The Medical Countermeasures Clinical Studies Network (MCM CSN)

BARDA Industry Day

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MCM CSN is a BARDA Core Service

- Centers for Innovation in Advanced Development & Manufacturing
- ADS Modeling Hub (2009)
- Nonclinical Network (2010)
- Strategic Innovations Portfolio
- Clinical Studies Network (2014)
- TBD

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

Domestic and International

During an Emergency

Hospitalized & Outpatient

MCM CSN: Stakeholders

- 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

Conduct clinical studies during emergencies

Conduct clinical studies crucial to BARDA’s mission

Award Contracts

Thank You

QUESTIONS?

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Request a meeting:
https://www.medicalcountermeasures.gov/