



**ASPR**  
ASSISTANT SECRETARY FOR  
PREPAREDNESS AND RESPONSE



# **BID2020**

## **BARDA Overview**

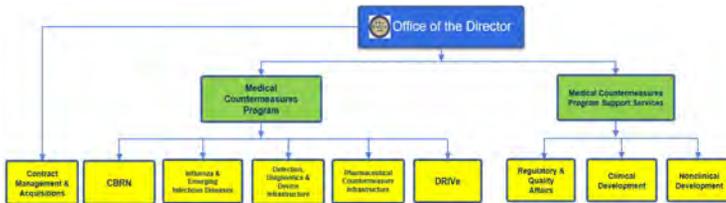
## BARDA's Office of the Director (OD)

### OVERVIEW

BARDA uses an integrated, systematic, portfolio-based approach to support advanced research and development of medical countermeasures (MCMs) to mitigate Chemical/Biological/Radiological/Nuclear (CBRN) threats, Pandemic Influenza (PI) and Emerging Infectious Diseases (EIDs). To accomplish this BARDA has established more than 350 partnerships with industry stakeholders resulting in 56 FDA approvals, licensures or clearances.

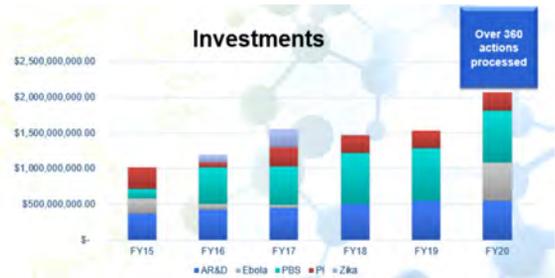
### BARDA'S WORKFORCE

BARDA has: 9 Divisions, 203 FTEs and 140 CTRs

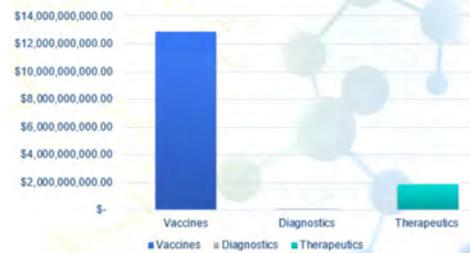


### BARDA INVESTMENTS FY20

#### ARD, Ebola, PBS, PI, Zika



#### COVID Investments > \$16B



### BARDA'S 2020 ACCOMPLISHMENTS

#### BARDA FY 2020 Approvals



#### BARDA Firsts/Highlights FY20



### EXPANSION OF BARDA'S WORKFORCE FOR COVID-19 – FY 20 – FY21

In FY20, BARDA's workforce grew significantly to support the COVID-19 response

- 91 new federal employees
- 46 new subject matter experts (CTRs)
- 48 rapid support consultants supporting BARDA's mission

Transition of OWS activities to BARDA to support in FY21 will require:

- Hiring additional federal and contractor employees
- Increase in our M&A budget

# BARDA'S 2021 GOALS

## Non COVID-19

CBRN	DRIVE	DDDI	PCI	PBS	PI
<ul style="list-style-type: none"> <li>Evaluate new technologies for                             <ul style="list-style-type: none"> <li>Countering the opioid epidemic</li> <li>Novel blood products for acute radiation exposure</li> <li>Non-surgical burn wounds</li> <li>Addressing Ebola Sudan and Marburg</li> </ul> </li> <li>Approval of new therapeutics for Ebola</li> </ul>	<ul style="list-style-type: none"> <li>Launch BARDA Ventures</li> <li>Establish DRIVE Start</li> <li>Collaborate across the USG with new partnerships with IDFC, the VA and others</li> </ul>	<ul style="list-style-type: none"> <li>Improve stability of supply for Ebola Diagnostics</li> <li>Establish primer/probe stockpile and rapid manufacturing for emerging infections diseases</li> <li>Increase domestic manufacturing capacity for emerging infections disease</li> </ul>	<ul style="list-style-type: none"> <li>Launch BIOMAP</li> <li>Support shipment of COVID vaccines to CDC depots</li> </ul>	<ul style="list-style-type: none"> <li>Increase advanced development, manufacturing and procurement of a novel antibiotic to enhance America's preparedness to respond to both biothreat attacks and secondary bacterial infections</li> </ul>	<ul style="list-style-type: none"> <li>Continue to support the EO for modernizing influenza vaccines</li> <li>Clinical trials to support licensure of recombinant PI vaccine</li> <li>Faster platform/ sustainable approach for seasonal/ pandemic/ EID vaccines</li> <li>Alternative delivery and adjuvants</li> </ul>

## COVID-19

- Ensure the wellbeing of BARDA's workforce by managing workload, bringing in additional hires
- Support OWS vaccine manufacturing and dose tracking
- Support OWS therapeutic manufacturing and distribution
- Strong collaborations with interagency partners to support success

## 2020 STAKEHOLDER ENGAGEMENTS / COLLABORATIVE EFFORTS

### VIRTUAL BARDA INDUSTRY DAY



Annual event that brings together industry and interagency partners to showcase BARDA's programs, future plans

2020 Event – largest audience to date

### CORONA WATCH MEETINGS



Portal to identify potential MCMs technologies, assays, platforms, and models for COVID-19

3,800+ meeting requests  
500+ meetings held with interagency partners

### MORE STAKEHOLDER ENGAGEMENT



Updated [MCM.gov](https://www.mcm.gov) website

Increased social media presence in collaboration with ASPR Comms Team

### - INNOVATION -

Blue Knight with J&J Innovations



CARB-X w/ multiple collaborators



## BARDA's COVID-19 Response

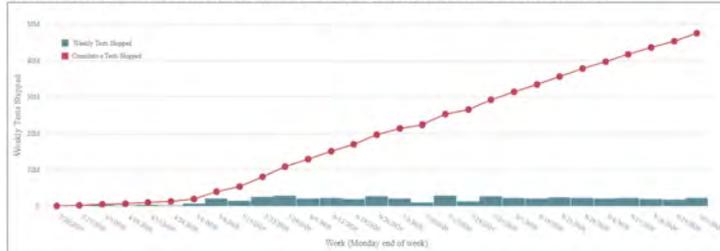
*BARDA has a track record of success in delivering countermeasures in response to public health emergencies.*

### HOW IS BARDA LEADING THE RESPONSE TO COVID-19

The Biomedical Research and Development Authority (BARDA) is leading U.S. efforts to develop COVID-19 vaccines, therapeutics, and diagnostics. Our COVID-19 response started in mid-January 2020, with the earliest awards in February. Since January, we have leveraged over \$15 billion in supplemental funding to accelerate development of 65 products (see [BARDA's COVID-19 Portfolio](#) to learn more), including vaccines, therapeutics, diagnostics, and rapidly deployable capabilities. Our strategic approach was to first leverage proven platforms and technologies from our 300 existing industry partnerships. The results today include: 4 Phase III Vaccine candidates, 4 Phase III therapeutic candidates, and 16 EUAs for SARS-CoV-2 diagnostics. We also identified new industry partners to address gaps as they materialized, and we have partnered with agencies across the U.S. Government.

### IMPACT OF BARDA'S DIAGNOSTIC INVESTMENTS

BARDA Diagnostic Partners Rapidly Deploying Test Kits to Americans



### BY THE NUMBERS

- **3,800+** market research submissions to the BARDA TechWatch/CoronaWatch program
- **510** CoronaWatch meetings this year
- Invested over **\$16 billion** in COVID-19 funding, either directly or through our interagency partnerships.
- **102** COVID-19 Partnerships
- **65** Products Supported
- **16** diagnostic Emergency Use Authorizations for SARS-CoV-2 product candidates
- Contracts awarded in a few as **9** Days
- **45 million** diagnostics test kits shipped by BARDA-supported partners

*Our response to and lessons learned from COVID-19 will continue to improve our response to this pandemic and prepare us for future pandemics.*

### WHY IS BARDA INVOLVEMENT IN THE COVID-19 RESPONSE CRITICAL?

America needs reliable and available diagnostics to detect infection, effective therapeutics to save the lives of those infected, and safe and effective vaccines so Americans can return to work. BARDA has a track record of success in delivering effective medical countermeasures in response to public health emergencies, including H1N1, Ebola, and Zika. BARDA also has unique authorities to rapidly expand partnerships to push candidates forward to the review, testing, and approval phase. BARDA's long-standing expertise in the acceleration of advanced research and development of candidate diagnostics, therapeutics, and vaccines is a testament to the dedicated and experienced team.



### CORONAVIRUS DISEASE 2019 (COVID-19) PANDEMIC

A decade of investments in platform technologies under flexible agreements facilitated BARDA's rapid pivot to developing COVID-19 MCMs.

# BARDA's COVID-19 Response

As of October 15, 2020

## BARDA'S COVID-19 Strategy



BARDA has engaged over 100 partners. Visit [BARDA's COVID-19 Portfolio](#) to learn about the role of each partner in the response and the [Pharmaceutical Manufacturing in America Page](#) to learn about Domestic Manufacturing and Infrastructure investments.



### ACCELERATE DEVELOPMENT

- Platform technologies
- Repurpose licensed products
- Parallel, not sequential, activities

### MITIGATE RISK

- Multiple technologies
- Multiple targets
- Redundancy

### DOMESTIC MANUFACTURING

- Scale Up & Scale Out Capability/Timeline
- Raw materials and supply chains
- Leverage existing facilities

BARDA has leveraged existing public-private partnerships, established new contractual agreements with qualified parties, and streamlined its market research, request for proposals, and funding solicitation mechanisms to bring as many potential medical countermeasures into its pipeline, as quickly as possible. Our response strategy will continue to revolve around the imperatives of speed, risk mitigation, and creation of expanded manufacturing capabilities to blunt the impact of the pandemic. Conventional vaccine and therapeutic development timelines are being compressed to the greatest extent possible, while ensuring product safety. We have invested in infrastructure and domestic manufacturing to ensure American access to approved products. Multiple product lines are being developed in parallel rather than sequentially to mitigate the risk of a single product failing. We will continue to leverage partners at the National Institute of Allergy and Infectious Diseases (NIAID) and the Department of Defense (DoD) to conduct human studies to assess the possibility of repurposing approved drugs to treat patients, and to develop critical reagents, assays, and animal models to evaluate candidates.



Infrastructure & Expansion Support



Next Generation Manufacturing Investments



Domestic Manufacturing Capacity

## Successes

4

Vaccine candidates in Phase III trials with potential to deliver 300M+ doses by March 2021



4

Therapeutics in Phase III clinical trials



16

Diagnostics under Emergency Use Authorization for SARS-CoV-2 product candidates



16

Infrastructure & domestic manufacturing investments



# BARDA's Division of Chemical, Biological, Radiological, and Nuclear (CBRN) Medical Countermeasures

## CBRN PROGRAMS

CBRN manages programs that support advanced research and development and procurement of CBRN MCMs including vaccines, antivirals, antibiotics and therapeutics.

## RAPID RESPONSE

A decade of investments in platform technologies under flexible agreements facilitated BARDA's rapid pivot to developing COVID-19 MCMs



≥1 product in SNS ■  
 1 product in SNS ■  
 BARDA is developing MCM(s) ■  
 BARDA is not developing MCM(s) ■

## BY THE NUMBERS

### CBRN FY20 Accomplishments



## CBRN's Goal: Make Available at Least One Countermeasure for all CBRN Material Threats



Invest in MCMs to treat the injury, not the threat

Develop innovative MCMs for unknown threats

Deliver novel MCMs against bacterial and viral threats

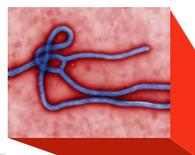
## Project BioShield: A Commitment



## VISION FOR THE FUTURE



Develop robust alternative skin and blood products



Take viral hemorrhagic fevers off the table



Bend the opioids epidemic curve



Use novel approaches to combat antimicrobial resistance



Be prepared to immediately respond to ANY threat

Updated: 10/13/2020

**ANTIBACTERIALS**



**GOAL:** Reduce the morbidity and mortality caused by a biothreat or antimicrobial resistant infection following a mass casualty event or a disease outbreak

**STRATEGY:**

- Revitalize and incentivize the antimicrobial pipeline through innovative public-private partnerships and investment in new types of antimicrobials and products that target MDR and/or bioterrorism-related pathogens

**ANTIVIRALS & ANTITOXINS**



**GOAL:** Protect the population by developing and maintaining safe and effective therapeutics for anthrax, botulism, smallpox and filoviruses

**STRATEGY:**

- *Sustainability:* reduce life cycle costs, use flexible stockpiling strategies
- *Improve operational logistics and capabilities:* incorporate better formulations
- *Reduce risk:* diversify portfolio of countermeasures

**CHEMICAL**



**GOAL:** To improve health outcomes for all victims of chemical exposure

**STRATEGY:**

- *Treat the injury, not the agent*
- *Enable community resiliency*
- *Repurpose approved medicines and late stage drugs*

**RADIOLOGICAL & NUCLEAR**



**GOAL:** To improve health outcomes for all victims of nuclear detonations and radiation exposure

**STRATEGY:**

- *Comprehensive:* address systemic injuries from initial to definitive care
- *Innovative:* employ new technologies and treatments for robust systemic care
- *Sustainable:* use existing products or develop transformative products for routine care

**THERMAL BURNS**



**GOAL:** Mitigate treatment bottlenecks for burn and blast injuries, transform current standard of care with adoptable MCMs, and build national preparedness

**STRATEGY:**

- *Comprehensive:* coverage from initial to definitive care
- *Adoptable:* partner with end-user community
- *Sustainable:* integration into routine use ensures access, familiarity

**VACCINES**



**GOAL:** Develop vaccines to protect against smallpox, anthrax, viral hemorrhagic fever, and antimicrobial resistant bacterial threats

**STRATEGY:**

- *Expand* utility of current vaccines and support licensure of new vaccines
- *Improve operational logistics and reduce life cycle costs*
- *Facilitate* interactions with partners

# BARDA's Influenza and Emerging Infectious Diseases Division: FLU

## DETECTING, TREATING AND PREVENTING FLU

	2005-2006	Today	Impact
<b>DOMESTIC PRODUCTION</b>			<b>New formulations (2017-2018)</b> <b>Prevented:</b> <ul style="list-style-type: none"> <li>• 210,000 illnesses</li> <li>• 17,000 hospitalizations</li> <li>• 1,700 deaths</li> </ul> <b>Saved:</b> <ul style="list-style-type: none"> <li>• \$9.8B total costs</li> <li>• \$660M immediate costs</li> <li>• \$9.1B value of life</li> </ul>
<b>SEASONAL VACCINE</b>		  	
<b>PANDEMIC CAPABILITIES</b>		 	

The Biomedical Advanced Research and Development Authority (BARDA), within HHS' Office of the Assistant Secretary for Preparedness and Response (ASPR), has supported FDA approval of 23 influenza medical countermeasures since 2006. These products are currently used to detect, treat, and prevent infections, saving lives and reducing economic loss from seasonal influenza every year, as well as preparing the Nation to respond to an influenza pandemic.



BARDA support will allow approval of the next generation of products. The achievements to date have been tremendous, but more needs to be done. Every year, Influenza still infects millions, kills tens of thousands, and costs billions in economic loss in the United States alone. Better vaccines, diagnostics, and therapeutics candidates have been identified, and with continued support, BARDA can expand the number of partnerships to license and manufacture these life saving products, making them available to all Americans.

Influenza remains one of the Nation's leading infectious disease killers, and an influenza pandemic could cost hundreds of thousands of lives and trillions in economic loss. BARDA is addressing this dual threat by supporting development, licensure and manufacturing of better products to detect, treat, and prevent seasonal and pandemic influenza.

**23 FDA APPROVALS: BARDA SUPPORT BRIDGES THE 'VALLEY OF DEATH'**

- New influenza diagnostics, vaccines and treatments
- Doctors and patients have more options to detect, treat, and prevent influenza than ever before

**MORE US-BASED VACCINE MANUFACTURING**

- BARDA has supported all 3 US based influenza vaccine facilities, increasing production capacity 10-fold
- Current capabilities must be sustained
- More capacity for vaccines produced with modern technologies is necessary to save more lives

**DEFEATING INFLUENZA: INTEGRATED STRATEGY**

- BARDA utilizes an end-to-end strategy to address seasonal epidemics and pandemic threats
- This strategy relies on better diagnostics and treatments and vaccines that work better and can be made faster



BARDA INFLUENZA CONTRACT FACTS



\*includes H1N1 2009 response

- By partnering with product developers and manufacturers, BARDA has supported licensure of improved therapeutics, respiratory protective devices, vaccines and diagnostics
- Approvals include 6 diagnostics, which allow for improved detection and earlier start of treatment for patients
- BARDA has enabled licensure of vaccines based on newer technologies as well as expanded the available options to ensure the right vaccine is available at the right time to everyone

MORE US-BASED VACCINE MANUFACTURING



- A strong domestic vaccine manufacturing capability is critical for national security and response to seasonal or pandemic flu:
  - ✓ **2004: loss of 50% of vaccine manufacturing capacity**
  - ✓ **2009: H1N1 pandemic, no country allowed vaccine export until their population was covered**
- BARDA has supported expanding the manufacturing capability of all domestically manufactured vaccines
- Domestic manufacturing remains critical for pandemic response

Protecting the Nation-The Time is Now



- A new vaccine with just 5% better efficacy would have prevented an additional 1 million illnesses and 25,000 hospitalizations in the 2017 flu season.

President Council Of Economic Advisors Report

<b>Pandemic: 500,000 Deaths</b> 670,000 to 4.3 million hospitalizations.	<b>Pandemic: Vaccine delay could cost \$41 billion each week.</b>
<b>Pandemic: \$413 billion to \$3.79 trillion losses</b>	<b>Seasonal: \$361 billion loss per year</b>

New technologies have yielded a record number of candidate products that could reverse these National public health and economic vulnerabilities.

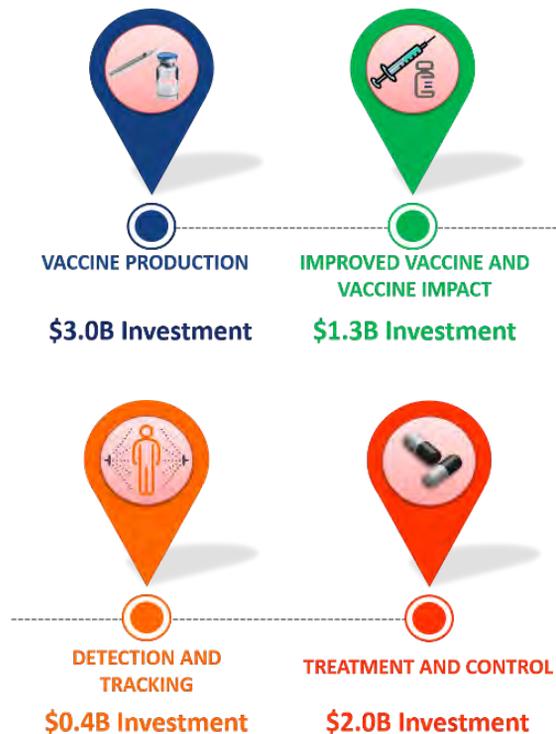
BARDA is committed to making all products widely accessible to all populations through clinical trials and increasing domestic manufacturing.

SUMMARY:

BARDA's pandemic influenza preparedness and response efforts allowed a rapid pivot and acceleration of vaccine, diagnostic, and therapeutic development against COVID-19. It also validated known gaps in pandemic preparedness and response efforts, as well as identified new challenges.

Influenza and other emerging infectious diseases with pandemic potential continue to mutate, evolve, and infect animals and humans, continuing to pose significant threats to global public health and to the security of the United States. Together with our Federal and industry partners, ASPR and BARDA have made huge progress towards pandemic influenza preparedness. Our Nation must sustain these advances and continue to invest in domestic pandemic preparedness efforts and work with key global partners to prepare for, prevent, detect, and respond to emerging pandemic threats. Building on a decade's worth of progress, partnered with industry, the time is right to make better seasonal and pandemic influenza vaccines, antivirals, and diagnostics widely available, and in the process, improve the Nation's ability to respond to other emerging pandemics.

BARDA has a unique responsibility in supporting advanced research, development, and procurement of pandemic influenza medical countermeasures. Current budget estimates to address gaps in pandemic influenza preparedness and response capabilities, as outlined in the Presidential Executive Order and the DHHS Pandemic Influenza Plan Update of 2017 are estimated at \$4.3B for vaccine development, facilities, and production capabilities, \$0.4B for diagnostics, and \$2.0B for investment.



# Influenza and Emerging Infectious Diseases Division (IEIDD)

## COVID-19 IS A PRIME EXAMPLE OF AN EMERGING INFECTIOUS DISEASE

### A Nation Under Attack

- Emerging infectious diseases in the USA result in billions in economic losses each year
- Constant threat of epidemic or pandemic that could significantly disrupt the government and economy

### A Nation Vulnerable and Unprotected

- Lack of timely vaccines, therapeutics and diagnostics to detect and treat emerging infectious diseases
- No sustained advanced development and manufacturing funding to fill current critical gaps
- The 'valley of death' that prevents new products to detect, treat, and prevent EIDs from being licensed has persisted due to lack of funding

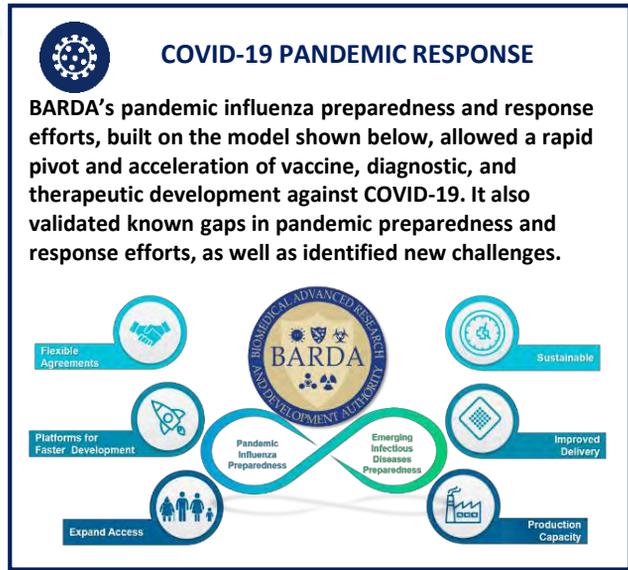
### Protecting the Nation-The Time is Now

- BARDA support of advanced development to obtain FDA approval for vaccines, therapeutics, and diagnostics can defeat this threat and save lives
- BARDA can leverage existing capabilities to develop the fast, flexible manufacturing capability required to respond to current and new EID threats

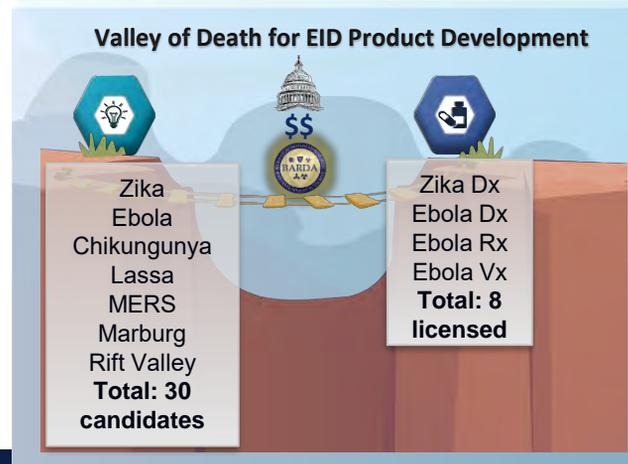
**The Biomedical Advanced Research and Development Authority (BARDA), within HHS' Office of the Assistant Secretary for Preparedness and Response (ASPR), was created to address the national health security threat posed by Emerging Infectious Diseases.** Since its inception, ASPR/BARDA has supported licensure and domestic production of life-saving vaccines, therapeutics, and devices to protect Americans against a multitude of threats.

- 56 Licensed products since 2006
- Five domestic public/private partnerships to support production of licensed vaccines
- Contracts and authorities to provide for rapid response capabilities, including manufacturing
- Support for platform technologies

*"BARDA partners with industry to bridge the "valley of death" between basic research and advanced-stage product development for MCMs—an area where more traditional US government research enterprises do not operate." GHTC*



**The ASPR/BARDA strategy works with EIDs:** One-time supplemental funding allowed BARDA to successfully bridge the 'valley of death' and support the only FDA cleared Point of Care (POC) Zika diagnostics, and the only FDA cleared Ebola POC diagnostics. Targeted, sustained funding allowed the necessary investment to support the Nation's only licensed vaccine and therapy for the deadly Ebola virus. With sustained EID funding, the ASPR/BARDA proven integrated countermeasure strategy can transform the nations preparedness and response posture against existing and future EIDs, moving from a reactive to a proactive posture.



# EMERGING INFECTIOUS DISEASES

## A Nation Under Attack



New and re-emerging infectious diseases pose a constant threat. While the ongoing COVID-19 pandemic is at the forefront, they are just one of many examples from the last 20 years.

Geographical Expansion

New Pathogens Identified

Behavior/Population Changes

Genotypic Change

Zika  
Chikungunya  
West Nile Virus

SARS/Co-MERS

Coccidioides (Valley Fever)

Antifungal resistance

### West Nile in US:

- 2019 Cases in 47/50 states
- \$56M in 2019

### COVID19 in US:

- >200,000 deaths
- ~9.5% GDP loss
- \$2 Trillion

## A Nation Vulnerable and Unprotected



The US Government has invested in research and early development of products to diagnose, treat and prevent EIDs, but sustained funding for advanced development, licensure and manufacture is lacking, as demonstrated by the lack of a single approved vaccine or therapeutic against emerging coronaviruses in spite of three outbreaks over the last 16 years.

SARS-2003

CoMERS  
2012-  
Current

COVID-19  
2019-  
current

0 License  
vaccines/  
herapeutir

In the past decade, BARDA has leveraged pandemic influenza funding to support flexible infrastructure and platform technologies to manufacture products for Pandemic Influenza and other Biological threats. These gains were significant but insufficient of establish the large-scale US-based manufacturing capacity to produce early diagnostics, therapeutics and vaccines to blunt the health and economic impacts of the next pandemic.

## Protecting the Nation-The Time is Now



# Rapid Pandemic Response: Medical Countermeasure Needs

Early detection

Host-based  
therapeutics

Direct Acting  
Therapeutics

Vaccine

### Solving the Problem

Recognition of the Valley of Death led to substantial funding for advanced development, licensure, and increased manufacturing capacity for Pandemic Influenza and CBRN. The product development and infrastructure building strategy coupled with BARDA public:private partnership, funding authorities, and product pipeline provided the foundation for the rapid establishment of a comprehensive COVID-19 therapeutic, vaccine, and diagnostic portfolio, which eventually evolved to serve as the basic portfolio for the whole of Government Operation Warp Speed effort. Further, the COVID-19 response demonstrated the ability of BARDA's model to, when adequately funded, rapidly pivot and develop countermeasures against new threats.

Currently, BARDA does not receive dedicated funding to address gaps in Emerging Infectious Diseases medical countermeasure diagnostic, treatment or detection. As a result, the many product candidates that have been identified and gone through initial testing, languish in early stages of development. In the absence of the funding and other resources necessary to take these products to licensure, people will continue to be infected and die from EIDs, and the response to new pandemics will be delayed. Adequate sustained funding to unleash BARDA's strategic plan and capabilities on advanced development, licensure, and production of vaccines, therapeutics, and diagnostics for emerging infectious diseases will save lives against current known diseases as well as future emerging diseases.

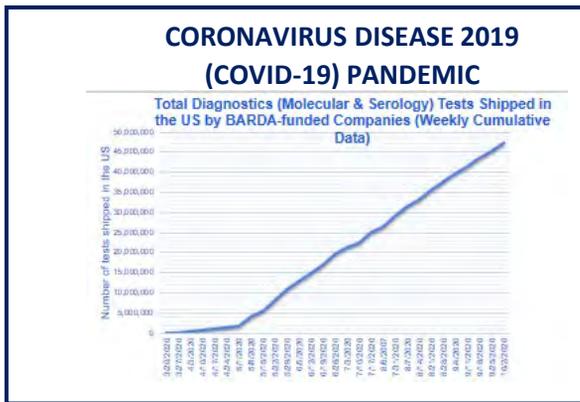
*"Unpredictable funding and prioritization for EID countermeasures also hinders BARDA's ability to engage industry partners who are critical to bringing these products across the finish line." GHTC*

# BARDA's Detection, Diagnostics & Devices Infrastructure Division (DDDI)

## DIAGNOSTIC/ MEDICAL DEVICE NEEDS ACROSS BARDA'S PORTFOLIO

DDDI supports development of diagnostic and medical device countermeasures needed to effectively and efficiently respond to chemical, biological, radiological and nuclear (CBRN) threats, pandemic influenza, emerging infectious diseases (Ebola, Zika, COVID -19), along with diagnostics to inform appropriate use of antibiotics to address the increasing threat of antimicrobial resistant bacteria.

## DDDI AND INDUSTRY PARTNERS DELIVER ON COVID-19 DIAGNOSTICS



### COVID-19 DX CAPACITY EXPANSION: BARDA'S ROLE

BARDA in collaboration with the Joint Acquisition Task Force is funding capacity expansion for select manufactures with:

- 1) Mature manufacturing operation – shipping product;
- 2) Mature products and Quality Management System (QMS) – obtained EUA or 510K
- 3) Product being developed under contract with BARDA
- 4) Have applied to and met acceptance criteria for a JATF solicitation

### 16 FDA EUA's – COVID-19 Diagnostics

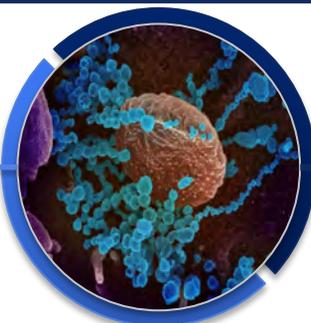
(as of October 10, 2020)

 <b>HOLOGIC</b> Panther - Fusion - TMA	 <b>Cepheid</b> GeneXpert - SARS-CoV2 - Flu/CoV2/RSV	 <b>DiaSorin</b> LIAISON - MDx - XL	 <b>QIAGEN</b> - QIAstat	 <b>Luminex</b> - Aries - NxTag	 <b>VELA</b> DIAGNOSTICS - Manual - Automated	 <b>mesabiotech</b> - Accula	 <b>CLUE</b> - Point-of-Care	 <b>SIEMENS Healthineers</b> - Centaur COV2T - Atellica COV2T	 <b>GenMark dx</b> - RP2
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## BARDA BAA AND EZ-BAA SOLICITATIONS: COVID-19 DIAGNOSTICS/DEVICES

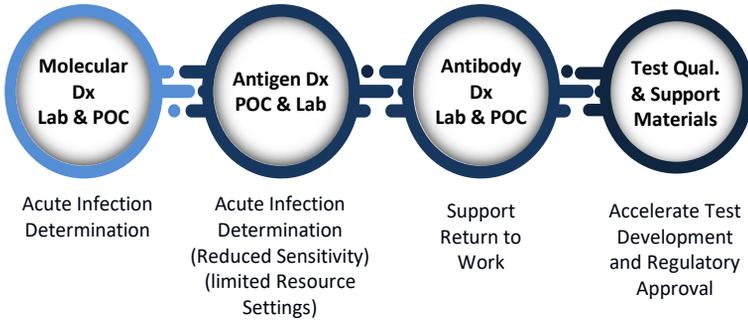
Since January when the COVID-19 PHE was issued:

- 115 submissions to BAA (Dx Tests, RPD, Ventilators)
- 239 submissions to EZ-BAA AOI AOI 4.1A-C
- 807 diagnostic CoronaWatch and Industry contacts



Development of over 30 COVID-19 Diagnostic tests have been funded resulting in 16 EUAs so far

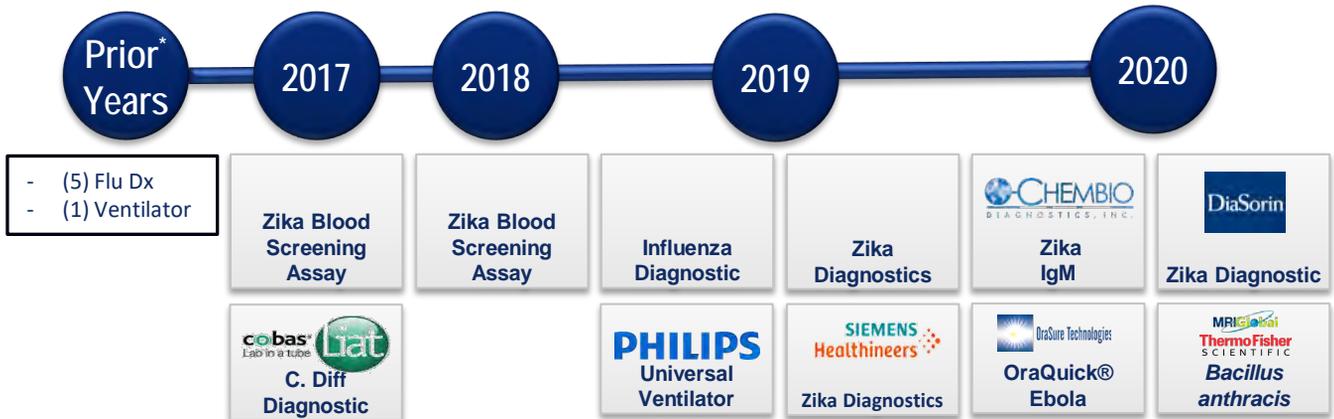
**BARDA COVID-19 DIAGNOSTICS DEVELOPMENT: FOUR-PRONGED APPROACH**



**DDDI Outlook**

- **Near Term**
  - COVID-19 Focus
  - Flu & CBRN Programs Limited
- **Medium Term**
  - COVID-19 Dx to 510(k)
  - Reengagement of CBRN & Flu Solicitations
- **Long Term**
  - Rapid Dx Manufacturing Capability for PHE's

**17 FDA 510(K) CLEARED OR APPROVED DIAGNOSTICS / DEVICES**



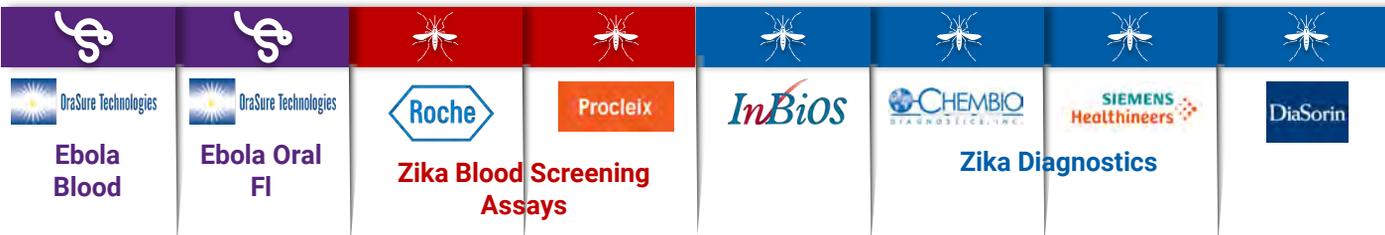
\* Summarized in the interest to space

**EBOLA & ZIKA PUBLIC HEALTH EMERGENCY RESPONSE**

**FDA EUA - Ebola**

**FDA IND - Zika**

**FDA EUA - Zika**



**NOW FDA CLEARED/APPROVED**

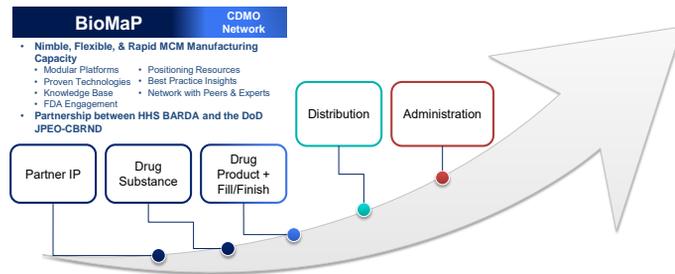
# BARDA's Pharmaceutical Countermeasure Infrastructure (PCI) Division

## BUILDING A NATIONAL BIOPHARMACETICAL MANUFACTURING PARTNERSHIP (BIOMAP) AFTER A DECADE OF NEED

The Nation currently lacks the domestic manufacturing capacity to rapidly produce and package a vaccine for the American public in the face of a pandemic... The PHEMCE Review, August 2010

### BUILDING OPERATIONAL READINESS

#### OPTIMIZED WOG APPROACH TO MCM MANUFACTURING RESPONSE



### BIOMAP MISSION

Provide for the “whole of government” leadership to manufacturing capabilities established by the USG and willing industry partners for biothreat responses

Maintain HHS/DoD manufacturing infrastructure in a state of readiness to respond to emerging MCM manufacturing requirements

### COLLABORATING WITH OUR INDUSTRY PARTNERS

#### BIOMAP IN ACTION FOR COVID-19 RESPONSE

<b>emergent</b> biosolutions <sup>®</sup>	<b>ology</b> BIOSERVICES	<b>FUJIFILM</b> Di-synth	<b>THE TEXAS A&amp;M UNIVERSITY SYSTEM</b>
<b>AZD 1222</b> Non-replicating viral vector	<b>Ad26.COV2-S</b> Non-replicating viral vector	<b>INO-4800</b> Plasmid vaccine	<b>AZD 7442</b> Combo of 2 antibodies
<b>NOVAVAX</b>	<b>NOVAVAX</b>	<b>NOVAVAX</b>	<b>NOVAVAX</b>
<b>AstraZeneca</b>	<b>Janssen</b>	<b>NOVO</b>	<b>NOVAVAX</b>
<b>THE JENNER INSTITUTE</b>	<b>NOVO</b>	<b>NOVO</b>	<b>NOVAVAX</b>

### SUPPORTING OPERATION WARP SPEED (OWS)

## OPERATION WARP SPEED

### ACCELERATED VACCINE PROCESS

**MISSION:** Deliver 300 million doses of safe and effective vaccine by 1 January 2021.

### BARDA'S 2013 FILL FINISH MANUFACTURING NETWORK (FFMN): UP TO THE OWS CHALLENGE IN 2020

<b>Pandemic Surge inventory</b>	<b>Analytical development; Lab Services</b>	<b>Technology Transfer</b>	<b>Clinical and Commercial Lot Manufacturing</b>	<b>Reduce bottlenecks during emergency responses</b>
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#### Fill and Finish expertise in the following:

- Formulation, Fill & Finish Vials and Syringes
- Technology Transfers
- Regulatory Support
- Analytical Development
- Clinical Trial and Commercial Scale lots
- Lyophilization
- Labeling & Packaging
- Storage and Distribution

### ACCELERATING CAPABILITY BUILDING IN RESPONSE TO OPERATION WARP SPEED

<p>COVID-19 Response has led to full engagement of BioMaP's capabilities:</p> <ul style="list-style-type: none"> <li>cGMP manufacturing at commercial scale!</li> <li>Additional staff &amp; training</li> <li>Facility expansion &amp; equipment</li> <li>Regulatory engagement on Quality systems &amp; multi-product use</li> <li>Enhancing physical and cyber security</li> </ul>	<p>BioMaP's rapid manufacturing capabilities uniquely supports OWS mission</p> <ul style="list-style-type: none"> <li>Supporting scale up for national-level response</li> <li>Utilizing Best Practice insights across HHS &amp; DOD</li> <li>Leveraging known manufacturing processes &amp; proven technologies</li> <li>Building, diversifying, and strengthening the Nation's response portfolio</li> </ul>
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Updated: 10/09/2020

# BARDA's Division of Research Innovation and Ventures (DRIVE)

## WHAT IS DRIVE?

Team of scientists, entrepreneurs, and govt. innovators advancing new technologies and approaches for health security

### Approach to Innovation

- We tackle big **health security challenges and threats**
- We fund **breakthrough devices and technologies**, model the **best practices** of the entrepreneurial world, and **streamline contracting processes** (e.g. EZ-BAA)



<u>DRIVE Portfolio</u>	<u>COVID-19 Portfolio</u>
<b>25</b> Funded companies	<b>34</b> Funded companies
<b>\$30.7</b> Million funded	<b>\$19.5</b> Million funded
<b>\$20.7</b> Million cost share	<b>\$15.3</b> Million cost share

## CURRENT DRIVE PROGRAM AREAS



### ENACT

Supporting pathogen-agnostic technologies that enable earlier infection diagnoses

### SOLVING SEPSIS

Reducing the incidence, morbidity, mortality, and cost of sepsis

### BEYOND THE NEEDLE

Developing alternative delivery technologies beyond syringes/needles



## DRIVE CATALYST OFFICE

### BARDA Ventures

Partnership to use venture-style equity financing to invest in breakthrough technologies (launching in 2020)

- Act with speed and flexibility of venture capital
- Fortify U.S. influence on health security technology development
- Maximize taxpayer value by recycling returns from successful ventures

### Health Accelerator Network

National network to hold local events, identify next-generation startups and equip DRIVE partners with tools to be successful



**DRIVE Start:** Incubating new programs and offering prize challenges to advance innovation



DRIVE Start Talk Series

DRIVE Start Prize Challenges

DRIVE Start Incubator

Updated: 10/14/2020

## Solving Sepsis and ENACT Programs

Solving Sepsis and ENACT are DRIVE's foundational programs that have defined threat agnostic gaps and opportunities to more effectively address health emergencies and their impacts on health

### ENACT

*Early Notification to Act, Control, and Treat*

- Supporting pathogen-agnostic technologies that enable earlier infection diagnoses
- Empowering individuals to take early action on their health
- Providing early actionable information to medical care providers; patient triage
- Following the spread of an epidemic in near real-time

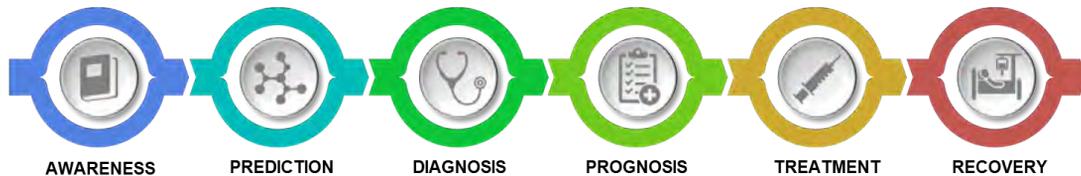


**Act**  
Pre-symptomatic information: Empowering patients

**Treat**  
Early diagnostics for medical care providers

**Control**  
Actionable information for public health organizations

**DRIVE SOLVING SEPSIS aims to reduce the incidence, morbidity, mortality and cost of sepsis by investing in key strategic areas**



### Success Stories

During COVID-19, the Solving Sepsis and ENACT teams pivoted their work to develop remote patient monitoring and disease severity tools for COVID-19

Solving Sepsis partner Immunexpress developed the first FDA-cleared host-based sepsis diagnostic, and with partner Cytovale, pivoted to COVID-19

The Sepsis team led the development of a new partnership with the Department of Veterans Affairs (VA) to pilot new technologies that could benefit veterans

ENACT partner Evidation was named a Time 2020 Innovator for their approach to use telehealth analytics to predict emerging disease hotspots including COVID-19



## BARDA's Division of Contract Management & Acquisitions (CMA)

### OVERVIEW

#### Mission

CMA is a dynamic organization that provides flexible, consistent, and innovative acquisition solutions in support of necessary medical countermeasures

#### Vision

To operationalize contracting by focusing on sound business practices and quality outputs that enhance the U.S. Government's capability to respond quickly to both known and emerging public health threats

#### CMA's Core Values



##### INTEGRITY

Commitment to ethics through fairness, transparency, and accountability in decisions made by CMA business advisors



##### EXCELLENCE

Commitment to exceptional performance in all aspects of the acquisition process



##### CUSTOMER FOCUSED

Commitment to ongoing collaboration with internal and external partners, to ensure that BARDA's critical business needs are supported

### BY THE NUMBERS

#### CMA Success in FY 2020

##### Non-COVID Awards

- **Over 360 actions processed**
- **\$1.95+ Billion Executed**

##### COVID Awards

- **CMA Contracting Officers executed 140+ award actions in support of COVID-19**
- **Awards totaling over \$5 billion, between mid-March and Sept. 30, 2020**
- **Variety of funding vehicles, including new FAR contracts, task orders, OTAs, and modifications of existing vehicles**
- **Collaboration with USG counterparts, including JPEO and NIH. Awards totaling over \$9.6 billion**

##### CMA Team

- **55 staff (CTRs and FTEs) Oct. 2020**
- **Ongoing aggressive recruitment of top acquisition talent**



### CMA'S MAJOR OBJECTIVES



Execute and manage procurements in support of the BARDA mission



Ensure procurement integrity is upheld throughout the acquisition lifecycle



Modernize BARDA acquisition processes through implementation of advanced technologies



Continue expansion of BARDA's contracting division by attracting ethical and innovative acquisition professionals

Updated: 10/09/2020



## BARDA's Division of Contract Management & Acquisitions (CMA)

### CMA BRANCHES

#### MEDICAL COUNTERMEASURES DEVELOPMENT



##### **Chemical, Biological, Radiological and Nuclear (CBRN) Acquisition Branch**

The CBRN branch awards traditional contracts and other transactions through a rolling Broad Agency Announcement (BAA) with multiple areas of interest. The BARDA BAA encourages the advanced research, development, and acquisition of medical countermeasures such as vaccines, therapeutics, and diagnostics, as well as innovative approaches to meet the threat of CBRN agents, emerging infectious diseases, and pandemic influenza. The CBRN branch is also responsible for "Project BioShield" (PBS) requirements. PBS was derived from the passage of the Project BioShield Act of 2004 (P.L. 108-276) and is a critical part of a broader strategy to defend America against weapons of mass destruction, through the accelerated research, development and purchase of effective medical countermeasures (MCMs) against CBRN agents.



##### **Influenza & Emerging Infections Diseases (IEID/Flu) Acquisition Branch**

The Flu branch provides cradle-to-grave acquisition management services for advanced research, development, and procurement of medical countermeasures against influenza viruses with pandemic potential to support our mission of public health preparedness and medical response to a probable or actual influenza pandemic.

#### MEDICAL COUNTERMEASURES SUPPORT SERVICES



##### **Clinical, Nonclinical and Regulatory Services (CNCR) Acquisition Branch**

The CNCR branch supports procurement activities for the Division of Clinical Development, the Division of Nonclinical Development, the Division of Regulatory Science and Quality Affairs, and the Division of Diagnostics, Devices, and Device Infrastructure within BARDA. CNCR team members work alongside BARDA program officials to manage critical requirements under the Clinical and Nonclinical Studies Networks and to address diagnostic and medical device needs in support of various Medical Countermeasure Program divisions in advancing CBRN and Influenza product development and testing.



##### **Pharmaceutical Countermeasure Infrastructure (PCI) Acquisition Branch**

The PCI branch supports procurement activities related to critical domestic manufacturing infrastructure, as well as to increase capacity of pre-pandemic and pandemic influenza vaccines, and other medical countermeasures (MCMs). PCI team members work alongside BARDA's Division of Pharmaceutical Countermeasures Infrastructure program officials to advance and maintain the core capabilities provided by the Centers for Innovation in Advanced Development and Manufacturing and the Fill-Finish Manufacturing Network.

#### INNOVATION IN ACQUISITIONS



##### **Division of Research, Innovation, and Ventures (DRIVE) Acquisition Team**

DRIVE's acquisition team takes a new approach to tackle the biggest national health security threats – developing innovative technologies and practices for transformative solutions. The division intends to bring together the best ideas from the medical and scientific communities, together with government and venture capital investment, to drive innovation that will strengthen our nation's health security. Aligned with that mission, the DRIVE Acquisition team has forged an integrated team who puts emphasis on transforming business practices. The goal of the team is to maximize public dollars by exploring and implementing innovative acquisition practices, increasing industry engagement, and leveraging BARDA investments.

#### CONTRACT PORTFOLIO MANAGEMENT AND SUSTAINABILITY



##### **Station Support and Administrative Contracting (SSAC) Team**

The SSAC is, first and foremost, a product execution team established to aid in securing our nation from CBRN threats, as well as from pandemic influenza (PI) and emerging infectious diseases (EID). The SSAC is the newest team within CMA, which provides contract administration services to the CBRN, Flu, PCI, and CNCR branches. The primary role of SSAC is to provide post-award functions related to the administration of contracts and agreements, as well as several assigned pre-award responsibilities. SSAC also provides overall management of contractor compliance with contract terms and conditions. Additionally, this team is responsible for the execution and administering of BARDA contract actions that are non R&D related.

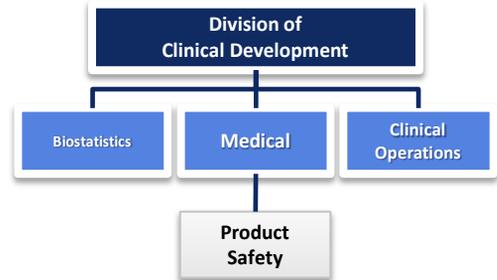
Updated: 10/09/2020

## BARDA's Division of Clinical Development (DCD)

### OVERVIEW

#### The value we bring to BARDA and its partners

- Expert knowledge in advanced product development
- Experienced clinical trial infrastructure support through contracts with established clinical contract research organizations
- Ensuring that robust clinical data are available to support investment decisions and product development
- Promoting innovative approaches to accelerate development timelines and reduce costs
- Generating clinical data via BARDA-sponsored studies in BARDA's Clinical Studies Network



The DCD is comprised of three branches and 20 subject matter experts with advanced clinical development experience in industry, academic, and government settings.

### CLINICAL STUDIES NETWORK CONTRACTS

The Clinical Studies Network (CSN), first established in 2014 under the direction of the DCD's network operations center, designs, conducts, and analyzes clinical studies to support BARDA's MCM development programs. Re-engineered in 2020, the CSN is a consortium of clinical contract research organizations that fall into one of 3 collaborative domains: clinical trial planning and execution; statistical and data coordination; and biological specimen and investigational product storage.



- Statistical & Data Coordinating Center (SDCC)**
  - Biostatistics
  - Data Management
  - Records Archive
- Clinical Trial Planning & Execution (CTPE)**
  - Routine
  - Response
- Biological Specimen & Investigational Product Storage Facility (BSIP)**



#### Clinical Trial Planning and Execution (CTPE)

- Multiple Contracts Awarded
  - ICON, Pharm-Olam, PRA and TRI
- 5 Year Period of Performance -2 Year Base Contract + 3 one-year options
- Routine and Emergency Response Capabilities



#### Statistical & Data Coordinating Center (SDCC)

- Single award IDIQ contract to Rho Federal
- 5 Year period of performance-2-year Base Contract + 3 one-year options



#### Biological Specimen & Investigational Product Storage Facility (BSIP)

- Single Award IDIQ Contract to ATCC
- 10 Year Period of Performance- 5-year Base Contract + 5 one-year options



Updated: 10/13/2020

Since 2014, the CSN has supported 9 major projects including a phase 3 Ebola vaccine study in Sierra Leone, a phase 1 pharmacokinetic study of sublingual atropine as a potential nerve agent antidote, and an ongoing phase 3 master protocol of immunomodulators for treating hospitalized COVID-19 patients.

Description	Start Date	Program Area
Midazolam autoinjector (Neurotoxin MCM)	2014	CBRN-Chem
STRIVE Ebola vaccine, Sierra Leone	2015	CBRN-Biologic
H5N1 influenza vaccine	2015	Influenza
Zika serum collection (diagnostics)	2016	Emerging ID
H5 influenza vaccine heterologous prime boost	2016	Influenza
H7 influenza vaccine mix and match	2017	Influenza
Anthrax vaccine in the elderly	2017	CBRN-Biologic
Sublingual atropine PK (Neurotoxin MCM)	2019	CBRN-Chem
ACTIV-1 COVID-19 Master Protocol	2020	Emerging ID

### BY THE NUMBERS

- **DCD has supported:**
  - CY2020: 85 Contracts/Project teams and 20 technical evaluations
  - CY2019: 72 Contracts/Project teams and 24 technical evaluations
- **Since its inception in 2014, the CSN has supported:**
  - 9 clinical studies
  - \$151M in study costs



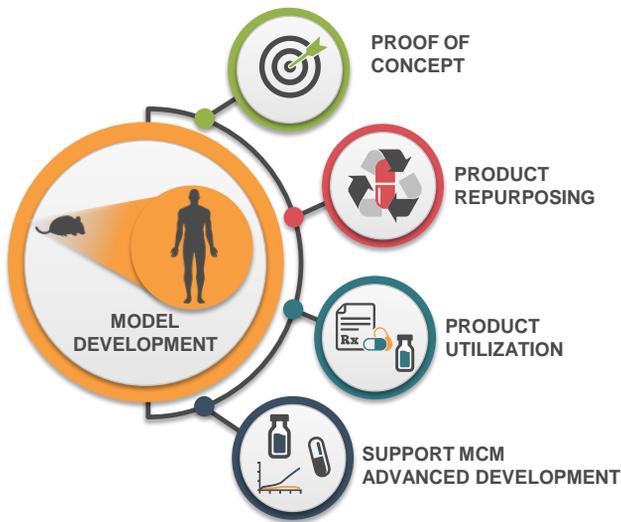
### CORONAVIRUS DISEASE 2019 (COVID-19) PANDEMIC

- Provide operations, statistical, medical, and pharmacovigilance SME support to OWS vaccine and therapeutics project teams
- Via the Clinical Studies Network, leading global execution of the ACTIV-1 master protocol in collaboration with NCATS
- Coordinated the Medical Countermeasure Task Force’s interagency Clinical Trials working group
- Coordinated the interagency management of the chloroquine/hydroxychloroquine Emergency Use Authorization and associated clinical trial requests
- Managed the phase 3 high dose IV famotidine clinical trial contract
- Established a COVID-19 clinical specimens storage facility

## BARDA's Division of Non-Clinical Development (DNCD)

### DNCD DEVELOPMENT FUNCTIONAL AREAS

DNCD supports the establishment and qualification of animal models, assays and reagents that can withstand regulatory rigor for the development of chemical, biological, radiological and nuclear MCM.

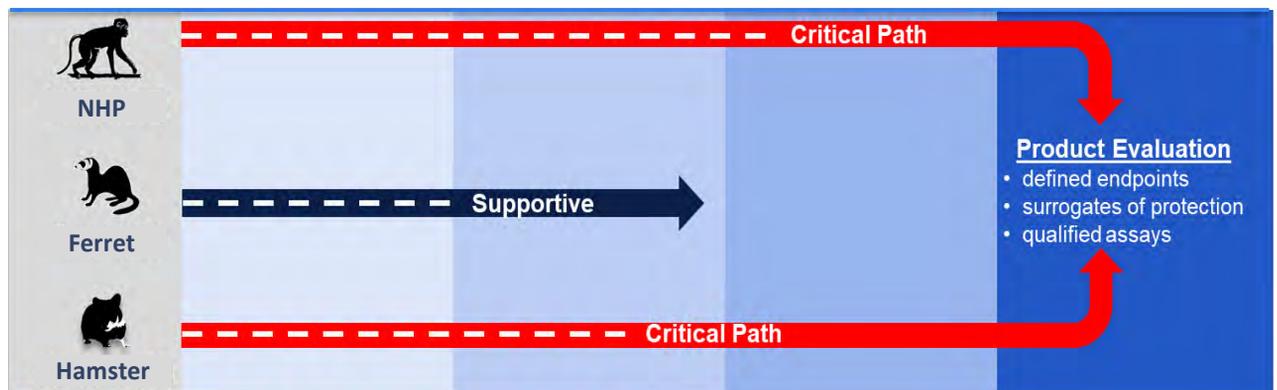


### DNCD CRO NETWORK PARTNERS



### DNCD SARS-COV-2 RESPONSE SUPPORTING OPERATION WARP SPEED

<p><b>Model Development</b></p> <ul style="list-style-type: none"> <li>• species down-selection</li> <li>• natural history studies</li> <li>• endpoint characterization</li> </ul>	<p><b>Model Refinement</b></p> <ul style="list-style-type: none"> <li>• viral isolate comparison</li> <li>• viral stock QC</li> <li>• molecular clone characterization</li> </ul>	<p><b>Product Support</b></p> <ul style="list-style-type: none"> <li>• fit for purpose assays</li> <li>• harmonized protocols</li> <li>• Vx/Tx proof-of-concept studies</li> </ul>
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## BARDA FY21 Nonclinical Development Priorities

### BIOLOGICAL PROGRAM

#### Sudan/Marburg

#### Nonclinical Models

- Therapeutics and Vaccines
- Regulatory pathways: CDER and CBER

#### Universal Influenza Vaccines

- Refine naïve and immunologically experienced, predictive ferret models
- Vaccine candidate testing

#### SARS-CoV-2 models

### RAD/NUC PROGRAM

#### Thrombocytopenia/ Endotheliopathy

- Efficacy of therapeutics
- Product Repurposing

#### Enhance ARS Nonclinical Models

- Inter-laboratory reproducibility
- Periodic performance verification

#### New Areas:

- Next Generation Blood Products
- Antibiotics in context of nuclear detonation

### CHEMICAL PROGRAM

#### Opioids

- POC/efficacy studies

#### Pulmonary Agents Systemic Asphyxiants Vesicants

- Nerve Agents
- Model characterization
- Inter-laboratory reproducibility

IMPROVE EFFICIENCY

DIMINISH REDUNDANCIES

IMPROVE PARTNER ALLIANCES



# DNCD

Division of Nonclinical Development

ENHANCE REGULATORY RIGOR

ADDRESS OPERATIONAL PRIORITIES

INCREASE LABORATORY CAPACITY

# BARDA's REGULATORY AND QUALITY AFFAIRS DIVISION (RQA)

## OVERVIEW

### RQA

- Supports regulatory and quality strategy for project coordination teams to ensure safe and effective medical countermeasures and minimize risks
- Interprets and advises on regulations, guidance and best practices
- Reviews FDA submissions and other relevant documents
- Participates in pre- and post-award activities, site visits, FDA meetings, etc.

### Regulatory Branch

- Provides Regulatory subject matter expertise
- USG-interagency collaborations/working groups

### Regulatory Operations Branch

- Responsible for all BARDA official communications with FDA
- Prepares FDA submissions and management for BARDA-sponsored applications (e.g. investigational new drug applications, **Emergency Use Authorizations**, etc.)

### Quality Branch

- Performs Good Laboratory, Clinical and Manufacturing Practice quality audits for BARDA sponsored projects.
- Product acceptance of BARDA procured MCMs
- Oversees BARDA Quality Management System (SOPs, policies and procedures)

### BY THE NUMBERS

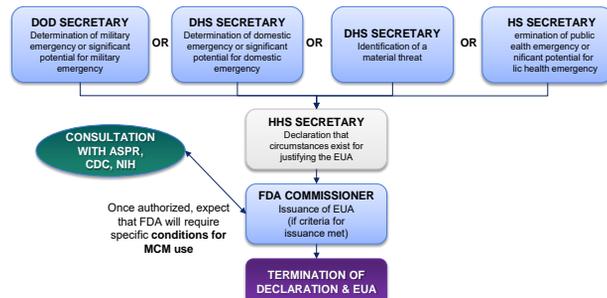
**Geared for Success**  
56 FDA Approvals, Licensures & Clearances for BARDA-supported Products

### COVID-19 PANDEMIC RESPONSE

Since the onset of the pandemic, RQA has been front and center in providing regulatory and quality support to the COVID-19 response and Operation Warp Speed for vaccines, therapeutics and diagnostics. The team has prepared and submitted 2 Emergency Use Authorizations, performed virtual manufacturer facility audits, and collaborated with our manufacturing partners, FDA and CDC to navigate the expedited and complex MCM regulatory pathway from development to distribution.

## EMERGENCY USE AUTHORIZATION (EUA)

With an EUA, FDA can authorize the use of an unapproved MCM, or the unapproved use of an approved MCM, when scientific evidence is available to support the MCM's intended use in a CBRN or other emerging infectious disease emergency (i.e., pandemic), or for a potential emergency, provided the EUA statutory criteria are met.



Updated: 10/09/2020