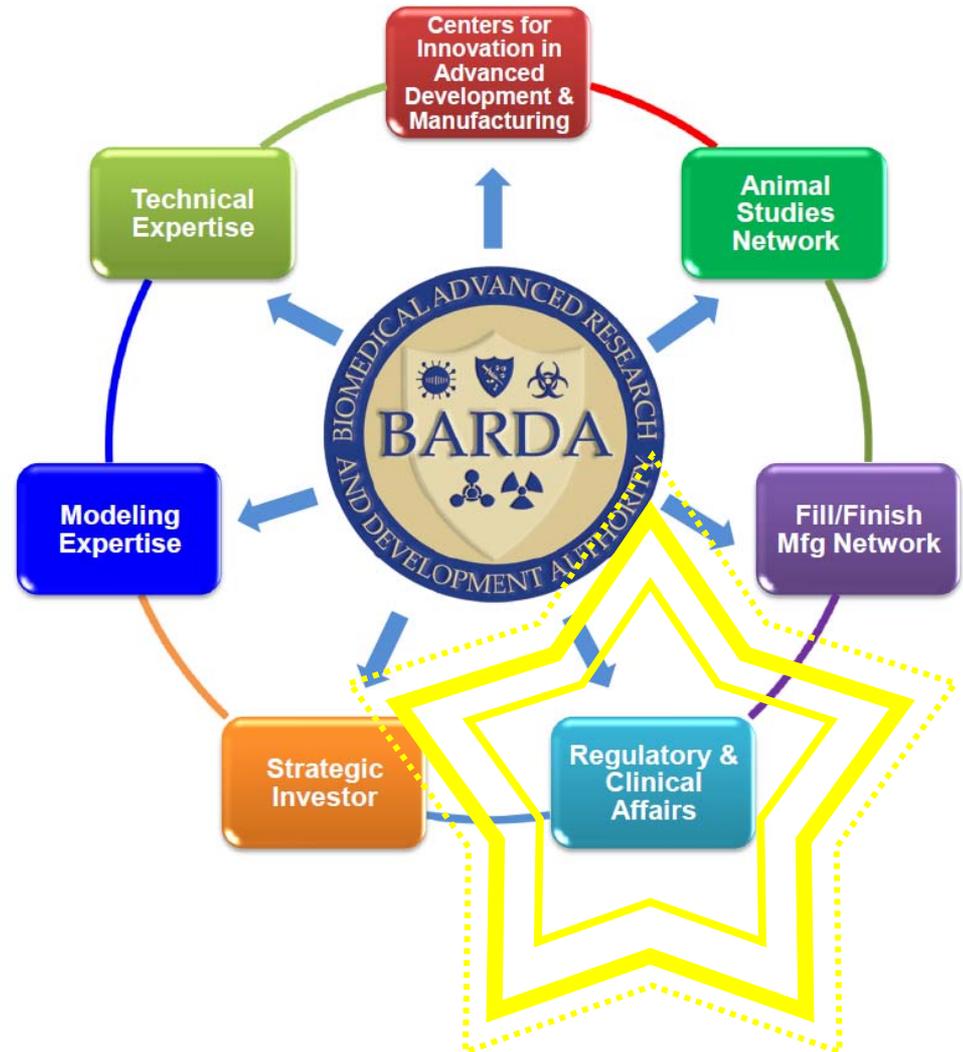




BARDA

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



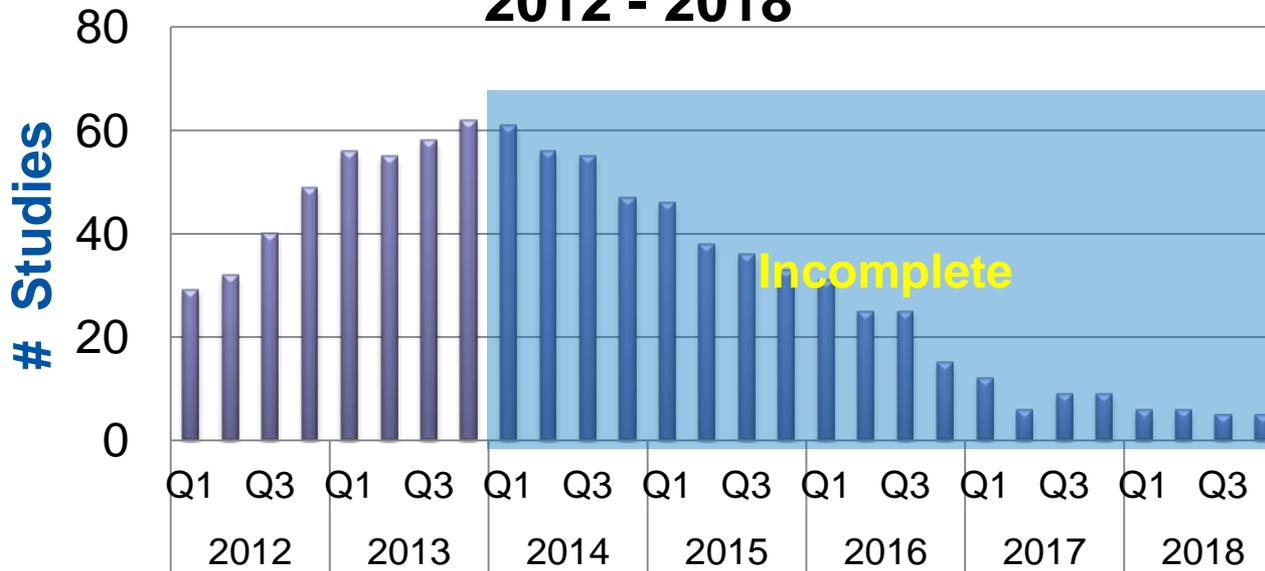
- Christopher Davis
- Shar’Ron de Dreu
- Michael Elisseou
- Jim King
- Corrina Pavetto
- Ron Reisler
- Jo Schweinle
- Josh Speidel
- Lynne Wathen



Projected BARDA Clinical Trials



Total # Studies by Quarter 2012 - 2018



Other Studies

2014	2015	2016	2017	2018	TOTAL
5	2	4	2	3	15



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.



Under Consideration



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.



United States Department of

Health & Human Services

Office of the Assistant Secretary for Preparedness and Response



QUESTIONS?

OR CONTACT US:

Jo Ellen Schweinle

jo.schweinle@hhs.gov

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

Request Meeting