

Vaccine Development in a Crisis Situation:  
The roles of BARDA and CEPI in Developing Vaccines  
against Pathogens of Pandemic Potential  
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Course Number PB-VI01P: Development of a Vaccine During a Pandemic  
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Conflicts of Interest: None

# Department of Health and Human Services

- National Institutes of Health (NIH) – mainly supports investigator-initiated research, generally open ended and not targeted.
- Biomedical Advanced Research and Development Authority (BARDA) – established in 2006, responsible for the procurement and development of medical countermeasures, principally against bioterrorism and pandemics. An official interface between the U.S. federal government and the biomedical industry.

# Biomedical Advanced Research and Development Authority

- Product-driven approach supporting transition of experimental vaccines from research through advanced development towards FDA approval and inclusion into the Strategic National Stockpile.
- Support ranges from a clinical research organization network to Centers for Innovation in Advanced Development and Manufacturing, and a fill-finish manufacturing network.

# BARDA – COVID-19 Vaccine Projects

- AstraZenca - AZD1222 vaccine - replication-deficient simian adenovirus vector ChAdOx1 with Spike protein. \$1.2B
- Moderna - mRNA based vaccine encoding a pre-fusion stabilized Spike protein. ~\$500M
- Merck + IAVI - Recombinant vesicular stomatitis virus (VSVΔG)-vectored vaccine expressing the spike protein. \$38M
- Sanofi-Pasteur - Recombinant spike protein with deleted transmembrane region. ~\$31M
- Jansen (J&J) - non-replicating Adenovirus 26 – spike protein vaccine. viral-vector vaccine. ~\$457M

<https://www.medicalcountermeasures.gov/app/barda/coronavirus/COVID19.aspx>

<https://www.sciencemag.org/news/2020/03/1-billion-bet-pharma-giant-and-us-government-team-all-out-coronavirus-vaccine-push>

# The Coalition for Epidemic Preparedness Innovations (CEPI)

- Global partnership between public, private, philanthropic, and civil society organizations to accelerate development of vaccines against emerging infectious diseases and enable equitable access to these vaccines during outbreaks.
- Launched in 2017. Headquartered in Oslo, Norway.

# Development of CEPI

- Concept outlined in 2015 NEJM paper "Establishing a Global Vaccine-Development Fund", by Jeremy Farrar, Stanley Plotkin and Adel Mahmoud.
- Concept expanded at the 2016 World Economic Forum as a solution to the problems encountered in developing and distributing a vaccine for the Western African Ebola virus epidemic.

# Development of CEPI

- At the 2016 World Economic Forum:
  - Bill Gates said: "The market is not going to solve this problem because epidemics do not come along very often — and when they do you are not allowed to charge some huge premium price for the tools involved".
  - Sir Andrew Witty, CEO of GlaxoSmithKline commented, "It is super-disruptive when the red phone rings in our vaccine division because of a health emergency. People do not realize that there's no spare capacity in the world's vaccine production system today".



# CEPI Missions

1. Advance vaccines against known threats through proof-of-concept and safety testing in humans and will establish investigational vaccine stockpiles before epidemics begin—“just in case”.
2. Fund new and innovative platform technologies with the potential to accelerate the development and manufacture of vaccines against previously unknown pathogens (eg: within 16 weeks from identification of antigen to product release for clinical trials)—“just in time”.
3. Support and coordinate activities to improve our collective response to epidemics, strengthen capacity in countries at risk, and advance the regulatory science that governs product development.

# CEPI Investors and Partners

Founded by Norway and India, the Bill and Melinda Gates Foundation, the Wellcome Trust, and the World Economic Forum.

Additional support from the European Commission, Australia, Belgium, Canada, Denmark, Ethiopia, Germany, Japan, Mexico and the United Kingdom.

The COVID-19 vaccine programs have garnered \$1.4 B from Austria, Australia, Belgium, Canada, European Commission, Finland, France, Greece, Germany, Italy, Japan, Luxembourg, Kingdom of Saudi Arabia, Norway, the Netherlands, New Zealand, Serbia, Spain, Switzerland, the United Kingdom private sector companies.

<https://cepi.net/covid-19/>

Accessed June 21, 2020

# **CEPI Funded COVID-19 Vaccine Projects as of June 5, 2020**

**Curevac, Inc.**

**Inovio Pharmaceuticals Inc.**

**Moderna, Inc.**

**Novavax, Inc.**

**The University of Queensland**

**The University of Hong Kong,**

**The University of Oxford,**

Consortium led by **Institut Pasteur,**

**Clover Biopharmaceuticals**

[https://cepi.net/news\\_cepi/the-university-of-queensland-cepi-and-csl-partner-to-advance-development-and-manufacture-of-covid-19-vaccine-candidate-2/](https://cepi.net/news_cepi/the-university-of-queensland-cepi-and-csl-partner-to-advance-development-and-manufacture-of-covid-19-vaccine-candidate-2/)

Accessed June 21, 2020