



United States Department of

Health & Human Services

Office of the Assistant Secretary for Preparedness and Response



BARDA Core Services: Innovations Program

BARDA Industry Day

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BARDA's Mission



- To support development and availability of countermeasures for CBRN threats, pandemic influenza, and emerging infectious diseases through advanced product development, stockpile acquisition/building, manufacturing infrastructure building, and product innovation.



- Product licensure
- Countermeasure stockpiling
- Manufacturing capacity
- Effective delivery
- Development infrastructure
- Technical innovations



Innovation is a Key Part of BARDA's Mandate*



- “shall develop and make public a strategic plan to integrate biodefense and emerging infectious disease requirements with the advanced research and development, strategic initiatives for **innovation**, and the procurement of qualified countermeasures and qualified pandemic or epidemic products”
- “...shall guide...**innovation** in technologies that may assist advanced research and development of qualified countermeasures and qualified pandemic or epidemic products”
- “...shall coordinate the acceleration of countermeasure and product advanced research and development by...promoting **innovation** to reduce the time and cost of countermeasure and product advanced research and development”
- “**SUPPORTING INNOVATION**- ...may award contracts, grants, and cooperative agreements, or enter into other transactions, such as prize payments, to promote--
 - (i) **innovation** in technologies that may assist countermeasure and product advanced research and development;
 - (ii) research on and development of research tools and other devices and technologies; and
 - (iii) research to promote strategic initiatives, such as rapid diagnostics, broad spectrum antimicrobials, and vaccine manufacturing technologies.”

*Pandemic and All-Hazards Preparedness Act, Title IV, Sec. 319L



Innovation to Meet the Challenge of Public Health Emergency Preparedness and Response



- The call for innovation is a recognition that current thinking, approaches, and technologies may not provide adequate solutions to the problems posed.

Innovation:

- new idea or method: a new invention or way of doing something
- origination: the act or process of inventing or introducing something new



- What does innovation mean in the context of developing and manufacturing medical countermeasures for public health threats?



- New technologies, tools, approaches, and capabilities will help adapt the current enterprise to better produce and supply medical countermeasures in case of public health emergency.
- BARDA encourages and supports new technologies that enable solutions to countermeasure challenges.

- BARDA's Innovations program provides support for technology-focused projects that lead to new capabilities and approaches to medical countermeasure development, testing, manufacturing, and use.





BARDA Innovations Program



- Technology-focused projects that offer solutions to specific countermeasure challenges
- Technologies that provide new capabilities that may be applied to multiple countermeasures (platform technologies)
- New technological approaches that propose new countermeasure paradigms for public health emergency preparedness
- BAA-13-100-SOL-00014
- Areas of Interest have covered manufacturing technologies, testing and evaluation tools, product formulations, host-directed therapeutic approaches, and diagnostic platforms
- Areas of Interest are updated every 1-2 years.

Current Areas of Interest:

- Technologies that allow vaccines or drugs to be delivered by parenteral administration with limited access to trained medical personnel
- Technologies that allow non-parenteral administration by the user and may deliver the countermeasure over a longer period of time



BARDA Innovations Program Investments



- Diagnostic test platform applied to influenza
- Improved recombinant protein production system applied to rPA
- Rapid sterility test system for vaccines
- Synthetic biology for production of vaccine seed strains
- In vitro system for immune response testing
- Formulations to increase vaccine stability and shelf-life
- Formulations to increase vaccine effectiveness and decrease antigen dose





ASPR Special Technology Area of Interest:

Ensuring power for Durable Medical Equipment during an emergency event



- Patients who rely on electrically powered, life-saving or sustaining equipment in their residences are at risk during an emergency that causes sustained power outages. Locating and providing assistance to these individuals may be challenging during in a large-scale event. Desired capabilities may include:
 - ❖ Technology that improves battery life
 - ❖ Tools for identifying and tracking users of electrically powered home medical equipment
 - ❖ Technology that monitors battery and equipment status and notifies the user or contacts regarding location and needs

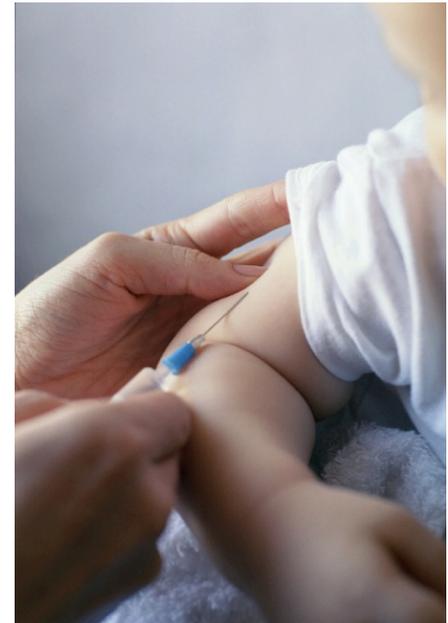




Implementation of BARDA's Innovation Mandate



- Look to the biopharm/biotech community to provide fresh ideas for safeguarding public health
- Seek the technological tools to enable a rapidly responsive medical countermeasure capability
 - More effective countermeasures
 - Multi-use products
 - Platform technologies
 - Improved manufacturing infrastructure



- Will provide the flexibility to deal with diverse threats
 - Bioterrorism
 - Pandemic Influenza
 - Emerging Infectious Diseases



BARDA TechWatch Program



- Forum for discussion about stakeholder's technologies/products and BARDA's interests and programs in seminar format at BARDA's offices in Washington, D.C.
- Opportunity to receive feedback from BARDA Program and Technical staff
 - Specific direction about stakeholder's plans cannot be given
- Request through www.medicalcountermeasures.gov
- Limitations
 - Generally cannot be held while requestor has a proposal under review by BARDA
 - Generally cannot be held to discuss topics related to an acquisition under an open RFP
 - Generally can discuss projects that may fall under an Area of Interest of an open BAA
- Allow ~6 weeks to schedule

- www.phe.gov
 - Program description, information, news, announcements
- www.medicalcountermeasures.gov
 - Portal to BARDA
 - Register, request a meeting
 - Tech Watch
- www.fedbizopps.gov
 - Official announcements and detailed information about all government contract solicitations

