

*United States Department of*

**Health & Human Services**

**Office of the Assistant Secretary for Preparedness and Response (ASPR)**

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# **BARDA Innovations Program**

## **BARDA Industry Day 2014**

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**HHS/ASPR/BARDA**



# 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



# BARDA Innovation Program Goals



- **Identify 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**
- **The Innovations Program does not have a single countermeasure or threat focus but rather an over-riding technology-centric approach**
- **Innovations Program can be opportunistic, allowing investments to be made as technology options and BARDA needs align**
- **Success of projects can be defined as:**
  - **Approved product**
  - **“Graduation” to BARDA Program for further development**
  - **Adoption of technology for use by partner(s)**
  - **Availability of technology to the countermeasure community**

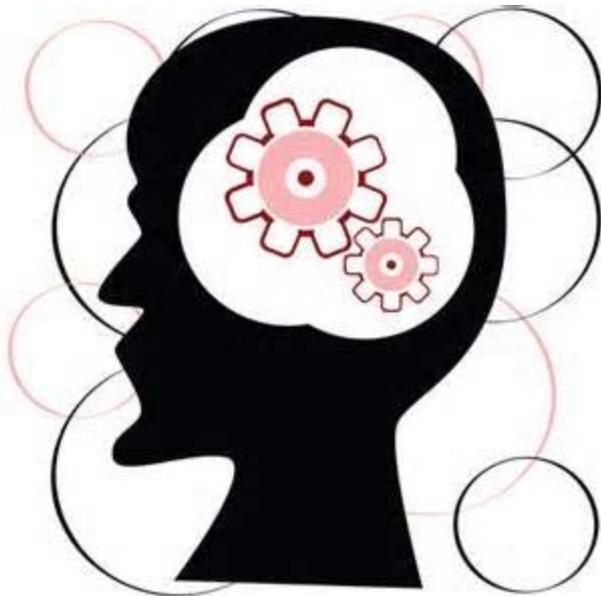




# BARDA Innovations Program Projects



- **Technology-focused projects that offer solutions to specific countermeasure challenges**
- **Technologies that provide new capabilities applicable to multiple countermeasures (platform technologies)**
- **New technological approaches that propose new countermeasure paradigms for public health emergency preparedness**



- **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.**



# 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





# General Criteria for Innovation Projects



- **Address a BARDA countermeasure or capability need and offer a technology solution to a current problem**
- **Make a case for a scenario in which the product or technology will improve response capability in case of a public health emergency**
- **Apply to at least one BARDA threat but ideally may be used for other applications (platform technology)**
- **Be scientifically well-founded, but are not necessarily in advanced development**
- **Present a plan for the evaluation of feasibility, but not necessarily for proceeding to a final product approval**
- **Work toward a positioning for application or implementation in the medical countermeasure enterprise after SST funding**



# Current BARDA Innovations Focus



- **BAA-13-100-SOL-00014**
- **Current Area of Interest: Technologies that allow countermeasures to be dispensed, delivered, and administered more efficiently and effectively**
  - **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**
- **Technology should apply to a specific public health emergency scenario where implementation is practical and improved response capability will result**





# Interfacing with BARDA

- [www.phe.gov](http://www.phe.gov)

- Program description, information, news, announcements

- [www.medicalcountermeasures.gov](http://www.medicalcountermeasures.gov)

- Portal to BARDA
- Register, request a meeting
- Tech Watch



- [www.fedbizopps.gov](http://www.fedbizopps.gov)

- Official announcements and detailed information about all government contract solicitations

