



BARDA Industry Days Report October 29-30, 2018

Below is a summary of the BARDA Industry Days Conference in D.C. on October 29-30, 2018. Each year this conference is organized by 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). This year's theme was innovation in products and partnerships for flexible, dynamic response capabilities. There were about 1,000 attendees and because BARDA is an interagency entity several military and public health agencies were at the event. G2G talked with not just BARDA leaders, but several from the USAMRMC's Military Infectious Disease Research Program and the Medical Countermeasure Systems Joint Project Management Office that is also based at USAMRMC. There are several opportunities companies can pursue within BARDA as well as DoD.

Opening Session

- **Robert Kadlec – Health and Human Services Assistant Secretary for Preparedness and Response** opened the first day with general comments about the work of HHS in sponsoring innovation and work toward new countermeasures for infectious diseases, which remains a top priority. In addition, improving the ability to treat people as quickly as possible is another priority for the biodefense programs.
- **Dr. Steven Walker – DARPA Director** was the keynote speaker for the first day of the conference. He focused on the need for the U.S. to deter and prevail in large scale conflicts around the world and for DARPA to be the technology leader in this strategy, using biodefense programs and biosurveillance. This is increasingly important because of the growing number of people that are living in large cities. DARPA is focusing on ways to sense biothreats through rapid detection. DARPA and BARDA are working together to build upon the success in combating infectious diseases with the need for additional advances in infectious disease detection and new technologies to combat and slow down influenza. These include a focus on new instantaneous detection methods, new vaccine development, moving from an action posture to a proactive posture, and being able to more quickly defend against biothreats through biodetection. He also highlighted the work on gene encoded vaccines and other gene-encoded therapeutic platforms.

ADM Brett Giroir – Assistant Secretary for Health

- G2G spoke with the new head of Tech Watch meetings who explained how they have changed the process to ensure the right experts are in the room for these meetings. They are using a more focused approach for each of these to ensure no time is wasted and only focus on areas of most interest to BARDA.
- ADM Giroir stressed the importance of innovation to address public health issues while highlighting the challenges HHS is facing in dealing with drug overdoses. He said the U.S. had the highest number of STDs in 2016, making infectious diseases a continuing challenge for the country.
- Some of the biggest challenges facing the public health space is getting new products over the Valley of Death and getting civilian physicians to adopt new technologies and

treatments. However, the military is much quicker and more open to adopting new technologies and treatments.

- They are focusing on the development of technologies to solve the costliest medical issues (falls, pain, and sepsis) and end infectious disease epidemics in the U.S. and abroad through early warning signs, detection and rapid mitigation.

Dr. Rick Bright – Deputy Assistant Secretary for Preparedness and Response and Director, BARDA

- G2G has worked with Dr. Bright for several years and finds him always approachable in gauging whether BARDA is the right fit for companies.
- He shared that in FY2018, BARDA made over \$1.4 billion in investments and secured nine new approvals. They also launched DRIVE (Division of Research, Innovation and Venture), which is a new division at BARDA to focus on spurring innovation and transforming health security as well as decentralizing idea generation and capture. They also streamlined the acquisition process through their new EZ BAA system. Dr. Bright also talked specifically about their goal to combat and solve sepsis, which is the first time he has emphasized this focus in his opening remarks at these BARDA conferences.

Dr. Chris Houchens – Chemical, Biological, Radiological and Nuclear Threat Program (CBRN), CARB-X (Combating Antibiotic Resistant Bacteria)

- CARB-X plays a critical role in the development and delivery of new antibacterial products and antimicrobial resistance. The CARB-X program is designed to support early stage antibacterial product development. Through this program, for every \$1 of CARB-X investment there was a \$8.7 investment from private funding sources.
- There is also a focus on vaccine development, chemical attack countermeasures, next generation of opioids for pain, and burn care (thermal burn program, initial burn care and prevention of burn conversion).

Dr. Robert Johnson – Influenza and Emerging Infectious Diseases Program

- There were major successes in getting stockpiles of vaccines by working with their partners. However, there is still a lot of work to do in some major areas including:
 - o Respiratory Protective Devices and reusable masks
 - o Getting over the second Valley of Death, which is sustainability

Tyler Merkeley – Interim Director of Division of Research, Innovation and Venture (DRIVE) and Program Manager for CARB-X

- G2G talked with Tyler and his SME for infection control. They told us they want “game-changing” innovations and if a company has data showing vast improvements in the reduction of infections, spread of infection/infectious diseases, earlier/better diagnostics, and more user-friendly sensors/wearables, you are a fit.
- The focus of the DRIVE program is to stimulate public-private partnership collaborations that spur innovation and investment in health security products and technologies by building a funnel for innovation and reinvestment. They are seeking novel diagnostics, biosensing technologies and wearables to help detect and treat infections. The DRIVE program is supporting new and innovative ways to solve sepsis, where 270,000 patients die yearly and that accounts for 1 out of 3 patients who die in hospitals.
- Through the ENACT (Early Notification to Act, Control and Treat) program, they are seeking new wearable devices that catch infections before the person even knows they are sick, empowering both patients and providers and reducing the impact of illnesses. They believe BARDA needs to invest in wearables and other devices that can be effortlessly incorporated into everyday life, especially if can be sustainable. They are looking for products that can be readily available and can be integrated into daily life

to predict changes in health status, behavior and even potential exposure to illness. They are particularly interested in products that leverage big data analytics and AI prediction.

- Some examples they mentioned are biomarker advancement. Sweat can now be used to measure these health changes whereas before blood was the only measure that could be used. They also mentioned noninvasive health monitoring, such as a health tag that can be worn on clothes that measures sleep, activity, stress, heart rate and respiration rates.

S. Kyle Roberts – BARDA Contracts, Management and Acquisitions

- Through the 21st Century Cures law, BARDA moved their contracts process back in house, which will help with several contracting issues and allow them to have better targets.
- The EZ-BAA opened in August of 2018 and awarded its first award on September 14th. Through this process they are looking at new ways to engage industry and are focused on industry outreach and transparency in the contracting process. They also have an accelerator network with 8 around the country.
- This year Congress passed an on-time budget giving them a lot more time to plan and carry out acquisitions. Many of their investments were early phase technologies and they are looking for products or therapeutics that will have a successful FDA approval.

The conference held breakout sessions on CBRN and CARB-X that G2G attended.

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

- BARDA is supporting advanced research and development and looking for accelerated product development. Their priorities are drug class, biothreats, and antibiotic resistance. They stressed the need for unmet needs, nontraditional therapeutics and novel therapeutics, including
 - Vaccines
 - Antitoxins and Antivirals
 - o Anthrax Antitoxin Program
 - o Botulinum Antitoxin Program
 - o Smallpox Antiviral Program
 - o Filovirus Antiviral Program
 - Antibacterial
- When evaluating proposals, they are looking for the following:
 - Innovation
 - Ability to differentiate once on the market
 - Sustainability in the market long-term
 - Novel chemistry
 - Novel mechanism
 - Higher level of technical advancement
 - What is the FDA saying about your program/product?

CARB-X (Combating Antibiotic Resistant Bacteria)

- CARB-X is extremely successful for BARDA and the companies in the program. It offers non-dilutive funding opportunities as well as support teams and accelerator support for companies that qualify. Most of the companies that receive support through CARB-X also get significant private funding as well which shows they are investing in the right types of technologies and companies. They are also growing rapidly with the United Kingdom and the Bill and Melinda Gates Foundation both joining in with partnerships. He emphasized this program is focused on companies that are working on products that are

close to development and have other outside investors. This is not a program to fund post-doc research work.

Venture Capital Panel

- Patrick Heron, Managing General Partner, Frazier Healthcare Partners
- Andrew Levin, MD, PhD, Managing Director, RA Capital Management
- Ankit Mahadevia, MD, President & CEO, Spero Therapeutics
- Moderator: Jay Lichter, PhD, Avalon Ventures
- These individuals spoke on the advantages of partnering with investment companies and shared some helpful hints on making it a successful partnership. It is often difficult to even get a foot in the door with these companies, so it is often helpful to use connections to set up meetings and get to know the firm quickly. Most of these investors can know in the first 10 minutes if it is something they are interested in pursuing. They are looking for breakthroughs and devices or therapeutics that are new and innovative. They aren't looking for incremental change on things that already exist. For anti-bacterials, they are extremely interested in innovations that can make money outside the hospital setting.

Melinda Richter – Global Head, Johnson & Johnson Innovation, JLABS

- JLABS is looking to change the world of life sciences by helping small companies get started and grow. By working with Johnson & Johnson JLABS, companies can focus on R&D while getting help setting up a business, finding capital and growing through the program. They have a successful track record of helping small companies grow through their JLABS program throughout the world, and they are expanding.

Solving Sepsis

- Solving sepsis was a big theme this year and many of the presentations mentioned this focus. They are looking for transformative technologies and approaches to protect individuals from sepsis. They are interested in exploiting electronic health records to leverage this data to develop toolkits and improve outcomes. They are specifically looking for a sepsis focus and not just pathogen targeted diagnostics.

Conclusion

The conference shed light on the types of investments BARDA is looking to make this year and the vehicles they are using (DRIVE, ENACT and the EZ-BAA). Their priorities range from innovations in diagnostics and sensors to therapeutics to AI and the best approaches to addressing conditions ranging from influenza to infections to infectious disease to sepsis. They also addressed the Valley of Death and ways to leverage investments from both BARDA and VCs. Finally, the BARDA leadership shared helpful insights on their new developments over the last year and how these are major improvements for not only BARDA but for companies. It is clear BARDA is working to be much more business-friendly than in years past.