



United States Department of

Health & Human Services

Office of the Assistant Secretary for Preparedness and Response



The Medical Countermeasures Clinical Studies Network

BARDA Industry Day October 15, 2014

Robert Walker, MD

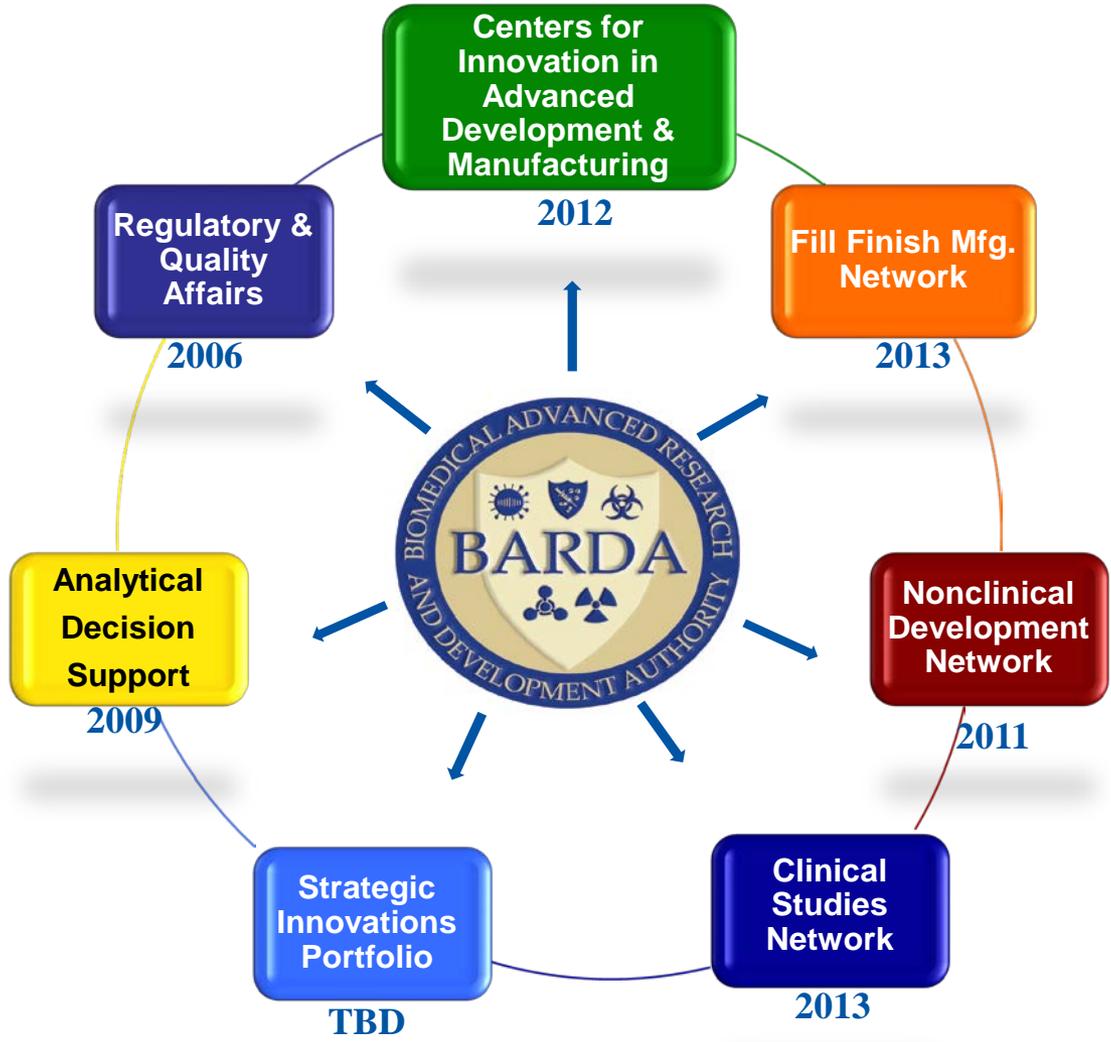
Deputy Director, Division of Clinical Studies

Biomedical Advanced Research and Development Authority

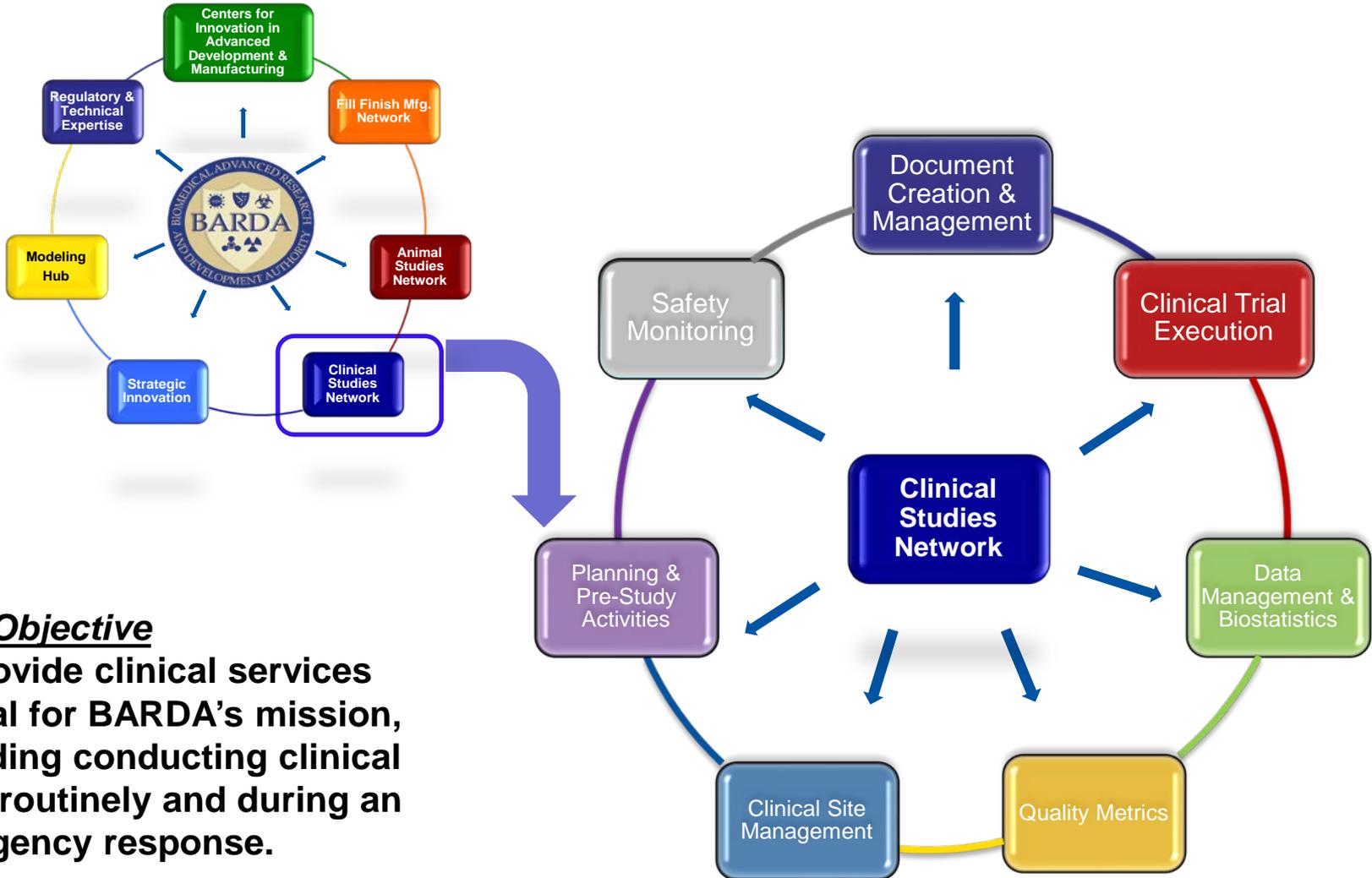
ASPR/HHS



BARDA Provides Comprehensive Critical Core Service Assistance to MCM Developers



Capabilities of the Clinical Studies Network (CSN)



CSN Objective

To provide clinical services crucial for BARDA's mission, including conducting clinical trials routinely and during an emergency response.



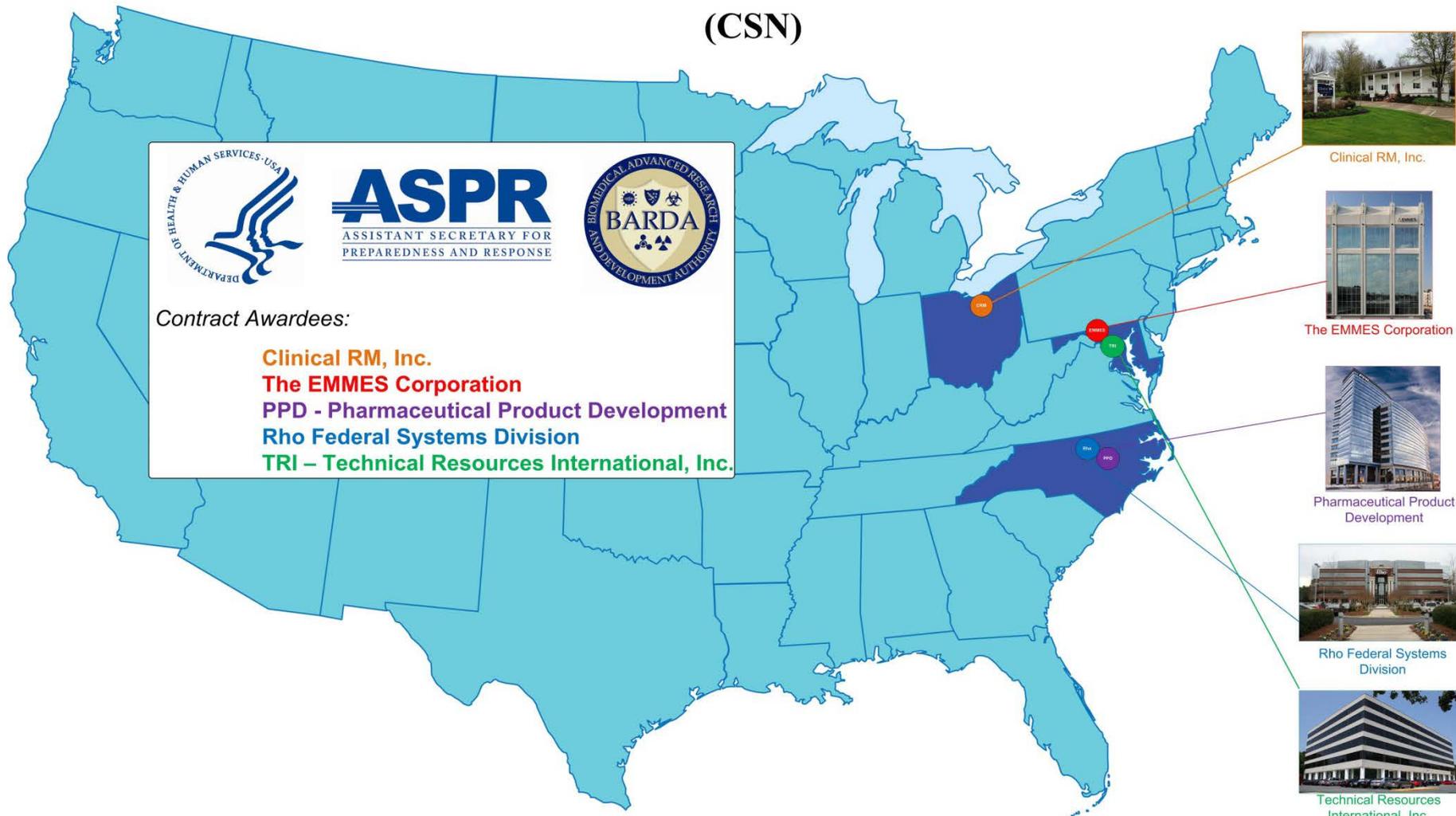
BARDA Medical Countermeasure Clinical Studies Network



- An ID/IQ contract was awarded to 5 Contract Research Organizations (CROs) in April 2014
 - Clinical Research Management, Inc.
 - EMMES Corp.
 - PPD, LLC
 - Rho Federal Systems, Inc.
 - Technical Resources International, Inc.
- Each CRO has the ability to provide the full range of clinical development support services



Clinical Studies Network



Clinical Trial Types

- Drugs (small molecules, peptides, mAb)
- Biologics (vaccines, cell therapies)
- Devices
- Diagnostics
- Procedures
- First-in-human through pivotal efficacy
- Post-marketing
- Special populations
- Stockpile safety and efficacy/immunogenicity



Domestic and international

Routine and during emergencies





BARDA Division of Clinical Studies Has Experienced Staff



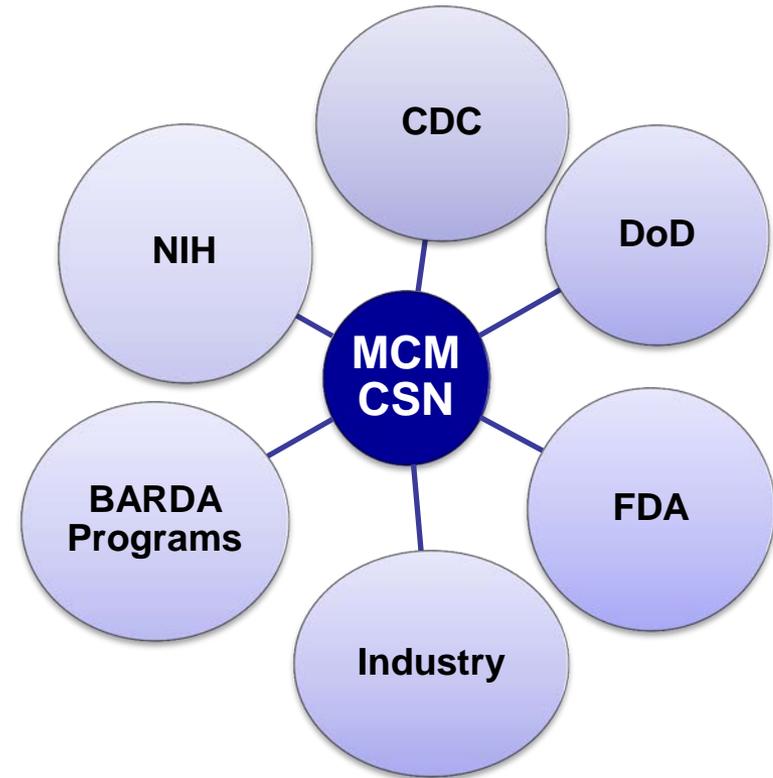
- 9 full-time healthcare professionals including
 - 4 clinical research physicians
 - 1 biostatistician
 - 4 clinical development/operations subject matter experts
- Years in product development
 - Total = 135, average = 15
- Years in industry
 - Total = 72, average = 8



CSN and Partner Interactions

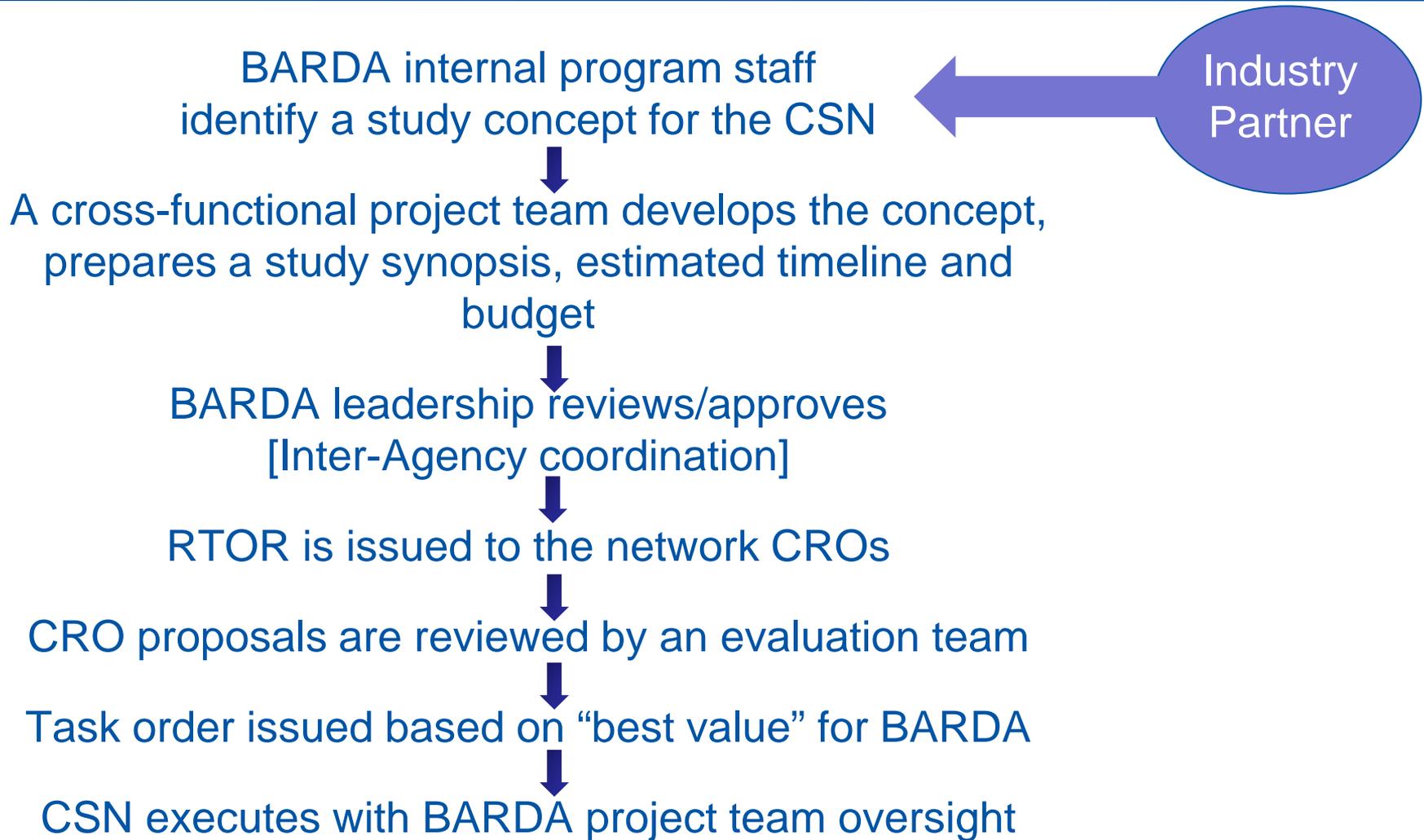


- Coordination of CSN activities with HHS and industry partners will be key, to ensure efficient product development and appropriate stewardship of government resources
- The CSN will use CRO networks of community-based clinical sites to complement academic, military, and other institution-based clinical research sites





CSN Process Flow





Future Plans



- Establish CSN infrastructure, i.e., charters, governance, templates, SOPs
- Initiate at least one clinical trial (issue at least 1 task order) by mid-2015



Thank You

QUESTIONS?

CONTACT US:

1. Existing programs

via your contract project officer or
program manager

2. New programs

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