THE MEDICAL COUNTERMEASURES CLINICAL STUDIES NETWORK

BARDA INDUSTRY DAY
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CSN Program Objectives

- Provide comprehensive, Phase 1 – IV clinical study services to evaluate safety, dosage, PK/PD, and efficacy of MCM candidates
- Provide preparedness and execution capabilities for clinical studies during public health medical emergencies
- Collaborate with other core services and PHEMCE partners to contribute to the National MCM Response Infrastructure

CSN Program Strategy

- Establish a network of full service Clinical Research Organizations (CROs) using an ID/IQ multi-year contract
- Criteria for CRO selection included demonstrated capabilities to function in both preparedness and response environments

BARDA's National MCM Response Infrastructure

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. (Ohio)
  - Emmes Corp. (Maryland)
  - PPD, LLC (North Carolina)
  - Rho Federal Systems, Inc. (North Carolina)
  - Technical Resources International, Inc. (Maryland)

Clinical Trial Types

- Drugs (small molecules, peptides, mAb)
- Biologics (vaccines, cell therapies)
- Devices
- Diagnostics
- Procedures

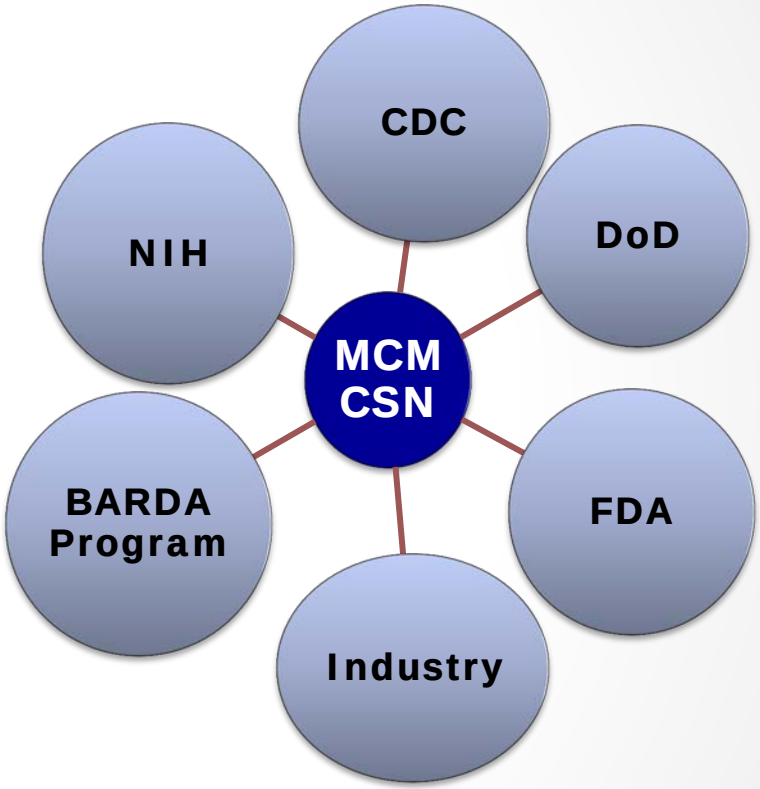
- First-in-human through pivotal efficacy
- Post-marketing
- Special populations
- Stockpile safety and efficacy/immuno-genicity

Domestic and international

Routine and during emergencies

CSN and Partner Interactions

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



Key Accomplishments

Project	Date of Issue	CRO	Description
Task Order 001	December 2014	PPD	Compile medical record data for sNDA (midazolam for neurotoxin-induced seizures)
Task Order 002	February 2015	TRI/FHI360	Clinical operations, project management, and site support for CDC Sierra Leone Ebola vaccine study – Phase 2/3
Task Order 002A	February 2015	Emmes	Data management, statistical, and safety support for CDC Sierra Leone Ebola vaccine study – Phase 2/3
Task Order 003	July 2015	PPD	Conduct stockpiled H5N1 influenza vaccine study – Phase 2
Draft RTOR	Not issued	--	Conduct H5N8 influenza vaccine study – Phase 1
Draft RTOR	Not issued	--	Back-up support for NIAID Ebola therapeutic master protocol in Guinea – Phase 2
RTOR 006	In progress	TBD	MERS-CoV therapeutic master protocol – Phase 2

BARDA's Division of Clinical Studies Provides Oversight of the CSN

- 12 full-time healthcare professionals
  - 4 clinical research physicians
  - 1 safety/pharmacovigilance physician
  - 2 biostatisticians
  - 3 clinical development/operations subject matter experts
  - 1 project manager
  - 1 administrative assistant
- Average 15 years in product development
  - 8 years in the pharmaceutical/biotechnology industry

Initiation of New Clinical Projects

BARDA internal program staff identify a study concept for the CSN

Industry Partner

A cross-functional project team develops the concept, prepares a study synopsis, estimated timeline and budget

BARDA leadership reviews/ approves [Inter-Agency coordination]

RTOR is issued to the network CROs

CRO proposals are reviewed by an evaluation team

Task order issued based on “best value”

CSN executes with BARDA project team oversight

Thank You

QUESTIONS?

CONTACT US:

1. **Existing programs**

   via your contract project officer (COR) or program manager

2. **New programs**

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