



Investing in the Future of Health Security

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BARDA DRIVE



ASPR's mission:
Assist the country in
preparing for,
responding to,
and **recovering**
from public health
emergencies and
disasters.



The BARDA Model

Mission: to develop medical countermeasures that address the public health and medical consequences of chemical, biological, radiological, and nuclear (CBRN) accidents, incidents and attacks, pandemic influenza, and emerging infectious diseases

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

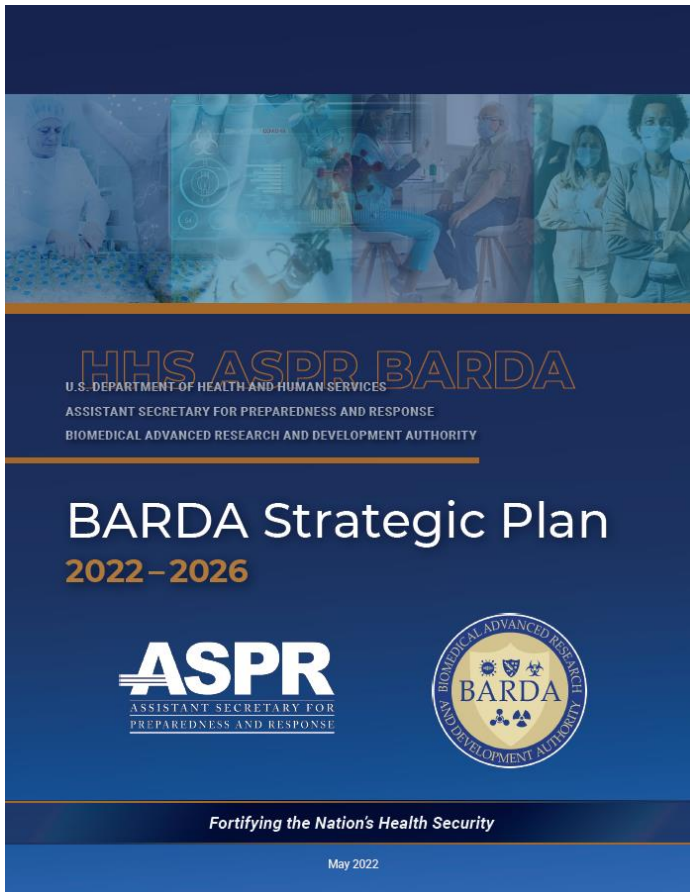
Facilitate partnerships

Promote innovation

BARDA Strategic Plan 2022-2026

The 2022-2026 document serves to effectively communicate our mission and vision to BARDA stakeholders

Learn more: www.medicalcountermeasures.gov/barda/strategic-plan/



Goal 1 – Preparedness: Rapidly develop safe, effective medical countermeasures accessible to all Americans



Goal 2 – Response: Enhance and maintain a sustainable, mission-ready response posture



Goal 3 – Partnerships: Leverage mechanisms to foster flexible partnerships



Goal 4 – Workforce: Build and support a world class workforce



Our Government Partners



Our Industry Partners



88 FDA Approvals, Licensures, and Clearances

BARDA supports a diverse portfolio of medical countermeasures and these products have received a total of 88 FDA approvals, licensures, or clearances.

10



Devices

31



Diagnostics

24



Therapeutics

23



Vaccines

AND WE HAVE MORE IN THE PIPELINE

These products cut across our threat space and have been supported with annual and supplemental appropriations. Explore more about BARDA's expanding medical countermeasure portfolio by visiting our [website](#).

Biomedical Advanced Research and Development Authority (BARDA) Office of the Director

MEDICAL COUNTERMEASURES (MCM) PROGRAM

Chemical, Biological, Radiological and Nuclear (CBRN) MCMs



Influenza & Emerging Infectious Diseases (IEID)



Detection, Diagnostics, & Devices Infrastructure (DDDI)



Division of Research, Innovation, and Ventures (DRIVE)



Pharmaceutical Countermeasures Infrastructure (PCI)



MEDICAL COUNTERMEASURES SUPPORT SERVICES PROGRAM

Regulatory and Quality Affairs (RQA)



Clinical Development (DCD)



Non-Clinical Development (DNCD)



CONTRACT MANAGEMENT & ACQUISITIONS AND BUSINESS PLANNING AND STRATEGY

Medical Countermeasures Development Services



Medical Countermeasures Support Services



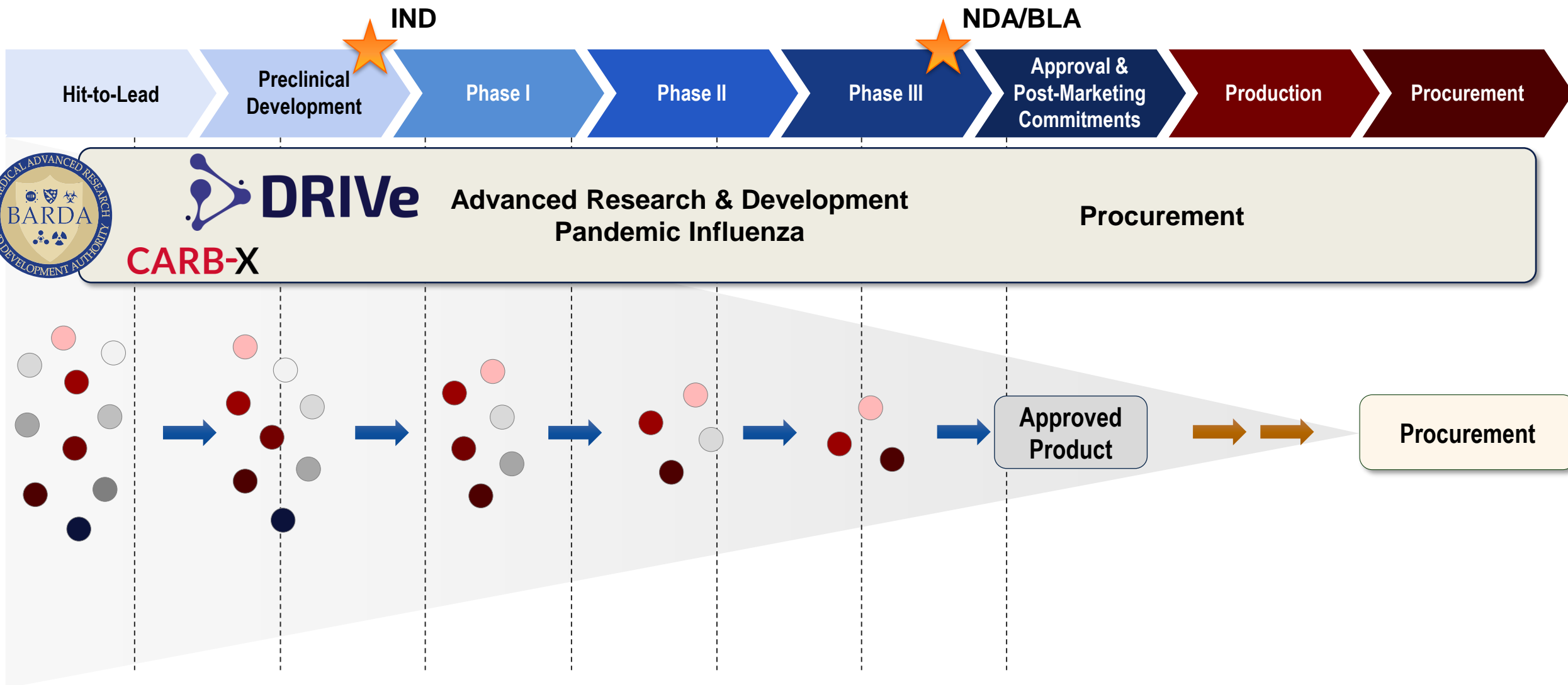
Business Operations and Compliance



DRIVE Acquisitions and Partnerships



BARDA's Medical Countermeasure Development Pipeline



Partnering for Innovation



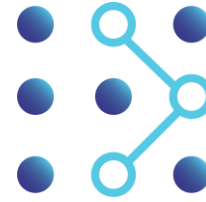
BARDA Ventures

Public-private venture capital partnership



JLABS Blue Knight

Incubating health security startups with industry & BARDA mentorship



BARDA Accelerator Network + CARB-X

Commercialization support and rapid product development



EZ-BAA

Agile R&D partnering mechanism, <\$750k



D-COHR

Building decentralized clinical trial infrastructure w/industry



Market Shaping

Prizes, target product profiles & other pull incentives to meet desired outcomes



RRPV & BioMaP

New scalable, rapid response partnering mechanism

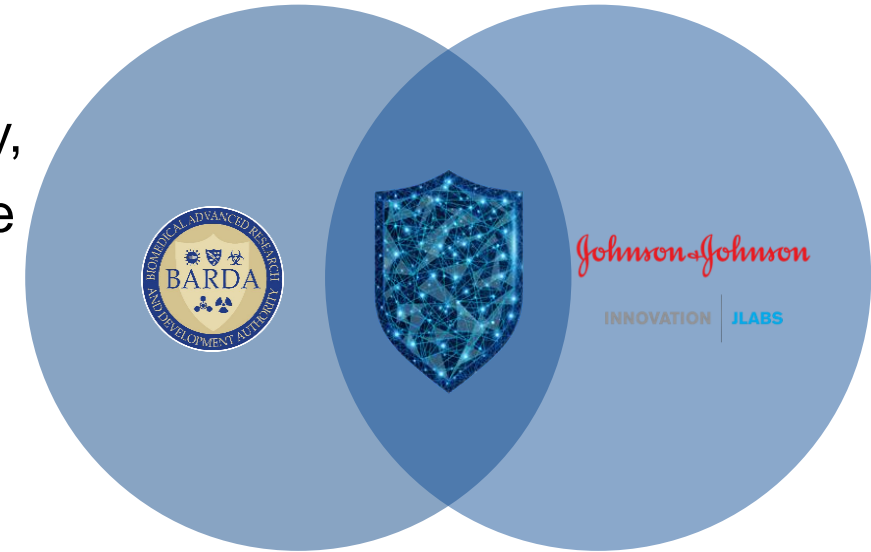


BAA

R&D partnering mechanism

BARDA – J&J Blue Knight Partnership Overview

A **public-private partnership** dedicated to **anticipating** potential health security threats, **activating** the global innovation community, and **amplifying** scientific and technological advancements with the aim of preparing for and responding to our rapidly evolving global health security landscape.



Benefits for Blue Knight Companies:

JLABS Space Access + Fee assistance

access to modular lab units, office space & shared core laboratory equipment and fee assistance for certain costs

Grant Funding

Strategic funding opportunities for portfolio companies via internal Quickfire Challenges

Cross-Sector Mentorship

dedicated mentorship from both the Johnson & Johnson Family of Companies and BARDA

Visibility and Connections

opportunities for **Blue Knight** companies to be showcased at relevant conferences and connections to investors and partners

BARDA Accelerator Network



Technology Sourcing



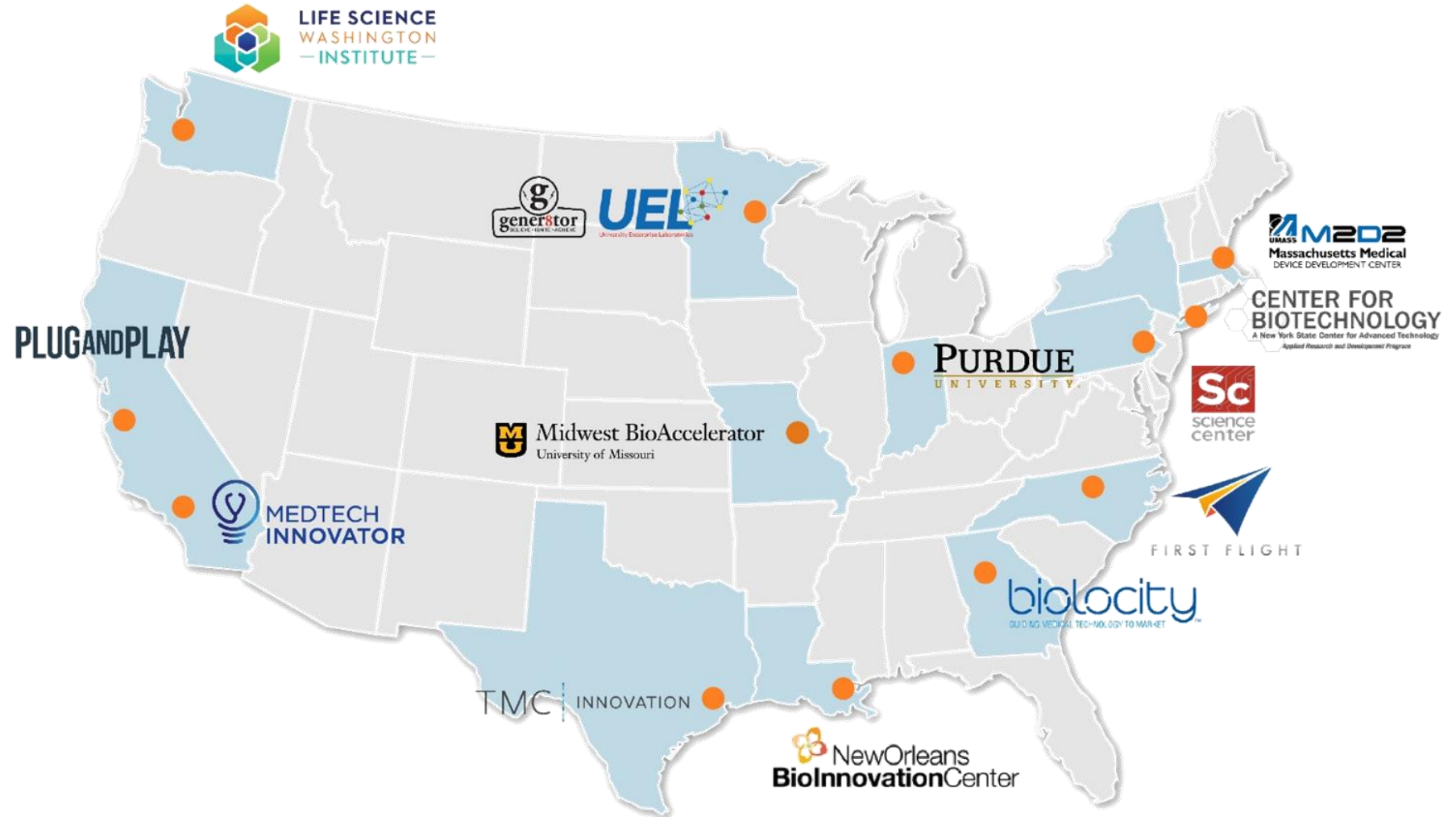
Outreach, Events
& Networking



Wrap Around Support



Market Research



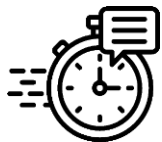
BARDA Accelerator Network 2.0



**Wraparound
Accelerator Support
Services**



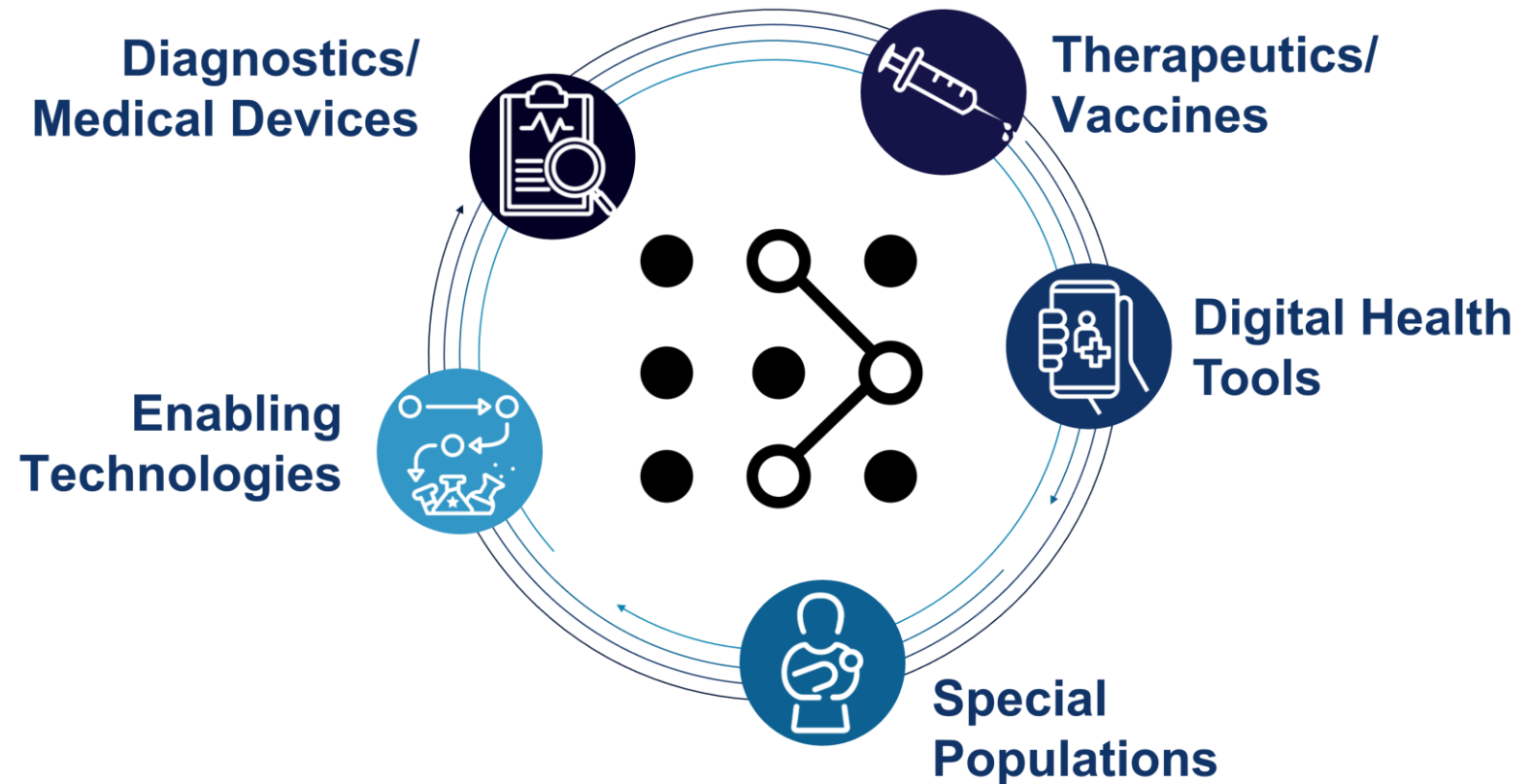
**Development,
Evaluation, and
Validation Services**



**Rapid Response
Capability**

HUB TECHNOLOGY FOCUS AREAS

Launching in 2024



CARB-X

An Engine to Accelerate Preclinical Products into Clinical Development

33

Active Projects

5 progressed in Phase I Trials

trellis
INDIRECT-ACTING
LARGE MOLECULE
ANTIBACTERIAL

Peptilomics
NOVEL CLASS OF
DIRECT-ACTING
ENGINEERED PEPTIDES

SNIPRBIOME
A CRISPR COMPANY
CRISPR-ENGINEERED
PRECISION PREVENTATIVE

bugworks
GYRASE-
TOPOISOMERASE
INHIBITOR

GSK

Non-typhoid conjugate vaccine

14

Projects Graduated

10
Approved or in clinical evaluation

T2 Biosystems

pattern
CLARAMETYX
biosciences

HELIXBIND

VEDANTA
BIOSCIENCES

PROTEUS



SERES
THERAPEUTICS

ITERUM
therapeutics

SPECIFIC

gsk

97

Projects

63

Therapeutics

18

Preventatives

16

Diagnostics

1 in 5 Supported Candidates Initiate Phase 1 Trials

THERAPEUTICS

15

Active

7

Graduated

PREVENTATIVES

13

Active

2

Graduated

DIAGNOSTICS

5

Active

5

Graduated

PARTNERS



ASPR
ADMINISTRATION FOR STRATEGIC
PREPAREDNESS AND RESPONSE

novo nordisk
foundation
Benefitting people and society



Bundesministerium
für Bildung
und Forschung



Canada



National Institute of
Allergy and
Infectious Diseases



BILL & MELINDA
GATES foundation

BOSTON
UNIVERSITY

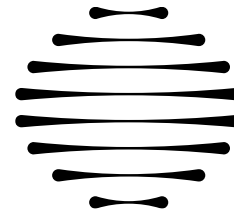
BARDA Ventures in Partnership with GHIC

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

- Active since 2021
- Venture capital investments – Equity, SAFE, Notes, etc. (not grants/contracts)
- Stage and technology type agnostic – anything within BARDA mission space
- Platform technologies with emphasis on commercial sustainability
- Investment decision made by GHIC independent of other BARDA funding/support programs
- Leverage private investment
- Evergreen funding model

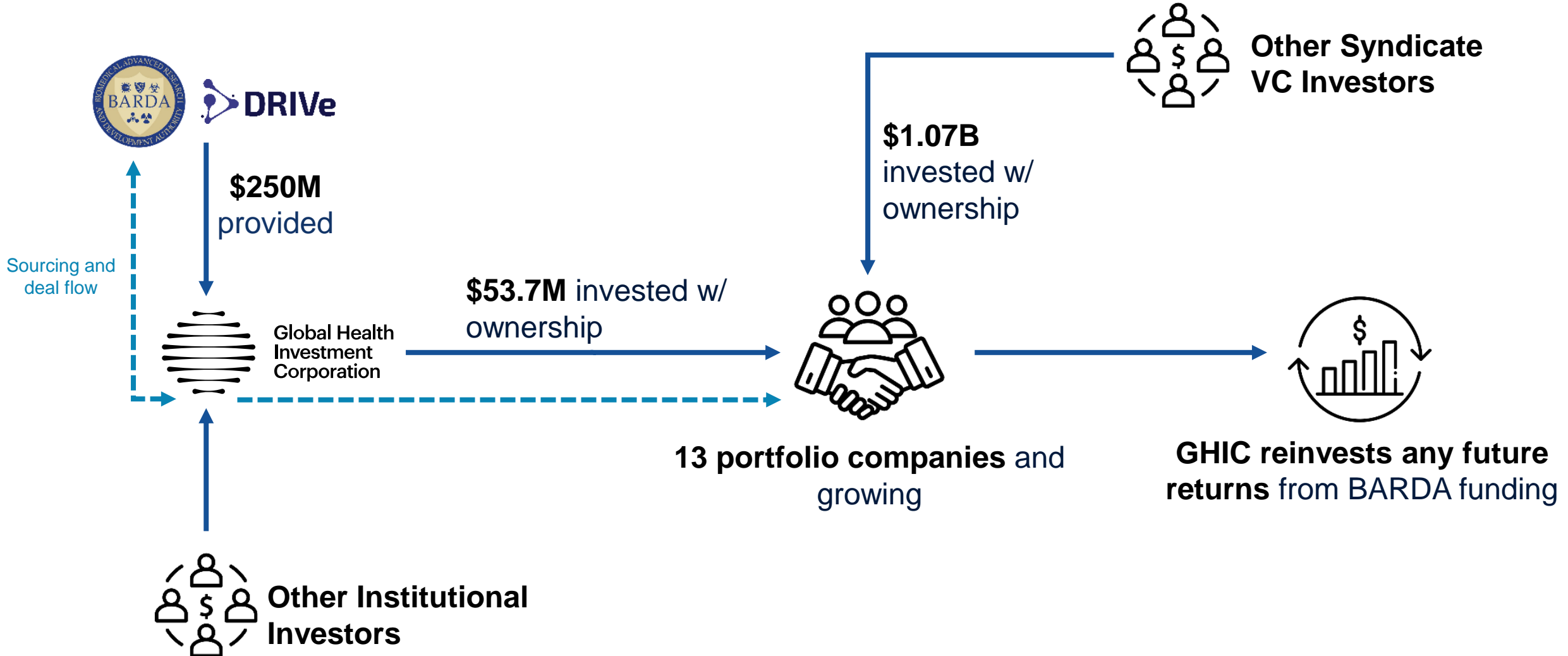


- Strategy and prioritization of opportunities
- Scientific and technical expertise
- Mobilize financial resources



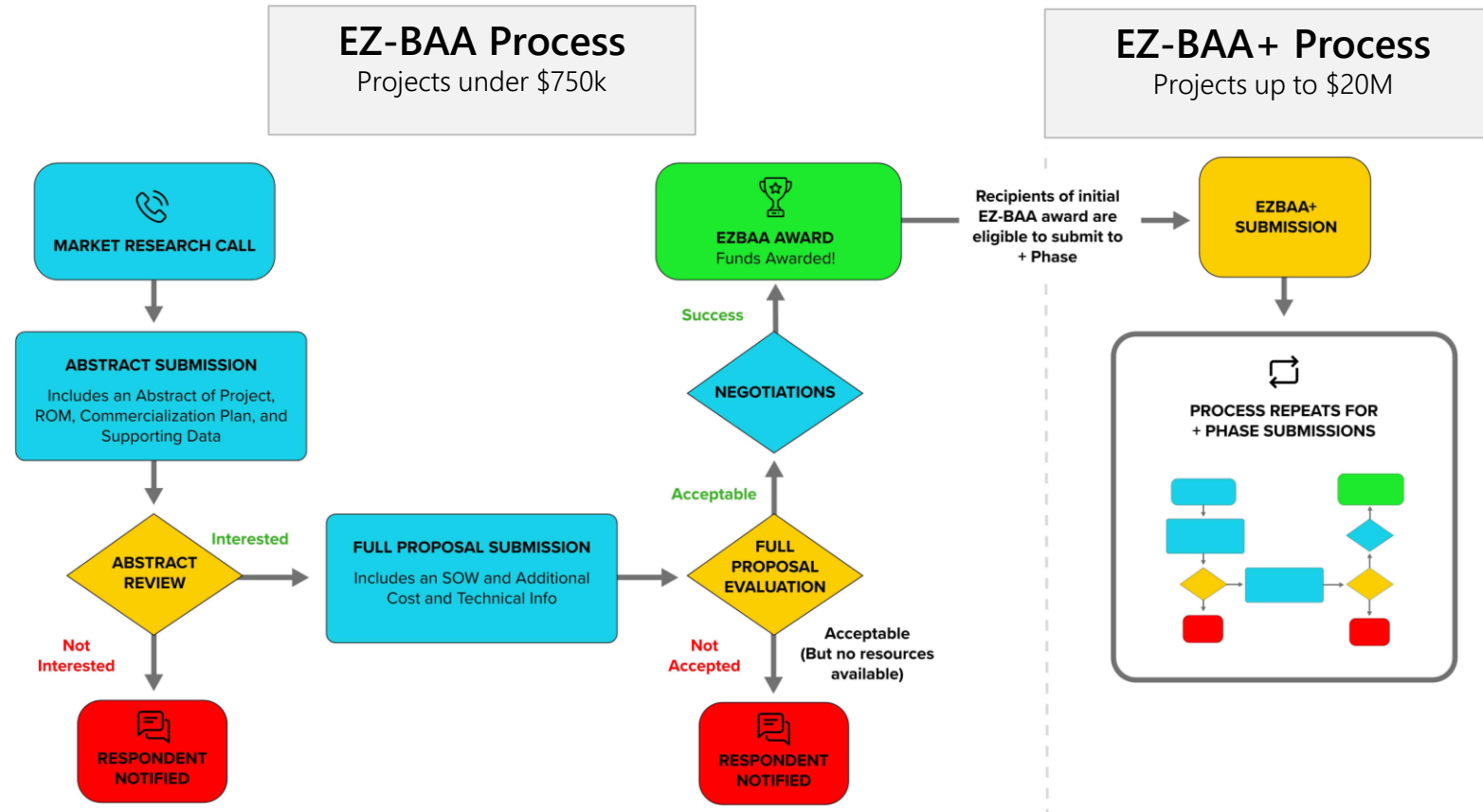
- Strategic venture capital investments
- Accelerate innovative medical countermeasures
- Facilitate commercial sustainability

BARDA Ventures Partnership Mechanics



Partnering With DRIVE's R&D Programs

- ❑ Easy Broad Agency Announcement (EZ-BAA) is designed to be fast, easy-to-use, and flexible
- ❑ Inspired by DARPA
- ❑ **\$749,999** initial contract award & 30-50% cost share requirement
- ❑ Can request a pre-submission Market Research call
- ❑ Can award contracts within 30 days of submission



R&D PROGRAMS



Agnostic Diagnostics



Healing Lungs



Proactive Immunity



Beyond the Needle



Host-Based Diagnostics



ReDIRECT



COVID-19 At Home Diagnostics



Host-Directed Therapeutics



ReBoot



Digital MCMs



ImmuneChip+



RePAIR



ENACT



Lab at Home



Vaccines on Demand

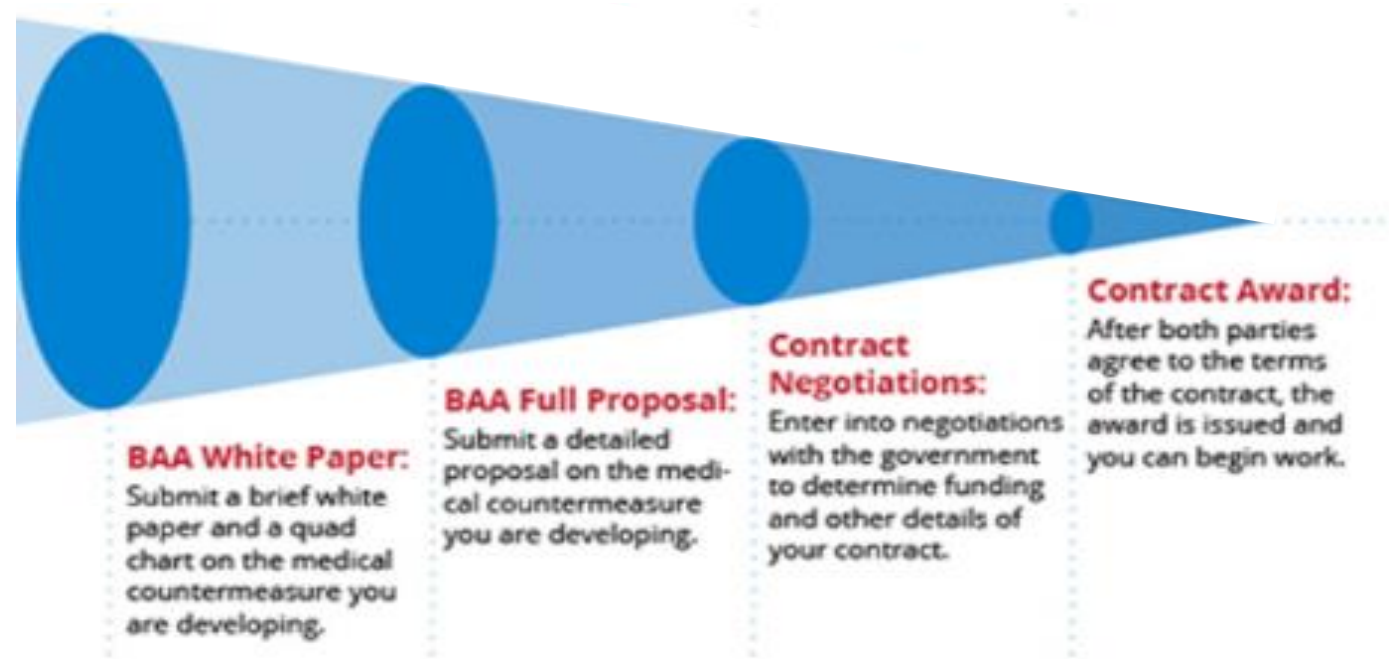
BARDA Broad Agency Announcements (BAA)

Active Areas of Interest

	CBRN VACCINES	+
	CBRN ANTIVIRALS AND ANTITOXINS	+
	ANTIMICROBIALS	+
	RADIOLOGICAL/NUCLEAR THREAT MEDICAL COUNTERMEASURES	+
	CHEMICAL THREAT MEDICAL COUNTERMEASURES	+
	BURN AND BLAST MEDICAL COUNTERMEASURES	+
	DIAGNOSTICS	+
	INFLUENZA AND EMERGING INFECTIOUS DISEASES (IEID) VACCINES	+
	INFLUENZA AND EMERGING INFECTIOUS DISEASES (IEID) THERAPEUTICS	+
	FLEXIBLE AND STRATEGIC THERAPEUTICS (FASTX)	+
	NEXT-GENERATION COVID-19 VACCINES	+

BAA Acquisition Process

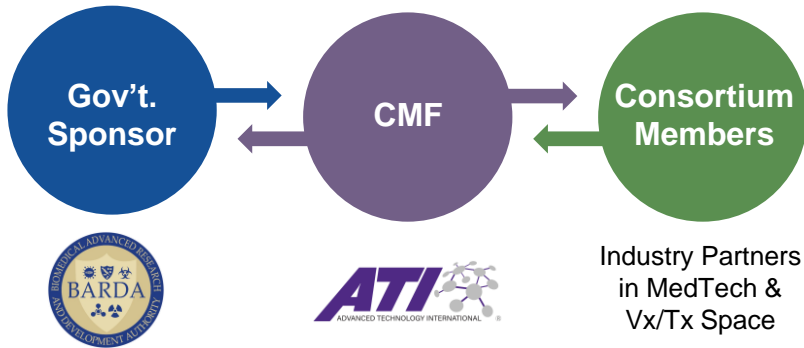
TechWatch
Request to meet with BARDA



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

BARDA's Rapid Response Partnership Vehicle (RRPV) Consortium

OTA Consortium Model



NEW MULTI-PURPOSE ACQUISITION VEHICLE

10-year, multi-purpose acquisition vehicle to support medical countermeasures that address biological threats such as pandemic influenza and emerging infectious diseases, from early-stage development through advanced development, procurement, sustainment, and commercialization



CUSTOM SOLUTION TO TRUSTED MODEL

Borrows from DoD's Medical CBRN Defense Consortium model and incorporates COVID-19 lessons learned to evolve and support implementation of existing and new HHS and USG strategies



READY FROM DAY ONE

Built for the speed of response, leveraged for preparedness, and appropriately staffed to ensure it's tested and familiar to staff & partners for accelerated response time through Pre-Negotiated Terms to meet the speed necessary to respond to a Public Health Incident



To learn more about the RRPV Consortium and join, visit www.rrpv.org



Agile Execution

Rapid execution and partnering using an established model



Increased Competition

Integrates traditional, nontraditional, and university partners



Enhanced Collaboration

Teaming is encouraged & teaming services are provided to members at no cost



Dynamic Partnership Pool

Ability to add partners to capture new and proven technologies



Single-Point Contracting

Use of Consortium Management Firm (CMF) lessens burden on USG

Agreements mechanism that will leverage BARDA's Other Transaction Authorities (OTAs) to fund vaccine manufacturing and supply chain industrial base expansion and advanced manufacturing technology innovations.

KEY DOMAINS:

Industrial Base Expansion of Biomanufacturing Supply Chain

Engaging providers of goods and services that support the entire biomanufacturing process to strengthen the domestic supply chain (raw materials, consumables, etc.)

Biomanufacturing Capacity Expansion and Reservation

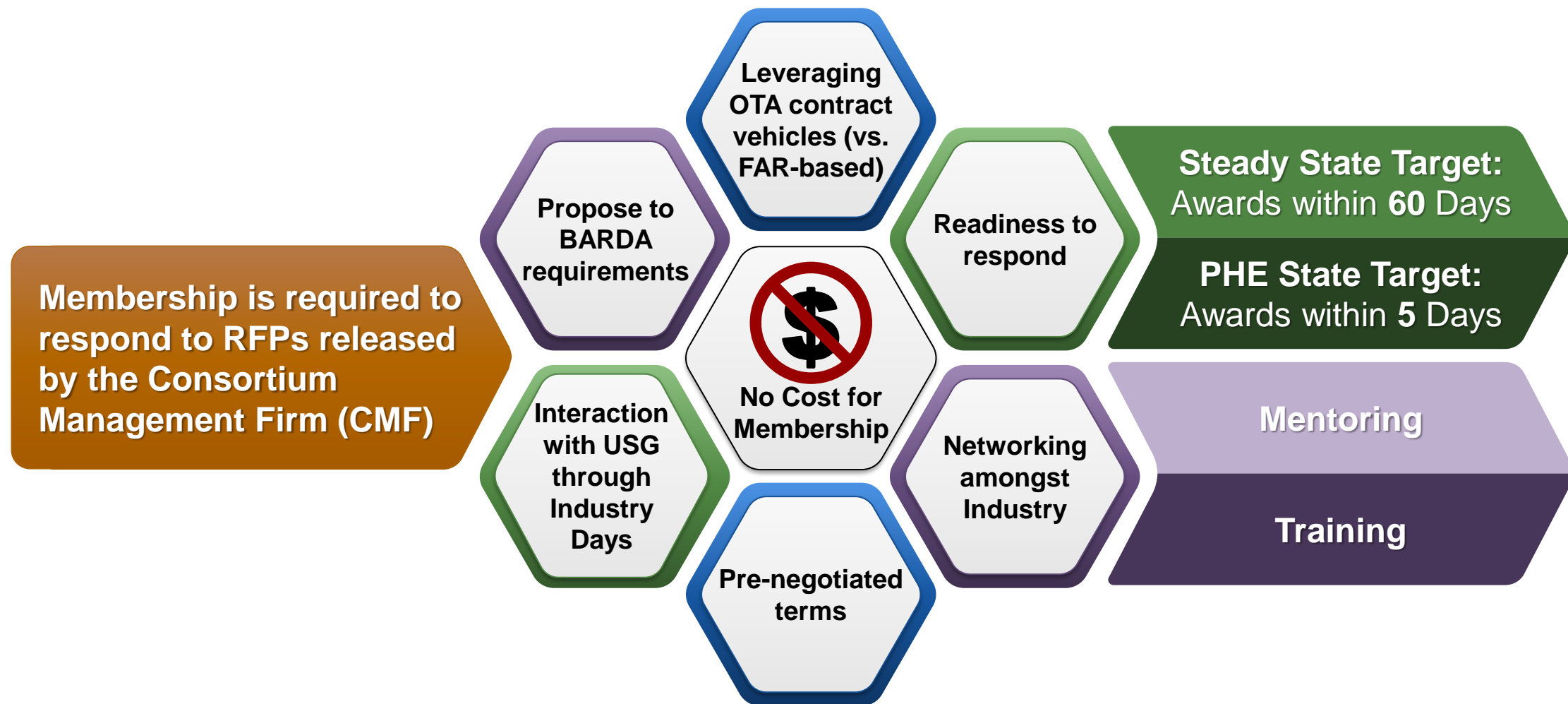
Establishing, expanding, and reserving drug substance and drug product to prepare timely and sufficient MCMs in response to emerging pathogens with pandemic potential

Advanced Biomanufacturing Technologies

Addressing technologies that:

- » Are new, emerging, and innovative
- » Enhance existing technologies
- » Increase the speed, quality, safety, yield, and efficiency of the biomanufacturing process

BioMaP- Consortium Membership Benefits



Visit <https://www.biomap-consortium.org> to Join

Project BioShield: A Commitment

BARDA-specific Product Support*



- BARDA has procured MCM(s)
- BARDA is developing MCM(s)
- * Excludes SNS procurements

36

Products Supported

26

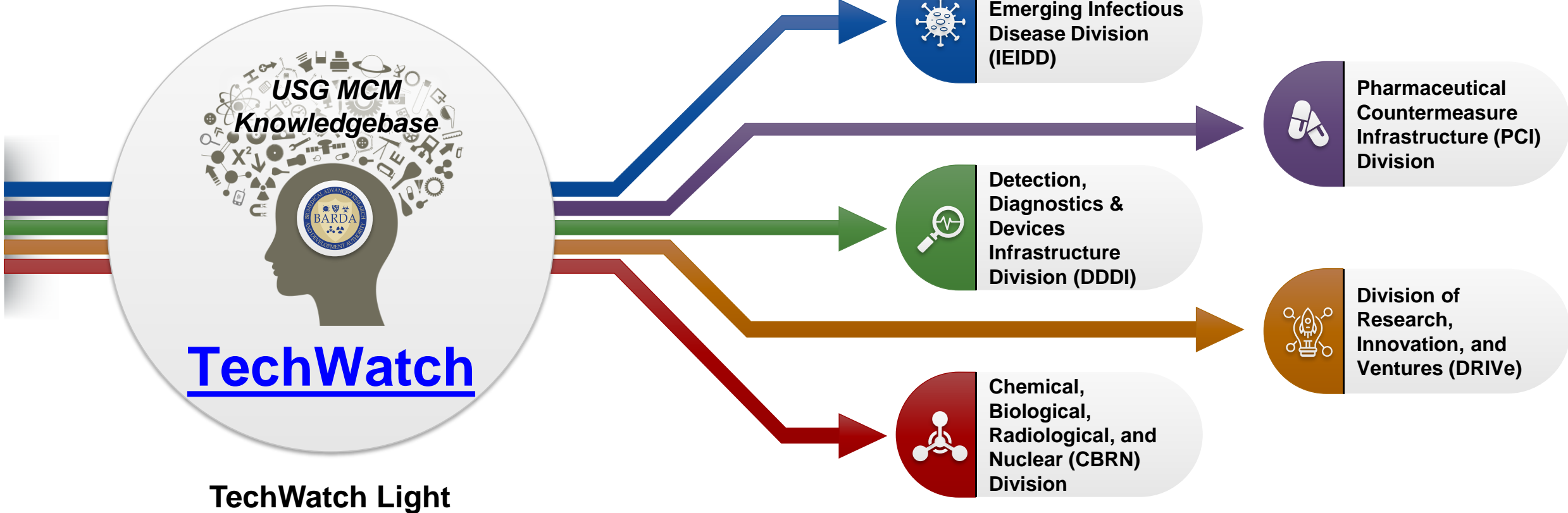
New Products
Procured

30

CBRN Approvals,
Licenses &
Clearances

Engage with BARDA: TechWatch

Market Research Calls





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/BARDA/

Program description, information, news, announcements



drive.hhs.gov

Learn about DRIVE, including our Accelerator Network and EZ BAA



www.usajobs.gov

Join the team!



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Biomedical Advanced Research and Development Authority



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