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;
  - (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
• 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?
Adapting the Current Enterprise through Technological Innovation

• 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
Interfacing with BARDA

- **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