



United States Department of

Health & Human Services

Office of the Assistant Secretary for Preparedness and Response

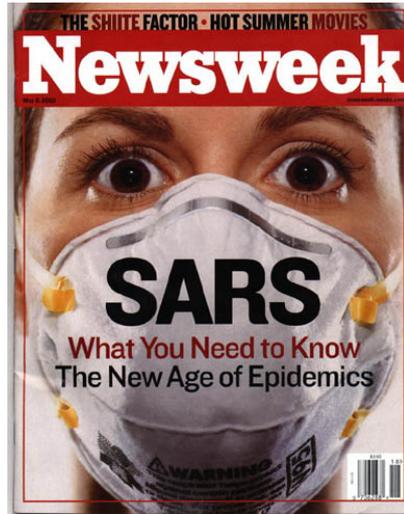


BARDA Today & Tomorrow: Goals, Priorities, Successes & Challenges

**BARDA Industry Day
October 15, 2014**

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

Man-Made & Natural Threats Have Become Annual Realities Since 9/11

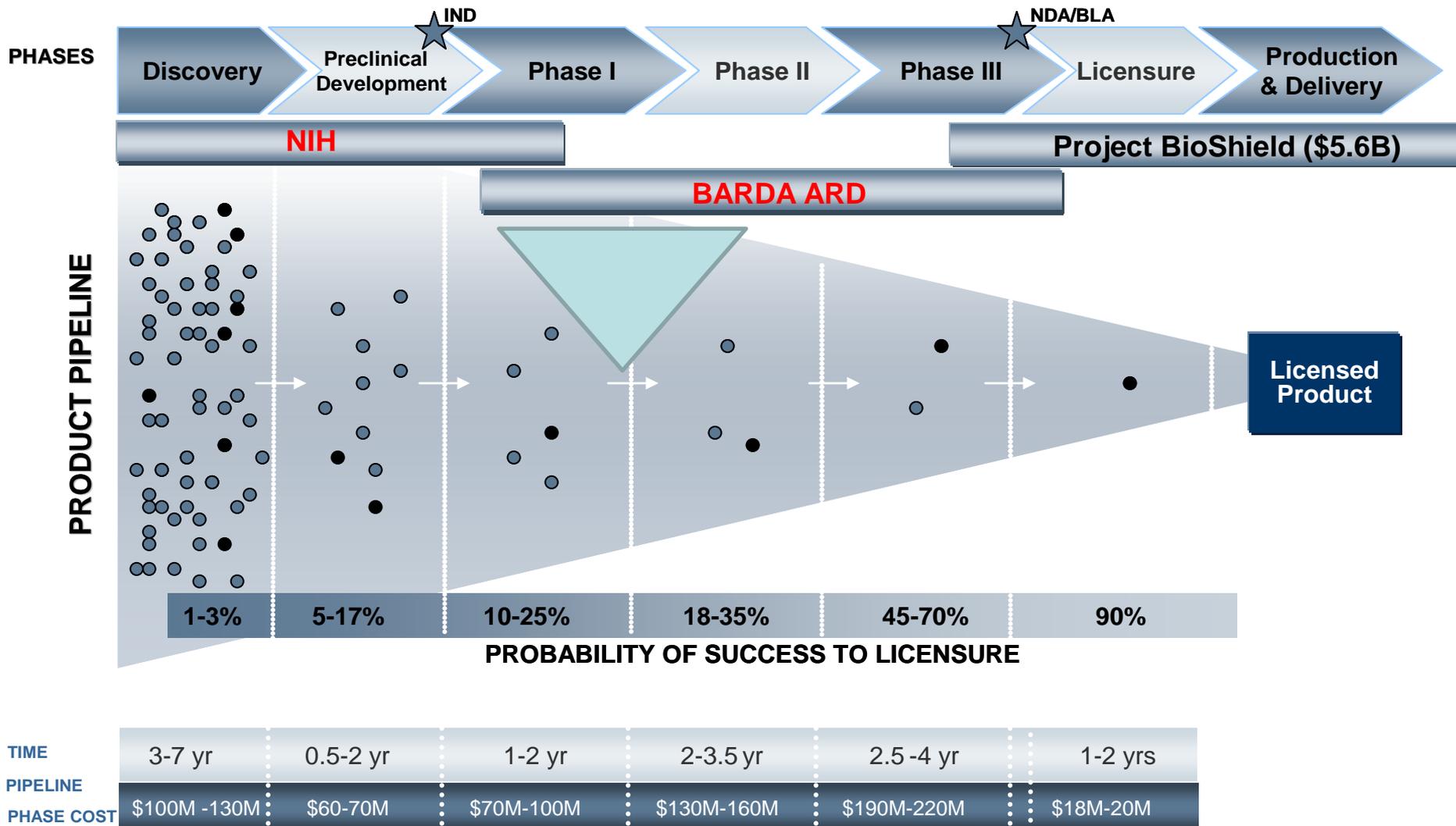


Ebola 2014: Worst Ebola Epidemic in History





Drug Development is Still Expensive, Lengthy, & Risky



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



BARDA's Commitment to Medical Countermeasures



BARDA Mission: Support advanced development of and make available countermeasures for CBRN threats, pandemic influenza, and emerging infectious diseases through product development, innovation, and acquisition, stockpiling, building manufacturing infrastructure, & core service assistance



O'Neil Building



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



BARDA Has Built a Formidable & Robust MCM Development Pipeline



- **150+ MCM candidates in development through 2013**
 - Using better business practices (e.g. OTA, IPR)
 - 12 new CBRN MCM candidates and 5 new H7N9 vaccine candidates in FY2013
- **12 MCMs provided under Project BioShield since 2004 with 12 more by 2019**
- **National stockpiles of H5N1 & H7N9 pre-pandemic vaccines & adjuvants**
- **7 FDA-approved MCMs in 2012-13 with more expected by the end of 2015**
 - Simplexa® influenza & RSV diagnostic POC device (Jun. 2012) – 3M/Focus [510K clearance]
 - Flucelvax cell-based influenza vaccine (Nov. 2012) – Novartis [licensure]
 - Raxibacumab anthrax antitoxin (Dec. 2012) – GlaxoSmithKline/Human Genome Sciences [approval]
 - Aura portable ventilator (Dec. 2012) – Covidien [510k cleared for adults]
 - FluBIØk recombinant-based influenza vaccine (Jan. 2013) – Protein Sciences
 - HBAT botulinum antitoxin (Mar. 2013) – Cangene [licensure]
 - Q-PAN H5N1 pandemic influenza vaccine (Nov. 2013) – GlaxoSmithKline [licensure]



BARDA Has Established Robust CBRN MCM Development Pipeline



- **BARDA CBRN MCM development pipeline has supported 85+ candidates since 2004 (\$2.6 B)**

- **Biothreats**

- Anthrax vaccines (7) and antitoxins (7)
- Smallpox vaccine (3) and antiviral drugs (2)
- Botulinum antitoxin (1)
- Other biothreat antimicrobial drugs (9)
- Viral hemorrhagic fever (2)



- **Rad/Nuc threats**

- Acute Radiation Syndrome drugs (36)
- Decorporation agents (6)
- Thermal burn therapies (9)
- Biodosimetry devices (11)

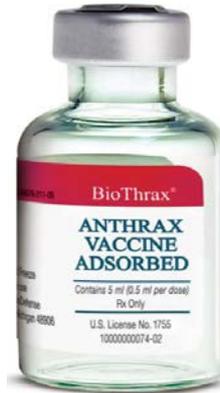


- **Chem threats – antidotes & decon (4)**

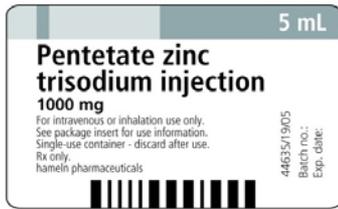
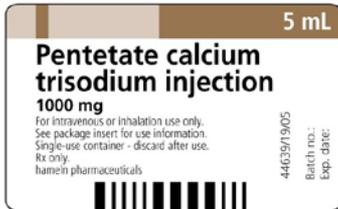
BARDA MCMs Developed & Purchased under Project BioShield



Smallpox



Anthrax



Radiation



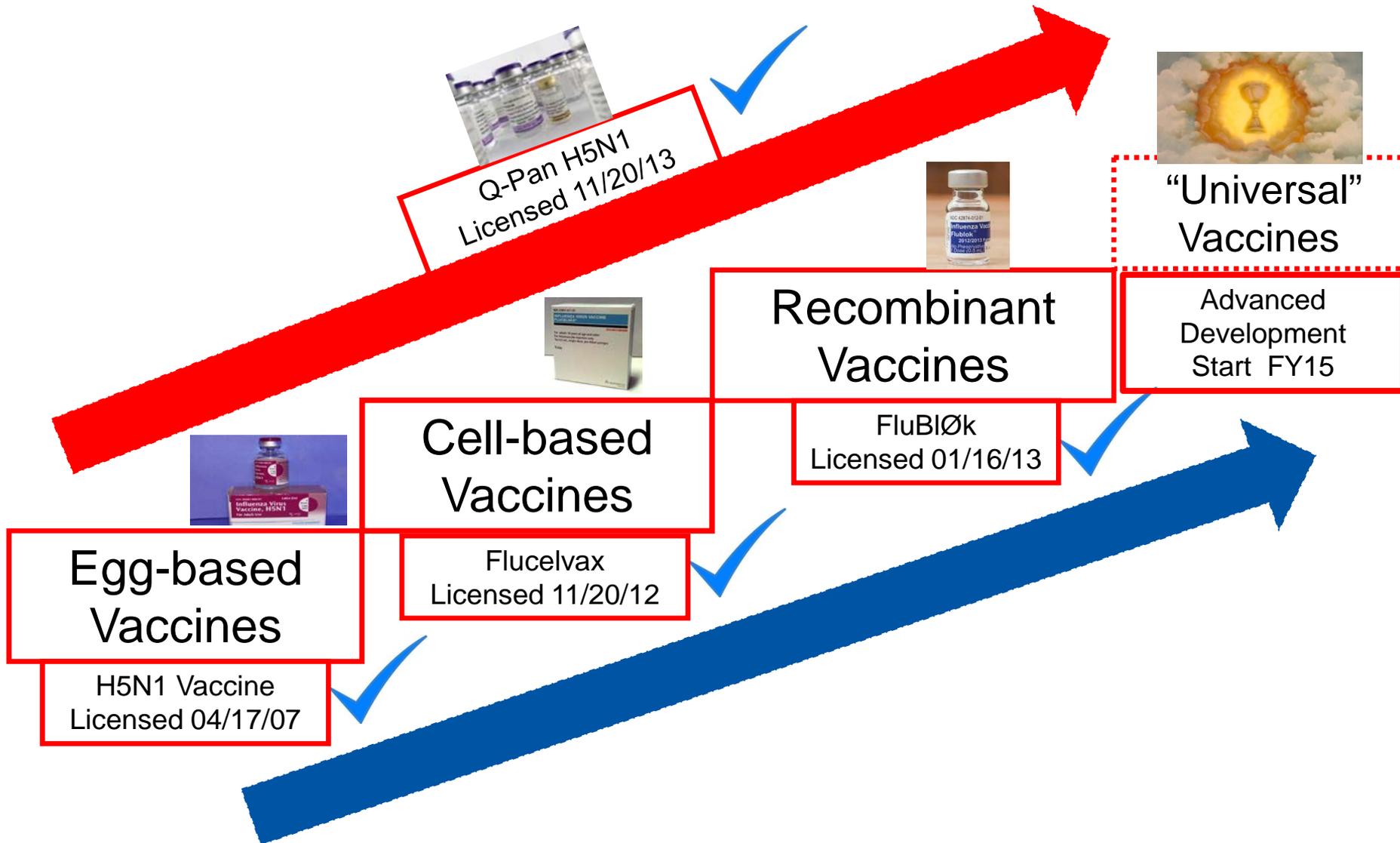
Chemical

Botulism





BARDA Influenza Vaccine Development Programs Have Delivered More Vaccine Sooner But What About Better



FOUO- Procurement Sensitive

Q-PAN H5N1 Vaccine



GlaxoSmithKline

Cell-based Influenza Vaccine



Novartis

Next-Gen Portable Ventilators



Covidien

Recombinant-based Influenza Vaccine



Protein Sciences

Flu/RSV POC Diagnostic



3M/Focus



- **BARDA has established multiple solid public-private partnerships with industry and academia to expand domestic & international manufacturing response capabilities**
 - Retrofitted manufacturing facilities
 - Sanofi – PA
 - MedImmune – CA and PA
 - New manufacturing facilities (Novartis – NC)
 - Centers for Innovation in Advanced Development & Manufacturing
 - TAMUS – TX
 - Emergent – MD
 - Novartis - NC
 - WHO and PATH with NC State & Utah State for pan flu vaccine manufacturing in developing countries
 - OTA agreement with GSK for antimicrobial drug development



BARDA Uses Public-Private Partnerships to Build Domestic MCM Manufacturing Capacity



- **Expanding Existing Capacity by Retrofitting Vaccine Manufacturing Infrastructure**



sanofi pasteur – Swiftwater, PA

- **Changing Flu Vaccine Industry**



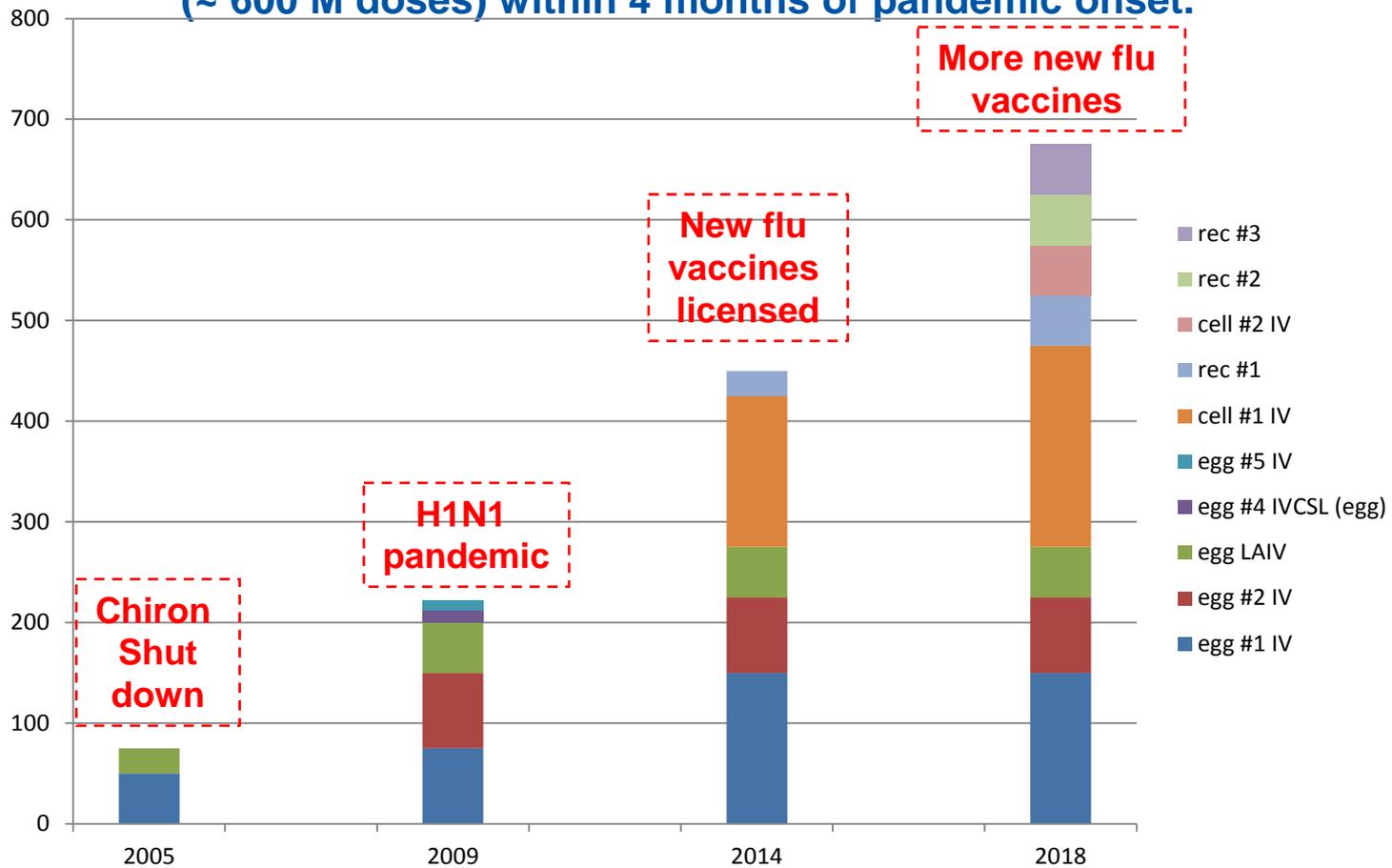
Novartis – Holly Springs, NC



BARDA Expanded Domestic Flu Vaccine Manufacturing Surge Capacity Multi-fold



USG pandemic influenza vaccine policy is two doses for everyone (~ 600 M doses) within 4 months of pandemic onset.



BARDA Expands Flu Vaccine Manufacturing Capacity in Developing Countries





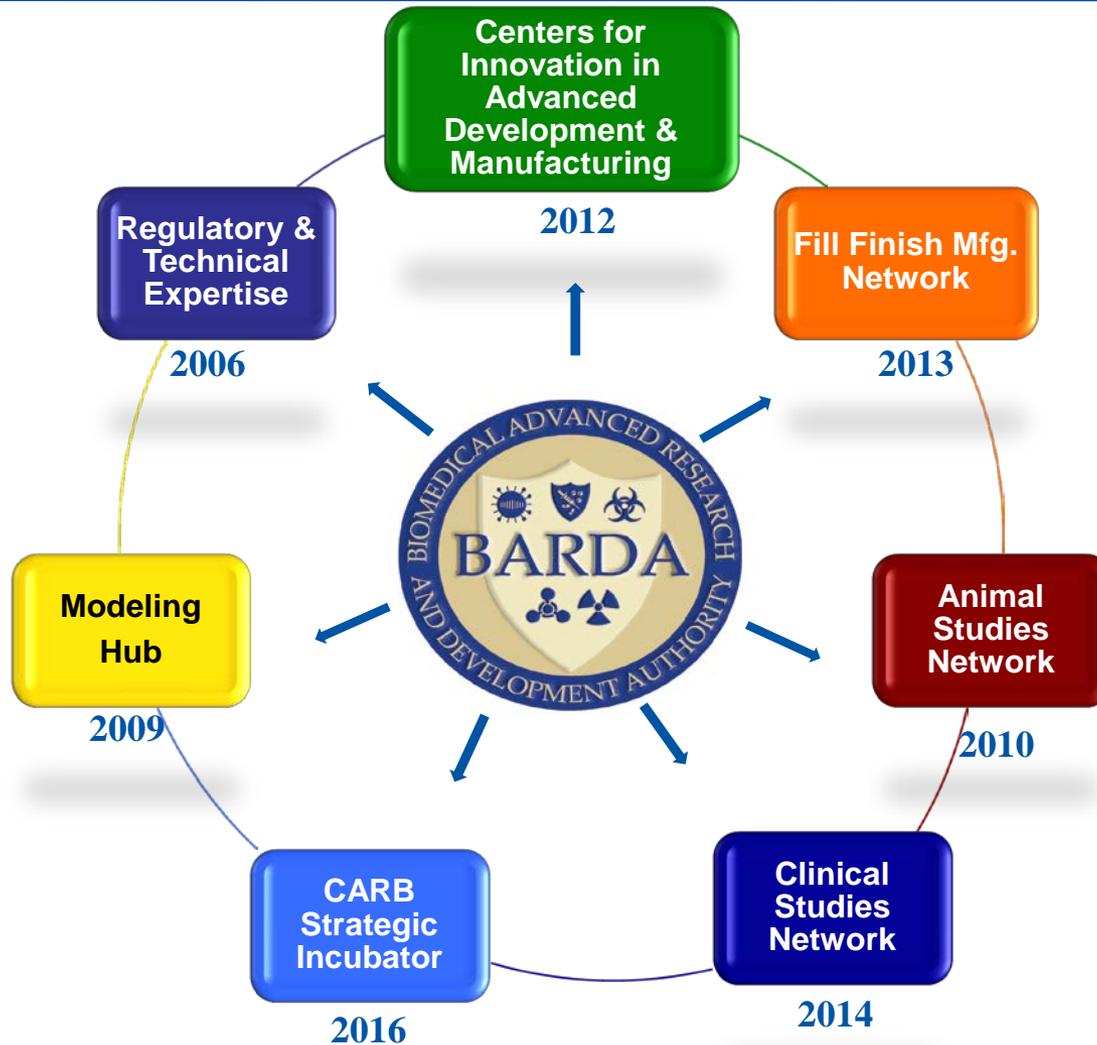
BARDA 2014: CBRN & Influenza MCM Programs Stayed the Course & Responded to New Threat



- **BARDA leadership succession**
- **BARDA CBRN MCM programs continued support for existing projects as warranted and funds are available & began support for new projects**
 - Broad spectrum antimicrobial drugs & immunomodulatory drug
 - Immunomodulatory candidate
 - Viral hemorrhagic fever vaccine & therapeutic programs – **NEW**
- **BARDA supported the purchase of MCMs under Project BioShield:**
 - Smallpox vaccines
 - Botulinum antitoxins (FDA–mandated studies)
- **BARDA Influenza MCM program continued support for existing/new projects**
 - Vaccine – cell, recombinant, Ag-sparing, universal (with NIAID)
 - Antivirals (host-targeted) – Nitazoxanide Phase 3 study continued
 - Flu Diagnostics – new POC diagnostics
- **BARDA added new All–Hazards next generation ventilator**



BARDA Provides Critical Core Service Assistance to MCM Developers





BARDA Core Service Assistance Programs Became an Everyday & Emergency Response Infrastructure



- **BARDA has established critical core service assistance programs to help MCM developers and provide national response capabilities to public health emergencies**
 - Animal Studies Network (17 CRO labs) - 2010
 - Centers for Innovation in Advanced Development & Manufacturing (3 consortia) - 2012
 - Fill Finish Manufacturing Network (4 CMOs) – 2013
 - **Clinical Studies Network (5 CROs) – 2014 NEW**
- **BARDA's Nonclinical Studies Network has provided assistance on 20+ projects & presented smallpox animal model to FDA for qualification.**
- **BARDA-supported projects entering CIADMs for assistance in 2014.**
- **BARDA FFMN engaged influenza vaccine manufacturers to facilitate tech transfers and work with FDA, drug companies to address drug shortages for several products as pilot project, & assisted Ebola vaccines & therapeutics.**
- **BARDA Clinical Study Network established internal infrastructure in 2014 to conduct clinical studies next year.**



BARDA 2015 Maintains MCM Development Pipeline, Transitions MCM Candidates from ARD into PBS, & Launches New Initiatives



- **CBRN MCM Program:** (new BAA 2015)
 - Continue existing projects incl. enhanced vaccines & therapeutics for smallpox and anthrax
 - Expand **Viral Hemorrhagic Fever Vaccine & Therapeutic Programs**
 - Launch **CARB initiative** to expand **BSA Program** to combat antimicrobial drug resistance using OTAs **New**
- **Project BioShield:** New MCMs from BARDA ARD (RFPs in 2015)
 - Artificial skin replacement & debridement for thermal & radiation burns **New**
 - Biodosimetry device for measuring radiation exposure **New**
 - Chemical antidotes for cyanide poisoning
 - Ebola MCMs **New**
 - Replenishing anthrax antitoxins & smallpox vaccines,
- **Influenza MCM Program:**(new BAA & RFPs in 2015)
 - Continue existing projects incl. modern vaccines & antiviral drug candidates
 - Launch **New Universal Influenza Vaccine Development Program**
 - Launch **New Influenza Immunotherapy Program** for Critically Ill
- **Other New Initiatives - Emerging Infectious Disease Program & Continuous Manufacturing Innovation Program**



BARDA is Always Open



BARDA Director: robin.robinson@hhs.gov

202-368-6608



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 core service programs
- Regulatory guidance
- Federal strategies and reports

