



United States Department of

Health & Human Services

Office of the Assistant Secretary for Preparedness and Response



The BARDA Multi-Broad Agency Announcement Pre-Proposal Conference 2013

Hubert H. Humphrey Building - The Great Hall
September 4, 2013



BARDA Mission

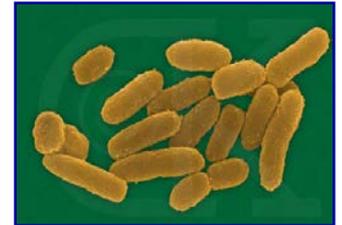


Develop and provide countermeasures for CBRN threats, pandemic influenza, and emerging infectious diseases by product development, stockpile acquisition, building manufacturing infrastructure, and product innovation.



Tip O'Neill Building (FOB8)
ASPR: Resilient People. Healthy Communities. A Nation Prepared.

- CBRN Threats
 - Chemical nerve agents & cyanide
 - Radiological and Nuclear agents
 - Biothreats (anthrax, smallpox, plague, tularemia, VHF, and others)
- Pandemic influenza
- Emerging infectious diseases



Medical Countermeasures



Medical Devices



Antimicrobials



Diagnostics

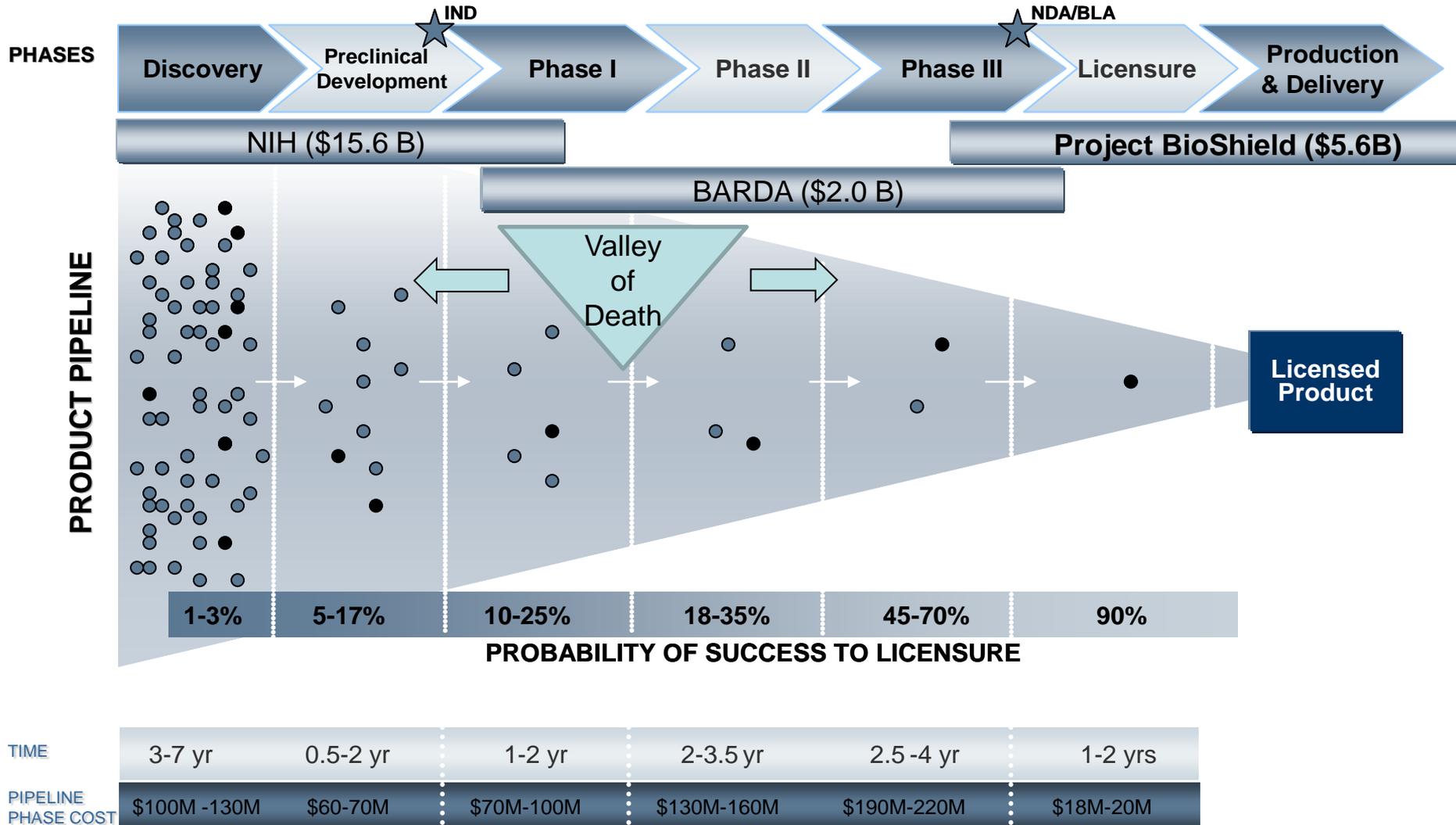


Vaccines



Therapeutics

CBRN MCM Development is Expensive, Lengthy, & Risky



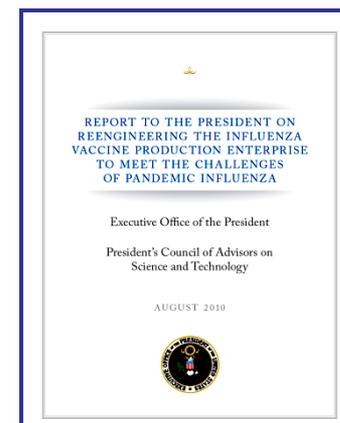
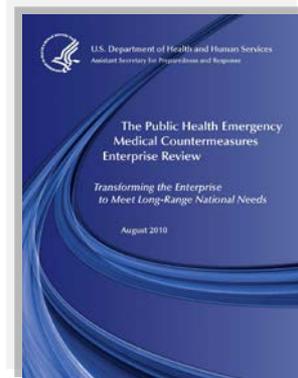
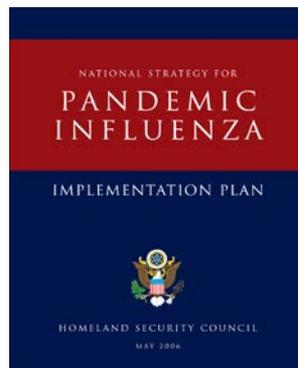
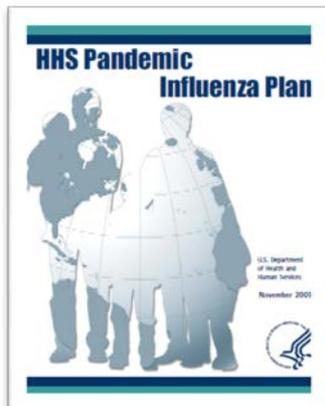
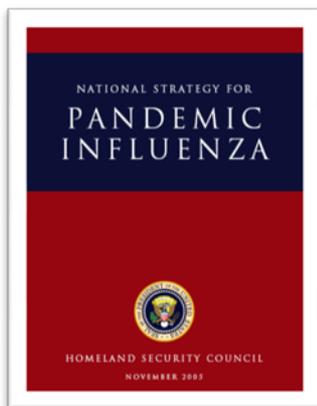


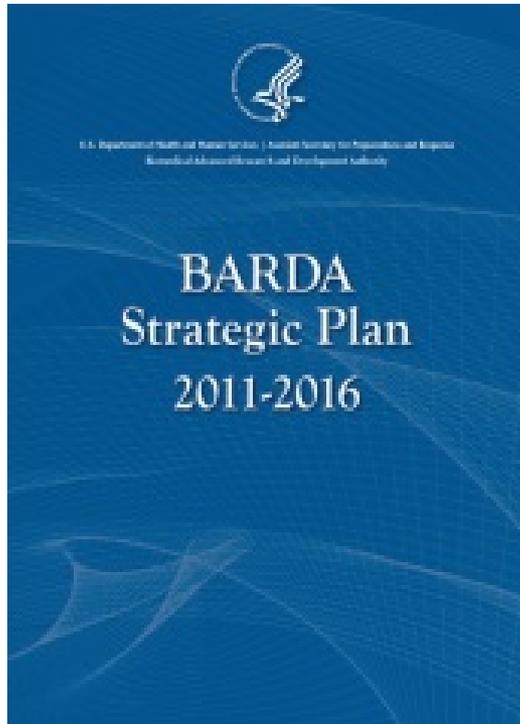
2012 PHEMCE Strategy and Implementation Plan

- ***PHEMCE Strategy and Implementation Plan*** will set the course for federal medical countermeasure (MCM) activities for next five years
 - Builds upon 2007 SIP, which established civilian MCM priorities with focus on advanced research and development
- ***Strategy [June 2012]*** – Mission, scope, goals, and objectives
- ***Implementation Plan [December 2012]*** – Prioritized programs to accomplish goals and objectives identified in Strategy

Pandemic Influenza Strategic Plans & Reviews

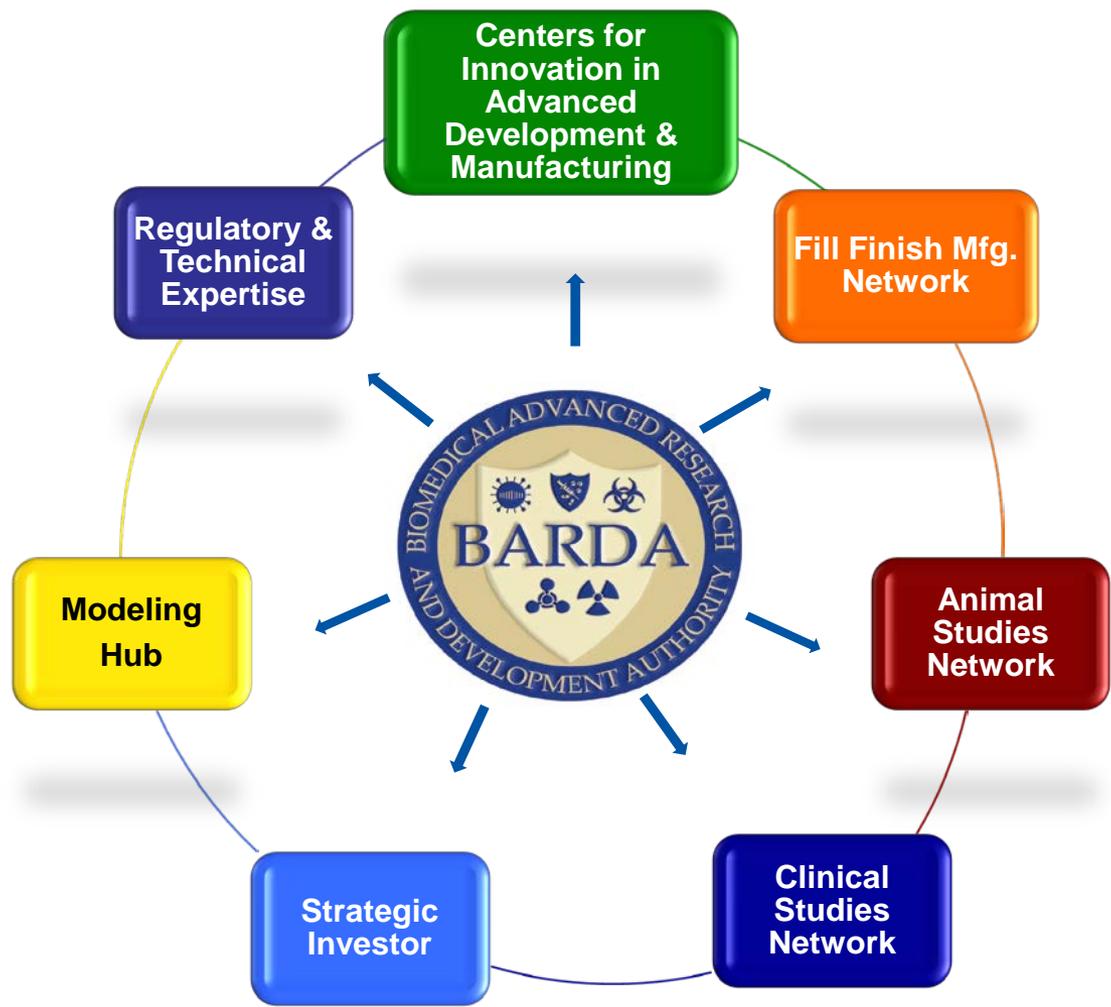
- The requirements addressed by the BARDA Influenza Portfolio are derived from a number of documents that guide the US Government efforts to prepare for pandemics
 - *National Strategy for Pandemic Influenza* (Nov 2005)
 - *HHS Pandemic Influenza Plan* (Nov 2005)
 - *Nation Strategy for Pandemic Influenza Implementation Plan* (May 2006)
 - *Public Health Emergency Medical Countermeasures Review* (Aug 2010)
 - PCAST report on *Reengineering the Influenza Vaccine Production Enterprise* (Aug 2010)





- GOALS
 - Abundantly 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 Core Services





BARDA 2013



- 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



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





CBRN Broad Agency Announcement Areas of Interest and Priorities for Focus

Gerald R. Kovacs
Director, CBRN Programs

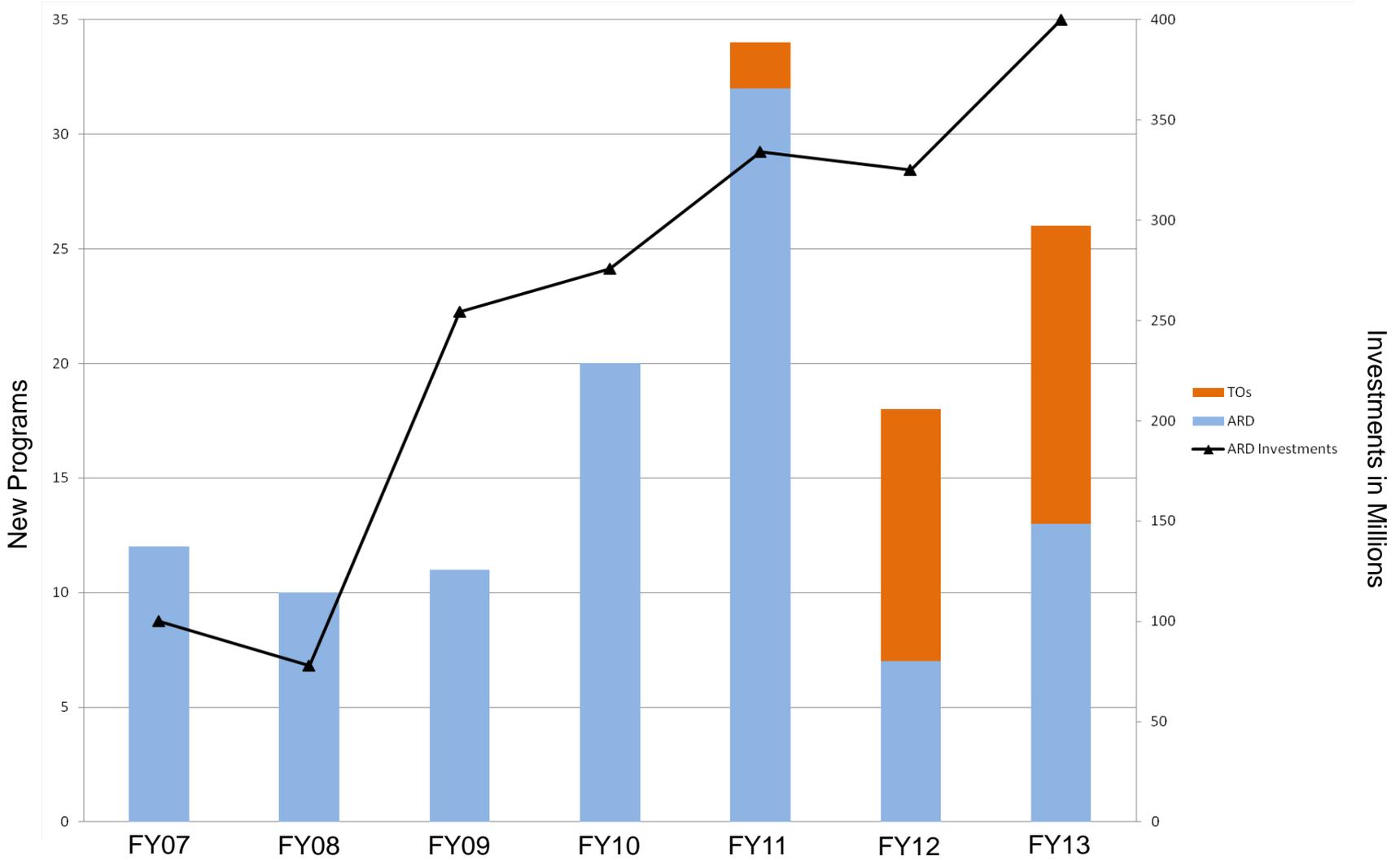
BARDA/ASPR/HHS
4 September 2013



- BARDA CBRN MCM Broad Agency Announcement (BAA) announces annually to the public BARDA's intentions and priorities in funding development of CBRN MCMs since 2009
- The BAA has served as an excellent tool to build a robust pipeline of 80+ CBRN MCM candidates
 - Nearly all of the BARDA CBRN MCM development projects emanate from the BAA
 - Special Instructions afford highlighted areas of emphasis
 - Fast and flexible
- BAA stats
 - Total number of White Papers received: **424**
 - Total number of Full Proposals: **106**
 - Total number of awards: **28**



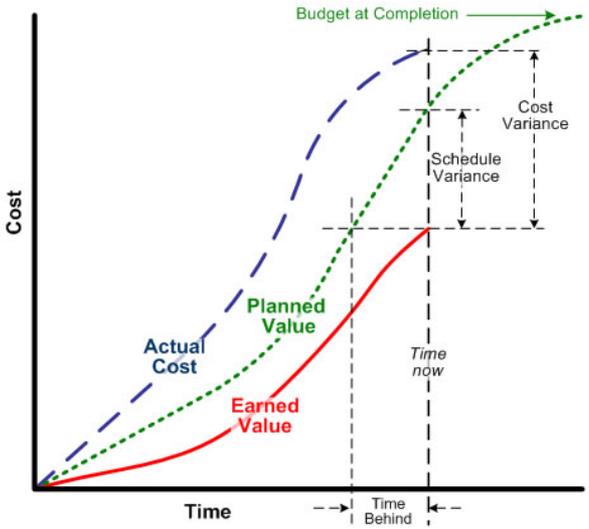
Advanced R&D Investments by Year



- In-Process Reviews
- Source Selection and Milestone Decision Authorities
- Solicitations Open Year Round
- Five Year Budgets
- Earned Value Management



Now Open: Broad Agency Announcements
 Broad Agency Announcements for Advanced Research and Development of Medical Countermeasures for Pandemic Influenza and Chemical, Biological, Radiological and Nuclear Threats...



- Products
 - Raxibacumab – monoclonal antibody (FDA approved 2012)
 - Botulinum antitoxin – equine polyclonal (FDA approved 2013)
 - Anthrax Immune globulin – human polyclonal (approval in 2014/15)
 - Anthrax vaccine adsorbed – sterile filtrate (approval in 2014/15)
 - Modified Vaccinia Ankara – live attenuated vaccine (approval in 2016, EU approved in 2013)
 - ST-246 – smallpox antiviral (approval in 2017)
- Total R&D investment ~\$2.2 B
- ~ \$373 M per approved product
- 7- 8yr to FDA approval from Phase I/II

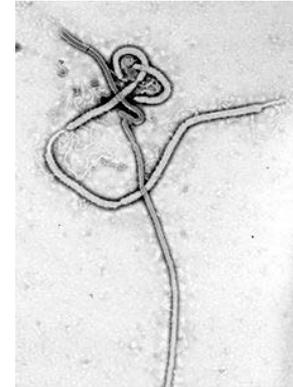


- **De-emphasizing mature programs**
 - Smallpox – vaccines and antiviral drugs
 - Anthrax antitoxins
 - Botulinum antitoxins
 - Field use MCMs to treat Acute Radiation Syndrome
 - Anticonvulsants
 - Biodosimetry tools
- **Emphasizing programs to fill unmet gaps**
 - Therapeutics for hemorrhagic fever viruses
 - Broad-spectrum antimicrobials for Burkholderia
 - Thermal burn products
 - Biothreat diagnostics



• Vaccines

- Smallpox vaccines
 - Enhancements to current vaccines in SNS
- Anthrax vaccines
 - 12 months of stability
 - Non-inferiority to AVA in non-clinical study



• Antivirals & Antitoxins

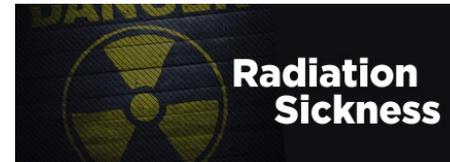
- Accepting proposals for therapeutics for viral hemorrhagic fever viruses
- Enhancements to current antitoxins in SNS

• Broad Spectrum Antimicrobials

- TRL raised to indicate lead compound must be identified
- *In vitro* resistance data must be submitted
- Favorable review for proposals that address pediatric subjects, propose cost sharing and have supportive responses from the FDA concerning development plan for candidate

• Rad/Nuc/Chem

- No longer accepting proposals for “field use” MCMs (cytokines) for anti-neutropenics
- Chem MCM candidates must be TRL-5 or higher (i.e., submitted pre-IND)
- No longer accepting proposals for products to replace diazepam (anticonvulsant)

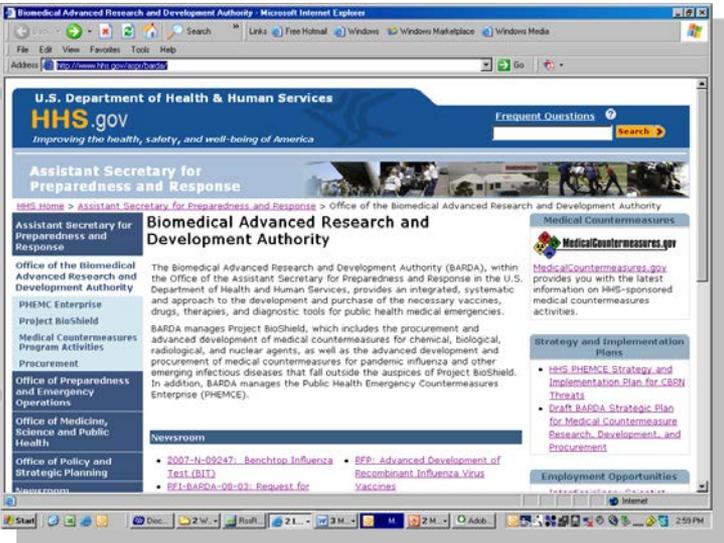


• Biodosimetry/Diagnostics

- Biodosimetry products must have shown biomarker feasibility
- Encouraging submissions for biothreat diagnostics (material threats only)



Contact Us



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BARDA Influenza Division

BAA 2013-2014

Robert C. Huebner, Ph.D.
Director, Influenza Division

September 4, 2013

BARDA Mission

Develop and provide countermeasures for CBRN threats, pandemic influenza, and emerging infectious diseases by product development, stockpile acquisition/building, manufacturing infrastructure building, and product innovation.



Preparing for Influenza Pandemics which are Unpredictable Events



Credit: US National Museum of Health and Medicine

1918: “Spanish Flu”
A(H1N1)
20-100 m deaths
~500,000 in US

1957: “Asian Flu”
A(H2N2)
1-4 m deaths
60-80,000 in US

1968: “Hong Kong Flu”
A(H3N2)
1-4 m deaths
~30,000 in US

“2009 H1N1 Pandemic”

2012 H3N2v, 2013 H7N9?



U.S. Pan Flu MCM Strategic Goals



- Vaccines
 - Goal #1: Establish and maintain a dynamic pre-pandemic influenza vaccine stockpile available for 20 M persons (2 doses/person) *or more depending on vaccine mfg. capacity, results of dose-sparing adjuvant studies and prime-boost immunization studies: H5N1 vaccine stockpiles - Achieved*
 - Goal #2: Provide pandemic vaccine to all U.S. citizens within 6 (or less) months of a pandemic declaration: pandemic vaccine (600 M doses)
- Antivirals
 - Goal #1: Provide influenza antiviral drug stockpiles for pandemic treatment of 25% of U.S. population (75 M treatment courses) *and federal share of antivirals for outbreak prophylactic usage as a community mitigation measure as shared responsibility - Achieved*
 - Goal #2: Provide influenza antiviral drug stockpiles for strategic limited containment at onset of pandemic (6 M treatment courses) - Achieved
- Diagnostics
 - Goal #1: Develop new high-throughput laboratory, point-of-care (POC), and home detection influenza diagnostics for pandemic influenza virus detection
- Other Countermeasures
 - Goal #1: Develop and acquire other MCMs including syringes/needles, masks/respirators, ventilators & other supplies

National Strategy for Pandemic Influenza (Nov 2005) and HHS Pandemic Influenza Plan (Nov 2005) www.pandemicflu.gov

ASPR: Resilient People. Healthy Communities. A Nation Prepared.

All-Hazards Principle





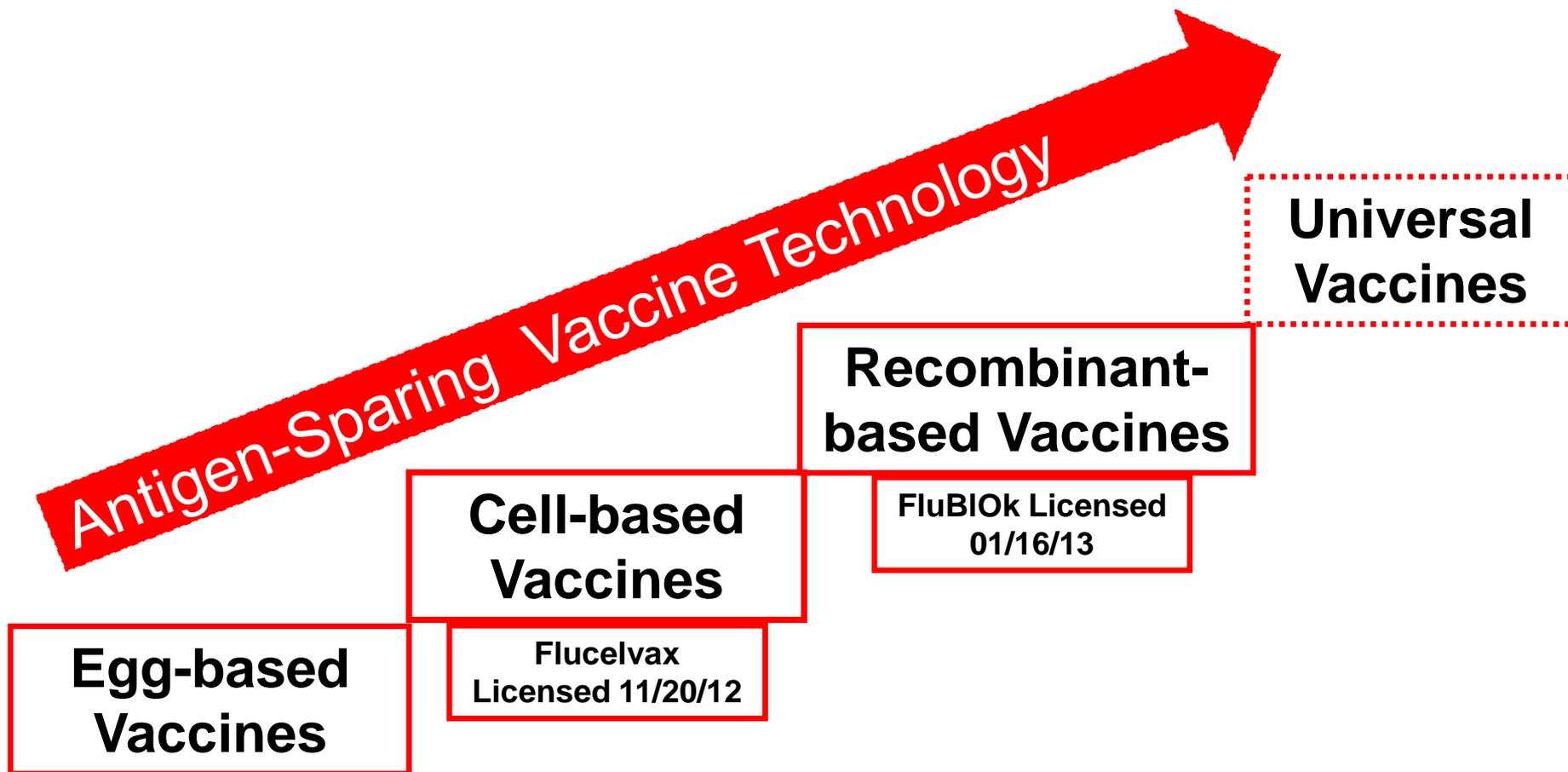
BARDA MCM Integrated Portfolio Matrix Approach



	Vaccines	Antivirals	Diagnostics/ Respiratory Devices
Advanced Development	Cell-based Antigen-sparing Recombinant & Molecular	Peramivir Laninamivir Fludase Nitazoxinide	<u>Diagnostics</u> Point of Care Clinical Lab Next Generation Ventilators
Stockpiling & Acquisitions	H5N1 Pre-Pandemic Vaccine H1N1 Vaccines	Federal & State Stockpiles IV Antivirals: EUA	Masks & Respirators
Infrastructure Building	Retrofit Existing Mfg Facilities Build New Mfg Facilities (Cell/CIADM) Egg-based Supply		



National Pandemic Influenza Vaccine Development Strategy Is Multi-Step & Integrated Approach



“More and better vaccines sooner”

ASPR: Resilient People. Healthy Communities. A Nation Prepared.



BARDA Influenza Division BAA 2013-2014

Filling in the medical countermeasure gaps



Area of Interest #1 & #2



- Area of Interest #1: Personal Protective Equipment (Mask & Respirators) for Influenza Infection and All-Hazards
 - Offerors for Area of Interest #1 should describe the maturity level of their proposed technology. Proposed activities should offer clinical and public health benefits.
 - 1.1 Development and characterization of improved respiratory protective devices (RPD).
- Area of Interest #2: Full-Featured Continuous Ventilators for Influenza Infection and All-Hazards
 - At this time BARDA is not accepting any submissions for Area of Interest #2.
 - Watch this space



Area of Interest #3

- Area of Interest #3: Clinical Influenza Test Systems and Diagnostic Tools
 - Proposed activities should offer beneficial clinical and public health impact.
 - 3.1 Development of improved respiratory specimen collection materials and methods.
 - 3.2 Development of advanced sequence detection methods for identifying novel influenza strains.
 - 3.3 Development of expanded respiratory pathogen tests on existing test platforms.
 - 3.4 Rapid identification of antiviral resistant influenza strains.



Area of Interest #4



- Area of Interest #4: Influenza Therapeutics
 - 4.1 Antiviral Therapeutics for Treatment of Influenza A & B Infection
 - Therapeutics proven to reduce influenza virus replication in cell culture and animal models are examples of therapeutics that would be considered. Therapeutics with a mechanism of action that precludes the rapid emergence of drug resistance and with proven broad influenza strain susceptibility are preferred. Combination therapeutics that include novel investigational compounds and licensed therapeutics would also be applicable.



Area of Interest #5



- Area of Interest #5: Influenza Vaccines
 - Under this Area of Interest, BARDA is seeking technologies achieving TLR 6 or greater that will improve preparedness against influenza subtypes with pandemic potential.
 - 5.1 Advanced development of novel influenza vaccine candidates. Support for advanced development of novel influenza vaccine candidates with the potential to stimulate a broader and more efficacious effective immune response than currently available products. Proposed activities should enable improvements to key vaccine attributes, including dose schedule, time to onset of protection, induction of improved immunogenicity, broader cross-protection across influenza A virus subtypes, and duration of protection. Use of approved or novel adjuvants to achieve enhanced or broadened immunogenicity may also be a component of the advanced development program.



Thank You for Your Attention

Robert Huebner, Ph.D.

Director of Influenza Division

Biomedical Advanced Research and Development Authority (BARDA)

US Department of Health and Human Services

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Room G644

Washington, DC

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United States Department of

Health & Human Services

Office of the Assistant Secretary for Preparedness and Response



Strategic Science and Technology (SST) Innovations BAA: Science and Technology Platforms Applied to Medical Countermeasure Development

**Adam M. Clark, PhD.
SST Project Officer
BARDA**



SST BAA Overview



- **History**

- Originally issued July 9, 2009 and re-issued January 1, 2011 and June 20, 2012
- BAA-13-100-SOL-00014 was issued July 31, 2013

- **Success**

- Ten (10) contracts have been awarded across all of the previous four (4) areas of interest
- ~\$105M obligated to-date

- **New Area of Interest for 2013**



SST BAA Intent



- **Same overall intent as previous 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)
 - Support innovation through development of platform technologies that enhance capabilities for development and manufacturing of MCMs

- **Narrowed focus for the upcoming year**



SST BAA



- **Specific interest exists in the promotion of science and technology advancements focused on technologies that facilitate administration of medical countermeasures during a public health emergency.**
- **The specific application of the platform technologies will be focused on biodefense, pandemic influenza, or other emerging infectious diseases (EID).**
- **Offerors should propose platforms having a maturity level equal to or greater than a Technology Readiness Level (TRL) of 3**
- **Submission Deadlines:**
 - **October 30, 2013 January 30, 2013 April 30, 2014 July 30, 2014**



Area of Interest



- **SST Area of Interest #1: Technologies that facilitate administration of medical countermeasures during a public health emergency**
 - 1.1 Technologies, such as jet injectors or autoinjectors, that may allow vaccines or drugs to be delivered by parenteral administration with limited access to trained medical personnel resources
 - 1.2 Technologies, such as oral or transdermal delivery, that allow non-parenteral administration by the user and may deliver the countermeasure over a longer time interval



SST BAA Team



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



Broad Agency Announcements (BAA)

AMCG Contracting Officer



Process Overview



❖ White Papers vs. Full Proposals

- White Papers strongly encouraged
- Following a White Paper submission, a decision letter is sent notifying the Offeror whether a full proposal is requested

❖ Timing

- White Paper Decision letters – 90 calendar days after submission deadline (or receipt)
- Cyclical review dates

❖ Communication

- Contracting Officer will be the *only* point of communication
- “Blackout period” for communication with technical team



Additional Information Available



❖ Business Toolkit.

- If you have not yet had a Government contract/award (or just new to BARDA), a “Toolkit” including samples and additional Earned Value Management information is available. The Business Toolkit can be found on PHE.gov , under the “About ASPR” tab, then “Office of Acquisition Management, Contracts & Grants” link.

❖ Program and Contracting Office Availability.

- In addition to TechWatch meetings and online resources, please feel free to contact the Contracting Professionals and Program Officers listed in the BAA, as appropriate.



Helpful Information



New additions available this year:

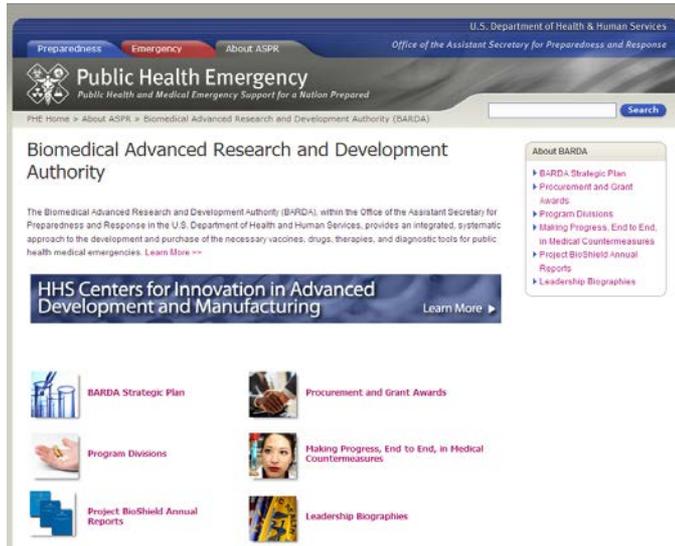
- Frequently Asked Questions (FAQ):
<http://www.phe.gov/about/amcg/Documents/baa-faq.pdf>
- Information is available on Other Transaction Agreements, including sample agreements:
<http://www.phe.gov/about/amcg/Pages/default.aspx>



Conclusion



Thank you for your interest in BARDA and the BAA process.



PHEMCE:

URL: <http://www.medicalcountermeasures.gov>

BARDA e-mail: BARDA@hhs.gov

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MedicalCountermeasures.gov

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Session Closing Notes



- **Please exit through the rear of the auditorium into the Great Hall**
- **For those who scheduled one-on-one meetings with BARDA, there will be four sessions following the presentations. Meetings will be kept to 15 minutes. Please be on time.**
- **AMCG staff will be available for contracting questions**
- **Reminder: All guests of the Humphrey building need to be escorted by ASPR Staff when leaving this area (i.e. bathroom/anywhere)**



Save the Date



BARDA Industry Day

November 12-14, 2013

Washington, DC metro area