BioMaP-Consortium Industry Day

Scan code for Digital Program:

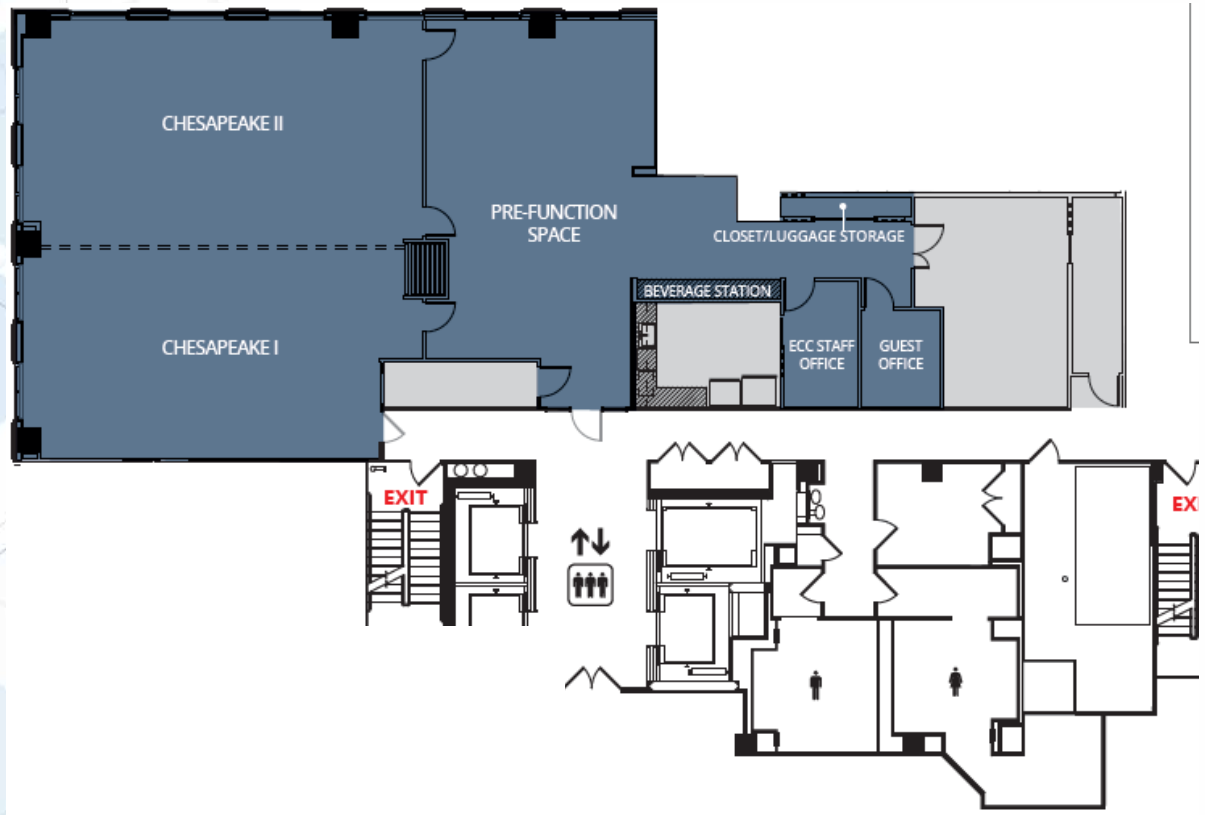
April 5th, 2024

Welcome and Administrative Housekeeping

Nathan Clark
Senior Program Manager, Medical and Threat Countermeasures Division
Advanced Technology International

Administrative Information

In-Person Attendees



- 3 exits along back wall; 2 stairwells
- Security: Please keep badge visible throughout the event
- Please silence electronics
- Beverage Station available all day

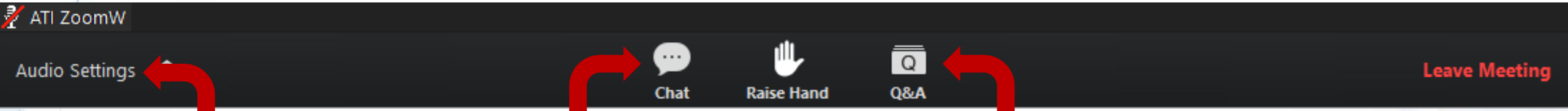
- Questions? Go see the ATI staff at the registration desk.

Network: SA_Guests
Password: $trategicWifi1

Administrative Information

Virtual Attendees

- All participants are muted and will not be able to unmute themselves.
- Please use the “chat” function for technical difficulties only.
- Place all questions in the Q&A Box.
- Please check your Audio Settings if you are having difficulties hearing us.



Check **Audio Settings** if you can’t hear us.

Click **Chat** to or to ask for technical assistance.

Use **Q&A** for direct questions on meeting content.

Agenda

09:00 AM	Welcome and Administrative Housekeeping
09:05 AM	The BARDA Strategic Plan
09:30 AM	IBMSC Overview
09:45 AM	BioMaP Program Alignment with the BARDA Strategic Plan
10:05 AM	Networking Break
10:20 AM	Keynote Speaker
10:30 AM	BioMaP Technology Roadmap
11:30 AM	Manufacturing Roadmap Q&A
12:00 PM	Lunch
01:00 PM	TechWatch and IBx Connect
01:30 PM	Member Company Introductions
02:30 PM	Networking Break
03:00 PM	Roundtable Discussions (30 min each)
	- Supply Chain
	- CDMO, Drug Substance, & Drug Product Manufacturing
	- Advanced Manufacturing Techniques
04:30 PM	Closing Remarks

BioMaP Consortium
Biopharmaceutical Manufacturing Preparedness - Consortium

Scan code for Digital Program:

BioMaP-Consortium At A Glance

- OTA Signed September 2023
- $20B Ceiling
- 10-year Period of Performance
- 130+ Members and growing!
- 3 Key Domain Areas:
  - Industrial Base Expansion of Supply Chain
  - Biomanufacturing Capacity Expansion and Reservation
  - Advanced Biomanufacturing Technologies

- RPP's:
  - Task Order 1: "Production of Biologically Derived Small Molecule Regulatory Starting Materials and/or Active Pharmaceutical Ingredients at Commercial Scale"
  - Task Order 2: "Production of Drug Substances and Drug Products at Commercial Scale"
  - Task Order 3: "Sterilization Capacity for Vaccines and Therapeutics"
  - Additional RPPs planned for release in FY24

BARDA STRATEGIC PLAN

Robert Johnson, PhD

Director, Medical Countermeasures Program, BARDA

BioMaP Consortium Industry Day

April 05, 2024

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

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















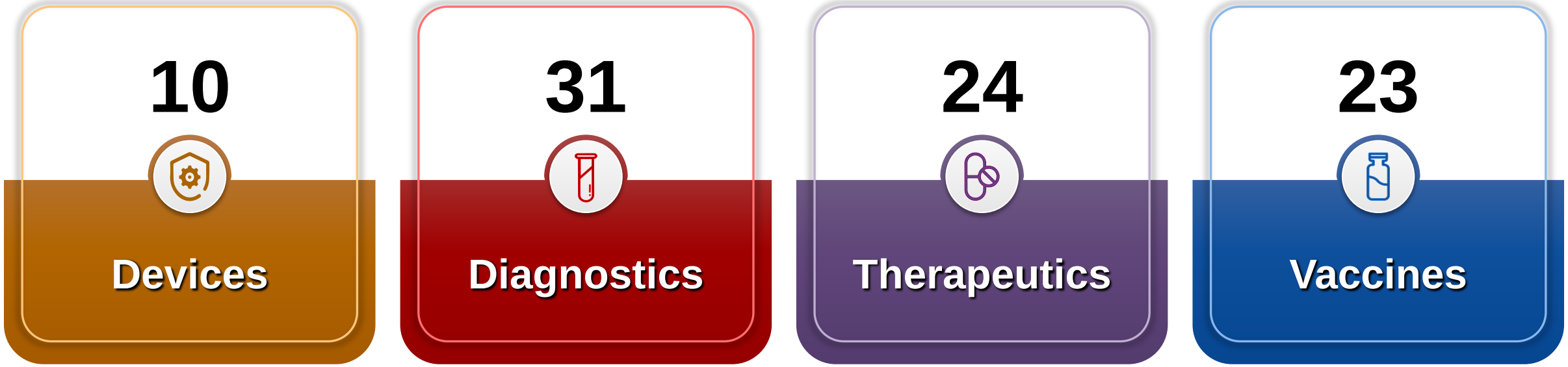







88 FDA Approvals, Licensures, and Clearances

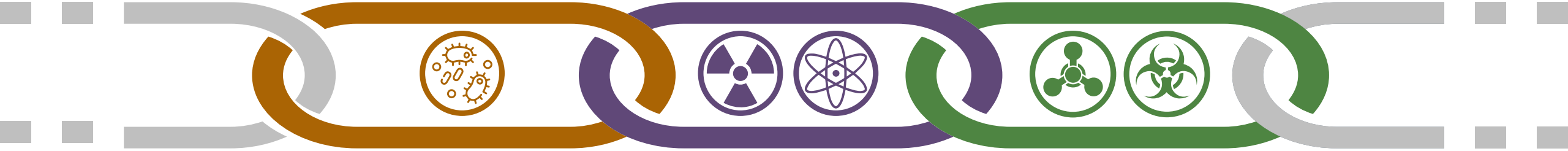
BARDA supports a diverse portfolio of medical countermeasures and these products have received a total of 88 FDA approvals, licensures, or clearances.



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.

Examples of BARDA Supported MCMs Used in Routine Care:
Enable Faster Emergency Response through Easier Access, Familiarity



INFECTIOUS DISEASE

- **Cepheid Xpert Xpress**
  CoV-2/Flu/RSV plus diagnostic
- **Selux Next Generation Phenotyping System**
  Gram Positive & Gram-Negative Diagnostic Panel
- **InBios Zika Assay**
  Detects Zika virus infection
- **Tetraphase Xerava**
  Antibacterial treatment of complicated IAI
- **Paratek Nuzyra**
  Treatment of anthrax and secondary MDR infections

RAD/NUC

- **Stratatech StrataGraft**
  Skin substitute
- **Philips Lumify**
  Detection of lung injuries
- **Amgen Neulasta and Amgen Neupogen**
  Neutropenia caused by acute exposure to radiation
- **Partner Therapeutics Leukine**
  Neutropenia caused by acute exposure to radiation
- **Amgen Nplate**
  Thrombocytopenia caused by acute exposure to radiation
- **Argentum Medical Silverlon**
  Burns resulting from Cutaneous Radiation Injury, Sulfur Mustard exposure, and Radiation Dermatitis

CHEM/BURN

- **MediWound NexoBrid**
  Non-surgical debridement
- **AlloSource PureSkin and Community Tissue Services skin allografts by Maxxeus**
  Skin substitute
- **Avita Medical ReCell**
  Autograft sparing and acceleration of healing
- **Meridian Seizalam**
  Seizures caused by chemicals, including nerve agents
- **Indivior OPVEE**
  Opioid overdose treatment
- **Argentum Medical Silverlon**
  Burns resulting from Cutaneous Radiation Injury, Sulfur Mustard exposure, and Radiation Dermatitis

Global Regulatory Filings of BARDA-Supported MCMs

During outbreaks, MCMs with data packages that can support approval by SRAs can expedite local approvals, SRA collaborative registration, and WHO EUL or PQ.

Regulatory approval is critical because it enables governments and agencies to procure, stockpile, or rapidly manufacture products, supporting prompt deployment during outbreaks.

87

U.S. FDA Approvals, Licensures, or Clearances

50+

National Regulatory Authorities approved non-COVID-19 supported products

10+

WHO Prequalifications or Emergency Use Listings

140+

National Regulatory Authorities authorized COVID-19 supported products

Licensed Products Enable a Better Response

1 Faster Response

- 24 hours to ship a licensed product from stockpile
- About 70 days for a COVID-19 vaccine strain change
- Over 11 months to take a prototype pathogen product to licensure

2 Confidence the product works

- Over 40% of products fail Phase III efficacy trials
- Speed is irrelevant if the product does not work

3 Potential to increase uptake in a response

- MCMs must be used to have impact
- Increased confidence associated with licensure impacts uptake

BARDA Strategy: 2022-2026

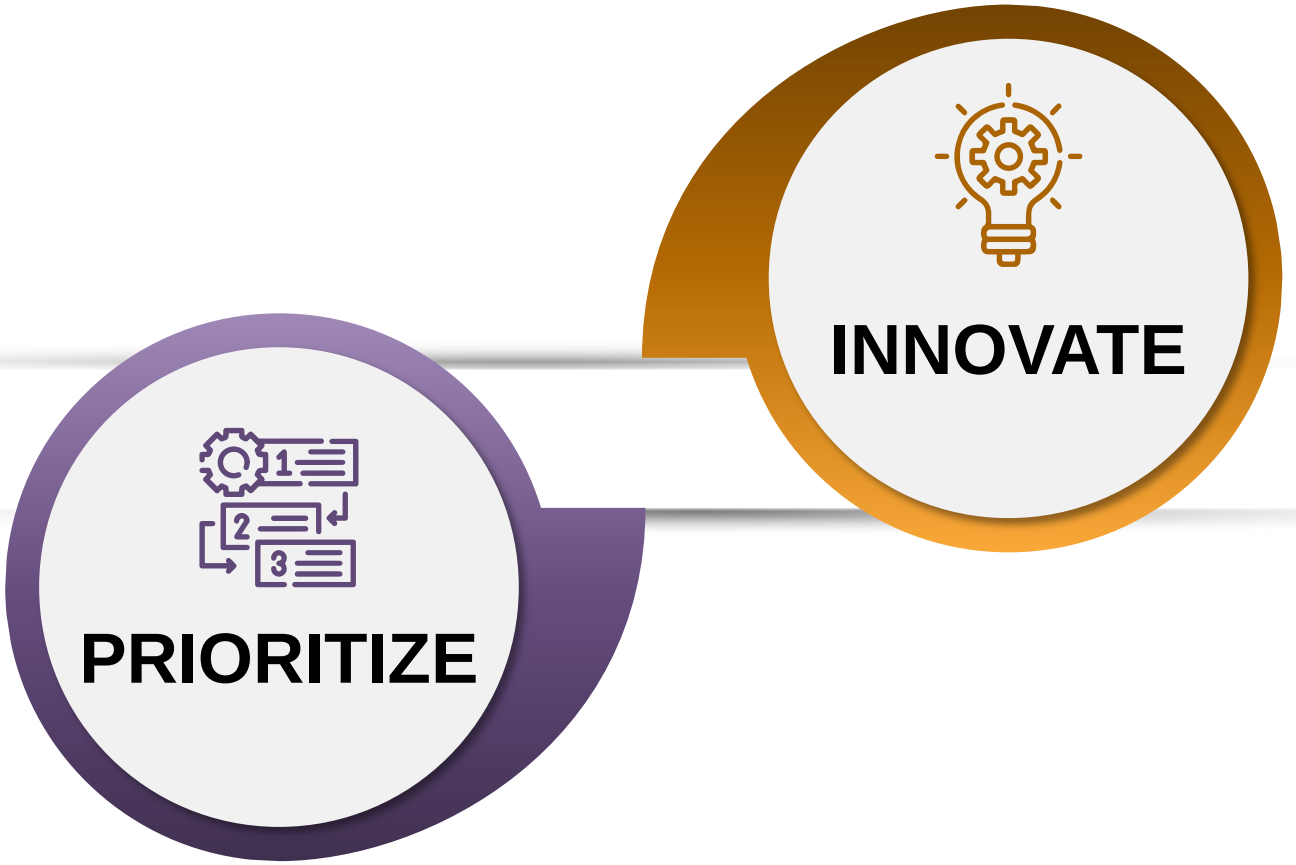
The Balancing Act

What Is the Challenge We Are Solving

It's not *"what we are asked to do"*…

...but *"what do we do given current constraints"*

How Will BARDA Address This Challenge

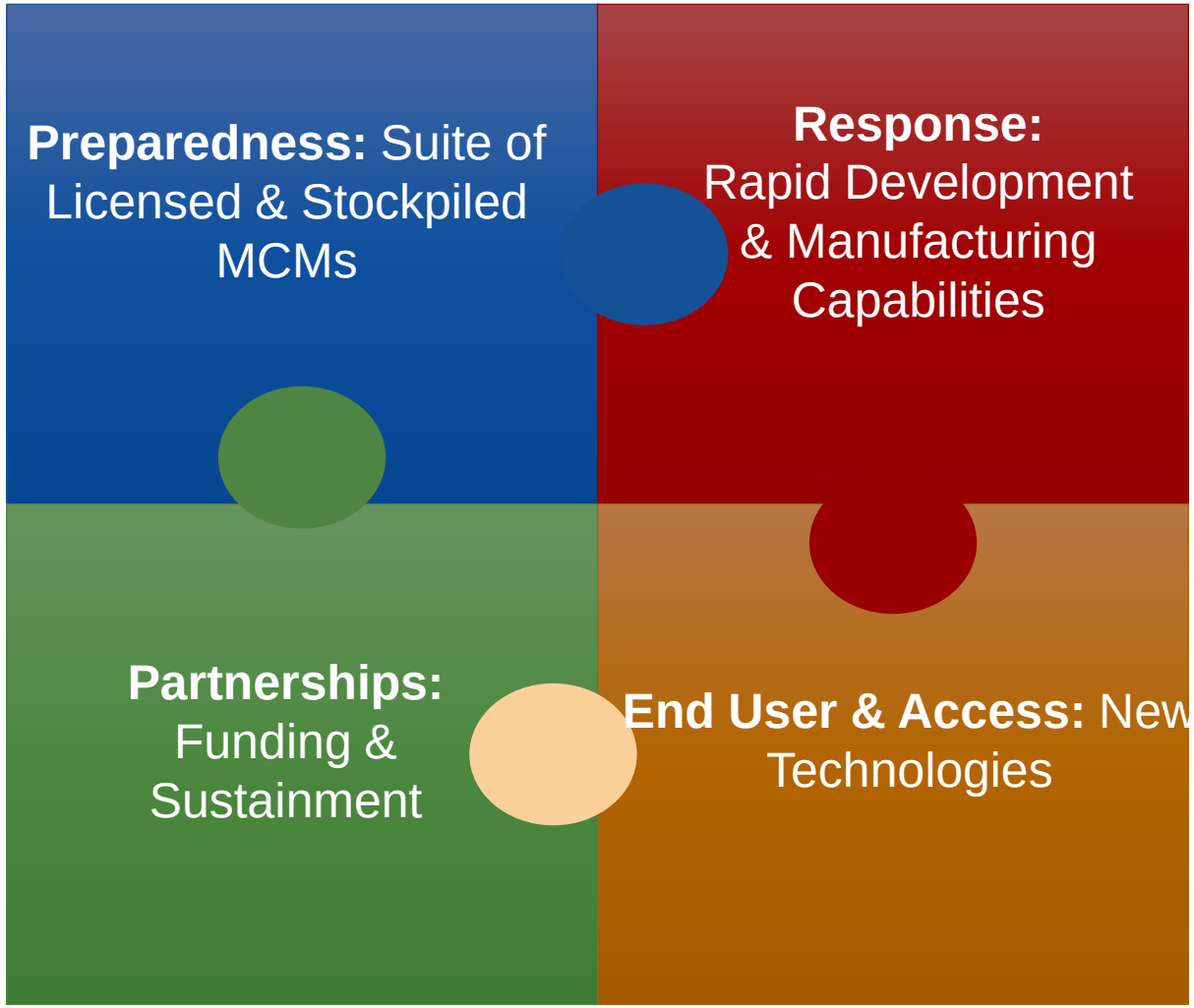


Prioritize

- **Specific threats that align with mission/funding**
  - Threats with an MTD as they are highest National Security Threats, and align with PBS funding
  - Threats for which we have dedicated funding
    - Pandemic Influenza annual funding or supplemental funding for other threats
- **Rapid MCM Development and Response Capability-'one bug one drug' approach is not feasible for all threats**
  - Threat agnostic capability
  - Platforms
- **Taking MCMs to licensure to enable faster response and better access**

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



- Nimble operations and infrastructure response framework
- End-to-end development partnerships
- Faster clinical, non-clinical, and manufacturing approaches

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

- Simpler/self-administration
- No cold chain requirement
- Reduced number of administrations/doses required
- At-home delivery/use to maximize uptake

Example: Project NextGen

Product and Product Attributes

Next Generation Vx/Tx Platforms

- Testing of new platforms
  - Potential improvement in speed, breadth, duration and manufacturing costs
  - Includes multiple routes of vaccination

Better Operational Attributes

- Single dose primary series capability
- Alternative administration routes

Manufacturing Footprint

- Manufacturing on demand

Improved Screening Tools

- Development of microphysiological tools to support therapeutic testing

More Informative Clinical Trials

Correlates of Protection

- Enable enrollment of more representative population
- Approaches to efficiently enroll larger trials

Decentralized trials

- Improve capabilities for clinical trial sites ‘closer to the home’.

End-to-End Point of Need Solutions

Clinical study linking digital monitoring with behavioral impacts

Support for new technologies that could dramatically decrease monoclonal antibody production costs

Partnering Opportunities

Rapid Response Vehicle Consortia

Non-traditional

- Incentives/prizes to support improved concept of operations

FY 23-25 Innovation targets for product development, testing, use and partnerships

Product and Product Attributes

- Threat agnostic
- Con-Ops improvements
- Manufacturing improvements
- Improved candidate identification/screening tools

More Informative Clinical Trials

- Clinical trial demographics match target MCM use population
- Ability to obtain more data, from a larger population, faster and less expensively

End-to-End Point of Need Solutions

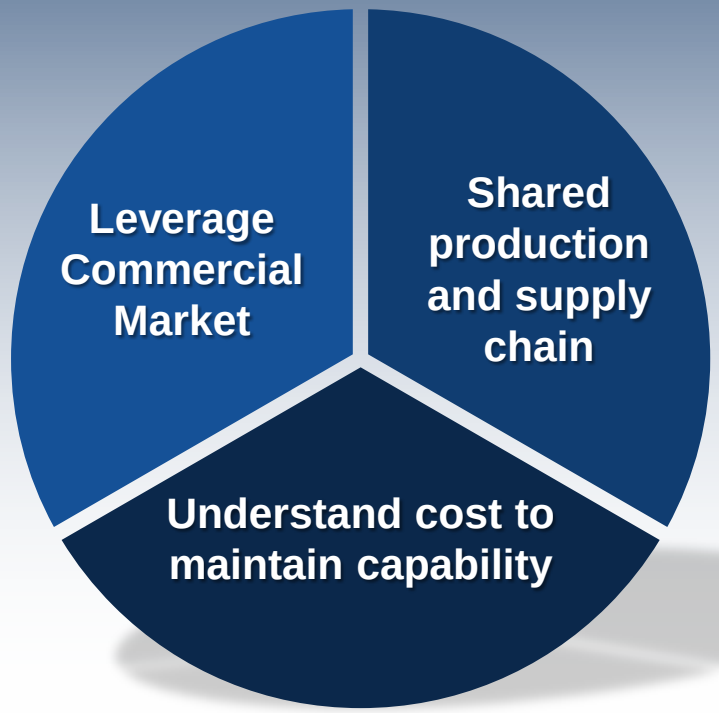
- Pre-symptom alerts through monitoring for drug-drug interactions
- Improve access through new technologies to reduce manufacturing costs (1-2 log reduction)

Partnering Opportunities

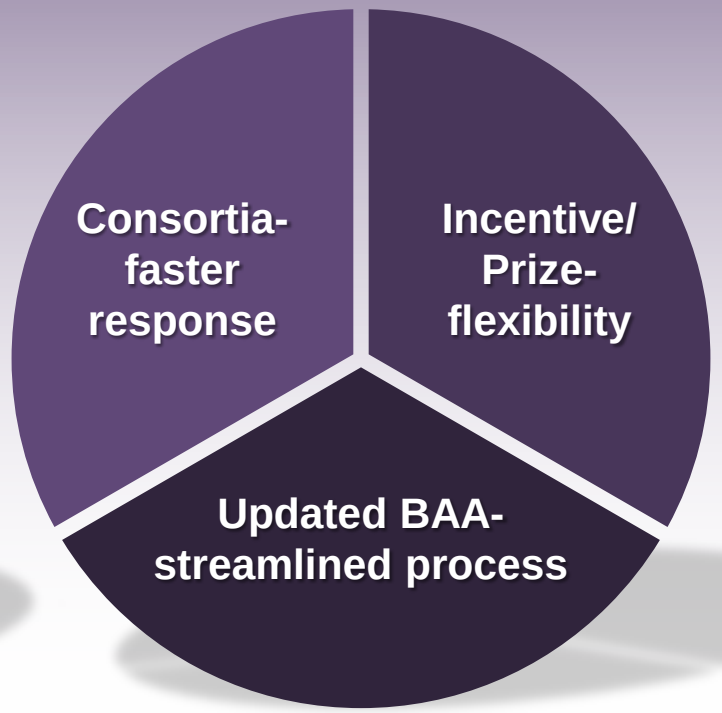
- Partnerships that address sustainment
- Partnerships that enable rapid response
- Opportunities for non-traditional partners

Partnering Opportunities

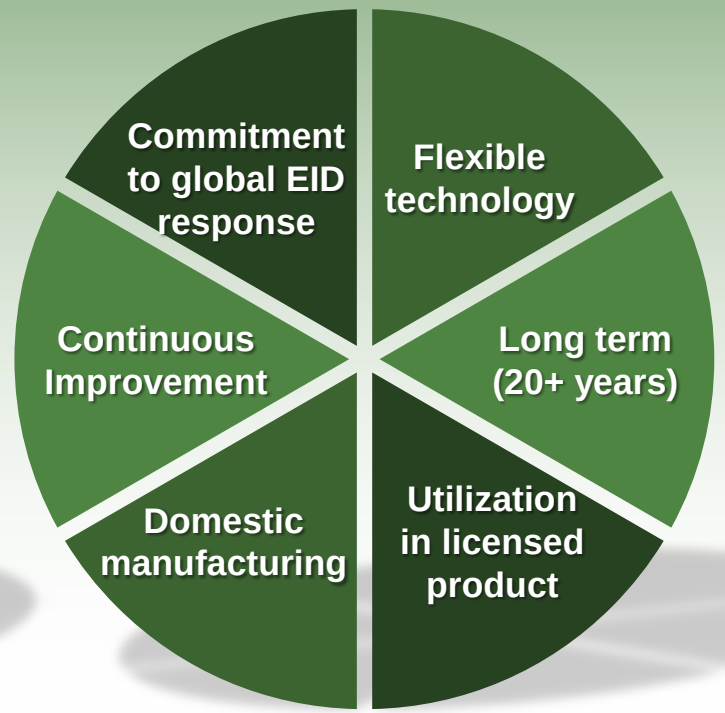
Partnering approaches to support long term access to MCM/MCM manufacturing capability within available budget **(sustainment)**



New Partnering Approaches



Long Term Partnerships Around Flexible Platforms



Key Take Aways

Pivot Existing MCMs

Rapid MCM Development Through Platforms

Develop and Sustain: Budget Balancing Act

Product Access Attributes

Product Approval/Everyday Use

As Close as Possible to Point of Need

medicalcountermeasures.gov
Portal to BARDA: ***Register to request a TechWatch meeting!***

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!

@BARDA | **Biomedical Advanced Research and Development Authority** | **@BARDAGOV**

U.S. Department of Health and Human Services

ASPR Administration for Strategic Preparedness & Response

BioMap-Consortium Industry Day
05 April 2024

Center for Industrial Base Management and Supply Chain (IBMSC) Overview

Arlene Joyner
Deputy Assistant Secretary

Evolution of The Public Health Industrial Base Through COVID-19

Pre COVID-19
before Jan 2020

Limited public health industrial base to address pandemic needs

- Reliant on “just-in-time" manufacturing inputs that were vulnerable to supply disruptions
- High dependency on a consolidated, geographically limited foreign supply, e.g.,
  - 90%+ gloves, syringes, needles from Asia
  - 95%+ generic drugs made in India and China

Peak COVID-19
2020-2022

Inadequate availability of critical medical supplies; USG & industry responded

- Accelerated global transport and domestic allocation of critical raw materials and medical countermeasures in shortage
- Increased domestic production capacities for PPE, vaccines, diagnostics, and pharmaceuticals

Today
March 2024

Demand & supply stabilizing, continued manufacturing investments required

- Addressing new increased demand from virus variants, additional vaccinations, global support for vaccines
- Establishing acquisition workforce to actively manage supply and production capacities
- Ensuring investments are sustainable for long term competitiveness and needs

Future
(next 24 months)

Build resilient industrial base to respond to future pandemics

- Actively manage health and resiliency of our domestic public health industrial base
- Preserve production capacities in US supply chain as demand wanes
- Expand professional acquisition workforce
- Expand supply chain monitoring & industrial base analysis capabilities

Immediate

ASPR Industrial Base Management & Supply Chain (IBMSC) Office

A permanent capability within ASPR to enhance preparedness and save lives by building a resilient domestic public health industrial base with the following key focus areas:

- Critical Medical Equipment *(Personal Protective Equipment)*
- Testing and Diagnostics
- Enabling Innovations and Technologies *(Advanced Manufacturing Technologies)*
- Supply Chain Optimization
- Defense Production Act & Emergency Response Authorization

What IBMSC is Currently Managing

KEY ACTIVITIES

- **$18B in investments in domestic production and products to-date**
  - PPE - $1.7B
  - Advanced Manufacturing - $940M
  - Testing - $2.3B IBX; $10B Procurement
  - Vaccines manufacturing & materials- $3.3B
- Establishing innovative manufacturing technologies and fill-finish capacities to better avail drug products and vaccines
- Distribute tests to thousands of LTCFs, CHCs, Schools, Food Banks and CL Centers

INVESTMENTS & EXPECTED CAPACITY

Not exhaustive

N95 respirators

+83m / month

Surgical masks

+44m / month

Gloves

+1.5B / month

Gowns

+125k / month

Drug products*

+200m doses for 6 meds in shortage

Lab-based Tests

+72m / month

Point-of-care Tests

+73m / month

At home Tests

+80M / month

Vaccine production & supplies**

Up to 600M doses / month

POC and OTC Test Procurements

+1.39B Tests

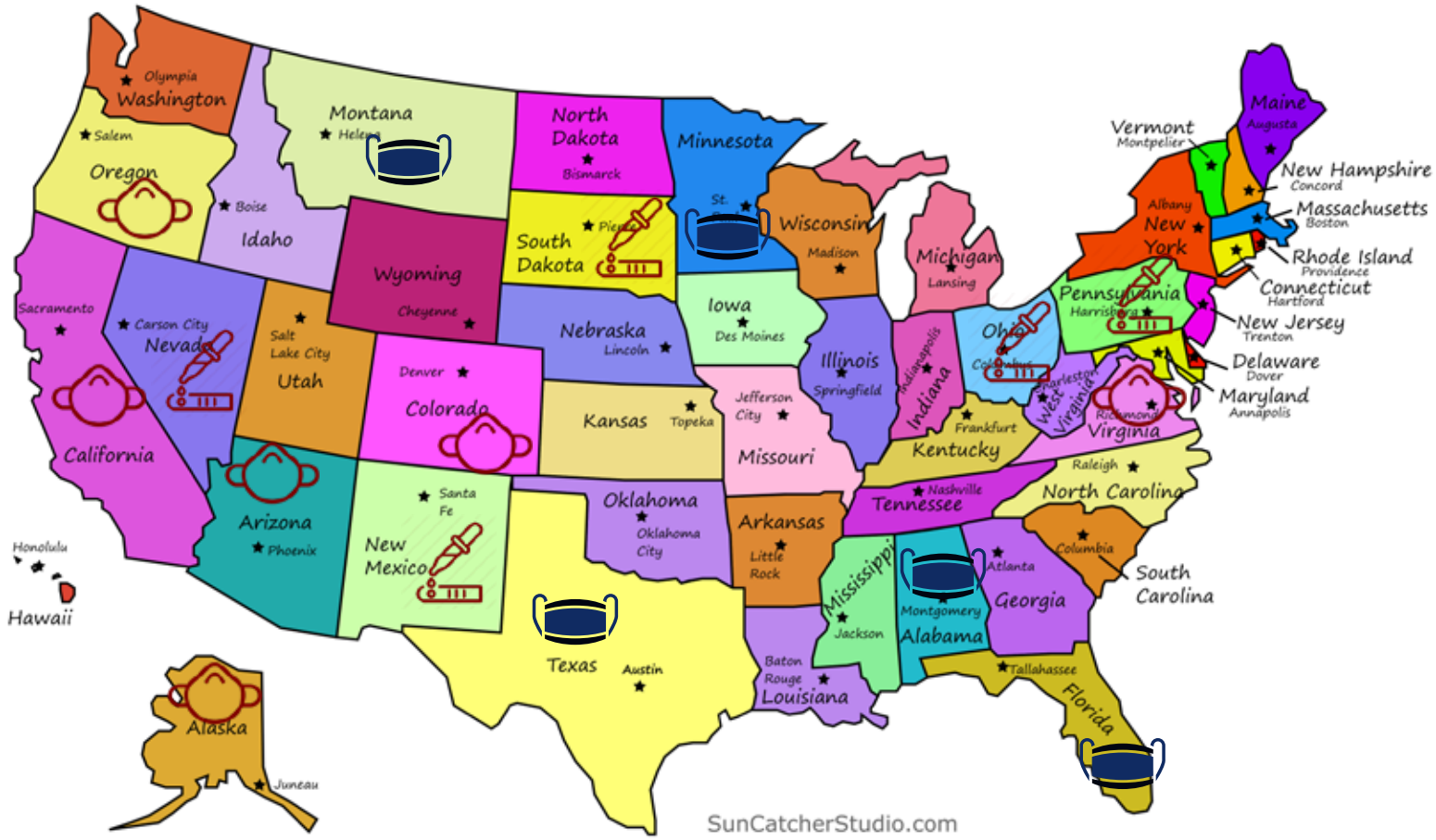
** Including active pharmaceutical ingredients (API)*

*** Includes consumables and raw materials, fill-finish capacity, vials, and needles & syringes*

Personal Protective Equipment

- ASPR IBMSC PPE investments are new investments in domestic manufacturing.
- These investments were dispersed throughout all regions of the country.

- Major investments include:
  - Nitrile glove manufacturing
  - Production of surgical masks
  - Increase production of meltblown fibers
  - Increase the production of N95 respirators
  - Increase capacity for nitrile butadiene rubber manufacturing



Testing and Diagnostics

- Testing and Diagnostics works with USG partners to help ensure continuity of COVID-19 diagnostic tests and supplies for the US population.
- Through acquisition and distribution of tests through the ASPR Stockpile, distributed over 200 million diagnostic devices to over 30,000 location in the US.
- Manage the diagnostic Stockpile of over 260 million devices.
- Weekly distributions to long-term care facilities, schools, federally qualified health clinics, border sites, food banks occur through our logistics network. Now adding a new program with HUD and over 6500 sites.
- Manage the inventory for other test distribution programs such as covidtests.gov in partnership with USPS. Just completed Round 6 of the program.

USDA

FEEDING AMERICA

Advanced Manufacturing Technologies

- Small molecule drug production
  - Continuous manufacturing and cGMP validation of sedatives, neuromuscular blocking agents and analgesics in shortage
- Saline manufacturing
  - Development and validation of saline-on-demand technologies
- Blow Fill Seal technology for Fill-Finish (“Plan B” for pandemic response)
  - Development of novel fill-finish capabilities for small molecule and biologic injectables
- Aero mobility solutions for supply chain optimization- EVTOL
- Supply chain optimization efforts with the Advanced Regenerative Manufacturing Institute, Inc (ARMI) Foundry for American Biotechnology (NextFAB)

Essential Medicines

223 Total Drug Products on the FDA List Medicines, Medicines, Medical Countermeasures and Critical Inputs under EO13944

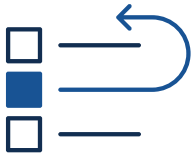
Essential Medicines Supply Chain and Manufacturing Resilience Assessment
(Ongoing analysis)

- Narrowed and prioritized list of Essential Medicines (n= 86)
- Supply Chain Challenges (6) illuminated and Strategies Identified (5)
- Developed the “Essential Medicines Supply Chain and Manufacturing Resilience Assessment” Action Report

Supply Chain Optimization

- Experts on the supply chain landscapes of our core commodities
- Conduct marketing and economic analysis on PPE for instance to understand the current “as is” situation
- Determine the future investments and or sustainability levers, policies, or legislations that would be needed to keep them viable and the capacities available for supporting the next pandemic

Defense Production Act Authorities



Title I:
Priorities & Allocations

Priority Ratings: Requires mandatory acceptance of contracts and orders for health resources and receives preferential performance to help mitigate delays

Allocations authority: USG can allocate scarce and essential "health resources" materials for National Defense

Title III:
Expansion of Production Capacity

Domestic industrial base: Presidential authority to *create, maintain, protect, expand, or restore essential domestic industrial base capabilities*

Incentives:
Gives HHS Secretary authority to provide *appropriate incentives to develop, maintain, modernize, restore, and expand the productive capacities of domestic sources*

Executive Order 13603 delegates DPA authorities for "health resources" to the HHS Secretary

Each title of the DPA functions independently and collectively to help ensure the availability of resources to meet the national defense needs.

IBx Connect

- Advanced manufacturing efforts for drug substances and drug products
- Supply chain optimization
- Testing and diagnostic devices and consumables and
- Personal protective equipment

On the Web:
aspr.hhs.gov

Facebook:
facebook.com/ASPRgov

X (formerly known as Twitter):
twitter.com/ASPRgov

X (formerly known as Twitter):
Dawn O'Connell: twitter.com/HHS_ASPR

Instagram:
instagram.com/ASPRgov/

YouTube::
youtube.com/c/ASPRgov

Flickr:
flickr.com/ASPRgov

LinkedIn:
linkedin.com/showcase/hhs-aspr/

Contact me: arlene.joyner@hhs.gov

BioMaP Program Alignment with the BARDA Strategic Plan

Tim Belski

Branch Chief, BARDA BioMaP Pharmaceutical Countermeasures Infrastructure

Networking Break

10:20 AM	Keynote Speaker – Nikki Bratcher-Bowman Principal Deputy Assistant Secretary for Preparedness and Response and Chief Operating Officer, ASPR
10:30 AM	BioMaP Technology Roadmap
11:30 AM	Manufacturing Roadmap Q&A
12:00 PM	Lunch

Network: SA_Guests
Password: $trategicWifi1

Scan code for
Digital Program:

Keynote Address

Mrs. Nikki Bratcher-Bowman is the Principal Deputy Assistant Secretary for Preparedness and Response and Chief Operating Officer for the Administration for Strategic Preparedness and Response (ASPR) at the U.S. Department of Health and Human Services (HHS).

Mrs. Bratcher-Bowman served as the Acting Assistant Secretary for the Administration for Strategic Preparedness and Response from January through June 2021. During that time, she led ASPR as it continued to respond to the COVID-19 pandemic by expanding the use of monoclonal antibody therapeutics; deploying responders from the National Disaster Medical System (NDMS) to serve in hard-hit areas of the country; and continuing to develop, procure, and deploy the medical countermeasures needed to respond to the pandemic.

BioMaP Technology Roadmap

U.S. Department of Health and Human Services

ASPR
Administration for Strategic Preparedness and Response

BARDA
Biomedical Advanced Research and Development Authority

BARDA Pharmaceutical Countermeasures Infrastructure Division (PCI) Overview and Requirements

Michael Angelastro

Division Director, ASPR BARDA PCI

Inaugural BioMaP-Consortium Industry Day (Arlington, VA)

April 5, 2024

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

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**

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)
- Nonclinical 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

Pharmaceutical Countermeasures Infrastructure Division (PCI)

VISION

Maintain manufacturing capability to respond to any pandemic or public health emergency (PHE)

STRATEGY

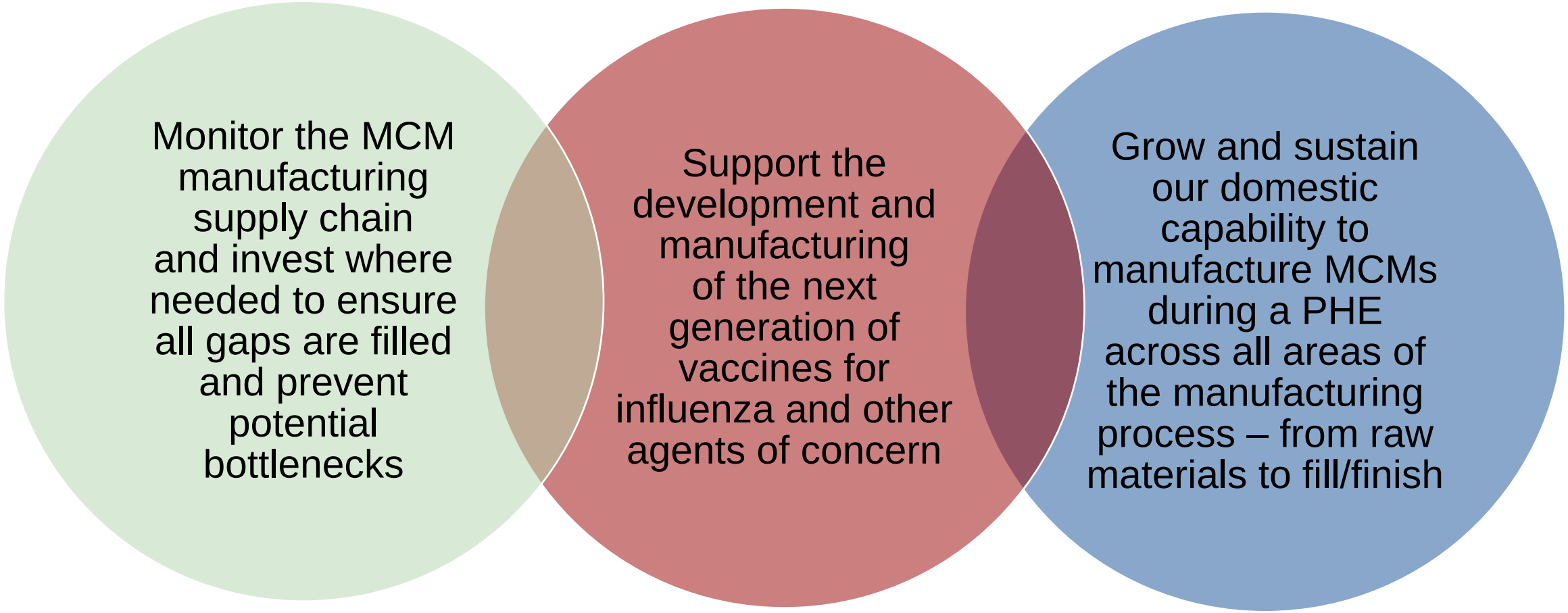
Product Development Process Expertise

Providing industry expertise to ensure manufacturing *scalability* in advanced research development efforts.

Biopharmaceutical Manufacturing Capacity

Strengthening the Nation's biopharmaceutical manufacturing infrastructure to prepare and secure a comprehensive and resilient domestic MCM response to public health emergencies.

PCI's Overarching Strategy



Aligns with BARDA Strategic Plan (BSP) 2022-2026 Objectives 2.1 (Enhance BARDA's Response Posture by Leveraging a Diverse MCM Portfolio of Proven Technologies)

Aligns with BSP Objective 1.1 (Accelerate the Development of Agile MCMs that can Pivot & Brought to Scale in Response to New Threats)

Aligns with BSP Objective 2.2 (Build a Resilient, Surge-Capable, Flexible Manufacturing Ecosystem)

PCI Division

Director
Michael Angelastro

BIOPHARMACEUTICAL MANUFACTURING PREPAREDNESS (BioMaP) BRANCH

Tim Belski, M.S., PMP – Branch Chief

- BioMaP-Consortium
- BioMaP Exercise (BioMaP-X)
- BioMaP Workforce Development (BioMaP-W)

Bob Huffman, PE – Acting Branch Chief

- Manufacturing of qualified medical countermeasures
- Engagement with industry, inter-agency, and international partners
- Supply chain resilience, including industrial base expansion

CGMP CAPABILITIES READINESS (CCR) BRANCH

Joseph Figlio, MBA – Branch Chief

- Supporting influenza capacity and response capabilities
- Capacity expansion of fill-finish response capabilities
- Supporting expanded use of adjuvants and alternative administration for vaccines

PCI's Impact in Recent PHEs

CHALLENGES OF PAST PHEs

- Revealed/exacerbated supply chain weaknesses
- Reliance on foreign sources for multiple vaccine precursor materials
- Displacement of other life-saving medications and therapeutics
- Supply constraints of Co-60 further stressed critical supply chain needs
- Needs of the northern hemisphere influenza vaccine manufacturing campaign
- Weather impacts such as Texas deep freeze, plastic resins, and Tyvek force majeures

LEVERAGE EXPERIENCE FROM THE COVID-19 RESPONSE TO BE BETTER PREPARED FOR FUTURE PHEs

STRENGTHEN RELATIONSHIPS WITH INDUSTRY

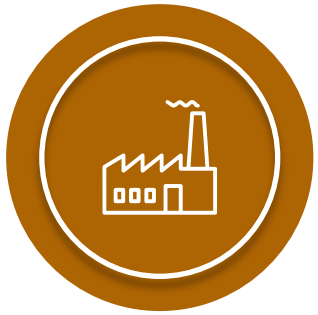
INCREASE DOMESTIC CAPACITY TO REDUCE THE NEED FOR RATED ORDERS

PCI Potential Target Areas for Fiscal Year 24

Establish BioMaP's core components

- BioMaP-Consortium
- BioMaP Workforce Development
- BioMaP Exercise

Expand capabilities for recombinant and mRNA influenza vaccine manufacturing



Enhance the manufacturing and resilience of qualified medical countermeasures, with a focus on investments, engagement, and supply chain resilience

Expand domestic manufacturing capacity, specifically in

- BSL-2 fill-finish
- Sterilization - with a focus on new modalities (i.e., X-ray and e-beam)
- mRNA raw materials

+ Any other areas where the biomanufacturing industry sees gaps in PHE preparedness…

Contact Information

Michael Angelastro
Division Director, ASPR BARDA PCI
michael.angelastro@hhs.gov

CONNECT WITH BARDA

social media

@BARDAGOV

@BARDA

@BARDA

U.S. Department of Health and Human Services

ASPR
Administration for Strategic Preparedness and Response

BARDA
Biomedical Advanced Research and Development Authority

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

Karen Martins, Ph.D.

Director, Antivirals and Antitoxins Program

CBRN Medical Countermeasures
Administration for Strategic Preparedness and Response (ASPR), Department of Health and Human Services (HHS)

BioMaP Consortium Industry Day 5 April 2024

Unclassified

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

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**

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)

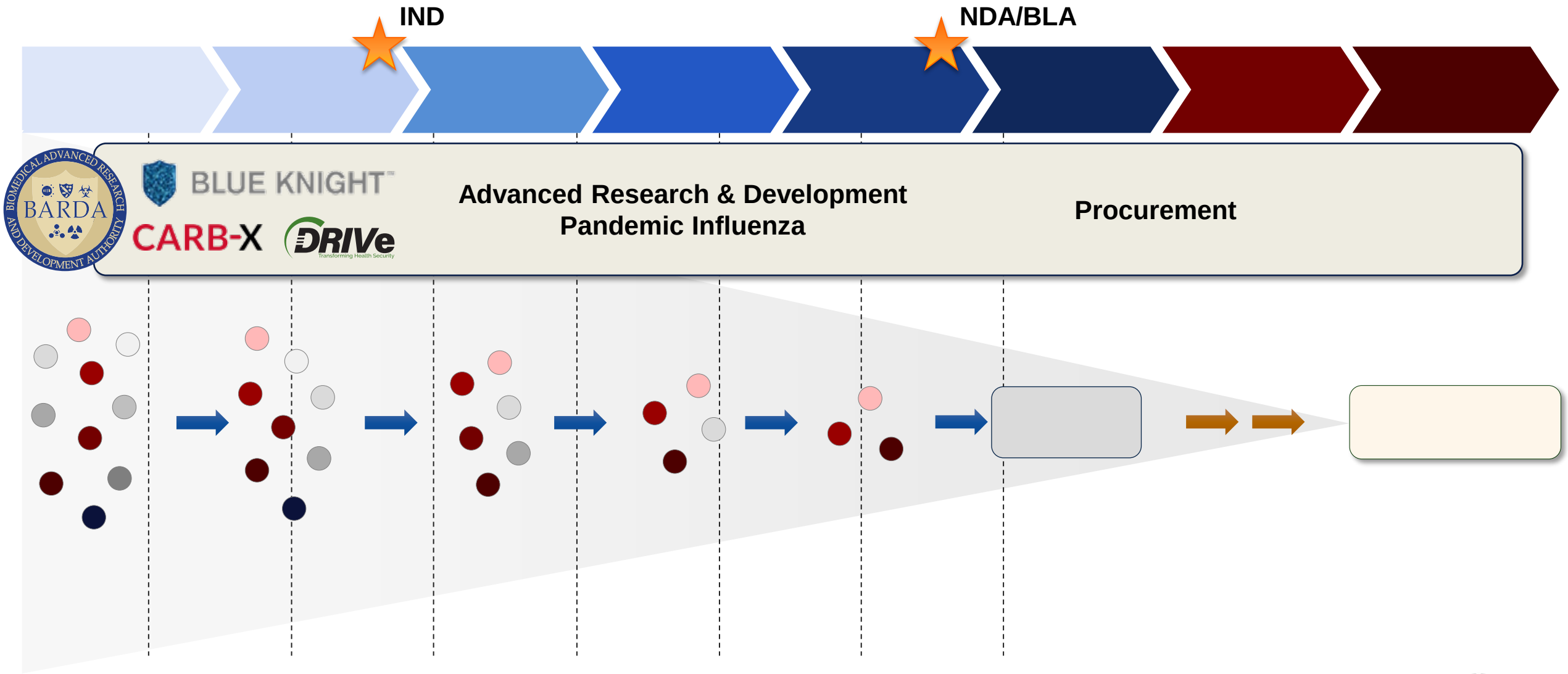
MEDICAL COUNTERMEASURES SUPPORT SERVICES PROGRAM

- Regulatory and Quality Affairs (RQA)
- Clinical Development (DCD)
- Nonclinical 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



CBRN MISSION

Establish capabilities to respond to any natural or intentional CBRN health security threat

CBRN Threat Space

CHEMICAL: Chemical MCMs

Nerve Agents, Vesicants, Pulmonary Agents, Cyanide, Opioids (including Fentanyl)

BIOLOGICAL: Antivirals & Antitoxins, Antimicrobials, Vaccines

Viruses: Ebola Virus, Sudan Virus, Marburg Virus, and Variola Virus

Bacteria: *Bacillus anthracis, Burkholderia pseudomallei, B. mallei, Francisella tularensis, Yersinia pestis,* Priority AMR Bacteria

Fungi: *DR Candida spp., DR Aspergillus fumigatus,* Rare molds such as *Mucorales*

Toxin: Botulinum Neurotoxin

RADIOLOGICAL & NUCLEAR: Rad & Nuc MCMs, Burn & Blast MCMs

Nuclear Detonation, Radiological Dispersal Devices

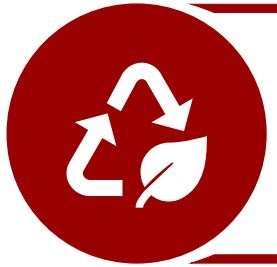
CBRN 1.0	CBRN 2.0
THREAT-SPECIFIC MCMs	THREAT-AGNOSTIC MCMs
TRADITIONAL DEVELOPMENT	PLATFORM AND ENABLING TECHNOLOGIES
FDA APPROVAL FOR TRADITIONAL THREATS	FDA APPROVAL THAT ENABLES RAPID RESPONSE TO NEW THREATS
CENTRALIZED CDMO MANUFACTURING	ON DEMAND DISTRIBUTED MANUFACTURING
PROCUREMENT FOR NATIONAL PREPAREDNESS	IMPROVED SUSTAINABILITY AND ACCESSIBILITY

Ensuring the Nation is Prepared to Rapidly Respond to Any CBRN Threat

Develop host-directed threat-agnostic MCMs

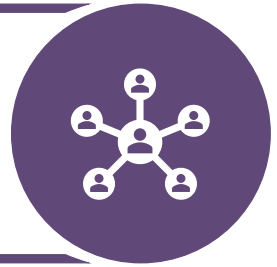
Develop fit-for-purpose countermeasures

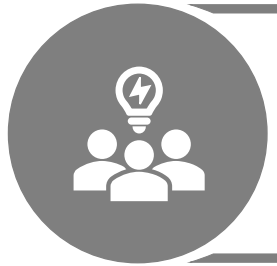
Invest in flexible & innovative technologies to address known & unknown threats



Improve MCM sustainability

Engage stakeholders & end users





Foster a world-class workforce

Chemical MCM Program – Strategic Objectives

MISSION

Improve health outcomes for all affected by chemical exposure

GOAL

Ensure that MCMs for chemical injury are readily available for the end-users

STRATEGIC OBJECTIVES

Develop a threat-agonist pipeline of countermeasures

Broad spectrum use for chemical and conventional indications

Ease of availability during chemical emergency

Repurpose common drugs for chemical indications

Facilitate use of readily available drugs for chemical injury

Far forward positioned drugs: already with the end-user

Improve end-user engagement

Ensure that first responders have the products they need

Create a communication channel directly with end-user

Bring awareness and obtain input on BARDA's products for emergency response

Radiological & Nuclear MCMs

Mission

Improve health outcomes for all victims of nuclear detonations and radiation exposure

Goal

Ensure the nation is prepared to rapidly respond to any RN threat

Priorities

Acute Radiation Syndrome & Traumatic Injury
Innovative platforms & technologies
Repurposed products
Preparedness & Sustainability

Burn & Blast Program Mission

GOAL

Build Preparedness for Range of Burns & Trauma Injuries

PRIORITIES

High Impact
- » Early Detection - Rapid Triage
- » Address Bottlenecks

Transformative
- » AI-Enabled - Innovative
- » Adaptable Technology

Solutions Driven
- » Demonstrates Value
- » Adoptable in Routine Care

STRATEGY

Comprehensive – Adoptable – Sustainable Solutions

Antimicrobials

MISSION

Reduce the morbidity and mortality caused by a biothreat or AMR secondary infection following a mass casualty event or a disease outbreak

STRATEGIC PRIORITIES

- Develop drug candidates with direct activity against biothreat pathogens and/or DR secondary bacterial and fungal infections
  - CDC AMR priority pathogens
  - Broad spectrum
  - Novel mechanisms of action
  - Non-traditional/first-in-class antimicrobial
- Underserved/special populations (e.g., pediatrics)

END-GAME

Enhanced preparedness to biological threats and AMR infections

Successes

- **3 approved products: VABOMERE, ZEMDRI, XERAVA**
- **Advanced 5 candidates into Phase 3 clinical development**
- **Supporting 7 novel compounds including phage & microbiome**

Near term goals

- **2 NDA submissions in 2024 for DR infections**
- **1 NDA approval for DR bloodstream & skin infections**
- **Initiation of pediatric studies for 2 antibiotics**
- **Initiation of antifungal projects**

Long term goals

- **Licensed products for DR secondary bacterial infections and DR fungal infections**
- **Effective antibiotics for the treatment of DR infections in adults and pediatrics**

CBRN Vaccines

MISSION

Develop and procure vaccines against biological threats for which pre- or post-exposure prophylaxis are critical to the overall response

STRATEGIC OBJECTIVES

- Establish interim preparedness for vaccines against priority unmet threats
- Invest in flexible technology to 1) enable rapid shifts to emerging threats, 2) improve sustainability, and 3) reduce downstream bottlenecks
- Expand and improve CONOPs of licensed/late-stage products

END-GAME

Be prepared to protect against priority biological threats

Successes

- Licensed products
  - ERVEBO (+ pediatric)
  - JYNNEOS (+ mpox)
  - CYFENDUS
- Filovirus natural history studies
- Early filovirus R&D investments

Near term goals

- Interim preparedness for Marburg and Sudan
- Lyophilized JYNNEOS
- Operational CYFENDUS studies
- Evaluate platform technologies
- Vaccines on Demand PoC

Long term goals

- Licensed Marburg and Sudan products
- Interim preparedness for additional threats advancing to licensure where feasible
- Improved program sustainability

Antivirals and Antitoxins

MISSION

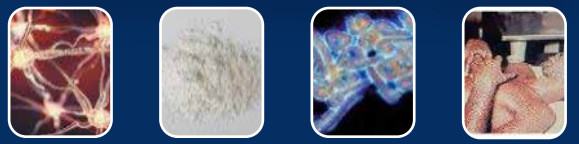
To establish a layered defense against priority biothreats while prioritizing investments that will address emerging and reemerging biological threats for all members of our community

STRATEGIC OBJECTIVES

- Establish **interim preparedness** for therapeutics against priority unmet threats while advancing products to **licensure**
- Invest in **technologies and host-directed** countermeasures with potential cross-threat impact
- Expand and improve **CONOPs** of licensed/ late-stage products

END-GAME

Layered defense against priority biological threats



Investments that can pivot to new responses

Successes

- Licensed products
- Launch of ReBoot, FASTx, BoNT Preclinical Testing Service
- Collaborative preclinical evaluation of product candidates
- Response readiness posture

Near term goals

- Improved manufacturing for mAb
- Regulatory path for priority threats
- Investment in therapeutic platforms
- Enabling activities for host-directed countermeasures

Long term goals

- Licensed MARV, SUDV products
- Stress test of therapeutic platforms for new threats
- Licensure or clinical guidelines supporting host-directed tx
- Improved sustainment strategy

Three-Pronged Approach to Readiness for Future Biothreats

Host-Directed Therapeutics

- Identify **pathways and syndromes**
- Characterize appropriate **preclinical models**
- Establish **regulatory pathway**

Therapeutic Platforms

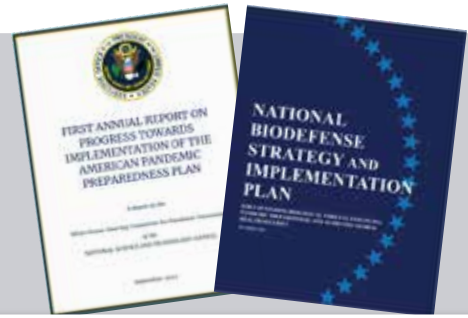
- Invest both in the **technologies** and in **products**
- Identify **regulatory mechanisms** to support platform technologies
- Improve upon platforms' **efficacy, speed, and cost**

Broad-Spectrum Antivirals

- **Prioritize** products with **broad efficacy** against multiple viruses or viral genera/families
- Identify ways to improve **sustainability** and manage costs

Manufacturing Investments Align with Key Domestic Policies

1. **Preparedness**: Rapidly develop safe, effective medical countermeasures accessible to all Americans
2. **Response**: Maintain a sustainable, mission-ready response posture



- **Goal 2:** Ensure biodefense enterprise capabilities to prevent bioincidents.
- **Goal 3**: Ensure biodefense enterprise preparedness to reduce the impacts of bioincidents

Enhancing accessibility through reliable and sustainable manufacturing

Improving stockpile sustainability by reducing cost of goods

Enabling emergency response while also ensuring reliable supply chain and manufacturing capabilities

Particular focus on mAb manufacturing and medical countermeasure platforms

Current CBRN BioMaP Discussions

- **Antivirals and Antitoxins: Notice of RFI & Sources Sought: BARDA Manufacturing Optimization for Filovirus Human Monoclonal Antibodies**
  - SAM.gov RFI issued 20 March; **closes 20 April**
  - **Objective**: Identify a high yield, low-cost manufacturing process for the two identified mAbs that does not impact potency
  - **Initial award**: Multiple CDMOs funded to establish cell line for mAbs of interest
    - Downselect based on cell line yield, mAb potency, and other product specs
  - **Potential follow-on award**: One or two CDMOs funded to support manufacturing optimization
- **Vaccines: Capability Assessment**
  - **Current plans:** Evaluate process and gaps to tech transfer live virus vaccine manufacturing (fill/finish) to the US from a foreign source
  - **Next step:** Apply first phase to a licensed product in a tabletop exercise
  - **Ultimate goal:** Demonstration of successful transfer (pending additional BARDA discussions and funding)

medicalcountermeasures.gov
Portal to BARDA: ***Register to request a TechWatch meeting!***

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!

@BARDA | **Biomedical Advanced Research and Development Authority** | **@BARDAGOV**

U.S. Department of Health and Human Services

ASPR
Administration for Strategic Preparedness and Response

BARDA
Biomedical Advanced Research and Development Authority

Influenza and Emerging Infectious Diseases Division (IEIDD) Portfolio Overview

Frank Arnold, Ph.D.

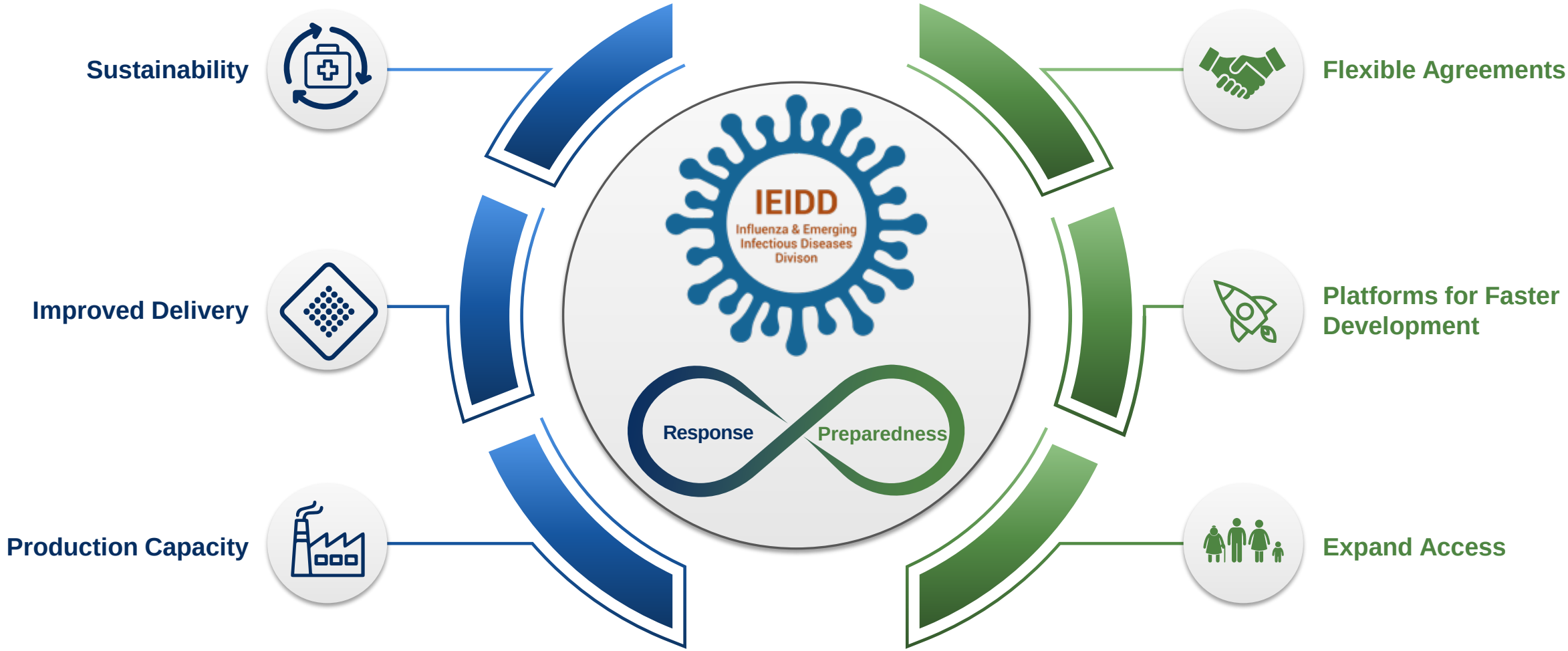
Tunnell Contractor on behalf of

Vaccines Development Branch

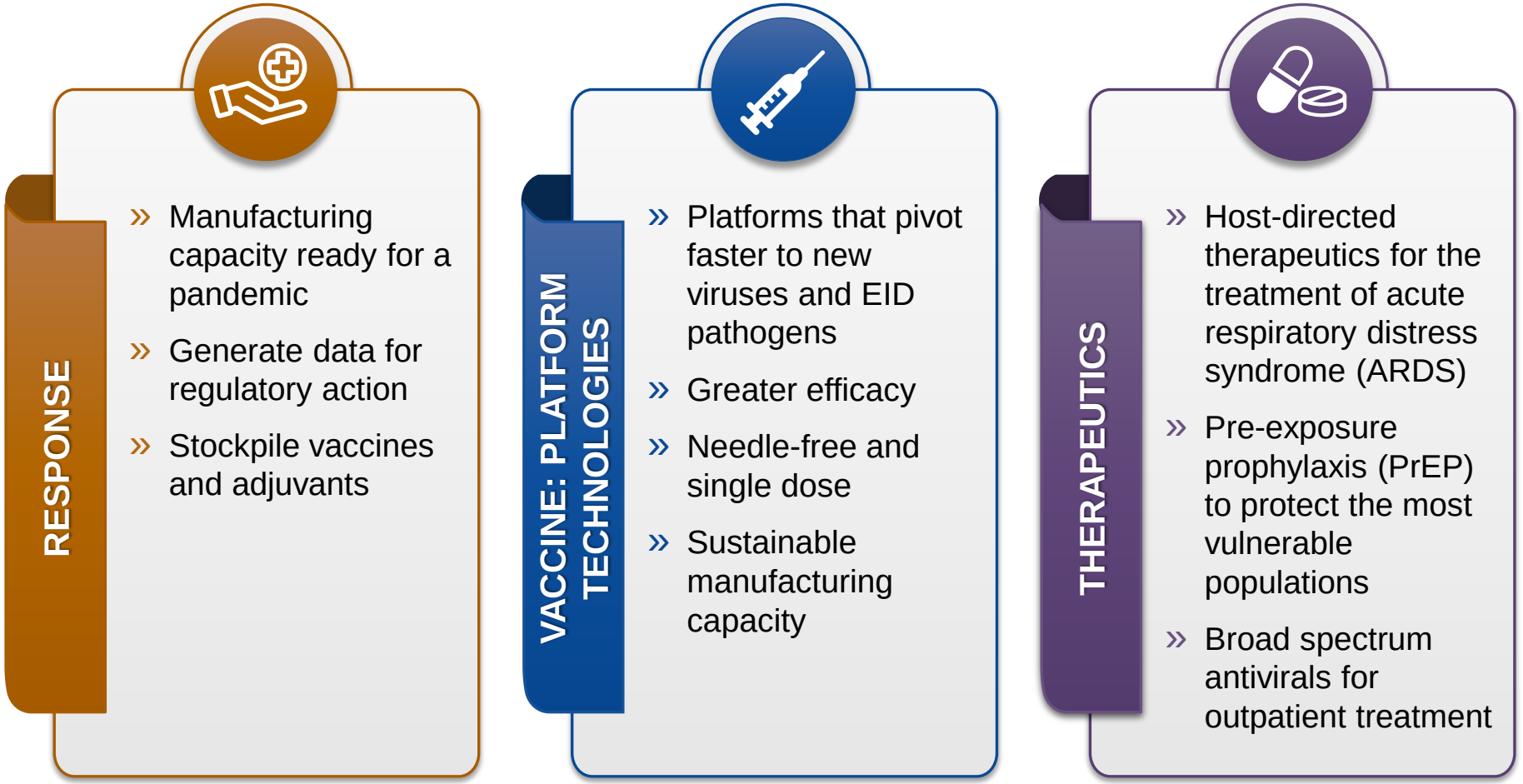
Influenza and Emerging Infectious Diseases Division (**IEIDD**)

Biomedical Advanced Research and Development Authority (**BARDA**)

IEIDD Strategy: Establish New & Leverage Existing Infrastructures & Capabilities to Support Response & Preparedness



MCM Portfolio for Influenza & Emerging Infectious Diseases (EIDs)*



**Aligned with BARDA 2022-2026 Strategic Plan*

IEID Vaccines Advanced R&D Portfolio

Flexible vaccine platforms

» **Goal**: Enable design, testing, and manufacture of safe and effective vaccines against novel influenza viruses within 100 days of recognition

Greater efficacy, improved vaccine performance

» **Goal**: Achieve immunity in the population more quickly with a formulation that confers protection against a novel virus with a single dose of vaccine

GOAL
To advance development of a flexible, better influenza vaccine

Alternative vaccine administration

» **Goal**: Use delivery methods that reduce the need for cold chain and needles/syringes; may enable self-administration and/or improve efficacy and performance

Increased manufacturing capability

» **Goal**: Enable production of enough vaccine for the United States population within 120 days after recognition of a novel pandemic Influenza virus

vaxxas · AAHI · ARCTURUS therapeutics · Takeda · Janssen · sanofi · moderna · AstraZeneca

Pandemic Influenza Readiness Gaps

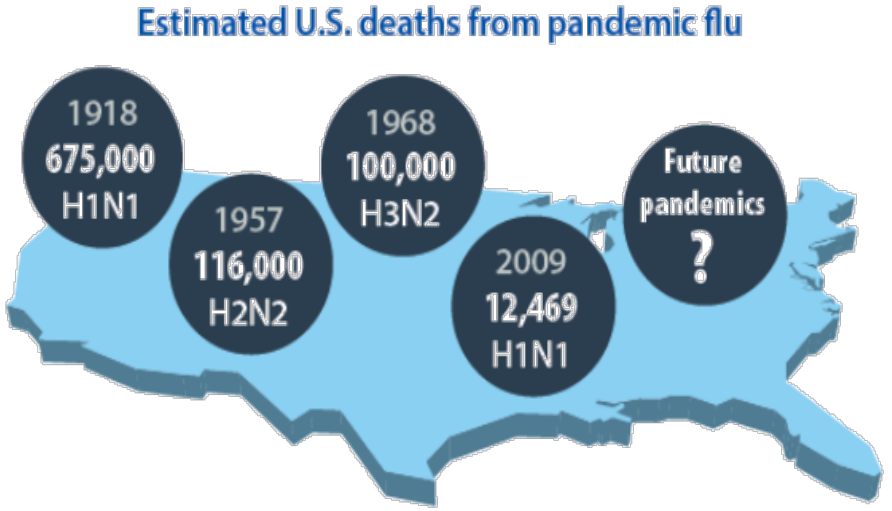
Available Medical Countermeasures

FDA-Licensed Vaccines

- CSL Seqirus AUDENZ
- GSK H5N1 influenza vaccine
- sanofi H5N1 Vaccine
- Seasonal Flu Vaccines

Outpatient Treatments

- Oseltamivir
- Zanamivir
- Baloxavir
- Peramivir



Gaps in Influenza Pandemic Vaccine Readiness

Safety and immunogenicity data for all influenza viruses with pandemic potential to reduce response timelines

Expanded Vaccine Licensures

- Additional influenza virus strains and subtypes
- Mix-and-match formulations
- Special populations

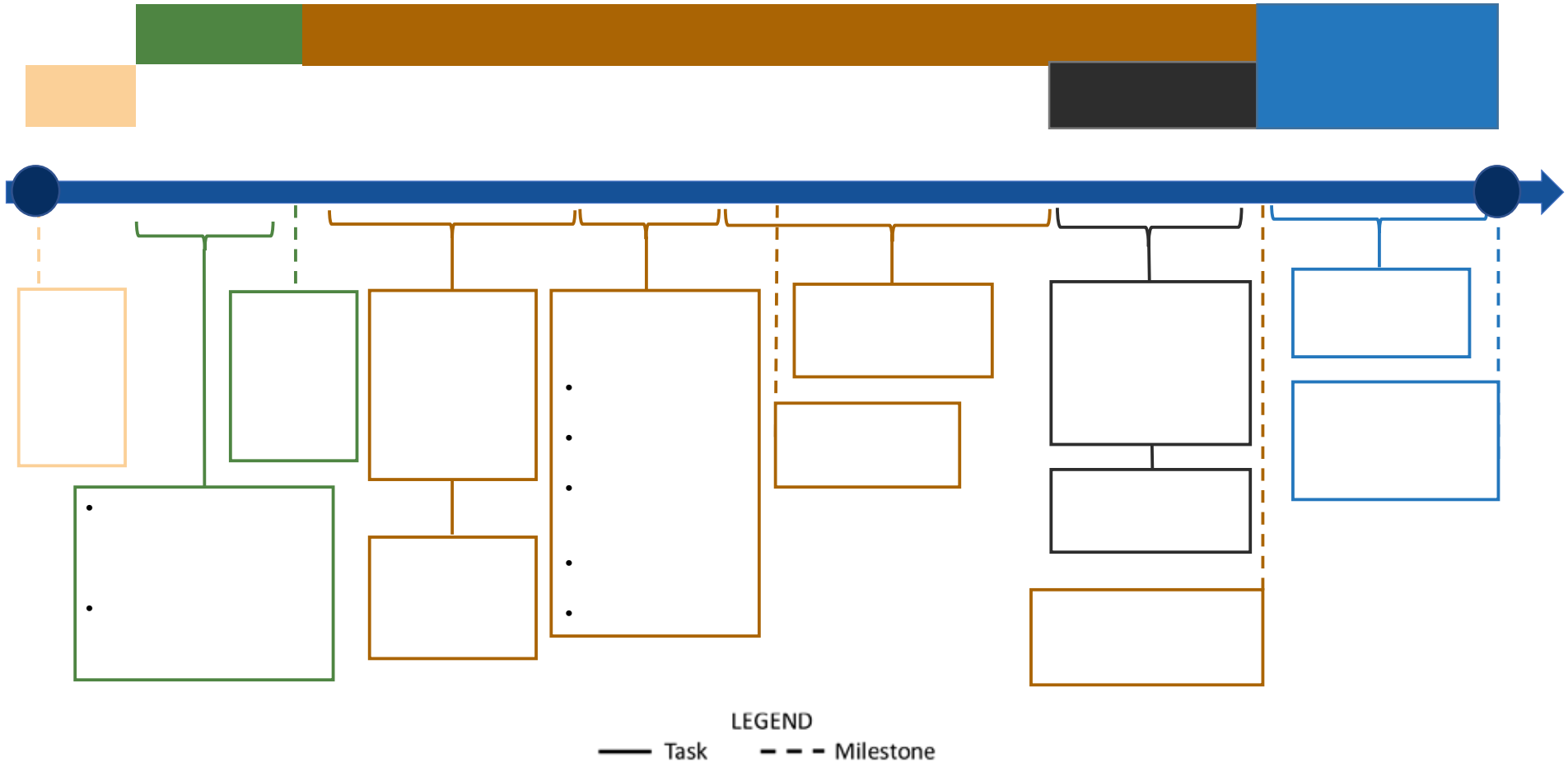
Faster and better influenza vaccines

- Fast vaccine platforms (e.g., RNA)
- Alternative delivery technology
- More temperature-stable formulations
- Single-dose formulation
- Broadly priming vaccine (Pan Flu)
- US-based manufacturing capacity for new technologies

https://www.cdc.gov/flu/pandemic-resources/1918-commemoration/pandemic-preparedness.htm

Lessons Learned Evaluation Methodology

- 18 focus groups and 2 interviews were conducted, with a total of 77 U.S. government (USG) personnel interviewed between February 3 and June 7, 2023
- 6 / 6 manufacturers provided feedback via a survey



This lessons learned initiative focused on the activities of the COVID-19 Therapeutics Project Coordination Team.

Observations from Manufacturers

Challenges

- Supply shortages (e.g., ancillary & laboratory supplies) & limited human resources
- Limited clinical trial site availability & participant diversity
- Real World Evidence (RWE) data collection & attribution to variants were challenging due to evolving variant landscape
- Public-facing product locator and tracking tools were not immediately available
- Initial onsite reporting of available product and utilization was inefficient
- Messaging of product information, critical product updates, & product availability was not always consistent

Strengths

- Close collaboration with suppliers & manufacturing partners was key to manufacturing readiness & capacity
- Per manufacturers, BARDA & USG served a key role in partnering with manufacturers for product procurement & distribution
- Regular touchpoints between BARDA & manufacturers prior to contract award expedited product distribution & administration once Emergency Use Authorization (EUA) was granted

USG Lessons Learned

Challenges

- Urgency of response compressed timelines
- Changing variant landscape impacted authorization for existing products
- Rapidly changing case rates required constant reviews & updates to supply allocations for all jurisdictions and impacted equitable access
- Managing misinformation & disinformation
- Differing cold-chain requirements and routes of administration between therapeutic products caused confusion in the field
- Package labeling changes for dose adjustments and shelf-life extensions

Strengths

- Strength of relationships with manufacturers
- Intra- & interagency coordination
  - Collaboration with DOD to leverage its contracting authorities to accelerate contract awards
  - Frequent & productive discussions with FDA allowed for prompt resolution of uncertainties, timely fact sheet updates, & coordination for pauses in EUA
  - FDA website centralized expiry extension announcements
- Expansion of provider outreach & efforts to increase access to products
  - Home delivery of therapeutics allowed for expansion of access to products otherwise available only at an HCP office or pharmacy

Key Takeaways

Need for a Layered Response

- Therapeutics are a critical component of a response, and sometimes are the only options (PrEP for immune compromised)
- A layered approach with depth & breadth is critical

Strength of Partnerships

- Regular & open communications between industry partners is important
- Intra- & interagency collaborations aid the EUA process

Coordinated Comms/Messaging

- Joint Information Center could help
- Message amplifiers are vital
- Key opinion leader / influencer relationships are required to counteract misinformation & amplify public health messages

Integrate Pandemic Infrastructure into Standard Practices

- HHS Coordination Operations and Response Element (H-CORE) established
- Hot washes & lessons learned are critical

Contract Development and Manufacturing Organization Gaps and Challenges

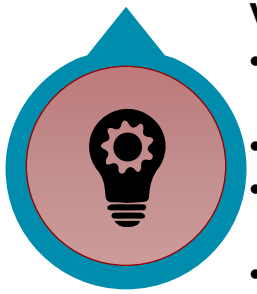
Fill-Finish capacity for pandemic preparedness, including, but not limited to:

- Increased speed
- Lower cost
- New flexible systems (e.g., blow fill seal)
- Live vaccine product(s)

Make **available solutions for raw material and consumable bottlenecks** (e.g., supply of bags, tubing, custom assemblies, filters, specialty chemicals etc.)

Capability to manufacture unique drug substance(s) and adjuvants that involve complex production processes (e.g., cell culture and viral infections, etc.)

Ability to assume the risk of fill/finishing non-released drug substance to **shorten pandemic response timelines**



Validated processes in place:

- Drug product labeling according to the DSCSA
- Drug product storage
- Domestic transport at all temperatures
- Domestic fill/finish of antigen and/or adjuvant from FDA-licensed pandemic influenza vaccines

Provide **opportunities to add improvements** in technology, alternative delivery systems, or newly licensed vaccines to the pandemic influenza readiness program

Current Portfolio of mRNA Vaccine Candidates

Goal: Enable design, testing and manufacture of safe and effective vaccines against novel influenza or EID viruses within 100 days of recognition.

ARCTURUS THERAPEUTICS

- Arcturus' STARR™ self-amplifying mRNA (samRNA) technology
- Scope: Lower-dose, freeze-dried, pandemic H5 influenza vaccine candidate through phase 1 clinical testing

ARCTURUS therapeutics

ACCESS TO ADVANCED HEALTH INSTITUTE

- Develop an intranasal pandemic H5/H7 influenza RNA vaccine candidate in liquid and dry powder presentations through phase 1 clinical trials
- Technology delivers samRNA bound to the exterior of a nanostructured lipid carrier (NLC)

AAHI

ASTRAZENECA

- Apply mRNA platform to a range of viral threats to enable more rapid responses
- Alternate routes of administration (e.g., microneedle patch)

AstraZeneca

Thank You

FRANK ARNOLD, Ph.D. (CTR)

Influenza and Emerging Infectious Diseases Division

BARDA

Frank.Arnold@hhs.gov

medicalcountermeasures.gov
Portal to BARDA: ***Register to request a TechWatch meeting!***

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!

@BARDA | **Biomedical Advanced Research and Development Authority** | **@BARDAGOV**

U.S. Department of Health and Human Services

ASPR Administration for Strategic Preparedness & Response

ASPR's Center for Industrial Base Management and Supply Chain (IBMSC) Advanced Manufacturing Update

Advanced Manufacturing Technologies At-a-Glance

Small molecule drug production

- Continuous manufacturing and cGMP validation of sedatives, paralytics and analgesics in shortage

Saline manufacturing

- Development and validation of saline-on-demand technologies

Fill-Finish

- Development of novel population scale fill-finish capabilities for small molecule and biologic injectables

Aero mobility solutions for supply chain optimization- EVTOL

Supply chain optimization efforts with the Advanced Regenerative Manufacturing Institute, Inc (ARMI) Foundry for American Biotechnology (NextFAB)

Essential Medicines

223 Total Drug Products on the FDA List Medicines, Medicines, Medical Countermeasures and Critical Inputs under EO13944

Essential Medicines Supply Chain and Manufacturing Resilience Assessment
(Ongoing analysis)

- Narrowed and prioritized list of Essential Medicines (n= 86)
- Supply Chain Challenges (6) illuminated and Strategies Identified (5)
- Developed the “Essential Medicines Supply Chain and Manufacturing Resilience Assessment” Action Report

Upcoming Efforts

- PPE Capacity Sustainment
- Ancillary Products for Vaccine Development and Diagnostic Use
- Raw Materials for PPE Manufacturing

Manufacturing Roadmap Q&A

Lunch

01:00 PM	TechWatch and IBx Connect
01:30 PM	Member Company Introductions
02:30 PM	Networking Break
03:00 PM	Roundtable Discussions (30 min each)

- Supply Chain
- CDMO, Drug Substance, & Drug Product Manufacturing
- Advanced Manufacturing Techniques

Scan code for Digital Program:

Network: SA_Guests
Password: $trategicWifi1

BARDA TechWatch Program

John Tegeris, PhD, aka *TechWatch Johnny*

Sr. Program Manager, BARDA TechWatch Program

BioMaP-Consortium Industry Day

April 5, 2024

The Great Eight

BDR Team	TechWatch Team
Joe Chapman	John Rigg
Katie Barradas	Dave Howell
Matt Rowe	Ralph Balsamo
Lucas Deatley	Alex Ovechkin

...Plus 500+ in BARDA and another 500+ across the USG that make TechWatch great!

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

The BARDA Model

BARDA develops and makes available medical countermeasures (MCMs) and builds manufacturing Infrastructure 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

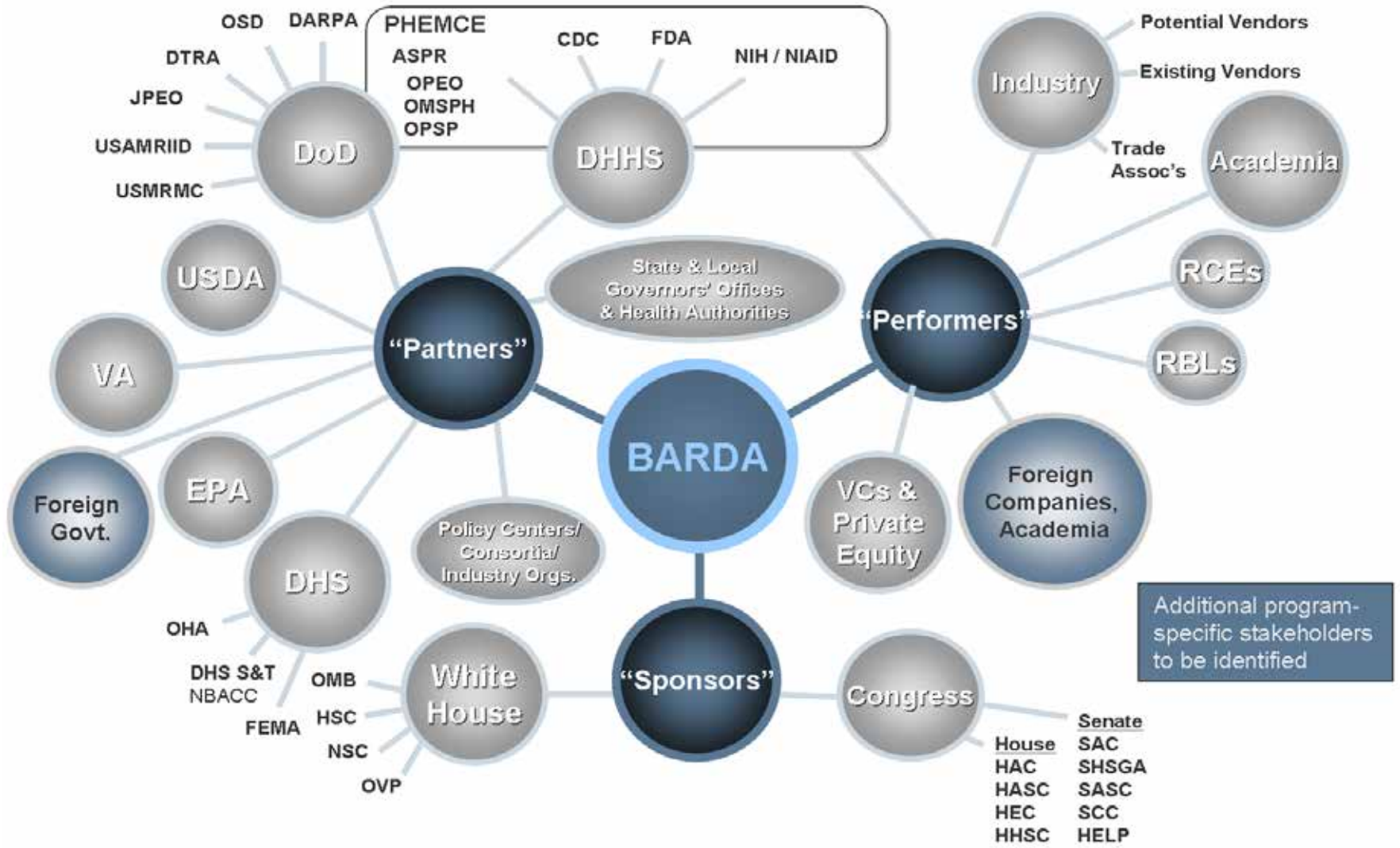
Goal 2 – Response: Enhance and maintain a sustainable, mission-ready response posture

Goal 3 – Partnerships: Leverage mechanisms to foster flexible partnerships

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

MCM Stakeholders – A Broad and Diverse Ecosystem

PHEMCE



Our Government Partners

USAMMDA

NASA

USAID

ARMATI COMPARATOR CUSTOS

PSC

OLAW

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

FEMA

DARPA

FDA

HRSA
Health Resources & Services Administration

GSA

National Institute of Neurological Disorders and Stroke

NIH National Heart, Lung, and Blood Institute

COUNTER ACT
National Institutes of Health

BERKELEY LAB

DFC U.S. International Development Finance Corporation

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Transcom

Manufacturing USA

USAMRIID
United States Army Medical Research Institute of Infectious Diseases
Biodefense solutions to protect our nation

NIH

NIH National Institute on Drug Abuse

NIH National Institute of Biomedical Imaging and Bioengineering

NIH NATIONAL CANCER INSTITUTE

OAK RIDGE INSTITUTE FOR SCIENCE AND EDUCATION
Managed by ORAU for DOE

NIH NATIONAL CANCER INSTITUTE
Technology Transfer Center

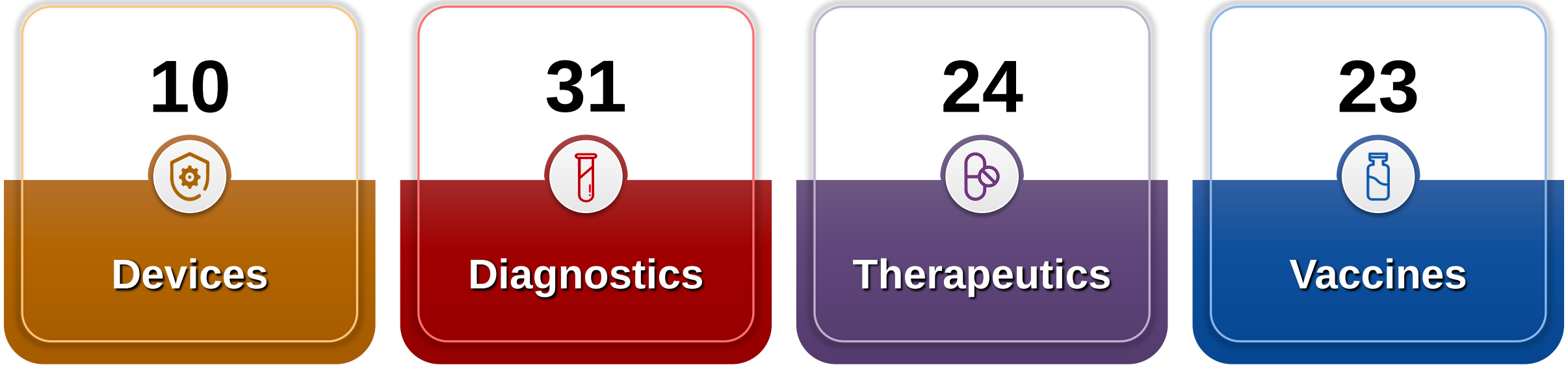
NIH National Center for Advancing Translational Sciences

NIH National Institute of Allergy and Infectious Diseases

Our Industry Partners

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.*



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.

Legislative Mandate for TechWatch – Industry Engagement is Serious Business for BARDA

PAHPA

- *"Convene meetings with representatives from relevant industries, academia, other Federal agencies, international agencies as appropriate, and other interested persons."*

- *"Conduct ongoing searches for, and support calls for, potential qualified countermeasures and qualified pandemic or epidemic products."*

- *…also bound by federal law to maintain confidentiality for whatever is presented, shared, discussed*

TechWatch and CoronaWatch Meetings Since Inception - 2008

OVER A DECADE OF INDUSTRY ENGAGEMENT

CORONAWATCH DASHBOARD

4,500+
COVID-19 TechWatch
Meeting Requests

780+
COVID-19 TechWatch
Meeting Held To-Date

CoronaWatch Program is no longer active and any Covid related technologies can be addressed as part of our ongoing TechWatch Program

COVID-19 CoronaWatch requests
from **every state in the USA**

30+
Countries – CoronaWatch Meeting Requests
from Around the Globe

TECHWATCH DASHBOARD

2,540+
TechWatch Meeting Requests
(since program inception in 2008)

1,320+
TechWatch Virtual Market
Research Meetings with
Innovative Companies

TechWatch requests from
every state in the USA

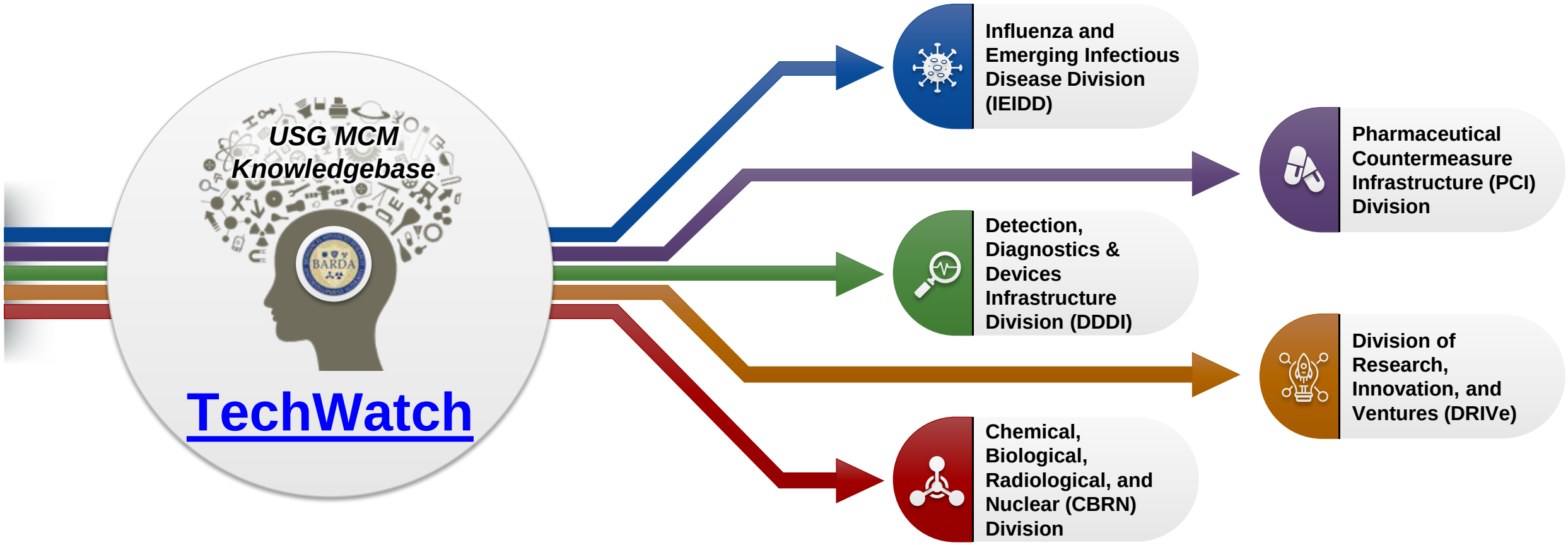
70+
Countries – TechWatch Meeting Requests
from Around the Globe

BARDA Workflow - Opportunity Funnel

Benefits to Industry of End-to-End BARDA Engagement

- **Industry Awareness and Outreach:** Improve responsiveness and feedback from BARDA
- **Pre-Award Applications:** Streamlined confidential reviews and automated progress updates
- **Post Award:** Online and Secure reporting and dashboards to augment existing collaboration

TechWatch: Always Accessible for Our 2 Equally Important Clients - Companies and BARDA/USG



Medical Countermeasures.gov

Meeting Request Process – Company Facts, Detailed Product/Capability Description, BAA Relevant AOIs (RRPV, BioMaP), TRL, Meeting Objectives

TechWatch Meeting Objective – Initial PHEMCE Splash

The TechWatch meeting's objective is twofold:

To help *"accelerate success"* and to better inform next steps:

- for the organization to understand if their product development program/manufacturing capability are responsive and competitive to any open opportunities in BARDA (exclusively addressed during closeout Q&A)

- for BARDA/USG benefit to clearly define the utility of the technology/capability in addressing our common mission priorities

TechWatch Program Details – In the Trench

- TechWatch Triage Review Process for selecting a company for a TechWatch meeting:
  - Full (1 hr) TechWatch Meeting
  - Targeted (30-45 min) TechWatch Light meeting (smaller audience, specific to ask)
  - PowerPoint slide to guide you on how to assemble your slide deck for your presentation
  - Preliminary calls and walkthrough of draft slide presentation to ensure on point for our data-driven and highly technical audience – we want you to have an impactful meeting!

- TechWatch Program meetings organized by BARDA are attended by program management personnel, scientific subject matter experts (SMEs) who have multiple years of industry experience in product development and manufacturing, as well as colleagues from our contracting office (DCMA)

- BARDA also provides insight on how a specific product or technology may address BARDA's objectives and provide general information about BARDA's mission and programs

Value of a BARDA/USG TechWatch Meeting

TechWatch meetings provide organizations with the following:

» The chance to receive technical and strategic input from experts in BARDA and interagency partners

» Opportunity to socialize/showcase your technology to BARDA and a wider audience across the USG

» A roadmap as to how organizations may interact/work with the USG as part of the partnering process

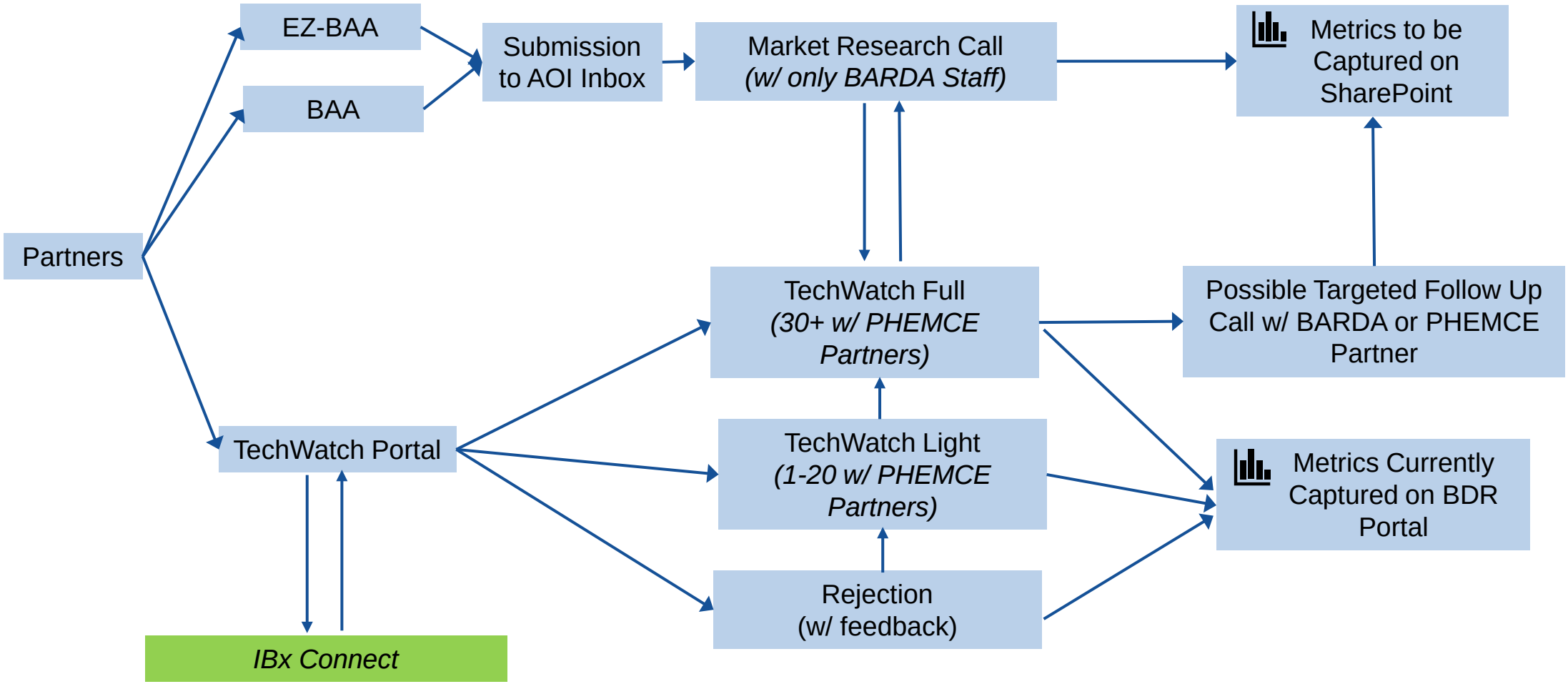
» To hear techniques and strategies for addressing technical and regulatory challenges

» Get insight on how your solution could fit within the USG to address priorities/gaps for the PH mission

» Better prepare you for a formal submission (marketing research abstract or full proposal to the BAA or abstract to the EZ-BAA), or to provide clarity on why the timing may not be right (i.e., PNG TW Mtgs)

» Provide downstream contacts within BARDA and USG for either targeted follow up through BARDA Market Research Calls or to interagency colleagues for other potential USG partnering opportunities

BARDA Industry Engagement – Two Processes
TechWatch Meetings (~250/yr) & MRCs (~750+/yr)



TechWatch Light and Market Research Calls Coexist

TechWatch Light

- Incl. PHEMCE partners
- Earlier stage technologies
- Slide presentation from potential partners (cleared)
- Companies value feedback (BARDA braintrust)
- Metric captured in BDR portal
- Protects sustainability/strong turnout for full TechWatch

Market Research Calls

- Targeted to specific BARDA teams
- Formal presentation not required
- New tracking system for engagement

Find Us Online With These QR Codes -

Learn more about BARDA's TechWatch Program

To further discuss a match for TechWatch, email:
John Tegeris at John.Tegeris@hhs.gov (cell: 301-996-5102) or
Ralph Balsamo at Ralph.Balsamo@hhs.gov

Review BARDA's Broad Agency Announcement (BAA)
TRL Document found in Appendix of the BAA

Visit the EZ-BAA that governs BARDA DRIVe
to review our open Areas of Interest (AOIs)

medicalcountermeasures.gov
Portal to BARDA: ***Register to request a TechWatch meeting!***

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!

@BARDA | **Biomedical Advanced Research and Development Authority** | **@BARDAGOV**

U.S. Department of Health and Human Services

ASPR Administration for Strategic Preparedness & Response

ASPR's Center for Industrial Base Management and Supply Chain (IBMSC): IBx Connect

Industrial Base Expansion (IBx) Connect

Why did we create IBx Connect?

- During the COVID-19 pandemic, ASPR's IBX Office was inundated with meeting requests from various diverse stakeholders who thought they had the best solutions for the nation's needs.
- Processing the incoming requests was extremely time consuming and often required expertise from across multiple domains.
- IBx needed effective ways to be responsive to customer requests while providing an efficient platform for companies to share their technologies with interested government agencies.
- We didn't have to look far to find the a great example : BARDA's TechWatch platform.
- With the great support from our BARDA's colleagues we were able to replicate the TechWatch platform to meet our specific needs and IBx Connect was created.

Industrial Base Expansion (IBx) Connect

IBx Connect Goals

- **Goal 1:** Provide a fair and equitable platform for organizations to present ideas to IBMSC.
- **Goal 2:** Enables IBMSC a capability to conduct the broad market research required to expand America's Medical Industrial Base.
- **Goal 3:** Establish a conduit with the private sector to bring solutions to life.
- **Goal 4:** Creates a clearinghouse for solutions that can be leveraged by ASPR and other USG Inter-Agency partners.

Industrial Base Expansion (IBx) Connect

Who attends these meeting from the government?

- We have over 130 Federal partners who have subscribed to attend these meetings.
  - Including professionals from other federal agencies with shared equities, such as the NIH, CDC, FDA, NIST, the GSA, DHS, DoD, VA, State Dept and the Dept of Commerce

- You will meet with a panel of scientific, technical, and contracting professionals

Industrial Base Expansion (IBx) Connect

IBx Connect Process

Submit
- Company registers to present through the portal : **aspr.hhs.gov/IBxConnect**

Review
- An IBMSC SME will review and rate the potential innovation and its alignment with IBMSC priority areas

Schedule
- If deemed a fit, a capabilities presentation is scheduled

Presentation
- Company presents and receives feedback from Federal Participants

Close Out
- Appropriate next steps are taken to close out the opportunity which can include follow up meetings.

Industrial Base Expansion (IBx) Connect

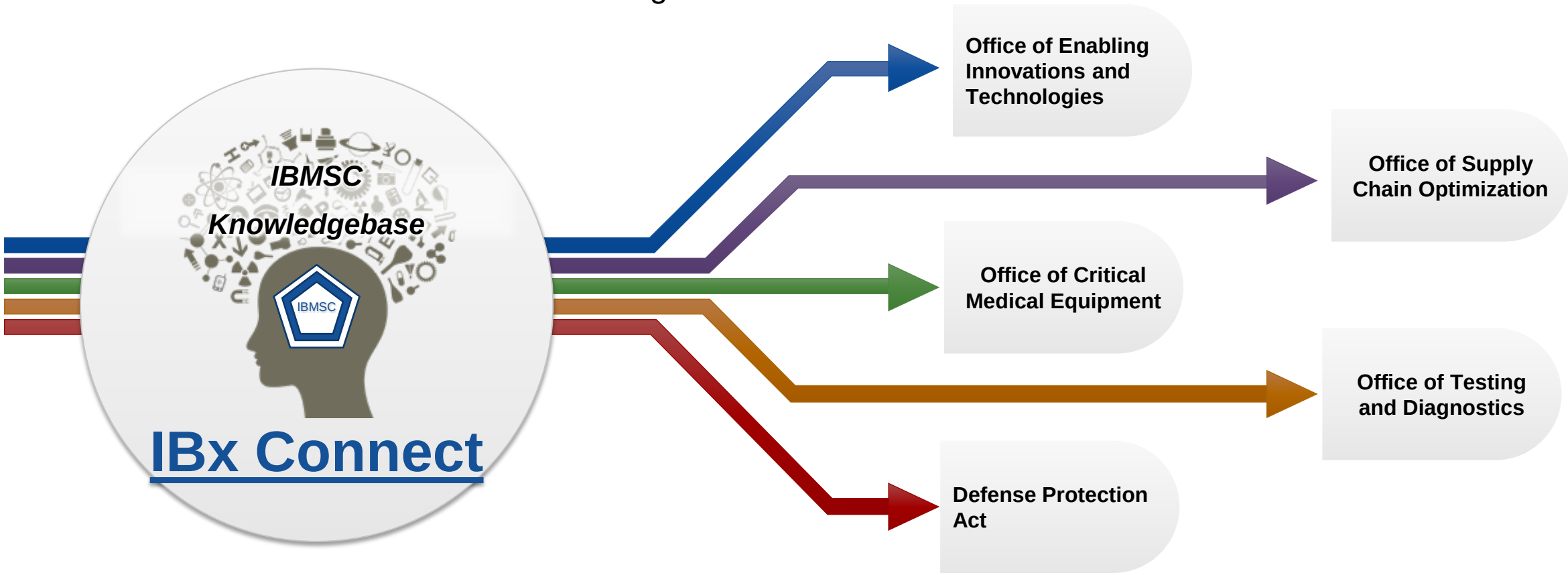
Current Areas of Interest

Office of Enabling Innovations and Technologies	Office of Supply Chain Optimization	Office of Critical Medical Equipment	Office of Testing and Diagnostics
• Advanced manufacturing technologies for drug substance and drug products manufacturing • Distributed manufacturing of drug substances and drug products • Additive manufacturing • Biologically-derived manufacturing of drug substances or drug products	• Supply chain surveillance capabilities. • Last mile delivery solutions • National and global supply chain optimization tools • Tools or systems for supply chain resiliency, including grid-independent solutions • Logistics and transportation innovations, automation, AI and ML applications.	• PPE manufacturing expansion • Novel sub-tier manufacturing capabilities • Materials science applications for PPE reuse • Innovative materials to lower cost and increase capacities	• Testing and diagnostic manufacturing expansion • Novel sub-tier manufacturing capabilities • Next-generation sequencing and multi-omic approaches • Antibodies/antigens • Proteins/peptides/proteomic

IBx Connect meetings are for Market Research purposes only and are not considered submissions for potential funding

Industrial Base Expansion (IBx) Connect

Better market research leads to better strategies



Industrial Base Expansion (IBx) Connect

IBx Connect meetings provide organizations with:

- **Visibility!**
  - Present your idea, solution or service to broad group of experts in the multiple government agencies
- **Feedback!**
  - Receive feedback and recommendation from Government experts relevant to your innovation
- **Potential!**
  - Contribute to future strategies.

On the Web:
aspr.hhs.gov/IBxConnect

Find Us Online

Sean.Cease@hhs.gov

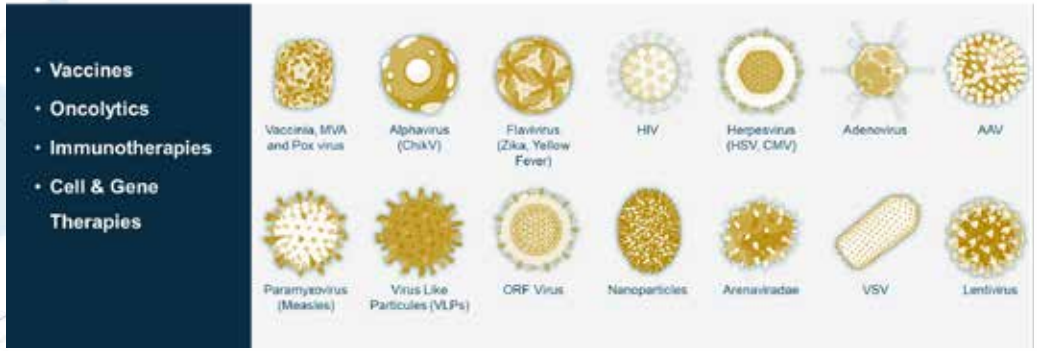
Company Introductions

ABL inc.
ADVANCED BIOSCIENCE LABORATORIES

BioMaP Consortium
Biopharmaceutical Manufacturing Preparedness - Consortium

BioManufacturing

- Viruses for cell/gene therapy, vaccines, and oncolytics



Company Points of Contact

- Timothy Fouts, Ph.D./CSO/240-565-1595/ timothy.fouts@ablinc.com
- Kumar Reddy, Ph.D./Contracts/216-225-5994/ kumar.reddy@ablinc.com

Government Solutions

Translational Solutions Integrator

Government Contracting	Project Management	Financial Management
Quality Oversight	Subject Matter Expertise	Subcontractor Management
Internal cGMP Production/Testing Capabilities	External Vendor Collaboratory	

ABL's Product Development Collaboratory
A Virtual Biologic CDMO

Over 50 vendors in the USA and Europe participate

Substrate Platform
- Mammalian
- Insect
- Avian
- Yeast
- Microbial
- Plant
- Synthetic
- Suspension
- Adherent

Product Development Services
- Product Development Plans
- Technology Transfer
- Cell Line Development
- Process Innovation
- Process Development
- Analytical Development
- cGMP Manufacture
- Formulation, Dosage Form, Lyophilization
- Safety/Toxicology Testing
- Efficacy Testing
- ADME, pK/pD studies
- Bioassay development
- Fill/Finish
- Release & Stability Testing
- Regulatory Strategy

Product Type
- Oligonucleotides (ASO, siRNA, etc)
- Vaccines (subunit, RNA/DNA, Viral, etc.)
- Gene Delivery
- Antibody-based Biologics
- Peptides
- Cell-based Therapy (iPSC, CAR-T, exosomes, etc.)
- Gene-editing technology
- Formulations (liposomes, micelles, metallic nanoparticles, etc.)
- Multipurpose Prevention Technology

Advanced Concept Innovations

Company Overview

- Founded in 2004 – Lakeland, Florida.
- ACI has been FDA Registered since 2006.
- 348,000 SF manufacturing and warehouse facility.
- We designed and built the first-of-kind fully automated, continuous motion, high-speed, NIOSH approved and FDA cleared surgical N95 respirator manufacturing lines. Manufacturing capability of more than 2.5 million N95s per day.
- In addition to manufacturing our NIOSH approved and FDA cleared surgical N95 respirators, ACI is a manufacturer and packager working within healthcare, medical device, consumer health, and nonwoven industries.
- We run manufacturing lines for multiple Fortune 100 companies.
- All of our operations from manufacturing, packaging, warehousing, fulfillment, and distribution are located in Lakeland, Florida where we also provide manufacturing and packaging solutions for Class I, II and III medical devices including both sterile and non-sterile products.
- ISO 7 (Class 10,000 Cleanrooms).
- Additional Certifications that ACI hold are: ISO 13485, ISO 9001, ISO 22716, and a NIOSH manufacturing site.

Company Points of Contact

- Matt Muller, President, 863-529-4579 - mmuller@acipak.com
- Kevin Pulcini, SVP, 914-240-4661- kpulcini@acipak.com

Company Interests

- Provide the highest level of protection for healthcare personnel, first responders and others at a globally competitive price.
- Ensure the commercial sustainment and expansion of our NIOSH approved and FDA cleared N95 manufacturing in the United States.
- Secure our nation's healthcare supply chain by expanding the industrial base and building a more resilient and responsive supply chain.
- To continue to innovate and provide an ability to immediately and efficiently flex production rates in response to surge requirements.

American Type Culture Collection (ATCC)

Company Overview

- ATCC, a nonprofit organization established in 1925, is a global leader in the production, characterization, storage, and worldwide distribution of biological reagents and standards. Our collection of cells, bacteria, viruses, fungi, parasites, protozoans, and ancillary reagents comprise one of the world's most diverse biorepositories for use by the scientific community and in support of government contracts for NIAID, CDC, NCI, DoD, and BARDA.
- ATCC employs over 660 employees at our headquarters in Manassas, Virginia, in Gaithersburg and Germantown, Maryland, and deployed at several government sites in the US, such as the NCI Frederick National Laboratory, USDA Plum Island Animal Disease Center, and CDC.

Company Points of Contact

- Ted Mullins, PhD, Sr. Director AFS Business Development
  (703) 365 2741; tmullins@atcc.org
- Carolina Morell-Perez, MS, Program Manager
  (703) 365 2700, ext. 2481; cmorell-perez@atcc.org

Company Interests

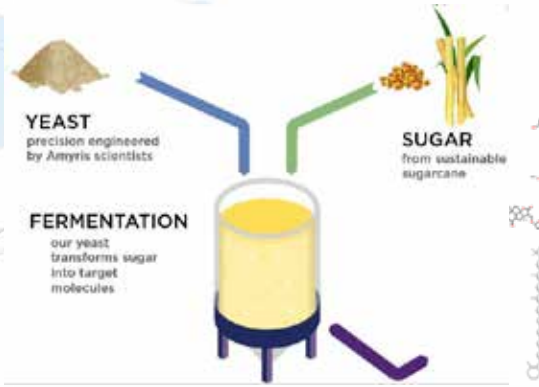
ATCC Federal Solutions continues to be a key performer for the federal government's pandemic preparedness and response by providing:

- Rapid accession of critical emerging pathogens (up to risk group 3) for expansion, characterization, and distribution to key stakeholders for the development of diagnostics and therapeutics
- Repository services for isolates from clinical studies
- Large scale production of well-characterized challenge material (WCCM) for testing MCMs to support product development and regulatory approval
- High quality biological reagents and standards for development of diagnostic and therapeutic medical countermeasures
- Production and distribution of diagnostic assays to support the Public Health Laboratory system, and surveillance kits for seasonal, emerging, and re-emerging pathogens
- A well-developed global supply- and cold chain management pipeline

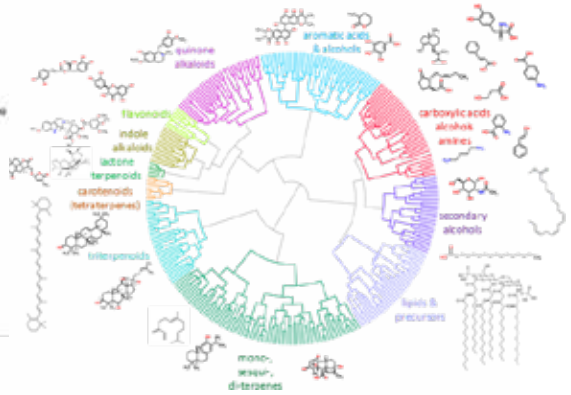
Amyris

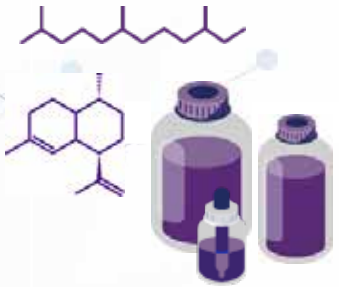
Seeking partnerships to advance new molecules to market leveraging our proven fully integrated capabilities including commercial scale manufacturing.

We program yeast to transform sugar into sustainable and abundant high value ingredients



Over 400 molecules and thousands more accessible with our platform





higher performing, lower cost, more resource efficient.

We're a **proven DoD & DoE performer** with a fully-integrated platform with process development and **commercial manufacturing**

We sell our ingredients into **20,000+** products Our ingredients reach **300 million** consumers

BioMADE
kuraray
Givaudan
Ingredion
DSM
Firmenich

KEY CONTACTS:

Derek Abbott abbott@amyris.com
Paul Hill hill@amyris.com
Darren Buchwald buchwald@amyris.com

amyris

apiject™

BioMaP Consortium
Biopharmaceutical Manufacturing Preparedness - Consortium

Company Overview

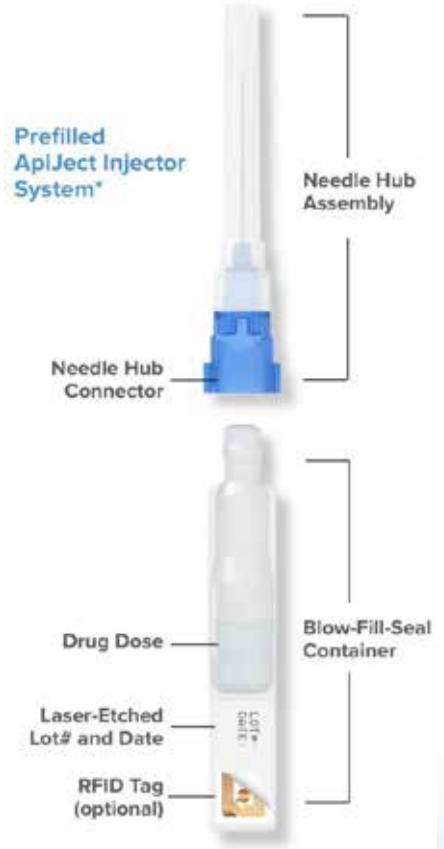
- Mission: To make injectable medicines and vaccines safe and accessible to everyone.
- Year Founded: 2019.
- people.
- Capabilities:
  - Bringing first prefilled syringe product made with Blow-Fill-Seal (BFS) technology through FDA application and review process.
  - Have established high-speed, high-volume manufacturing capability for over a billion doses annually in U.S. and Europe combined in part through Operation WARP Speed DoD contract.
  - Created research and development center in U.S. for reshoring of product development and testing capabilities for BFS manufacturing.

Company Point of Contact

Philip Tull VP, Government Projects and Contracts
ptull@apiject.com, (571) 235-7088

Company Interests

- Additional drug-product partners interested in addressing injectable drug shortage list.
- Expanded fill-finish capacity through partnerships using ApiJect platform for wide-range of injectable drug applications.
- Export opportunity for single-dose injectors focused on global health market demands.



* Device has not been cleared by regulators. Needle Safety Shield will be incorporated into commercial device.

BioTechnique, LLC

Company Overview

- CRDMO located at 250 Cross Farm Lane, York, PA 17406
- Registered small business, and is 100% American with no foreign ownership
- Year Founded - 2014
- Size & Nature of Business
  - Nearly 3000,000 ft^2 of manufacturing, labs, cold and frozen storage, warehousing and logistics services situated on 38 acres land, with potential for expansion and currently have 50 employees and growing
- Capabilities
  - Sterile injectable fill-finish with Lyophilization
  - Cold and Frozen storage
  - Full Analytical Testing Capabilities

Company Points of Contact

John Clapham / CEO / +1 626-786-7035
/ jclapham@biotech.com

Company Interests

- BioTechnique established relationships with customers in global markets in the following areas:
  - Therapeutic, Potent (Cytotoxic)

  Clinical Material Manufacturing and Veterinary Products
  - Suspensions / Lyophilized and Attenuated Vaccines
- BioTechnique is looking for collaboration and partnerships in th following areas:
  - For manufacturing lines for sterile injectables for vaccines and essential medicines in our facility (where partner has equipment no facility)
  - For shared risk projects for novel vaccines, essential medicines, novel delivery devices, combination products, needless delivery systems, etc.
  - Partnerships with vaccine manufacturers for fill/finish opportunities and collaboration
  - Partnerships with large molecule and small molecule API manufacturers.
  - Partnerships with CROs that generate ANDAs and 505(b)(2) products
  - Non-dilutive funding opportunities with the Federal government Non-Profits focused on Global Health

ChromaTan, Inc.

Company Overview

- Mission: Empower biopharmaceutical manufacturers with the **first-ever, single-use, steady-state continuous elution chromatography platform (BioRMB™)** offering increased recovery and productivity, enhanced purity, flexibility and scalability, while reducing resin usage and downtime for the cost-effective production of life-saving therapies.
- Year Founded: 2012.
- Size & Nature of Business: 23 Employees. Intensification & integration of biopurification technologies for continuous biomanufacturing.
- Capabilities: Process Sciences, Engineering, Automation.
- Area of Expertise: Bioprocess technology development.

Company Points of Contact

- Rajiv Datar / President & CEO / 9493510860 / Rajiv.Datar@chromatan.com
- Oleg Shinkazh / Founder & CTO / 6175290784 / Oleg.Shinkazh@chromatan.com

Company Interests

- Related Technology Development
- Integrating upstream and downstream unit operations.
- Intensification of bioprocess unit operations.
- Developing digital twins – for product and for the manufacturing process.
- Advanced Manufacturing Technology Designation.
- Developing an RNA-in-a-Box concept designed for rapid deployment to points of need.
- Partnering and collaborations with public and private sector entities.
- Project contracts.

- Mike Radomsky - mike.radomsky@cmcpharm.com

EverGlade Consulting

Company Overview

- Unparalleled experience managing government funded life science programs for both product development and capital projects since 2020.
  - Pursuit – Tech Watch to Abstracts
  - Proposal – White Papers to Full Proposals
  - Post Award – Financial and Project Management

Company Points of Contact

- Tyler Kessler- Managing Consultant
- (202) 470-2718 tkessler@everglade.com

- Tyler Maxwell - Managing Consultant
- (202) 539-8260 tmaxwell@everglade.com

Company Interests

- Health and Human Services
  - BARDA
  - ARPA-H
  - NIH/NIAID
  - ASPR-IBx

- Department of Defense
  - DTRA
  - DARPA
  - JPEO

- Consortia Membership
  - RRPV
  - MCDC
  - DBIC

FUJIFILM Diosynth Biotechnologies

Company Overview

- Our Vision – To be the leading and most trusted global Contract Development and Manufacturing Organization partner in the biopharmaceutical industry.
- Founded in NC in 1995, currently at 4200+ globally
- Sites Overview
  - RTP, NC – Mammalian & Microbial PD & SS GMP MFG
  - Holly Springs, NC– Mammalian LS GMP MFG, DP & FG
  - College Station, TX – Advanced Therapies PD & MFG
  - Thousand Oaks, CA – Cell Therapy PD & MFG
  - UK – Mammalian, Microbial and Gene Therapy PD & SS GMP MFG
  - Denmark – Mammalian Large Scale GMP MFG, DP & FG

Company Points of Contact

-
-

Company Interests

- We are an end-to-end CDMO that is expanding to provide the right capability and capacity when needed, where needed
- Cell line, strain development & expression studies
- Process invention & optimization
- Formulation development; molecule personality assessment and optimization for process robustness
- Advanced analytical characterization
- Process characterization, control strategy and validation with 24 approved biologics globally
- Drug product development and manufacturing
- Finished goods
- Product lifecycle management
- Aside from a handful of remaining Stability timepoints, FUJIFILMDiosynth has no active programs with the DoD

Integrated Pharma Services

Company Overview

IPS is a woman-owned ISO certified small Biotechnology company in Rockville, MD. IPS has been focused on advancing novel solutions for infectious pathogens. IPS has two PPE Manufacturing and four BSL-2 laboratories.

Company Points of Contact
Mina Izadjoo, President
mizadjoo@ipharmaservices.com
Phone: 301-204-4201

Parviz Izadjoo, Vice President
pizadjoo@ipharmaservices.com
240-441-8131

A pleated filter with spacer is installed in the 3M-5301respirator.

3M Respirator

IPS Respirator

Company Interests

Technology relates to improved protective masks by introducing pleats which are held open by using spacer inserts. The pleats and spacer inserts act to increase the size of filter's surface area and thereby improve airflow and provide more effective particle and microbial filtration.

Respirators	Inhalation Resistance	Exhalation Resistance
3M Filter	35	25
IPS Pleated Filter	12	11

Advantages

- **One filter rather than two is used.**
- **No exhalation valve is needed therefore the wearer and the public are protected.**
- **100% Bacterial Filtration (FDA /ASTM Standard)**
- **99% Particle Filtration (NIOSH Standard)**

manus

BioMaP Consortium
Biopharmaceutical Manufacturing Preparedness - Consortium

Company Overview

- Michael Best Practice Areas:
  - Strategies: Bipartisan government relations and procurement consulting, offering both federal and state- level capabilities.
  - Healthcare Innovation Group (HIG): Accelerating new healthcare firms' entry to regional payers and health systems.
  - Legal representation: Comprehensive regulatory, policy, and litigation services. Venture Best practice focuses on startup businesses.
- 175+ Years Old. Locations in Washington DC, Wisconsin, North Carolina, Illinois, Texas, Colorado, Utah.

Company Points of Contact

- Sarah Helton | Partner and Procurement Practice Chair | 202.747.9560 | Sarah.Helton@michaelbest.com
- Lucia Alonzo | Principal |202.747.9560 | Lucia.Alonzo@michaelbest.com

Company Interests

- State and federal government procurement consulting and advocacy: Michael Best Strategies has successfully led clients through procurement and grantmaking collaborations with BARDA and ASPR, Department of Defense (examples: Defense Production Act office, Defense Commissary Agency), Department of Energy among many others.

- Michael Best Strategies (targeting government procurement) and HIG (targeting payers and regional health systems) offer clients competitive landscape review, messaging guidance that resonates with purchasers, a go-to-market strategy, and more proprietary guidance.

- Legal, lobbying, and consulting services to support growth of new and emerging firms in the healthcare, defense, technology industries

SCORPIUS BIOMANUFACTURING

BioMaP Consortium
Biopharmaceutical Manufacturing Preparedness - Consortium

Company Overview

- Biologics CDMO in San Antonio, TX specializing in microbial and mammalian programs from pre-clinical development through commercial manufacturing.
  - Founded in 2020 to address the unmet needs of early-stage and small-scall biomanufacturing.
  - ~100 employees and growing, including a veteran leadership team from large and small pharma, CDMOs, and academia.
  - Future, large-scale biomanufacturing site underway in Manhattan, Kansas.

Areas of Expertise

- Flexible facility capable of cGMP manufacturing of antibodie s, recombinant therapeutic proteins, enzymes, and vaccines
  - Up to 200 L microbial and 500 L mammalian
- GLP manufacturing and IND-enabling studies
- In-house process development and analytical services
- Experience with of government-funded programs (current clients funded by DOD, NIH, DTRA, etc.)
- Flexible, modular cleanrooms designed to be easily configurable for custom programs

Contact

- Joe Payne, President & COO
  jpayne@scorpiusbiologics.com

Immediate capacity available at a U.S. based, U.S. owned, and U.S. financed biomanufacturing facility

SENTIO BIOSCIENCES LLC (WOSB)

Company Overview

- **Mission** To develop, manufacture and commercialize complex molecules in specialty therapeutic segments by applying advanced chemistry and biology in development and manufacturing.
- **Year Founded** - 2008
- **Size & Nature of Business** – 35 Employees | | FDA Audited Pharmaceutical Commercial Manufacturing facility of 22K sq ft | Vertical Integration from KSM to DP | R&D of new & generic API & DP for Human & Animal therapeutics
- **Capabilities & Areas of Expertise**
  - 2 FDA approved drug products (DP) | 1 Human generic drug under FDA review
  - R&D and Commercial Manufacturing of Complex Small and Large molecules, potent and toxic products.
  - Advanced, continuous, batch, flow-chemistry manufacturing including automation
  - Synthesis, crystallization, purification, distillation, high potency suites, etc
  - Strong cGMP Quality Systems inspected by FDA since MAY 2015
  - Workforce development through rigorous and focused training
- **Company Points of Contact**

Flavia D'Souza/Founder-Head of Quality/314-227-3703/ Flavia.Dsouza@sentiobiosciences.com
Karthik Raghavan/Founder-CEO/314-227-3702/ Karthik.Raghavan@sentiobiosciences.com

Company Interests

- **On-shoring Oncology and other Critical DP, API and KSM manufacturing.**
- Therapeutic Ostheoarthritis treatment caused due to injury – Phase 1 studies
- Additional Manufacturing of small/large molecules, potent, complex, and specialty therapeutics.
- Use of innovative manufacturing techniques.

- Provide collaborative development and manufacturing services for US Innovators
- Grow commercial API Manufacturing Facilities and R&D Infrastructure for new and generic DP, API and KSM.
- Setup Fill/Finish DP manufacturing facility.
- Collaboration with Universities and Regional Organizations to support talent and work force development in STEM
- ***Investment to support above Expansion & Growth***

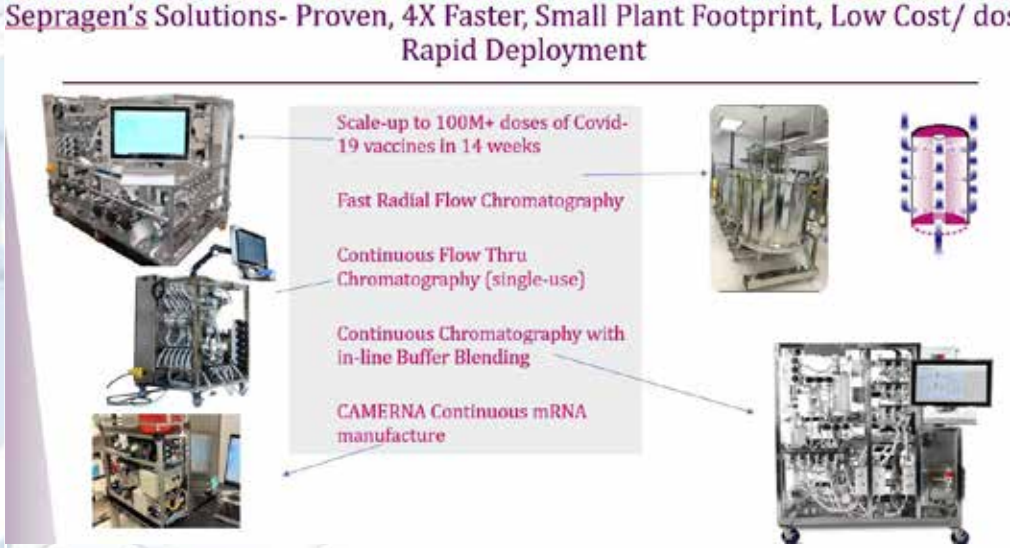
SEPRAGEN
Innovators in Bioprocessing

SEPRAGEN CORPORATION

BioMaP Consortium
Biopharmaceutical Manufacturing Preparedness - Consortium

Company Overview: Breakthrough Bio Process Equipment and Technology since 1985

- Novel Downstream and Upstream Continuous processing and Integration



Company Points of Contact

- Vinit Saxena, CEO, 510-475-0650 x123; vsaxena@sepragen.com
- Susan Rathbun, 5104750650 x120; srathbun@sepragen.com

Sepragen's Interests

- Rapid, Low-cost , Low FTE, Mab production
- Continuous Integrated Biopurification with in-line media/buffer blending for small footprint, low cost vaccine plant
- Process upstream-downstream Integration "Plant-in-a-box model"
- Continuous Low Cost mRNA based vaccine production
- Two NIIMBL awards for Continuous mRNA and novel Car-T cell bioreactor
- Etc.

Slide must not exceed one page

STERIS

BioMaP Consortium
Biopharmaceutical Manufacturing Preparedness - Consortium

Company Overview

- STERIS is a global leader of products and services that support patient care with a focus on infection prevention
- STERIS is supported by over 17,000 associates, operating in over 100 countries
- STERIS's 4 product segments:
  - Healthcare
  - Applied Sterilization Technologies (AST)
  - Life Sciences
  - Dental
- STERIS Customers include hospitals, surgery and GI centers, medical device and pharmaceutical manufacturers, as well as dental practitioners and educators

Company Points of Contact

- Whitney Tull, VP of Government Affairs
- Phone: 571-481-7906
- Email: whitney_tull@steris.com

Company Interests

- STERIS is a pioneer of many sterilization technologies, most notably vaporized hydrogen peroxide and x-ray sterilization
- STERIS AST supports BARDA's efforts to expand domestic manufacturing capacity for biomedical countermeasures with an emphasis on the value of commercial sterilization networks to domestic production of critical countermeasures, market flexibility and surge capacity
- STERIS is the only sterilizer accepted into all of FDA's Masterfile Pilots, and the only company accepted into the Radiation Masterfile Pilot
- Through STERIS's Healthcare business, STERIS supports the DOD's DLA Troop Support's Supply Chain program, supplying DOD facilities across the globe with critical Sterile Processing Department (SPD) capital equipment products.

TENAGRITY™ SOLUTIONS

Tenacity + Integrity

Where tenacity and integrity are combined to help you excel.

BioMaP Consortium

Biopharmaceutical Manufacturing Preparedness - Consortium

Company Overview

- Types of Consulting provided:
  - Strategy – including government affairs
  - Communications
  - Operations
- CEO Caroline DeBerry has almost 20 years of experience in government affairs, strategy, and public policy.
- Examples of DeBerry's past successes:
  - Passage of federal and state legislation
  - Regulatory reforms re: Medicare reimbursements
  - Successful navigation of the FDA approval process
  - Public-private partnership management

Company Point of Contact

Caroline DeBerry, CEO

- caroline@tenagrity-solutions.com
- (202) 494-9989

Company Interests

- Examples of Client products / services:
  - Medical research
  - Vaccine availability / delivery
  - AI
  - Medical Devices
  - Public-private partnerships

Thaddeus Medical Systems

Real-time GPS and Data Logging

- -20°, 5°,20° setpoints
- Unlimited holdover time
- -40° to 60°C working range

Company Overview

Mission: To drive the evolution of cold chain technology, in support of pharma and biologics delivery, to improve patient outcomes worldwide.
Year Founded: 2015
Size & Nature of Business: Startup
Capabilities: OEM for high-performance cold chain tech.
Areas of Expertise: Cold Chain Technology and Supply Chain Logistics.

Company Points of Contact

Frank Cable/ CEO/ (413) 682-6624/ frank.cable@thaddeusmed.com
Lori Gabrek/CCO/ (317) 771-7576/lori.gabrek@thaddeusmed.com

Company Interests

- In support of BARDA Project NextGen and the CEPI '100 Days Mission', Thaddeus Medical has partnered with INTACT Solutions, PAXAFE and AET Technologies to develop a consortium for rapid, low-cost, decentralized vaccine production with a capacity of 60 million doses/year providing the following features and benefits:
- Fill/finish is performed in a 4 m^2 lab space (CapEx: $300K).
- Tabletop fill/finish machine utilizing a 200-dose pouch, that provides an overall cost reduction of up to 90% per dose.
- Vaccine administration via a disposable safety needle with high patient throughput (T=30s)
- AET Logistics provides middle mile transport active refrigeration via powered ULD devices with 70% cost reduction per-dose.
- The Thaddeus device allows for last mile transport of vaccine with unlimited holdover time within extreme conditions (-40° to 60°C).
- Thaddeus Medical is working with Texas Children's Hospital to evaluate the proposed system in a pilot study.
- Our consortium is actively looking to partner with a BioMaP vaccine developer interested in advancing Project NextGen and CEPI 100 Days mission objectives.

Enabling A Continuum Of Care From Hospital To Home For Inhaled Nitric Oxide Therapy

Founded 2016

60 Drug and Critical Care Medical Device Professionals

- Mechanical, Electrical, Systems, Software Engineers
- Drug/Device; Clinical Ops, Regulatory and Quality Team
- R&D, Manufacturing, Marketing and Finance Groups

Our Focus

Make devices that treat cardiopulmonary disease, lower respiratory tract infections and improve outcomes in acute Heart and Lung interventions

Alignment with BioMaP Initiatives

Potential to be a viable substitute for many of the anti-infectives on the Essential Medicines List. Third Pole drug manufacturing technology delivers a broad spectrum, on demand, inhalable, natural-product antimicrobial agent: nitric oxide (NO), produced in a portable device at point-of-care using only electricity and ambient air to treat refractory lung infections without inducing antimicrobial resistance.

Company Points of Contact

- Bill Athenson/CEO/847-226-5106/bathenson@pole3.com
- Liz Holmberg/CFO/908-310-0596/eholmberg@pole3.com

™

NICU

OR

ICU

Transport

™

Step-Down Unit

Home

Ambulatory

™

In the Field

Emergency Room

Clinic

Whitepaper entitled Disruptive Drug Manufacturing Technology submitted in response to BioMaP Request for Prototype Projects (RPP) 24-02-KSM-API

eNOcare in final development; eNOfit in clinical trials; eNOcare HD, proposed development * FDA breakthrough device designation

Virtual Attendee Presentations

Company Overview

American Medicines Company, PBC (“AMC”), is a U.S.-based pharmaceutical manufacturing company specializing in the development and production of high-quality pharmaceuticals. (Founded 2021)

- Mission: create U.S. based manufacturing capacity for critical oral solid generic medicines utilizing innovative manufacturing and pharmacy distribution concepts. AMC’s model allows for manufacturing of 6 billion bulk generic tablets within an 80,000 sqf footprint
- Expertise in oral solid product development, facility/equipment design/engineering, quality, and commercialization

Company Points of Contact

- Nicole Monachino/Board Member/216.538.6001/ nmonachino@americanmedicinescompany.com
- Kathy Meyer/Head of Start Up/720.463.4061/ kmeyer@americanmedicinescompany.com

Company Interests

- Industrial base expansion for oral solid dose manufacturing of generic chronic care medicines, essential medicines, and medical countermeasures
- Utilization of state-of-the-art continuous manufacturing equipment with integrated process analytical technology (PAT) and process automation to produce high volume, high quality, cost competitive oral solid dose (OSD)
- Discussions ongoing with Industrial Base Expansion team and Center for Drug Evaluation and Research
- Partnering with state and federal entities to fund initial facility

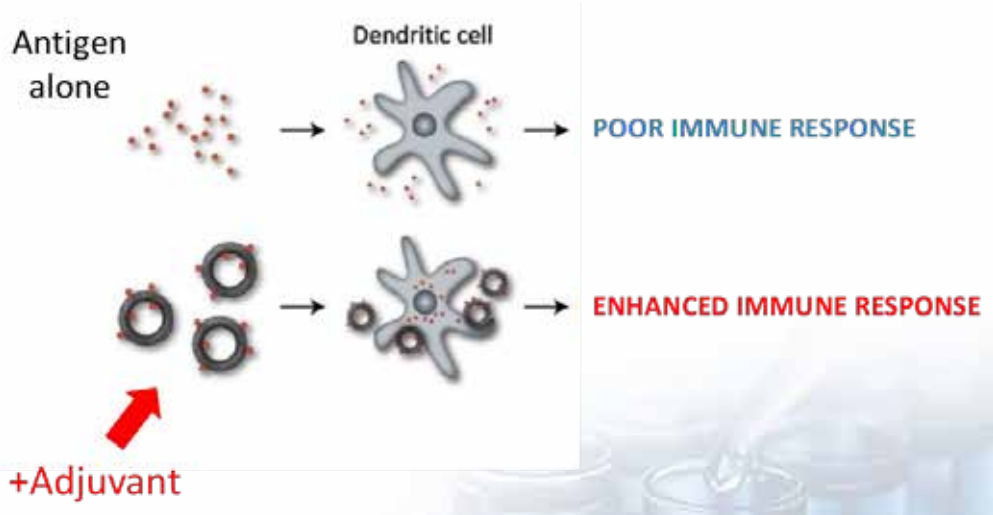
AmerStem

Company Overview

- Our core technology (AeroStemix) is disrupting the sourcing of QS-21 and other saponins, which are the key ingredients for the most effective vaccine adjuvants
- QS-21 is effectively used in vaccines to prevent malaria, tuberculosis, shingles and RSV
- We are committed to sustainable, clean, and responsible domestic production of these plant-derived ingredients
- AeroStemix is an indoor miniaturized tree cultivation technology that enables large-scale biomass production as the source of saponins
- AeroStemix is modular allowing seamless scalability for industrial production
- We are a small biotechnology business that is minority- and woman-owned
- We pledge to serve any vaccine that may be crucial for our national security and global health

The 3 key effects of a vaccine adjuvant:

- Increased potency
- Lasting protection
- Dose sparing



Contact:

- Jaime Flores-Riveros / CSO / jfriveros@amerstem.com
- 805-573-1309

AntoXa

Company Overview

- Developing life saving therapeutic defense solutions
- Found 2016
- Development and production of biological drugs
- Unique versatile plant-based production platform
- High yield of mAbs, proteins and vaccines; animal free; low cost of goods, controllable modification of glycosylation.

Company Points of Contact

- Don Stewart, CEO, +1 (416) 452 7242
- don.stewart@antoxacorp.com

Company Interests

Developing 3 main products; seeking partnerships

- Ricin Antidote – 100% efficacious with a long therapeutic window; mAb; efficacy demonstrated in mice and monkeys (supported by DRDC)
- Nerve Agent Antidote – recombinant product similar to human form; BuChE; established, scaled production process (developed with DARPA)
- Chlorine / Phosgene Antidote – recombinant Hemopexin; efficacy demonstrated in mice; cross over application Sickle Cell Anemia (partner University Alabama at Birmingham)

BDO USA

BioProcess Technology Group (BPTG)
Biodefense/Life Sciences Product Development and Government Contracts Group

Company Overview

- Mission
  - BPTG provides Chemistry, Manufacturing and Control (CMC) services to support development of biopharmaceuticals
  - Biodefense offers strategic services through each phase of the contract award cycle to ensure success, from strategic planning to post-award compliance and management
- Year Founded
  - BPTG was founded in 2019 following the acquisition of BioProcess Technology Consultants, a consulting group with a 25 year history
- Size & Nature of Business
  - BPTG is a team of 25 consultants that provide technical, quality and regulatory support to biologics product development with annual revenues of $12M-15M.
- Capabilities and Areas of Expertise
  - Technical expertise in development and execution of process development, analytical development, manufacturing, regulatory, and quality assurance.

Company Points of Contact

- Nick Vrolijk, Ph.D./BPTG/Practice Leader /912-580-9971/ nvrolijk@bdo.com
- Adey Pierce/Biodefense/Director/703-638-0623/ apierce@bdo.com

Company Interests

-
-
-
-
-
-
-

New Horizon Biotech

Mission: Develop and manufacture fermentors, bioreactors, and SU bags providing new value to bioprocessing pharmaceutical customers.

- Founded 2017
- Pre-revenue
- Key Team of 7
- Funding: Founders, Ben Franklin Tech Partners, NSF, Pennsylvania Infrastructure Technology Alliance (PITA)
- Beta Testing
- newhorizonbiotech.com

Company Interests:

Reduce risk, OpEx, and CapEx while increasing yields, lifetime value, speed and flexibility of deployment.

Novel Disruptive Technology:

- Horizontal Single-Use Systems
- Modular Scale-out Capacity
- Pressurizable Bags / Improve OTR
- Scalable 50L to 3000L Working Vol.
- Agile, mobile expansion
- Improved Metabolic Heat Removal
- Flexibility – Multiple agitators

Ernest.Stadler@newhorizonbiotech.com CEO (610) 570 - 3096
Dwight.Rose@newhorizonbiotech.com VP Op's (610) 751 - 9935
Janice.Phillips@newhorizonbiotech.com VP Tech. (610) 216 - 3624
Matthew.Stadler@newhorizonbiotech.com CBO (412) 874 - 0197

OcyonBio
Making Medicines Affordable

BioMaP Consortium
Biopharmaceutical Manufacturing Preparedness - Consortium

Company Overview

- OcyonBio is a partnership development and manufacturing organization (PDMO) focused on advancing multiple technologies for the development and manufacturing (up to commercialization) of biologics, genetic, and cellular life-saving therapies.

- Our ~200,000 sq. Ft. Facility offers R&D suites, cutting-edge cell and gene therapy capabilities, drug substance and drug product manufacturing, vector manufacturing, and cell processing capabilities to accelerate your development and production needs.

- Available Drug Product capacity for vial, syringes, and cartridges.

Company Points of Contact

- Robert Salcedo / CEO
  robert.salcedo@ocyonbio.com
- Joel Mendez / Business Development
  joel.mendez@ocyonbio.com
- Amilcar Guzman / Project Management & Operations
  amilcar.guzman@ocyonbio.com

Company Interests

OcyonBio provides capabilities in the following areas:

- Biologics
  - Drug Substance
    - Bacterial
    - Mammalian
  - Drug Product
    - Vials
    - Syringes
    - Cartridges
- Cell & Gene Therapy
  - Viral Vector Manufacturing
  - Blood Processing
- Clinical Scale Solid Dosage
  - Direct compression
  - Granulation
  - Coating
  - Continuous Manufacturing

Capabilities can support partners from Process Development,
through Clinical Production, all the way to Commercialization.

www.OcyonBio.com

* SBA Minority owned

Company Overview

- 30+ years of development & commercialization history
- 120K square footprint
- Regulatory Approvals include: U.S. FDA, U.S. DEA, and multiple foreign Heath Ministries
- Potency capability up to Category 3B
- DEA Controlled Substance Registrations:
  - Analytical Lab: Schedules I, II, IIN, III and IV
  - Manufacturer: Schedules II, IIN, and III
  - Exporter: Schedules II and IIN

Company Points of Contact

- Kyle Keese, Strategic Partnerships, kyle.keese@societalcdmo.com, 252.545.5028
- Jeff Folks, Business Development, jeff.folks@societalcdmo.com, 913.481.5141

Company Interests and Expertise

- Specializations:
  - Solid oral dosage
  - Modified release technology
  - Phase appropriate formulation / analytical dev
  - Complex formulations
  - Controlled substances and high potency compounds
  - End to end solutions from clinical to commercial mfg
- Clinical Packaging:
  - Over-encapsulation
  - Primary and secondary packaging
  - Storage, distribution and logistics

We are seeking partners to meet USG needs

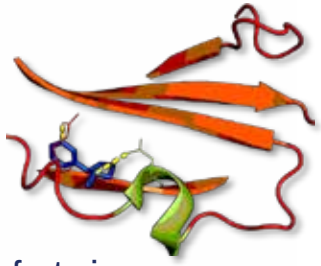
Southwest Research Institute

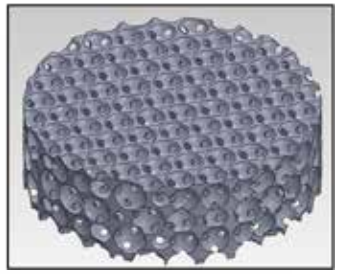
BioMaP Consortium
Biopharmaceutical Manufacturing Preparedness - Consortium

Overview

Applied R&D organization, 76 years, nonprofit 501(c3), ~3000 employees, cover physical science & engineering

- San Antonio, Texas
- Clinical Supply cGMP API and Drug Product
- FDA Inspected, DEA Licensed
- ISO 9001:2016; ISO 13485:2016
- Structure-based virtual drug screening/ML
- Predictive catalyst development
- Difficult synthesis, separation, optimization
- Bioinformatics Data Analysis Services/AI
- Human Performance Solutions
- Novel Bioreactor for cells and biologics manufacturing





Point of Contact

Jian Ling, PhD
(210)522-3953
jling@swri.org
https://www.swri.org

Interests

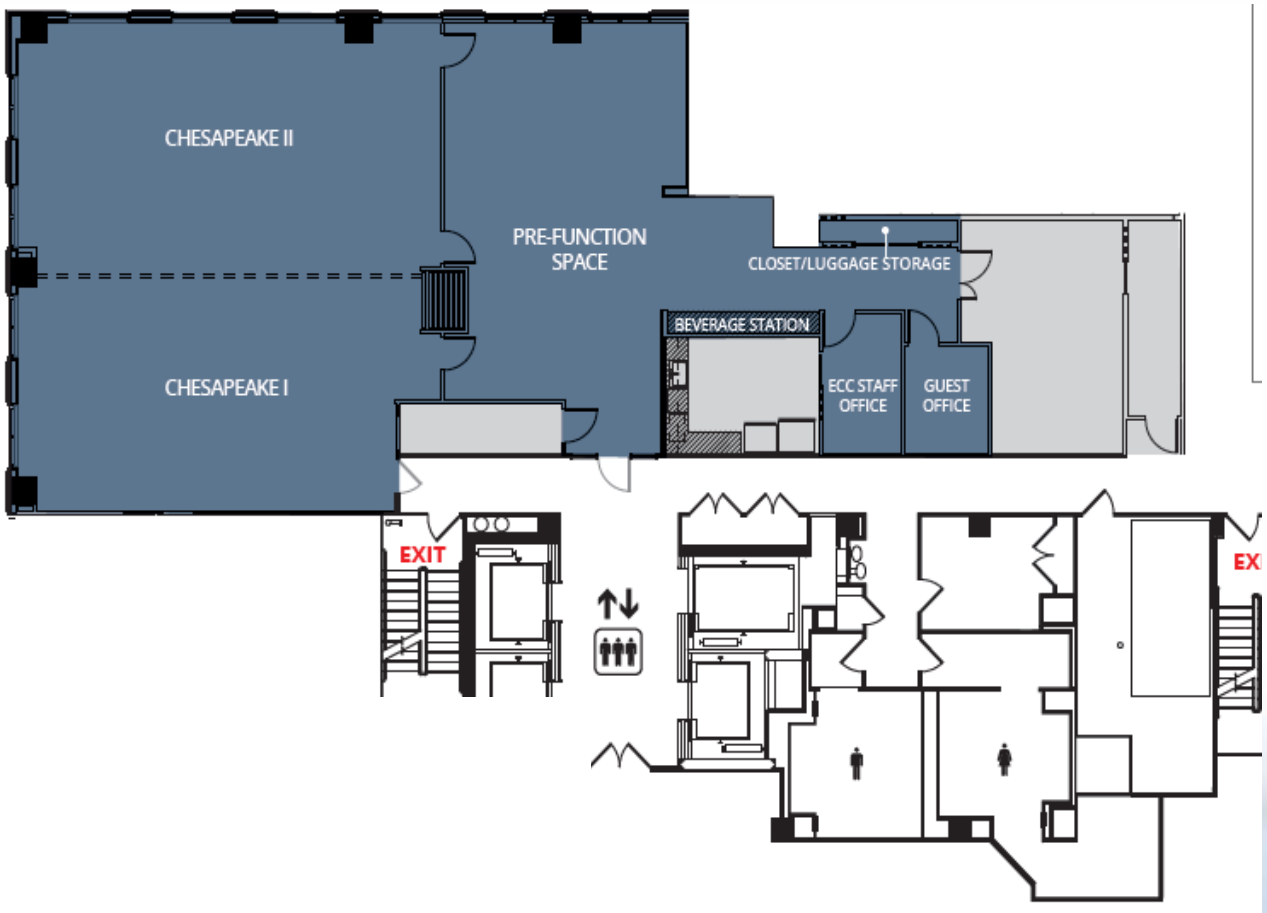
- Nerve agent, Toxin, Opioid, and other medical countermeasures development
- Prediction of *in vivo* endpoints
- Formulation and Encapsulation, vaccine stabilization
- Biomanufacturing process development
- On-demand vaccine manufacturing platform development
- Scale-up and cGMP Clinical Supply
- Analytical and Regulatory
- Medical Devices Development
- Disease detection and prevention
- Musculoskeletal & Human Performance quantification
- Human-in-the-Loop performance optimization
- Human digital twin
- Computational Biomedicine
- Electronic health record analysis
- Digital pathology

Networking Break

03:00 PM Roundtable Discussions

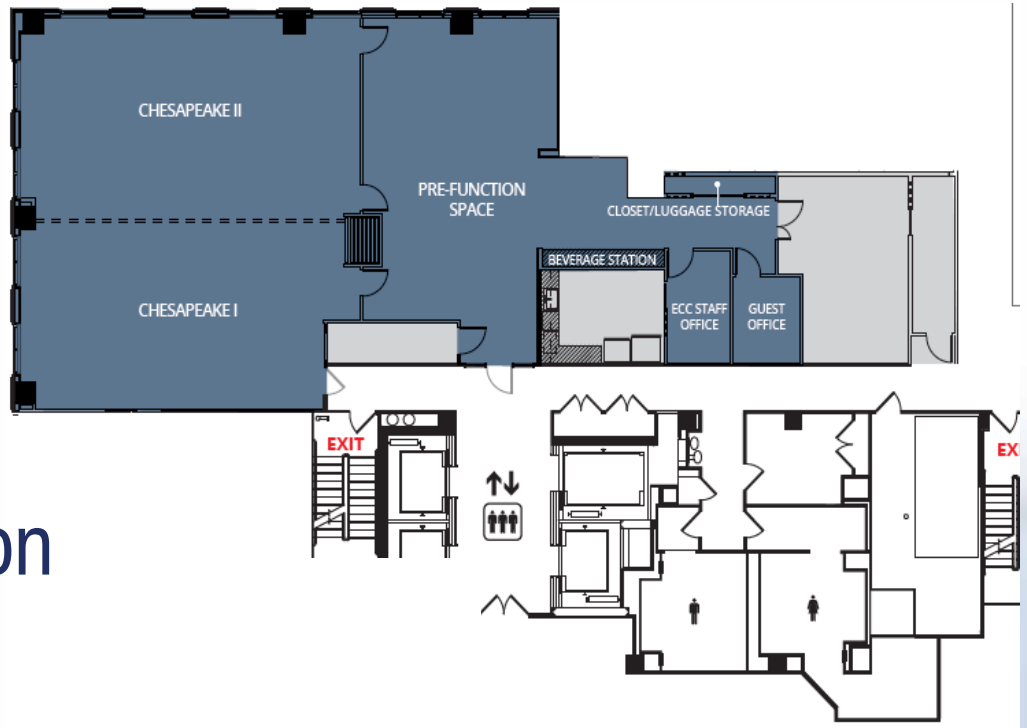
- 25 min each, 5 min to transition
- Open networking in the Foyer

04:30 PM Closing Remarks



Roundtable Discussions

BioMaP Consortium
Biopharmaceutical Manufacturing Preparedness - Consortium



- 3 sessions of 30 min
- 25 min discussion, 5 min to transition
- Open networking in the Foyer