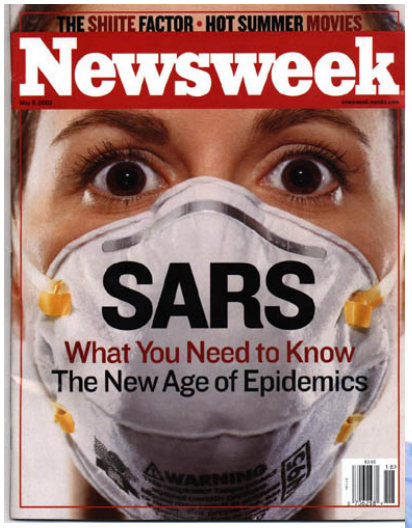
BARDA Today & Tomorrow: Goals, Priorities, Successes & Challenges

BARDA Industry Day
October 15, 2014

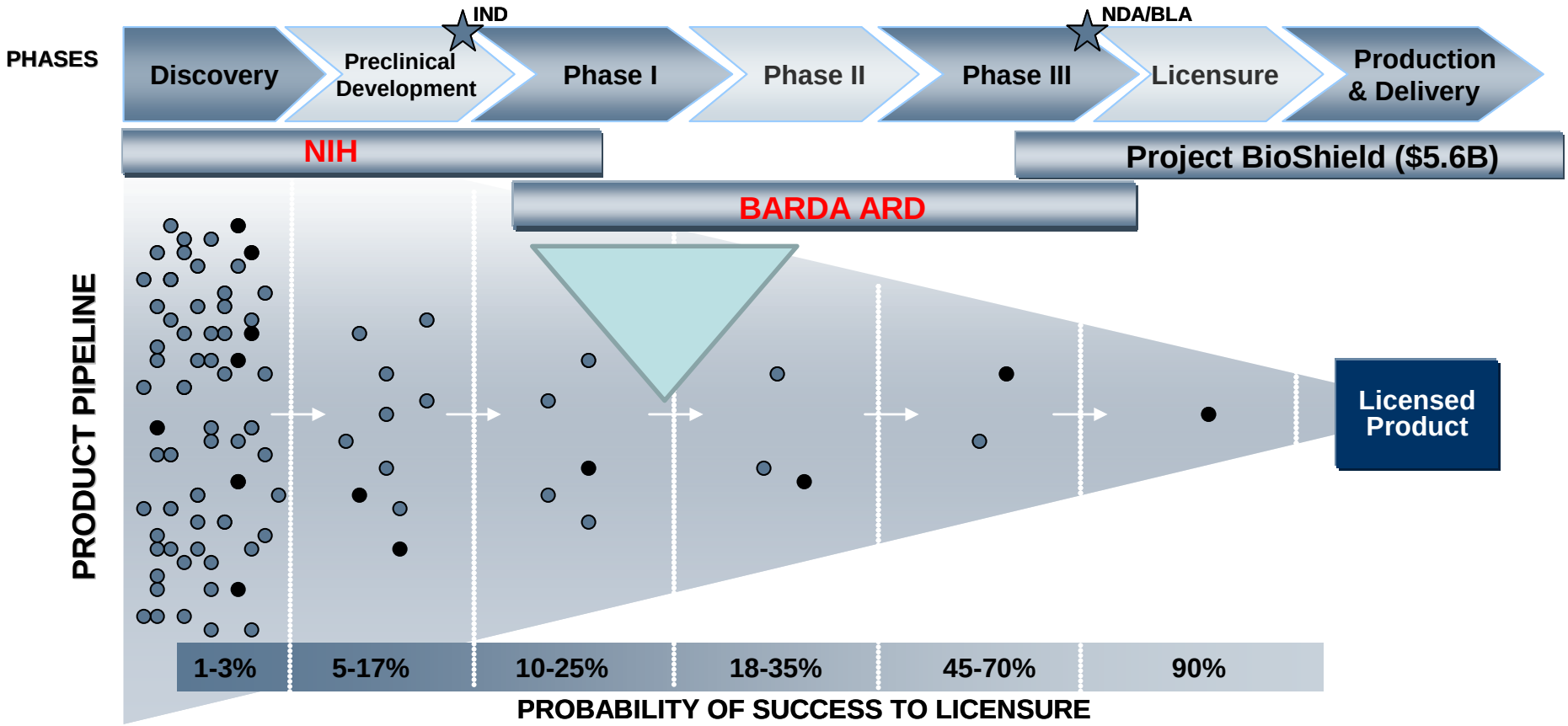
Dr. Robin Robinson
BARDA Director
ASPR Deputy Assistant Secretary

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



TIME	3-7 yr	0.5-2 yr	1-2 yr	2-3.5 yr	2.5 -4 yr	1-2 yrs
PIPELINE PHASE COST	$100M -130M	$60-70M	$70M-100M	$130M-160M	$190M-220M	$18M-20M

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

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 <u>development pipeline</u> has supported 85+ candidates since 2004 ($2.6 B)***

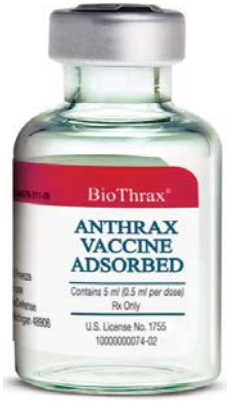
- ***Biothreats***
  - *Anthrax vaccines (7) and antitoxins (7)*
  - *Smallpox vaccine (3) and antiviral drugs (2)*
  - *Botulinum antitoxin (1)*
  - *Other biothreat antimicrobial drugs (9)*
  - *Viral hemorrhagic fever (2)*

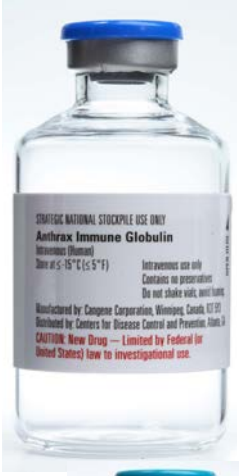
- ***Rad/Nuc threats***
  - *Acute Radiation Syndrome drugs (36)*
  - *Decorporation agents (6)*
  - *Thermal burn therapies (9)*
  - *Biodosimetry devices (11)*

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

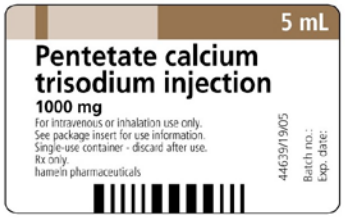
BARDA MCMs Developed & Purchased under Project BioShield

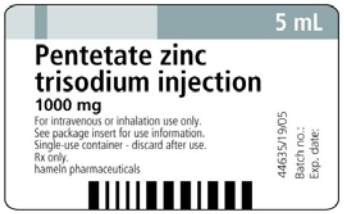
Smallpox





Anthrax

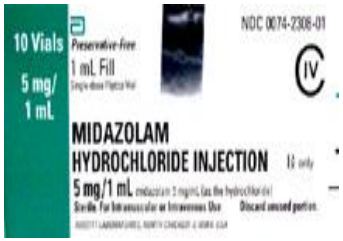




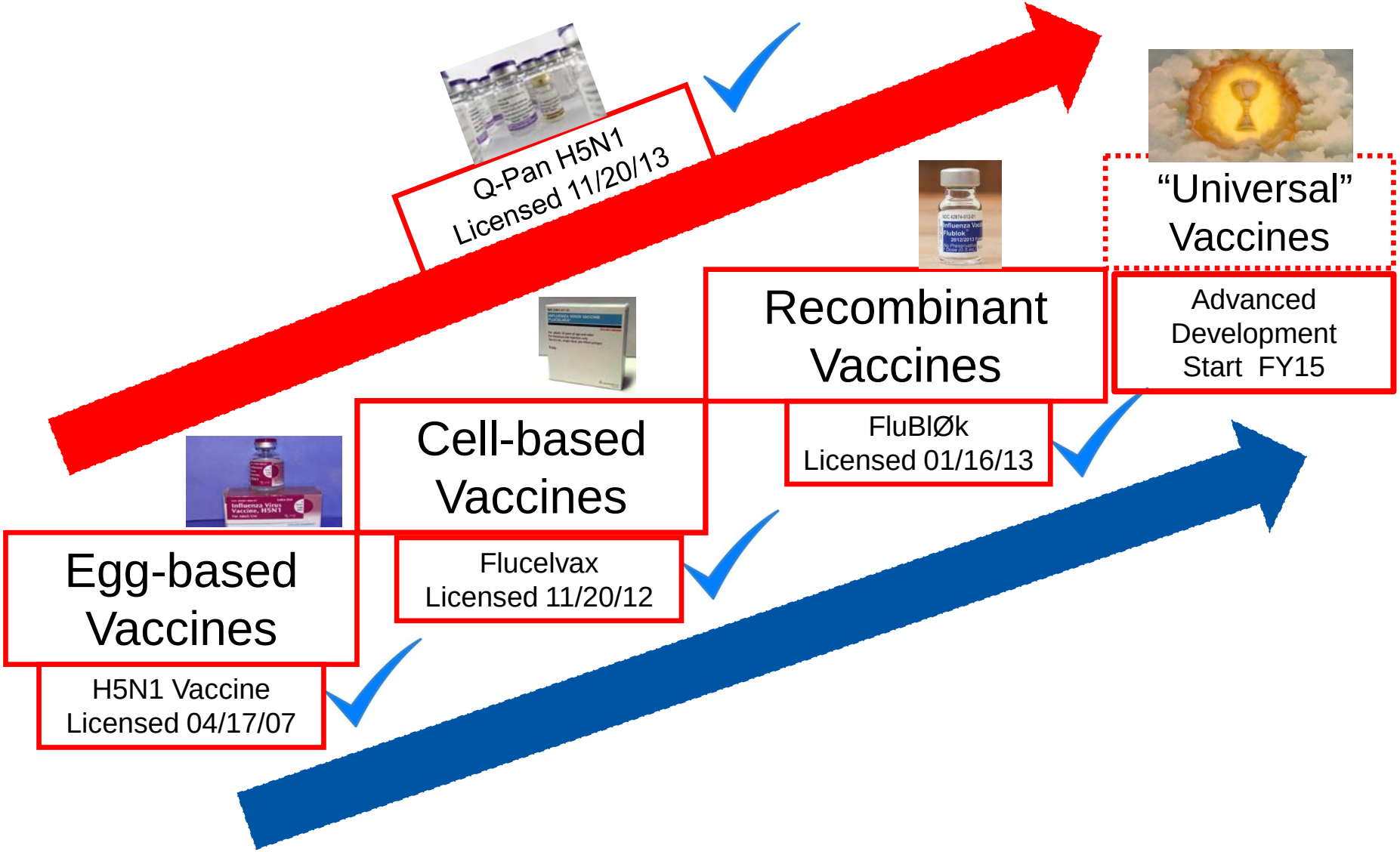
Radiation

Botulism

Chemical



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

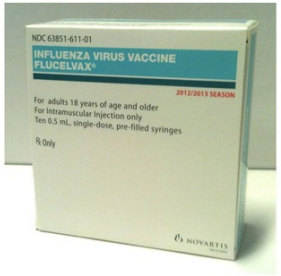


FDA-Approved BARDA Influenza MCMs

Q-PAN H5N1 Vaccine

GlaxoSmithKline

Cell-based Influenza Vaccine



Novartis

Recombinant-based Influenza Vaccine

Protein Sciences

Next-Gen Portable Ventilators

Covidien

Flu/RSV POC Diagnostic

3M/Focus

BARDA MCM Public-Private Partnerships

- **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**

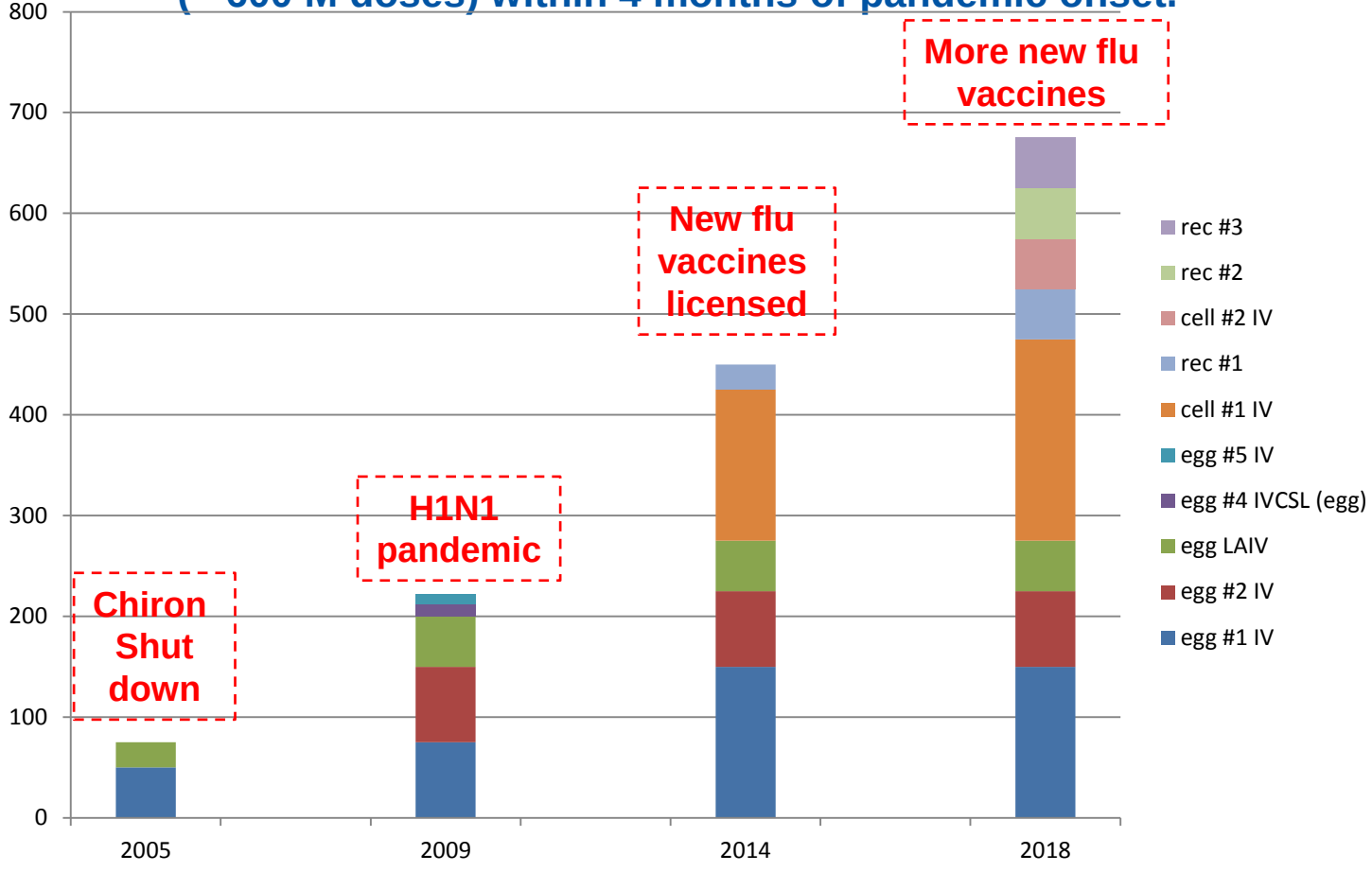
sanofi pasteur – Swiftwater, PA

- **Changing Flu Vaccine Industry**

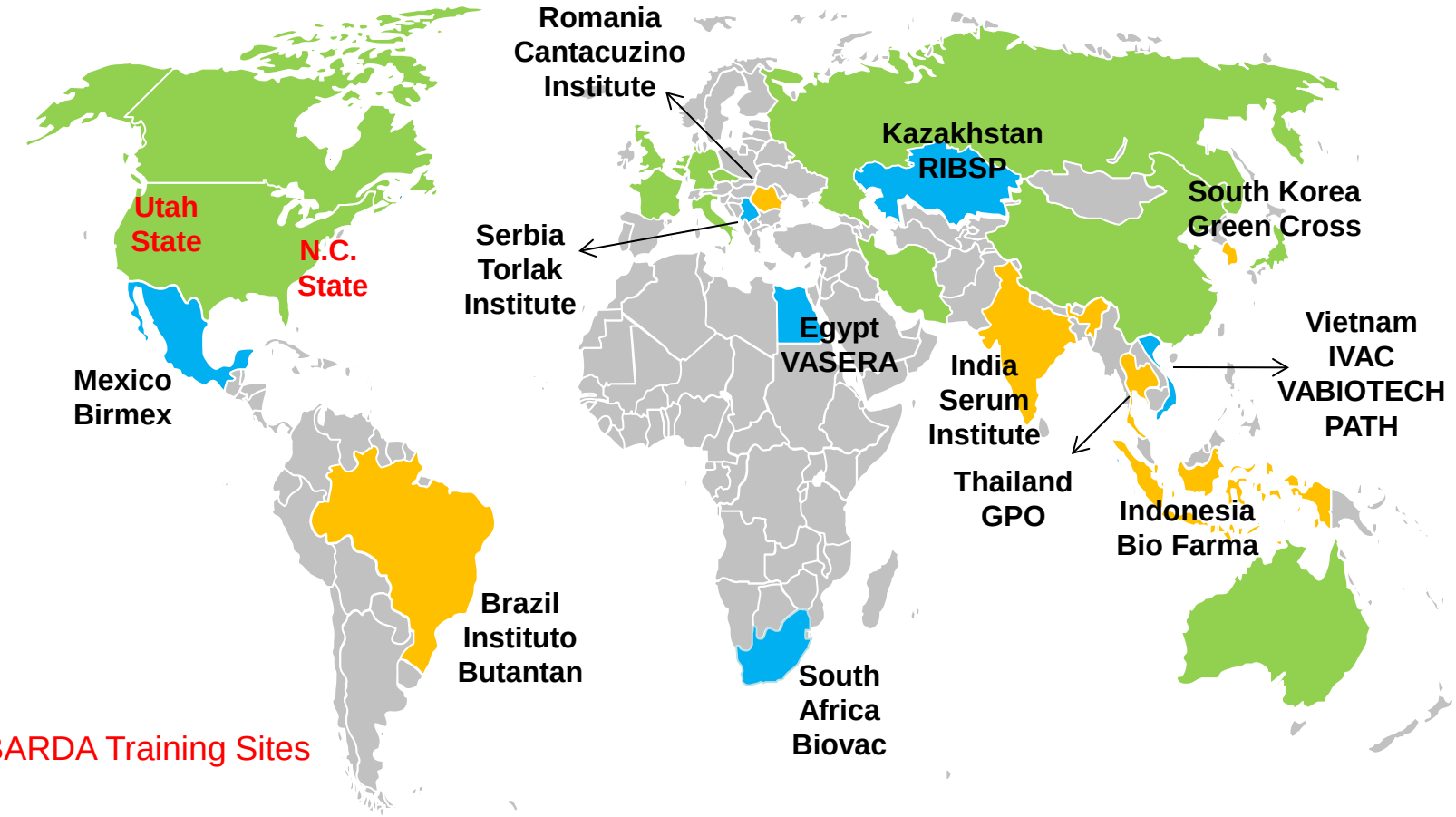
Novartis – Holly Springs, NC

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

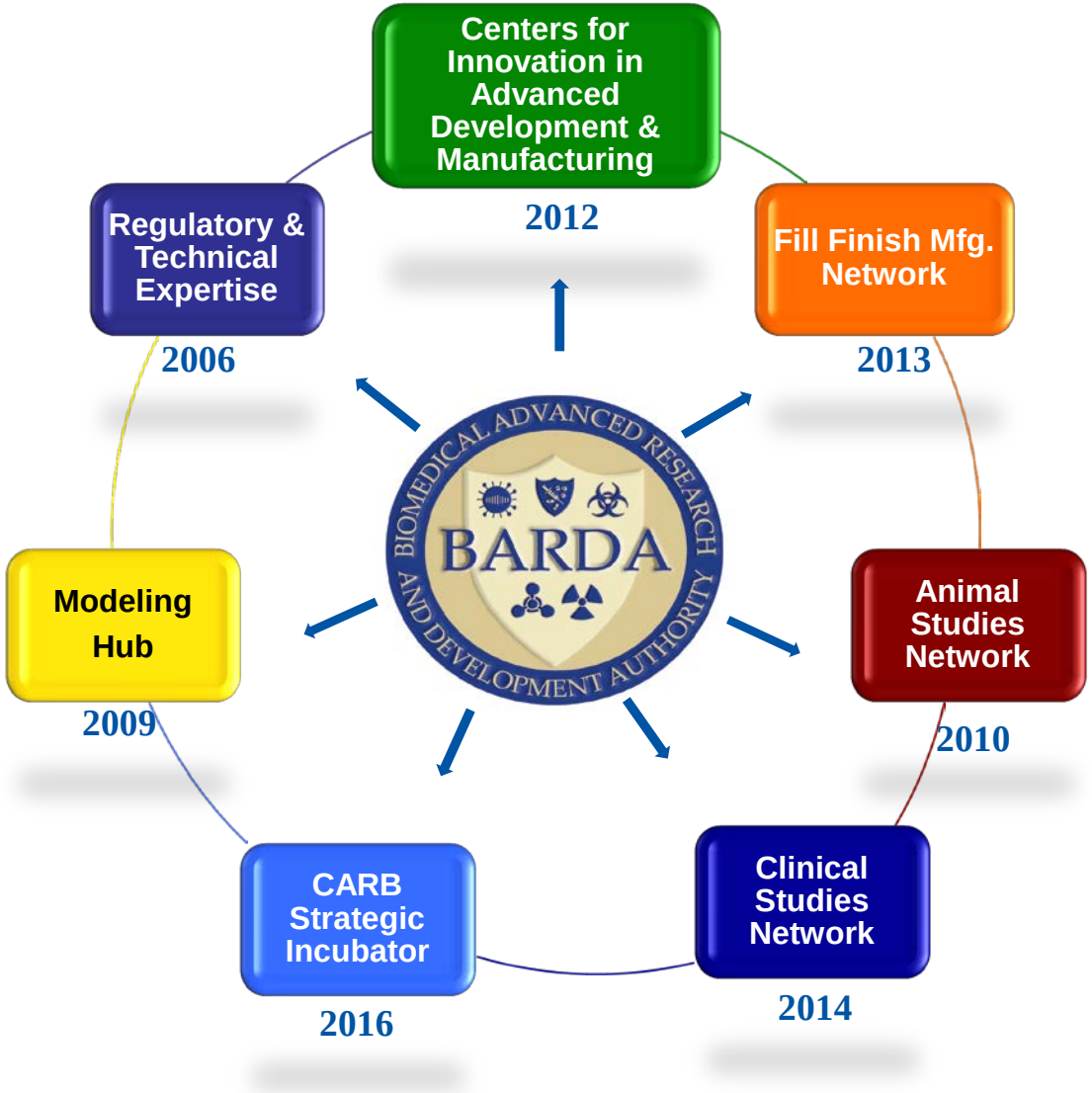


- BARDA Training Sites
- Licensed/Active Influenza Vaccine Producers
- BARDA/WHO Cooperative Agreement Grantees
- BARDA/WHO Licensed Pandemic Vaccine for Human Use as of 2013

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**

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