BARDA Industry Day Report
November 13-14, 2023

OVERVIEW

G2G attended the annual BARDA Industry Day (BID) on November 13-14 that was held in person in Washington D.C. and virtually. The Biomedical Advanced Research and Development Authority (BARDA), and the Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR) host this event each fall. The purpose is to communicate U.S. government medical countermeasure (MCM) priorities, facilitate facetime for potential performers with BARDA/ASPR staff, and encourage cross-sector collaboration to develop MCMs or platform technologies to combat pandemic influenza, emerging infectious diseases (EIDs) and chemical, biological, radiological, or nuclear (CBRN) threats. Below is a summary of the breakout sessions and insights we gleaned from this year's conference.

DIRECTOR'S UPDATE

BARDA Director Gary Disbrow spoke to how BARDA is meeting the preparedness, response, partnership, and workforce goals outlined in the agency's 5-year Strategic Plan (2022-2026). He noted that BARDA's purview has expanded to include responding to ***supply chain issues***, while maintaining its ***core focus on MCM product development***. ***A major concern is enterprise sustainment***. Neither BARDA nor the Strategic National Stockpile (SNS) can continue building partnerships and scaling product development at current funding levels (~$2 billion). Assuming that agency funding and re-authorization of the Pandemic and All Hazards Preparedness Act (PAPHA) is settled, ***priorities for FY24 include advancement of threat agnostic MCMs, meeting the needs of a diverse user base, and reimaging partnerships***. Partnership opportunities include:

- Biopharmaceutical Manufacturing Preparedness (BioMaP) – consortium launched in 2022, that intends to make its first awards in Q2 2024 through other transaction agreements (see PCI section for details)
- Rapid Response Preparedness Vehicle (RRPV) – consortium modeled after the Medical CBRN Defense Consortium (MCDC) to facilitate advanced product development and procurement in a single vehicle. This ten-year initiative will cover diagnostics, vaccines and therapeutics, among other technologies
- BARDA Broad Agency Announcement (BAA) and EZ-BAA – longstanding vehicles for engagement that highlight agency areas of interest (AOIs) and have been recently updated.
- TechWatch Program – forum for prospective performer engagement with BARDA on the BAA and EZ-BAA, that has expanded in scope to include other agencies that fund product development

BARDA FY2023 accomplishments highlighted by Director Disbrow:

- ***$3.75 B*** in investments
- ***20 new FDA approvals***
- ***722 contracting actions***
- ***35 new partners***

OTHER SPEAKERS

Dawn O' Connell, Assistant Secretary for Preparedness and Response (ASPR), HHS – She emphasized that with COVID-19 in the rearview mirror, HHS must now decide which emerging threats should take priority from a preparedness standpoint, adding that a reconvened interagency Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) has been meeting with industry over the past year to understand emerging technologies. She added that the agency has ***invested $17B to support domestic manufacturing*** and highlighted ***ASPR's new Industrial Base Management and Supply Chain office***, which aims to build a healthy, diverse public health supply chain and sustain long-term American manufacturing capabilities. Lastly, she spoke about the SNS, which was moved from the CDC to ASPR, and said that continued investments here are needed.

Representative Richard Hudson (R-NC-9) – Representative Hudson, who sits on the powerful House Energy and Commerce Health Subcommittee lauded BARDA's track record of 84 FDA approvals. He spoke about the need to provide the agency with certainty with the much-needed reauthorization of the PAHPA and requisite funding. He collaborates on these efforts with Representative Anna Eshoo (D-CA-16), with whom he co-chairs the Congressional Biodefense Caucus. The Congressman emphasized that public health security is critical to national security and that CBRN threats keep him up at night, particularly amid ongoing conflicts in Ukraine and Israel. Rep. Hudson also discussed the ***Healthy Future Task Force***, which was developed to i***mprove cures/therapies, build on Operation Warp Speed, and ensure that HHS is effectively utilizing private sector capabilities***.

Robert Johnson – Director of BARDA Medical Countermeasures Programs (MCMP) – Discussed emerging key challenges at BARDA including ***turning on manufacturing at moment's notice in a crisis, reducing product stagnation after licensure, and keeping current with advanced manufacturing technology while maintaining quality***. He noted ongoing MCM prioritization of innovation in the numerous spheres including:

- Threat agnostic MCMs – moving away from the "one bug, one drug" maxim
- Faster licensure processes to enable faster response and improve access
- Smaller footprint manufacturing
- More informative, decentralized clinical trials, that are better representative of national demographics
- End-to-end, point of need solutions, responsive to pre-symptom alerts
- Novel partnership vehicles, to address sustainment challenges and bring in non-traditional performers

BARDA DIVISION UPDATES

Chemical, Biological, Radiological and Nuclear (CRBN)

CBRN's mission is to make available at least one countermeasure for all CBRN material threats. Their priorities include developing chemical MCMs, antivirals with efficacy against multiple viruses, treatments for burn and blast injuries, innovative antifungals, and flexible technologies for vaccine manufacturing,

- **CBRN Funding**
    - Advanced Research and Development (AR&D) – The goal of AR&D funding is to ***build a sustainable MCM pipeline to prevent or treat illnesses and injuries caused by CBRN threats***. AR&D funds support innovative products through all phases of the development pipeline, from discovery and preclinical research to clinical trials needed to prove safety and efficacy, and manufacturing and regulatory approval needed to bring a product to market. CBRN also uses AR&D funding to develop and utilize preclinical models to study illnesses and injuries caused by CBRN threats and MCMs to treat those illnesses and injuries.
    - Project BioShield (PBS) – BARDA uses Project BioShield funding to ***support late-stage development, including post-marketing requirements and Phase IV clinical trials, and***

procurement of critical medical countermeasures, including vaccines and therapeutics, to prevent and treat CBRN threats. These MCMs are made available when a public health emergency, such as an anthrax attack or a nuclear detonation, occurs.

Influenza and Emerging Infectious Disease (IEID)

IEID continues a focus on pandemic flu response preparedness. Advancing next generation mRNA vaccines are critical to achieving this goal and relevant partnerships with Arcturus, AstraZeneca and the Access to Advanced Health Institute were highlighted. The overarching goals of IEID's Advanced R&D Vaccines portfolio are:

- Flexible Vaccine Platforms – Enable design, testing, and manufacturing of safe and effective vaccines against novel influenza 100 days from recognition
- Greater Efficacy & Improved Vaccine Performance – Achieve immunity in the population more quickly with a formulation that confers protection against a novel virus with a single dose of a vaccine
- Manufacturing Capacity – Enable production of enough vaccines for the US population within 130 days after recognition of a novel pandemic influenza virus
- Alternative Vaccine Administration – Utilize delivery methods that reduce the need for cold chain and needles/syringes (e.g. microneedle patch, intranasal, and oral routes of administration) and may enable self-administration and/or improve performance

IEID also includes a Therapeutics Portfolio that is focused on:

- Pre-exposure Prophylaxis (PrEP) – Advancing therapeutics and technologies for seasonal and pandemic influenza viruses through the FDA process with the goal of a single dose per season (6 months coverage)
- Treatment of Acute Respiratory Distress Syndrome – A critical gap, since no FDA approved therapies exist for hospitalized influenza patients
- Expanded Therapeutic Options Against Influenza – Broad spectrum antiviral therapies that can protect against many respiratory viruses, and mitigate antiviral resistance

Division of Research, Innovation and Ventures (DRIVe)

DRIVe's mission is to help BARDA be prepared for any public health emergency by ***identifying and de-risking the world's most promising technologies and capabilities***, no matter their origin, towards the development of tomorrow's medical countermeasures. DRIVe funds ***early-stage companies for life saving innovation***. It forms unique public private partnerships to prepare for the unknown, proof and scale, and address market and commercial viability.

DRIVe currently has funding opportunities open for:

- Healing Lungs – Advancing technologies that help patients with acute respiratory distress syndrome (ARDS), oxygenate their blood, without further straining ARDS patients' lungs
- Digital MCMs – Empowering people to respond to infectious disease outbreaks through rapidly deployable digital health tools
- Lab At-Home – On-demand, at-home detection of biochemical health markers to enable diagnostics and telemedicine services
- Reboot – Repurposing drugs for biological threats
- Immunechip+ – Enhance the usability of 3D human tissue models as tools for drug development
- Agnostic Diagnostics – A diagnostic test to identify any and every pathogen from a single sample
- DRIVe Forward – Funding program to support high risk, high reward innovation on specific topics

Selected FY24 priorities for DRIVe include creating a more resilient ecosystem of health security startups, lowering barriers for startups to develop health security technology, expanding decentralized clinical trial infrastructure, facilitating better adoption of MCMs, and studies of wearables and host directed therapeutics. Additionally, ***DRIVe will be launching the Accelerator Network 2.0 that is more product development focused than the current iteration.***

Pharmaceutical Countermeasure Infrastructure (PCI)

PCI includes three branches: Biopharmaceutical Manufacturing Preparedness (BioMAP), Manufacturing and Resilience (M&R) and CGMP Capabilities Readiness (CCR). They primarily support other BARDA divisions in their R&D efforts.

The division prioritizes:

- BioMAP consortium buildout (see below)
- Bilateral agreements with key drug substance manufacturers for pandemic-scale manufacturing
- Supply chain resilience and industrial base sustainment to support large-scale manufacturing
- Continued onshoring and capacity expansion for vials and consumables, fill/finish, and raw materials (particularly mRNA) for future emergencies
- Biopharmaceutical manufacturing workforce development and training programs

Biopharmaceutical Manufacturing Partnership (BioMAP)

In February/March of 2024 (exact date to be announced), BARDA will host another ***Biopharmaceutical Manufacturing Consortium (BioMaC) Industry Day***. The consortium works to "connect the dots" to enable interactions with BARDA leadership and industry partners and is focusing on manufacturing drug/substances at relatively early stages and responding to public health emergencies by producing vaccines at large scale. Additionally, ***BARDA's BioMaP Exercise (BioMaP-X) Concept*** seeks to engage and sustain the industrial base through frequent, scheduled, and appropriately funded manufacturing exercises. BioMaP-X partners with industry to manufacture batches of target products and assesses speed, quality, and scalability to identify constraints and mitigate risks to accelerate production of MCMs. The consortium recently hosted a roundtable on biomanufacturing which yielded several takeaways:

- Industry is downsizing their manufacturing base for MCMs and the government may be able to help ensure that capabilities exist for surge in manufacturing
- BARDA's investments in industrial base expansion are not broadly known to industry
- BARDA is seeking input on new or alternative incentives to increase value of working with the government in pandemic preparedness
- Regarding manufacturing exercise design, one size DOES NOT fit all, and specialized strengths can be harnessed to scale through CDMOs

Detection, Diagnostics, and Devices Infrastructure Division (DDDI)

DDDI funds the development of testing and medical device countermeasures, along with cases for domestic manufacturing capacity, across all areas in BARDA's mission space: CBRN, influenza, and emerging diseases. These investments are for ***development of testing systems and medical devices for use across the entire spectrum of use cases***, from hospital or central laboratory settings to limited resource settings. DDDI invests in products throughout the product development life cycle, from ***late-stage research through FDA clearance/licensure***. DDDI goals are aligned with the National Biodefense Strategy (NBS).

Key initiatives for DDDI include:

Near Term

- Supporting COVID-19 programs through 510(k)
- Increasing home-use multiplexed diagnostic tests
- Pathogen family tests based on blood samples
- Metagenomic next generation sequencing (NGS) tools for enhanced bio surveillance

Medium Term

- Threat agnostic viral diagnostic testing
- Reducing home-use diagnostic test costs
- Direct from sample, rapid antimicrobial resistant diagnostics

Long Term

- Threat agnostic pathogen diagnostics with pre-cleared tests to be rapidly adapted for new threats
- Expanding the biothreat diagnostic menu

Overarching

- Pathogen specific tests within 30 days of identification, prior to an emergency declaration with better sensitivity than COVID-19 antigen tests
- Leveraging telemedicine and coordinating testing and treatment at the same location
- Completion of ongoing manufacturing capacity expansion programs
- Establishing improved rapid contracting mechanisms
- Expanding and maintaining domestic diagnostics manufacturing capacity

Building Sustainable Public Health Manufacturing Capabilities: ASPR's New Office of Industrial Base Management and Supply Chain (IBMSC)

The office was established to ***coordinate strategic industrial base expansion and innovation efforts*** across ASPR, federal partners, academia, and the private sector to ***bring novel solutions and practices for response and recovery operations to life***. During the COVID-19 pandemic response, multiple challenges needed to be overcome, including addressing critical deficiencies with personal protective equipment (N95 respirators, surgical masks, gloves, lab-based tests, point-of-care tests, etc.) pharmaceuticals, therapeutics, and vaccine supply chains. ***IBMSC is currently establishing innovative manufacturing technologies and fill-finish capabilities to better avail drug prices and vaccines***.

Conclusion

The conference reiterated the importance of public-private partnerships and how BARDA continues to make the necessary investments through its vehicles (DRIVe, BARDA Ventures, BAA, EZ-BAA, and BioMAP) to support both small and large companies in their research and development efforts. The best ways to engage with BARDA are through the TechWatch or applying to the BAA. G2G is experienced in both avenues. BARDA has primarily shifted its focus from COVID-19 to other priorities, mostly planning for future pandemics.

G2G always recommends arranging conversations with BARDA staff and reviewing the BAA to understand priorities, obtain feedback, and ensure what you are offering meets BARDA's needs before applying for funding opportunities.

For more information on how G2G can help your company navigate BARDA and other agencies to access non-dilutive government funding sources that can grow or expand your company, contact Liz Powell at lpowell@G2Gconsulting.com.