



**ASPR**

# Development of Medical Countermeasures for 2019-Novel Coronavirus

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BARDA/ASPR/HHS**

**National Vaccine Advisory Committee, 2/13/2020**

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# ASPR Mission

**Save Lives  
and Protect  
Americans from  
21st Century  
Health Security  
Threats**



### **Slide 3 | ASPR's Mission**

- ASPR's mission is to save lives and protect Americans from 21<sup>st</sup>-century health security threats

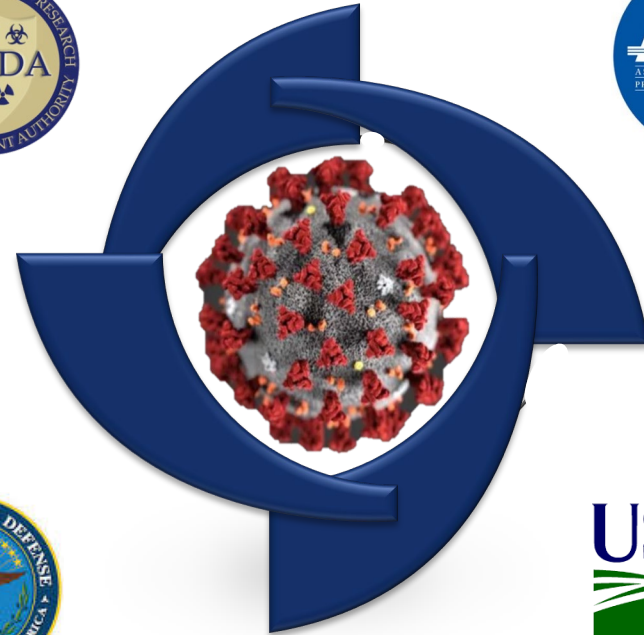
# 2019-Novel Coronavirus (2019-nCoV)

**16**  
Years

**3<sup>rd</sup> Coronavirus Outbreak**  
No Licensed products

# 2019-nCoV Medical Countermeasures Task Force

Align MCM development across interagency partners to avoid duplication of effort, identify opportunities for synergy, and fill potential gaps



# 2019-nCoV MCM Task Force Working Groups

**Therapeutics**

**Vaccines**

**Diagnostics**

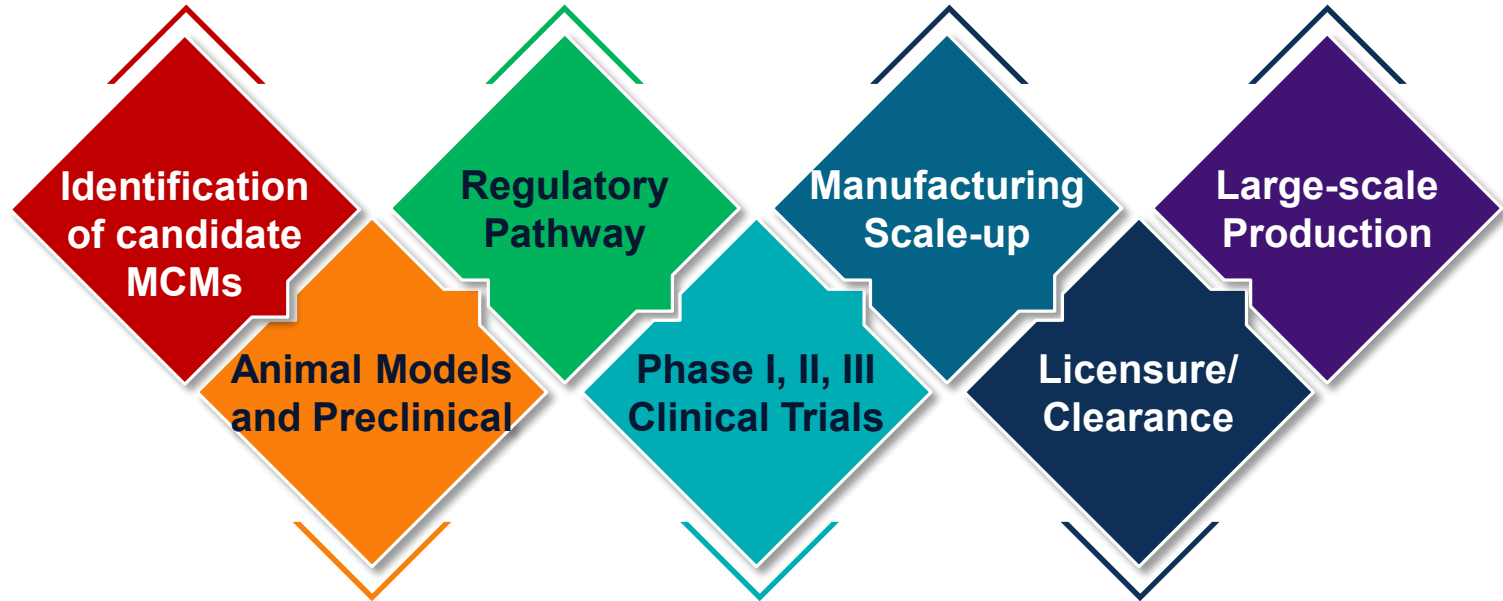
**Clinical Trials**

## Sub-Working Groups

**Animal  
Models**

**Sample  
Sharing**

# 2019-nCoV Interagency Partnerships: Early Development to Large-scale Production of MCMs



- Build on previous USG efforts to develop rapid response vaccine manufacturing platforms.
  - National Institutes of Health
  - Department of Defense
  - Bill and Melinda Gates Foundation
  - Coalition for Epidemic Preparedness Innovation
- No FDA approved human vaccines manufactured with rapid response platforms (e.g., DNA, mRNA, peptide)
- Many candidates in advanced stages of development.
- Two track approach to accelerate the development and domestic manufacturing
  - Use of established technologies (private sector)
  - Infrastructure for manufacturing (e.g., CIADMs or CMOs)
- Funding gap to support advanced development and eventual licensure.
- BARDA discussing with potential industry partners and USG agencies to align its strategy
- Benefits:
  - establish a framework for rapid MCM development
  - capability for large scale domestic cGMP manufacturing to respond to future EID outbreaks



# The BARDA Model

BARDA develops and makes available medical countermeasures (**MCMs**) by forming unique public-private partnerships to drive innovation off the bench to the patient to save lives.



As I said before,

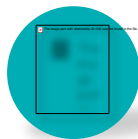
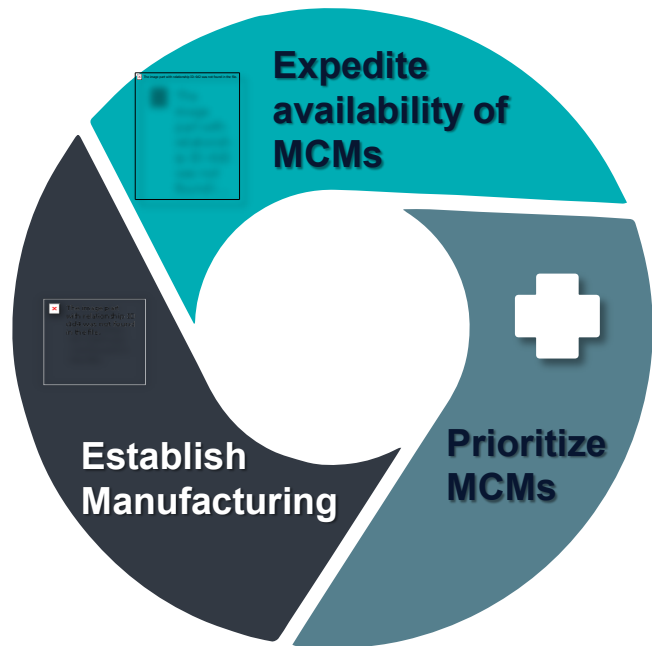
BARDA was created to partner to accelerate the development of lifesaving tools and technologies to detect, prevent, mitigate and recover from threats to our national health security.

We are grateful to congress for the support and special authorities that enable us to lead our mission.

While these authorities that form the foundation of the BARDA Model are essential...

it is the sum total of our partnerships that make us all successful in what we do.

# BARDA Medical Countermeasure Response Strategy



Leverage existing contracts, technologies, platforms, and capabilities to expedite availability of MCMs that detect, treat, and prevent COVID-19



Prioritize development of MCMs based on public health impact and their probability of success



Establish domestic-based manufacturing capabilities for 2019-nCoV MCMs

# Partnering to Improve Preparedness

## VACCINES

- Proven platforms
- Large scale manufacturability
- Speed
- Multiple approaches



## THERAPEUTICS

- Platform-based monoclonal antibodies
- Repurposed therapeutics
- Host targeted therapeutics



## DIAGNOSTICS

Faster and easier to use  
More accurate  
Subtype-agnostic  
↓  
Earlier Identification  
↓  
Earlier Treatment

## MANUFACTURING

- Expand production
- Increase fill/finish capacity

## 2019 NOVEL CORONAVIRUS



### MARKET RESEARCH PORTAL

U.S. Government 2019-nCoV MCM Task Force opened a portal for the submission of market research packages from interested stakeholders.

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

### EZ BAA and BARDA BAA

Open for 2019-nCoV Diagnostics

To support ongoing U.S. Government 2019-nCoV MCM development efforts, BARDA is pleased to open our EZ BAA and amend our BARDA BAA for abstracts and white papers for select 2019-nCoV diagnostics

EZ-BAA Solicitation: BAA-20-100-SOL-0002

Full BAA: Solicitation BAA-18-100-SOL-0003  
(Amendment 12)

[www.medicalcountermeasures.gov](http://www.medicalcountermeasures.gov)

# How to Contact BARDA



Medical  
Countermeasures.gov

[medicalcountermeasures.gov](http://medicalcountermeasures.gov)

*Portal to BARDA: Register to request a TechWatch meeting!*



[beta.sam.gov/](http://beta.sam.gov)

*Official announcements and info for all government contract solicitations*



[phe.gov/BARDA](http://phe.gov/BARDA)

*Program description, information, news, announcements*



[drive.hhs.gov](http://drive.hhs.gov)

*Learn about DRIVE, including our Accelerator Network and EZ BAA*



[www.usajobs.gov](http://www.usajobs.gov)

*Join the team!*

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*Saving Lives. Protecting Americans.*



And all credit and accolades go directly to one of the most dedicated, hardest working, creative, and energetic staff of public servants across the globe.

Oh, and did I mention their experience? BARDA staff has over 2400 years of experience in private industry and an impressive 3200 years of public service.

It is one of the greatest privileges of my life to work with this team and to learn something new from them every day.

I have a huge amount of gratitude for their service and commitment to our mission.