



BARDA Industry Day Report November 15-16, 2022

OVERVIEW

G2G attended the annual BARDA Industry Day (BID) on November 15-16 that was held virtually for the third year in a row. The Biomedical Advanced Research and Development Authority (BARDA), the Office of Acquisitions Management, Contracts and Grants (AMCG), and the U.S. Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response (ASPR) host this event each fall. The purpose is to increase potential partners' awareness of U.S. government medical countermeasure (MCM) priorities, provide direct interactions with BARDA and ASPR staff, and network with public and private sector colleagues to develop MCMs or platform technologies to combat COVID-19; pandemic influenza or other emerging infectious diseases; 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 opened the event by reflecting on FY2022 as an extremely busy and productive year. A major accomplishment was updating and releasing [BARDA's new 5-year Strategic Plan \(2022-2026\)](#), which has four main goals: preparedness, response, partnerships, and workforce. In 2022, the 3 main responses for BARDA included COVID-19, Monkeypox and Ebola Sudan.

- **COVID-19** — In partnership with JPEO, BARDA completed multiple procurements to ensure access to a wide range of vaccines and therapeutics specifically addressing adolescent and pediatric populations, booster doses, and variant formulations. This included 8 emergency use authorizations (EUA) and multiple EUA expansions, 1 FDA clearance, and 1 FDA approval expansion. They also accepted more than 549 million vaccines and 14.8 million therapeutics for COVID-19.
- **Monkeypox** — BARDA leveraged previously supported MCMs to secure vaccine and therapeutics for distribution across the U.S. Additionally, they supported domestic manufacturing of the vaccine.
- **Ebola Sudan** — BARDA collaborated with international and interagency partners to address and contain the outbreak. They also coordinated with a private sector partner to develop and deliver vaccines, therapeutics and diagnostics.

Click [here](#) to read [BARDA's 2022-2026 Strategic Plan](#)

BARDA FY2022 accomplishments highlighted by Director Disbrow:

- [\\$2.23B](#) in investments
- [141 TechWatch meetings](#) held
- [22% growth](#) in BARDA's workforce
- [70+](#) new [innovative partnerships](#)
- [10+](#) new [areas of interest](#) in the [EZ-BAA](#) and [BAA](#)



BARDA DIVISION UPDATES

Chemical, Biological, Radiological and Nuclear (CBRN)

CBRN's mission is to make available at least one countermeasure for all CBRN material threats. Their priorities include developing host-based threat-agnostic MCMs, developing spectrum antivirals with efficacy against multiple viruses, developing MCMs to detect and treat blast injuries, investment in development of innovative antifungals, MCMs to detect and treat blast injuries, investing in development of innovative antifungals, investing in flexible technologies for vaccine manufacturing, and improving MCM CONOPs and sustainability. The goal of CBRN is to ensure the nation is prepared to rapidly respond to any CBRN threat.

- **CBRN Funding**

- **Advanced Research and Development (A&RD)** —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 the illnesses and injuries caused by CBRN threats and the MCMs to treat those illnesses and injuries. BARDA is investing in an array of medical countermeasures to treat or prevent illnesses and injuries caused by CBRN threats under the [BARDA Broad Agency Announcement \(BAA-18-100-SOL-00003\)](#).
- **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. Requests for Proposals (RFP) for new efforts to be supported by Project BioShield funds will be available soon.

Influenza and Emerging Infectious Disease (IEID)

IEID continues a focus on pandemic flu response preparedness. Looking to 2023, their goal for any new virus is to have a 1st dose of a vaccines available in less than 100 days from the date the sequence is available. In 130 days, the goal is to have 660M doses available for the US and by 200 days to have doses available to meet the global need. They will do this through several initiatives, including fast vaccine platforms, alternative delivery technology, more temperature-stable formulations, single-dose formulations, broadly priming the vaccines, and focusing on US-based manufacturing capacity for new technologies. Additionally, there are still gaps in influenza therapeutics including hospitalized patient treatment, pre-exposure prophylaxis, and outpatient treatment, all of which are a priority for the therapeutics branch.

Advanced R&D for vaccines will include 4 projects:

- **Faster Vaccine Performance** — Enable design, testing, and manufacturing of safe and effective vaccines against novel influenza 100 days from recognition
- **Faster Vaccine Delivery** — Utilize delivery methods that reduce the need for cold chain and needles/syringes and may enable self-administration and/or improve performance
- **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 vaccines
- **Manufacturing Capacity** — Enable production of enough vaccines for the US population within 130 days after recognition of a novel pandemic influenza virus



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 forms unique public private partnerships to prepare for the unknown, proof and scale, and address market and commercial viability. Through the DRIVE Accelerator Network, teams will be forward deployed throughout the United States to identify promising solutions wherever innovation is happening.

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
- **Host-Based Diagnostics** — Harness a patient's systemic responses to inform on health threats and clinical impact
- **Host-Based Therapeutics** — Advancing therapies focused on fortifying and restoring balance to the patient's defense mechanisms
- **Lab At-Home** — On-demand, at-home detection of biochemical health markers to enable diagnostics and telemedicine services
- **Redirect** — Repurposing commonly available drugs to rapidly treat conditions caused by exposure to chemical agents
- **Vaccines On Demand** — Making vaccines where they're needed when they're needed
- **Reboot** — Repurposing drugs for biological threats

Pharmaceutical Countermeasure Infrastructure (PCI)

PCI includes three branches: Biopharmaceutical Manufacturing Partnership (BioMaP), Contract Development and Manufacturing (CDMO), and Pandemic Vaccine Preparedness Capabilities and Readiness (PVPCR). They seek to establish the Biopharmaceutical Manufacturing Consortium (BioMaC) to leverage technologies and capabilities to provide end-to-end domestic manufacturing and supply chain solutions.

The division prioritizes:

- Innovative advanced manufacturing technologies
- 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 for future PHEs
- Biopharmaceutical manufacturing workforce development and training programs

Detection, Diagnostics, and Devices Infrastructure Division (DDDI)

DDDI funds the development of testing and medical device countermeasures, along with select cases for domestic manufacturing capacity, to produce them to address all threats 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 traditional hospital or central laboratory settings to limited healthcare resource settings, such as outpatient clinics, doctor's offices, nursing homes, tribal clinics, businesses, temporary healthcare facilities and even homes. DDDI invests in products through-out the product development life cycle, from late-stage research through FDA clearance/licensure.



Key initiatives for DDDI include:

- Support of COVID-19 programs through 510(k)
- Realigning focus on CBRN and flu programs
- Completion of ongoing manufacturing capacity expansion programs
- Expanding availability of home use molecular diagnostics
- Establishing improved rapid contracting mechanism
- Threat agnostic diagnostics
- Viral family diagnostics
- Expanding and maintaining domestic diagnostics manufacturing capacity

OTHER BARDA TOPICS

Biopharmaceutical Manufacturing Partnership (BioMAP)

In January 2022, BARDA, hosted a Biopharmaceutical Manufacturing Consortium (BioMaC) Industry Day. BARDA issued a Request for Information (RFI) in November 2021 that proposed the establishment of the BioMaC to help transform and build core capabilities for biodefense. The consortium is a planned expansion for BioMAP, which is focusing on manufacturing drug/substance at relatively early stage and responding to public health emergencies by producing large scale vaccines. BioMAP engages with industry by looking at pandemic-scale manufacturing of licensed vaccines specifically looking for partners who have experience with FDA licensed products, and have proven GMP drug substance manufacturing, established quality systems and a have trained skilled workforce. They look to make innovative manufacturing technology ready for adoption within 5 years and target in investments of supply chain raw materials and consumables to enable large scale manufacturing. The mechanism by which agreements between partners and the government will be made will run through the BioMAC consortium.

Beyond The Needle

Beyond the Needle is developing alternative technologies for vaccine delivery that aim to make vaccines and therapeutics easier to administer, more widely available, without the need for needles, syringes, vials, and cold-chain distribution burdens. BARDA has partnered with 10 companies to date on this initiative but seek to expand partnerships. Beyond The Needle is looking for partners that use alternative delivery routes such as oral (gut, buccal, sublingual), intranasal, transdermal, and implant (subcutaneous), involve simplified logistics that facilitate more rapid deployment and uptake, and reduce the requirement for vaccination by trained healthcare professionals.

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, and EZ-BAA) 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 continues to shift 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.

