

*United States Department of*

# **Health & Human Services**

**Office of the Assistant Secretary for Preparedness & Response (ASPR)  
Biomedical Advanced Research & Development Authority (BARDA)**

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## **Division of Clinical Studies**

**Biomedical Advanced Research and Development Authority (BARDA)**

**Jo Ellen Schweinle, MD**

**Director, Division of Clinical Studies**

**HHS/ASPR/BARDA**

**October 2011**



# Division of Clinical Studies



- **June/July 2010 created**
  - Two physicians
  - One regulatory/clinical trial expert
  
- **September 2011**
  - Three physicians
  - One regulatory/clinical trial expert
  - Regulatory and Quality Assurance
  - CBRN Diagnostics
  
- **Resources going forward**
  - Statistician
  - Physician
  - Interdisciplinary Scientist



# Commitment to Influenza



## – Seasonal and Pandemic Influenza

- Vaccines
  - Egg based with adjuvants
  - Cell culture based +/- adjuvants
  - Recombinant +/- adjuvants
- Antiviral medications
- Diagnostic devices
- Safety
  - Safety reports
  - VAMPSS



# Commitment to CBRN



## — Anthrax

- MedKits
- Vaccines
- Therapeutics
  - Antitoxins
  - Antibiotics

## — Botulism

- Antitoxins



# Commitment to CBRN



- **Broad Spectrum Antibiotics**
- **Smallpox**
  - Vaccines
  - Antiviral Agents
- **Diagnostic Tests**
  - Especially Biodosimetry
- **Chemicals**



# Commitment to CBRN



- **Radiological/Nuclear**

- Mitigation of acute radiation syndrome

- Organ systems focus
    - Hematopoietic
    - Gastrointestinal
    - Epidermal

- Therapeutic agents

- Biologics
    - Small molecules
    - Oxygen radical scavengers



# Programmatic Responsibilities



- **Pre-Award**

- Clinical input on BARDA solicitations
- Critically review technical and business proposals
- Participate on technical evaluation panels

- **Post-Award**

- Member of the Project Coordination Team (PCT)
- Guidance on clinical program development
- Costs and budgets review



# Programmatic Responsibilities



- **Clinical Support for PCT**
  - Review protocols
  - Review safety data
    - Safety monitoring procedures
    - Serious Adverse Event (SAE) reports
    - Data safety monitoring board minutes
    - Potential safety signals
  - Review efficacy data
    - Early data reports
    - Interim data
    - Annual reports
    - Clinical study reports



# Programmatic Responsibilities



- **Regulatory Input from a Clinical Perspective**
  - Review
    - Regulatory strategy
    - FDA briefing packages
    - FDA correspondence
    - Clinical sections of regulatory submissions
    - IND submissions
  - Attend meetings with FDA



# Programmatic Responsibilities



- **Clinical Guidance for Licensure or Approval**
  - Participate in preparatory meetings
  - Review clinical summaries of BLA or NDA filings
  - Attend pre-BLA or pre-NDA FDA meetings
  - Participate in post-meeting assessments



# 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



# Team Members



- **Jo Ellen Schweinle, MD - Director**

- Board Certified in Internal Medicine and Infectious Disease
- Former Visiting Scientist at NIH
- Over 19 years career in academic medicine
- Primary academic interest in microbial pathogenesis and the complement system of immunity
- Over 18 years experience in industry drug development
- Vice President Medical Affairs
- Therapeutic areas – Small Molecules and Biological Products
  - Infectious Diseases
  - Osteoarthritis
  - Hematology
  - CNS
  - Vaccines
  - Urinary Tract
  - Endocrinology
  - Gastroenterology





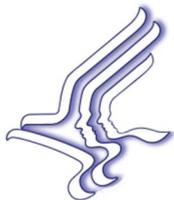
# Team Members



- **James King, MD - Senior Clinical Analyst**

- Board certified in Pediatrics
- Fellowship in adult and pediatric infectious disease
- Primary academic interest in vaccines
- Chief, Pediatric Primary Care Academic Division >10 years
- Over 20 years experience in conducting Phase I through IV clinical trials in adults and children
  - Respiratory virus vaccines
  - Combination and conjugated bacterial vaccines
  - Special populations (HIV infected children and adults, infants)
- Over 10 years service on an academic IRB





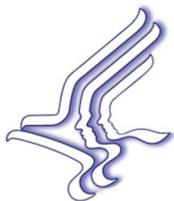
# Team Members



- **Christopher J. Davis, OBE, MD, PhD, FFPM – Senior Clinical Analyst**



- Board Certified in Pharmaceutical Medicine
- Doctorate in Clinical Pharmacology
- 30 years experience in CBRN weapons effects & countermeasures
- 10 years in intelligence community in bioweapons threat assessment
- 15 years experience in industry
  - Drug discovery
  - Clinical trials
  - Infectious disease diagnostics
  - Detection systems
- 2 years in Office of Policy & Planning at HHS/ASPR
- Member/Chair of NAS, NATO & HHS Committees on Bioweapons, Radiation & Critical Infrastructure Protection

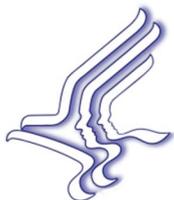


# Team Members



- **Corrina Pavetto, MS, RAC - Program Manager**
  - 3 years experience working on influenza contracts
  - Prior pharmaceutical industry and CRO experience
  - Over 15 years experience managing Phase I through IV clinical trials in the following therapeutic areas:
    - Infectious Diseases
    - Oncology
    - Cardiovascular Disease
    - CNS
    - Women's Health
  - Prior experience as a clinical research coordinator
  - Certified in regulatory affairs





# Team Members



- **Michael Elisseou, PhD - Regulatory Scientist**

- Doctoral degree in physical organic chemistry
- Prior pharmaceutical industry and CRO experience
- Experience in process development
- Participated in 4 successful NDAs
- Over 25 years experience managing clinical trials in the following therapeutic areas:
  - CNS
  - Pain
  - Osteoarthritis and Rheumatoid arthritis
  - Cardiovascular
  - Sepsis
  - Diabetes





# Team Members



- **Lynne K. Wathen, PhD – Interdisciplinary Scientist**
  - Primary academic interest in radiation biology, transplantation, immunology and oncology therapeutics
  - Over 15 years experience in running Phase 1 through 4 clinical trials in children and adults in the following therapeutic areas:
    - Infectious Disease
    - Women’s Health
    - Oncology
    - Medical Devices and Diagnostics
  - Over 15 years experience developing assays to support global regulatory approval of newly developed vaccines, therapeutics, and devices





# Aspirations



- **Strengthen partnerships with industry**
  - Clinical development plans
  - Protocols
  - Safety
- **Prepare for disasters**
  - Protocols ready
  - Relationships with healthcare/governments of other countries in place
  - Pre EUAs prepared
- **More attention to groups at special risk**



# Working Together



***DCS looks forward to working collaboratively to develop important MCMs for the public***

**Questions ?**