

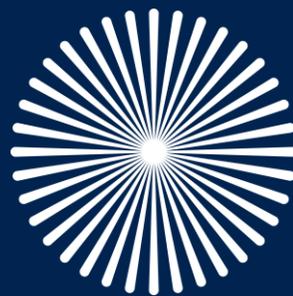
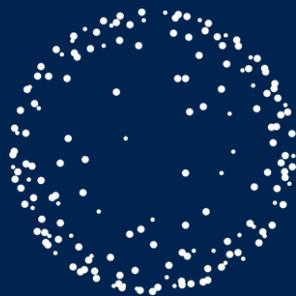
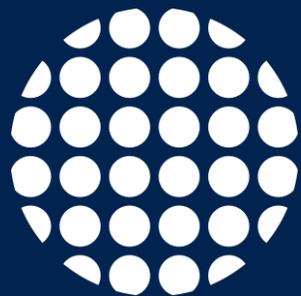
**International Cooperation on Economic Resilience:  
a World Trade Organization Webinar**



“The role of public-private-philanthropic partnership in research and development in vaccines”

Richard Wilder

General Counsel and Director of Legal and Business Development Affairs



**29 April 2021**

**Outbreaks of emerging infectious diseases are increasing in *frequency* and *severity*.**

**The devastating COVID-19 pandemic shows that we need to be better prepared.**

# The West Africa Ebola Outbreak (2014-2016)

**11,000+**

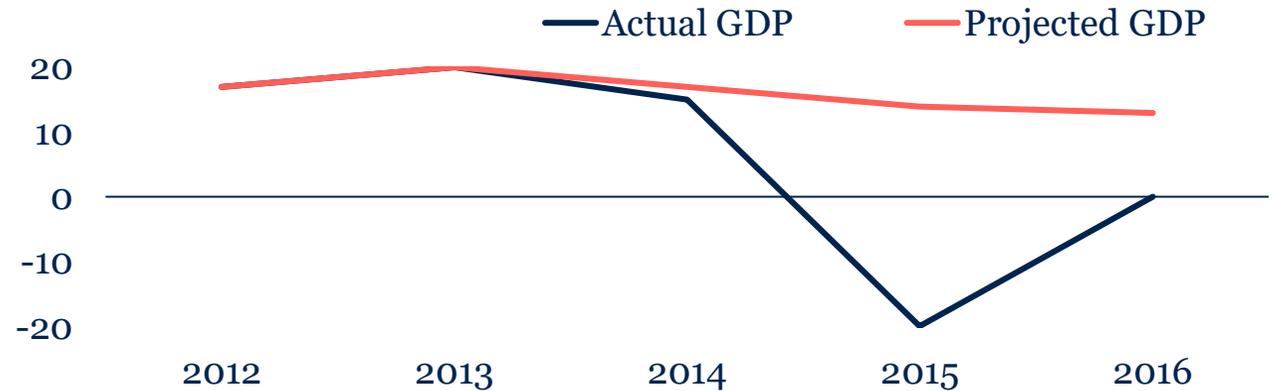
Deaths

**\$53 bn**

Estimated negative economic impact of 2014 outbreak in west Africa (Huber C et al, 2018)

CEPI

Impact on the GDP (%) of Sierra Leone



Devastating 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

# The Creation of CEPI



# A global partnership

OUR MISSION

OUR APPROACH

## Mission

To accelerate the development of vaccines and other biologic countermeasures against epidemic and pandemic threats so they can be accessible to all people in need.

Governments



Pharmaceutical industry



# CEPI

*A Global Partnership*

CEPI's unique connecting role and extensive networks allow it to pool and deploy resources in ways that nation states often cannot.

Regulators



Academia



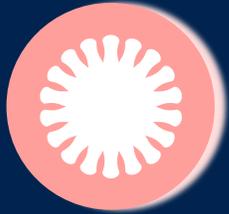
Philanthropies



Civil society and health organisations

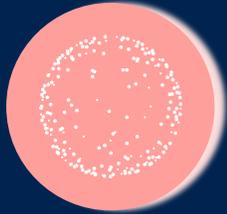


# CEPI's vaccine portfolio



MERS

5 vaccine candidates



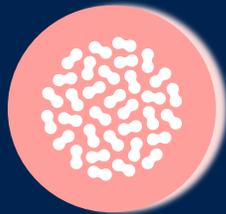
Lassa

6 vaccine candidates



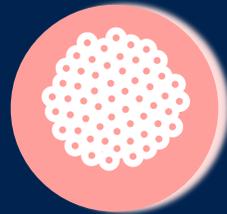
Nipah

4 vaccine candidates



Chikungunya

3 vaccine candidates



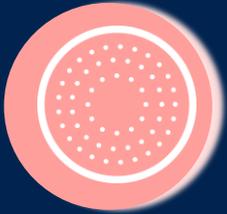
Rift Valley  
fever

2 vaccine candidates



COVID-19

12 vaccine candidates  
– 10 in active dev.



Disease X

3 platform technologies

# The challenge of global COVID-19 vaccine development, manufacture and access



Due to the accelerated case count and novel variants, demand for COVID-19 vaccines outstrips supply. Every country on the planet needs access to vaccines at the same time, to protect their most vulnerable populations.



The 'business as usual' model of vaccine development and procurement is not sufficient.



Making vaccines available to those who need them most is the fastest, as well as the fairest, way to bring the pandemic to an end.

# The solution: COVAX



COVAX is the only solution which will deliver fair, equitable and necessary access to vaccines for every country that participates.



Together we aim to produce 2 billion doses of vaccine and distribute them globally and fairly in 2021.



COVAX works by pooling financial resources to purchase vaccines at scale, sharing the risks associated with developing vaccines and investing up-front in manufacturing so that vaccines are ready to be distributed as soon as they are licensed.

# Disease X: The potential to jump species



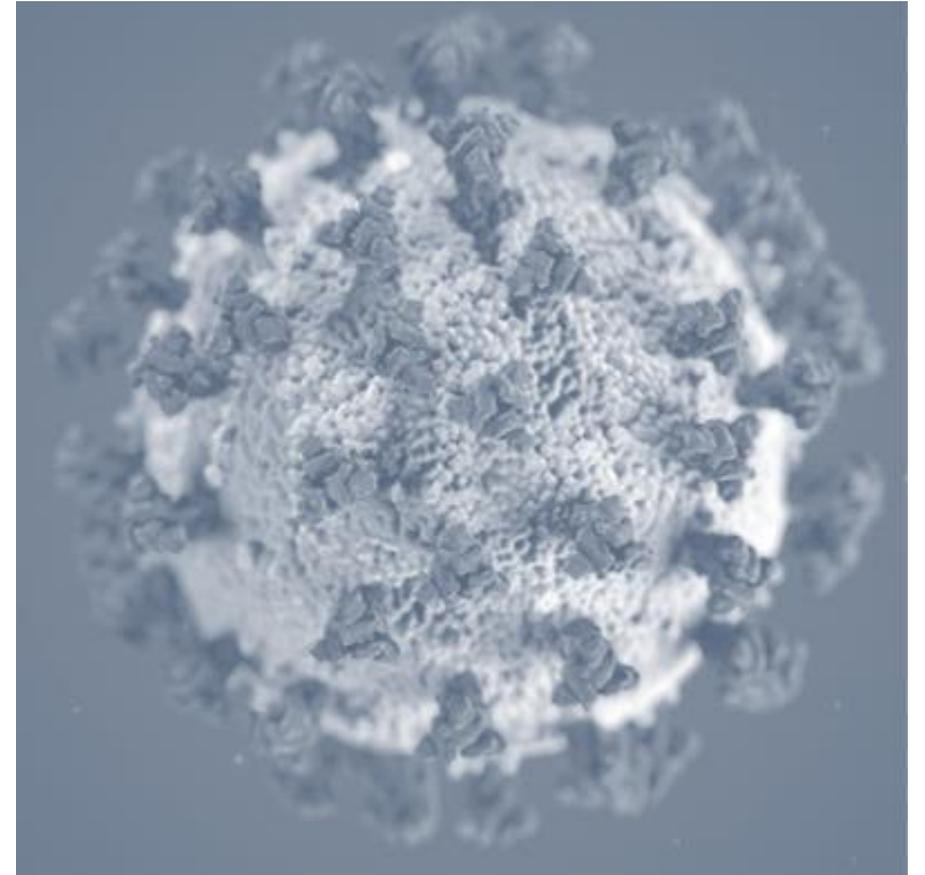
This is not the first pandemic of the 21<sup>st</sup> century and it will not be the last.



We don't know where or when Disease X will emerge, but we know that it will.



Zoonotic spillover events – viruses jump from animals to humans – have caused some of the world's most deadly outbreaks – HIV, Ebola, SARS, and likely COVID-19.



# CEPI 2.0 Mission

1

## Prepare

1. Strengthen our defences against COVID-19 and reducing the risk of future coronavirus pandemics
2. Develop vaccines for known threats

2

## Transform

3. Produce a library of vaccines and other biological interventions
4. Work to compress vaccine development timelines to 100 days

3

## Connect

5. Establish global networks for lab capacity, assays, and preclinical models
6. Support the efforts of LMICs to take full ownership of their national health security

## COVAX Manufacturing Taskforce:

- **Growing focus on improvement of global vaccine manufacturing & supply chain:**
  - 8-9 March 2021 – CEPI co-convened the “*Global Vaccine Supply Chain & Manufacturing Summit*”
  - 13 April 2021 – CEPI and the African Union have today entered into an MOU to boost African vaccine R&D and Manufacturing
  - 14 April 2021 - WTO Event: COVID-19 and Vaccine Equity: What Can the WTO Contribute? (Richard Hatchett (CEPI CEO) spoke on “Vaccine Manufacturing Capacity”)
- Work begun to create COVAX Manufacturing Task Force:
  - **Immediate supply issues impede equitable access** through the COVAX facility and require immediate attention, actionable solutions, and thorough implementation
  - **Broader ecosystem is preparing supply and manufacturing challenge solutions** which need to be coordinated for short-, medium-, and long-term impact – significant focus on increasing regional autonomy beyond COVAX

# Proposed Focus Areas for Manufacturing Task Force

	Aspiration	Impact
1	<p><b>Immediate COVAX Response</b></p> <ul style="list-style-type: none"> <li>Implement selected summit solutions with immediate impact (<i>e.g., accelerate export permits for bottleneck input supplies, support supply ramp up</i>)</li> <li>Create voluntary partnership with focus on input supply and demand visibility between core COVAX manufacturers and suppliers (with potential expansion to match making)</li> <li>Establish match making mechanisms for Fill &amp; Finish capacity connecting CMOs and manufacturers to alleviate bottlenecks</li> </ul>	<p><b>Short-term COVID-19 impact</b></p>
2	<p><b>Mid-term COVAX Response</b></p> <ul style="list-style-type: none"> <li>Utilize existing global capacities by, for example, supporting project and voluntary tech transfers to existing sites for approved and partner portfolio pipeline products</li> <li>Consolidate survey efforts and convene regional summits to create an overview of available and planned manufacturing capacities across regions</li> <li>Stimulate CMC, regulatory and manufacturing workforce development</li> </ul>	<p><b>Mid-term COVID-19 impact</b></p>
3	<p><b>Long-term Initiate regional health security through sustainable manufacturing and innovation</b></p> <ul style="list-style-type: none"> <li>Building capacity in selected LMICs by establishing new facilities and/or expanding existing facilities, through appropriate mechanisms such as technology transfer hubs.</li> <li>Develop normative policy frameworks. Enhance regional and national regulatory platforms.</li> <li>Stimulate manufacturing innovations and investments, incl. by all governments, that can accelerate pandemic response and adoption for the production of routine vaccines</li> <li>Facilitate and support member states to establish optimal and sustainable regional health security.</li> </ul>	<p><b>Long-term COVID-19 and beyond impact</b></p>
0	<p><b>Shared fact base / platform</b></p> <ul style="list-style-type: none"> <li>Map input supply and manufacturing initiatives driven by ecosystem and identify white spots and overlaps to be addressed</li> <li>Document learnings and facilitate exchange across focus areas</li> </ul>	<p><b>Common fact base to be used by all 3 workstreams</b></p>

# Mid-term COVAX Response

*“Which initiatives can be pursued by the manufacturing taskforce that lead to mid-term COVID-19 impact (next 3-12 months)?”*

**Utilize existing global capacities by supporting existing projects and for example tech transfers**

Convene technology transfer fora for CMOs and manufacturers to share best practices and enable fast ramp-up for players scaling or transitioning to COVID-19 vaccine production

Build voluntary tech transfer best practice sharing platform

Create industry-wide expert registry

Support technology transfers to existing sites for approved and partner-pipeline products

Streamline and harmonize CMC post-approval change regulatory practices to ease tech transfers

**Create manufacturing capacity transparency via survey and summits**

Consolidate existing and upcoming surveys to map drug substance and fill/finish capacities across regions and understand requirements for surge scaling

**Manufacturing workforce development**

Define additional CMC and manufacturing workforce need by geography

Define mechanisms to upskill and enlarge CMC and manufacturing workforce

Launch mechanisms to upskill and enlarge CMC and manufacturing workforce

## Suggested Leads



## Suggested Contributors



1. Full implementation of initiatives can take several years

- Consistent with the summary by WTO DG Okonjo-Iweala of the 14 April WTO event:
  - Pinpoint the obstacles, particularly the trade-related obstacles, to ramping up production, and to equitably distributing and administering vaccines and look at how the WTO could contribute to these solutions.
  - Collaborate to increase and to scale up manufacturing through sharing technology and knowhow financing additional manufacturing capacity.
  - Think about the road ahead, addressing IP issues and incentives for research and development, so that the world gets needed medical technologies.
- CEPI and COVAX are following this call through a specific engagement with the WTO and World Customs Union
- CEPI and COVAX are also following this call through our own work programs and vaccine and vaccine platform development efforts and collectively through the manufacturing task force
- COVID-19 has led to rapid and fundamental assessments of what we do and how we work together – in the case of COVAX to develop and deliver vaccines, in particular to LMICs.
- The current systems have proven to be resilient – rapid repurposing to meet the challenge.
- But reliance in the future requires making the necessary changes durable and sustainable to meet the challenges ahead when we are next tested.

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**[www.cepi.net](http://www.cepi.net)**

**@CEPIvaccines**