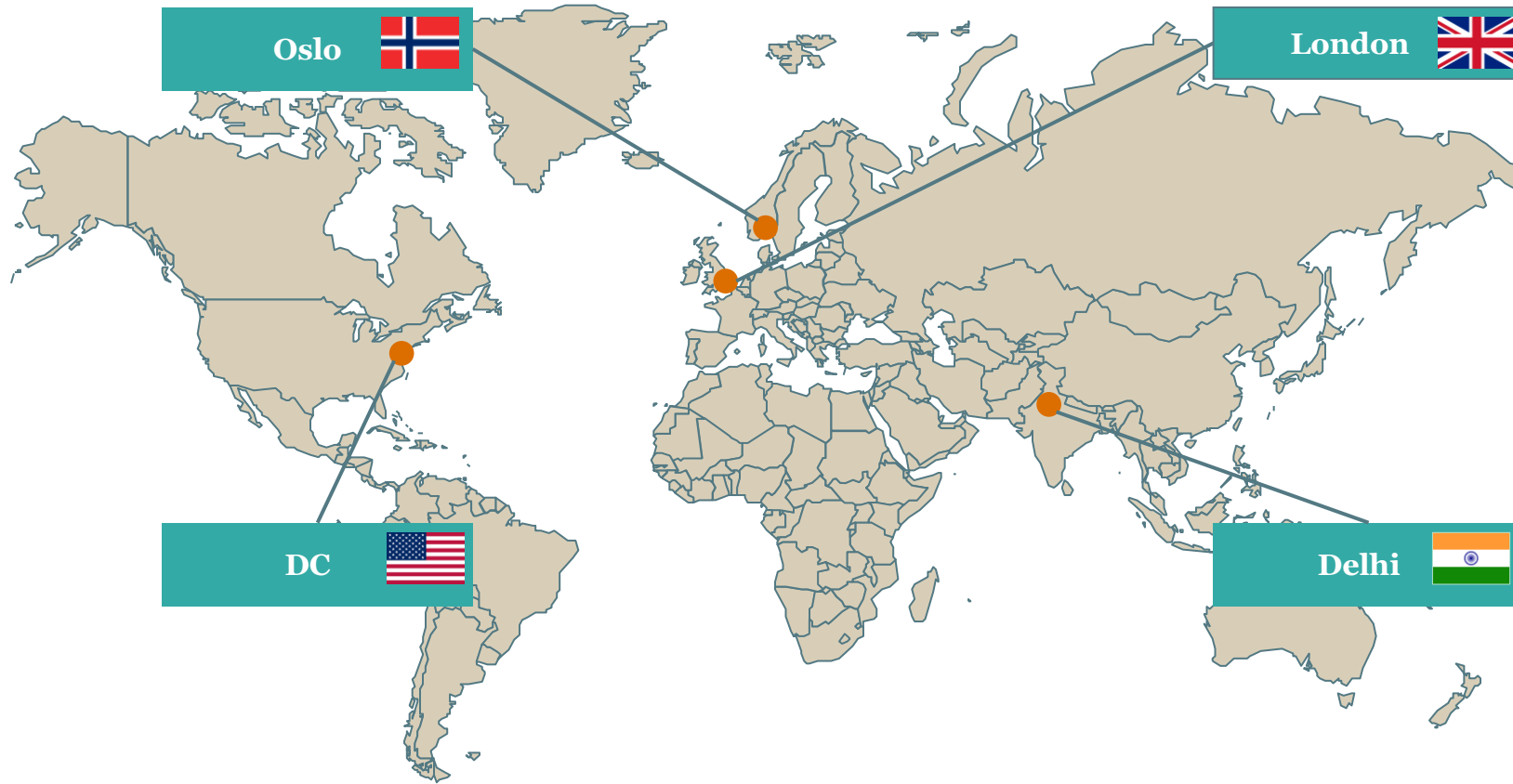
# Working groups and other activities

- Working groups
  - Stockpiling and procurement
  - Regulatory
  - Biological Standards, Assays & Animal Models
- Regulatory Science – Ebola
  - 22 March 2017 meeting at USNAM
- Chikungunya
  - February 2018 – India
- Partnerships/relationships
  - WHO
  - FIND
  - PATH
  - World Bank
  - AU/AVAREF/Africa CDC
- Rapid response

# Building the organization



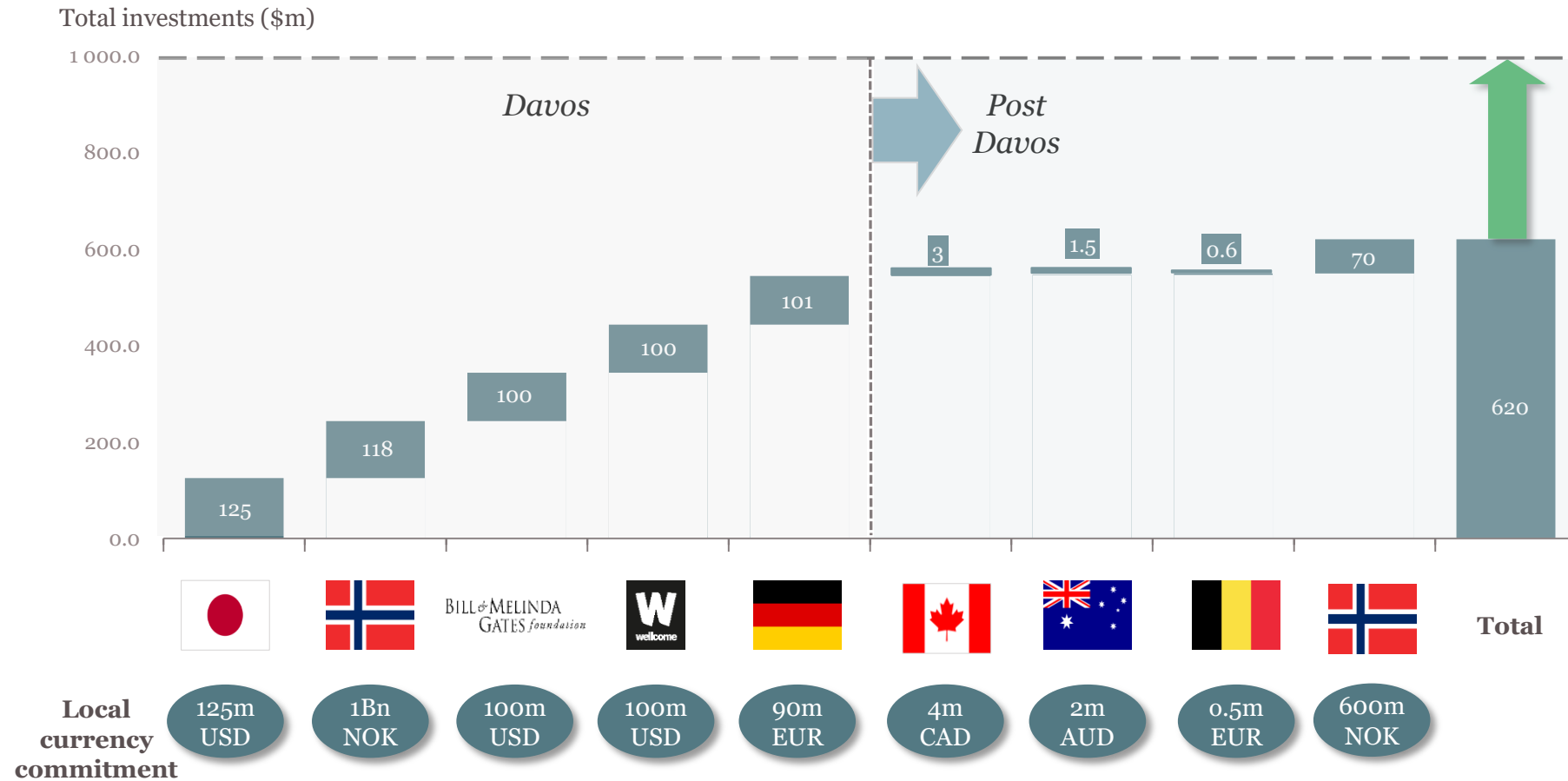
# One organization with global reach



Offices have distinct roles and responsibilities

1. Time divided between UK and Norway offices

# Resource mobilization



Note: Exchange rates NOK / USD: 8.44; EUR / USD 0.89; CAD / USD: 1.34; AUD / USD 1.32;  
Source: World Bank; CEPI donation data; BCG analysis



# Summary

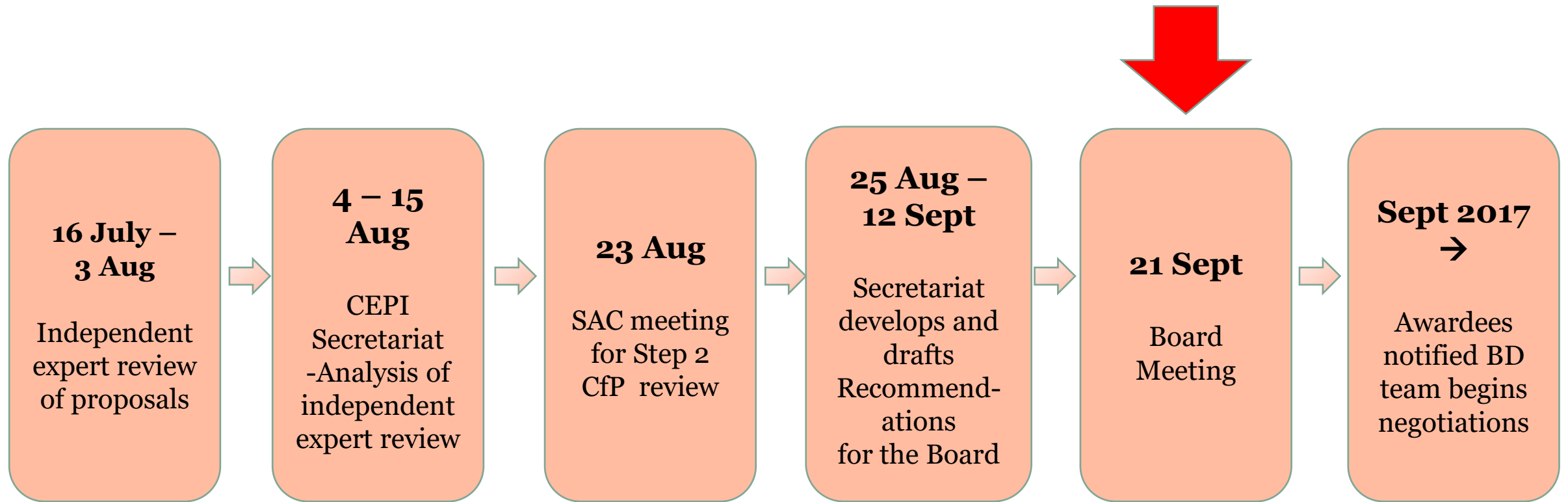
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- CEPI is a new PDP focused on developing vaccines and rapid response platforms as an insurance policy against epidemics
- CEPI represents a broad coalition of partners including sovereign and philanthropic investors, industry, and representatives of civil society
- CEPI's goals are to enhance preparedness, accelerate response, ensure market predictability, and promote equity of access
- CEPI seeks new members of the coalition and is actively recruiting professional staff

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**Thank you!**

# CfP process and Board engagement



# Risk management strategy

## Risk identification

### Regulatory



Lack of regulatory approval of cell line for manufacturing

### Science



Preclinical candidate not mature

### Clinical



Candidate weakly immunogenic

### CMC



Process scale up or CMO transfer not feasible

### Partner Management



Complex consortium

### Product strategy



Limited experience in licensing

### Delivery



Delivery device not ready for use

### IP



Freedom to operate limited by IP holders

## Risk mitigation

- Ensure that applicants develop detailed, integrated product development plans
- Stage gating assessments for go/no-go decisions
- Implement a robust portfolio management system
- Implement operating protocols and processes for go/no-go decisions on lead and back-up vaccine candidates



# Expertise in due diligence teams

## Expertise

Project management

Science & disease specific

CMC, process, QC

Pre-clinical, immune

Preclinical, safety & toxicology

Clinical trials

Management

RA and QA

Cost challenge



# Refocusing the Joint Coordination Group



## 10-15 long-term members whose interests cut across the portfolio:

- Multilateral institutions (e.g., WHO)
- Regulatory agencies (e.g., EMA)
- Procurement agencies (e.g., UNICEF, Gavi)
- Responders (e.g., MSF)



## Time-bound vaccine-specific members:

- National regulatory agencies
- National institutes of public health
- National research agencies
- +++



**Revised scope and function suggests more active engagement of JCG members**