Anthrax Vaccine Countermeasures

Biomedical Advanced Research and Development Authority (BARDA)

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Outline

- The Threat
- Requirements
- Current Program
  - Near term
  - Mid term
  - Long term
- Technical Issue of BAA
- Working with BARDA
**Bacillus anthracis the Threat**

- **General**
  - Gram positive spore forming bacterium
  - Resulting disease – Anthrax
  - Naturally occurring zoonotic disease

- ID50 – 3000 spores
- 1-6 day incubation period
- Non-contagious
- Highly stable
- Easily mass produced
• BARDA is building a balanced and diversified portfolio of anthrax countermeasures
  — Antibiotics
  — Antitoxins
  — Vaccines

• HHS Requirement to procure sufficient vaccine to protect 25M people

• Programs are supported by:
  — Advanced Research and Development
  — Project BioShield Special Reserve Fund
Anthrax Vaccines
Current and Near Term Preparedness

• Procurement of BioThrax® (AVA) has transitioned to the SNS
• Obtain extended expiry dating
• Label claim for PEP
• Evaluating Public Health Preparedness
Public Health Preparedness

• Evaluation of dose and antigen sparing
• Schedule
• Pediatrics and other special populations
• Potential to decrease antigen and/or dose
• Expands stockpile
Expanded Manufacturing – Mid Term

- Builds on AVA database
- Facility Validation
- Increases capacity to from 8 M to 26M doses/yr
rPA Based LongTerm

• Broadens manufacturing capabilities
• Reduces reliance on one product/manufacturer
Novel Technologies – Long Term

- Maintains pipeline of MCMs for future platforms
- Better delivery systems
- Supported by the NIH Tech Base
• Opportunities to address anthrax vaccine needs within the CBRN BAA
  — Area 1: Vaccines and vaccine enhancements
    • Improvements to current vaccines and other vaccine candidates at TRL-6 and above (pending availability of funds)
    • Interested in new approaches
    • Organizations should:
      — Demonstrate immunogenicity in one animal
      — Understand the manufacturing process at small scale
      — Determined one year stability
      — Define appropriate assay for potency, stability, and manufacturing
Anthrax Vaccine Successes

- PEP animal model
- New rPA vaccine contracts
- In conjunction with NIH several contract evaluating adjuvant and stability enhancing capabilities
- Under the platform BAA – evaluating another rPA expression platform
- BARDA resources available to support contractors
Working with BARDA

• BARDA awards contracts
  – Generally one year base with option years
  – Milestones
  – Deliverables

• Project Coordination Team (PCT)
  – Each contract has a unique BARDA PCT
  – Structure (matrix organized)
    • Contracting Officer (CO)
    • Project Officer (PO)
    • Manufacturing SME
    • Animal Model SME
    • Assay SME
    • Quality
    • Earned Value Management
PCT Objectives

• **PCT provide recommendation to the CO related to the contract**
  — Only the CO can change the contract (should be done in writing)

• **PCT provides technical information up the chain of command**
  — Assessment project status
  — Justification for funding
  — Coordination of intra-agency concerns

• **Intent of PCT is to leverage what has been learned**
Interaction with PCT for Success

- **Plan ahead**
  - Map out all major projects
  - Be realistic

- **Communications**
  - Provide honest and timely information
  - Inform BARDA of problems
  - Support path forward with data
  - Oral presentations should be supported by a written report
  - Scheduled meetings should include the key players
• **How to apply:**
  
  — Go to [www.medicalcountermeasures.gov](http://www.medicalcountermeasures.gov)
    • Click on Procurement and Grant Opportunities
    • Scroll down and click on CBRN Funding Activities
    • Click on link for 2011 Broad Agency Announcement

  — Or go to [https://www.fbo.gov/](https://www.fbo.gov/)
    • Search BARDA-CBRN-BAA-11-100-SOL-00009

  — Technical POC for Research Area #1: Vaccines
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