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BARDA Industry Day Report

November 8, 2020

OVERVIEW

G2G attended the annual BARDA Industry Day on October 27, 2020 that was online for the first time due to the pandemic. For background, 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 working in the Health Security space 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. With the Biden-Harris change in the White House next year and upcoming funding legislation from Congress, BARDA is expected to receive more funding, some new leadership and some operational changes, however the focus on coronavirus will not change.

DIRECTOR'S UPDATE

Acting Director, Dr. Gary Disbrow shared that BARDA investments have increased over the past few years. In 2020, BARDA has given $2.1B for MCMs, invested over $16B in therapeutics, diagnostics, and vaccines for COVID-19, and acquired Zika, Ebola, and Anthrax MCMs. BARDA measures success through FDA approvals and licensure, with six total in 2020, and through the development of a robust pipeline of products. **Over 3,800 TechWatch submissions were made in 2020**—more than in the past 15 years combined and the team held more than 510 meetings. BARDA continues to respond to requests for TechWatches and although it awaits further funding from Congress to issue additional contract awards, it continues to evaluate and make recommendations to Operation Warp Speed on where to invest in innovations.

Note: BARDA's Broad Agency Announcement (BAA) is extended through October 31, 2021 and is only accepting white papers or full proposals to address COVID-19 responses. All other research areas are in a queue for review once COVID-19 has subsided.

BARDA DIVISION UPDATES

Influenza and Emerging Infectious Diseases (IEID)

- Key Speakers
  - Dr. Robert Johnson, Director of IEID

    - Armen Donabedian, Scientific Technical Advisor and Chief of Vaccine Development
    - Kimberly Armstrong, Chief of Therapeutics
    - Jonathan Seals, Director of Strategic Science and Technology
- Overview
    - IEID played a large role in the COVID-19 vaccine response. After the EZ BAA and BAA opened in March and April respectively, it was a matter of weeks before the first vaccine candidate, AstraZeneca, was identified. By June 2020, $2.5B was provided to MCMs and by September 2020 that number grew to $14.88B. If recombinant and genetic vaccines are safe and effective, this may be a new avenue for COVID-19 efforts.
    - While COVID-19 is the priority, IEID knows it must keep other diseases in mind, especially influenza. IEID shared that they have a strategy to modernize influenza vaccines by strengthening development, promoting innovative approaches and new technologies, and increasing access to vaccines. With the right technology, they said we can have a quick vaccine timeline.
- Key Takeaways
    - They emphasized preparedness requires flexible agreements, platforms for fast development, expanded access, production capacity, improved delivery and sustainability. IEID is seeking partners to deliver in these areas.
    - **Vaccine modernization is a priority for IEID** through (1) faster vaccine production, manufacturing platforms and testing and release, (2) improved vaccine delivery through alternative routes of administration, (3) single dose vaccines, and (4) solutions for the needle/syringe supply gap.

Detection, Diagnostics, & Devices Infrastructure (DDDI)

- Key Speakers
    - Rodney Wallace, Director of DDDI
    - Paul Eder, Senior Medical Diagnostics Advisor
- Overview
    - BARDA has a four-pronged approach for diagnostics: (1) development of molecular diagnostics, (2) antigen diagnostics, (3) antibody diagnostics, and (4) test qualifications and support materials.
    - BARDA practices interagency coordination through:
        - Operation Warp Speed (OWS is a partnership among components of HHS and DoD, engaging with private firms and other federal agencies, and coordinating among existing HHS-wide efforts to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics)
        - RADx (established for new diagnostic test development and manufacturing capacity expansion)
        - DoD/JPEO (Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) protects the Joint Force by providing MCMs and defense equipment against CBRN threats and facilitates the rapid response, advanced development, manufacturing and acquisition of medical solutions, such as vaccines, therapeutics, and diagnostics), and the
        - Air Force Procurement partnership focused on capacity expansion.

- Key Takeaways
    - Since 2020, there have been four FDA clearances, 15 Emergency Use Authorizations, and 45 molecular diagnostics produced.
    - **DDDI is looking for rapid, portable tests that:**
        - Require minimal end-user training
        - Use easily collected samples with minimal to no sample processing (specifically, sample collection into test without the need for separate swabs, transport media, tubes, etc. and minimize disposable consumables)
        - Include all key reagents supplied by the company as a sample-to-answer system and ensure they are easily adaptable to novel or emerging pathogens
        - Rapidly screen
        - Reduce use of valuable testing resources
        - Are readily available tests that detect and differentiate disease families to quickly identify infected persons before disease specific tests are available

Research, Innovation, and Ventures (DRIVe)

- Speaker: Dr. Sandeep Patel, Director of DRIVe
- Overview
    - DRIVe's goal is to identify the future of health security and de-risk it by seeking breakthrough devices and technologies. DRIVe released a BAA in January and has since funded 25 companies. They formalized the DRIVe Catalyst Office (run by Dr. Justin Yang) to bridge the intersection between science and business.
    - DRIVe has 13 accelerators that assist startups in seeking funding through the Accelerator Network in regions where there is heavy activity in developing health security products and technologies in biotechnology, life science research, and medical innovations. The network supports early-stage companies throughout their journey.
    - DRIVe seeks to empower patients and health care providers and allocate resources more effectively. Near future goals include launching BARDA Ventures (which will work with venture capital partners to invest in potentially transformative technologies and drive them to market to enhance national health security), developing DRIVe Data Strategy, and holding more community-based events.
    - Both DRIVe Start and DRIVe ReDIRECT are important to note:
        - **DRIVe Start** is designed to find new ideas and support their development through their incubator, prize competitions, and community engagement events with internal and external partners.
        - **DRIVe ReDIRECT** is looking at MCMs that are easily accessible and effective and are available in community hospitals, pharmacies, as well as other community settings.
- Key Takeaways
    - DRIVe launched a BAA, inspired by DARPA, with a simple application process for projects under $750,000.
    - One of the biggest barriers to standard vaccination paradigm is the availability of needles. The supply chain would be overburdened by the number of needles needed to deliver vaccines. BARDA's "Beyond the Needle" aims to find ways to

lower barriers of vaccination including the supply chain, healthcare resources, and vaccine administrations by finding vaccine delivery methods that do not use needles.

Chemical, Biological, Radiological and Nuclear (CBRN)

- Key Speakers
  - David Boucher, Branch Chief Nonclinical Development
  - John Esker, Project Officer Radiological & Nuclear CMC Program
- Overview
  - Maintaining and enhancing preparedness for vaccines is one of CBRN's main focus areas. Ebola, Anthrax, and Smallpox vaccines are in process and near licensures. There are more than 70 million individuals under 18 and they want to include them in trials and are working with Merck to do so. Marburg and Ebola Sudan are threats and need to establish vaccine pipelines.
  - The Burn Countermeasures program's objectives are mitigating bottlenecks for burn/blast injuries, transforming current standards, and building national preparedness. They focus on initial care for burns and mechanical trauma, reducing the need for surgery, identifying alternative skin substitutes, and advance treatments for cutaneous radiation injury.
- Key Takeaways
  - **Antibiotic resistance is a huge public health crisis for which we have no solution**. Drug development has not kept pace with antibiotic resistance, and there are 700,000 global deaths per year due to antibiotic resistance. The needs of the anti-microbial programs are priority pathogens, with substantial improvements over existing products, with novel approaches, late-stage clinical development, special populations, supportive regulatory feedback, and cost-sharing.
  - Specific areas of interest are wound conversion prevention, smart imaging systems, wound closure promotion, burn injury deferment, MCMs for cutaneous radiation injuries and pulmonary and blast related injuries.

OTHER BARDA TOPICS

CARB-X

- Key Speakers
  - Dr. Cameron Bess, Project Officer
  - Justin Yang, Catalyst Office Director, DRIVe
  - Erin Duffy, Chief of Research and Development, CARB-X
  - Donna Boston, Program Manager, DRIVe
- Overview
  - CARB-X was founded in 2016 to accelerate antibacterial research to address the rising threat of drug-resistant bacteria and is led by Boston University. It contains accelerators across the globe with 140 subject matter experts, with an internal research and development team to lead support bids.
- Key Takeaways
  - CARB-X works in a similar way to and is the predecessor of DRIVe's accelerator program.
  - CARB-X accelerators offer pre-award, post-award, and cross-project support for applicable startups. CARB-X has received $180M in BARDA investment from 2016-

2021, $270M from donor funding, $1.57B in follow-on private sector funding. There are companies in 10 countries and 69 total projects

Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND)

- Speaker: Douglas Bryce, Joint Program Executive
- Overview
    - BARDA and JPEO share goals around diagnostics, therapeutics, and vaccines and work together very closely.
    - JPEO seeks to prevent against both naturally occurring and deliberate threats.
    - Future capabilities for JPEO include developing protection, medical and sensors technologies.
        - Protection developments are being made in next generation ensemble, non-restrictive respiratory and ocular protections, filtration technologies, integrated and contamination mitigation, and coatings in barriers.
        - Medical facilitates advanced development and acquisition of medical solutions to combat CBRN and emerging threats.
        - Sensors is focusing on robotics and autonomous systems, decision support tools, machine learning, artificial intelligence, space and intelligence, surveillance, reconnaissance, threat agnostic detection and identification, modernized radiological and integrated early learning.
- Key Takeaways
    - JPEO-CBRND exists to manage our nation's investments in chemical, biological, radiological, and nuclear (CBRN) defense equipment. Having "Joint" in their title signifies they support all Services.
    - The medical section of JPEO is focusing on rapid MCM response, genomic sequencing, pre-symptomatic diagnostics and advanced manufacturing.

Conclusion

The conference reiterated the importance of public-private partnerships and how BARDA continues to make the necessary investments through its vehicles (DRIVe and BARDA Ventures) to support both small and large companies in their research and development efforts. BARDA's priorities are focused on COVID-19 for the immediate future but they remain committed to discovering new technologies that range from innovations in diagnostics and sensors to therapeutics to AI but must align with the areas outlined in their BAA. The other key item is developing relationships to gain insights from the chiefs of each division. With COVID-19 and new threats emerging, BARDA encourages even more participation than ever from companies, an exchanging of information through its accelerator networks, and opportunities to submit new product ideas through TechWatch/CoronaWatch as valuable resources for addressing conditions ranging from influenza to infections to infectious disease to sepsis. With the new administration and upcoming funding legislation from Congress, BARDA operations will change and is expected to secure more funding in the coming year.