



# Improving access and sustainability through integration of new technologies into medical countermeasure development

Robert Johnson, PhD

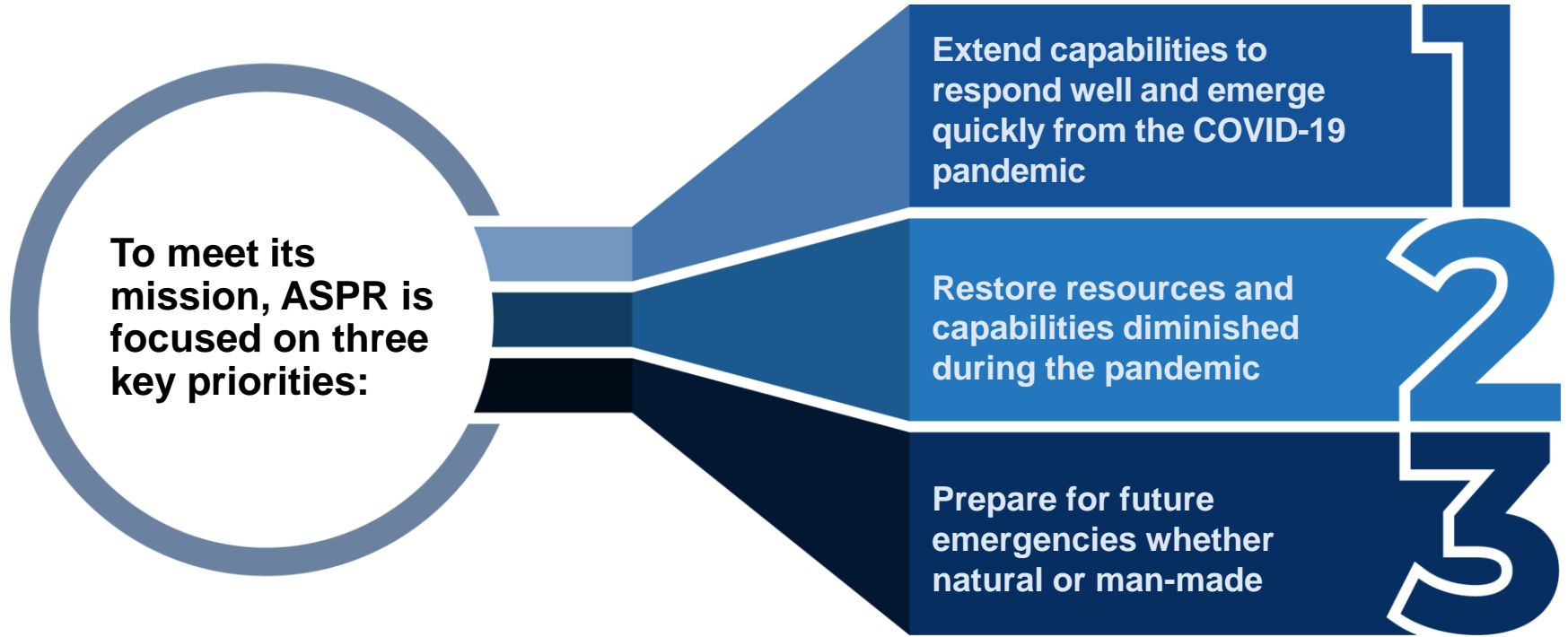
Director, Medical Countermeasures Program

Biomedical Advanced Research and Development Authority (BARDA)

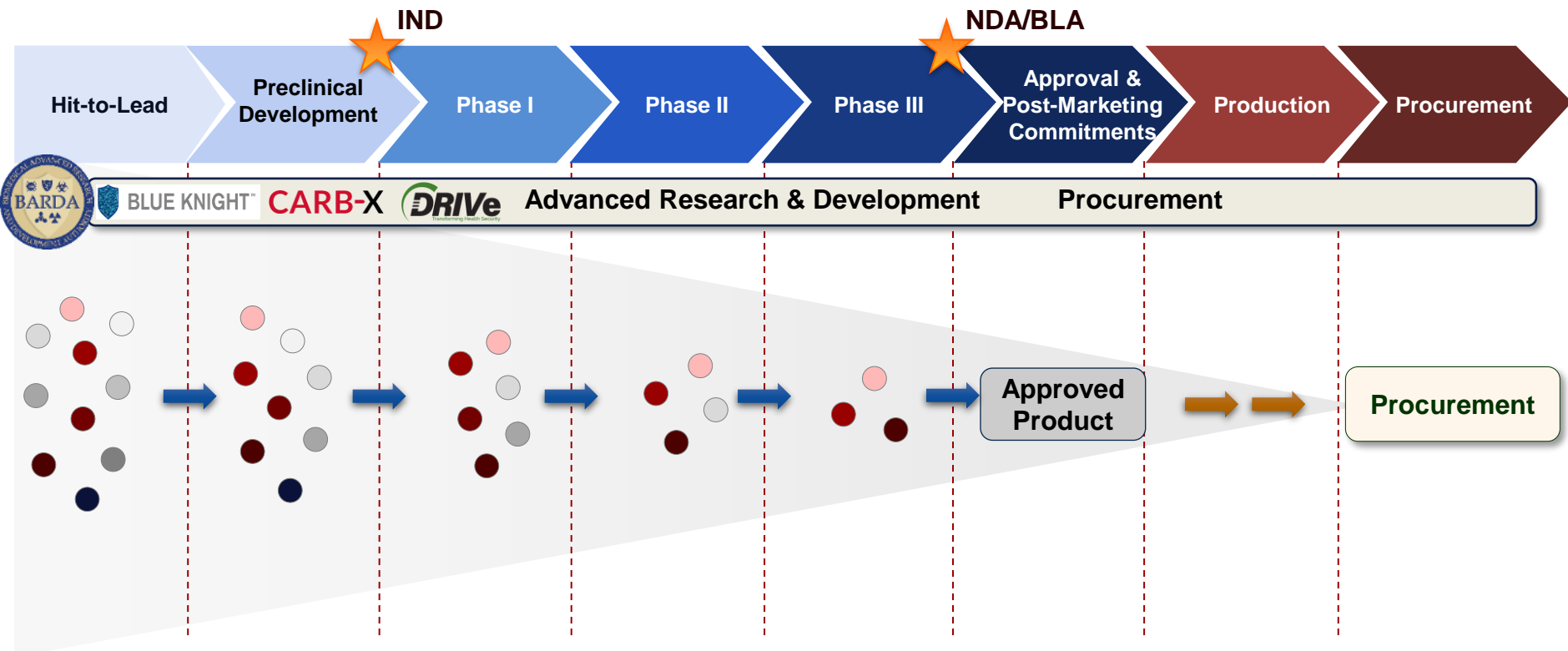
Non-Dilutive Funding Summit

January 11, 2023

# ASPR Key Priorities



# BARDA's Medical Countermeasure Development Pipeline



# How We Do It-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.



Flexible, nimble authorities

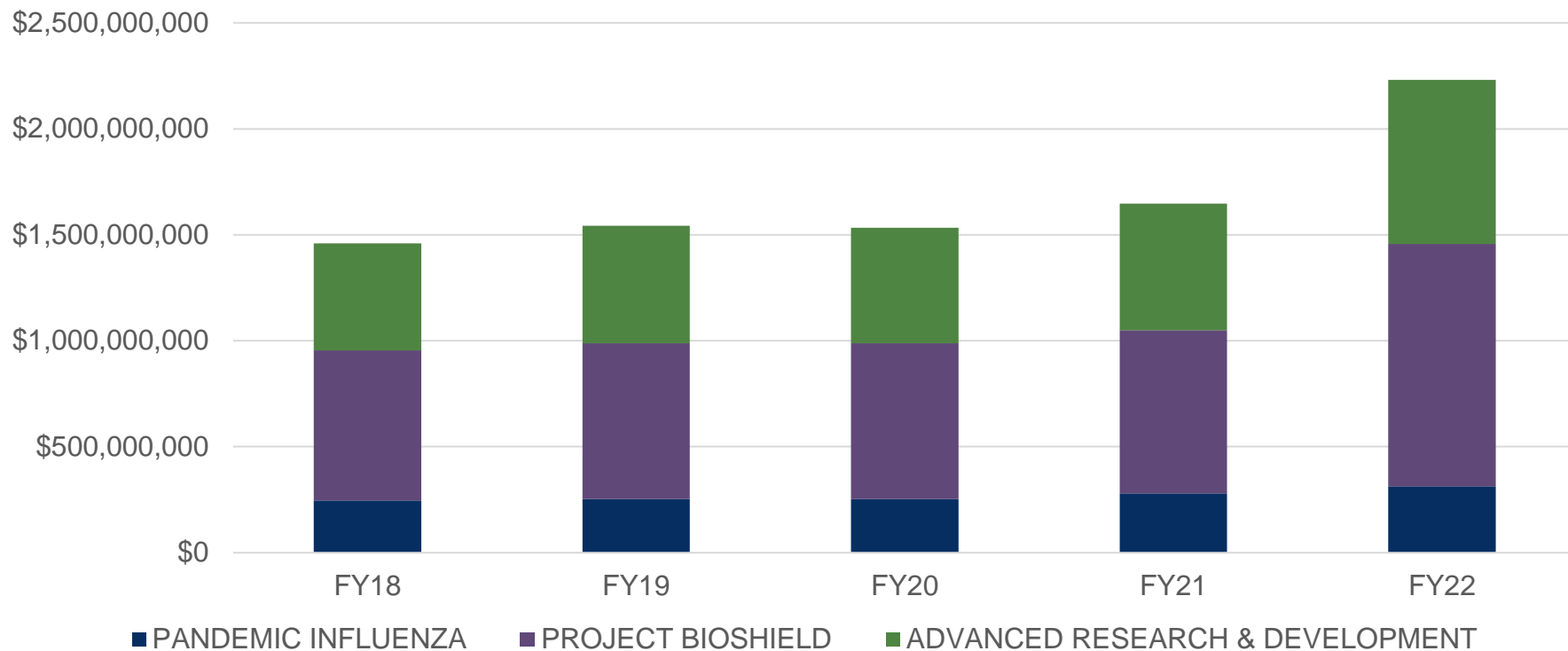
Multi-year funding

Cutting edge expertise

Facilitate partnerships

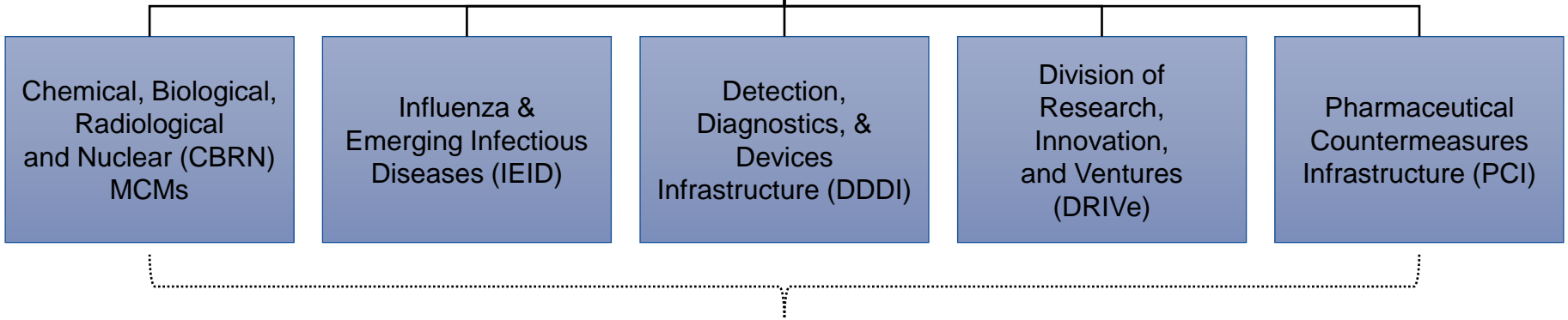
Promote innovation

# BARDA Investments – Annual Appropriations



# Biomedical Advanced Research and Development Authority (BARDA)

## Medical Countermeasures Program



## Medical Countermeasures Support Services



# Our Industry Partners

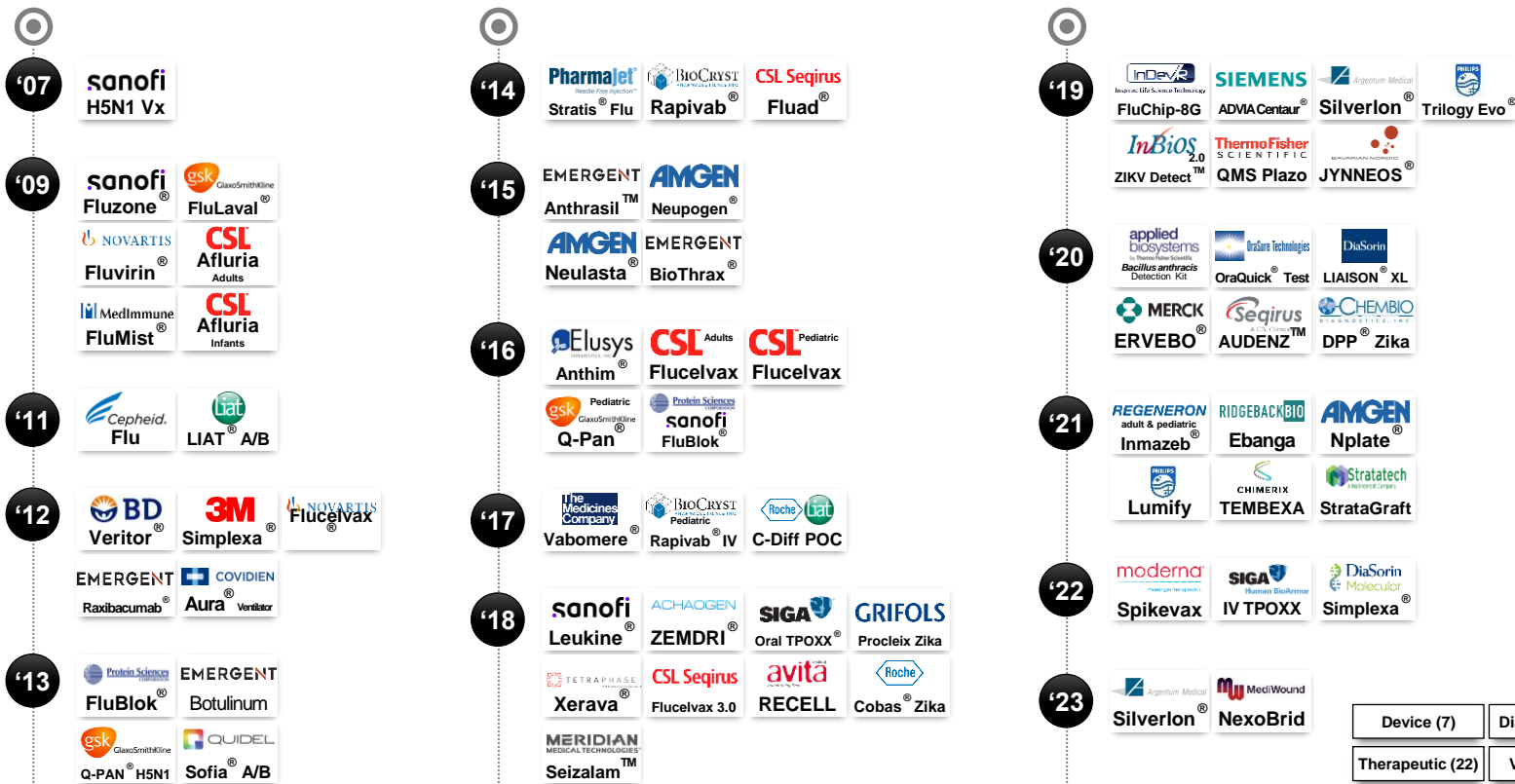


# Our Government Partners

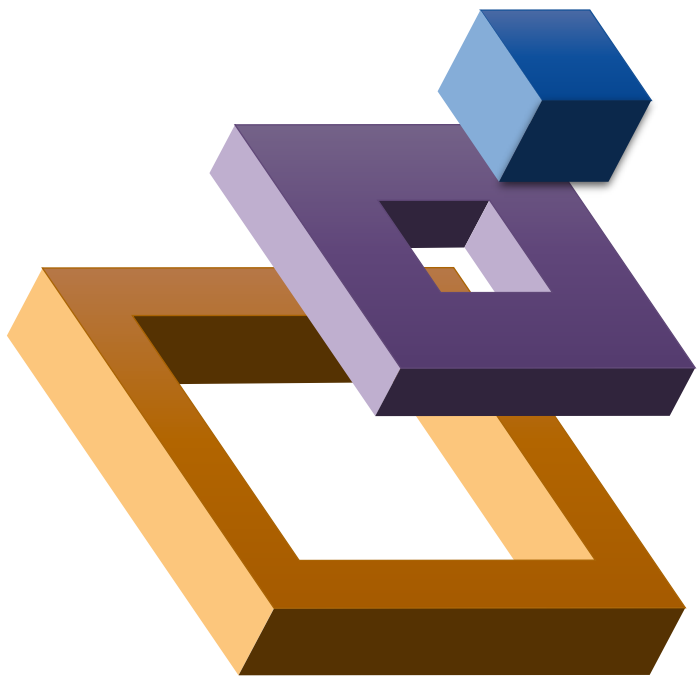





# 66 FDA Approvals, Licensures, and Clearances



# Impact of Product Approvals



## Response: Ebola MCMs

Therapeutics  
ebanga  Inmazeb™

Vaccines  
ERVEBO

Diagnostics  
 OraQuick® Rapid Antigen Test  
EBOLA

## Daily Use: Chemical and Burn Treatments

Novosorb



ReCell



StrataGraft



Silverlon



# Impact of Influenza Vaccine Partnerships

2005 - 2006

TODAY

DOMESTIC PRODUCTION FACILITIES



VACCINE PRODUCTION PLATFORMS



SEASONAL VACCINE



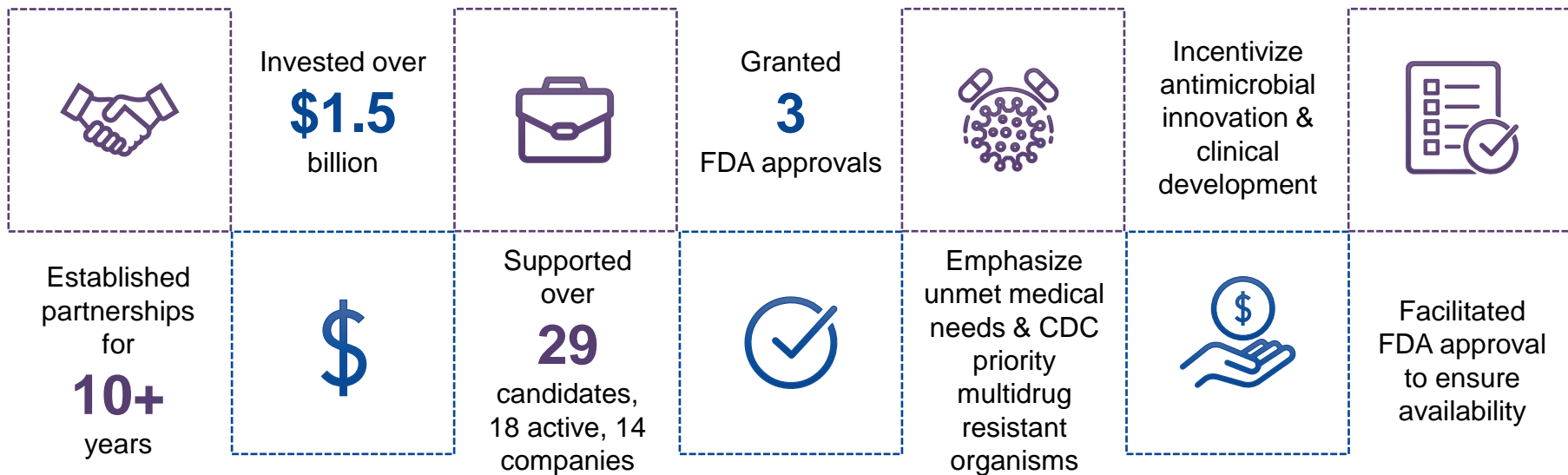
PANDEMIC CAPABILITIES

No licensed pandemic vaccines



Vaccine:

# BARDA Antibacterials: A Decade of Investment



 **VABOMERE**<sup>™</sup>  
meropenem and vaborbactam  
for injection (4 g)

 **ZEMDRI**<sup>™</sup>  
(plazomicin) Injection

 **XERAVA**<sup>™</sup>  
(eravacycline) for injection

# Examples of MCM Development During a Response



## H1N1

- » 6 FDA approved H1NA influenza vaccines
- » 186 million doses of H1N1 vaccine were produced and filled by the manufacturers
- » 120 million doses of bulk adjuvants as a contingency
- » H1N1 Diagnostic Tests

2009



## EBOLA

- » 1 FDA approved vaccine, 2 FDA approved therapeutics, 1 FDA cleared diagnostic test
- » Currently collaborating with international and interagency partners to address and contain the outbreak and coordinating with a private sector partner to develop and deliver vaccines, therapeutics & diagnostics

2014  
(and on going)



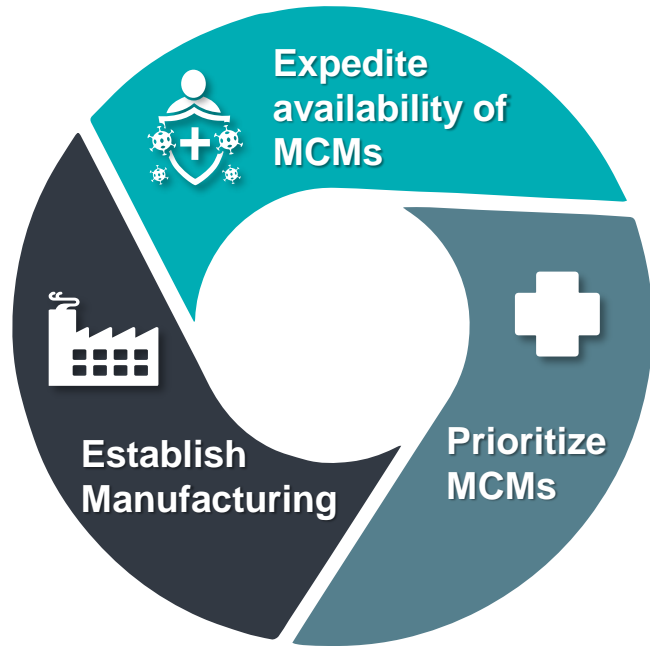
## ZIKA

- » 6 FDA-cleared diagnostic tests
- » mRNA platform vaccine that was quickly pivoted during COVID-19 response



2015

# BARDA COVID-19 MCM Response Strategy-February 2020



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

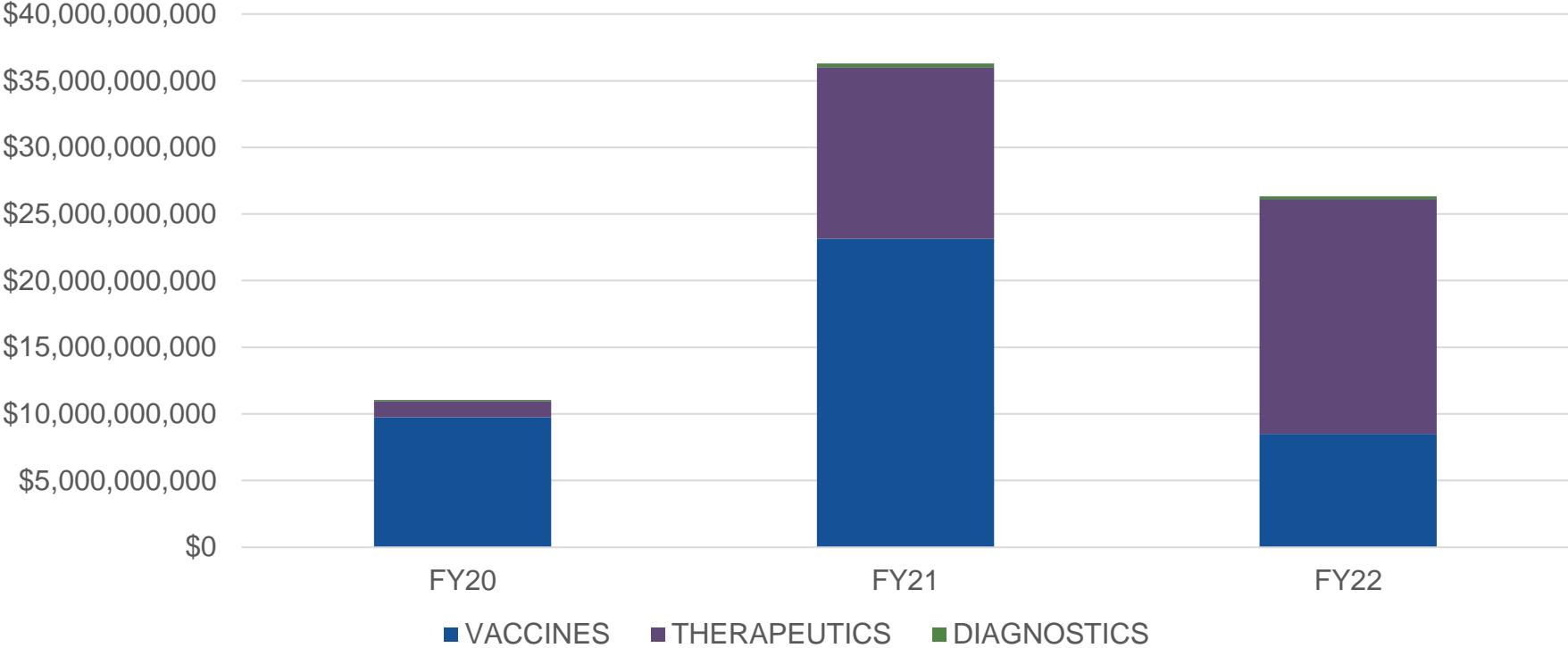


**Prioritize development of MCMs based on public health impact and their probability of success**



**Establish domestic-based manufacturing capabilities for 2019-nCoV MCMs**

# COVID-19 Investments



# BARDA Supported COVID-19 Vx and Tx with EUA

**BLA** Product Licensed

**EUA** Emergency Use Authorization Granted

## Therapeutics

**MERCK**

LAGEVRIO (Molnupiravir)

EUA

**Lilly**

Bebtelovimab

EUA

AstraZeneca

**DARPA**

Evusheld (tixagevimab administered with cilgavimab)

EUA

**gsk**

Sotrovimab

EUA

**Pfizer**

Paxlovid (nirmatrelvir co-administered with ritonavir)

EUA

**Lilly**

Bamlanivimab & etesevimab (administered together)

EUA

**REGENERON**

REGEN-COV (casirivimab and imdevimab)

EUA

**Roche** **Genentech**  
A Member of the Roche Group

ACTEMRA (tocilizumab)

EUA

## Vaccines

**Johnson & Johnson**  
janssen

Ad26 COVID-19 Vaccine

EUA

**moderna**  
messenger therapeutics

mRNA-1273

BLA

**NOVAVAX**  
Creating Tomorrow's Vaccines Today

NVX-CoV2373

EUA

**Pfizer**

BNT162 (mRNA)

BLA



# BARDA Supported COVID-19 Dx with EUA/Clearance

	Clearance Received		EUA includes Home Testing
	Emergency Use Authorization Granted		

## Laboratory

Molecular

EUA Panther Fusion SARS-CoV-2 Assay	EUA Aptima® SARS-CoV-2 assay	CLR Simplexa™ COVID-19 Direct	EUA ARIES® SARS-CoV-2 Assay	EUA NxTAG® CoV Extended Panel
EUA Aptima® SARS-CoV-2/Flu Assay	EUA QIAstat-Dx Respiratory SARS-CoV-2 Panel	EUA ePlex Respiratory Pathogen v2 Panel	EUA ViroKey™ SARS-CoV-2 RT-PCR Test (Manual)	EUA ViroKey™ SARS-CoV-2 RT-PCR Test v2.0 (Automated)

## Point of Care

EUA Accula® SARS-CoV-2 Diagnostic Test	EUA COVID-19 Health Monitoring System & Mobile App
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Antibody & Antigen

EUA Atellica® IM SARS-CoV-2 Total (COV2T) assay	EUA ADVIA Centaur® SARS-CoV-2 Total (COV2T) assay	EUA LIAISON SARS-CoV-2 TrimericS IgG Assay
EUA LIAISON SARS-CoV-2 IgM Test	EUA LIAISON SARS-CoV-2 S1/S2 IgG	EUA LIAISON SARS-CoV-2 Antigen
EUA VITROS® SARS-CoV-2 Ag (Antigen) Test		

<b>Both</b>	EUA Xpert Xpress SARS-CoV-2 test
EUA Xpert Xpress SARS-CoV-2/Flu/RSV test	

EUA SCoV-2 Detect™ IgG Rapid Test	EUA SCoV-2 Ag Detect™ Rapid Test	EUA ADEXUSx® COVID-19 Serology Test
EUA IntelliSwab™ COVID-19 Rapid Test	EUA IntelliSwab™ COVID-19 Rapid Test Rx	EUA IntelliSwab™ COVID-19 Rapid Test Pro



# COVID-19 Response

**146**

COVID-19 Partnerships

**4724**

Market Research Submissions

**789**

CoronaWatch Meetings

**3**

FDA Approvals, Licensures, and Clearances

**29**

Diagnostic Test EUAs

**286M**

Diagnostic Test Kits Shipped

Emergency Use Authorizations Supported by the USG  
**4** Vaccines  
**8** Therapeutics

**105** Products Supported

**\$80 billion** Awarded  
\$47.5B vaccines | \$31.4B therapeutics | \$.81B diagnostics

COVID-19 Vaccine Doses  
**918M** Delivered  
**653M** Administered

As of 12/01/2022



# Looking to the....



# BARDA Strategy: 2022-2026

## GOAL 1

Rapidly develop safe, effective medical countermeasures accessible to all Americans



## GOAL 2

Maintain a sustainable, mission-ready response posture

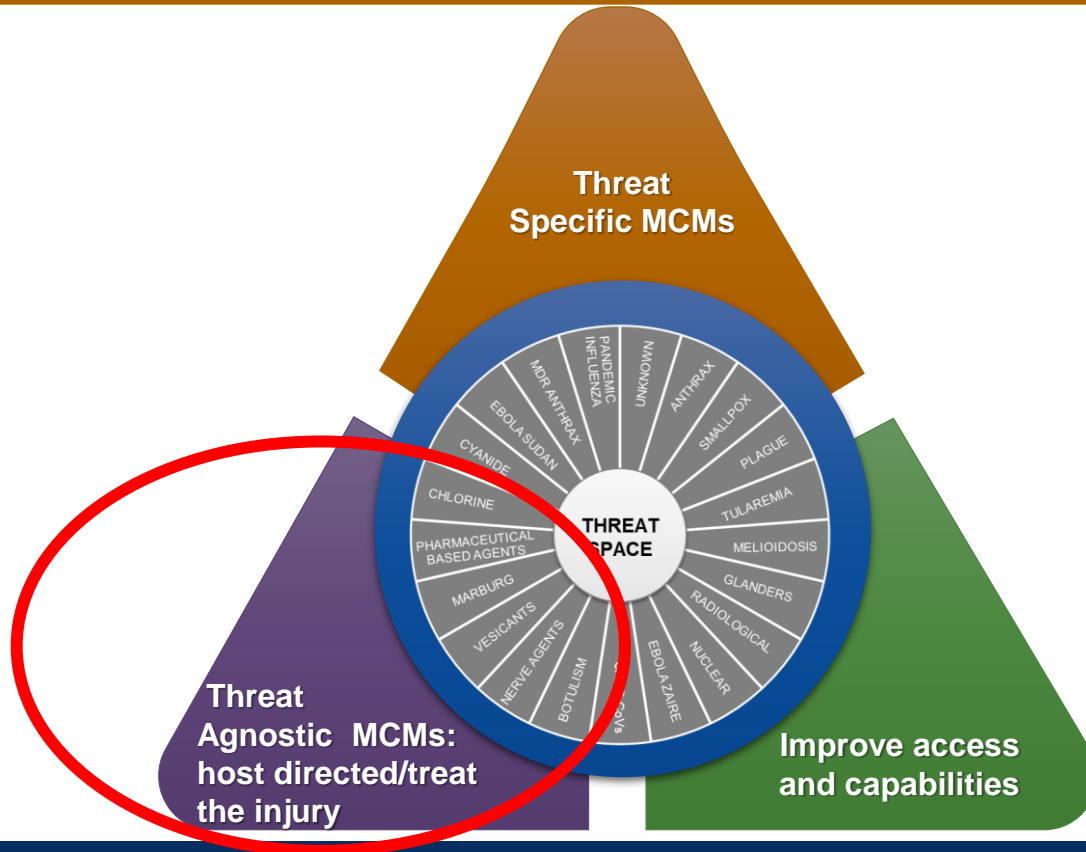
## GOAL 4

Build and support a world-class workforce

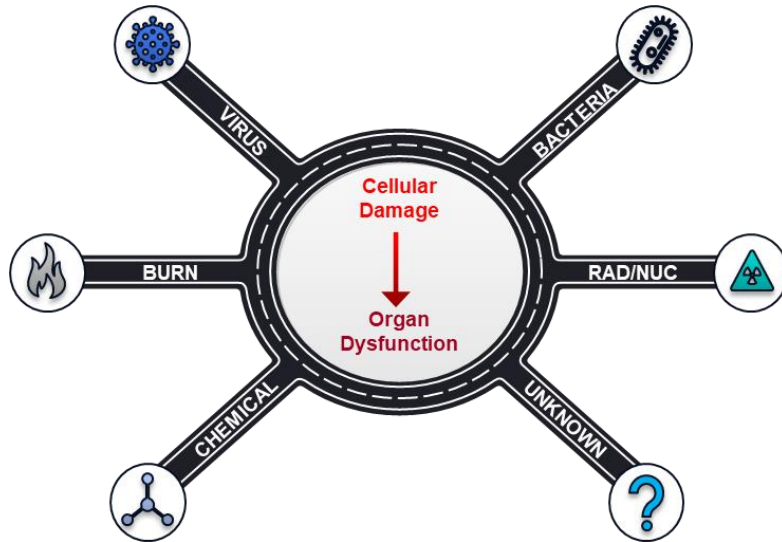
## GOAL 3

Leverage mechanisms to foster flexible partnerships

# MCM Development-What Does 2023 look like?



# We need to be fully prepared for the severe outcomes of public health emergencies (PHEs)



*All roads may lead to host dysregulation and organ dysfunction*

**Host directed therapeutics can mitigate common host pathways triggered by illness, injury, or infection**

# Strategic Objectives

## Multi-purpose

### Develop a threat-agonist pipeline of countermeasures

- » Broad spectrum use for chemical and conventional indications
- » Ease of availability during chemical emergency

## Repurposed

### Repurpose common drugs for chemical indications

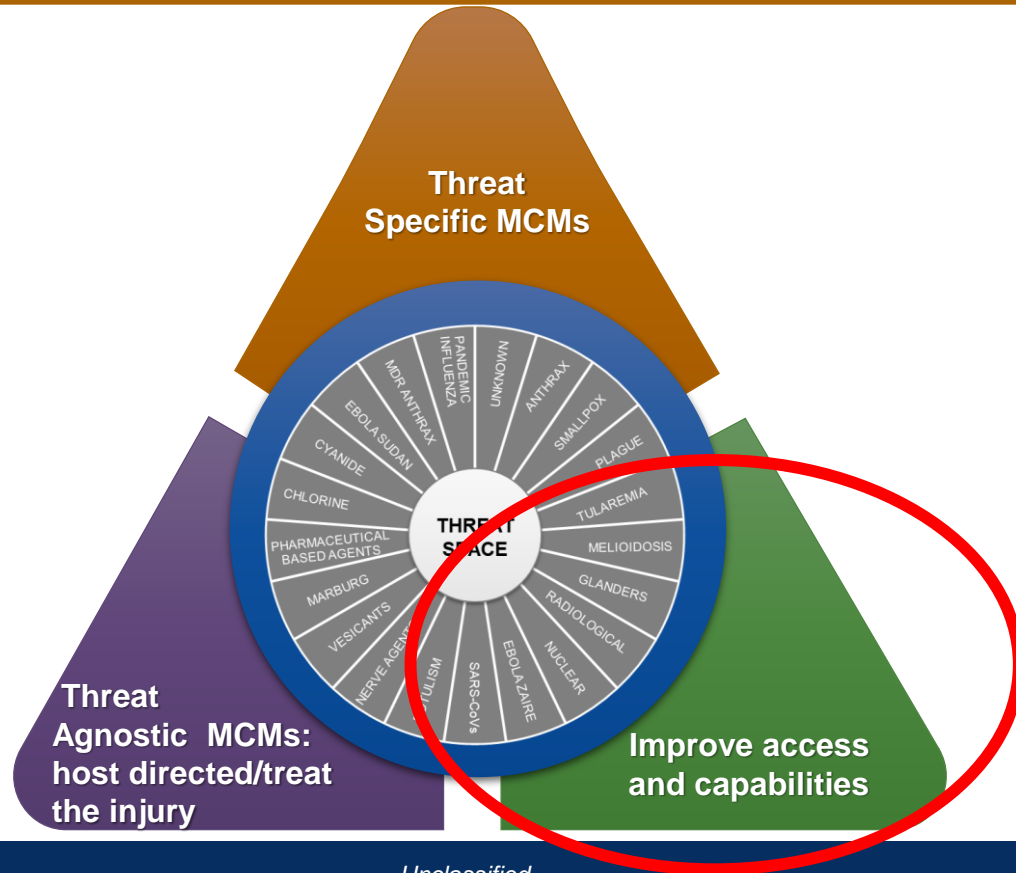
- » Allows for use of readily available drugs for chemical injury
- » Far forward positioned drugs with the end-user

## User Focused

### Improve end-user engagement

- » Ensure that first responders have the products when and where they need them
- » Create a channel of communication directly with end-users

# MCM Development-What Does 2023 look like?





# Harness New Technologies to Improve Capabilities/Access

**BARDA develops lifesaving medical products that are better, faster, and integrated into your life, to help keep you and your family safe from health threats**



## Products

We Invest in and secure FDA Approvals of a broad portfolio of safe and effective medical products for known health threats that expand access for all with a goal of home delivery and self-administration



## Rapid

We are building new capabilities to make and deliver new products to households. We will be prepared for known threats immediately with FDA approved products, and we seek to deliver products against novel health threats in as little as 130 days.



## Empower

Home use of FDA Approved medical products that can reduce your risk of getting sick, tell you if you are sick or those around you may be sick and even treat you, if you get sick



## Impact

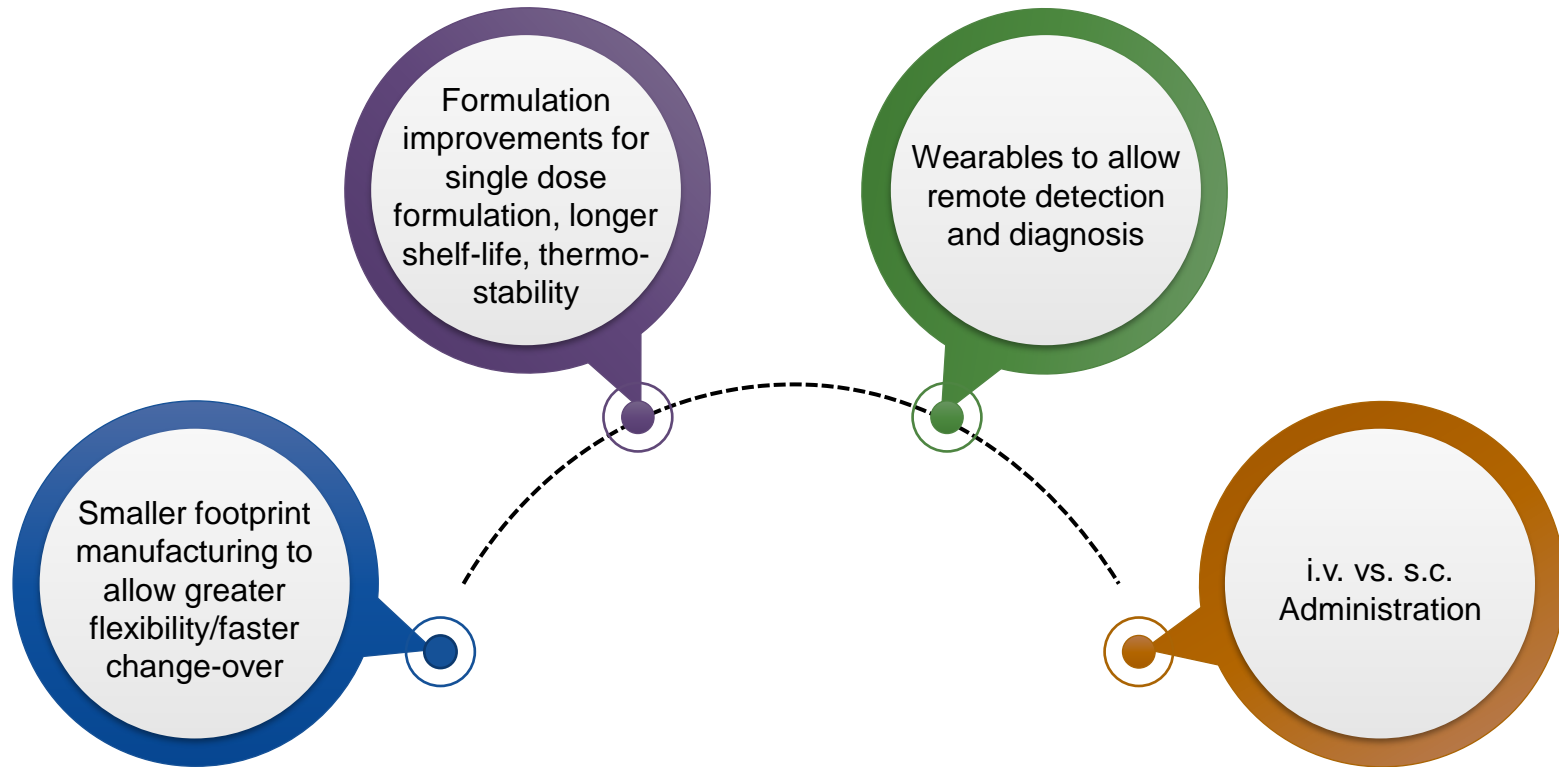
Products developed for home use requires a new model and individuals willing to support being part of clinical trials by testing products at home.



## Sustainment

We will do this while continuing to innovate, sustain the progress we have made and ensure next generation of products are available faster, safer, more effective, and easier to use.

# Technologies Exist to Improve Product Attributes...



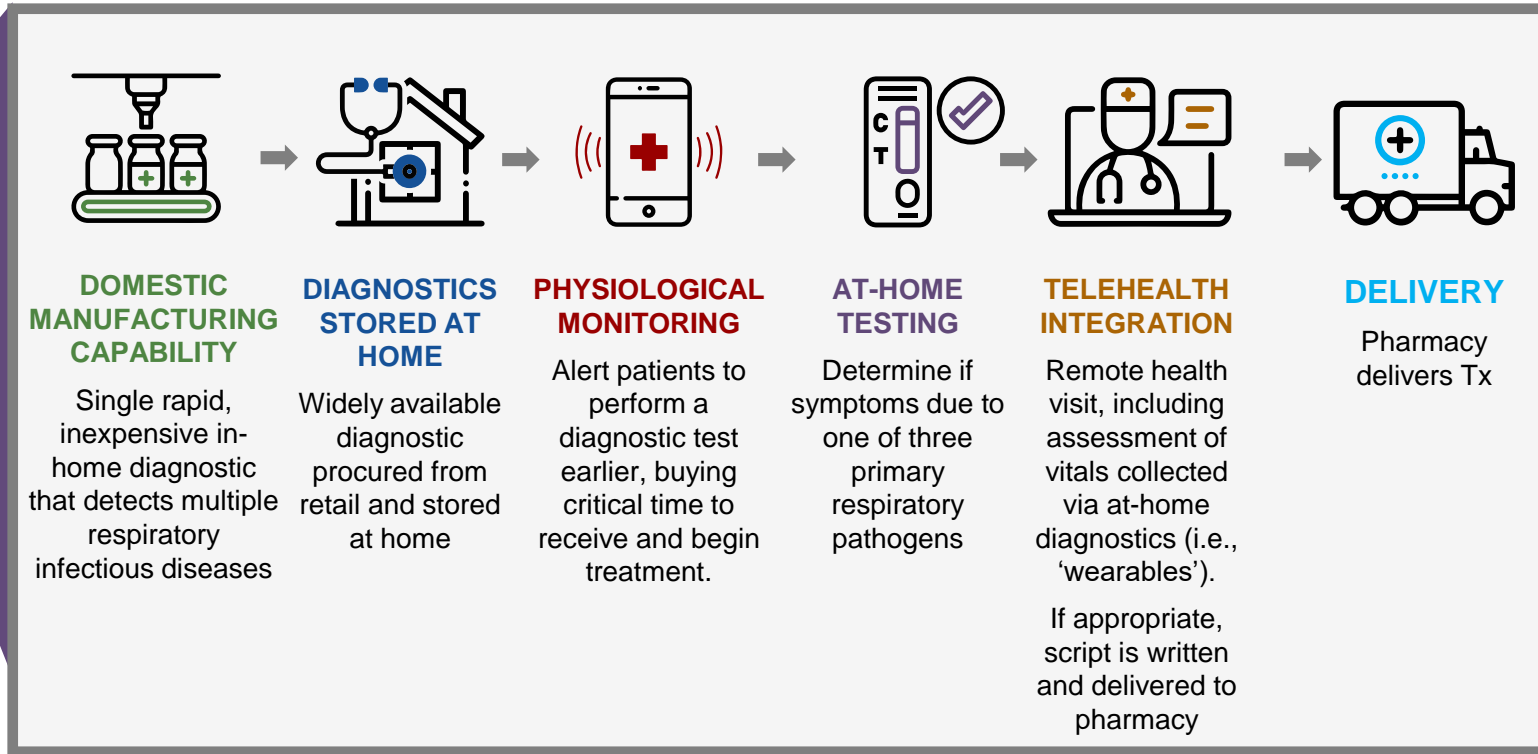
# ...But needs to be in the context of end-to-end solutions

Example: Utilize Technologies to Improve Existing Capabilities for Better Access

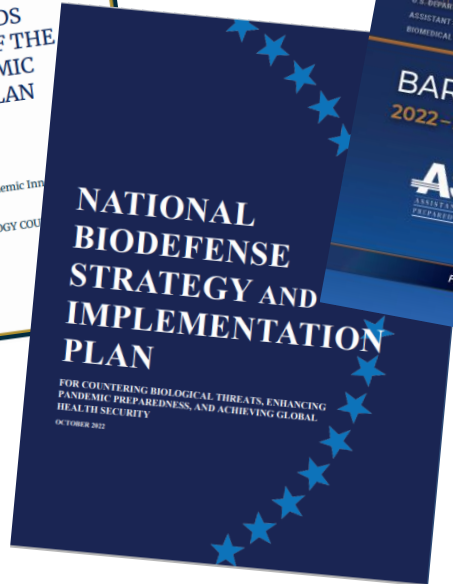
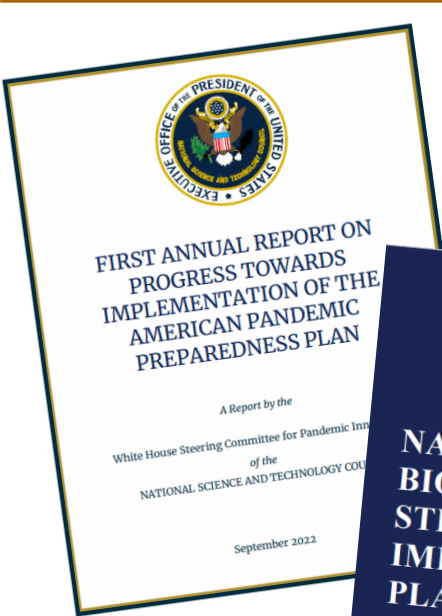


## TARGET

Wrap-around solution to improving access to diagnostics, diagnosis, and receiving treatment



# Pandemic Preparedness for Future Threats



HUMAN VACCINES & IMMUNOTHERAPEUTICS  
2020, VOL. 16, NO. 11, 2855-2860  
<https://doi.org/10.1080/21645515.2020.1741313>



COMMENTARY

OPEN ACCESS

Lessons learned from Zaire ebolavirus to help address urgent needs for vaccines against Sudan ebolavirus and Marburg virus

Daniel N. Wolfe, Marva J. Taylor, and Amanda G. Zarrabian

Division of CBRN Countermeasures, Biomedical Advanced Research and Development Authority, Washington, DC, USA

HUMAN VACCINES & IMMUNOTHERAPEUTICS  
2022, VOL. 18, NO. 6, e2129930 (6 pages)  
<https://doi.org/10.1080/21645515.2022.2129930>



RESEARCH ARTICLE

OPEN ACCESS

Advancing development of medical countermeasures: Incorporating COVID-19 lessons learned into future pandemic preparedness planning

Robert A. Johnson<sup>a,b</sup>, Richard C. White<sup>a,b</sup>, and Gary L. Disbrow<sup>a</sup>

<sup>a</sup>Department of Health and Human Services, Biomedical Advanced Research and Development Authority, Administration for Strategic Preparedness and Response, Washington, DC, USA; <sup>b</sup>Booz Allen Hamilton, McLean, VA, USA

EXPERT REVIEW OF VACCINES  
2021, VOL. 20, NO. 3, 235-242  
<https://doi.org/10.1080/14760584.2021.1886931>



PERSPECTIVE

Improving pandemic preparedness through better, faster influenza vaccines

Matthew Newland<sup>a</sup>, David Durham<sup>a</sup>, Jason Asher<sup>b</sup>, John J. Treanor<sup>a</sup>, Jonathan Seals<sup>a</sup>, Ruben O. Donis<sup>a</sup> and Robert A. Johnson<sup>a</sup>

<sup>a</sup>Biomedical Advanced Research and Development Authority (BARDA), Office of the Assistant Secretary for Preparedness and Response (ASPR), U.S. Department of Health and Human Services (HHS), Washington DC, USA; <sup>b</sup>Leidos Supporting the Biomedical Advanced Research and Development Authority (BARDA), Office of the Assistant Secretary for Preparedness and Response (ASPR), U.S. Department of Health and Human Services (HHS), Washington DC, USA

# Pandemic Preparedness Planning: Key Considerations

- » Licensed, off-the-shelf MCMs that can be rapidly deployed at the beginning of an outbreak
- » Threat-agnostic MCMs and platform technologies to enable pivoting between ongoing and emerging threats

- » New business models and technologies that reduce production and sustainment costs
- » Funding mechanisms that support rapid response to small and large outbreaks

**Preparedness: Suite of Licensed & Stockpiled MCMs**

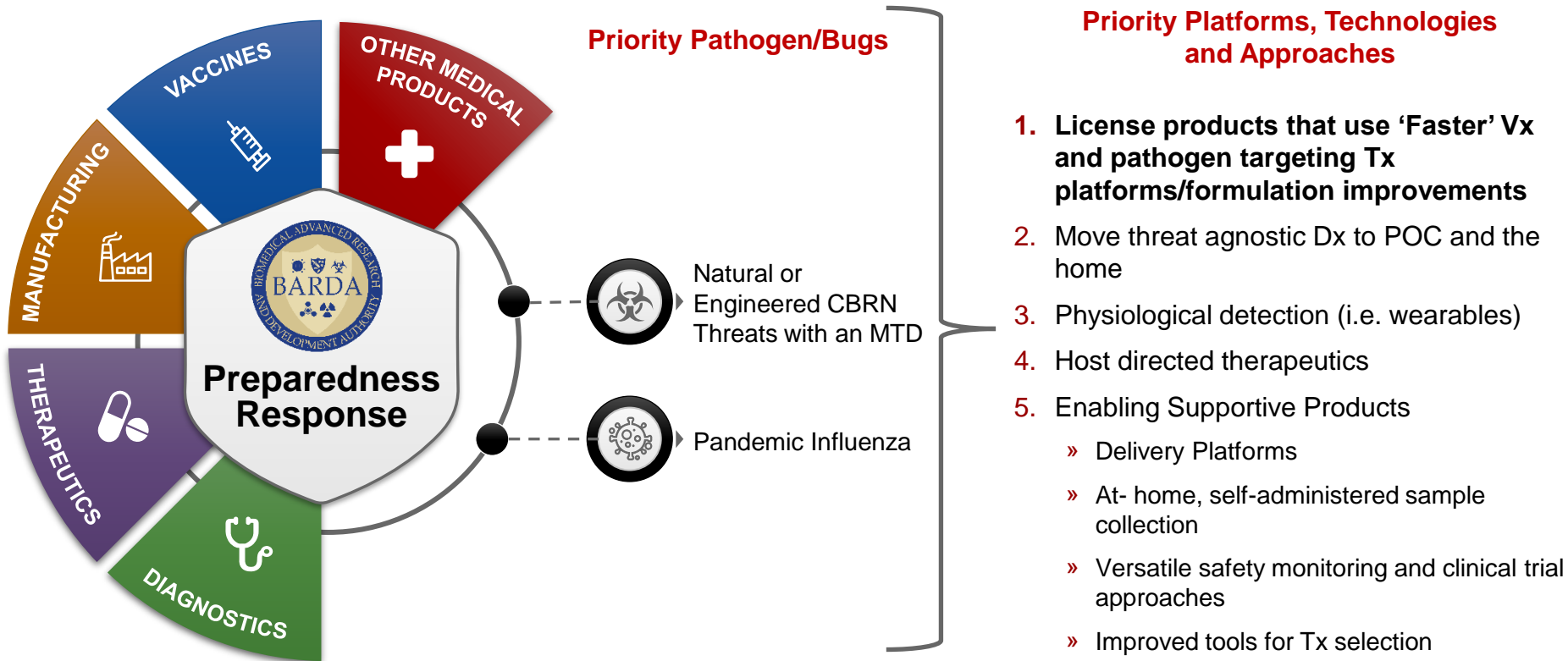
**Response: Rapid Development & Manufacturing Capabilities**

**Partnerships: Funding & Sustainment**

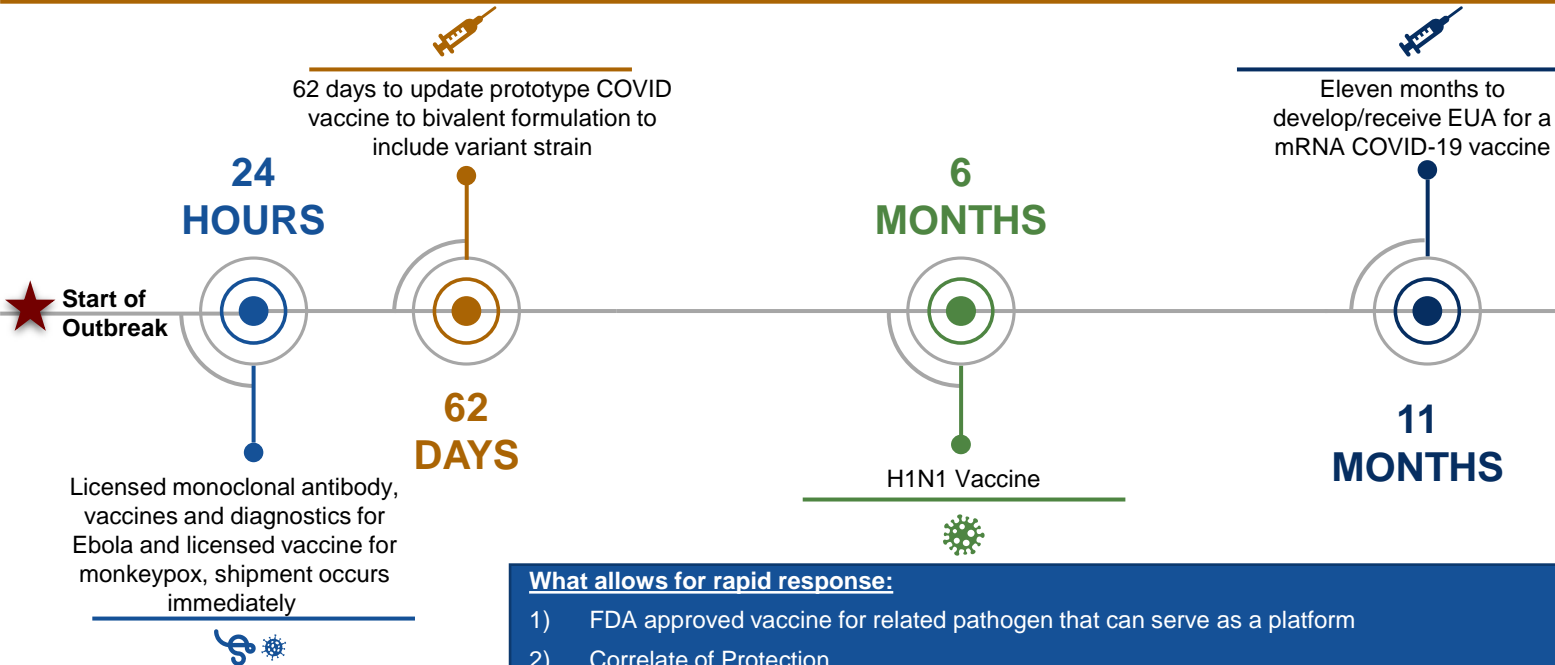
**End User & Access: New Technologies**

- » Nimble operations and infrastructure response framework
- » End-to-end development partnerships
- » Faster clinical, non-clinical, and manufacturing approaches
- » Simpler/self-administration
- » No cold chain requirement
- » Reduced number of administrations/doses required
- » At-home delivery/use to maximize uptake

# BARDA MCM Strategic Framework

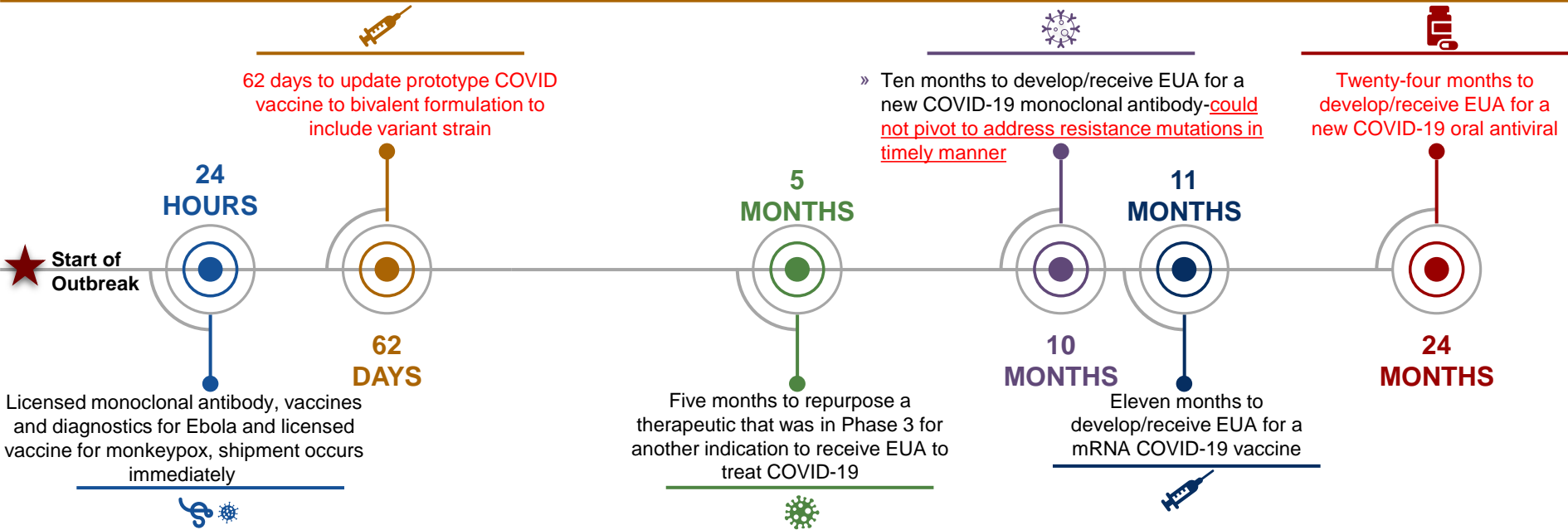


# Vaccine Approach to Address Rapid Response Capability



- What allows for rapid response:**
- 1) FDA approved vaccine for related pathogen that can serve as a platform
  - 2) Correlate of Protection
  - 3) Flexible Platform with ongoing manufacturing
  - 4) Ability to do large-scale production/filing in absence of any Clinical Trial data
  - 5) Clinical trial requirements that do not delay product release
- \*No one-size fits all platform, so important to maintain capability for other platforms even if they have a longer timeline*

# Technologies to Support Rapid Response Therapeutic Approach Needed



What we need: Direct acting Tx equivalent of mRNA for Vx. Affordable and sustainable 'platform' to rapidly pivot to new strains/viruses, identify, develop, and test new candidates, and achieve regulatory approval and large scale manufacturing



# Partnership Approaches



## **PUSH (Traditional)**

- » Broad Agency Announcement (BAA)
- » Request for Proposal (RFP)
- » EZ BAA



## **PUSH (Alternative)**

- » BARDA
- » Ventures GHIC
- » J&J Blue Knight



## **PULL**

- » Challenges

# Relevant BARDA Opportunities

## BARDA BAA

- » Non-Dilutive
- » Multi-million, multi-year awards
- » Advanced Development

<https://www.medicalcountermeasures.gov/barda/barda-baa/>

## BARDA DRIVe EZ-BAA

- » Non-Dilutive
- » < \$750,000; “Plus phase” > \$20 million
- » 30-50% resource sharing requirement
- » Rapid review /award – as fast as within 30 days of submission

<https://drive.hhs.gov/partner.html>

## BARDA Ventures

- » Equity investment
- » GHIC Partnership
- » Approximately \$1-5M
- » Any stage of development

<https://drive.hhs.gov/ventures.html>

## BARDA DRIVe Accelerator Network and JLABs Blue Knight Partnership

- » Wrap-around support with educational programming, mentorship opportunities, incubator space and networking
- » Quickfire Challenge: Next gen solutions for preparedness

<https://drive.hhs.gov/accelerators.html>

# 2022 Reissuance of the EZ-BAA

## WHAT REMAINS THE SAME?

### Initial Phase Awards

- Awards <\$750K
- Two-stage technical review process
- Resource matching/cost-share (30-50%)



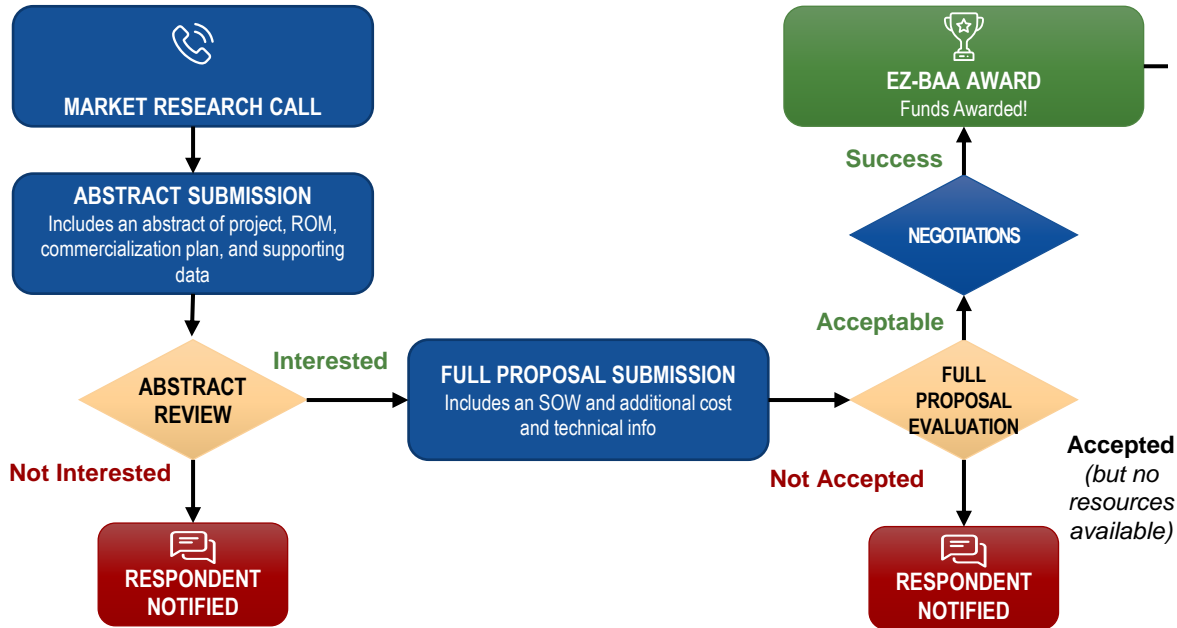
## WHAT CHANGED?

### Addition of the “+ Phase”

- Proposed projects each targeting \$2M-\$10M range, with \$20M ceiling
- Only recipients of an initial phase award eligible to submit a + Phase application
- Same two-stage review process, more in depth full proposals
- Also requires resource matching/cost-share (30-50%)

## INITIAL APPLICATION PROCESS

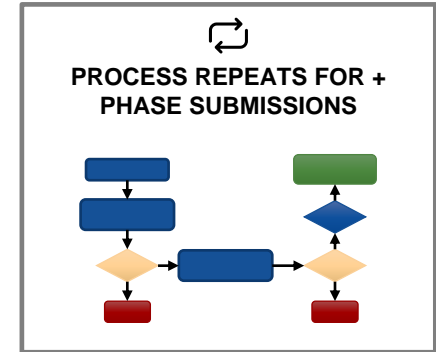
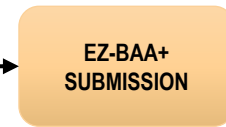
*Projects under \$750k*



## + PHASE PROCESS

*Projects up to \$20M*

Recipients of initial EZ-BAA award are eligible to submit to + Phase



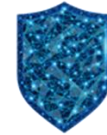
# DRIVE Ecosystems



Global Health  
Investment  
Corporation

## BARDA Ventures – GHIC Partnership

A novel public-private partnership using venture capital practices to invest in technologies for pandemic response and healthcare preparedness



## Blue Knight

Partnership between J&J and BARDA to stimulate the innovation and incubation of health security focused science and technologies



## HI-3: Healthcare Infrastructure, Implementation, and Impact

Strengthen clinical impact beyond regulatory approval by leveraging analytical insights and novel health ecosystems



## BARDA Accelerator Network

Partnership with 13 accelerators around the country to support early-stage companies overcome their biggest business, marketing, and operational hurdles, and achieve success sooner



- Catalyst
- Launch

# Mask Innovation Challenge: Phase 2 Winners



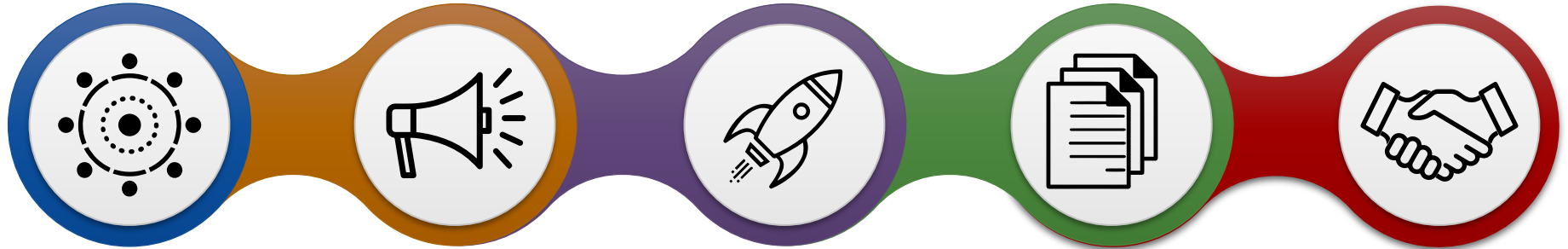
*Two overall winners each receive \$150,000 of the \$400,000 total prize purse.*



*Two runners-up receive \$50,000 each of the \$400,000 total prize purse.*



# Streamlining Partnership Opportunities-Potential 2023 Activities



Establishing National Biopharmaceutical Manufacturing Consortium (BioMaC) to enable rapid production of MCMs

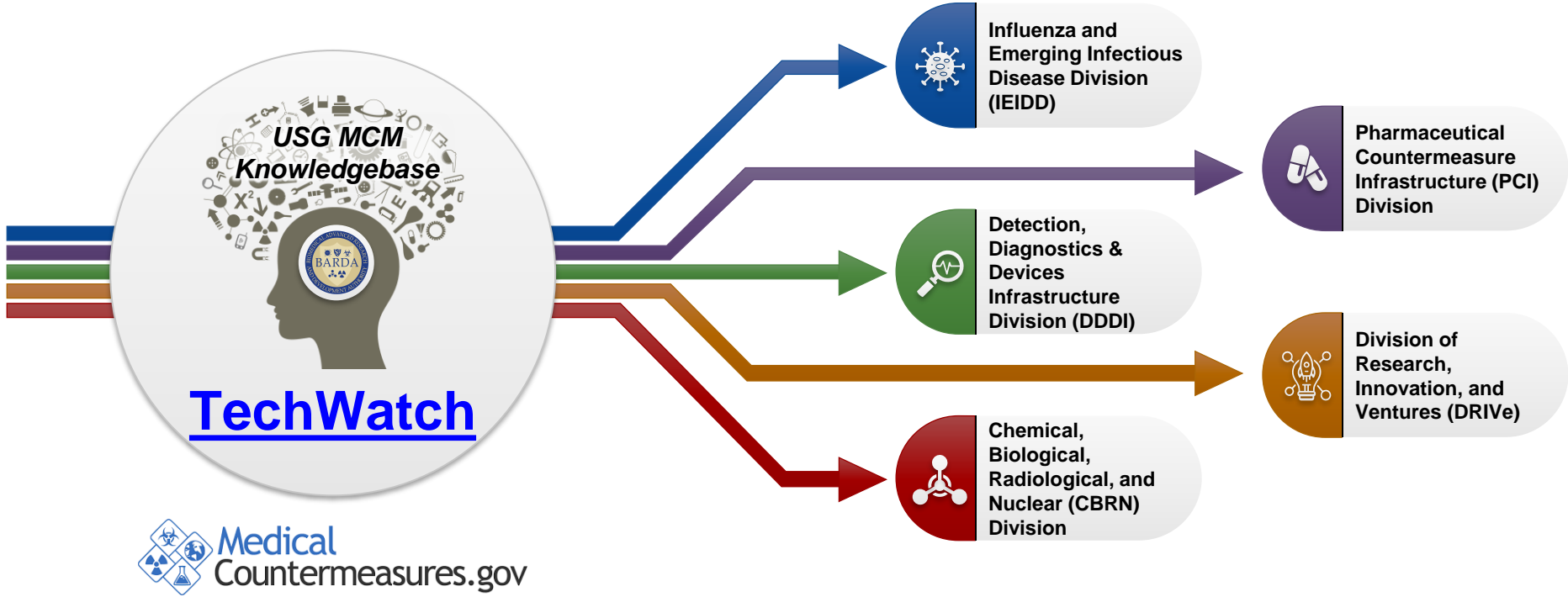
Modernizing the Broad Agency Announcement (BAA) to update and simplify the process

Launching Rapid Response Consortium with structure, speed, and agility to respond to emerging threats

Advancing multiple legislative proposals to improve the way we do business

Additional 'pull' efforts

# TechWatch: Open for Business







[medicalcountermeasures.gov](https://www.medicalcountermeasures.gov)  
*Portal to BARDA: Register to request a TechWatch meeting!*



[sam.gov/](https://sam.gov)  
*Official announcements and info for all government contract solicitations*



[aspr.hhs.gov/MCM/](https://aspr.hhs.gov/MCM/)  
*Program description, information, news, announcements*



[drive.hhs.gov](https://drive.hhs.gov)  
*Learn about DRIVE, including our Accelerator Network and EZ BAA*



[www.usajobs.gov](https://www.usajobs.gov)  
*Join the team!*



@BARDA



Biomedical Advanced Research and Development Authority



@BARDAGOV



Global Health  
Investment  
Corporation



## BARDA Ventures – GHIC Partnership

A novel public-private partnership using venture capital practices to invest in technologies for pandemic response and healthcare preparedness.





**BLUE KNIGHT™**

Anticipate. Activate. Amplify.

# BARDA Accelerator Network & Blue Knight

Supporting early-stage companies throughout their journey, to help them overcome their biggest business, marketing, and operational hurdles, and achieve success sooner



## Technology Sourcing

Identify novel technologies relevant to BARDA's strategic interest areas

## Market research

Provide insights into early-stage technology, business, and user trends to shape BARDA program strategies

## Wrap-around support

Provide focused educational programming to accelerate and scale health security challenges

## Outreach, Events, Networking

Amplifying the BARDA mission to localized innovation hubs



# Stimulating An Innovative Ecosystem

## BARDA Accelerator Network



## JLABS Blue Knight Partnership



Anticipate. Activate. Amplify.

26 companies supported



## BARDA Ventures-GHIC Partnership

7 Investments to date



Global Health Investment Corporation