



United States Department of

**Health & Human Services**

Office of the Assistant Secretary for Preparedness and Response



# **BARDA Today & Tomorrow: Goals, Priorities, Successes & Challenges**

**BARDA Industry Day  
October 14, 2015**

**Dr. Robin Robinson  
BARDA Director  
ASPR Deputy Assistant Secretary**

# Some Threats Are Very Large: Pandemic Influenza



## 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

**1976 Swine Flu – The “No-Show Pandemic”**

**2009 H1N1 Pandemic**

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

# *Other Threats Are Ominous: High Pathogenic Avian Influenza Viruses*



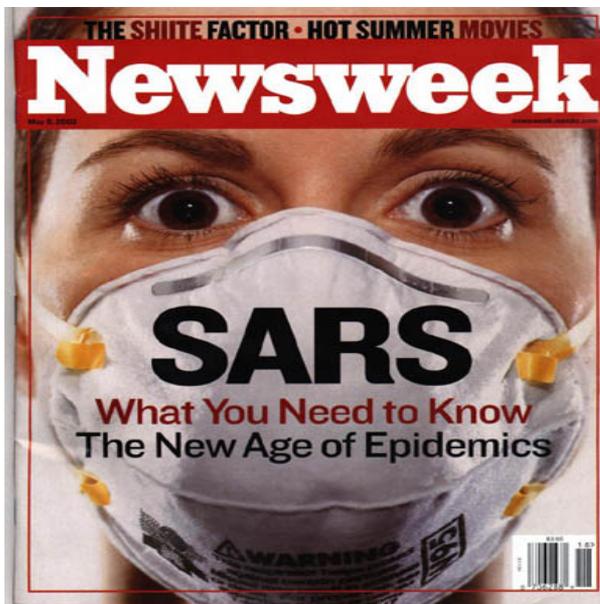
**H5N1**

**1998 - present**



**2013**

# *Some Threats Emerge Re-emerging Infectious Diseases*



**SARS-CoV**  
**2003-2004**



**MERS-CoV**  
**2012-2015**

# Some Threats May Be Man-Made

- Radiological and Nuclear agents
- *Bacillus anthracis* (anthrax)
- *Bacillus anthracis* – Multi-drug resistant (MDR anthrax)
- Botulinum toxins (botulism)
- Variola virus (smallpox)
- *Yersinia pestis* (plague)
- *Franciscella tularensis* (tularemia)
- Hemorrhagic Fever Viruses - Ebola, Marburg
- *Burkholderia mallei* (glanders)
- *Burkholderia pseudomallei* (melioidosis)
- *Rickettsia prowazekii* (typhus)
- Low volatility and volatile nerve agents
- Hydrogen, potassium, and sodium cyanide

**Pillar 1**  
Identify  
and Assess  
CBRN  
Threats



# *Ebola is both a biothreat and an emerging infectious disease*





# Threat-Based Preparedness & Response

# Resilience Chain

Detection  
and Diagnosis

Medical  
Countermeasures

Treating and  
Isolating Sick

Environmental  
Cleanup

Actionable  
Information

Countermeasure  
Dispensing

Protecting  
the Well





# Medical Countermeasures

# Medical Countermeasures



**Medical Devices**



**Antimicrobials**



**Diagnostics**



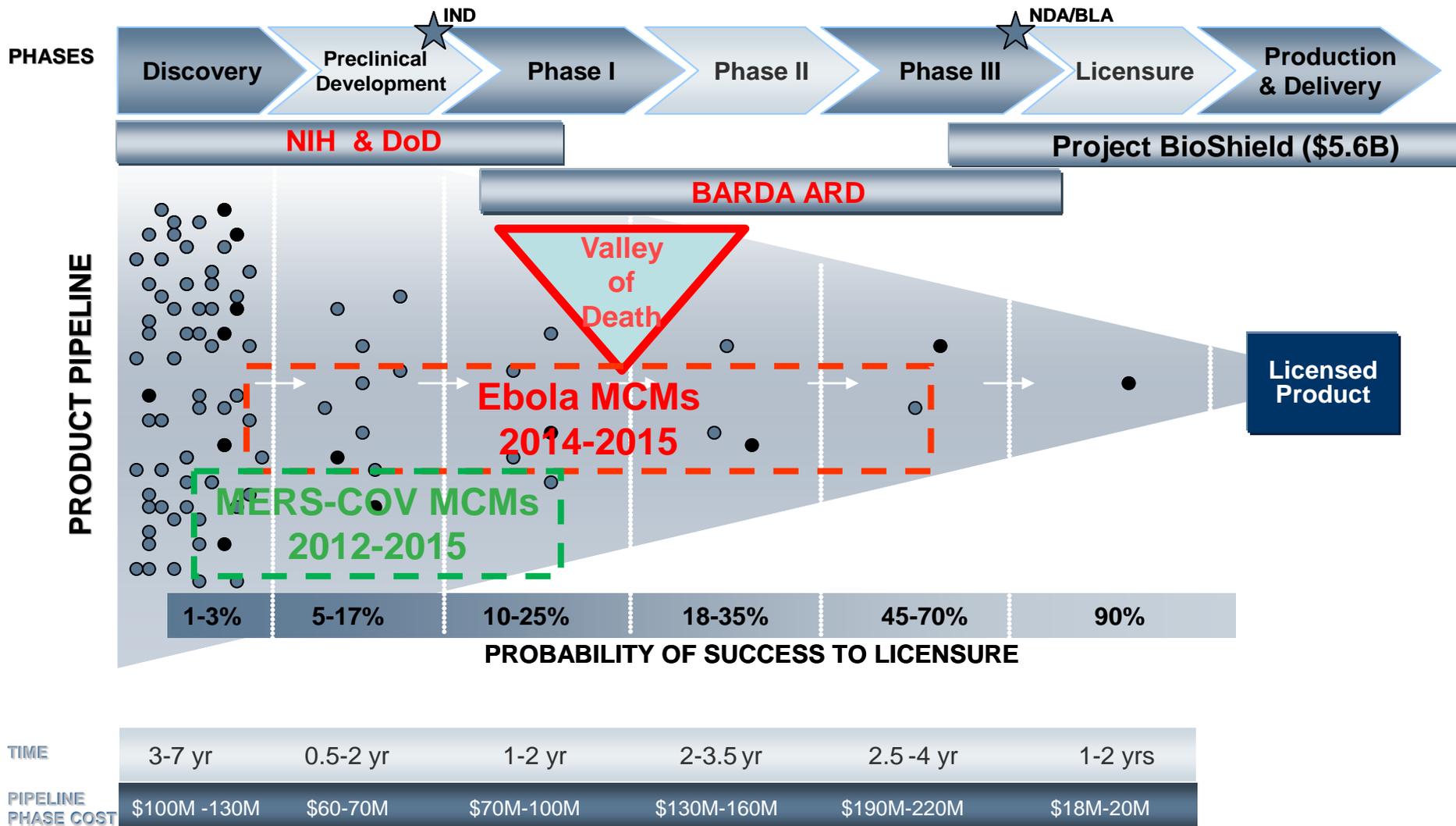
**Vaccines**



**Therapeutics**



# Vaccine & Drug Development is still Expensive, Risky and Lengthy



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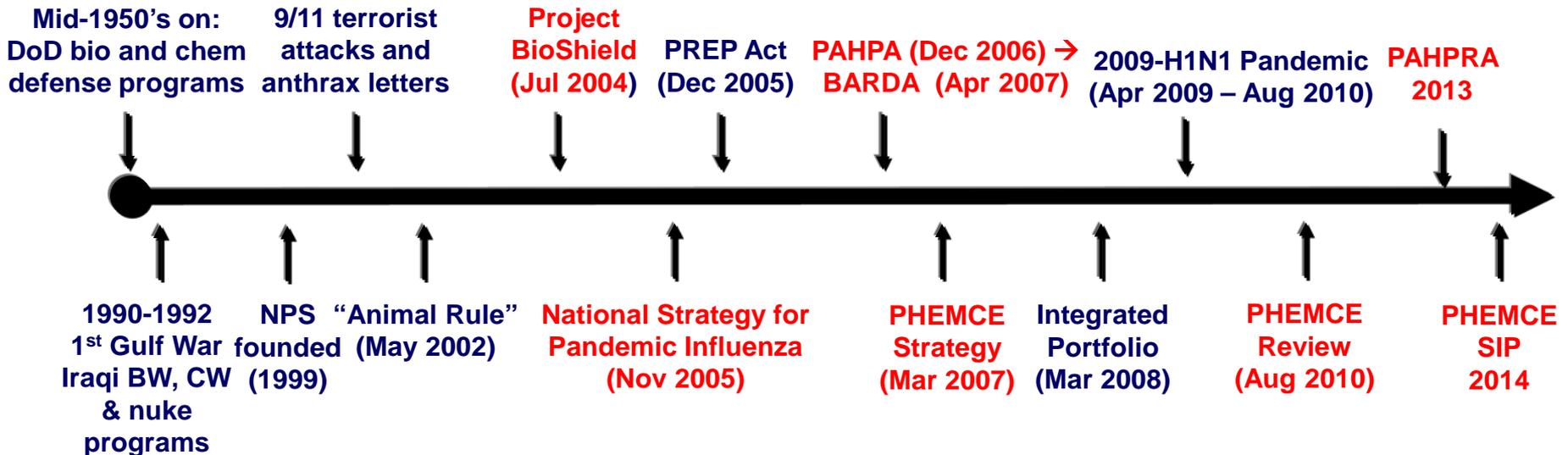
# Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) Governance Process



# Biodefense MCM History

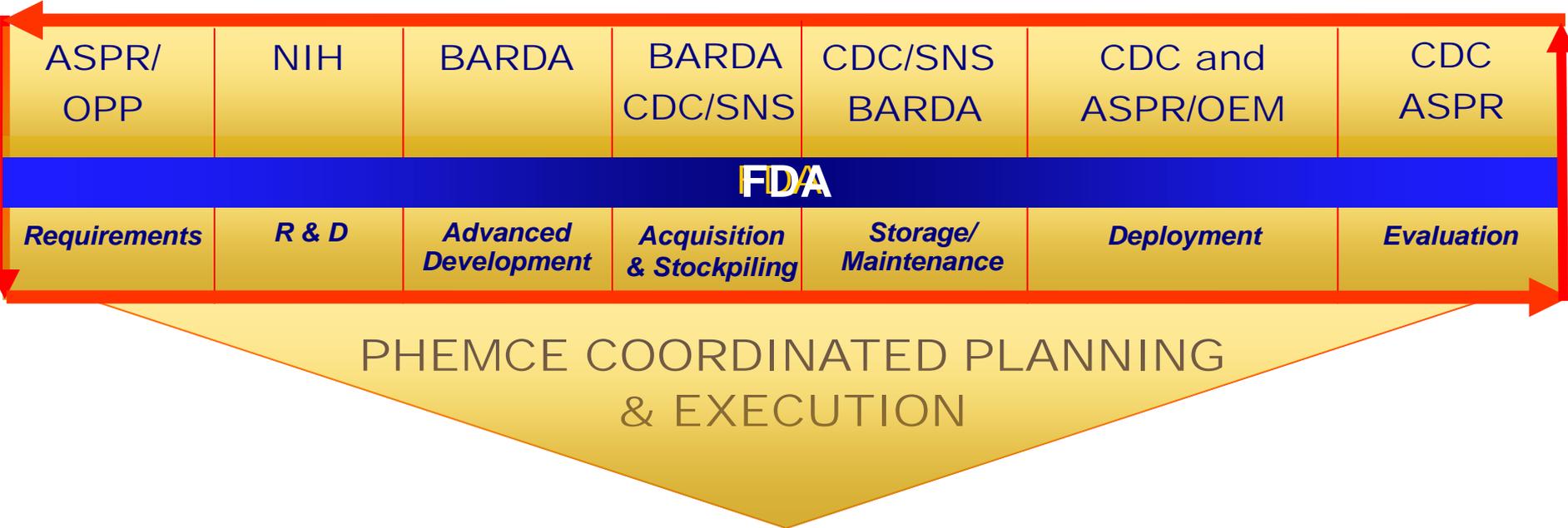


- Project BioShield Act (2004)
- Pandemic & All-Hazards Preparedness Act (2006)
- Medical Countermeasure Review (2010)
- Pandemic & All-Hazards Preparedness Reauthorization Act (2013)
- PHEMCE Strategic & Implementation Plan (2014)





# Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Governance

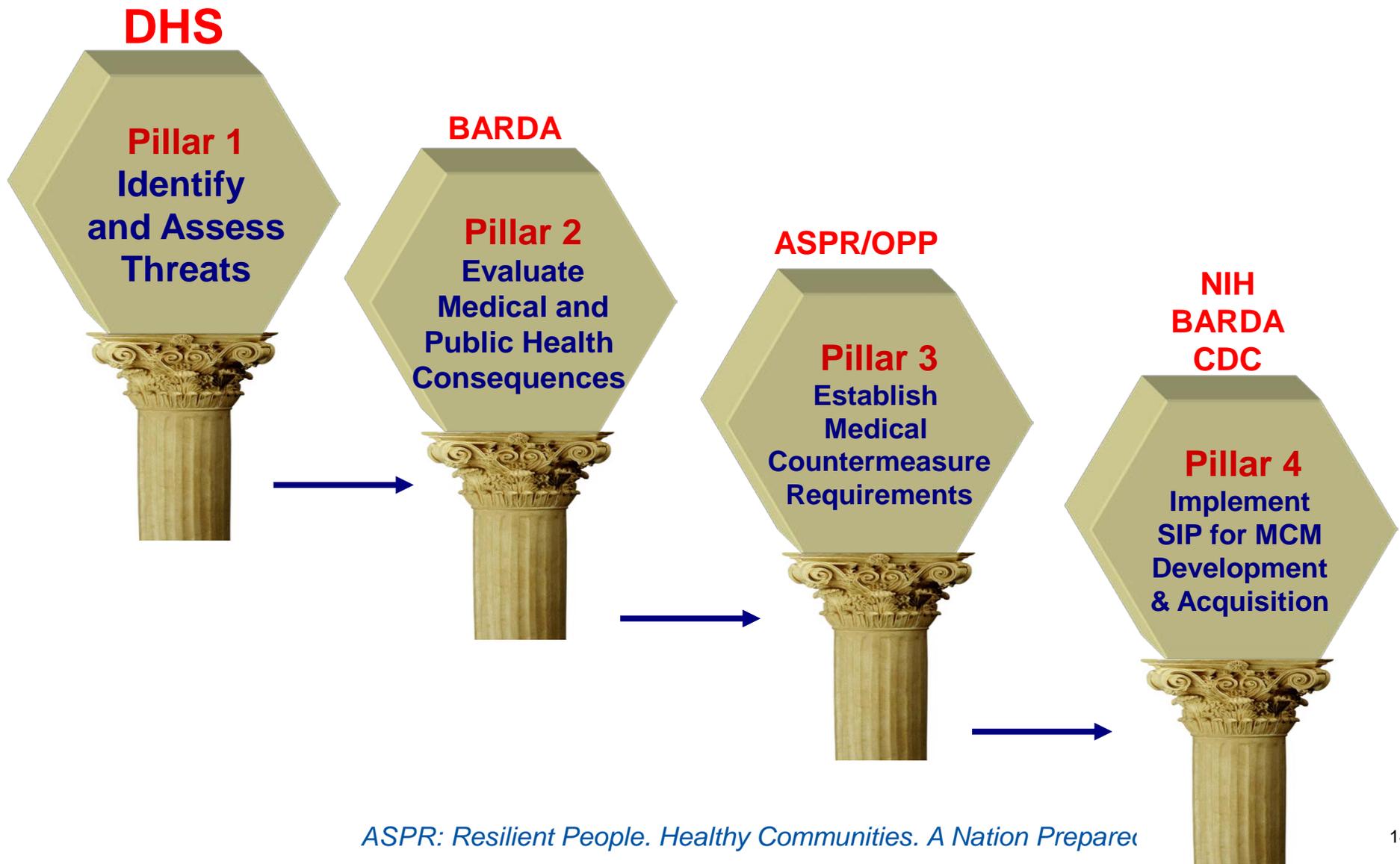


**Other Members:**



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# PHEMCE CBRN Medical Countermeasure Process





# BARDA MCM Story



## *BARDA's Mission*



***Support advanced development of and make available medical countermeasures for CBRN threats, pandemic influenza, and emerging infectious diseases by transitioning MCM candidates from early development across the “Valley of Death“ into advanced development to regulatory approval***



**O'Neil Building, Washington, DC**

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# *BARDA Strategic Goals 2011 -2016*



- **Goal 1:** An advanced development pipeline replete with medical countermeasures and platforms to address unmet public health needs, emphasizing innovation, flexibility, multipurpose and broad spectrum application, and long-term sustainability
- **Goal 2:** A capability base to provide enabling core services to medical countermeasure innovators
- **Goal 3:** Agile, robust and sustainable U.S. manufacturing infrastructure capable of rapidly producing vaccines and other biologics against pandemic influenza and other emerging threats
- **Goal 4:** Responsive and nimble programs and capabilities to address novel and emerging threats
- **Goal 5:** A ready capability to develop, manufacture and facilitate distribution of medical countermeasures during public health emergencies

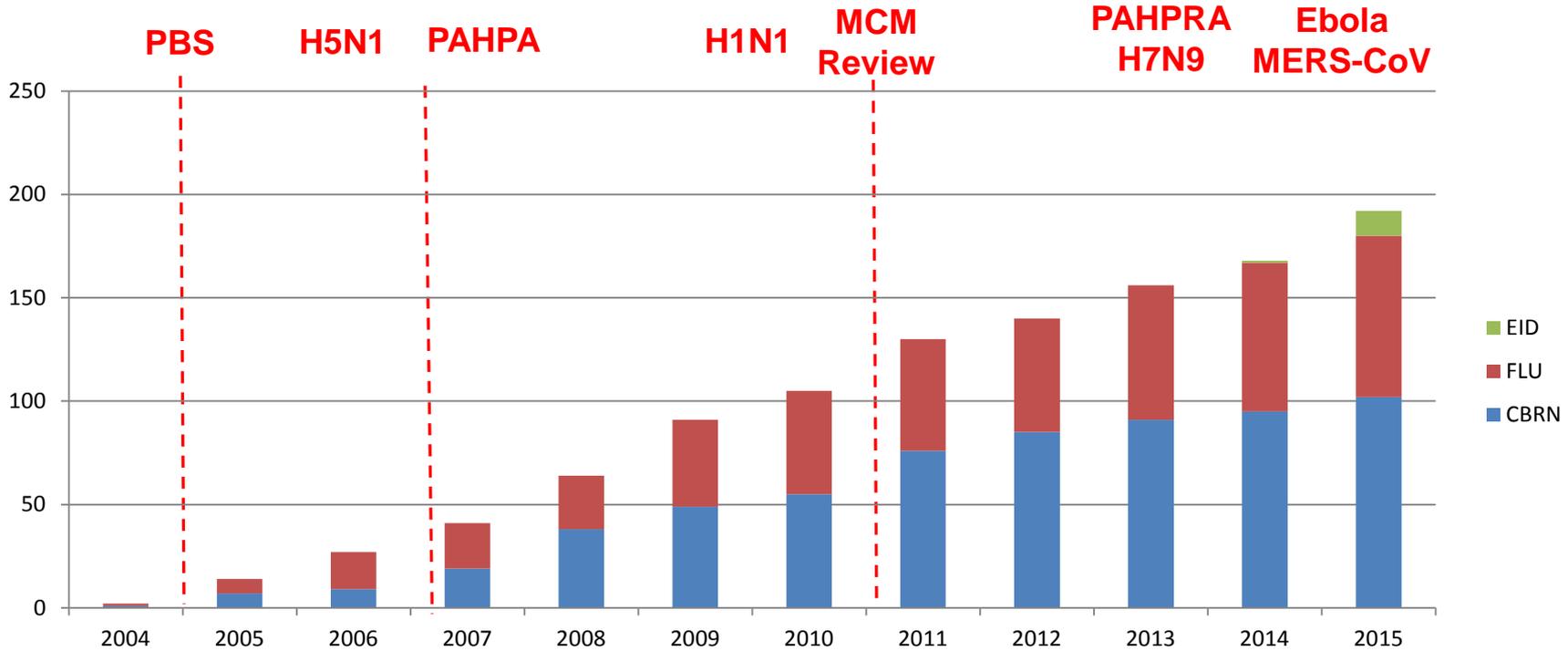


# BARDA Key Element #1: Create Robust & Innovative MCM Development Pipeline



- ~ 200 MCM product candidates in development

**BARDA ERA**



# BARDA Key Element #2: Stockpile CBRN MCMs under Project BioShield



**Smallpox**



**Anthrax**

**5 mL**

**Pentetate calcium trisodium injection 1000 mg**

For intravenous or inhalation use only. See package insert for use information. Single-use container - discard after use. Rx only. hameln pharmaceuticals

44639/19/05  
Batch no.:  
Exp. date:

**5 mL**

**Pentetate zinc trisodium injection 1000 mg**

For intravenous or inhalation use only. See package insert for use information. Single-use container - discard after use. Rx only. hameln pharmaceuticals

44635/19/05  
Batch no.:  
Exp. date:

**Radiation**

**Thermal Burns  
2015**

**Chemical**



**Botulism**



**AMGEN**

10 - 1.6 mL Single Use Vials NDC 5513-546-10

**Neupogen® Filgrastim**

A Recombinant Granulocyte Colony Stimulating Factor (G-CSF) derived from E. coli

**480 mcg**

480 mcg/1.6 mL 300 mcg/1 mL (3 x 10<sup>7</sup> Units/1 mL)

For Subcutaneous or Intravenous Use Only  
Sterile Solution - No Preservative

Refrigerate at 2° to 8°C (36° to 46°F). Avoid Shaking.

Amgen Inc. Thousand Oaks, CA 91320 U.S.A. U.S. License No. 1080

NDC 0024-5844-05

**5 x 500 mcg/mL**  
**2.8 x 10<sup>10</sup> IU/mL**

**Leukine® sargramostim**

A Recombinant GM-CSF-Yeast-Expressed

liquid injection, contains preservative

Sterile  
Rx only

**SANOFI**

~ 5 multiple use vials

10 Vials Preservative-free  
5 mg/1 mL Fill  
1 mL Fill Single dose Patient Kit

**MIDAZOLAM HYDROCHLORIDE INJECTION**

5 mg/1 mL Induction 1 mg/mL (See the hydrochloride) Sterile. For intravenous or intramuscular use. Discard unused portion.

NDC 0074-2308-01

# BARDA Success Key #3: Seek FDA Approval

## Cell-based Influenza Vaccine



## Influenza IV Antiviral Drug



## Recombinant-based Influenza Vaccine



Protein Sciences Corp.

## Anthrax Antitoxins



HGS/GSK



Emergent

## Botulinum Antitoxin



Cangene

## H1N1 & H5N1 Vaccines w/ Adjuvant



GlaxoSmithKline



## Next-Generation Portable Ventilators



Covidian

## Flu/RSV POC Diagnostic



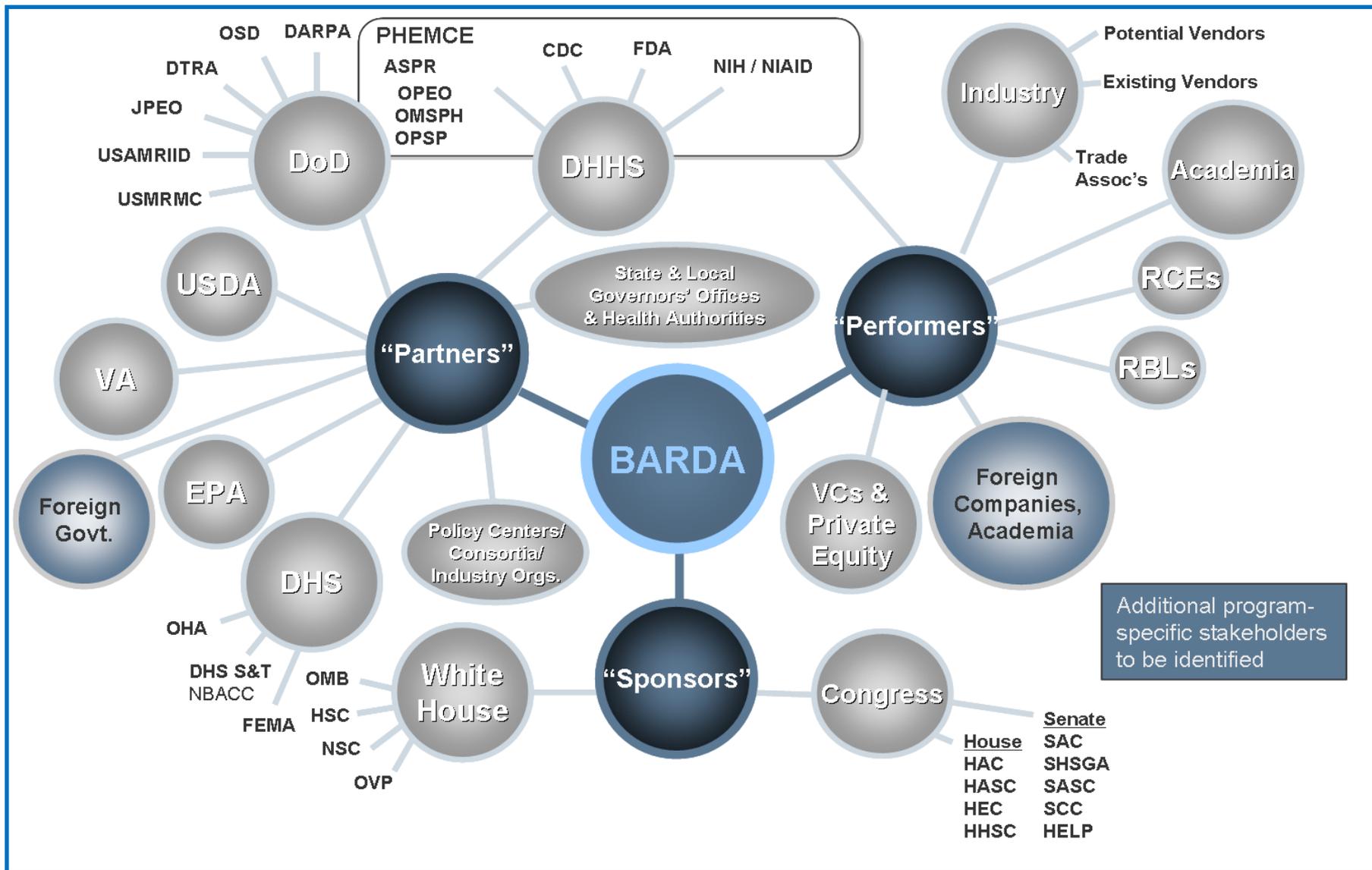
3M/Focus



Amgen



# BARDA Key Element #4: Establish & Nurture Partnerships





# *BARDA Key Element #5: Establish Robust Manufacturing Capacity*



- Expanding Existing Capacity by Retrofitting Vaccine Manufacturing Infrastructure



**sanofi pasteur – Swiftwater, PA**

- New Vaccine Mfg. Facilities



**2013 ISPE Facility of the Year**

**Novartis – Holly Springs, NC**

# BARDA Key Element #6: Help MCM Developers for Preparedness & Response





# *BARDA Key Element #7: Have the Best Technical, Clinical, & Regulatory Staff*





# BARDA State of Affairs



# *BARDA 2015: Harvesting ARD Bounty for PBS & Moving the Frontiers of Influenza MCMs*



- **Development pipeline**
  - Ebola Response – 12 MCMs & Natl. MCM Response Infrastructure
  - CARB launch preparations
  - More effective influenza vaccines with universal potential
  - 1<sup>st</sup> influenza immunotherapeutic development project started
  - Ebola epidemic winding down! **Impacts on Vax & Rx efficacy studies**
- **Stockpiling**
  - PBS – 4 new thermal burn treatments & **more MCMs on budget hold**
- **FDA approval**
  - FDA approval of Rapivab, Neupogen, AIG, Fluad, & Cobas
- **Partnerships**
  - Partnered with FDA/CDER on Continuous Mfg. initiative - 1<sup>st</sup> project
- **Manufacturing Expansion – International Flu Vax Mfg. Infrastructure**
- **Core Services Assistance programs**
  - 1<sup>st</sup> projects started in BARDA's CIADM, FFMN, & CSN
- **BARDA organization – new Division leaders & Life Cycle Mgmt.**
- **Antigenic drift & seasonal flu vaccine mismatch → HHS Action Plan**



# *BARDA 2016 Strategic Goals & Expectations: Expanding Horizons Amidst Uncertainties*



- **Development pipeline**
  - Formal launch CARB Action Plan for AMR Rx & Dx development
  - Launch MERS-CoV therapeutics program
- **Stockpiling**
  - Add new & enhanced MCMs under PBS
- **FDA approval**
  - Submit 1<sup>st</sup> IND as sponsor (H5N1 vax study)
  - Expect 2-3 FDA approved MCMs
- **Partnerships**
  - Establish clinical study infrastructure with Saudi Arabia for MERS-CoV MCMs
- **Core Services Assistance programs**
  - Expansion of CIADM capabilities with rapid platform technologies
  - Open BARDA's new Innovation Hub for modeling
- **BARDA organization**
  - Prepare new BARDA Strategic Plan 2017-2022
  - Build permanent home for BARDA EID program
- **Bioterrorism fatigue, disbelief, & denial → less funding?**
- **Global biopreparedness → IOM & WHO consultations → BARDA's role**



# BARDA is Always Open



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**BARDA - URL: <http://www.phe.gov>**

**BARDA e-mail: [BARDA@hhs.gov](mailto:BARDA@hhs.gov)**

- Upcoming Events
- PHEMCE Strategy and Implementation Plan
- CBRN and Pan Flu Programs
- Business Toolkit - [www.phe.gov/amcg](http://www.phe.gov/amcg)



## MedicalCountermeasures.gov

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

