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government services

Introducing BARDA, TechWatch and John Tegeris

We recently had an opportunity to sit down with Tunnell's John Tegeris to learn more about BARDA (Biomedical Advanced Research Development Authority) and its TechWatch Program. John joined Tunnell in 2006 and has been dedicated to supporting BARDA since then in a number of roles, including management of the TechWatch Program.

What is BARDA?

BARDA is a government agency within the Department of Health and Human Services (HHS) which is housed within the Office of the Assistant Secretary for Preparedness and Response (ASPR). One of ASPR's priorities is to develop and procure medical countermeasures (MCM) that address public health emergencies across a broad range of biological threats (including chemical, biological, radiological and nuclear (CBRN) incidents and attacks), pandemic influenza and emerging infectious diseases. This now extends to the newest division of BARDA, the Division of Research, Innovation and Ventures (DRIVe) focused on tackling large healthcare issues in the U.S. and globally, such as the Solving Sepsis initiative, and other innovative approaches and disruptive technologies for improving healthcare, including development of wearable medical devices for pre-symptomatic indicators of illness.

As part of its mission, BARDA supports the advanced development and procurement of drugs, vaccines, diagnostics, medical devices and other products that are considered priorities for national health security. The need for the agency became apparent after deliberate Anthrax attacks as well as naturally occurring outbreaks such as SARS and pandemic influenza. Since its inception in 2008, and aligned with the initial BARDA Strategic Plan, BARDA to date has supported 48 FDA licensures/approvals/clearances for medical countermeasures. There are approximately 200 people who currently make up the BARDA team.

How does BARDA find the companies and organizations with the technology needed to bring these important relationships to fruition?

BARDA has many ways to help make companies aware of possible opportunities. Grassroots marketing efforts such this newsletter is one example. There is also BARDA Industry Day (BID), an annual event attended by over 1,000 companies/individuals from industry, academia and non-profit organizations. BID is a two-day conference where we not only highlight the importance of industry partners, but also promote BARDA's TechWatch Program as a way to help companies with products in development and technology platforms relevant to BARDA's mission space take the next step in the process. Industry partners are crucial to the success of the BARDA mission.

BARDA technical experts and program managers often conduct due diligence and market research in their respective mission space in order to entice companies to meet with BARDA through TechWatch and discuss how their technologies can help us meet strategic goals for our public health mission. To this end, enter the BARDA TechWatch Program and its raison d'etre.

What is the BARDA TechWatch Program?

The TechWatch Program is the bridge that connects industry and academia to BARDA. It is ultimately designed to accelerate success for companies and for BARDA by engaging potential partners outside the government who have specific technology that can help address a BARDA threat area. As part of the TechWatch Program, we provide technical and strategic input to help these companies hone their White Paper or full proposal submission to more precisely address our mandated threat priorities and medical countermeasure gaps. It is intended that the right advice provided by BARDA and participating interagency SMEs will put a company on the "fast track" to fully understand where their technology is positioned relative to BARDA's funding opportunities.

It is also a focus of the program to help a company understand what other data is needed for funding consideration if they aren't yet at our front gate. Effective stewardship for the TechWatch Program will translate into more candidates ultimately finding their way into BARDA's portfolio, thanks in good part to the interaction between the company and BARDA and the relationship fostered along the way.

For some companies that attend an initial TechWatch meeting, it may be too early for funding according to the BARDA Broad Agency Announcement (BAA), but that's not the end of the line – TechWatch can advise them on what data may be missing and what studies may still be required, what discussions need to occur, such as interaction with FDA, and what regulatory pathway makes sense for our mission space. All of this helps, and while funding is often a consideration and a goal, it's not always about funding. We also ask these companies to establish their top three priorities for the meeting, which could center on topics such as protocol discussions and what the right study design should be. We also work to connect these companies to other interagency partners where the timing may be better suited to begin a working relationship.

All roads for industry engagement lead through the BARDA TechWatch Program, which integrates every division and branch across BARDA, and all interagency partners within HHS, including FDA, CDC, NIH and ASPR. The interagency cooperation is broad, and some of the medical countermeasures under development are important not only to the civilian world, but also to the warfighter. As such, BARDA sees active participation from the DOD, including groups such as DARPA and DTRA.
The TechWatch Program is the start to the relationship, and one that can evolve to help us better achieve our public health mission. Simply put, the TechWatch Program is one key way to build a bigger product pipeline and accelerate entry of MCMs into the BARDA portfolio, and it has helped many companies "get there faster."

Who is it for?

TechWatch is incredibly far-reaching as we fund many companies from around the world. We have companies approaching BARDA's TechWatch Program from Europe, Australia, Israel, Canada, and certainly across the U.S. With over 200 requests each year from around the world, many of the companies coming to TechWatch are for-profit companies, often in the pharma and biotech industries – both small and large – and there are also plenty of other groups that come from nonprofit organizations and academic institutions. While some meeting requests are to discuss specific vaccines, therapeutics, diagnostics or medical devices under development to address defined threats, others are broad spectrum and can be effective against many pathogens.

What are some noteworthy BARDA success stories that have in-roads through the TechWatch Program?

A few of the projects that are typical of BARDA would include development programs that address multi-drug resistant bacteria and sepsis, pandemic influenza and emerging infectious diseases, and other threats such as smallpox and anthrax. A few examples of successful projects which made a big impact include:

- SIGA Technologies, a health security company, entered into a Smallpox therapeutic development contract with BARDA that resulted in a large procurement contract for an orally administered antiviral drug.
- BARDA provided funding to Janssen, a subsidiary of Johnson and Johnson, for advanced development of pimodivir, used to treat hospitalized influenza patients. A second OTA contract with the CBRN Division in BARDA was also awarded to launch development for a countermeasure to address chemical attacks with nerve agents.
- BARDA awarded funding to Genentech through an OTA contract to develop baloxavir for a hospitalized indication to treat severely ill patients with influenza (recently FDA approved XOFLUZA to treat acute, uncomplicated flu). Also under this contract, Genentech is working with CBRN for another candidate to treat exposure to nerve agents (Alteplase). A third program could soon be added for Lep B to address multi-drug resistant bacteria.

How can you participate?

Whether you're ready for funding or just need guidance on how to get to that point, TechWatch is here to help. Please visit www.medicalcountermeasures.gov to learn how to formally request a BARDA TechWatch meeting, which is the starting point for most in the journey to what could one day be a contract with BARDA. Every organization will get a touch point. No exceptions.

The BARDA TechWatch Program simplifies the process and helps bring together companies and USG agencies which may be interested in the technologies those companies bring to the table. BARDA's goal to help secure our nation from both natural and man-made threats is paramount for the safety of mankind. The TechWatch Program, and all in BARDA who embrace it, are of critical importance to driving this success, which we hope will ultimately translate into saving many lives during a public health emergency.

About John Tegeris

John has over 25 years' experience in pharmaceutical testing and government program management. As Vice President at Tunnell Government Services, he also continues to provide Senior Program Manager support to BARDA's Office of the Director to assist in meeting pandemic influenza preparedness strategic goals. This support includes updates to HHS leadership throughout the influenza season on U.S. antiviral availability, as well as the status of the federal influenza antiviral stockpiles within the Strategic National Stockpile. John also supports therapeutic advanced development programs for the Influenza Division. He earned his BS in Biology from The College of William and Mary and his PhD in Pharmacology and Toxicology from The Medical College of Virginia.

While John considers himself "public property" for the BARDA mission and always available to support the cause, he focuses almost all of his other time on his wife and two kids, having fun as a family, traveling the country and sometimes the globe to watch them play in travel soccer tournaments and to learn about other cultures.