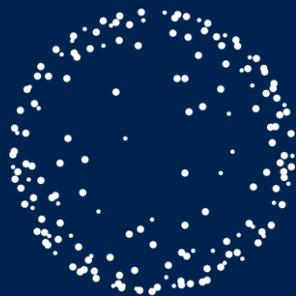


Tekna

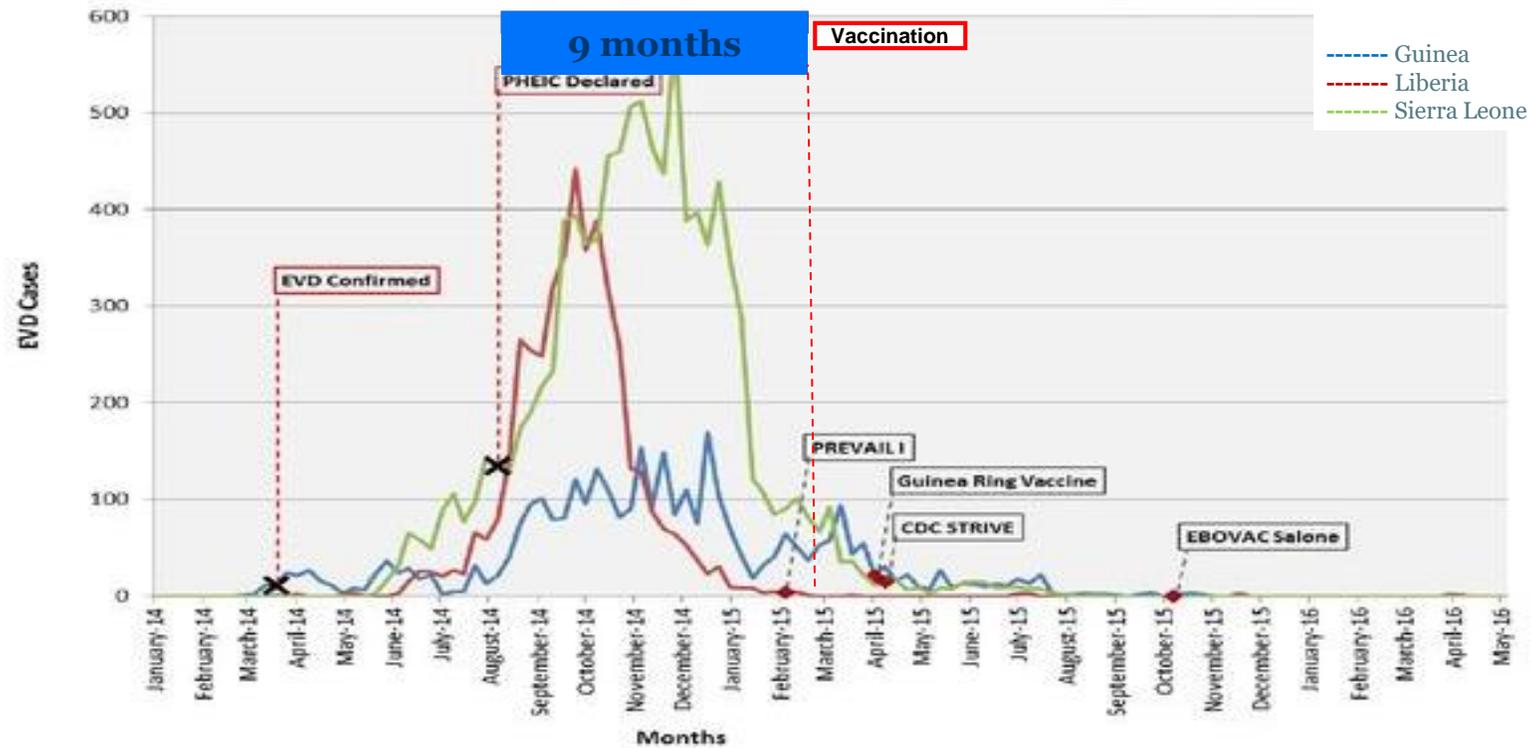
CEPI

# CEPI's mission and activities regarding COVID-19

Bjørg Nilsson, Head of Communication Nordic Countries  
Stig Tollefsen, PhD, Senior Scientist, CEPI



# Ebola vaccine trials – Lessons learned







## **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

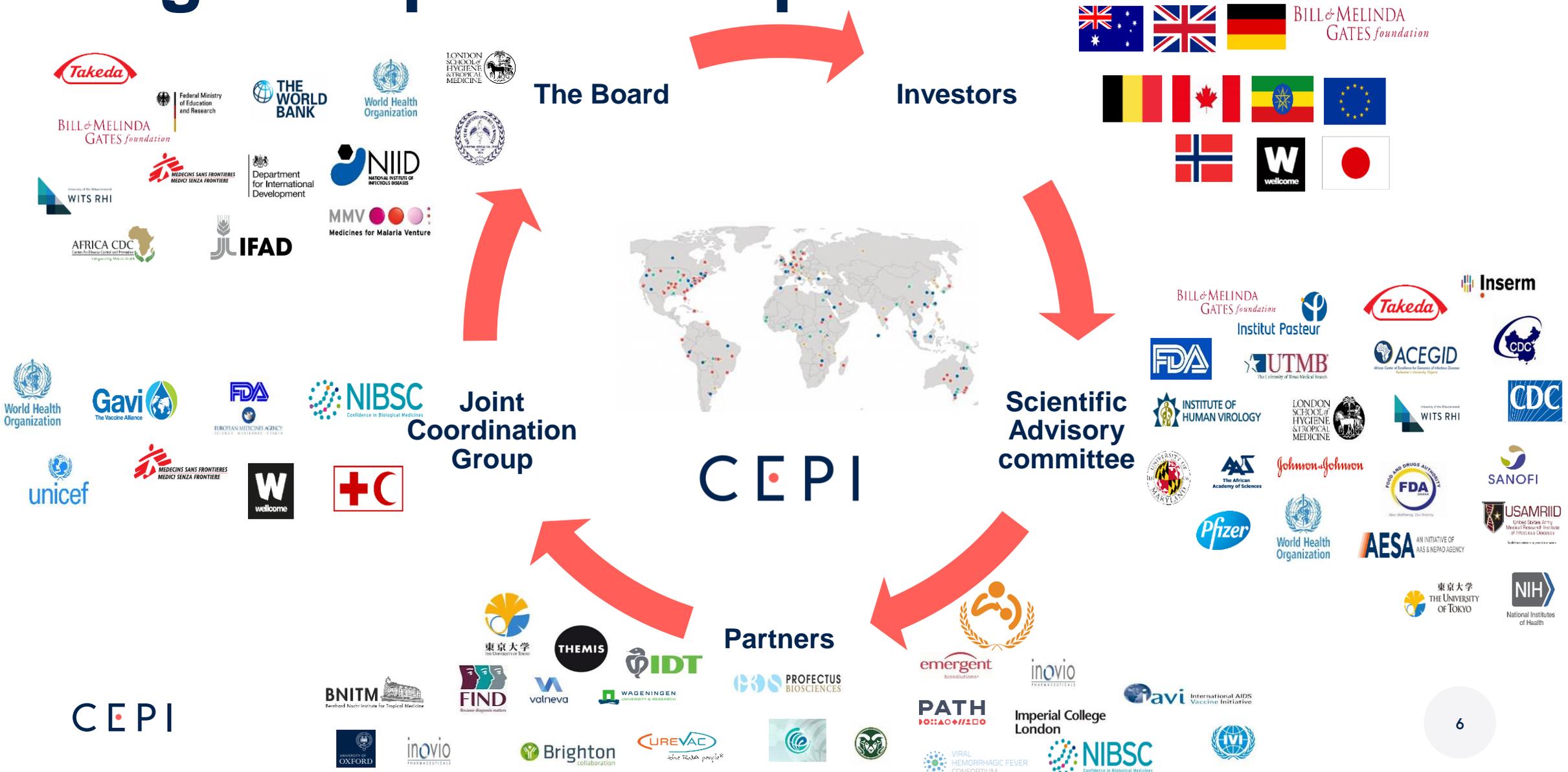
Accelerate the research, development and use of vaccines during outbreaks



## Sustainability

Create durable and equitable solutions for outbreak response capacity

# A global partnership



# A sustainable partnership

CEPI role as a facilitator

CEPI role as a funder



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

Industry  
Governments  
Regulators  
Wellcome Trust  
NIH  
EC  
IMI  
BMGF  
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  
Organisations (eg,  
MSF)

# The number of new emerging infectious diseases is on the rise

“I don't think we've ever had a situation where we're responding to so many emergencies at one time. This is a new normal.”

- Dr. Mike Ryan, Executive Director of WHO's Health Emergency Programme (June 2019)

# And the costs of EIDs are vast, in both human and economic terms



\$570 bn

The estimated annual global cost of moderately severe to severe pandemics (Fan VY, et al, NBER 2016)



\$2.8 bn

The minimum average cost for progressing one vaccine against each of WHO's 11 priority epidemic infectious diseases (Gouglas D, et al. Lancet 2018)



\$60 bn

China



>\$200 bn

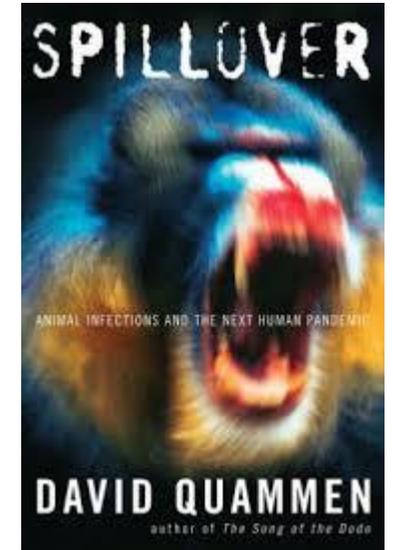
Globally

**COVID-19 estimated costs**

**Q1 2020**

# Epidemics affect us all

- They often arise in the most **vulnerable populations** – which are and will continue to be the focus of our work
- The threat posed by epidemics and pandemics represent one of humanity's greatest challenges:
  - **Paradox of Progress:** Dense cities, global trade, easy travel and ecological change mean they spread faster and further than ever before
  - **Harm is Immediate and Long-Lasting:** They cause disruption in travel, businesses to close, economies to struggle, and undermine fragile public health capabilities
  - **Costs are Clear:** The human and economic costs are staggering
- There are many examples of the harm infectious diseases can cause, from the loss of life and economic harm to the downfall of empires



# What is a vaccine?



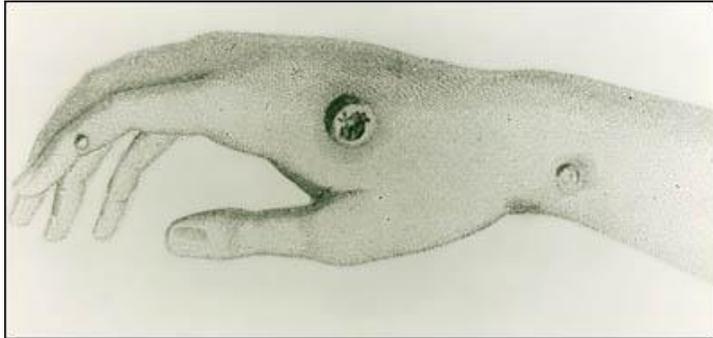
Nick Jackson –  
Head of Programs and Innovative Technology

“A vaccine is a biological preparation that provides active **acquired immunity** to a particular disease. A vaccine typically contains **an agent that resembles a disease**–causing microorganism and is often made from weakened or killed forms of the microbe, its toxins, or one of its surface proteins.”

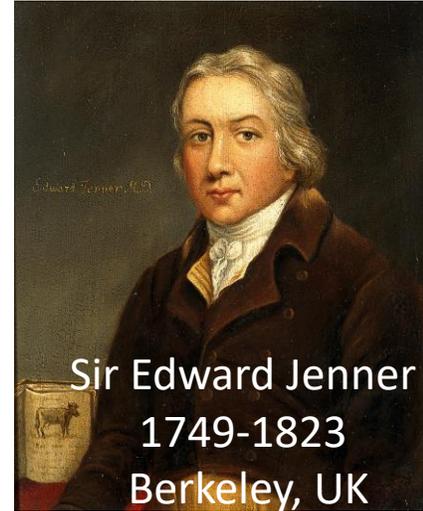
# Vaccination



Lady Mary Wortley Montagu  
1689-1762  
London, UK

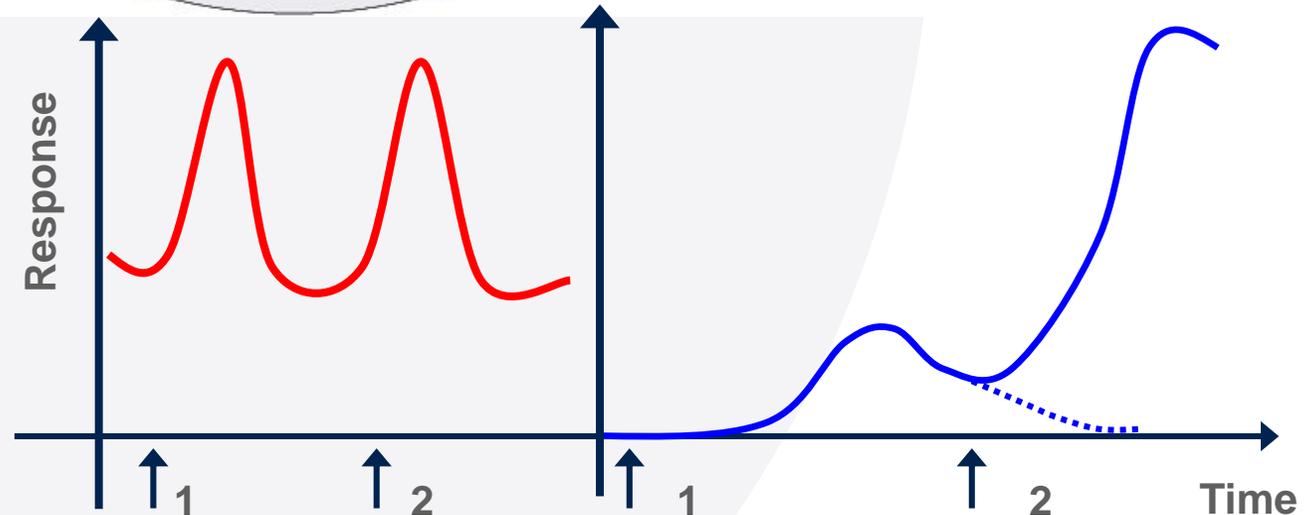
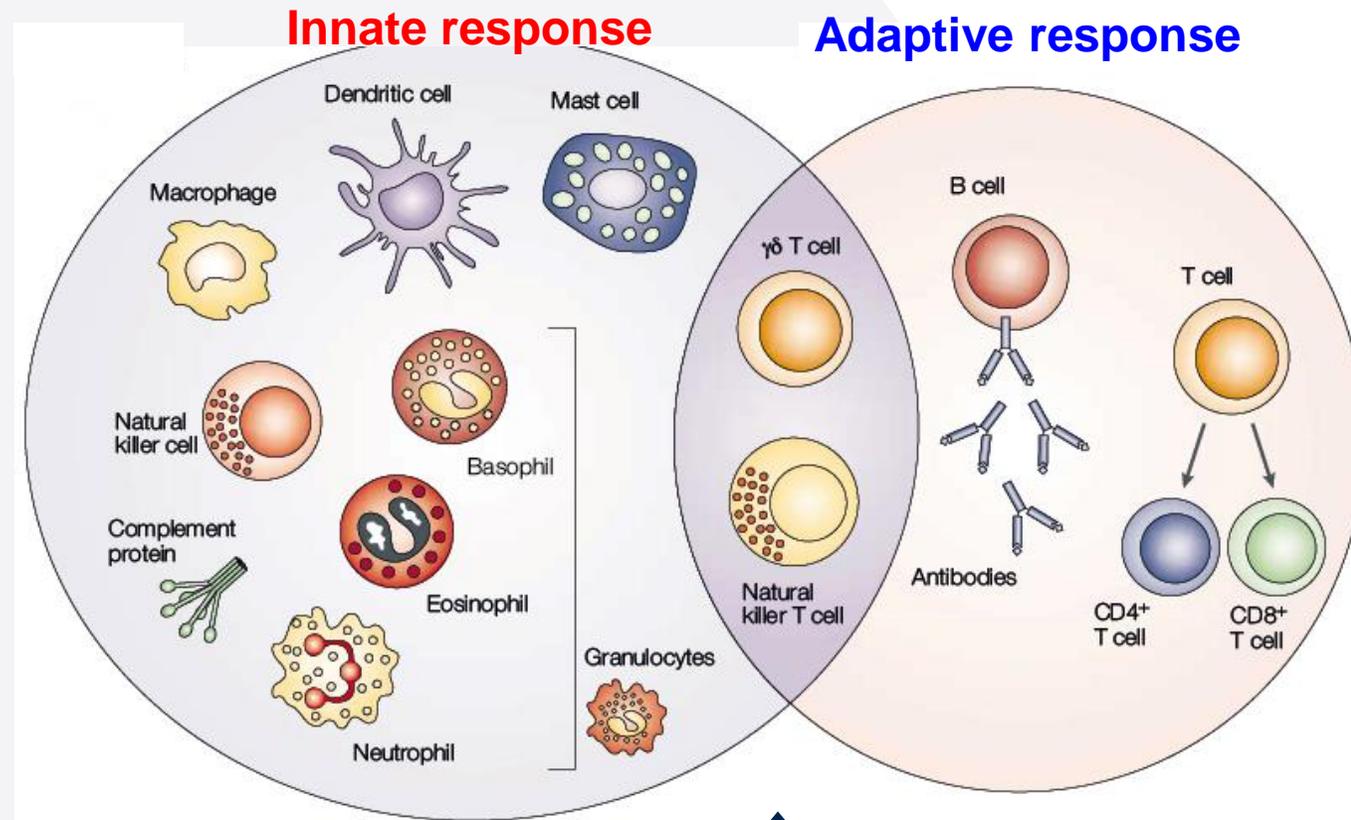


«In 1717 learned about **variolation** in Istanbul»

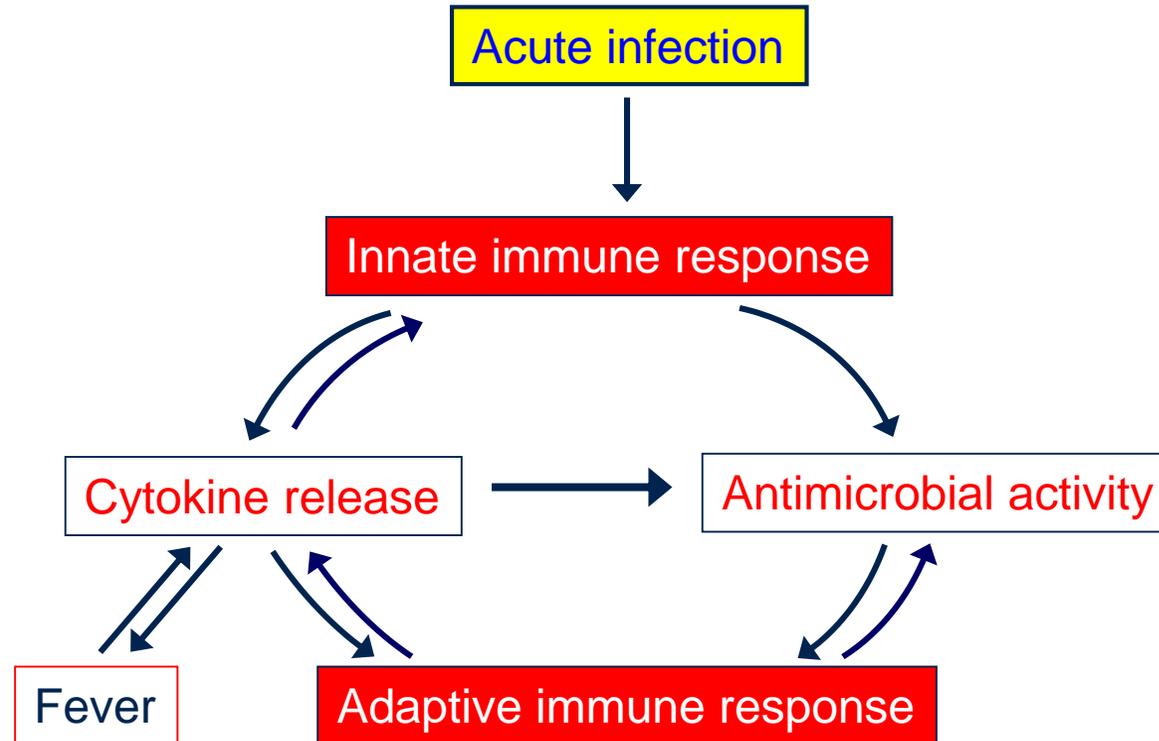


Jenner inoculating J. Phipps 1796

# Immune Response



# Interactions between the innate and adaptive immune systems



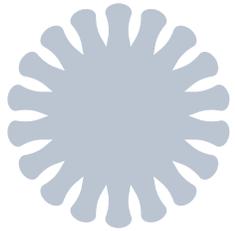
There is a cross-talk between the innate and the adaptive immune systems

# Vaccination and the immune system

- Vaccination prepares the immune system to handle the challenge.
- T cells
  - Regulate the adaptive immune response (CD4)
  - Cytotoxic effects (CD8)
- B cells
  - Antibody production
  - Antigen presentation
  - Plasma cells secrete antibodies

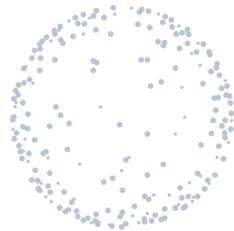


# CEPI's priority pathogens



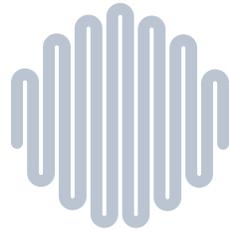
MERS

5 vaccine candidates



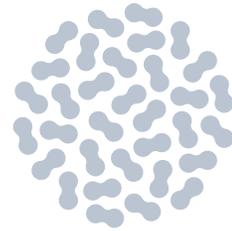
Lassa

6 vaccine candidates



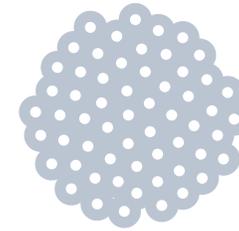
Nipah

4 vaccine candidates



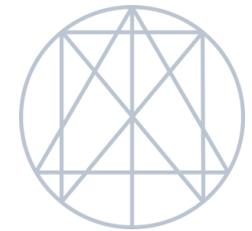
Chikungunya

2 vaccine candidates



Rift Valley fever

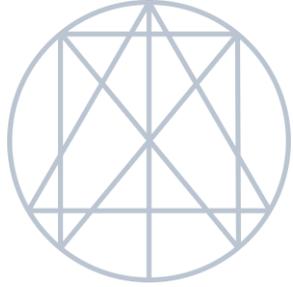
2 vaccine candidates



Disease X

3 platform technologies

# Disease X



## What is it?

“Disease X” represents the knowledge that a serious international epidemic could be caused by a pathogen currently unknown to cause human disease.

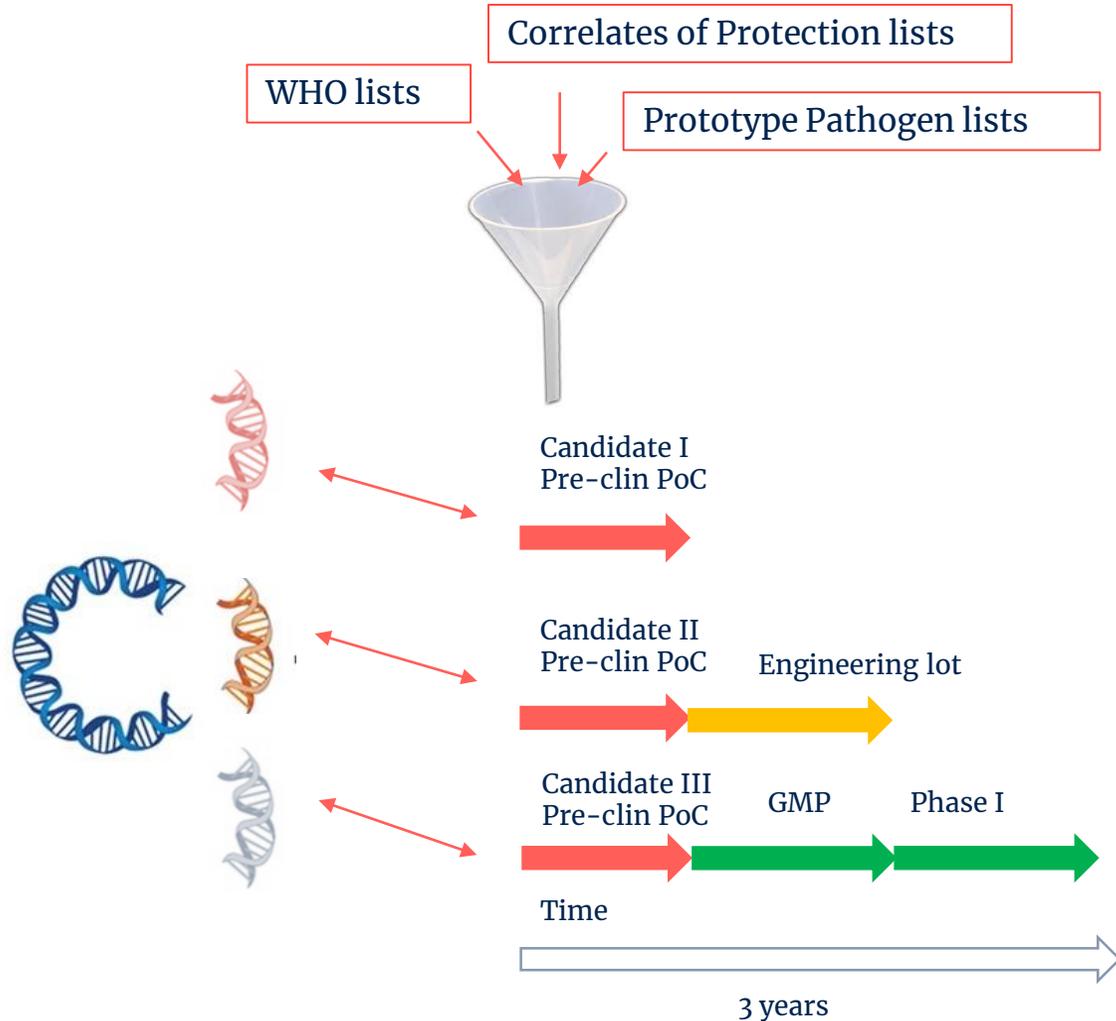
## Where does it occur?

By their very nature, we cannot predict what or where “Disease X” is likely to emerge. What we do know is that new diseases emerge all the time, from locations all around the world.

## Who does it affect?

Developing countries, particularly those with high rates of biodiversity, are at heightened risk, because of the increased risk of outbreaks and the limited capacity for surveillance and response in these countries.

# Platform technology



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- Technology TPP (Target product profile)
- Regulatory aspects
- Scope broadened beyond vaccine platforms
  - Monoclonal antibodies
  - Immunoprophylactic platforms such as gene encoded antibodies
  - Other innovations
- Aspirational Characteristics
  - 16 weeks from antigen to clinic
  - 6 weeks to clinical benefit
  - 8 weeks to manufacture 100,000 doses

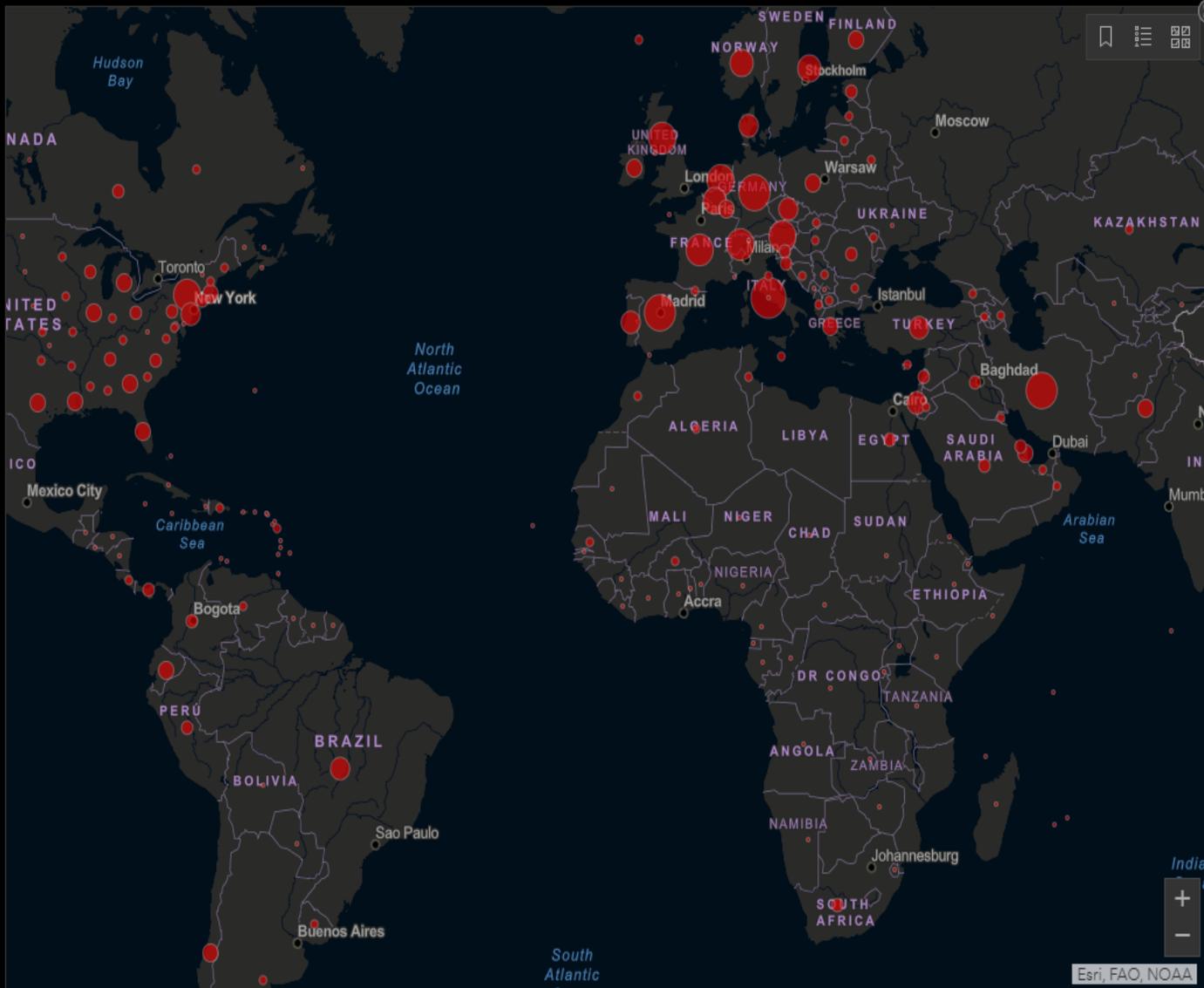


Total Confirmed

311,988

Confirmed Cases by Country/Region/Sovereignty

- 81,394 China
- 53,578 Italy
- 28,572 Spain
- 26,747 US
- 23,129 Germany
- 20,610 Iran
- 14,485 France
- 8,897 Korea, South
- 6,652 Switzerland
- 5,067 United Kingdom
- 3,643 Netherlands
- 3,021 Austria
- 2,815 Belgium
- 2,216 Norway
- 1,770 Sweden
- 1,420 Denmark
- 1,328 Canada
- 1,306 Malaysia



Cumulative Confirmed Cases | Active Cases

169

countries/regions

Lancet Inf Dis Article: [Here](#). Mobile Version: [Here](#). Visualization: JHU CSSE. Automation Support: [Esri Living Atlas team](#) and [JHU APL](#). Contact US: [FAQ](#).

Data sources: [WHO](#), [CDC](#), [ECDC](#), [NHC](#), [DXY](#), [1point3acres](#), [Worldometers.info](#), [BNO](#), state and national government health department, and local media reports. Read more in this [blog](#).

Downloadable database: [GitHub](#): [Here](#). Feature layer: [Here](#).

Total Deaths

13,407

4,825 deaths Italy

3,144 deaths Hubei China

1,720 deaths Spain

1,556 deaths Iran

562 deaths France

233 deaths United Kingdom

136 deaths Netherlands

104 deaths Korea, South

94 deaths Washington US

93 deaths

Total Recovered

93,790

59,433 recovered Hubei China

7,635 recovered Iran

6,072 recovered Italy

2,909 recovered Korea, South

2,125 recovered Spain

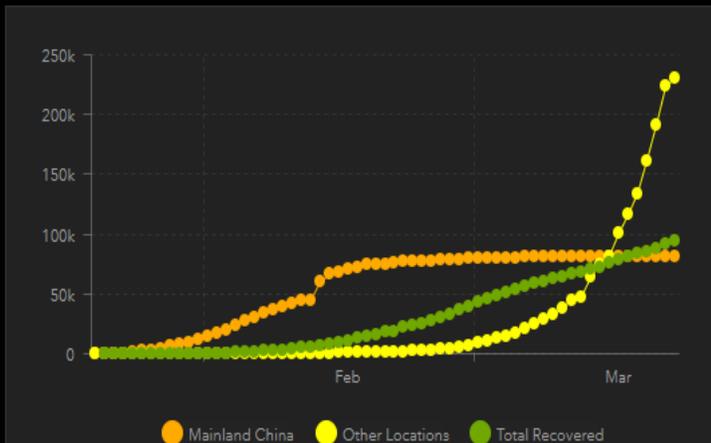
1,329 recovered Guangdong China

1,250 recovered Henan China

1,219 recovered Zhejiang China

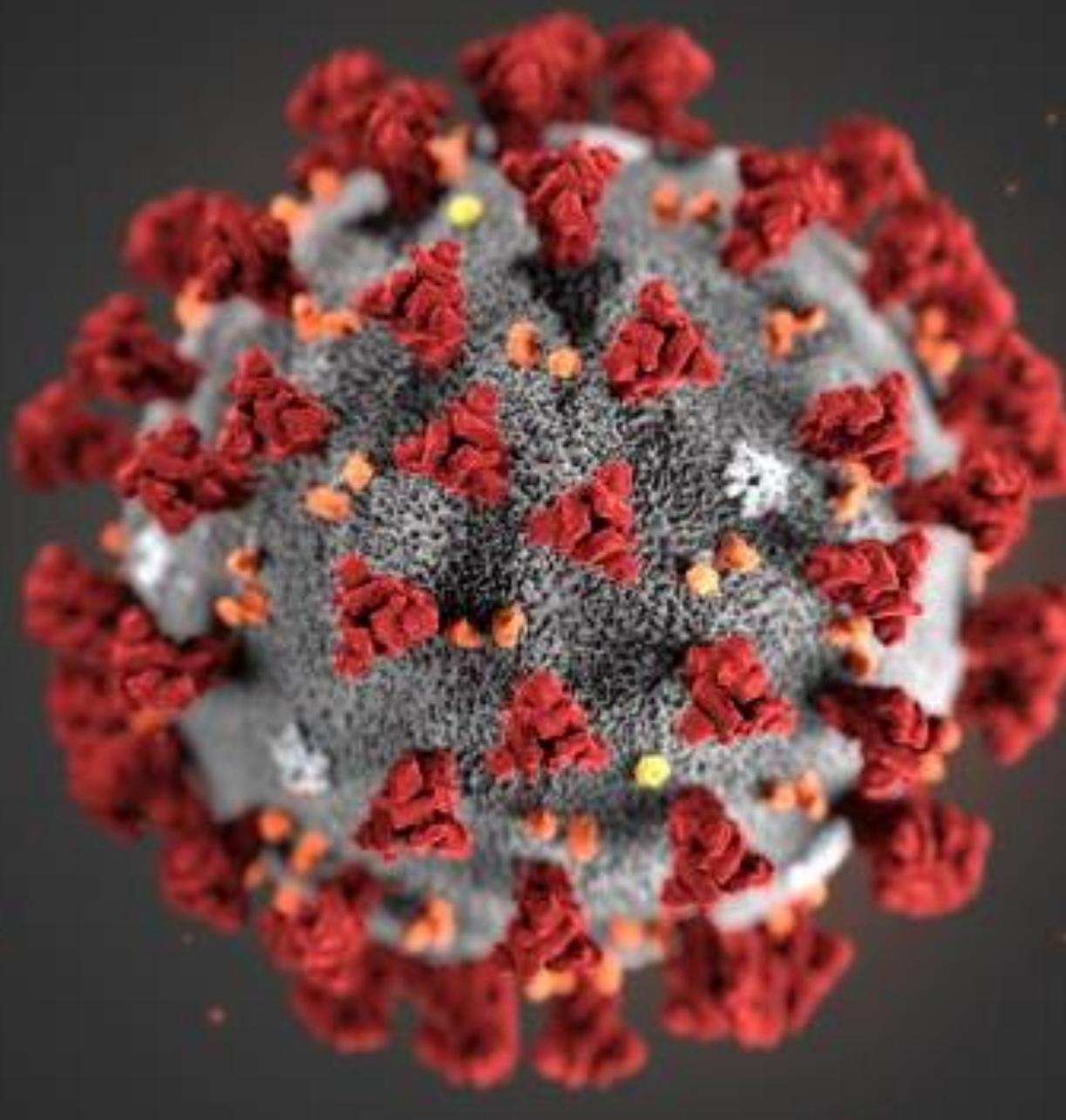
1,014 recovered Hunan China

984 recovered



Actual | Logarithmic | Daily Cases

Last Updated at (M/D/YYYY)  
3/22/2020, 12:43:03 PM



# Disease X: COVID-19

As of 22 March:

**CONFIRMED CASES: 311988**

**DEATHS: 13407**

**RECOVERIES: 93790**

**COUNTRIES: 169**

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.

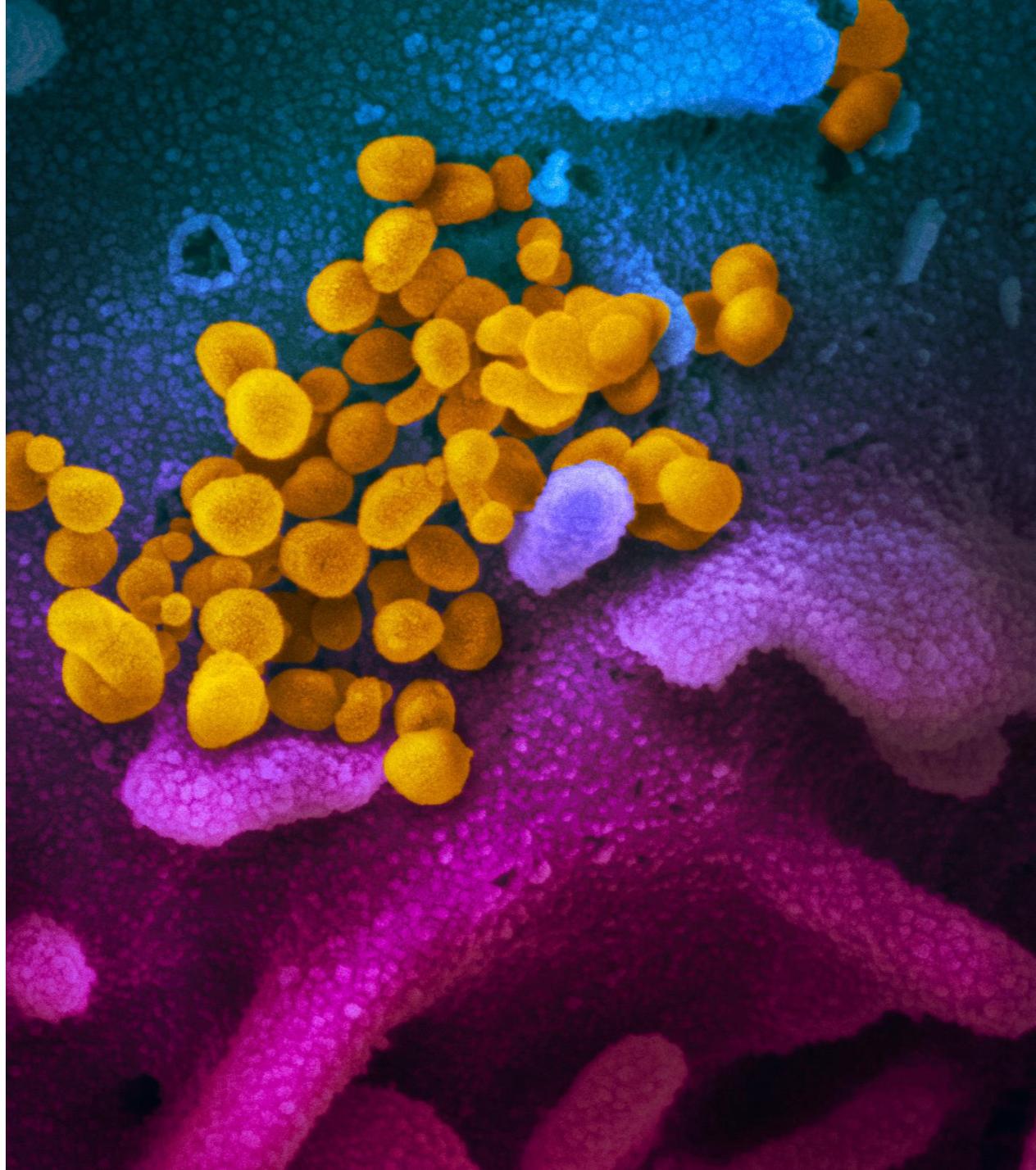
We have initiated several programmes which will leverage our work on MERS and innovative new technologies to speed up vaccine development against COVID-19.

# CEPI's response to COVID-19

We hope to get a vaccine through to clinical testing **in 16 weeks** – this is an extremely ambitious timeline and is unprecedented in the field of infectious diseases. We have already announced the following partnerships and programmes of work:

- **Inovio – Nucleic Acid platform**
- **University of Queensland – Recombinant protein**
- **Moderna – mRNA platform**
- **CureVac - mRNA platform**
- **Novavax, Inc. - recombinant protein nanoparticle technology**
- **The University of Oxford - ChAdOx1 vectored vaccine**
- **The University of Hong Kong - live-attenuated influenza vaccine platform**
- **Institut Pasteur – measles vector**

CEPI



# An Epidemic Cannot Be Defeated Without Access To The Vaccines

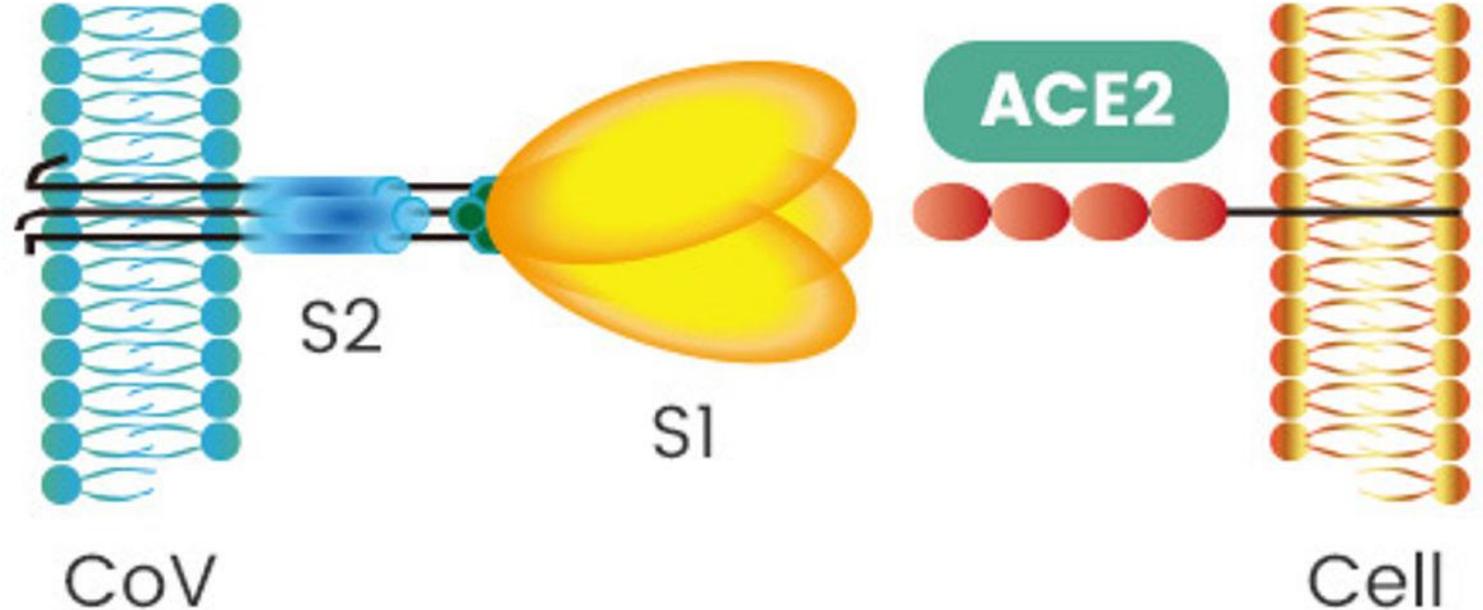
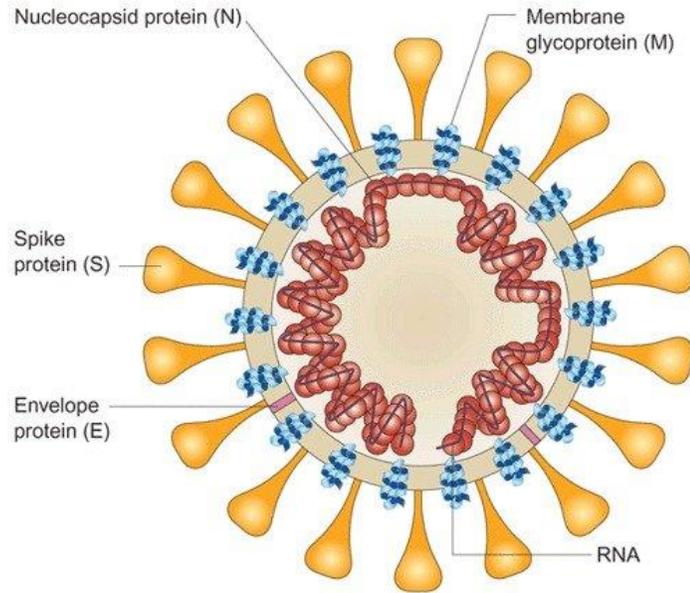
- **Equitable Access:** CEPI has obligation to ensure that *appropriate vaccines are first available to populations when and where they are needed to end an outbreak or curtail an epidemic, regardless of ability to pay*
- **Access to Markets:** CEPI vaccines may be used in areas where final regulatory approvals have not been granted – emergency use – and where regulatory processes not fully developed.
- **Access and Sustainability:** CEPI provides funding for vaccine and platform development and enabling science.
  - We seek to further develop push and pull funding mechanisms for R&D, capacity building and to promote sustainable manufacturing and distribution.

# CEPI's COVID-19 vaccine portfolio diversifies platform technologies, partnership types, geographical presence and risks.

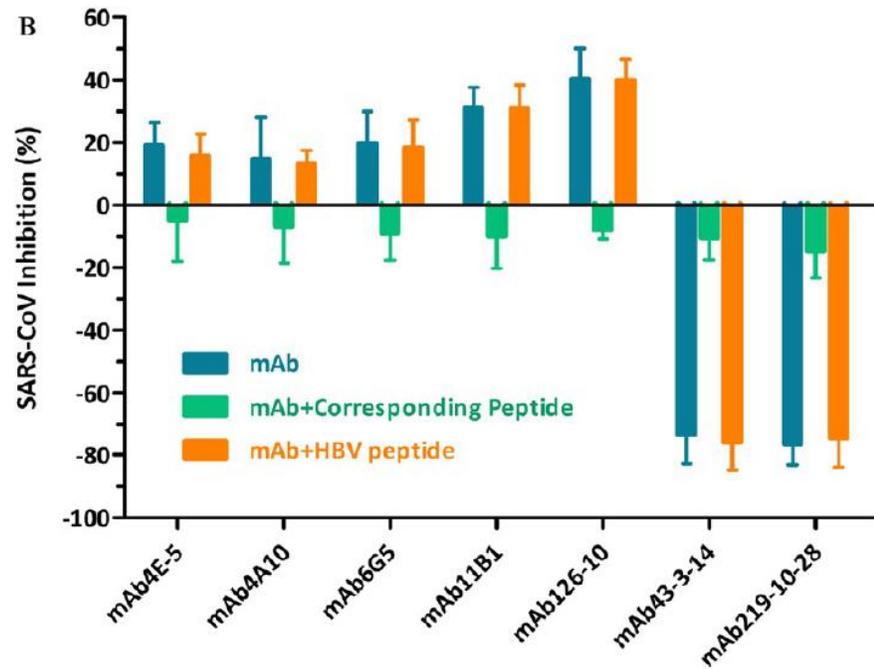
	Total project budget (m\$)	Technology platform	Antigen	Partner type	Geo allocation	Manufacturing scalability (High/medium/low)
	\$8.9m	DNA	Spike-protein	Biotech	USA	Low
	\$21m	mRNA	Spike-protein	Biotech	USA	Medium/High
	\$8.4	mRNA	Spike-protein	Biotech	Germany	Medium/High
	\$2.15m	Protein	Spike-protein	Academic	Australia	Medium/High
	\$12.8m	Nanoparticulate	Spike-protein	Industry	United States	High
	\$46m	Viral vector	Spike-protein	Industry	Belgium	High
	\$12/28m	Viral vector	Spike-protein	Academic/ Industry	France, Germany, India	Medium/High
	\$8.3m	Protein	Spike-protein timer	Biotech (phase 3 staged)	China	Medium/High
	0.35m	Viral vector	Spike-protein	Academic	UK	Low
	0.6m	Viral vector	RBD domain	Academic	Hong Kong	High



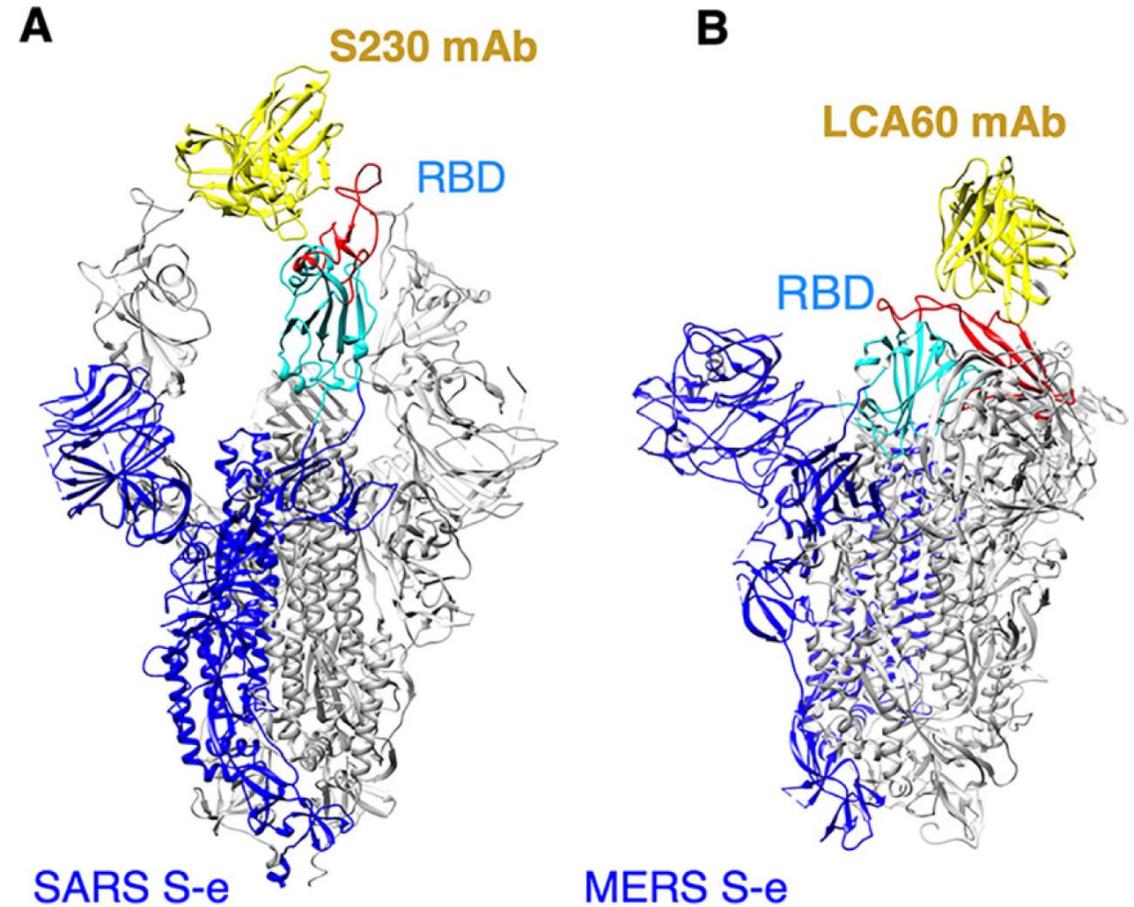
# Virus S protein binds to ACE2 receptor



# Ab to Spike, ADE of disease



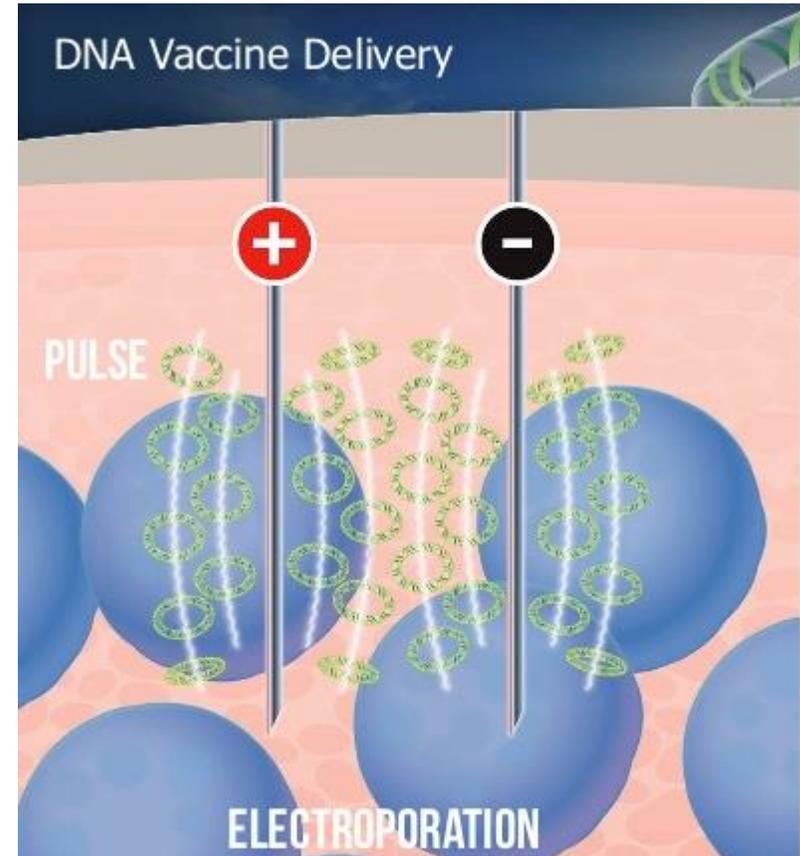
Wang et. al 2016



Wan et. al 2020

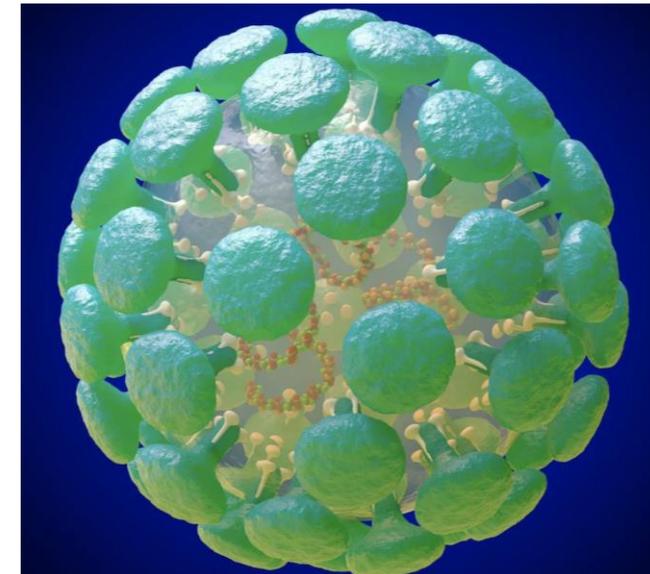
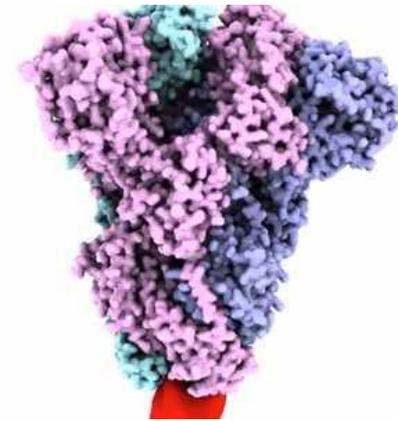
# Inovio (Nucleic acid platform)

- [Date of announcement: 23 January 2020](#)
- Inovio will be working to advance their MERS vaccine candidate using its DNA Medicines platform to deliver optimized synthetic antigenic genes into cells.
- These will then be translated into antigens that activate an individual's immune system to generate a robust immune response



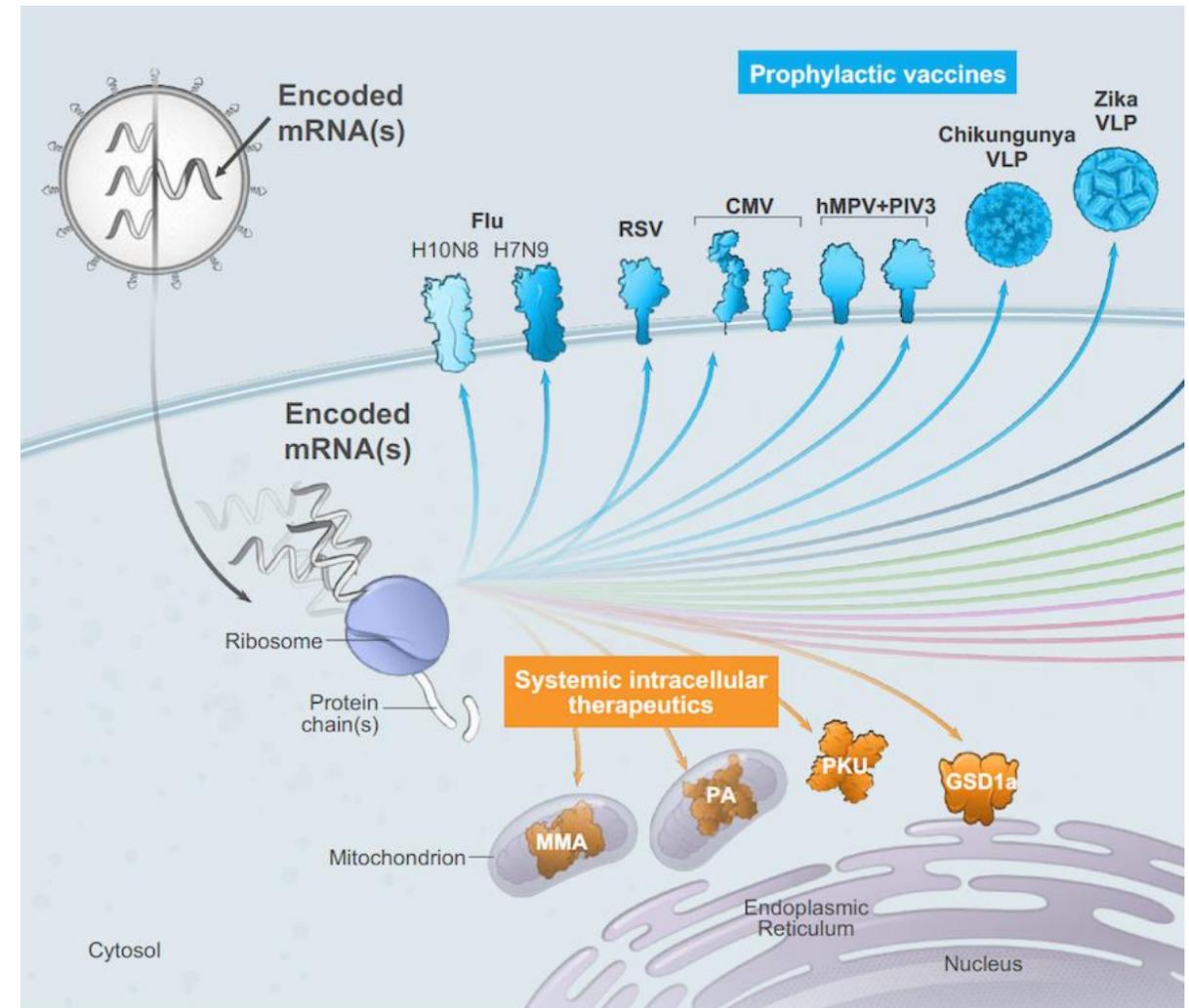
# University of Queensland (recombinant protein)

- [Date of announcement: 23 January 2020](#)
- The University of Queensland’s “molecular clamp” technology works by synthesizing **viral surface proteins** which attach to host cells during infection, and “clamp” them into shape, making it easier for the immune system to
- On Feb 21, the UQ team announced that they had created their first vaccine candidate in the lab and will move immediately into further development before formal pre-clinical testing.



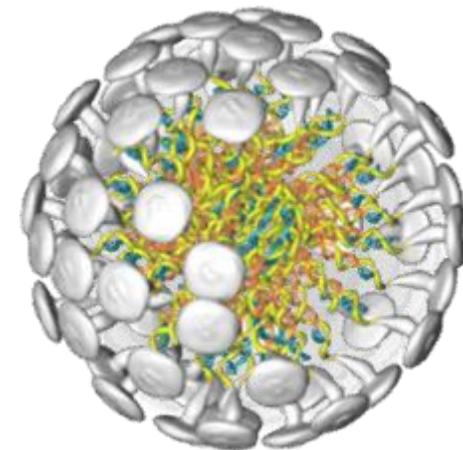
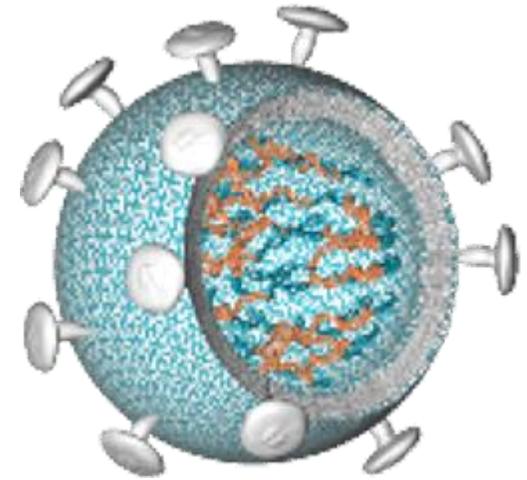
# Moderna (mRNA platform)

- [Date of announcement: 23 January 2020](#)
- Moderna will manufacture an mRNA vaccine against the novel coronavirus and will work with the US National Institute of Allergy and Infectious Diseases to conduct investigational drug studies to decide whether it is safe to progress to the next stage of clinical trials.
- On Feb 25, Moderna announced shipment of vials of their COVID-19 vaccine to NIAID to be used in a planned Phase 1 study in the US.



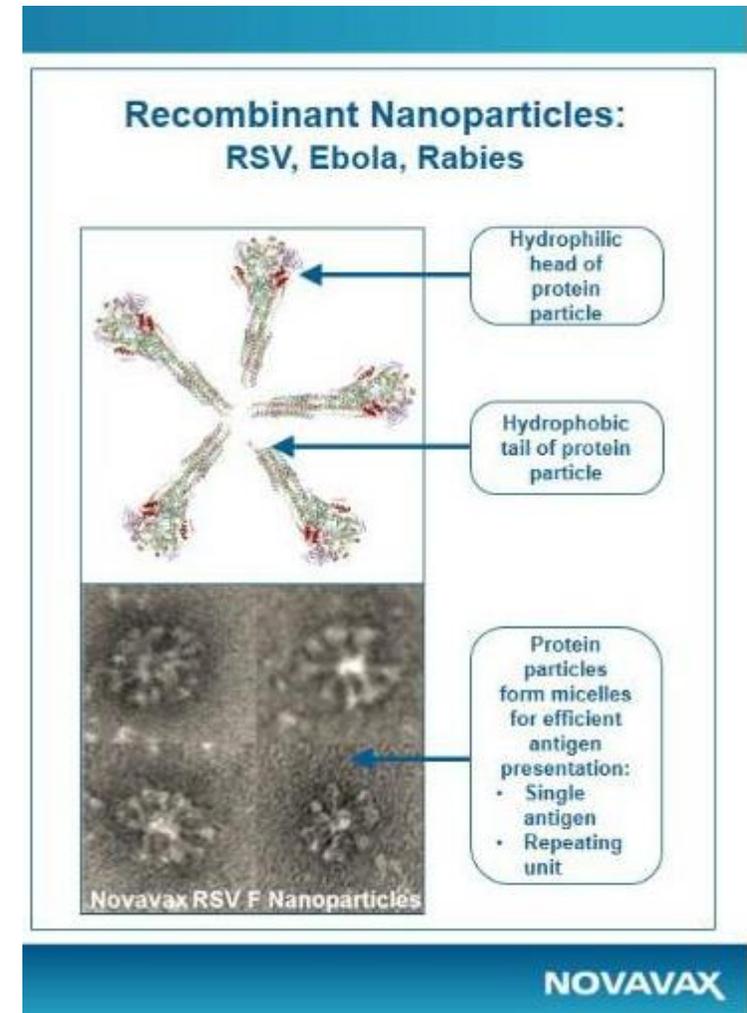
# CureVac (mRNA platform)

- [Date of announcement: 31 January 2020](#)
- CureVac's platform aims to optimize the properties of mRNA therapeutics and vaccines. The technology can be tailored to induce varying degrees of immune responses against antigens of choice, potentially providing potent prophylactic vaccines for the prevention of infectious diseases.
- mRNA in LNP



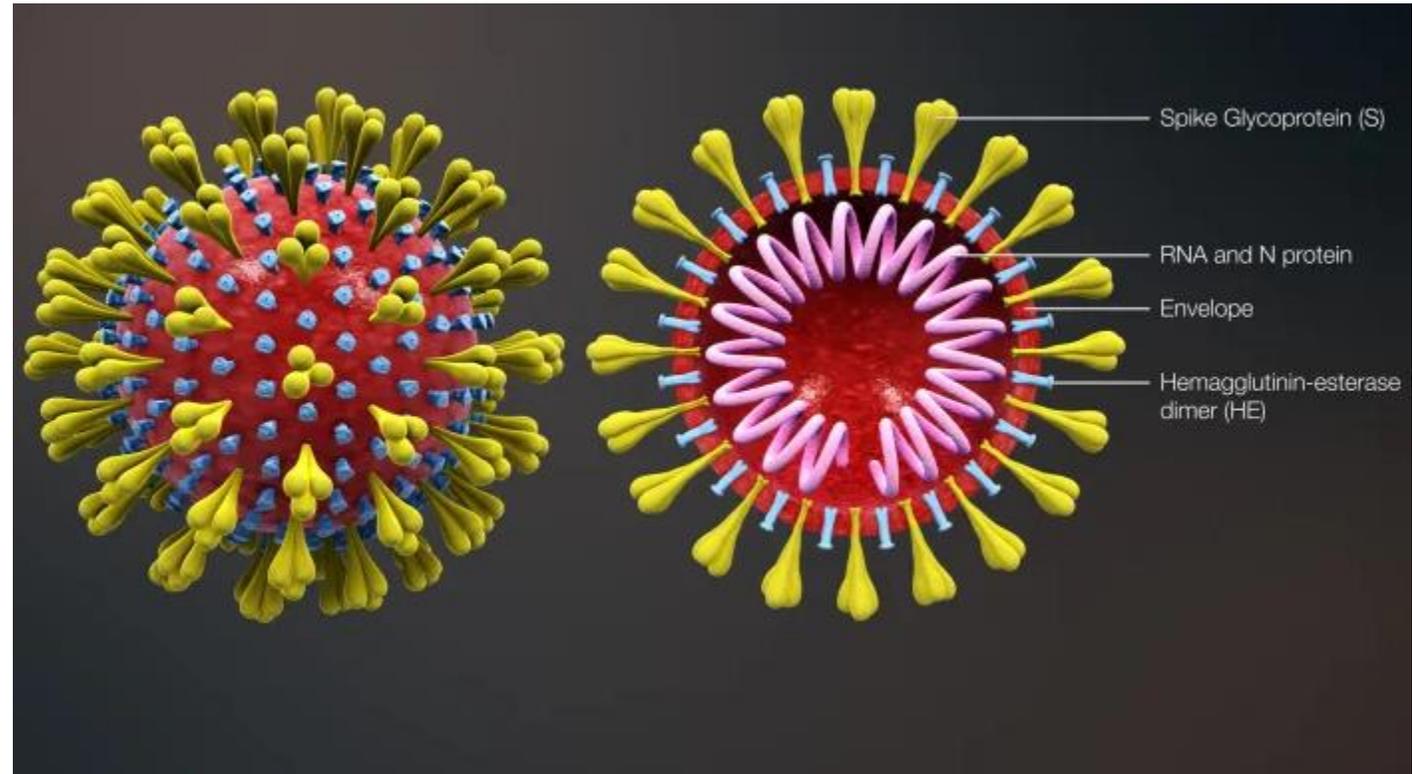
# Novavax, Inc. (recombinant protein nanoparticle technology)

- [Date of announcement: 10 March 2020](#)
- Novavax has produced and is currently assessing multiple nanoparticle vaccine candidates to identify the best candidate(s) for human testing, which is expected to begin by the end of spring 2020
- Novavax is creating COVID-19 vaccine candidates using its proprietary recombinant protein nanoparticle technology platform to generate antigens derived from the coronavirus spike (S) protein. Novavax expects to use its proprietary Matrix-M™ adjuvant with its COVID-19 vaccine candidate to enhance immune responses.
- Novavax has experience in rapid innovative vaccine development against novel emerging viruses, including efforts to develop vaccines against the similar coronaviruses Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS).



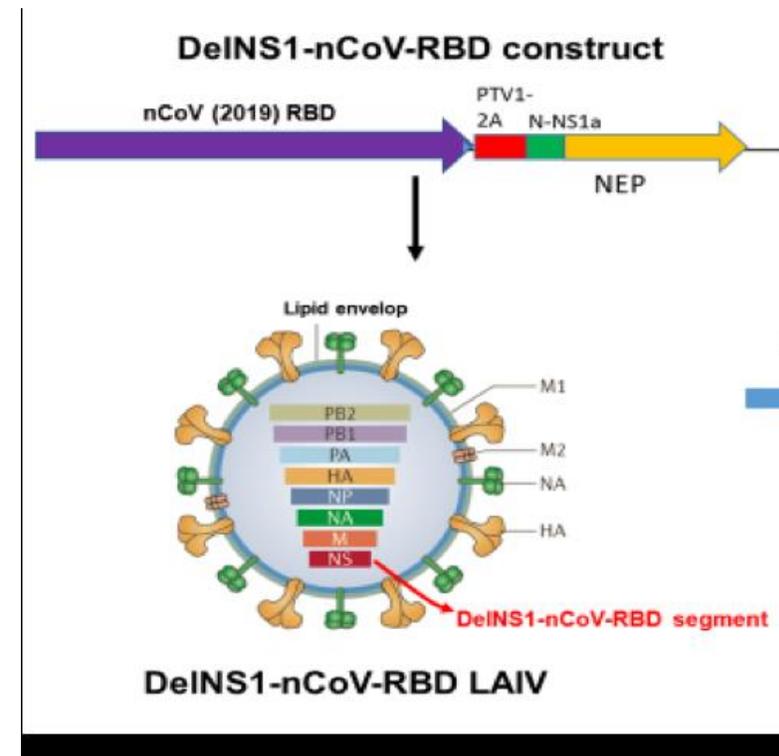
# The University of Oxford (ChAdOx1 vectored vaccine)

- [Date of announcement: 10 March 2020](#)
- ChAdOx1 is a replication-deficient **simian adenoviral vaccine vector**. This vaccine platform has been used to produce vaccine candidates against multiple pathogens, including Influenza, Chikungunya, and Zika.
- In 2018, CEPI provided [up to \\$19 million to Oxford](#) to develop vaccines against Lassa, Nipah, and MERS. Oxford's ChAdOx1 MERS candidate has completed phase 1 studies and a second clinical study is underway in Saudi Arabia.



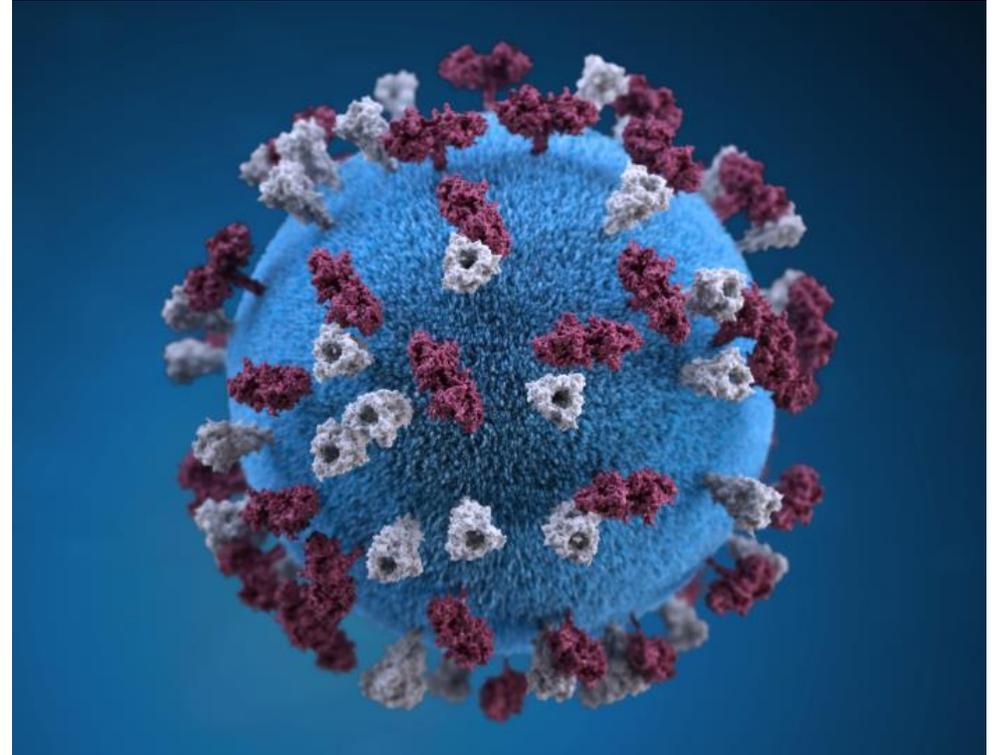
# The University of Hong Kong (live-attenuated influenza vaccine platform)

- [Date of announcement: 18 March 2020](#)
- Researchers at the University of Hong Kong have created a vaccine candidate using a weakened version of the flu virus and have adapted it to express the surface protein of the COVID-19 virus. This approach has previously been used to develop preclinical vaccine candidates against MERS.
- CEPI will provide initial funding to HKU to undertake preclinical testing of their vaccine candidate and will consider additional funding for further clinical testing pending results of these preclinical studies.



# Institut Pasteur, Themis, University of Pittsburgh (Measles vector)

- [Date of announcement 19 March 2020](#)
- Partnering agreement with the Institut Pasteur-led consortium that will include Themis and the University of Pittsburgh to develop a vaccine candidate against COVID-19. This collaboration brings CEPI's total investment in COVID-19 vaccine R&D to US\$29.2 million.
- In a first step, CEPI funding will support the preclinical testing, initial manufacture of vaccine materials, and preparatory work for phase 1 studies.



# What else is needed?

- Live virus
  - Challenge studies (animals)
  - Neutralization studies
- Diagnostics
  - Disease confirmation
  - DIVA?
- Developing standards and assays
  - Serum
  - Cellular
  - Molecular
- Serum samples/antibodies
  - Survivors
  - Standards Pos/neg control

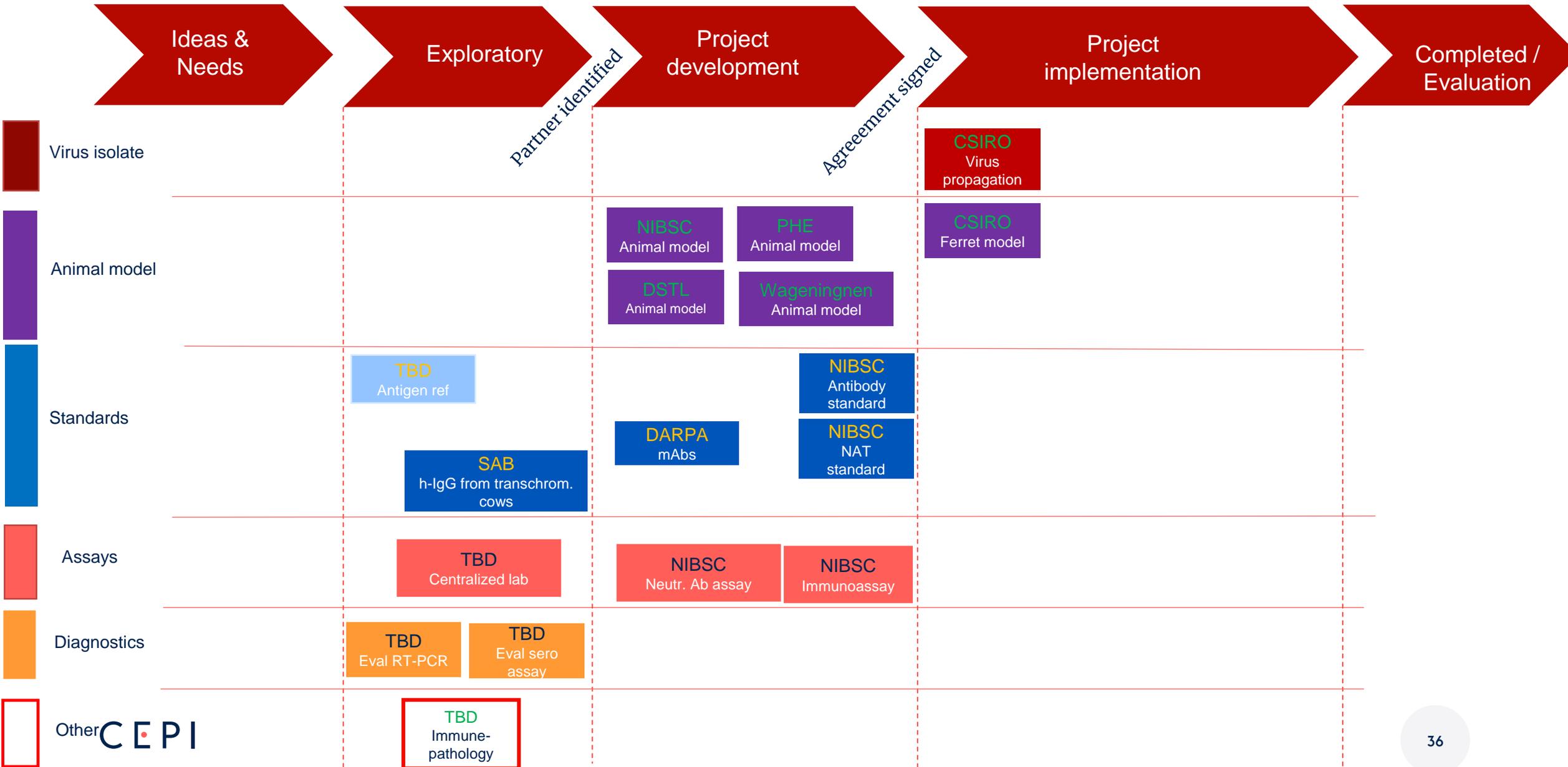


# What else is needed?

- Animal models
  - Ferrets
  - NHPs
- Regulatory requirements
  - Immunology proof of concept
  - Tox studies
  - Animal studies
  - Clinical trial data/Safety database
- Plans for clinical trials
  - Where?
  - Who?
- Testing of vaccine in the population
  - Who? (placebo/vaccine)
  - Where?



# Enabling science projects and activities (COVID-19)



# Equitable access

Equitable access to epidemic vaccines in the context of an outbreak means that:

- appropriate products are **first available** to populations when and where they are **needed**
- to **end an outbreak** or curtail an epidemic,
- regardless of **ability to pay**.



**CEPI**

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