# The BARDA Multi-Broad Agency Announcement Pre-Proposal Conference 2012

Hubert H. Humphrey Building - The Great Hall

**July 16, 2012**

# Housekeeping

- **Reminder: All guest of the Humphrey building need to be escorted by ASPR Staff when leaving this area (i.e. bathroom/anywhere)**
- **Please turn your cell phones to vibrate as to not disturb the presenters during presentations**
- **Please be on time to your meetings with the ASPR staff.**

# "Rolling" BARDA BAAs

## Pre-Proposal Conference
## 16 July 2012

**Carol D. Linden, Ph.D.**
**Principal Deputy Director**
**BARDA**

# BARDA Mission

***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.***

Washington Office Center

Patriots Plaza II

# Man-made and Natural Threats

- CBRN Threats
  - Chemical  nerve agents & cyanide
  - Radiological and Nuclear agents
  - Biothreats (anthrax, smallpox, plaque, tularemia, VHF, and others)


- Pandemic influenza

- Emerging infectious diseases

# Medical Countermeasures

Medical Devices

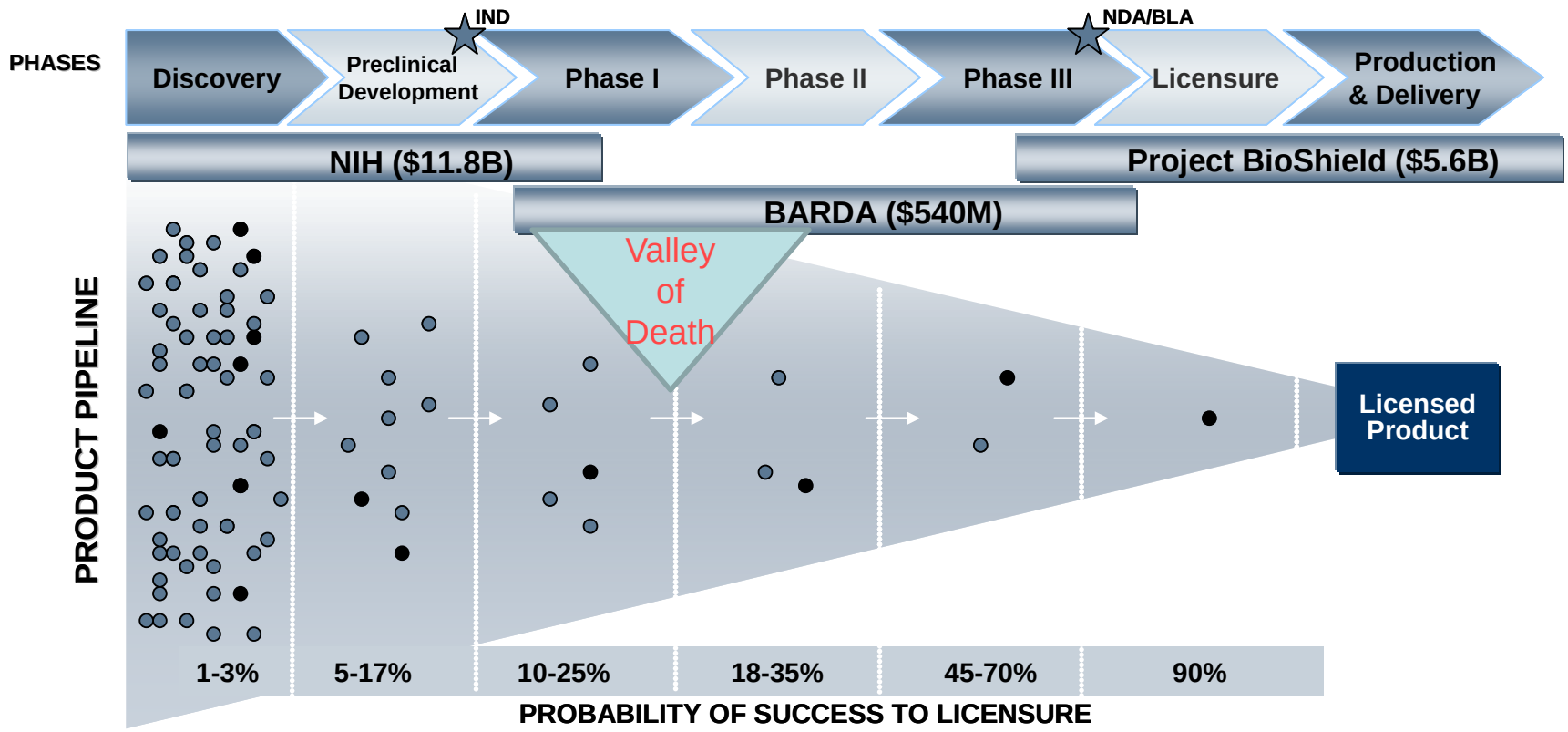
Antimicrobials

Diagnostics

Vaccines

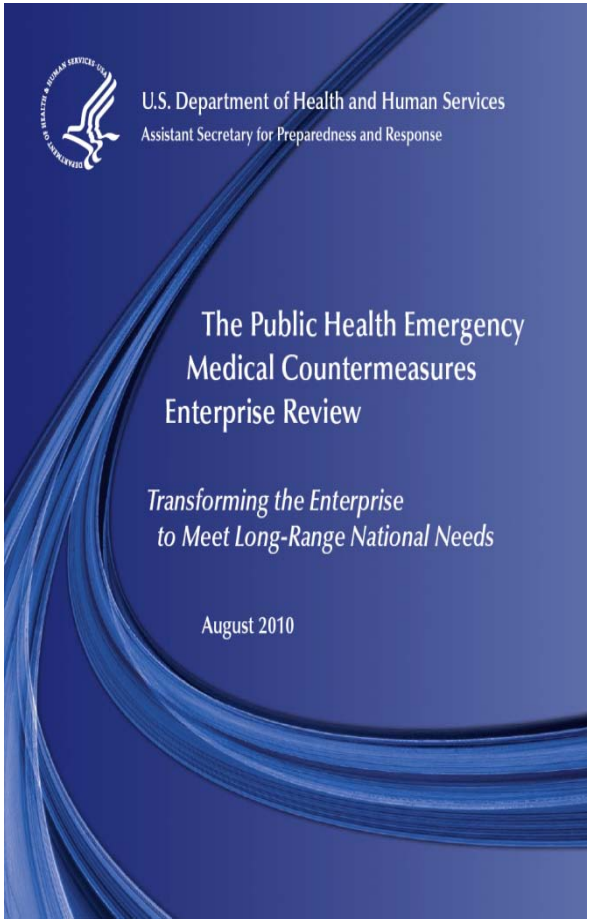
Therapeutics

# CBRN MCM Development is Expensive, Lengthy, & Risky




| | | | | | | |
|---|---|---|---|---|---|---|
| Time | 3-7 yr | 0.5-2 yr | 1-2 yr | 2-3.5 yr | 2.5 -4 yr | 1-2 yrs |
| Pipeline Phase Cost | $100M -130M | $60-70M | $70M-100M | $130M-160M | $190M-220M | $18M-20M |

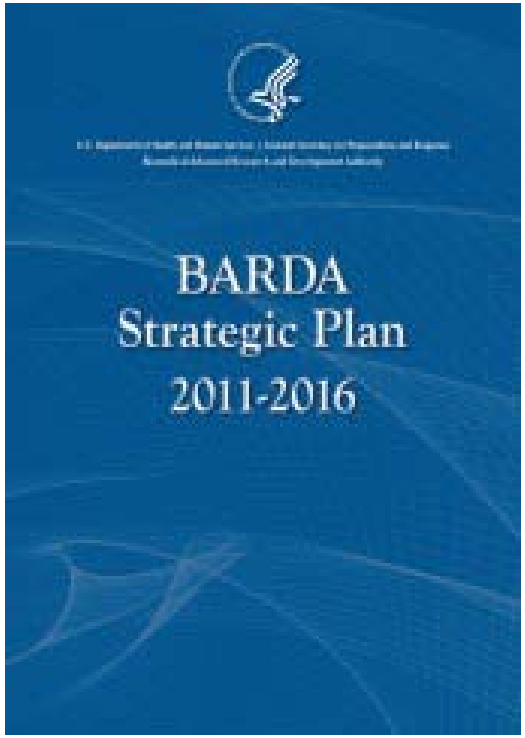
# MCM Enterprise Review: New Strategy




## Key Initiatives

1. Expand Product Pipeline through Concept Acceleration Program (CAP) at NIAID
2. Establish a Strategic Investment (SI) Fund to increase investments in commercial ventures with multi-use potential (BARDA)
3. Establish Centers for Innovation in Advanced Development and Manufacturing (BARDA)
4. Investment in upgrading science capacity at FDA
5. Optimize influenza vaccine development and manufacturing (BARDA. NIAID. FDA. CDC)
6. Enhance PHEMCE business practices

# Future: BARDA Strategic Plan 2011-2016




- GOALS
  - Abundently supply advanced development pipeline for all known threats
  - Core service capability
  - Robust domestic MCM manufacturing infrastructure
  - Address MCM needs for emerging infectious diseases
  - Nimble response capability to known & unknown threats
- Cascades from NHSS, ASPR Strategic Plan, MCM Review, and other national plans

# BARDA 2012

- BARDA is committed to developing and providing MCMs for civilian preparedness & response to CBRN, pandemic influenza, and emerging infectious threats

- BARDA utilizes public-private partnerships with industry to achieve these goals by providing funding support and critical core services to its partners

- BARDA maintains a balanced portfolio for specific and multiple threats and places a high priority on sustainable life cycle management

# Broader Challenges

- Preparedness against Unknown Threats
- Economic Woes & Budget Austerity
- Global Political Unrest Feeding Bioterrorism
- Erosion of State and Local Public Health Infrastructure
- Needs of Special Populations
- Identity Crisis in U.S. Pharmaceutical & Biotech Industry
- Sustainability of Programs and Products
- Spiraling Life Cycle Maintenance Costs of MCM Stockpiles

# Contact Us


## BARDA:

URL: http://www.phe.gov

BARDA e-mail: BARDA@hhs.gov

- Upcoming Events
- PHEMCE Strategy and Implementation Plan
- CBRN and Pan Flu Programs
- Business Toolkit
  - www.phe.gov/amcg

## MedicalCountermeasures.gov

- Tech Watch program
- Federally-sponsored conferences
- Funding opportunities
- Resources 7 core service programs
- Regulatory guidance
- Federal strategies and reports

# Save the Date

## BARDA Industry Day

## October 29 – 31, 2012

## Washington, DC metro area

# Chemical Biological Radiological Nuclear (CBRN) Medical Countermeasure (MCM) Development

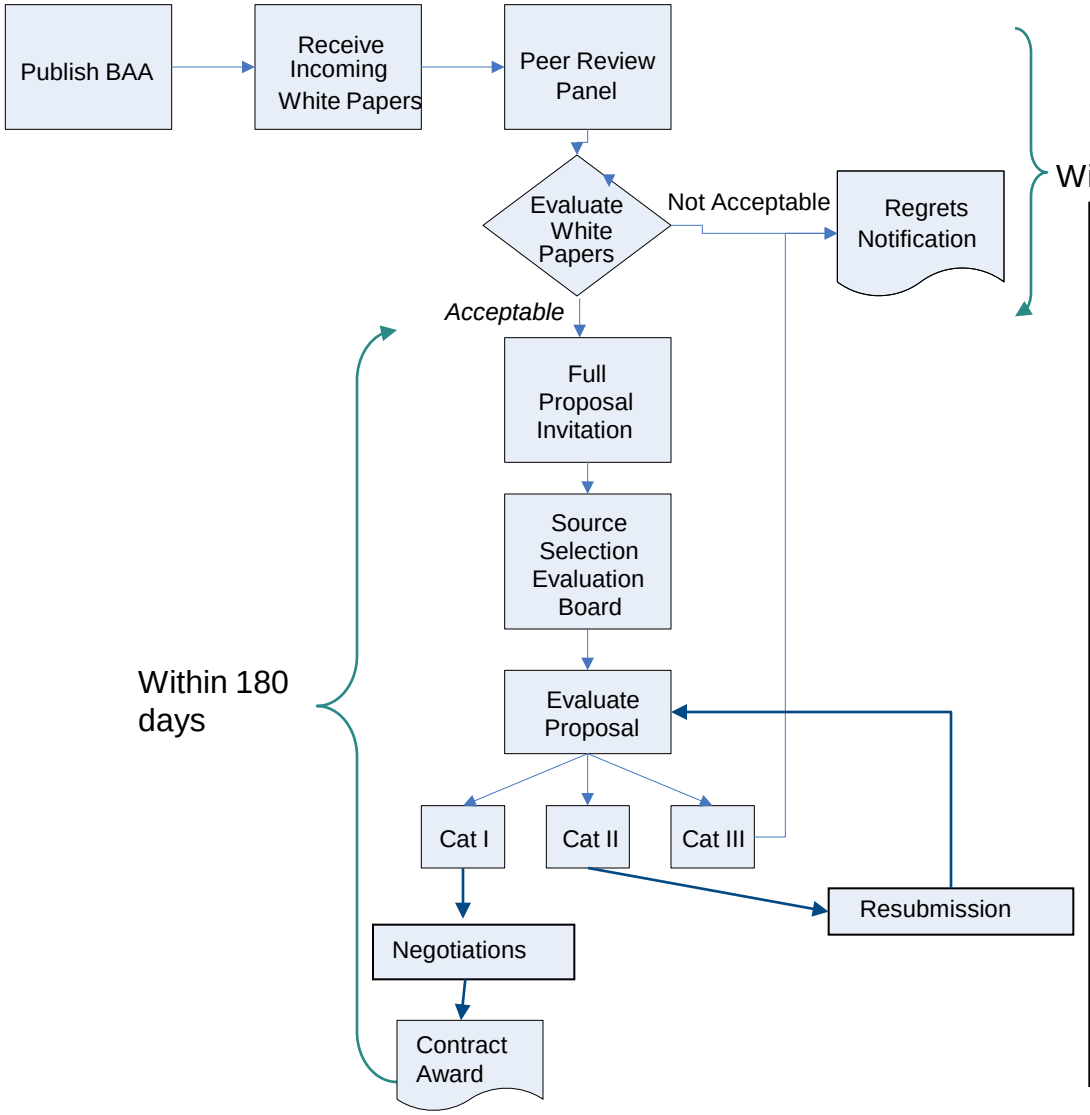
## "Rolling" BAA BARDA CBRN11-100-SOL- 00009

**Eric Espeland**
**CBRN Project Officer**
**BARDA**

# Purpose of the CBRN BAA

- Identify innovative and promising technologies for advanced development across CBRN Research Areas of Interest
  - Vaccines
  - Antitoxins and Therapeutics
  - Antimicrobial Drugs
  - Radiological/Nuclear Threat Countermeasures
  - Chemical Threat Countermeasures
  - Diagnostics
- Accelerate contract awards with a flexible solicitation
- Build a sustainable advanced development program to meet PHEMCE implementation plan goals and mature MCMs for eventual FDA approval and possible inclusion in the Strategic National Stockpile.

# Overall BAA Process




Cat I Well conceived scientifically & technically sound proposals important to program objectives. Recommended for negotiation and possible acceptance, subject to funds availability.

Cat II Scientifically & technically sound proposals with potential to advance program goals and objectives, provided substantial, further development. Need for changes and additional data/explanation is significant enough to require revised proposal. If invited for new proposal, a new technical review may be required to determine reassigning to Cat I. Cat II proposals are handled at lower priority than Cat I and are not guaranteed to be invited for resubmission.

Cat III Proposals not technically sound or do not meet program goals and objectives. Cat III have lowest priority and will be rejected.

# Areas of Interest

- Section within the BAA that identifies BARDA's funding targets for CBRN programs
- Areas of Interest under the CBRN BAA
  - Vaccines
  - Antitoxins and Therapeutics
  - Antimicrobial Drugs
  - Radiological and Nuclear Threat Countermeasures
  - Chemical Threat Countermeasures
  - Diagnostics
- Special Instructions used to target specific needs
  - Will be released as amendments to the CBRN BAA
  - Monitor FedBizOpps

# CBRN Broad Agency Announcement

## CBRN BAA History

- First BARDA Broad Agency Announcement issued in 2009
- Implemented as a 'rolling' BAA with renewals in 2010, 2011, 2012
- Foundation for implementation of the SST and Flu BAAs

## Success

- 22 contracts have been awarded across all 6 CBRN areas of interest
- ~$375.7M has been awarded through June 2012
- ~1.37B assuming all base and contract options are exercised
- Resulted in a robust ARD product pipeline to meet PHEMCE goals for CBRN

# Key Items to Remember…

- Read the BAA
- Communications
  - Recommend a pre-submission Tech-Watch meeting with staff
  - All pre-award communications must flow through Contracting Officer
  - Period following white paper submission consists of no communication
  - until decision letter is received
- All White Paper proposals should be sent to:
- CBRNBAA12.os@hhs.gov
- Notification of White Paper decisions
- Continue monitoring FedBizOpps

# BARDA Broad Agency Announcement
# Advanced Development of Medical Countermeasures for Pandemic Influenza

**Matthew Lawlor, PhD**
**Project Officer, Influenza BAA**
**BARDA**

# General Guidance

- Use FLU-BAA@HHS.GOV for all communications
  - Specify the Area of Interest or ADMIN in the subject line

- Assess maturity of technology using the appropriate Technology Readiness Level (TRL) criteria
  - All activities at a given TRL must be completed to rate a technology at that TRL
  - If technology is insufficiently mature, NIH and DOD solicitations may be more applicable

- Key elements to include in a quad chart and white paper
  - Maturity of technology, and data to justify the TRL rating
  - Clear project plan with key activities and milestones
  - Clinical and public health benefit of proposed project

# Influenza BAA Areas of Interest

**1) Personal Protective Equipment (Masks and Respirators)**

- Address essential attributes (functionality, usability, comfort, decontamination and reuse, cost efficiency, durability)
- Applicable for all ages (pediatric through adult)

**2) Ventilators**

- Support development of next-generation technologies to increase availability of ventilators during public health emergencies
- Key considerations include ease of use, portability, low cost, surge production, and use in patient populations from neonates to adults

**3) Rapid Diagnostics**

- Better point-of-care testing to improve patient treatment and management
- Relevance to clinical settings, especially point-of-care and near-patient venues
- Emphasis on innovation and increased capability

# Influenza BAA Areas of Interest

## 4) Influenza Therapeutics

- Focus on novel mechanisms of action, combination therapies, and utility in at-risk populations (e.g., pediatrics)
- TRL 6 maturity for an influenza indication is required
  - Antiviral therapeutics for treatment of influenza
  - Multi-purpose, broad-spectrum therapeutics with focus on influenza indication

## 5) Influenza Vaccines

- TRL 6 maturity is required
- Develop recombinant technologies applicable for multiple subtypes
- Emphasis on stimulating broadly protective immune responses
- Enhancements to production capabilities (improved methods for reagents, seed virus production, potency testing, etc.)

# SST Innovations BAA: Science and Technology Platforms Applied to Medical Countermeasure Development

**Brian Dattilo, PhD.**
**SST Project Officer**
**BARDA**

# SST BAA Overview

- **History**
  - Originally issued July 9, 2009
  - Reissued January 1, 2011 and June 20, 2012

- **Success**
  - Nine (9) contracts have been awarded across all of the previous four (4) areas of interest
  - ~$75M obligated to-date

# SST BAA Intent

- **Same overall intent as previous two BAAs**
  - Looking for new ideas that will improve our capabilities to prepare for and respond to public health emergencies
  - SST BAA focuses more on technologies and capabilities than developing products for specific threats (CBRN and flu focus on specific threats)

# Area of Interest Changes

- **New AOI #3 to address Goal 4 of the BARDA Strategic Plan: Therapeutics to treat novel and emerging pathogens**
  - 3.1 Therapeutics such as small molecule immune modulators, anti-inflammatory agents, and regulators of innate immunity
  - 3.2 Therapeutics with broad-spectrum mechanisms of action that target a host-response such as presentation of cell-surface markers of infection
  - Does not include pathogen-specific MCMs (e.g. broad-spectrum antimicrobials) or advanced development of immune-modulators applied to influenza

# Area of interest Changes (cont.)

- **Areas of Interest (AOI) 2 and 3 were combined into one – AOI#2: Formulation, delivery, and manufacturing improvements**
  - 2.1 Formulation chemistry, novel adjuvants, protein stabilization, and delivery technologies
  - 2.2 Innovative methods in bioprocess development and bulk/fill-finish manufacturing
- **Area of Interest #4: Methods and technologies to advance development of tests for rapid diagnosis of human injury and infection**
  - 4.1 Accelerating biomarker discovery predictive of clinical disease applicable for use with multiple platforms
  - 4.4 Collecting, processing (e.g. concentrating), and preparing human specimens for laboratory diagnostic testing

# SST BAA Team

- **SST-BAA@hhs.gov is the central mailing address for all communication**
- **Contract team**
  - Carolyn Keeseman (Contracting Officer)
  - Elizabeth Steiner (Contracting Specialist)
- **Program Team**
  - Brian Dattilo
  - Alan Goldberg (CMI contractor)
  - Adam Clark
  - Stephanie Sincock
  - Jonathan Seals

# Other Transactions and the BAAs
# What you need to consider…

**Glynis Fisher**
**Section Chief of CBRN R&D Contracts**
**AMCG**

# What is an OT?

- An **Other Transaction** is a transaction other than a procurement contract, grant or cooperative agreement.

- An **OT for Advanced Research** (OTAR) is a non-acquisition instrument used when the principal purpose is to further advanced research and development where the principal performer is a new R&D player or a Consortium

# When Can an OTAR Be Used?

- Only when one of the following circumstances exists:

  1) When there is Participation of a **NEW R&D Player/Commercial Firm**

  2) Where the use of a **consortium** is required to achieve the results of the proposed project or

  3) The DHHS Senior Procurement Executive has approved the use of the OTAR.

# How Can a Company Express Interest in an OTAR?

- ASPR AMCG must use competitive procedures to the maximum extent practicable and anticipates making awards from our Broad Agency Announcements
- Potential offerors should review the currently available BAAs
- When submitting a White Paper, indicate why an OT is the appropriate instrument

# Next Steps

- Your White Paper will be evaluated on its technical merit.
- If your White Paper has sufficient technical merit, ASPR/AMCG will internally evaluate whether an OTAR is appropriate.
- If ASPR/AMCG makes a determination that an OTAR is the appropriate instrument for your project, you will be encouraged to seek an OTAR.
- If not, you will be encouraged to seek a contract.

# Why OTARs are Important?

- OT's provide opportunity for:
  - AMCG to reach out to new, non-traditional government contractors
    - Broaden the industrial base
    - Encourage Commercial investments in critical Bio-medical countermeasures
  - AMCG to create new relationships with existing government contractors to increase efficiencies and effectiveness of  performance over existing contractual relationships

# Benefits of OTs

The process is viewed as a win-win for the Government and Contractors because OTs for Research:

- Allow for Generally Approved Accounting Procedures rather than Government cost accounting standards
- Allow cost and pricing data and certifications to be negotiable rather than mandatory
- Allow for commercially friendly intellectual property provisions
  - Handling of patents
  - Handling of technical data

# Benefits of OTs (cont.)

- Allow partnering between AMCG and “teams” of entities generally called consortium
- Allow for flexibility in management of agreements
  - Innovative business arrangements
  - Open lines of communications among “team”