CEPI

The origin and catalyst for formation of CEPI and priorities

Arboviruses: A Global Public Health Threat

21st June 2018

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NORWEGIAN GOVERNMENT

wellcome

The Federal Government

WORLD ECONOMIC FORUM

JAPANGOV
THE GOVERNMENT OF JAPAN

DEPARTMENT OF BIOTECHNOLOGY
Ministry of Science & Technology

BILL & MELINDA GATES foundation

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Global impact of epidemics

Spanish Flu

50 million
deaths

GDP loss
Gross domestic product (GDP) loss of 3% in Australia, 15% in Canada, 17% in the UK, and 11% in the USA

SARS

774
deaths

GDP loss
Gross domestic product (GDP) loss of US $52.2 billion

Zika

20
deaths, birth defects

GDP loss
Expected loss of US $3.5 billion in the Latin American and Caribbean region

Ebola: global impact

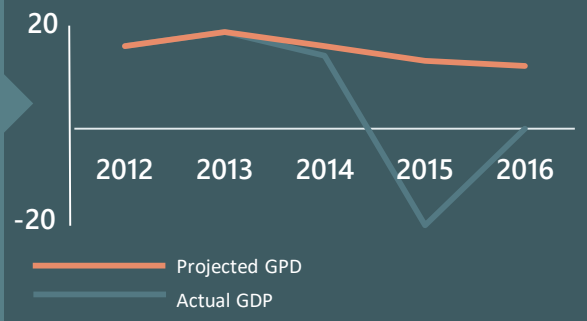
over 11,000
Deaths

£2.8 billion
Estimated negative economic impact (2014-2016)

Source: Yamay et al, 2017:
Financing of international collective action for epidemic and pandemic preparedness

Ebola: Economic impact

Sierra Leone Impact of Ebola on GDP (%)



Ebola: impact on health Systems

Most maternal and child health indicators significantly declined during Ebola outbreak

Malaria morbidity and mortality in Ebola-affected countries caused by decreased health-care capacity

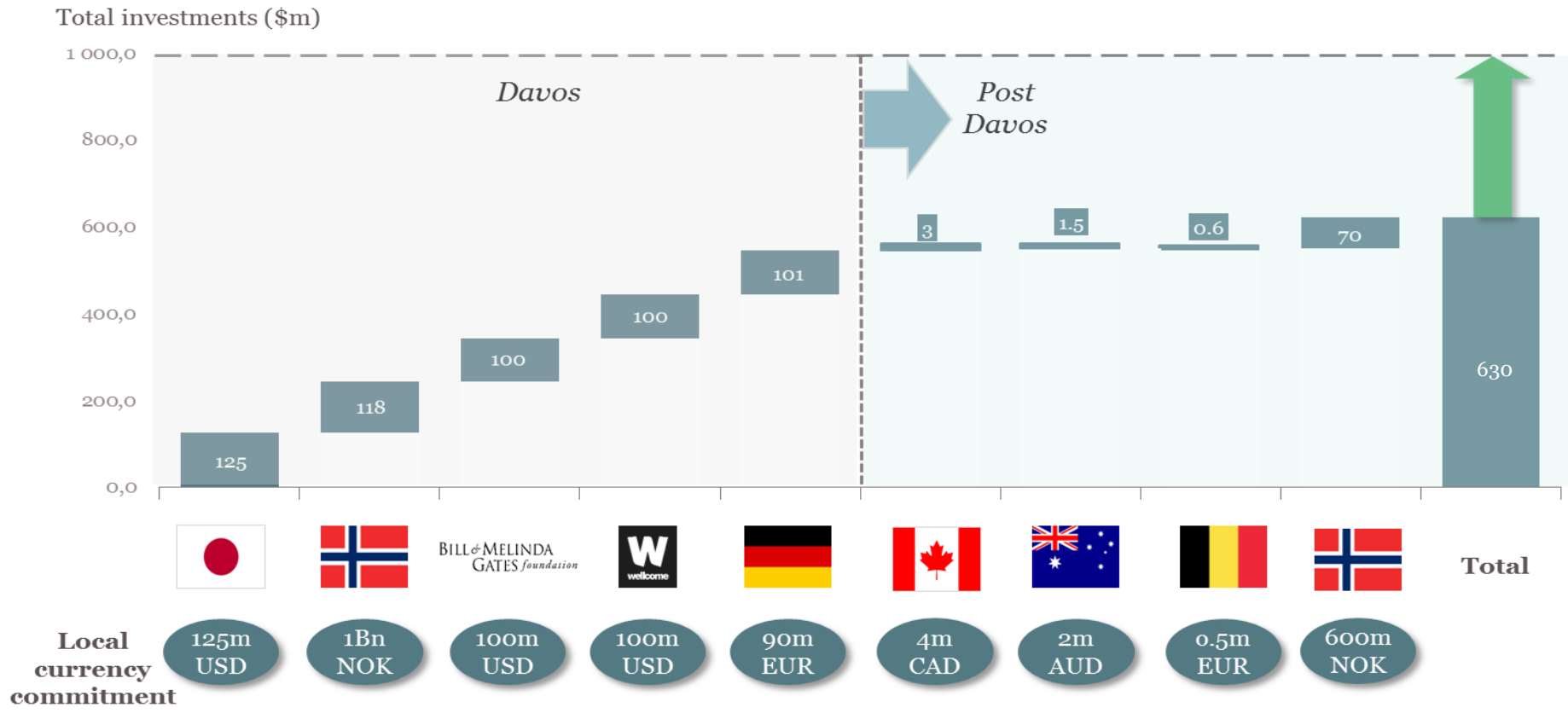
Coalition for Epidemic Preparedness Innovations, CEPI

- Official Launch: Davos World Economic Forum, January 2017
- Global coalition of public, private, philanthropic and civil society organisations
- Aims to stimulate, finance and coordinate vaccine development for emerging infectious diseases
  - Identify priority threats and act when market forces fail to drive needed development
  - Move vaccine candidates through late preclinical studies to proof of concept and safety in humans
  - Build capabilities for rapid response to unknown threats

CEPI in numbers …

- Age: 18 Months
- Number of employees: 37
- Gender Ratio: 18/19 (F/M)
- Number of employees leaving CEPI: 0
- Number of nationalities: 13 (USA, UK, Norway, Greece, Netherlands, India, Pakistan, Austria, Ethiopia, Vietnam, Mexico, France, Italy, Israel)
- Locations: 3, in Oslo, London, and Washington
- Committed budget for next 5 years: 630 M USD Gender Ratio: 18/19 (F/M)

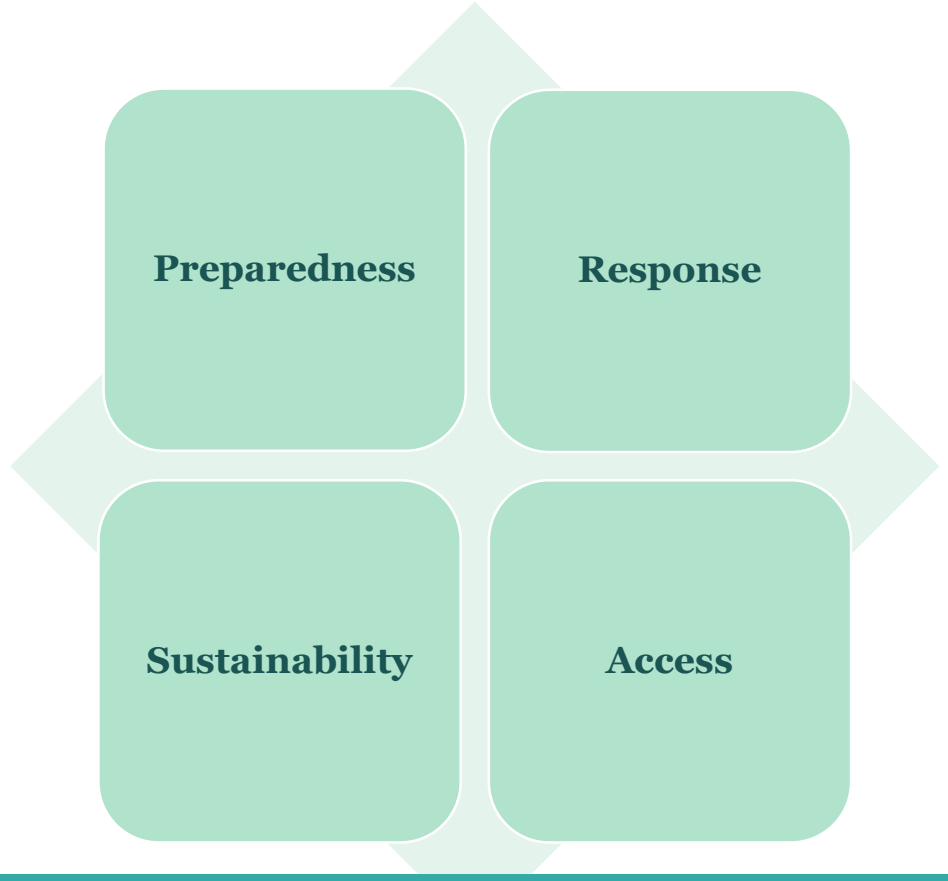
CEPI's first investors



In addition: EC plans to co-fund with up to €250 mill

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

CEPI's strategic objectives



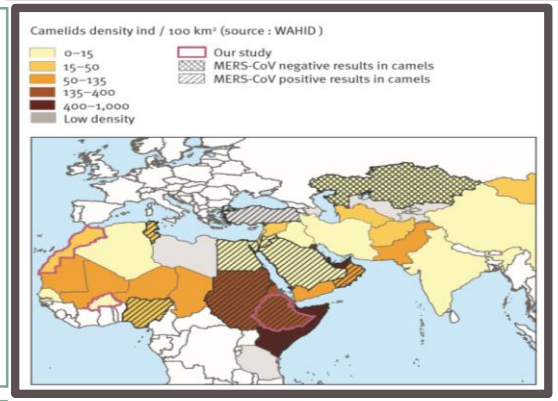
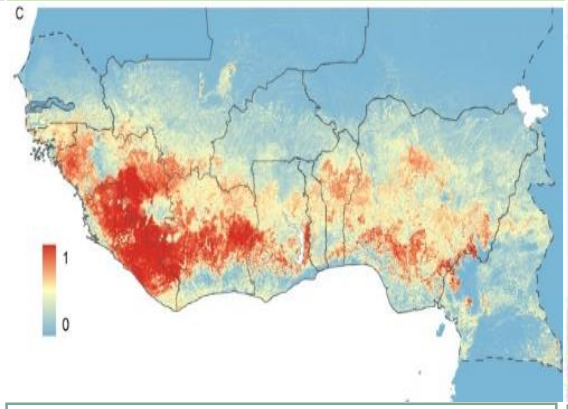
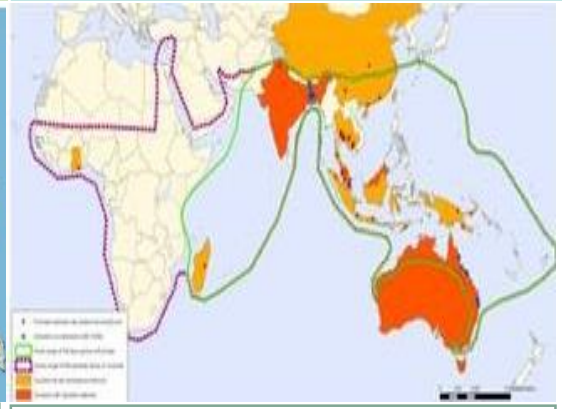
CEPI, facilitator and funder

CEPI as facilitator

Phase	1. Discovery	2. Development/ Licensure	3. Manufacturing	4. Delivery/ Stockpiling	5. "Last Mile"
Current Stakeholders	▪ Academia ▪ Governments ▪ WT/NIH ▪ EC/IMI ▪ GLOPID-R ▪ Industry ▪ Regulators ▪ Biotech	▪ Industry ▪ Governments ▪ Regulators ▪ WT/NIH ▪ EC/IMI ▪ Bill and Melinda Gates Foundation ▪ BARDA/DTRA etc. ▪ WHO ▪ Biotech ▪ PDPs	▪ Industry ▪ BARDA ▪ CMOs ▪ Regulators ▪ Governments ▪ WHO ▪ GHIF	▪ GAVI ▪ UNICEF ▪ PAHO ▪ Governments ▪ WHO ▪ Industry ▪ Pandemic Emergency Facility (World Bank) ▪ WHO Contingency Fund	▪ Countries ▪ WHO ▪ UNICEF ▪ Responding Organizations (e.g. MSF)

Significant focus by others ← CEPI as funder → Significant focus by others

CEPI's initial priority pathogens

	MERS	Lassa	Nipah	Disease X
Affected countries				
WHO TPP	Prophylactic and reactive use	Prophylactic prioritized	Reactive use	

CEPI's Scientific Advisory Committee chose three initial diseases based on expected

Public health impact | Risk of an outbreak occurring | Feasibility of vaccine development

Call for Proposal 1: Lassa, MERS, Nipah

Scope: Vaccine development from preclinical to Proof-of-Concept (Phase Iia)

More than 30 proposals received in first round

- Academic institutions, biotechs, large pharmaceutical companies and Product Development Partnerships
- Broad diversity in vaccine platform technologies
- Proposals from North America, Europe, Africa, Middle East, South East Asia and Australia

Planning

- Launch, Jan 2017
- Preliminary proposal review, April 2017
- Full proposal review, July-August 2017
- Assessment, Oct 2017 – now
- Four partnership agreements signed (as per 20 June 2018)

CfP1, CEPI priority pathogen portfolio

Scope of CEPI funding

Inovio DNA

IAVI* rVSVΔG

Themis* Measles vector

Themis Measles vector

Profectus subunit

Inovio DNA

Under contract negotiation

Non-rep vector

Rep. vector*

Rep. Vector

Non-rep vector*

Rep. vector

Non-rep vector*

Non-rep vector

Lassa

Nipah

MERS CoV

* Investment in preclinical

More than 30 applications received

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CfP1, Current portfolio of vaccines (June 20, 2018)

Pathogen	LASSA			MERS-CoV		Nipah
Company	Themis	Inovio	IAVI*	Themis*	Inovio	Profectus
Technology	Measles virus (Schwarz) Live replicating	DNA + Electroporation	rVSVΔG Live replicating	Measles virus (Schwarz) Live replicating	DNA + Electroporation	Recombinant subunit
Antigen	GPC + NP	GPC	GPC	Spike	Spike	Glycoprotein
Status	PoC in NHP	PoC in NHP	PoC in NHP	PoC in mice, Moraten	Ph I IM complete Ph I ID pngoing	PoC in NHP Tox performed
FIH	2019	2019	2020	2020	Ongoing	2019

* Investment in preclinical

#http://journals.plos.org/plosntds/article?id=10.1371/journal.pntd.0003736#abstract1

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CfP2, Platform technologies, rapid response

Develop **vaccine platform technologies that can be rapidly deployed against known and newly emerging pathogens,** to limit or prevent future outbreaks of known or new diseases

Projects must demonstrate

- Safety and immunogenicity in human
- Validation of the platform using 3 pathogens:
  - 2 with known correlates of protection & validated animal model
  - 1 from the WHO priority pathogen list

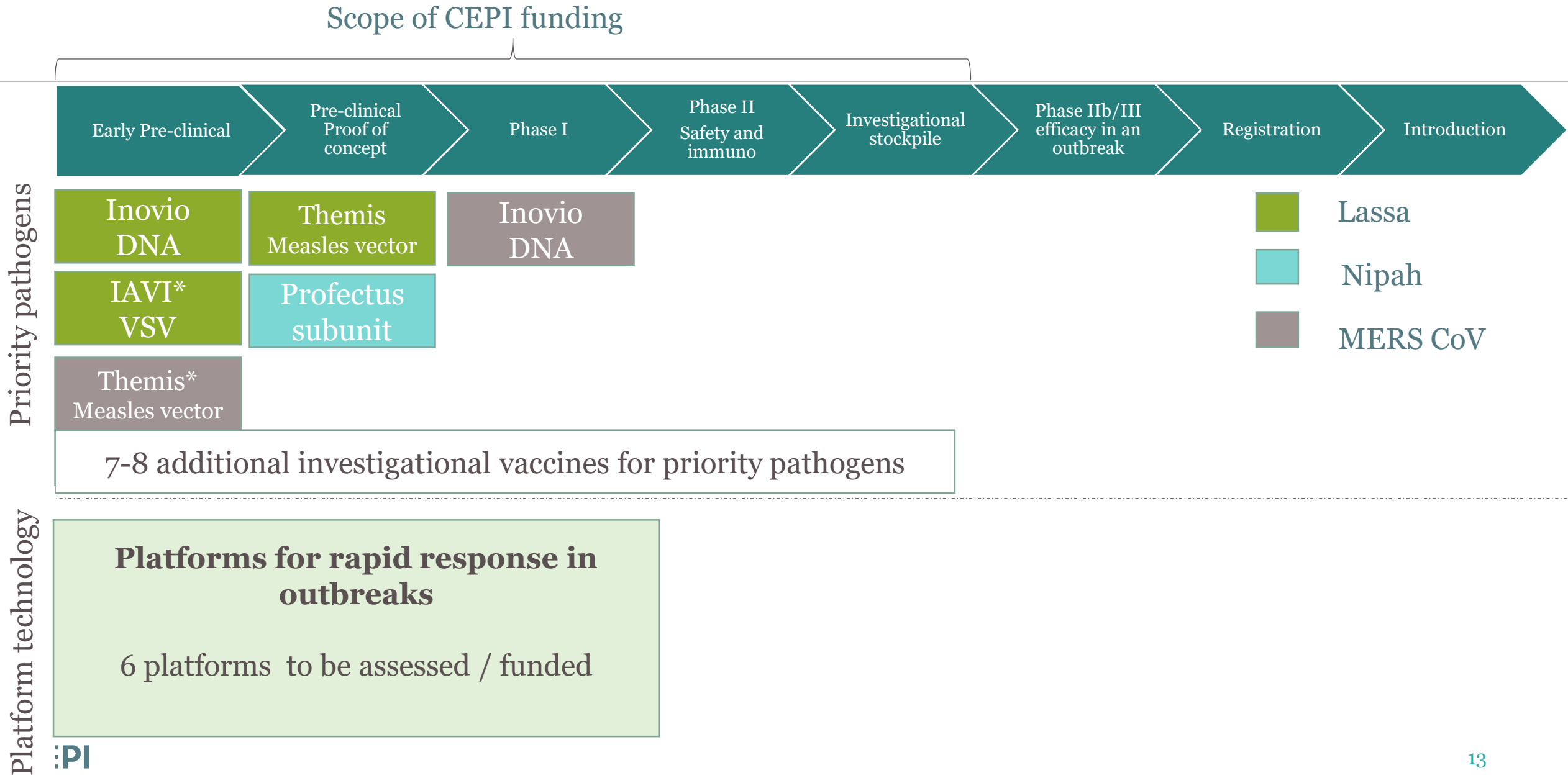
Manufacturing performance characteristics

- 16 weeks for development of vaccine for a new pathogen (up to PhI)
- 6 weeks to clinical benefit after 1st dose
- 8 weeks to produce 100,000 doses after go-decision

Planning

- Launch, preliminary proposals, Sept 2017
- Launch, full proposals, Dec 2017
- Deadline submission of full proposals, 27 Feb 2018
- Review by experts (April 2018) and by Scientific Advisory Board, June 2018

Portfolio: > 20 vaccines against WHO priority pathogens by end 2018

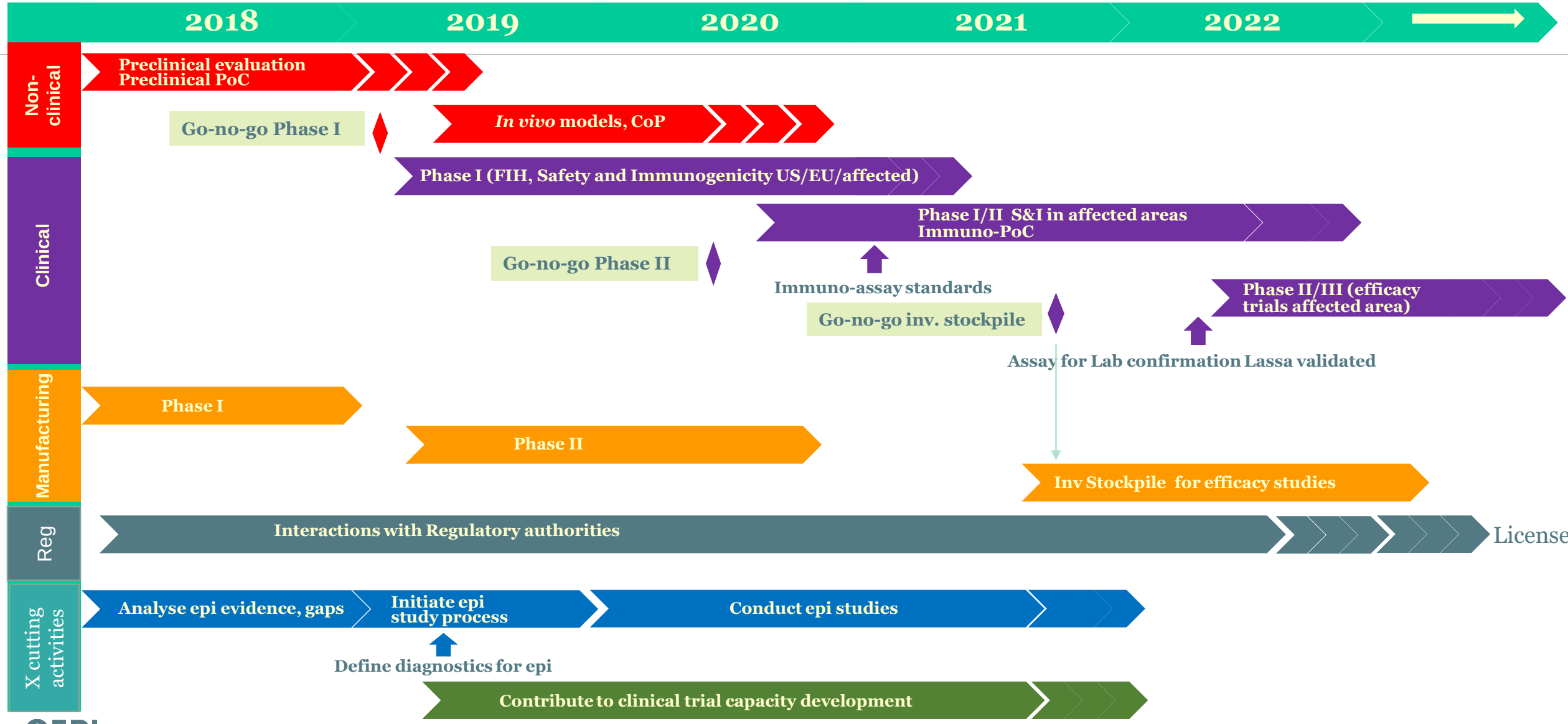


Cross cutting working groups: facilitate development

Biological standards and assays	• Supporting the development and availability of standardized reagents, validated assays and animal models for the ongoing vaccine development of CEPI funded projects • *Co-chairs*: **Emer Cooke** WHO; **Johan Holst** CEPI
Regulatory	• Identify regulatory gaps and specific regulatory scientific questions, and offer possible solutions that will support the development of vaccines against emerging infectious diseases (EID) • 2018 priorities – WHO EUAL/Pre-EUL, AVAREF emergency assessment of protocols, regulatory vehicles for platforms • *Chair*: **Daniel Brasseur**
Stockpiling and access to investigational vaccines	• Give guidance on criteria, mechanisms and processes for stockpiles and access to investigational vaccines • *Chair:* **Michael Thomas** GAVI

Progression, stage-gate process

PoC: Proof of Concept
CoP: Correlate of protection
S&I: Safety and immunogenicity



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Conclusions

- CEPI has a portfolio of 6 vaccines for priority pathogens, and this continues to grow
- CEPI is investing in vaccine platforms to be more reactive to future outbreaks
- CEPI is actively involved in cross cutting working groups to facilitate development and implementation

Thank you !

New vaccines for a safer world
www.cepi.net