



*United States Department of*

**Health & Human Services**

**Office of the Assistant Secretary for Preparedness and Response**



# **BARDA**

## **Division of Clinical Studies**

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**Director**

**BARDA Industry Day**  
**October 16, 2014**



# Overview



- **Who are we?**
- **What do we bring to the table?**
- **What do we do?**
- **Who do we do it for?**
- **What else do we do?**
- **Where do we want to go?**



# What Is the Division of Clinical Studies?



- We are a service group that uses our technical knowledge and professional experience to support BARDA on clinical and clinically-related issues across BARDA's entire portfolio.
- We also participate in any broader issues of biomedical ethics, operations and policy.
- We serve as clinical consultants within and external to BARDA to support:
  - BARDA Programs
  - BARDA Partners



# Mission and Vision



## Mission

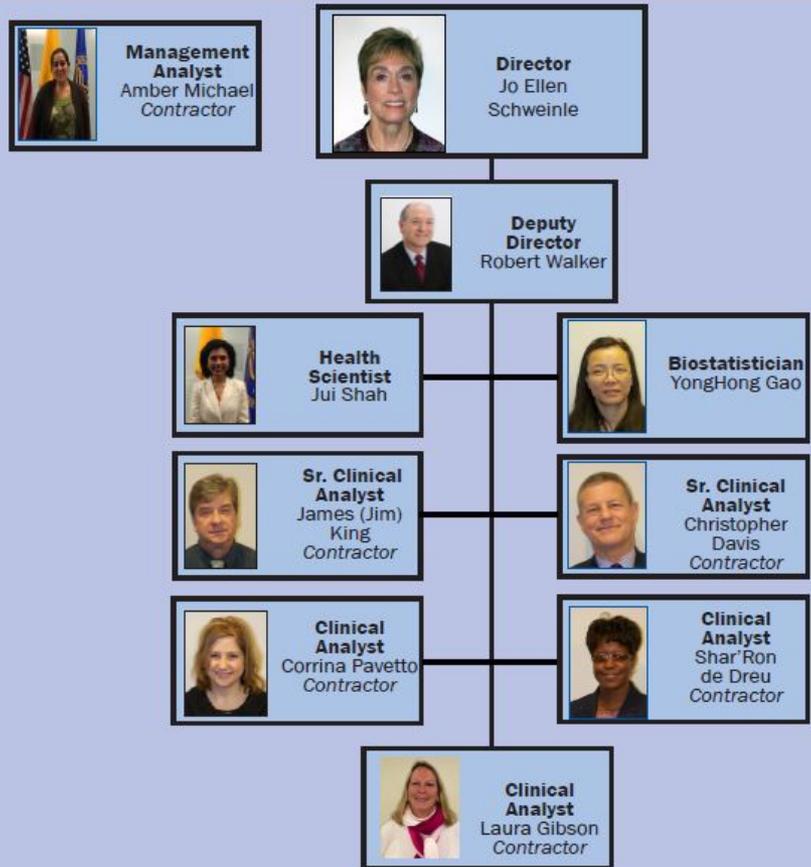
To assure performance of clinical studies that provide evidence of safety and efficacy or effectiveness for humans of medical countermeasures of interest to BARDA

## Vision

To rapidly perform clinical trials that meet the requirements for reliably demonstrating safety and efficacy or effectiveness of medical countermeasures for human use in a cost effective manner

# DCS Organizational Chart

## Division of Clinical Studies



Sept. 2014 v.1



# Personnel



- Years in product development
  - Total = 135
  - Average = 15
- Years in industry
  - Total = 72
  - Average = 8



# Program Support



- Before Contract Award
  - Clinical input on BARDA solicitations
  - Serve on Technical Evaluation Panels
- After Contract Award
  - Project Coordination Team (PCT) member
  - Guidance on clinical program development
  - Advice on clinical study budgets



# Program Support



- Clinical/Medical Support to PCT's
  - Review all clinical study protocol-related documents
  - Review all safety data; participate on DSMB's
  - Review efficacy data
  - Follow results of animal studies for clinical relevance
- Clinical Perspective on Regulatory Issues
  - Collaborate with Regulatory/Quality Assurance on clinical parts of BARDA regulatory documents
  - Review regulatory documents for BARDA partners from a clinical perspective
  - Attend meetings with FDA



# Program Support



- Statistical Support for Animal and Clinical Studies
  - Participate in protocol development
  - Provide sample size calculations
  - Evaluate sample size plans for soundness
  - Critically review Statistical Analysis Plans
  - Review analyses of study results
  - Independently analyze study results



# BARDA Partner Support



**MarketWatch**

**S&P 500**  
1,983 +16.86 +0.86%

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## FDA Gives NewLink Genetics Approval to Proceed to Phase 1 Clinical Studies of Their Ebola Vaccine

AMES, IA, Sep 04, 2014 (Marketwired via COMTEX) -- NewLink Genetics Corporation **NLNK, -3.00%** today announced that the United States Food and Drug Administration (FDA) has given permission for the Company to proceed to Phase 1 clinical trials with their Ebola vaccine candidate. This vaccine was initially developed by the Public Health Agency of



# Other Responsibilities



- Medical Countermeasures Clinical Studies Network
- Clinical Trials Database
  - Created in 2012 in the BARDA eRoom
  - Entered all BARDA-supported clinical trials since 2007
  - Information updated on a regular basis
  - Moving to the BARDA Tracking Tool



# Other Responsibilities



- ASPR, BARDA and Interagency Committees and Working Groups
  - Interagency Product Teams
  - PHEMCE Biological Agents Working Group
  - PHEMCE – MCSR Emerging Infectious Diseases Working Group
  - National Commission on Children and Disasters
  - Influenza Risk Management



# The Future



- **Clinical Studies Network**
  - Establish the infrastructure (charters, governance, templates, SOP's)
  - Initiate activities for at least one clinical trial by mid-2015
- **Clinical Trials Database**
  - Transition the current database into the BARDA Tracking Tool
  - Expand its capabilities to include clinical trial data (results, safety)
- **Personnel**
  - Add a pharmacovigilance expert
  - Add another statistician
  - Add a data manager



# Thank You



## QUESTIONS?

### CONTACT US:

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**Request a meeting:**

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