



# PROMOTING AN EFFECTIVE MEDICAL COUNTERMEASURES ENTERPRISE

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# Outline

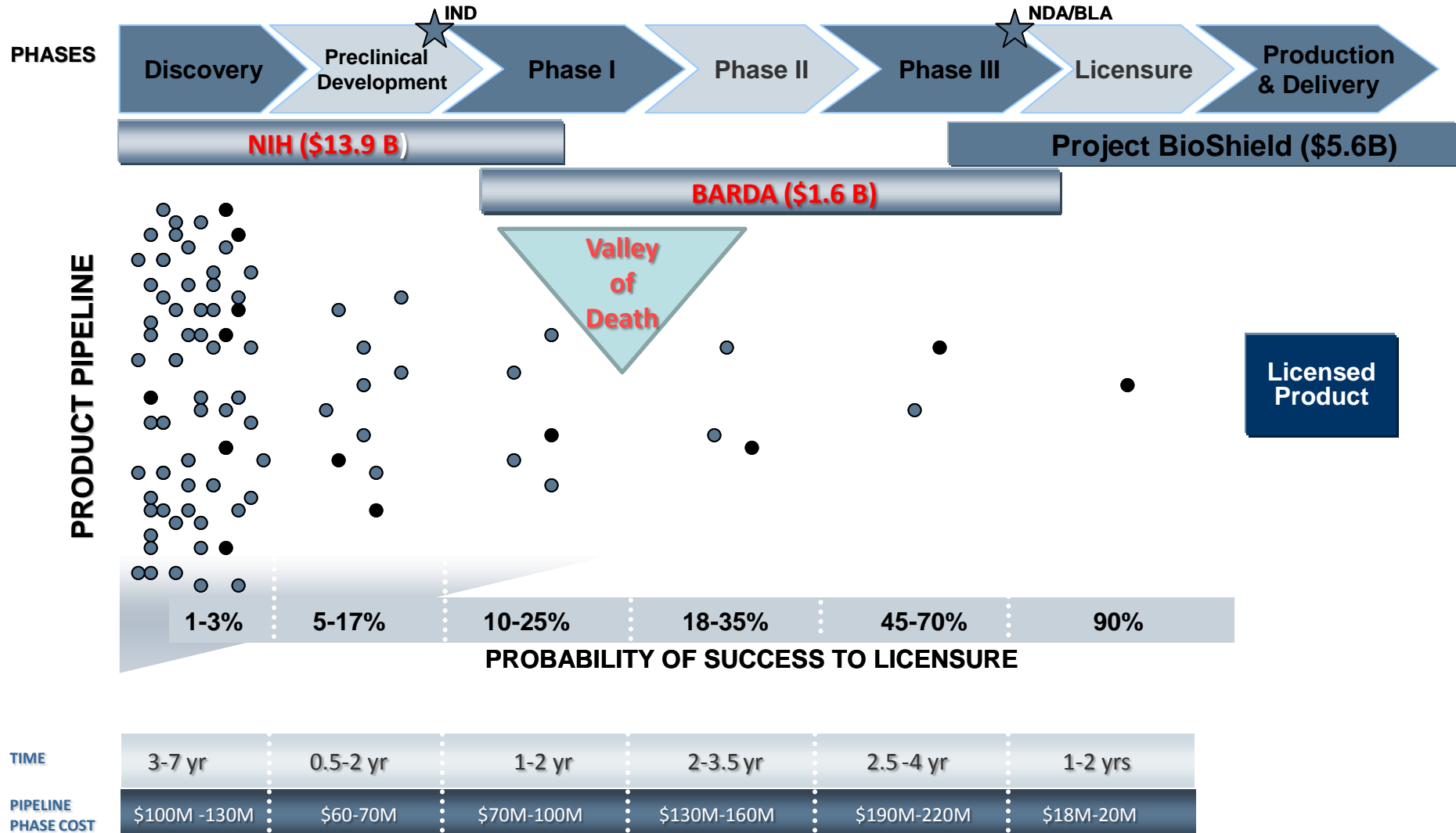


- **BARDA's Mission and Strategic Plan**
- **Key Legislation**
- **Product Development Models**
- **Core Services**
- **Successes in Public-Private Partnerships**
- **Top Ten Lessons Learned**





# Drug Development is Expensive, Lengthy, & Risky





# BARDA Mission and Modus Operandi



***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.***

**If a product fails, it should only be the result of failure of the product to achieve the desired safety or efficacy thresholds, and not as a function of our inability to provide the proper support from a technical, business and regulatory perspective**



# BARDA's Strategic Plan 2011-2016



- **Goal 1:** An advanced development pipeline replete with medical countermeasures..... emphasizing innovation, flexibility, multipurpose, broad spectrum application, and long-term sustainability
- **Goal 2:** Provide core services to MCM innovators
- **Goal 3:** Agile, robust and sustainable U.S. manufacturing infrastructure
- **Goal 4:** Responsive and nimble programs and capabilities to address novel and emerging threats
- **Goal 5:** Capabilities to develop, manufacture and facilitate distribution of MCMs during emergencies





# Legislation: The Basics



- **Project BioShield Act (JUL 2004)**
  - Established Special Reserve Fund
  - Established Emergency Use Authorization (EUA)
- **PAHPA (DEC 2006)**
  - Established the Office of Assistant Secretary for Preparedness & Response (ASPR)
  - Established BARDA and provided authority to invest in advanced product development
- **PREP Act (DEC 2005)**
  - Limitation of liability related to countermeasures
  - Declarations for specific countermeasures



**Goals: accelerate research, development, purchase, storage and distribution of medical countermeasures**



# Evolution of the MCM Enterprise



## 2004- 2010

- Implementing and improving legislation
- Establishing governance structures
- Requirements setting
- Developing products
- Facing challenges with Emergency Use and Animal Rule
- Establishing stockpiles

## 2011 and Beyond

- Lessons learned from the Pandemic – MCM Enterprise review
- New initiatives for all agencies
- Focus on Public/Private Partnerships
- Novel broad-spectrum and repurposing drugs
- Core services
- Sustainment models



# Commitment to MCM Development

## Developing & providing MCMs for CBRN, pandemic influenza, and emerging infectious threats

- Over 125 product candidates in pipeline across a wide array of threats
- 9 products available under Emergency Use Authorization
- 3 licensed products
- Supporting establishment of domestic manufacturing infrastructure to produce products against pandemic influenza and known or unknown emerging infectious threats
- Supporting development of novel antibiotics for use against emerging public health threats and bio-threat agents
- Providing core services to product developers at all stages





# Product Development Model



- **“Truth Seeking”**

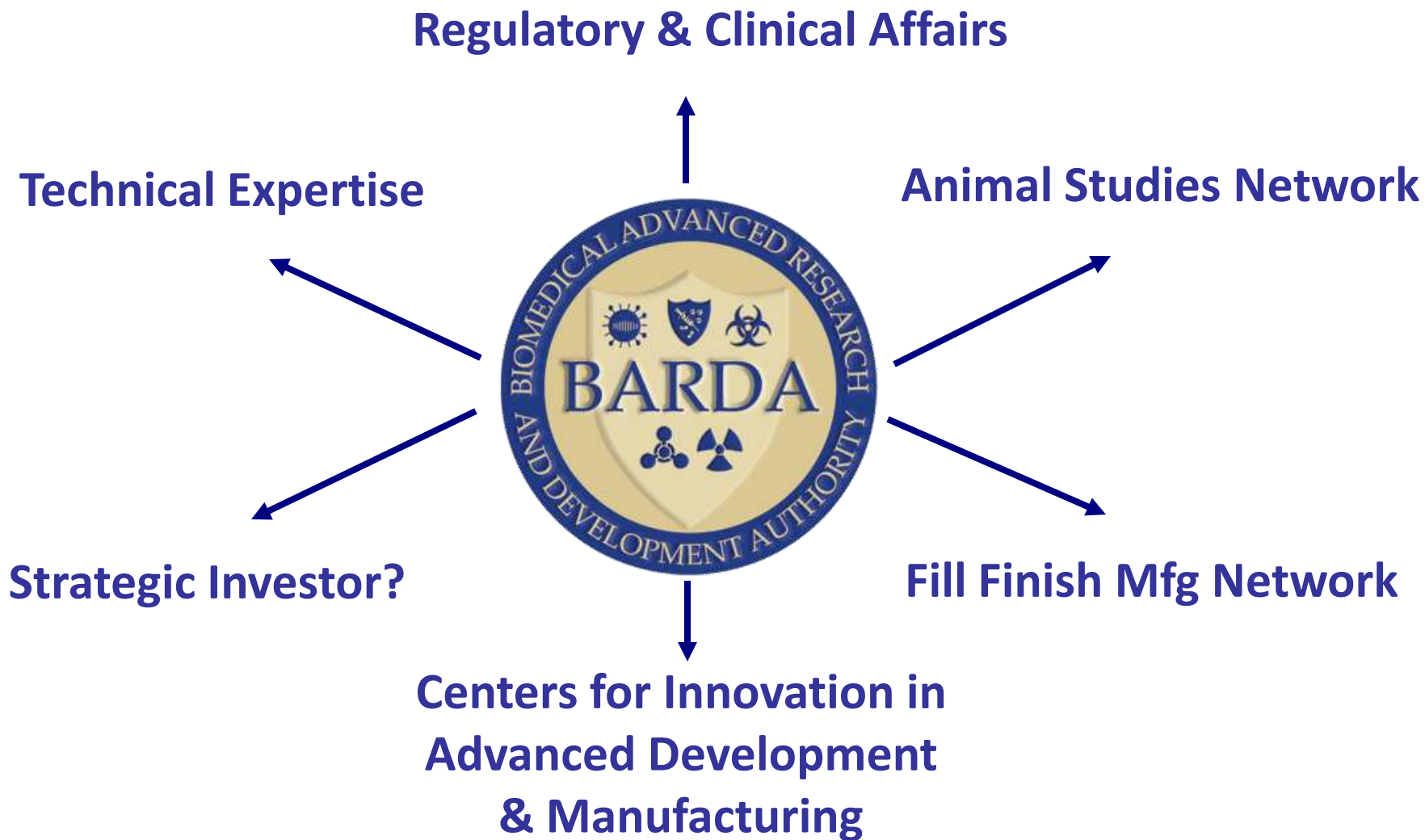
- Emphasis on Proof of Concept
- Early R&D
- Integration of platforms, CROs, CMOs
- Relies on tech-transfers, data and model sharing
- Rapid Go/No Go

- **“Success-Seeking”**

- Emphasis on licensure and stockpiling
- Scale-up, validation of manufacturing
- Phase II/III, pivotal animal studies
- Life cycle and sustainment important



# BARDA Core Services





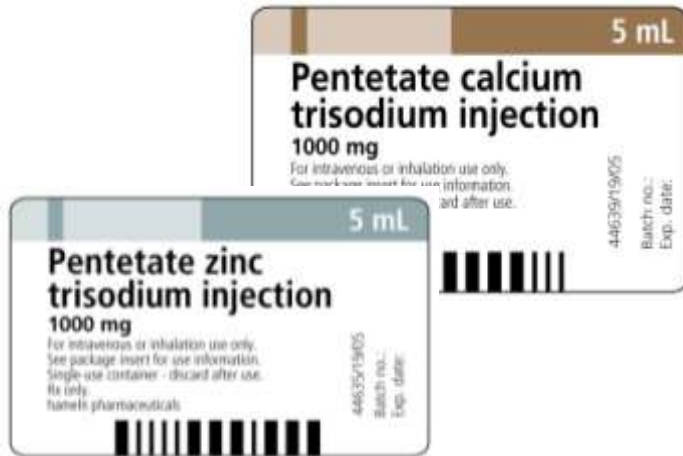
# New CBRN Medical Countermeasures



Smallpox



Anthrax



Radiation



Botulism



# Public-Private Partnerships Infrastructure Development



**Novartis  
Holly Springs, NC  
PanFlu Vaccine**

**Emergent BioSolutions  
Lansing, MI  
Anthrax Vaccine**





# Public-Private Partnerships Novel Antimicrobials



- **New approach for development of multi-purpose drugs**
- **Cost-sharing models implemented**
- **Biodefense and antibiotic resistance indications sought**
- **Supported by Pandemic and All Hazards Preparedness Act and the Secretary's MCM Enterprise Review**
- **Four partnerships initiated**
  - Achaogen - plague/tularemia/ventilator-induced pneumonia/catheter-induced UTI
  - GSK - anthrax/plague/tularemia/HAP/VAP/UTI
  - CUBRC— anthrax/plague/HAP/VAP
  - Chimerix - broad spectrum antiviral against double-stranded DNA viruses (e.g., smallpox and adenovirus)



# Top Ten List – Lessons Learned



- **Personnel – need experienced professionals**
- **Bureaucracy – limit it to a minimum (progress over process)**
- **Decisions – establish infrastructure of accountability (Source Selection, Milestone Decision)**
- **Don't reinvent – connect with other agencies (especially FDA)**
- **Project management – Project Coordination Teams, clearly defined metrics**
- **Contracting – contracting staff is integral to process**
- **Project evaluations – Interagency In-Process Reviews, transparency**
- **Solicitations –Broad Agency Announcement open 24/7, White Paper process**
- **Open door policy – TechWatch brings in ideas/projects**
- **Congress – establish firm relationships early**





# Contact Us



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 7 core service programs
- Regulatory guidance
- Federal strategies and reports

