



**United States Department of**

**Health & Human Services**

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

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# **An Open Dialog: Contracting and Communicating with BARDA**

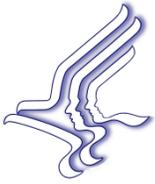
**The Who, When, Why, and How of Meeting with BARDA Personnel**

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**Strategic Science and Technology Division (SST)**

**June 9, 2011**



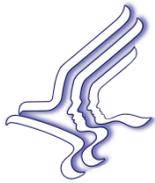
# Who - BARDA Organizational Matrix



## Core Functionalities

ion Responsibilities

	Clinical Studies	Manufacturing Facilities & Engineering	Regulatory & Quality Affairs	Other	Strategic Science and Technology
CBRN					
Influenza					
Emerging Infectious Diseases					



# BARDA Resources are Available to All R&D Contractors



- **BARDA's matrix organization has significant technical expertise that can be leveraged**
  - Clinical Studies Division
    - Physician staff with experience in designing and executing clinical trials
  - Regulatory & Quality Affairs Division
    - Staff with FDA regulatory experience
  - Manufacturing Facilities and Engineering Division
    - Engineering staff experienced in managing vaccine manufacturing facilities
  - Vaccine, therapeutic, and device product development expertise
    - Many years of product development experience from biotech and pharmaceutical industries
  - Threat-specific expertise supporting the mission responsibilities
    - CBRN and Influenza subject matter expertise from government, academia, and industry

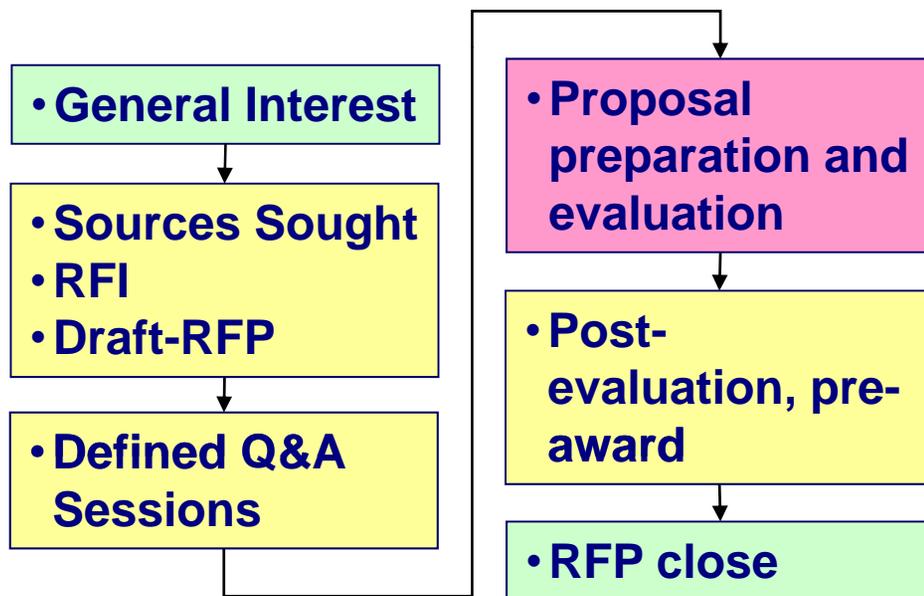


# When can the public meet with BARDA personnel?

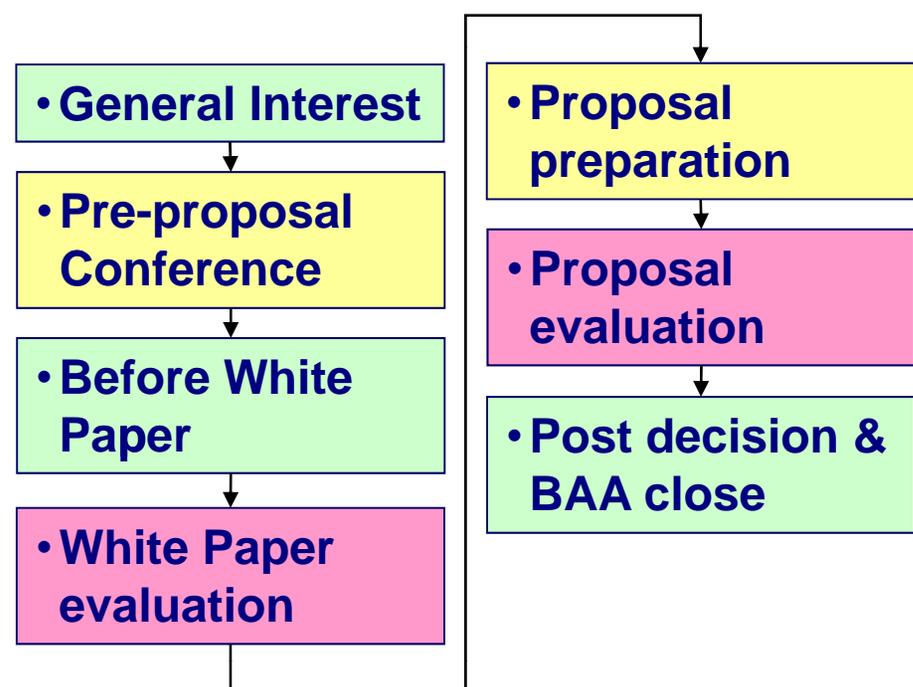


- *There are open and blackout periods where BARDA personnel can and cannot meet that vary by solicitation type*

## RFP



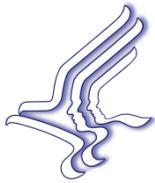
## BAA



Open with BARDA

Facilitated by CO

Closed Communication



# Why meet with BARDA? Both Parties Benefit



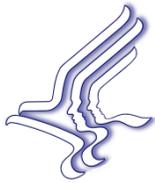
- **Initial information sharing benefits you**
  - Gain insight into BARDA’s priorities
  - Take advantage of SMEs and product development experts
- **It’s our job**
  - PCAST described the “paramount importance of the relationship between the Federal Government and industry partners”
  - MCM review also states “federal government partnerships with innovators in industry and academia are key to achieving success”
- **Information benefits us**
  - Setting priorities for future programs and evaluating existing programs
  - Staff awareness and education to emerging technologies and products entering our pipeline
- **Get used to us**
  - We’ll be meeting whenever, wherever, as allowed by the contract



# How can the public meet with BARDA personnel?



- **Public Forums**
  - PHEMCE Stakeholders
  - BARDA Industry Day
  - Scientific Conferences
- **POCs in BAAs/RFPs**
- **Central mailboxes, e.g. [SST-BAA@hhs.gov](mailto:SST-BAA@hhs.gov) or [CBRN-BAA-11@hhs.gov](mailto:CBRN-BAA-11@hhs.gov)**
- **TechWatch**

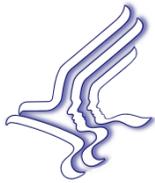


# TechWatch current setup



- It is critically important that we maintain a full and current understanding of the landscape of technical capabilities
- TechWatch was developed in late 2008 as one way to meet this need
  - provides an opportunity for external organizations to meet with the Federal Government to discuss their new and innovative medical countermeasure technologies
  - receive guidance from BARDA scientific and contracting staff
- TechWatch program is managed for the ASPR by the BARDA Strategic Science and Technology (SST) office
- Register on the website, log on, provide basic info on product or technology, and request a meeting with BARDA (or NIH, CDC, etc.)
- SST organizes meeting in DC office

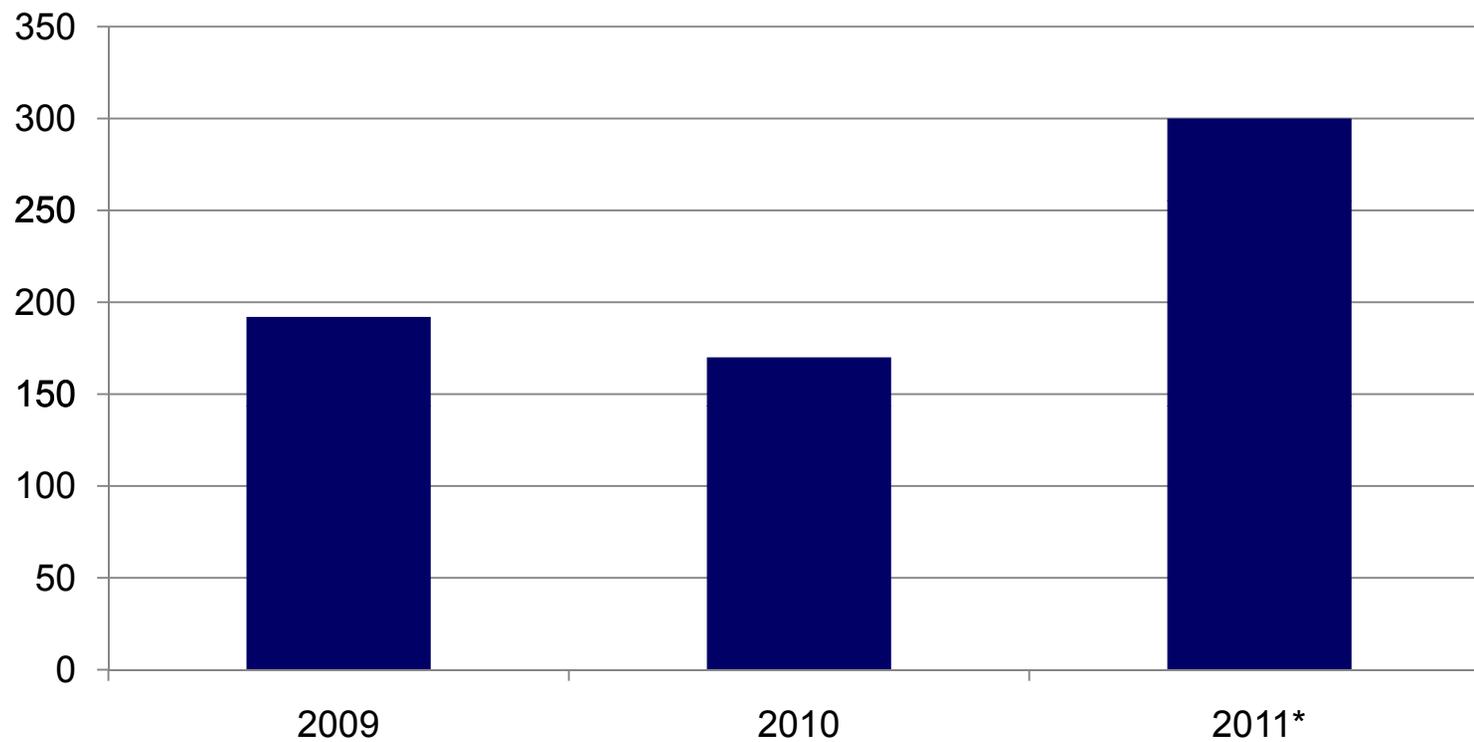




# Increasing TechWatch Demand Demonstrates Growing Interest in Public Health Preparedness



# of Meeting Requests



**\*Projection**



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**Questions?**