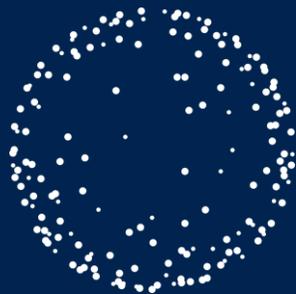


# Sustainable Manufacturing Project

Meeting at DCVMN  
25 June 2019



# A global partnership



# We are a global coalition

- Made up of public, private, philanthropic and civil society organisations
- We will stimulate, finance and coordinate vaccine development for emerging infectious diseases
- We identify priority threats and act when market forces fail to drive needed development
- We will build capabilities for rapid response to unknown threats
- We will move vaccine candidates through late preclinical studies to proof of concept and safety in humans before epidemics begin

# CEPI's investors

CEPI has reached over US\$ 750 million of its \$1 billion funding target.

	Investment	Type of investment
European Commission	€ 200 m	Multi year
Japan	US\$ 125 m	Multi year
Norway	NOK 1.6 b	Multi year
Bill & Melinda Gates Foundation	US\$ 100 m	Multi year
Wellcome Trust	US\$ 100 m	Multi year
Germany	€90 m	Multi year
United Kingdom	£10 m	Single year
Canada	CA\$ 14 m	Multi year
Australia	AU\$ 6.5 m	Multi year
Belgium	€0.5 m	Single year

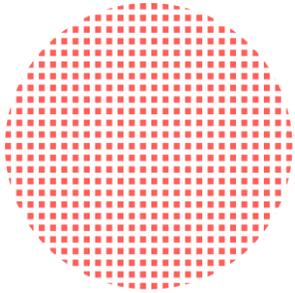
# Our vision

A world in which epidemics are no longer a threat to humanity

# Our mission

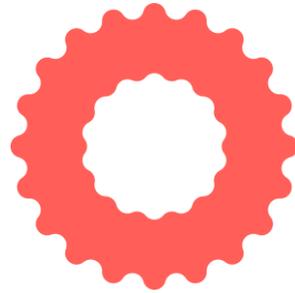
CEPI accelerates development of vaccines against emerging infectious diseases and enables equitable access to these vaccines for affected populations during outbreaks

# Our strategic objectives



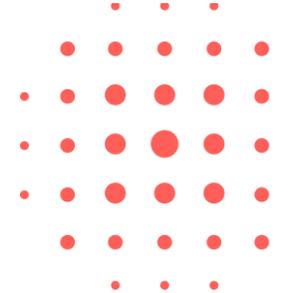
## Preparedness

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

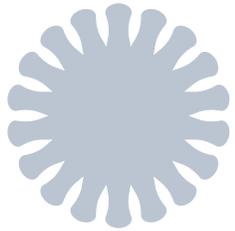
CEPI's role as a facilitator



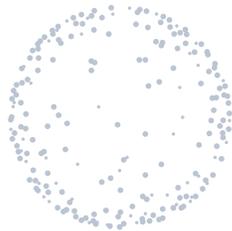
CEPI's role as a funder



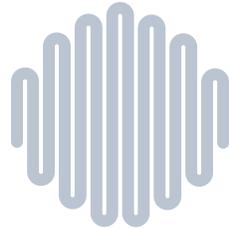
# CEPI's initial priority pathogens



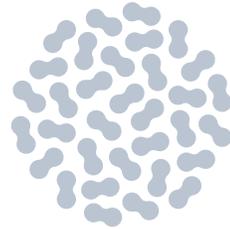
MERS



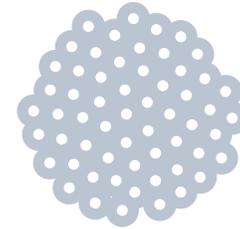
Lassa



Nipah



Chikungunya



Rift Valley  
fever



Disease X

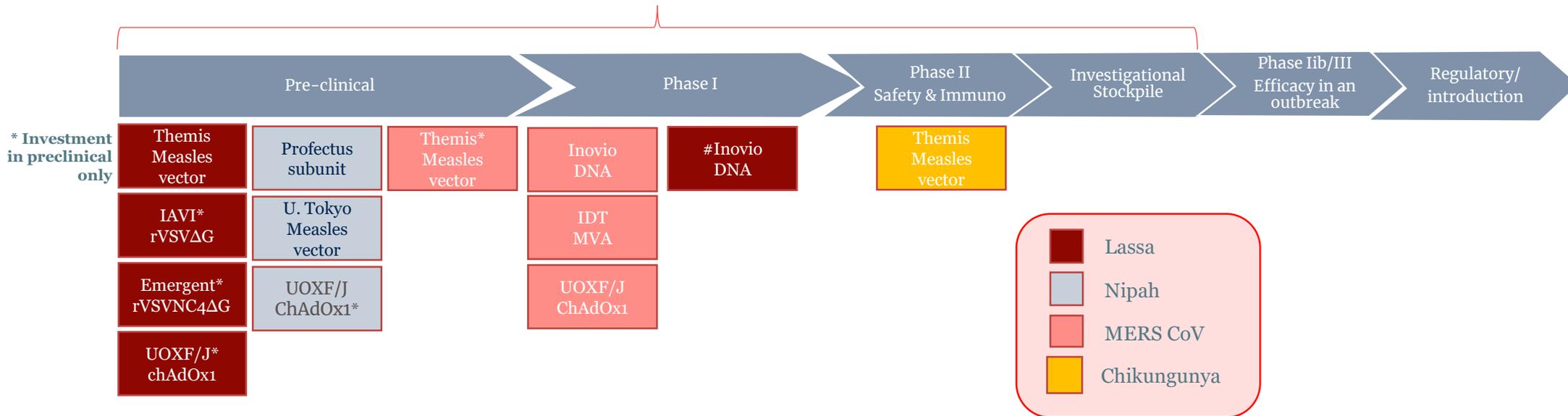
# 12 partnership agreements signed

<b>Themis Bioscience</b>	Lassa & MERS vaccines	Up to \$37.5million
<b>Inovio Pharmaceuticals</b>	Lassa & MERS vaccines	Up to \$56.0million
<b>International AIDS Vaccine Initiative</b>	Lassa vaccine	Up to \$54.9million
<b>Profectus Biosciences, Emergent Biosolutions &amp; PATH</b>	Lassa vaccine	Up to \$36.0million
<b>Profectus Biosciences, Emergent Biosolutions &amp; PATH</b>	Nipah vaccine	Up to \$25.0million
<b>IDT Biologika</b>	MERS vaccine	Up to \$36.0million
<b>Janssen Vaccines &amp; University of Oxford</b>	MERS, Lassa and Nipah vaccine	Up to \$19.0million
<b>University of Tokyo</b>	Nipah vaccine	Up to \$31.0million
<b>Imperial College London</b>	saRNA platform (Rabies, Marburg, 'Flu)	Up to \$8.4million
<b>University of Queensland</b>	Molecular clamp platform (MERS, RSV, 'Flu)	Up to \$10.6million
<b>CureVac</b>	RNA platform (Rabies, Yellow Fever, Lassa)	Up to \$34.0million
<b>Themis Bioscience</b>	Chikungunya vaccine	Up to \$21.0 million

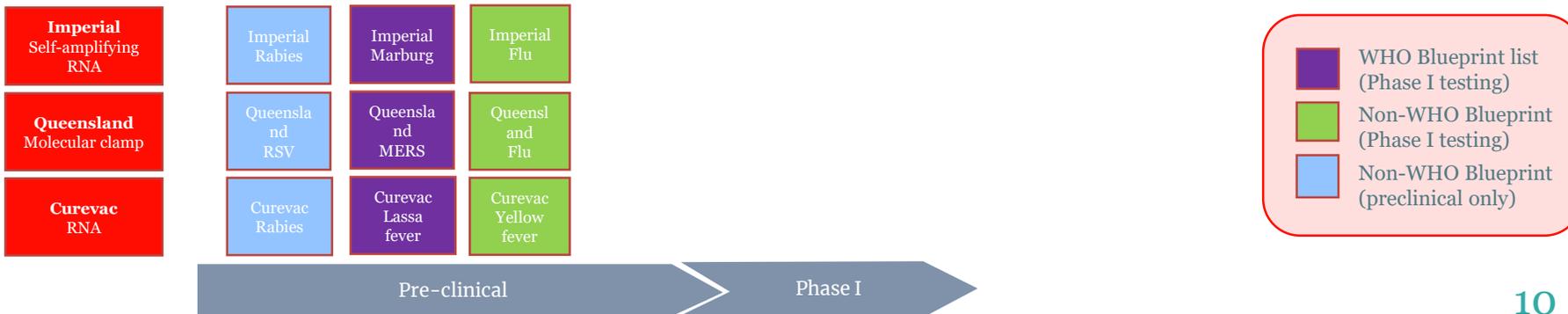
# CEPI priority pathogen and platform portfolio

Note: The diagram indicates where the projects are currently.

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



## Awardee/Platform



#NCT03805984

Version 22/05/19

# Calls for proposals

# Just in case vaccines: MERS, Lassa, Nipah

- More than 30 proposals received
- Applications from:
  - 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

# Just in case vaccines: Chikungunya and Rift Valley fever

- Call for proposals launched Jan, 2019.
- Rift Valley fever disease is included among the WHO R&D Blueprint list of priority pathogens in 2018, while Chikungunya is deemed to present a major public health risk where further R&D is needed.
- The decision to fund the development of vaccines against Rift Valley fever and Chikungunya is based on the feasibility of vaccine development and the potential public health impact of vaccines against these diseases.
- Funding will be provided by CEPI with support from the European Commission's Horizon 2020 programme.

# Just in time vaccines: platform technologies

- CEPI supports development of 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
  - 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 phase I)
  - 6 weeks to clinical benefit after 1st dose
  - 8 weeks to produce 100,000 doses after go-decision

# Epidemic response

## Learning to accelerate vaccine development, Lassa, 2018

- Even when vaccine candidates are not ready for trials, CEPI must ensure that critical information is collected, with the goal of accelerating vaccine development
- Epidemiology, good diagnostic tests, correlates of protection are all critical to vaccine development and trial design
- CEPI-WHO collaboration leverages work of WHO's R&D Blueprint and new response structure to accelerate vaccine development
- CEPI will contribute to strengthening in-country research capacity to conduct vaccine trials, between and/or during epidemics

# Sustainable Manufacturing Project

# Background

The Sustainable Manufacturing Group was initiated in 2018 as a sub-group of the JCG\* to evaluate potential sustainable manufacturing scenarios for epidemic vaccines. CEPI board accepted the following recommendations in December 2018:

1. Engage epidemiology research groups to model epidemiology of targeted diseases to better understand stockpiling requirements
2. Engage with CMOs, MNCs, DCVMs, equipment manufacturers, etc. to secure needed capacities for CEPI
3. Engage end users, regulators and any relevant authorities to define the minimum requirements for drug product presentation/stability criteria
4. Develop an “end-to-end” supply chain model
5. Explore which CEPI vaccine development and manufacturing processes can be standardized
6. Explore possible new business models, clarify funding requirements, identify financing solutions

# Summary – “The elevator pitch”

It is CEPI’s goal to facilitate vaccine supply to impact epidemic events. We are funding clinical development to that end and need to prepare for supply of vaccine for those development programs that are successful.

The sustainable manufacturing project consists of modelling the supply of vaccines (supply side), modelling the epidemiology of the CEPI priority diseases (demand side), evaluating potential manufacturing network to secure capacity for manufacturing and stockpiling to ensure flexibility, affordability and reliable supply.

We are focused on making sure the products exist when needed by our global health partners. Building manufacturing capacity has very long lead time therefore scenarios for manufacturing capacity need to be worked on very early

# Scope – “The elevator pitch”

In order to design sustainable manufacturing solutions, we need to design a supply chain for late phase clinical trial materials (mid term) and for licensed CEPI sponsored products (long term)

The rationale of including both late clinical trial materials and licensed products is due to the **current partnerships of CEPI**: multi-institutions partnerships that have little or no late phase manufacturing, regulatory and supply know how (startups, academic institutions, etc) . We partner with our stakeholders in the global health (WHO, UNICEF, GAVI, MSF, ICRC, etc) to ensure the solution integrates with the current emergency operations.

# Project Structure

Structured into a Steering Committee and 4 workstreams



# Scope

## 1. Manufacturing and Supply Chain Modelling

- To develop an end-to-end supply chain model. To undertake scenario modelling exercises to understand the most appropriate supply chain design to ensure timely delivery of the CEPI target pathogen vaccines

## 2. Epidemiology and Vaccine Demand Curve Modelling

- To develop epidemiology scenario models:
- To understand estimates for vaccine manufacturing for a) stockpile needs to prevent widespread outbreaks and b) outbreak response for CEPI target pathogens (Lassa, MERS, Nipah and now Chikungunya and Rift Valley Fever)
- To estimate vaccine demand curve needs across a number of different outbreak scenarios and different vaccination responses.
- To develop a modelling approach that can be modified for use in estimating CEPI vaccine demand for other pathogens

# Scope (2)

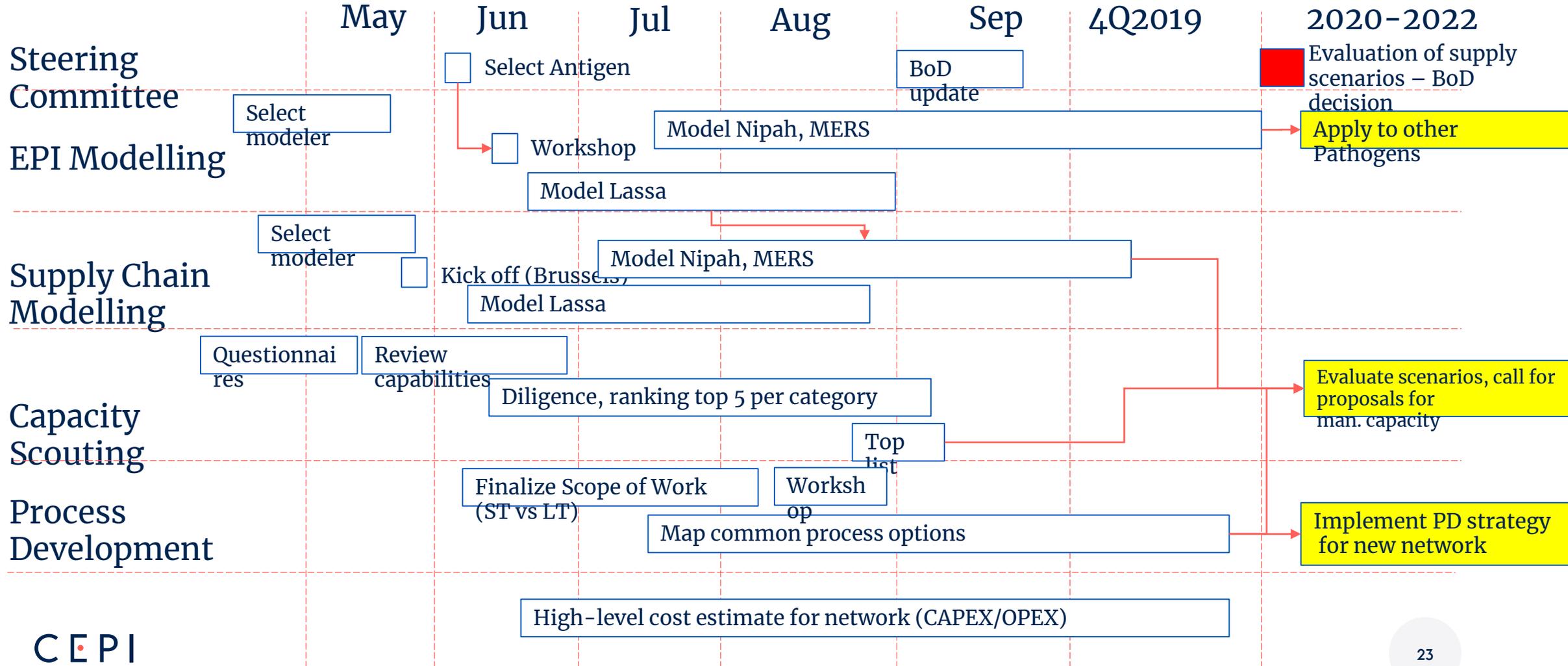
## 3. Manufacturing Capacity Scouting

- To identify manufacturing partners with available capacity for all CEPI products with a GMP quality level to meet WHO PQ or EMEA/FDA licensure.
- To evaluate whether manufacturing capacity is available or if we would need to build capacity and manufacturing
- To provide an initial financial evaluation on setup costs and running costs for stockpile maintenance

## 4. Vaccine Process Design

- To simplify and harmonise CEPI vaccine manufacturing processes
- To simplify technology transfer to LMIC manufacturers to increase worldwide capacity
- To limit diversity of facilities and leveraging common material inventories for multiple targets.

# Sustainable Manufacturing Project



# Next Steps

1. Supply chain and epidemiology modelling results for Lassa : end of August
2. Supply chain and epidemiology modelling results for MERS and Nipah : October 2019
3. Evaluation of Chikungunya and Rift Valley Fever demand and supply : December 2019
4. Down-selection and network design options with 4-5 companies per technology, decision to hire capacity or to build capacity : end of August.
5. Integration of CEPI partners on financing and funding solutions (4Q 2019-1Q2020)
6. Open Request for information to internet / media / social networks: 3Q2019
7. Call for Proposal for Sustainable Manufacturing in 1-2Q 2020

# Thank You

