



United States Department of

Health & Human Services

Office of the Assistant Secretary for Preparedness and Response



BARDA Core Service Overview

2013 BARDA Industry Day

***Centers for Innovation in
Advance Development & Manufacturing
(CIADM)***

***Fill and Finish Manufacturing Network
(FFMN)***

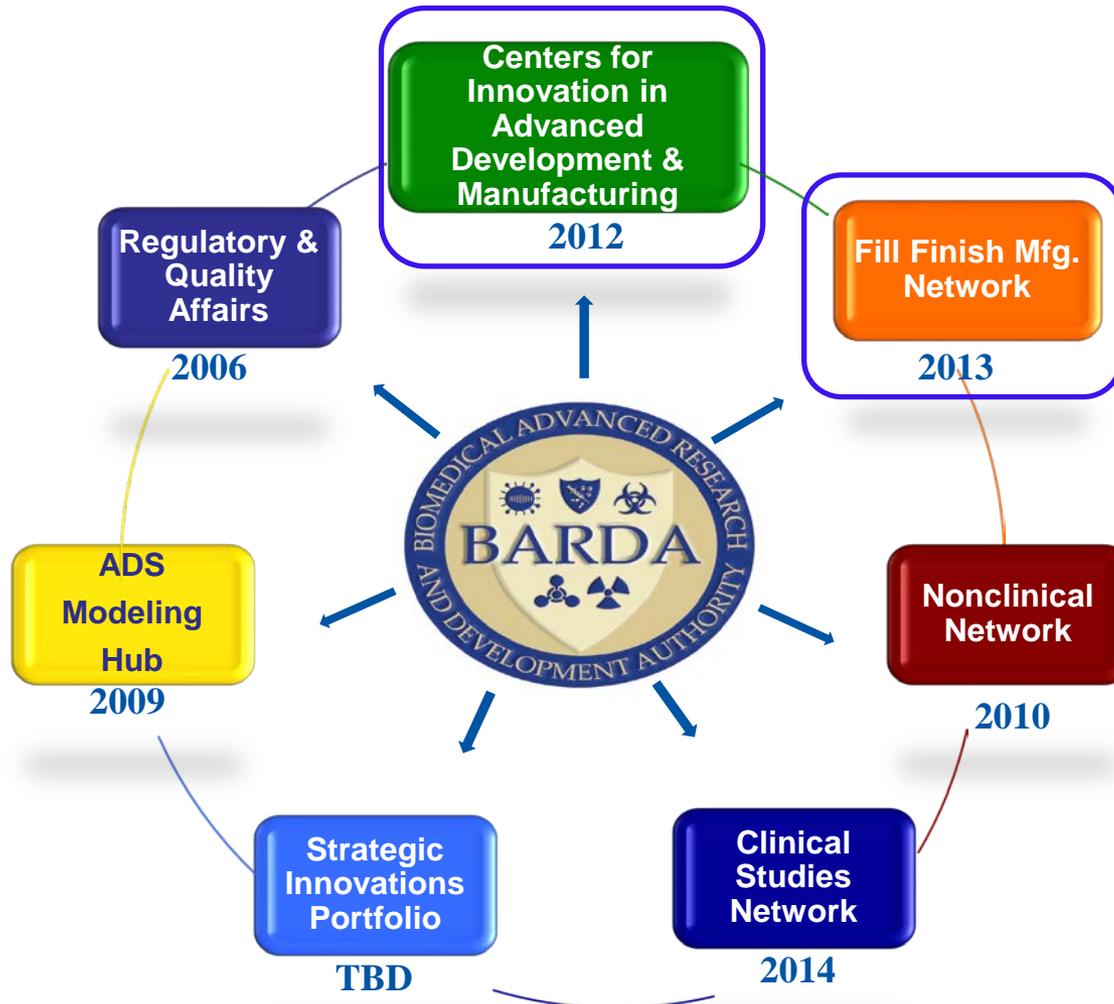
Tom Warf

Director, MFE

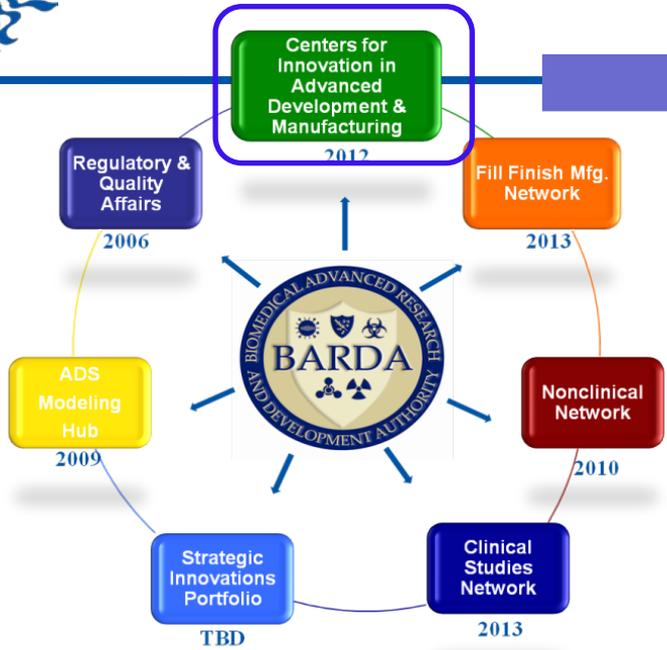
November 13, 2013

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

The CIADMs and FFMN are BARDA Core Services



CIADM: Capabilities



These public-private partnerships will provide advanced development and manufacturing capabilities as core service assistance to medical countermeasure developers for CBRN threats to augment national health security on a cost-effective, reliable and sustainable basis.

The Centers will also contribute to U.S. emergency preparedness by providing vaccine and biological product manufacturing surge capacity for pandemic influenza and other public health events.



CIADM Capabilities

- Pandemic influenza surge inventory (50M doses/center)
- CBRN Medical Countermeasures
- Regulatory support
- Analytical development
- Clinical trial and commercial scale lots
- Live virus vaccines
- 23 core services



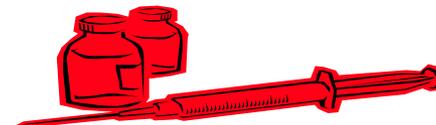
Pandemic Surge inventory



**Analytical development;
Lab Services**



Technology Transfer



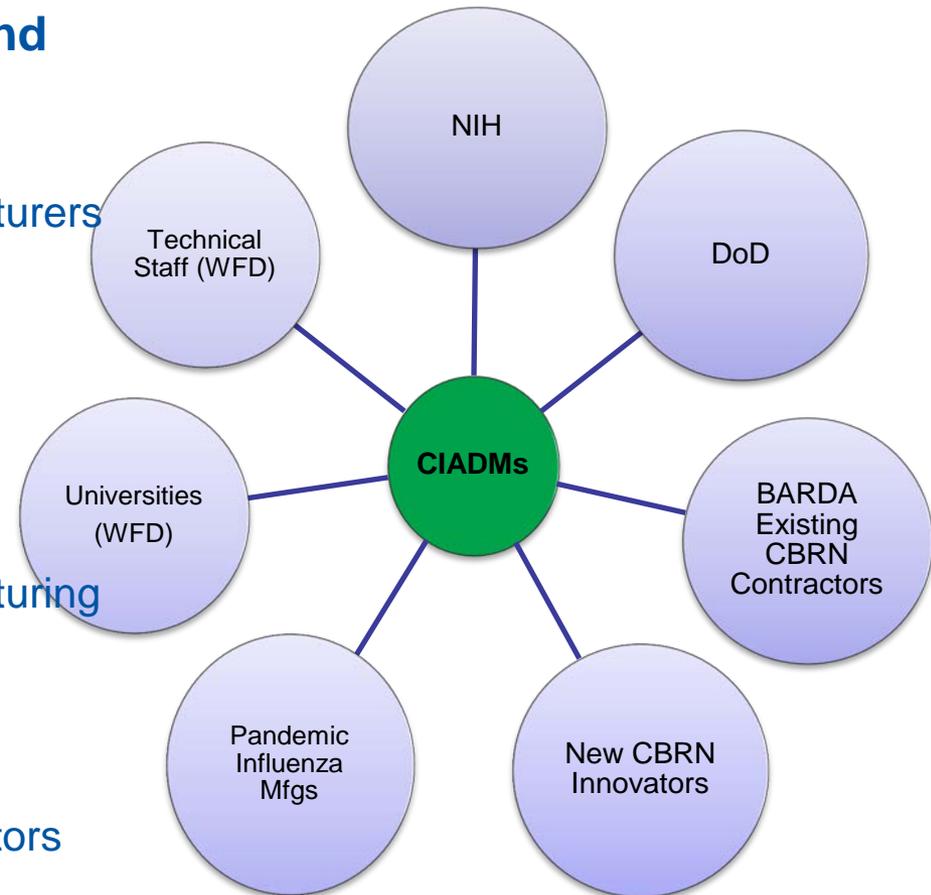
Clinical and Commercial Lot Manufacturing

- **CIADM will provide core services and pandemic surge capability by coordinating with:**

- Pandemic influenza vaccine manufacturers
- Universities
- MCM developers and manufacturers

- **CIADM supports:**

- Pandemic influenza vaccine manufacturing
 - Development and response
- NIH
- DoD
- BARDA existing CBRN MCM contractors
- Emerging infectious diseases





Centers for Innovation in Advanced Development & Manufacturing (CIADM)



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Novartis CIADM





Novartis CIADM



- Detailed design nearing completion
- NVD internal capital approved
- Long lead-time procurement in process
- Tech Services Building groundbreaking – Oct 2013

TAMUS CIADM





CORE SERVICES

- ‘Development Services’
 - Most are currently available in the NCTM
- ‘Manufacturing Services’ phase-in/ ramp-up as capacity is brought online
 - 4Q2013 – Adjuvant Facility Retrofitted [Marietta, PA] & Ready for Service
 - 2Q2015 – NCTM Core Retrofitted [College Station, TX] & Ready for Service
 - 4Q2015 – Live Virus Vaccine Pilot Facility [Bryan, TX] Ready for Service
 - 1Q2018 – Pandemic Influenza Facility [Bryan, TX] Ready for Production
- ‘Workforce Training Capabilities’ are ready by 3Q2014





NCTM Flexibility Mobile Bioprocessing Units

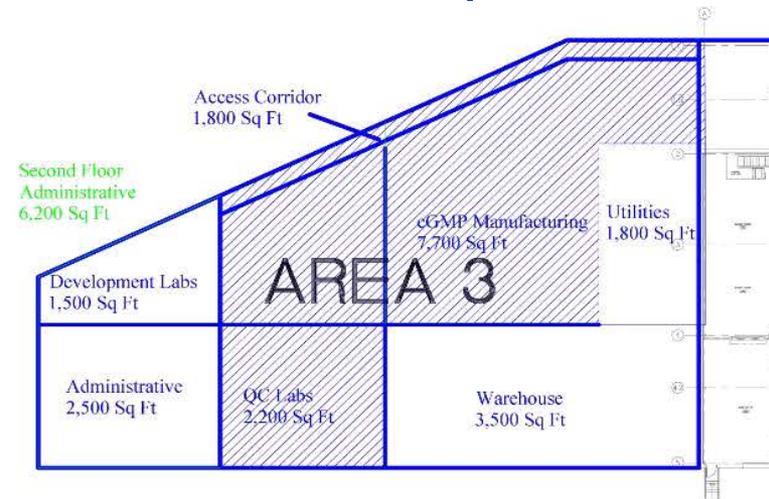


Emergent CIADM



Emergent CIADM

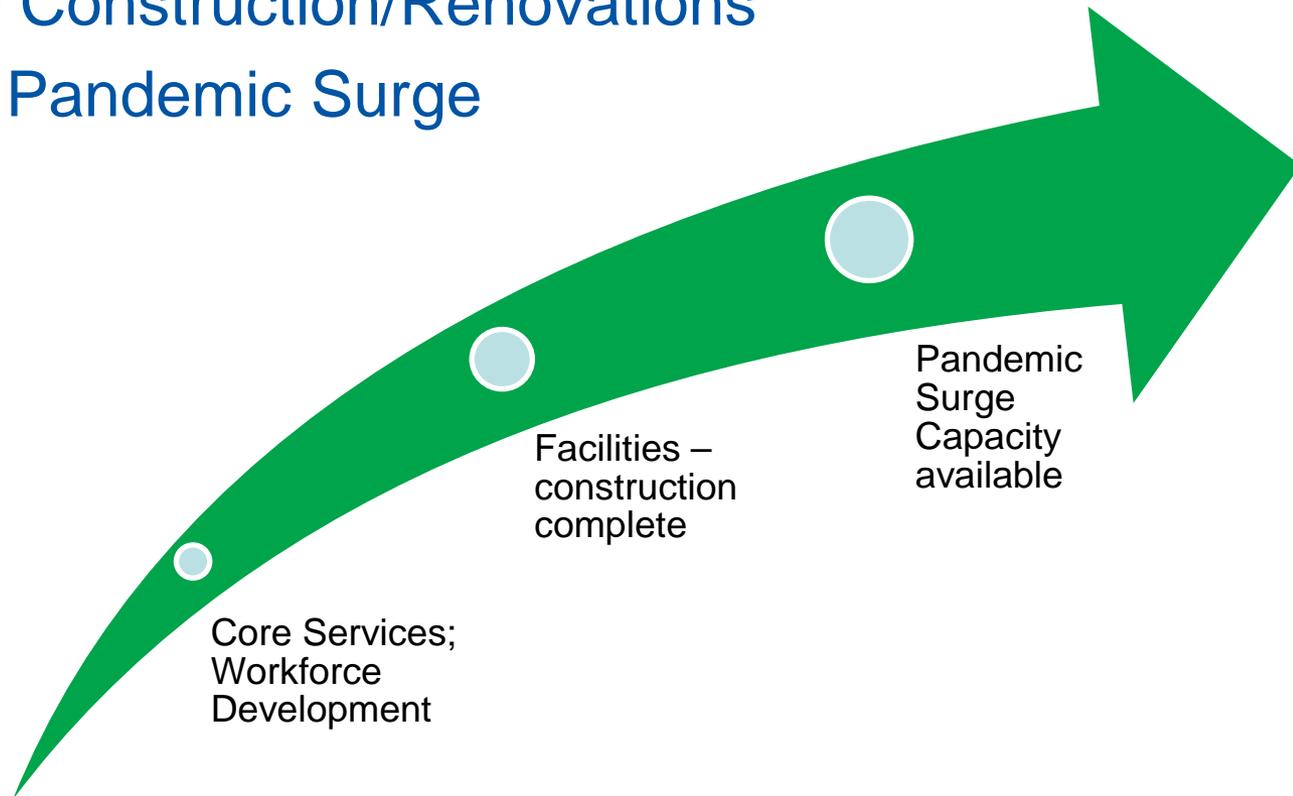
- VaxInnate signed as influenza candidate December 2012
- Conceptual design in progress for new Area 3 Manufacturing Suite, QC labs and Warehouse at the Baltimore facility
- Proof of Concept studies in progress at the Gaithersburg Development Lab for converting the VaxInnate process from traditional stainless steel reactors to disposables



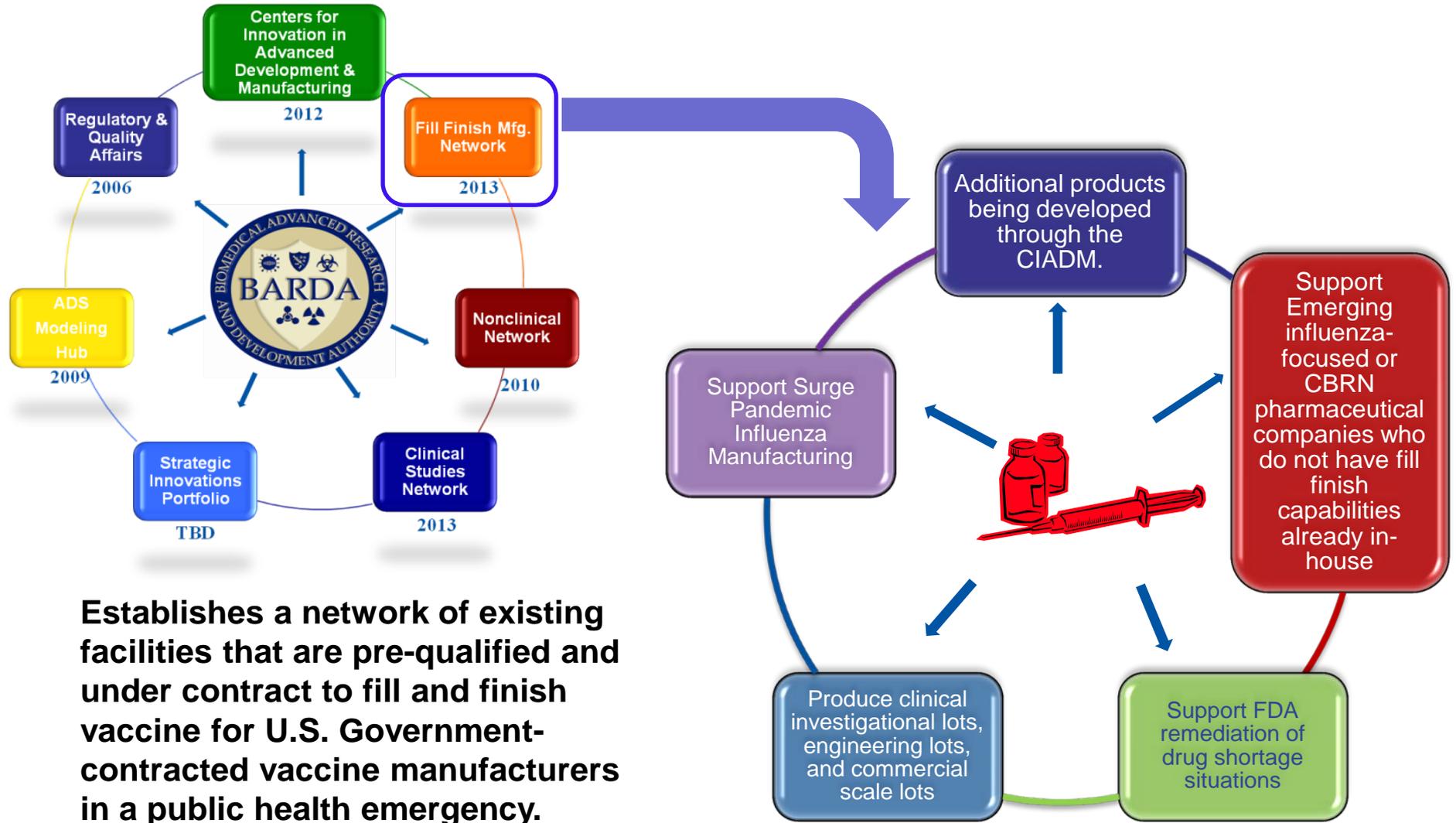


CIADM Trajectory for the Future

- Complete Core Services capabilities
- Establish Workforce Development
- Complete Construction/Renovations
- Establish Pandemic Surge



Fill and Finish Manufacturing Network: Capabilities



Establishes a network of existing facilities that are pre-qualified and under contract to fill and finish vaccine for U.S. Government-contracted vaccine manufacturers in a public health emergency.

FFMN Capabilities

Fill and Finish expertise in the following:

- Pandemic Influenza Surge Inventory (16M – 50M doses per Contract)
- CBRN Medical Countermeasures
- Regulatory Support
- Analytical Development
- Clinical Trial and Commercial Scale lots
- Labeling & Packaging
- Storage and Distribution
- Lyophilization



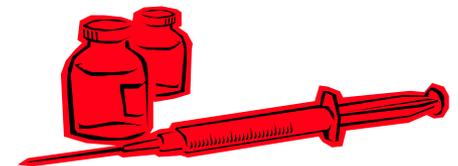
Pandemic Surge inventory



**Analytical development;
Lab Services**



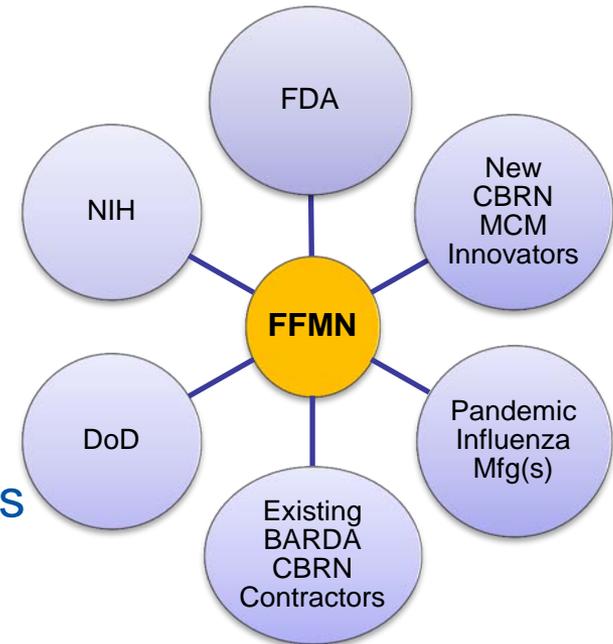
Technology Transfer



Clinical and Commercial Lot Manufacturing

- **FFMN will provide filling and finishing capabilities by coordinating with:**
 - Pandemic influenza vaccine manufacturers
 - Contract Manufacturing Organizations (Bulk CBRN MCMs)

- **FFMN supports:**
 - Pandemic influenza vaccine manufacturers
 - FDA (drug shortage)
 - Existing BARDA CBRN contractors
 - New CBRN MCM innovators
 - DoD
 - NIH





FFMN Contractors



Offeror	Potential Influenza Vaccine Candidate
Cook Pharmica	GSK *
JHP	CSL Biotherapies *
DSM	Novartis *
Nanotherapeutics partnered with Baxter Pharmaceutical Solutions (BPS)	Protein Sciences Corp (PSC) or Baxter Healthcare or Other

* BARDA Stockpile Contract company

Awarded Contracts on Sep 27, 2013 !!!

Fill and Finish Manufacturing Network

COOK[®]
PHARMICA

Syringe Packaging

DSM
BRIGHT SCIENCE. BRIGHTER LIVING.

JHP
PHARMACEUTICALS
Partners for Healthcare Excellence

nanotherapeutics[®]

Baxter

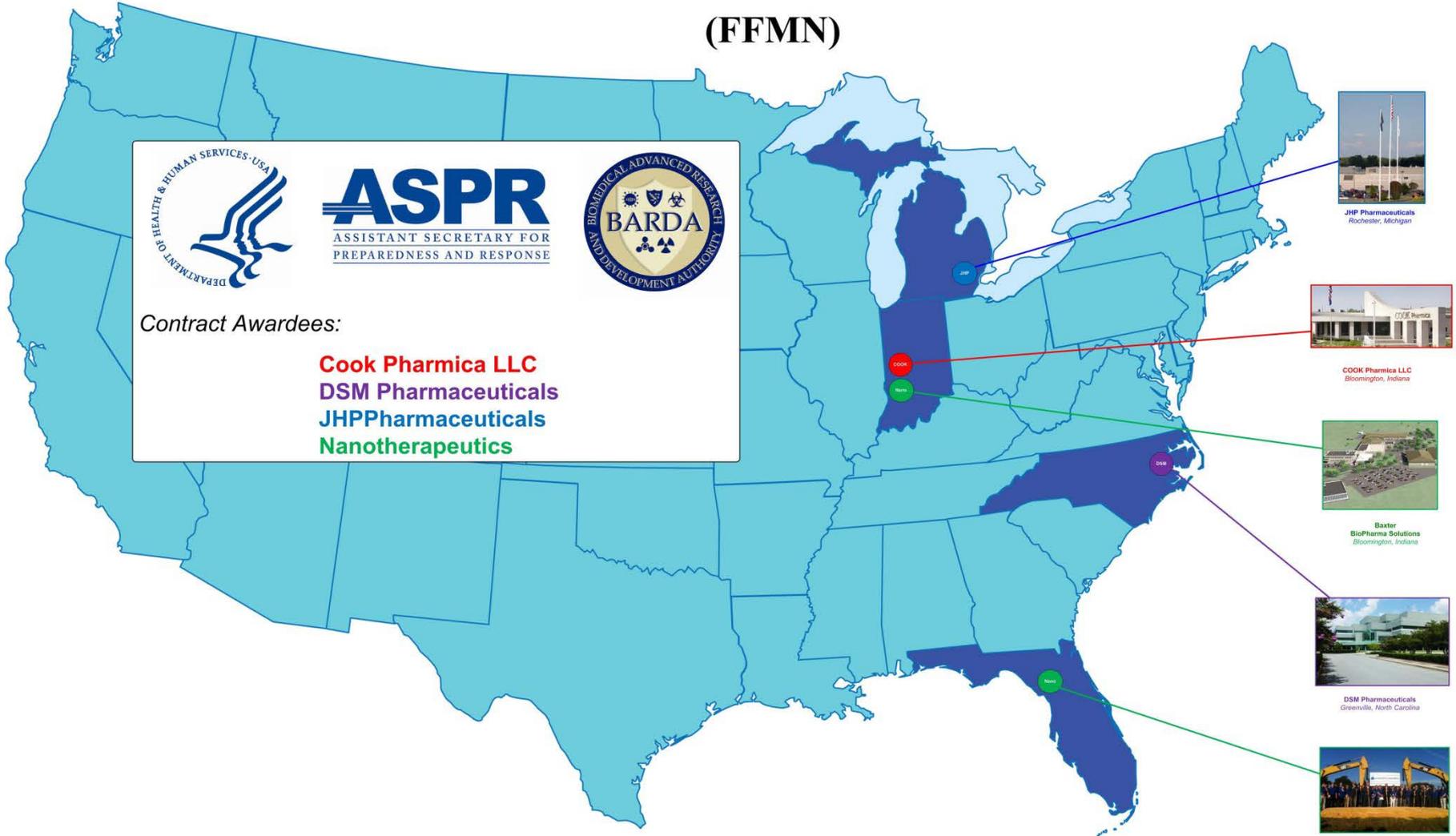
BioPharma Solutions



Fill and Finish Manufacturing Network



(FFMN)



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FFMN Trajectory for the Future

- Confirm Pandemic Influenza Partner
- Tech Transfer Pandemic Candidate
- Establish Pandemic Surge Capacity

