BARDA
Division of Clinical Studies

Jo Ellen Schweinle, MD
BARDA Industry Day
December 10, 2012
Division of Clinical Studies

• Created June/July 2010
  — Three members

• Today
  — Six full-time members
  — Three part-time members

• Going forward
  — Two statisticians
  — One interdisciplinary Scientist/Project Officer
Clinical Team

—Christopher Davis
—Shar’Ron de Dreu
—Michael Elisseou
—Jim King
—Corrina Pavetto
—Ron Reisler
—Jo Schweinle
—Josh Speidel
—Lynne Wathen
Projected BARDA Clinical Trials

Total # Studies by Quarter 2012 - 2018

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Commitments

- Seasonal and Pandemic Influenza
- Anthrax
- Botulism
- Broad Spectrum Antibiotics
- Chemicals
- Diagnostic Tests
- Radiological/Nuclear
- Smallpox
Other Responsibilities

• BARDA Clinical Representation
  — CDC Disaster Preparation Exercises
  — National Commission on Children and Disasters
  — Federal Immunization Safety Task Force (VSRAWG)
  — All Hazards Science Response Working Group (NBSB)
  — Participate with multiple government agencies and other stakeholders to address MCM issues including:
    • Special populations
    • Dosing strategies
      — Pediatric populations
      — Pre-event versus post-event
    • Flu Risk Management
BARDA Clinical Trial Requirements

- Facilitation of collaboration between product developers
- Safety and efficacy data in special populations
- Outside the remit of partnering USG agencies

The lack of clinical data threatens the integrity of medical countermeasure development and deployment.
Need: To be able to perform clinical studies crucial for BARDA’s mission and, when necessary, conduct a clinical trial during an emergency response.

One Solution: 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.
QUESTIONS?

OR CONTACT US:

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jo.schweinle@hhs.gov

https://www.medicalcountermeasures.gov/
Request Meeting