



*United States Department of*  
**Health & Human Services**

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

# **BARDA Strategic Plan**

**HHS PHEMCE Stakeholders Workshop**  
**Arlington, VA**  
**September 25, 2008**

**Dr. Robin Robinson**  
Director  
HHS/ASPR/BARDA

# BARDA Strategic Plan 2008



## BARDA Strategic Plan 2008

**DRAFT**

**For Public Comment  
 October 2008**

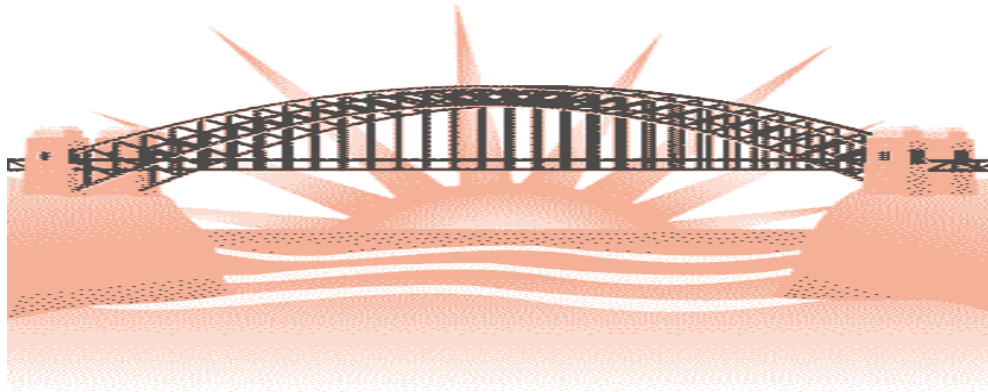


U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
 ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE  
 BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY

## BARDA Strategic Plan 2008 Contents

1. Executive Summary.....	3
2. BARDA Introduction.....	4
2.1. Background.....	4
2.1.1. BARDA's Role.....	4
2.1.2. BARDA History.....	4
2.2. Meeting The Mission.....	5
2.2.1. BARDA Goals.....	5
2.2.2. Extramural & Intramural Programs.....	6
2.2.3. Accomplishments.....	6
2.2.4. Challenges.....	6
2.3. The BARDA Organization.....	7
2.4. BARDA's Role In The Public Health Emergency Countermeasures Enterprise.....	8
2.5. BARDA And The National Biodefense Medical Countermeasure Portfolio.....	9
3. MCM Portfolio Approach To Achieving Preparedness.....	10
3.1. Setting Requirements.....	11
3.2. Developing Medical Countermeasures.....	11
3.2.1. Current Development Efforts.....	11
3.2.2. Coordinating And Transitioning Development Programs Across Agencies.....	11
3.2.3. Early Development.....	12
3.2.4. Late Development.....	13
3.3. Establishing And Maintaining Stockpiles.....	14
3.4. Building Infrastructure For Manufacturing.....	15
3.5. Innovation.....	16
4. BarDA Resources.....	17
4.1. Staff Profile.....	17
4.2. Technical Capabilities.....	17
4.3. Program Capabilities.....	18
4.3.1. Program Management.....	18
4.3.2. Acquisition Management System.....	18
4.4. Offices 18	
4.5. Funding.....	19
4.6. Technology Scouting.....	20
4.7. Communications & Stakeholder Engagement.....	20
5. Next Steps.....	22
5.1. Program Direction.....	22
5.2. Capabilities Development Plan.....	22
5.3. Risk Assessment & Mitigation Plans.....	23
5.4. Measures Of Success.....	24
6. Conclusion.....	24

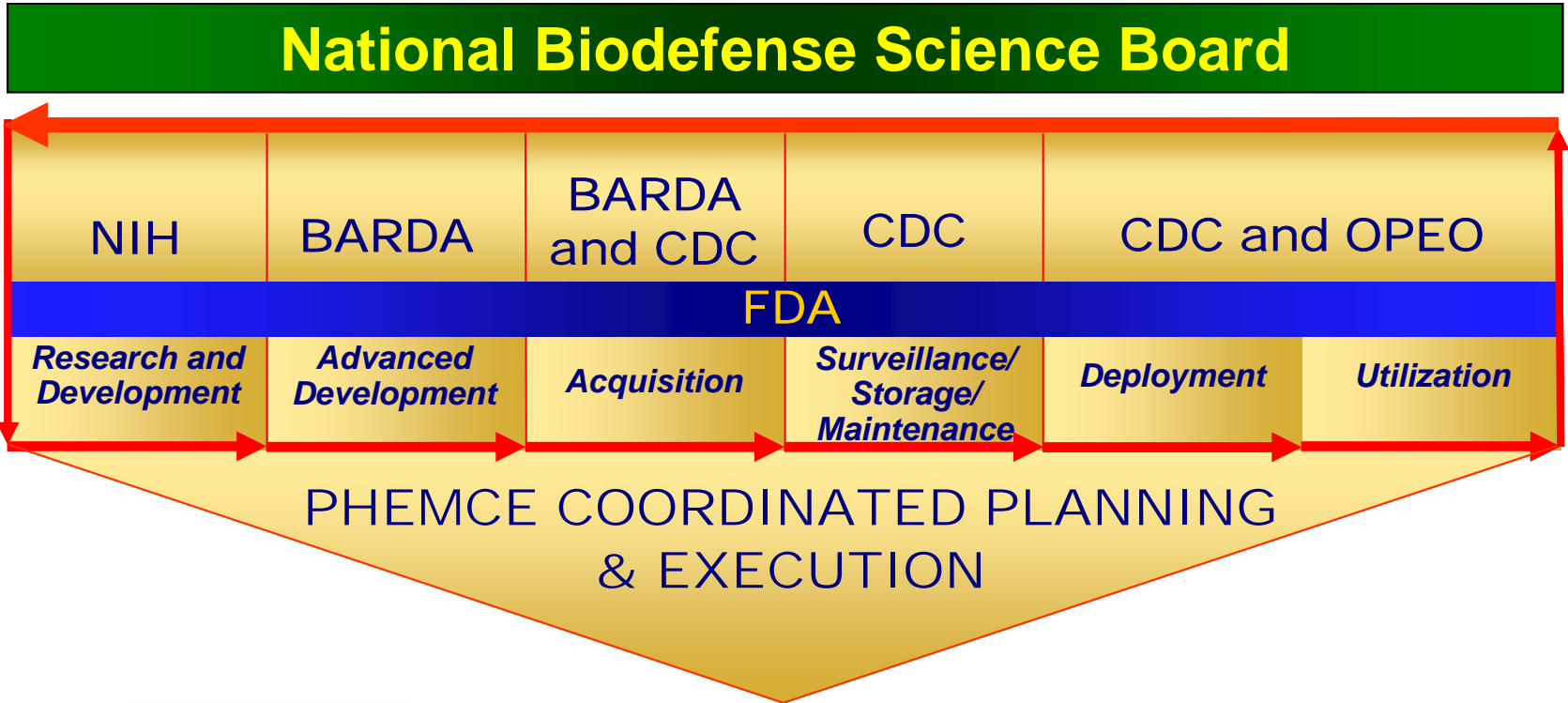
# BARDA Bridging Mission



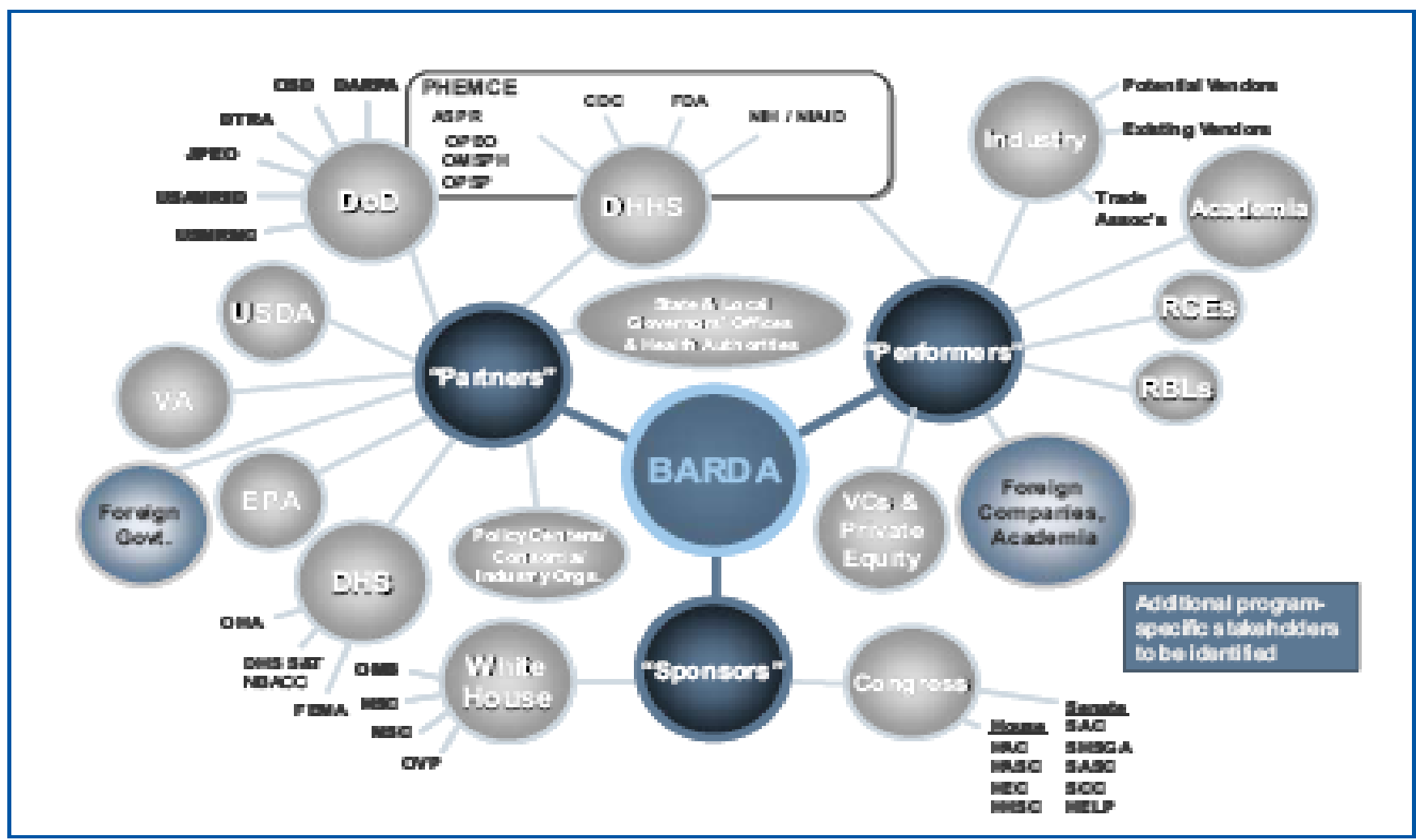
**BARDA = (CBRN + PI + ED)<sup>MCM</sup>**

- Coordination of PHEMCE Enterprise MCM Activities
- Advanced development
- Stockpile procurement & establishment
- Manufacturing infrastructure building
- Innovation

# HHS Public Health Emergency Medical Countermeasures Enterprise



# BARDA Partnerships



# BARDA Lane Assignments

- **BARDA receives from DNS WMD risk assessments**
- **BARDA with NIH & Enterprise members develops MCM requirements**
- **NIH supports MCM discovery, pre-clinical, and proof of concept Phase 1 studies**
- **BARDA supports MCM advanced development & commercialization towards FDA-licensure**
- **BARDA acquires MCMs for initial stockpiles until product licensure**
- **CDC/SNS acquires MCMs as licensed products**



# **BARDA Bridges of Product Development & Acquisition**

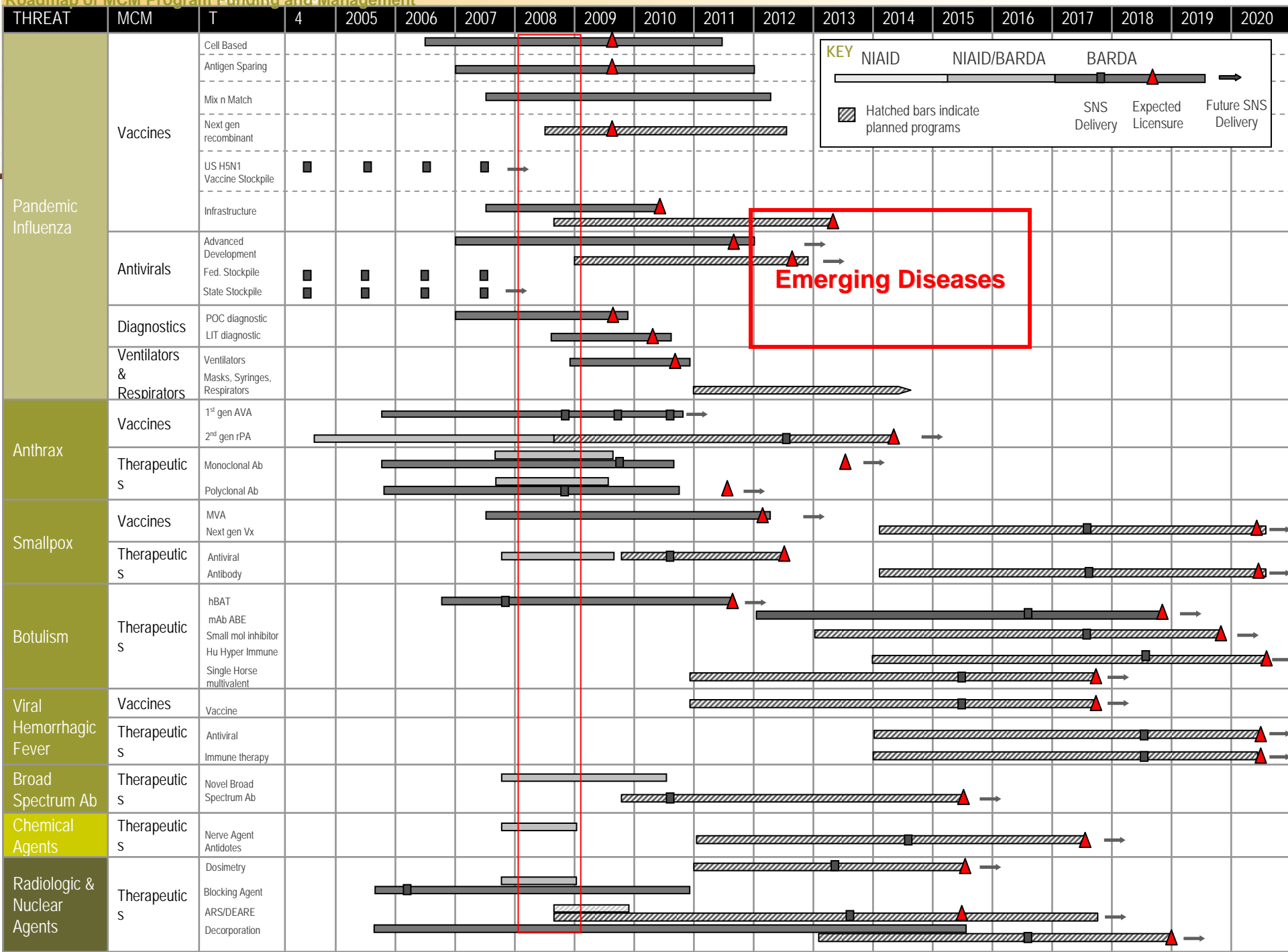
- **Utilize robust product pipeline at early stage development**
- **Nurture MCM platform technology development for cross-indication usage**
- **Foster focused and continued advanced development/commercialization of multiple product types**
- **Implement incremental milestone acquisitions for stockpile establishment with long term commitments**
- **Maintain multiproduct/multimanufacturer portfolio for sustainability & redundancy of preparedness/response**
- **Support supportive & ancillary product/services development & acquisition**

# BARDA Bridges of Product Manufacturing Infrastructure Building

- **Retrofit existing facilities for maximal capacity and flexibility**
- **Support new facility building with multiproduct manufacturing capability**
- **Establish centers of excellence for product development & production for non-commercial products and industry partner assistance**
- **Establish network of formulation/fill-finish manufacturers for emergency production/distribution**



# Roadmap of MCM Program Funding and Management



Emerging Diseases

**KEY**

NIAID      NIAID/BARDA      BARDA

SNS Delivery
  Expected Licensure
  Future SNS Delivery

Hatched bars indicate planned programs

# BARDA Innovation

- Capability to focus support to academia & industry on new ways to make MCMs better in coordination with partners (NIH, DoD, CDC, Industry)
  - Animal models
  - Immune modulation
  - Immunity assessment
  - Analytical assays (potency assays)



# BARDA Website



## BARDA:

URL: [www.hhs.gov/aspr/barda/](http://www.hhs.gov/aspr/barda/)

E-Mail: [BARDA@hhs.gov](mailto:BARDA@hhs.gov)

- **BARDA Strategic Plan (Oct. 08)**
- Upcoming Events
- Acquisitions
- BioShield
- Influenza Programs