CEPI | New vaccines for a safer world

Coalition for Epidemic Preparedness and Innovations:

Development of vaccines for emerging viruses

Georges THIRY – GVN, 28th Nov. 2018

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THE GOVERNMENT OF JAPAN

DEPARTMENT OF BIOTECHNOLOGY
Ministry of Science & Technology

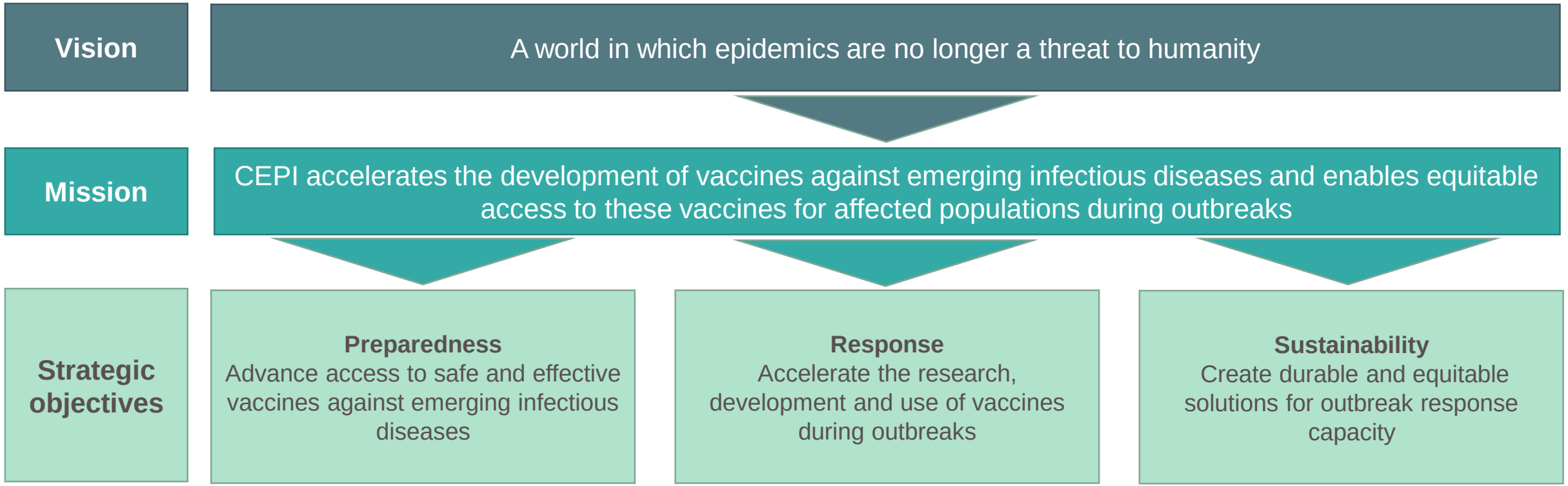
WORLD ECONOMIC FORUM

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
- Goal is to reduce the global risk of epidemics by developing vaccines to control outbreaks

- 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

Vision, mission, and strategic objectives



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CEPI is both facilitator & funder in a complex ecosystem

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

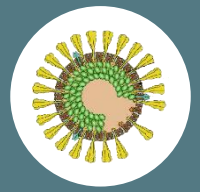
CEPI as funder

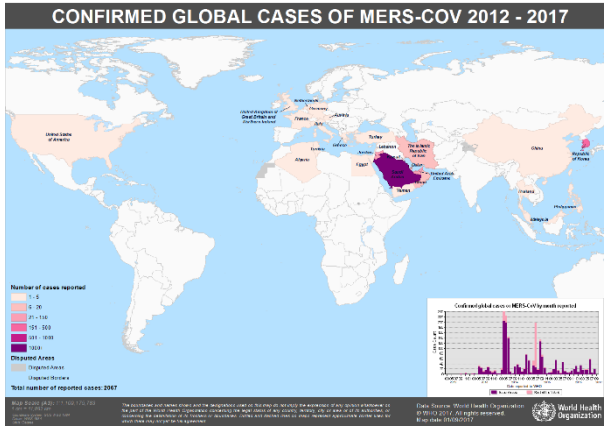
Significant focus by others

CEPI

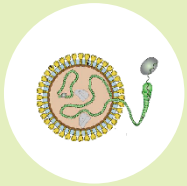
CEPI's initial priority pathogens

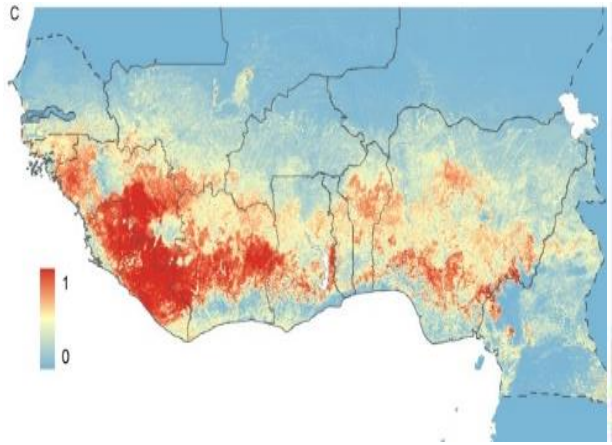
MERS



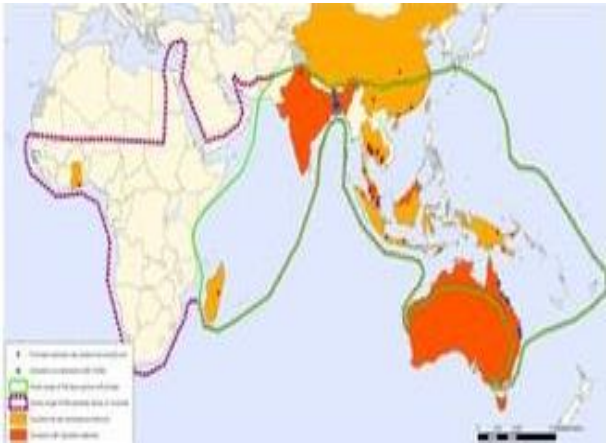


Lassa





Nipah



CEPI's Scientific Advisory Committee chose three initial diseases based on expected Public health impact | Risk of an outbreak occurring | Feasibility of vaccine development

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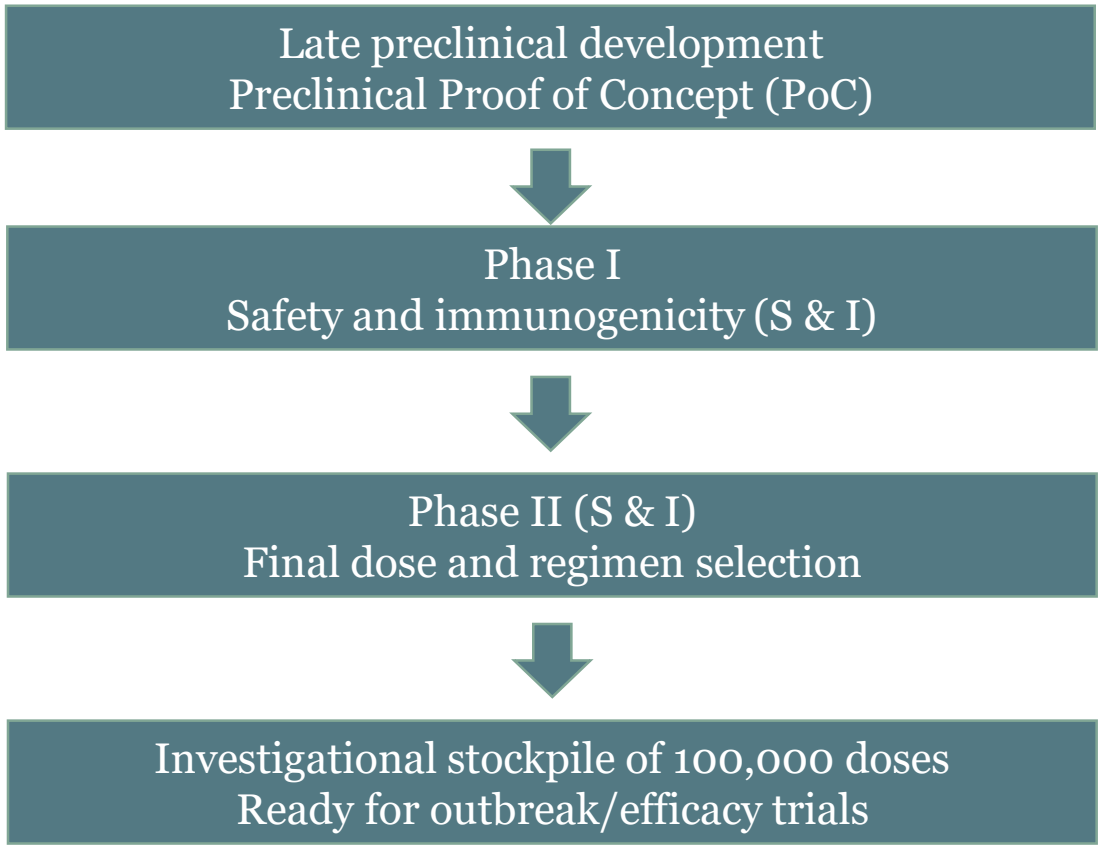
Objectives of priority pathogen vaccine development

Five year funding to advance the most promising vaccine candidates for the three priority pathogens



Seven partnership agreements signed

	THEMIS	inovio PHARMACEUTICALS	International AIDS Vaccine Initiative	PROFECTUS BIOSCIENCES emergent biosolutions PATH	PROFECTUS BIOSCIENCES emergent biosolutions PATH	IDT	janssen PHARMACEUTICAL COMPANIES OF Johnson & Johnson UNIVERSITY OF OXFORD
Disease	Lassa and MERS	Lassa and MERS	Lassa	Nipah	Lassa	MERS	Lassa, MERS, and Nipah
Investment (up to)	$37.5 M	$56.0	$54.9 M	$25.0 M	$36.0 M	$36.0 M	$19.0M

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Lassa portfolio – Vaccine profiles

Virus	Lassa				
Partner	Themis	Inovio	IAVI*	Profectus*	Oxford Janssen *
Technology	Measles virus Live rep	DNA + Electroporation	rVSVΔG Live replicating	rVSVNC4ΔG Live replicating	Chadox Live non replicating
Lassa transgene Josiah strain	GPC + NP	GPC	GPC	GPC	GPC

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* Investment in preclinical

MERS-CoV portfolio - Vaccine profiles

Virus	MERS			
Partner	IDT	Themis *	Inovio	Oxford Janssen
Technology	MVA Rep incompetent	Measles virus Live replicating	DNA + Electroporation	Chadox Live non replicating
MERS transgene	Spike	Spike	Spike	Spike

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* Investment in preclinical

Nipah portfolio - Vaccine profiles

Virus	Nipah	
Partner	Profectus	Oxford Janssen *
Technology	Recombinant subunit Alum	Chadox Live non replicating
Nipah transgene	Glycoprotein	Glycoprotein

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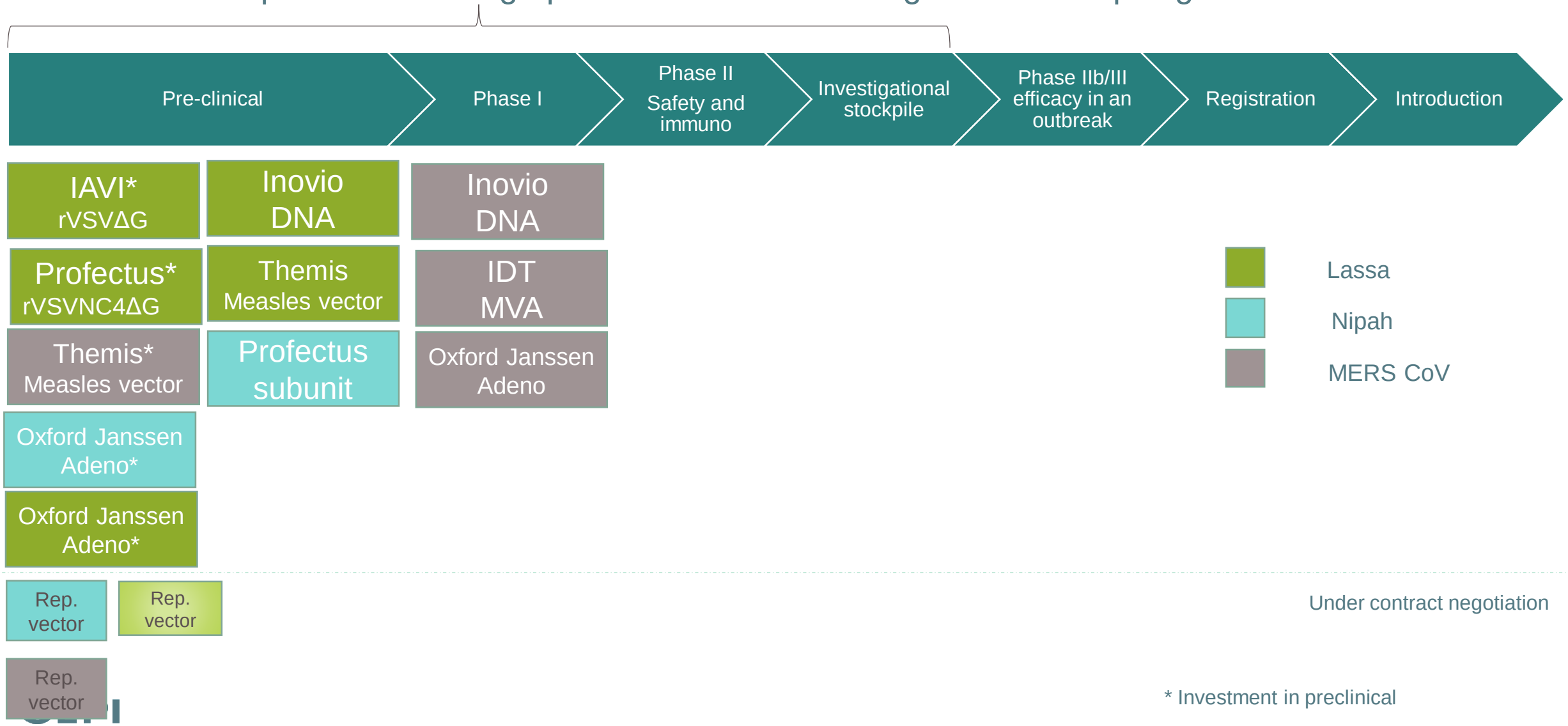
* Investment in preclinical

CEPI priority pathogen portfolio

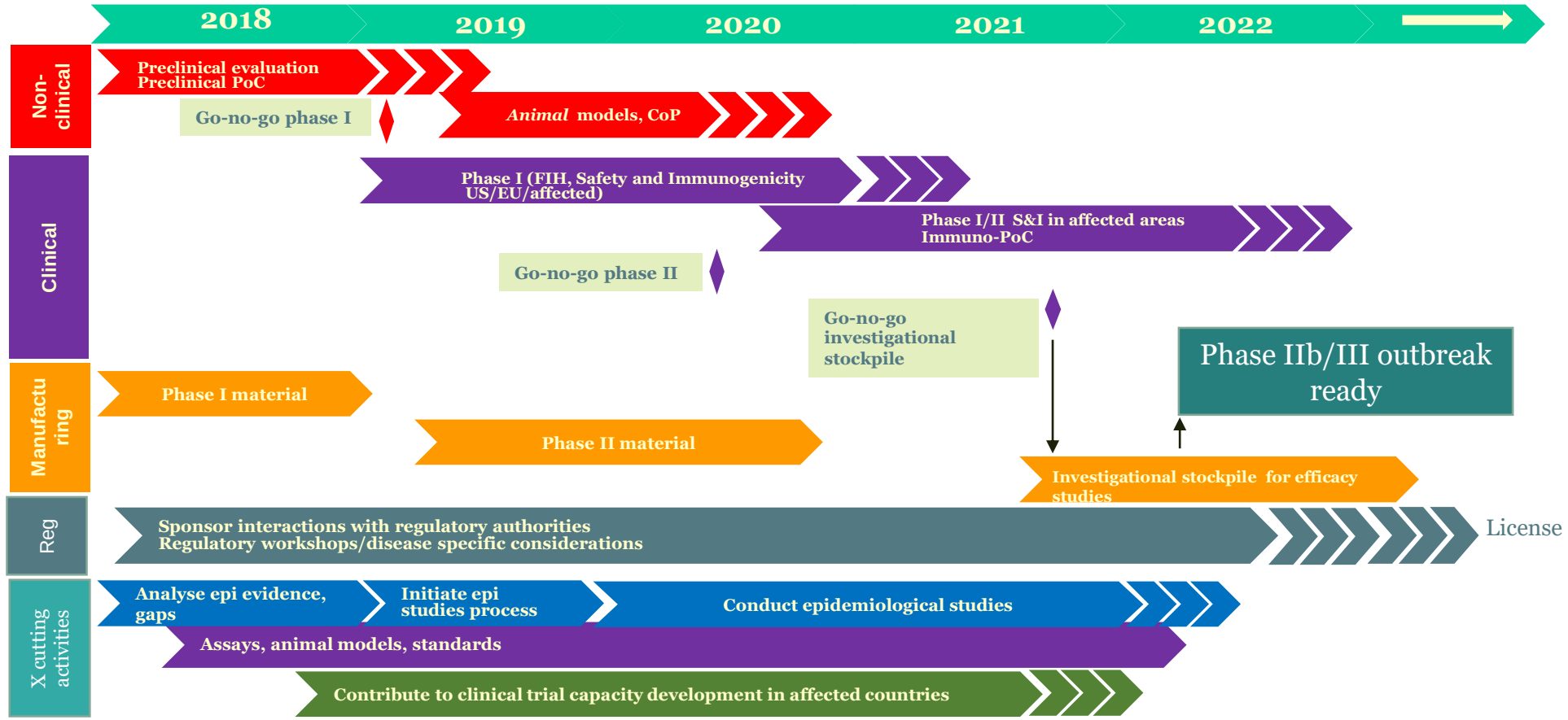
CEPI funds late preclinical through phase II S&I and investigational stockpile generation



Cross-cutting working groups and initiatives

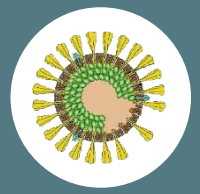
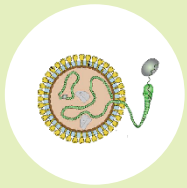
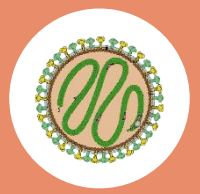
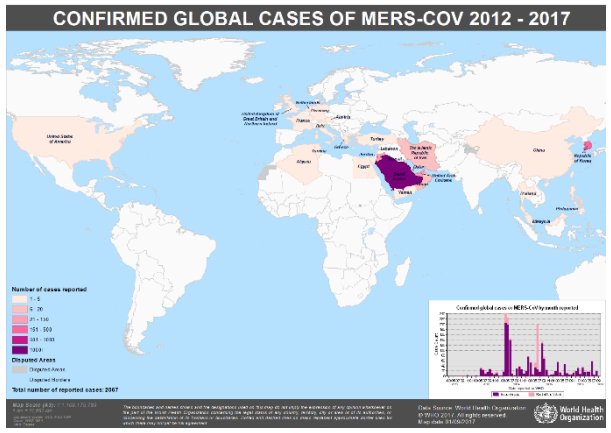
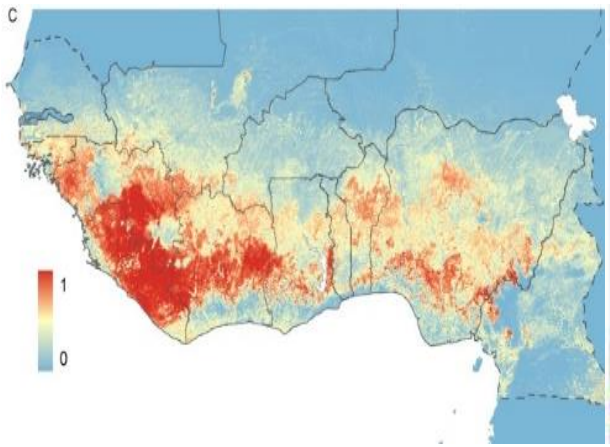
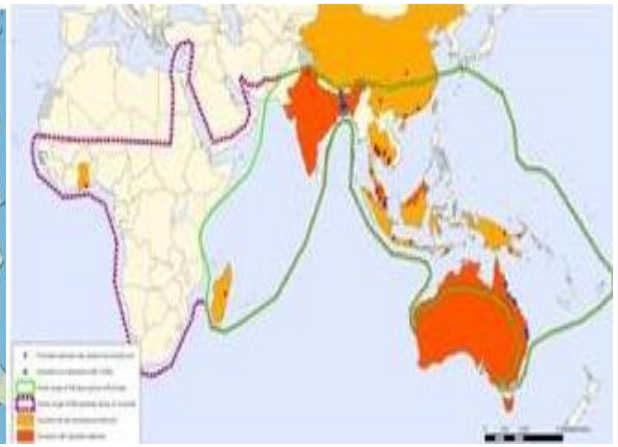
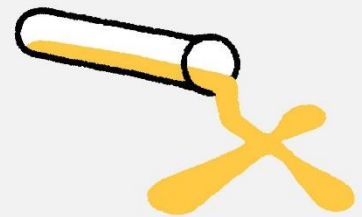
Biological standards and assays	• Supporting the development and availability of standardised reagents, validated assays and animal models for the ongoing vaccine development of CEPI funded projects
Regulatory	• Identify regulatory gaps and specific regulatory scientific questions, and offer possible solutions that will support the development of vaccines against emerging infectious diseases (EID)
Stockpiling and access to investigational vaccines	• Give guidance on criteria, mechanisms and processes for stockpiles and access to investigational vaccines
•Sustainable manufacturing	• the long-term manufacturing and stockpile strategy of CEPI to achieve sustainability of the vaccines developed in our portfolio beyond the 2022.
•Epidemiology	• Focused epidemiology studies for Lassa in West Africa to inform on vaccine efficacy study design

Integrated Product Development Plan –Advancing individual projects and cross-cutting enabling sciences



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

Disease X

MERS	Lassa	Nipah	Disease X
			
			

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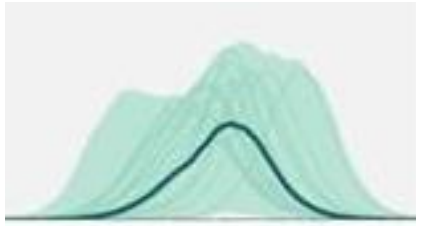
CfP2: Mitigating outbreaks by reducing vaccine development time



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

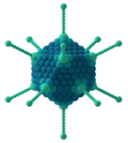
- Test platform versatility on three pathogens
- Two into phase I, to characterize safety and imunogenicity of the platform
- Funding decision to be annonced 4q18/1q19

Promising technologies

DNA

RNA / Self amplifying

Recombinant proteins



Viral vectors

CEPI is continuing to invest in vaccine development

- A third call for proposal to be launched in 2019 to expand priority pathogens for vaccine development

- Supporting activities towards licensure of Ebola vaccines

Conclusions

- CEPI's portfolio of vaccines in development is rapidly expanding
  - 11 vaccine projects for WHO R&D blueprint priority pathogens and further expanding
  - A portfolio of platform technologies for rapid response will be announced in the coming weeks

- Collaborative efforts are key for advancement of vaccine candidates
  - Working with partners
  - Key focus on cross cutting activities to facilitate the vaccine portfolio

The CEPI ecosystem – a snapshot