



BPSA 2022 Members' Roundtable

BARDA Perspectives on Single-Use Challenges: Supply Chain

July 13, 2022

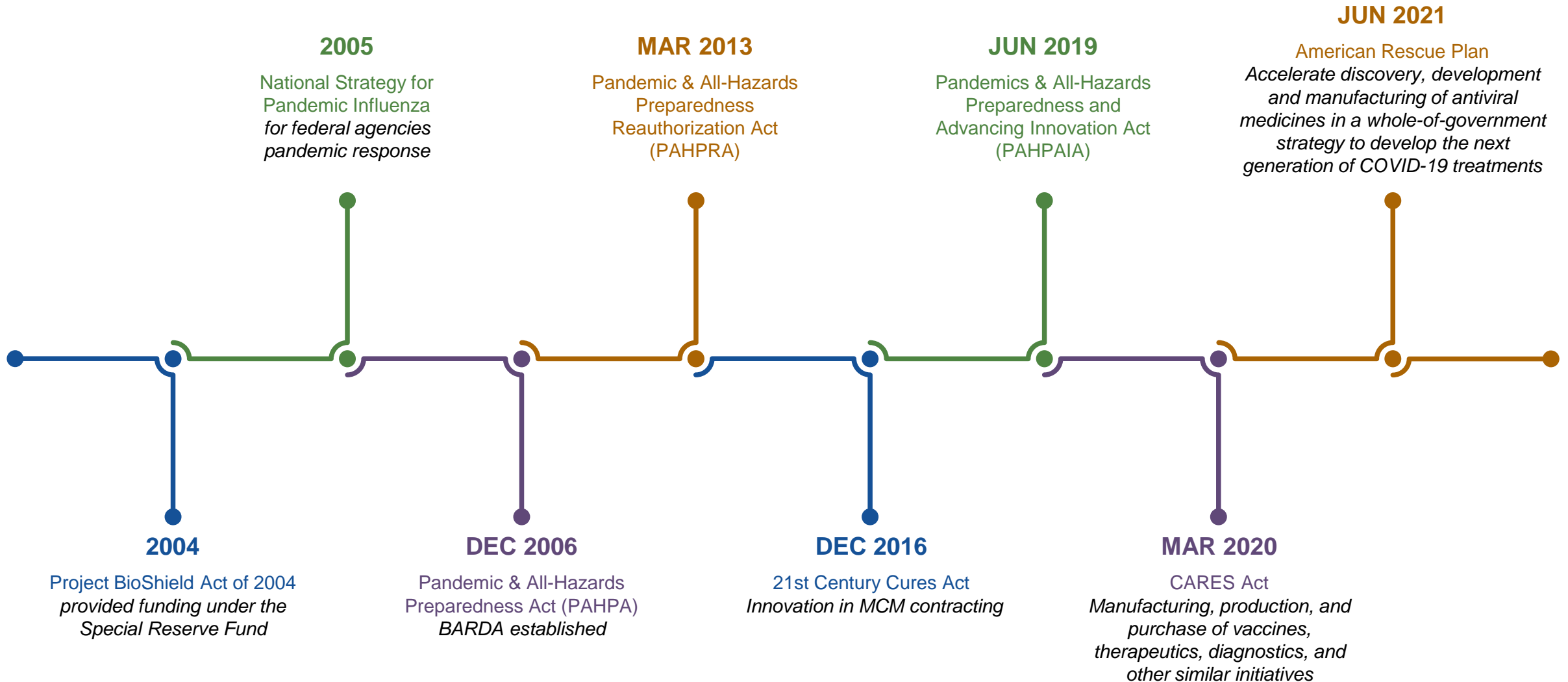
*Joe Figlio, BARDA Branch Chief,
Pandemic Vaccine Preparedness Capabilities & Readiness (PVPCR)*

Unclassified

Outline

- BARDA
- 2022 – 2026 Strategic Plan
- Covid Response
- Lessons
- Into the Future
- Questions

BARDA Origins



BARDA Facts

Located near the
National Mall in
Washington, DC



420+ employees
(HHS=80k+)



Five divisions within
the Medical
Countermeasures
Program (MCMP)



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

Our Industry Partners



Our Government Partners



Where Does BARDA Fit?



Medical Countermeasures (MCM) Program

**Influenza & Emerging
Infectious Diseases (IEID)**

**Chemical, Biological,
Radiological and Nuclear
(CBRN) Program**

**Detection, Diagnostics, &
Device Infrastructure (DDDI)**

**Pharmaceutical
Countermeasure
Infrastructure (PCI)**

**Division of Research, Innovation,
and Ventures (DRIVE)**

The Role of BARDA

BARDA is the premier biomedical countermeasure development agency for the U.S. federal government and is our frontline layer of defense in responding to future pandemics and bioweapons.

We provide an integrated, systematic approach to the development of the necessary vaccines, drugs, therapies, and diagnostic tools for public health medical emergencies such as chemical, biological, radiological, and nuclear (CBRN) accidents, incidents and attacks; pandemic influenza (PI), and emerging infectious diseases (EID).





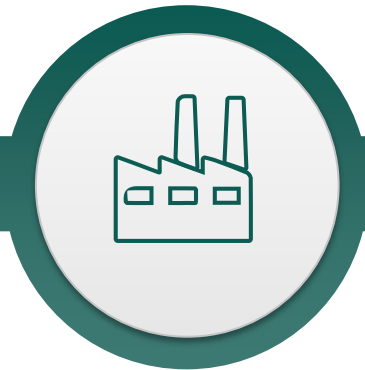
Goal 2: Response

Enhance and maintain a sustainable, mission-ready posture



OBJECTIVE 2.1

Enhance BARDA's response posture by leveraging a diverse MCM portfolio of proven technologies



OBJECTIVE 2.2

Build a resilient, surge-capable, flexible manufacturing ecosystem that prioritizes increased domestic capacity



OBJECTIVE 2.3

Enhance and sustain response-ready support services



OBJECTIVE 2.4

Leverage acquisition vehicles that enable rapid response



OBJECTIVE 2.5

Ensure BARDA's response posture accounts for the needs of all segments of the population



Goal 3: Partnerships

Leverage mechanisms to foster flexible partnerships



OBJECTIVE 3.1

Advance new, adaptable partnership models



OBJECTIVE 3.2

Foster existing and establish new partnerships



OBJECTIVE 3.3

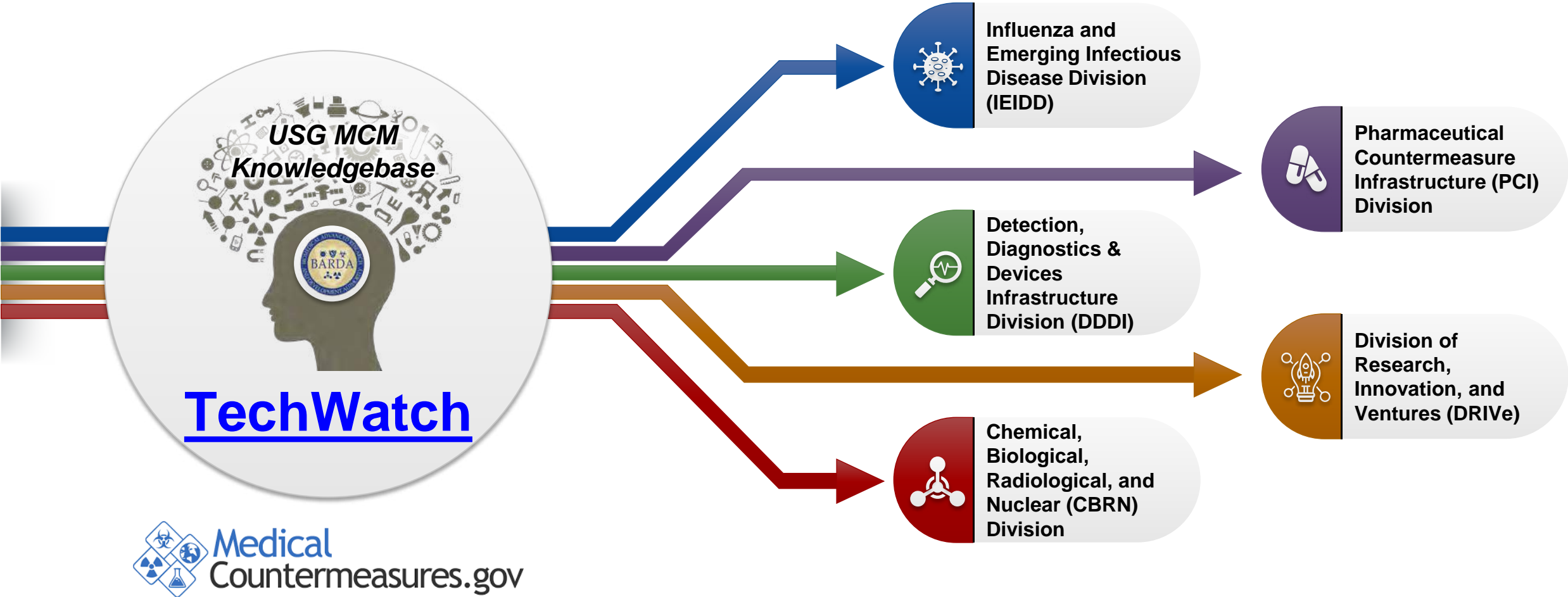
Enhance sustainability by supporting development and repurposing of products and technologies with commercial value



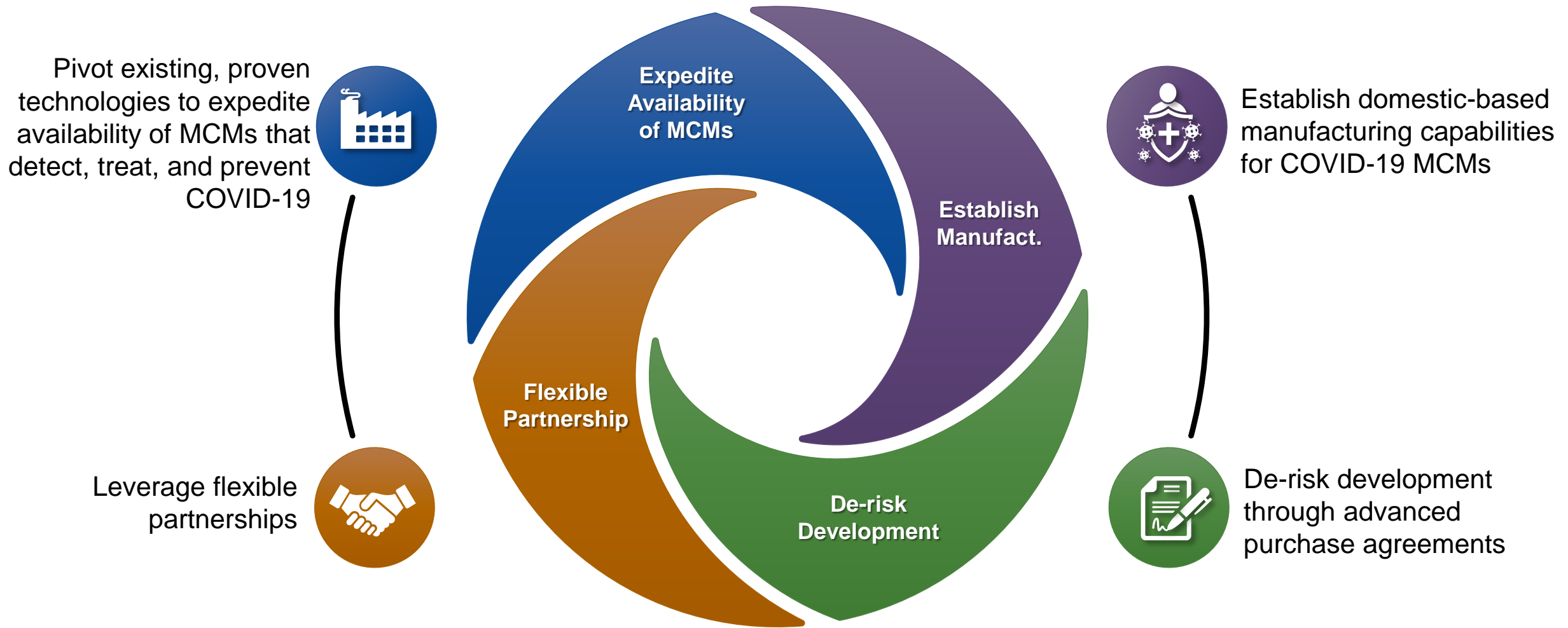
OBJECTIVE 3.4

Expand partnerships with socially and economically disadvantaged businesses

TechWatch: Open for Business



COVID-19 Medical Countermeasure Development Strategy





COVID-19 Response

141

COVID-19 Partnerships

4718

Market Research Submissions

765

CoronaWatch Meetings

2

FDA Licensure

29

Diagnostic Test EUAs

236M

Diagnostic Test Kits Shipped

101 Products Supported

\$68.4 billion
Awarded

\$42.9B vaccines
\$24B therapeutics
\$0.5B diagnostics

Emergency Use Authorizations Supported by the USG

3 Vaccines

7 Therapeutics

COVID-19 Vaccine Doses

730M

Delivered

577M

Administered

As of 05/20/2022

Pharmaceutical Countermeasures Infrastructure (PCI) and Industrial Base Expansion (IBx) Covid Response

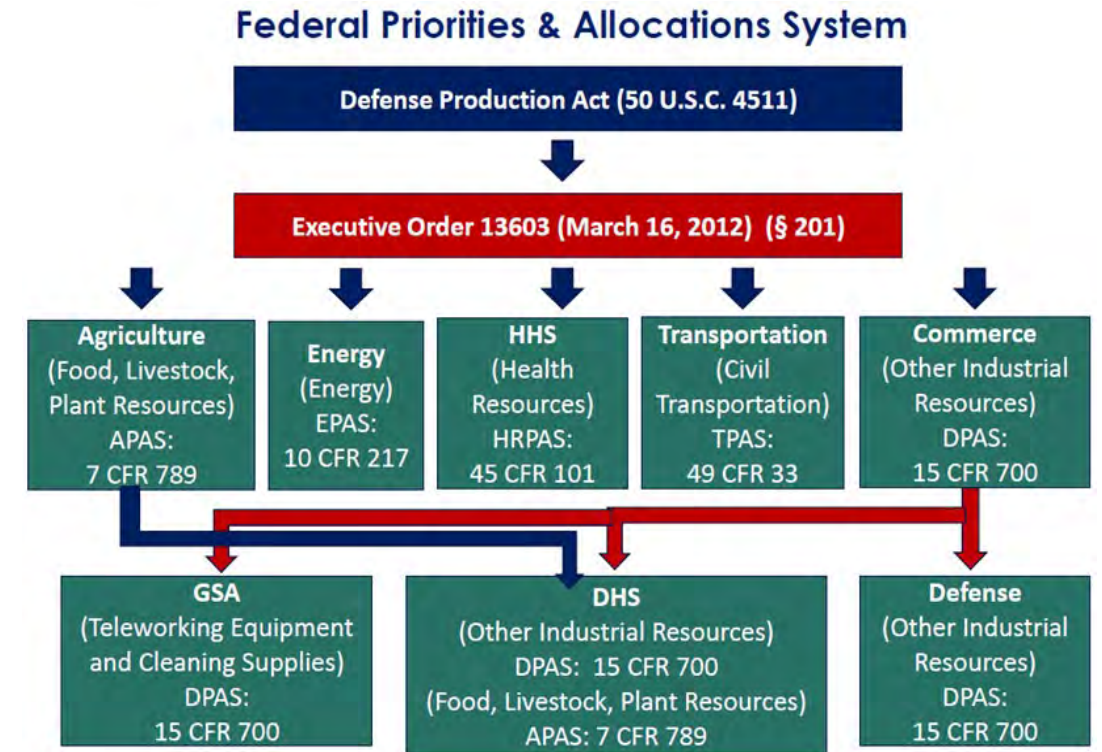
Defense Production Act

Health Resource Priority and Allocations System (HRPAS)

- » Drugs, biological products, medical devices, materials, facilities, health supplies, services and equipment required to diagnose, mitigate or prevent the impairment of, improve, treat, cure, or restore the physical or mental health conditions of the population

Defense Priorities and Allocations System (DPAS)

- » All materials, services, and facilities, including construction materials, but not including food resources, food resource facilities; domestic distribution of farm equipment and commercial fertilizer; all forms of health resources; civil transportation; water resources



Production or capacity expansion (increasing number or capacity of production lines) in support of vaccine or therapeutic manufacturing was deemed an Industrial Resource by Department of Commerce and falls under DPAS. Production of vaccine on those lines is considered a health resource and falls under HRPAS.

BARDA's PCI and IBx Covid Response – Solicitations

Contracting (FAR-based)

CSO - Commercial Solutions Opening

- » A competitive process to obtain solutions or new capabilities that fulfill requirements, close capability gaps, or provide potential technological advances. CSO procedures are similar to those for Broad Agency Announcements (BAAs), with the exception that a CSO can be used to acquire innovative commercial items, technologies, or services that directly meet program requirements, whereas BAAs are restricted to basic and applied research (also may be used to award non-FAR based agreements, with caveats)

BAA – Broad Agency Announcement

- » Used to obtain proposals for basic and applied research and development to advance or evaluate cutting edge technologies, not related to a specific system or hardware requirement. BAAs should be used when meaningful solutions can be expected. BAAs are typically “open” and proposals are accepted for a specified period of time. Proposals submitted in response to BAAs may or may not lead to contracts (may be used to award FAR-based contracts or non-FAR based agreements)

BARDA's PCI and IBx Covid Response – Vehicles

Innovative Contracting (non-FAR)

TIAs – Technology Investment Agreements

- » Used to stimulate or support commercial firm involvement in pursuing best technologies for defense research. TIAs are appropriate when research objectives are unlikely to be achieved using other types of contract instruments
- » To the maximum extent practicable, the non-federal parties carrying out a research project under a TIA are to provide at least half of the costs of the project
- » DoD policy is to award TIAs using merit-based, competitive procedures

OTAs – Other Transaction Agreements

- » Prototype OTs are appropriate for research and development and prototyping activities to enhance mission effectiveness of military personnel and supporting platforms, systems, components, or materials. Prototype OTs may be used to acquire a reasonable number of prototypes to test in the field before making a decision to purchase in quantity. Prototype OTs provide a streamlined path to award a non-competitive follow-on Production OT or FAR contract

Cooperative Agreements

- » Facilitate the transfer of something of value from federal agencies to states, local governments, and private recipients for a public purpose or benefit
- » Allows greater freedom to craft the terms of an agreement around new or innovative endeavors
- » Similar to a federal grant, but the awarding agency is substantially involved in the execution of the agreement

BARDA's Covid Response – Partnerships

What went well

Industry –
Tier 1
suppliers
(BPSA
members+)

Fill and Finish
CMOs

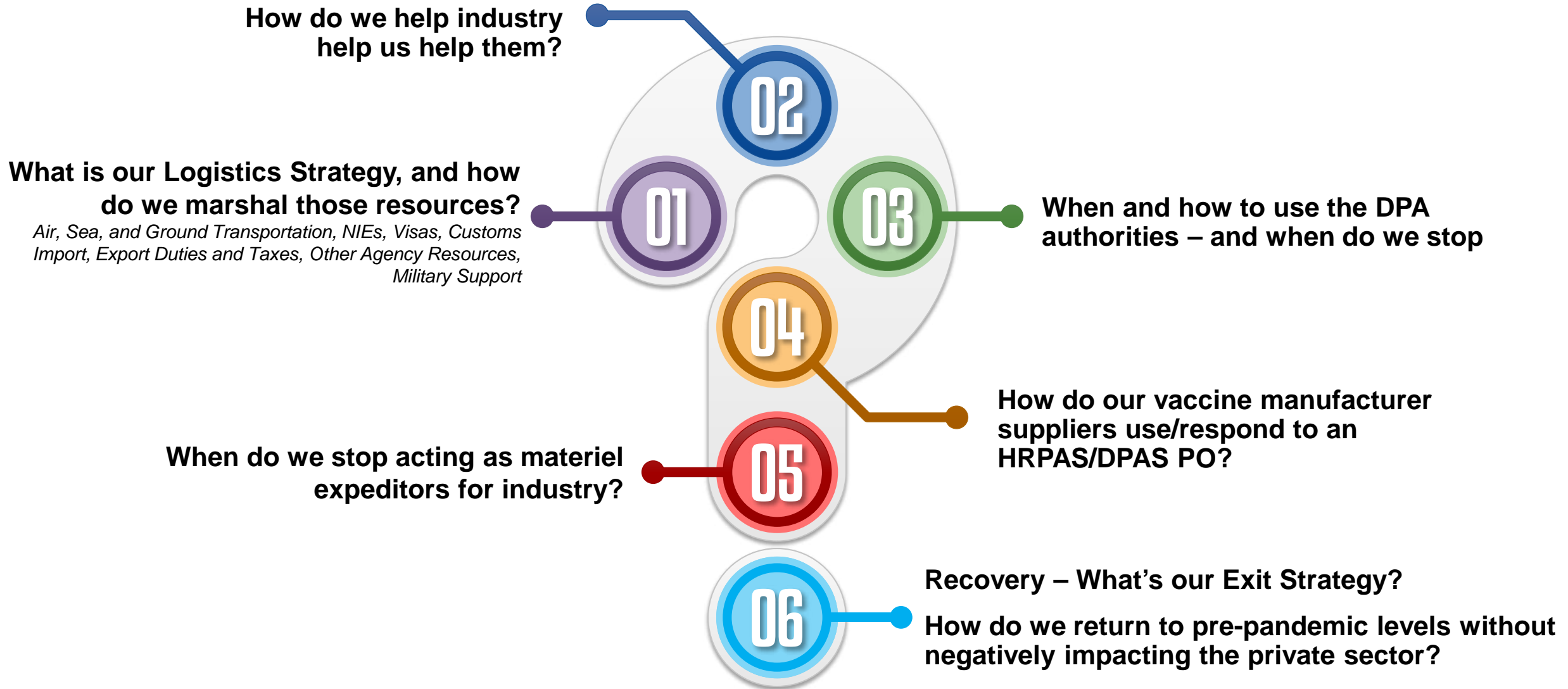
Vaccine
manufacturers

DoD – ACC,
JPEO, DLA,
OWS, FCRT,
CAG...

Interagency

Foreign
Suppliers

BARDA's Covid Response – Considerations



Key Lessons from the Pandemic – Planning Considerations

Future pandemic vaccine requirements unknown



Use pandemic experience to estimate required future quantities of bags, filters, tubing, raw materials, fill/finish... and sterilization



Single Use Technologies were critical. We recognized we would need a huge amount early in the pandemic – and industry stepped up to enable success



Goal: Use IBx assets to minimize future use of DPA authorities



Baseline production requirement estimated as 600M vaccine doses produced in 6 – 9 months



Use these estimates in building out our IBx portfolio



Important to build – and sustain - our relationships with industry



Develop a Proactive Approach to Future Pandemics – Pandemic Strategic Plan – Roadmap

BARDA Into the Future



Expanded Partnerships

Strengthening the Nation's MCM Supply Chain with Our Partners

Educate our industry partners on the United States government role in supply chain: BARDA's purpose (and the "interagency"), and how we can continue our partnership for mutual gain

Transitioning into the pandemic and now moving beyond, what did we learn that can be applied or improved upon in the event of another crisis?



Strengthen our relationships

Develop a more comprehensive understanding of our industry partner's capabilities, strengths, and expansion opportunities

How can we be a better partner with industry?



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
 Program description, information, news, announcements



drive.hhs.gov
 Learn about DRIVE, including our Accelerator Network and EZ BAA



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 Join the team!



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