



# **The Medical Countermeasures Clinical Studies Network (MCM CSN)**

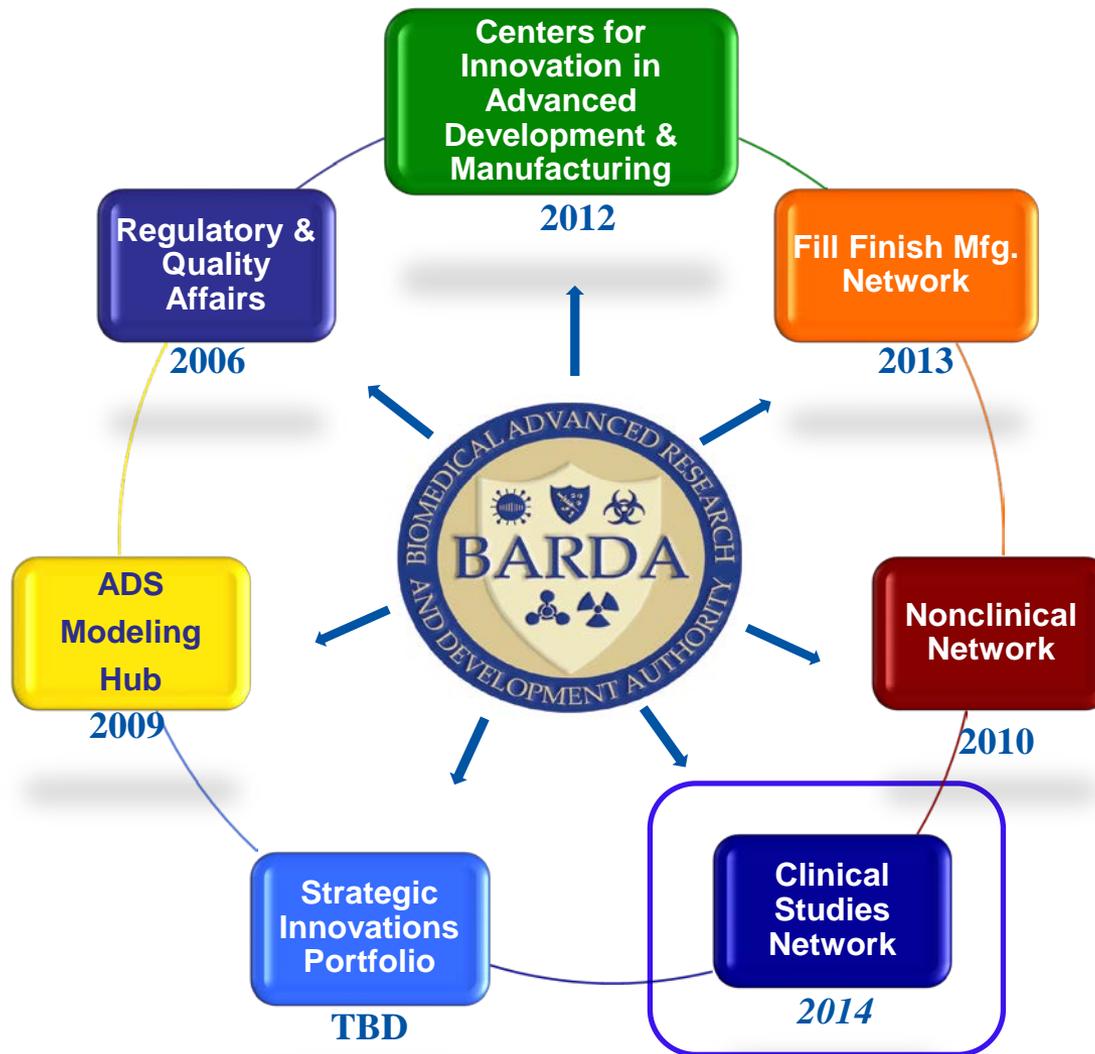
**BARDA Industry Day**

November 13, 2013

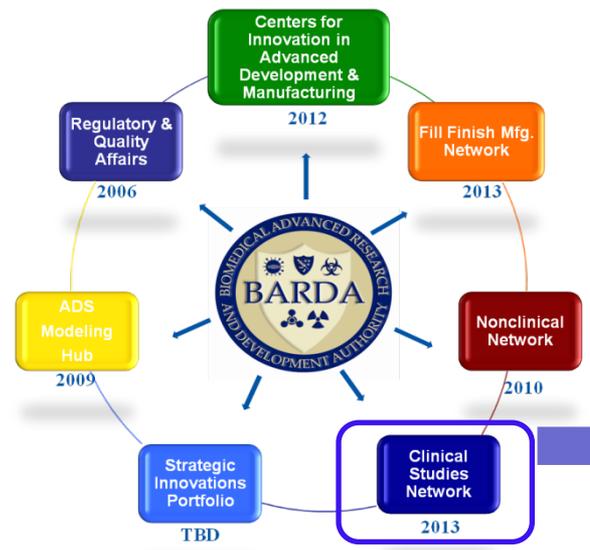
**Jo Ellen Schweinle, MD**  
**Director, Division of Clinical Studies**



# MCM CSN is a BARDA Core Service



# MCM CSN: Capabilities



**MCM CSN Objective: To perform clinical studies crucial for BARDA's mission and, when necessary, conduct clinical trials during an emergency response.**



# Program Strategy



Establish a network of CROs positioned to respond to BARDA's need for design and execution of clinical studies on both routine and urgent timelines.



# MCM CSN Product: Phase 1 – 4 Clinical Studies



- Drugs
- Vaccines
- Diagnostics
- Devices
- Procedures

## Special Populations



## Hospitalized & Outpatient

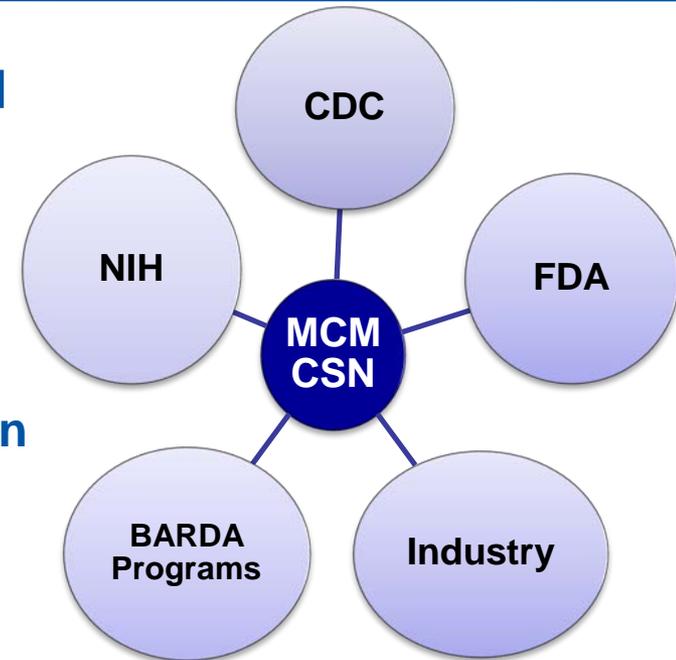


## During an Emergency



## Domestic and International

- **MCM CSN will provide clinical studies and coordinate with:**
  - **BARDA Programs**
  - **National Institutes of Health**
    - **Clinical samples for further study**
  - **Centers for Disease Control and Prevention**
    - **Clinical safety and efficacy of aging stockpile**
  - **Food and Drug Administration**
    - **Clinical studies during Public Health Medical Emergencies**
    - **Registries**
  - **Industry**
    - **Special populations**
    - **Proof of concept**





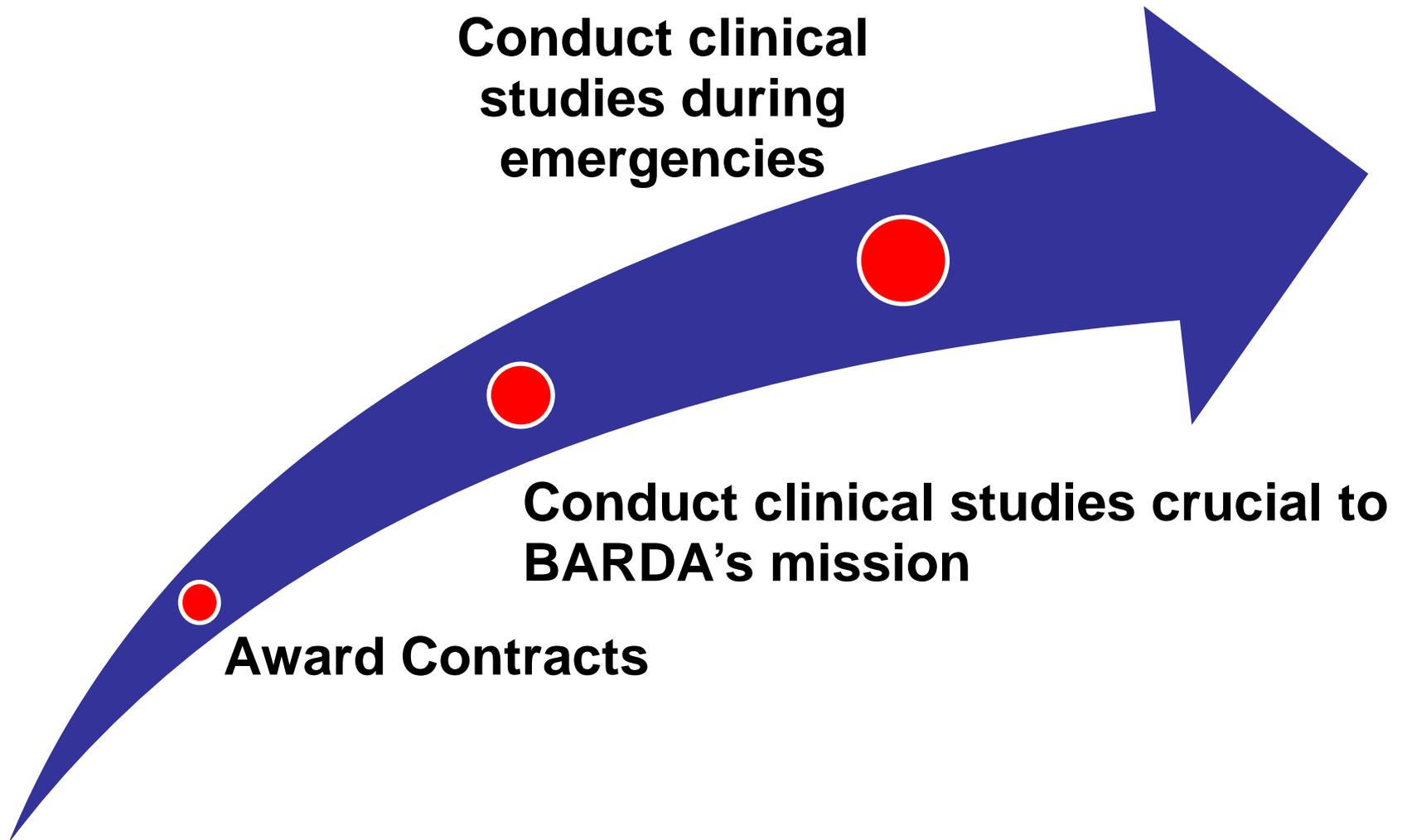
# MCM CSN: How Will It Work?

- **BARDA Program identifies need for a clinical study**
- **BARDA Program requests MCM CSN clinical core services**
- **Request is approved**
- **Study discussed with stakeholders**
- **Project team created**
- **Task order written and submitted to CROs**
- **Clinical contract research organization selected to conduct the study**
- **Study completed**
- **CRO submits data and reports to Contracting Officer and Project Officer**





# MCM CSN Trajectory for the Future





# Thank You



## QUESTIONS?

### CONTACT US:

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**Request a meeting:**

**<https://www.medicalcountermeasures.gov/>**