



**United States Department of
Health & Human Services
Office of the Assistant Secretary for Preparedness and Response (ASPR)**

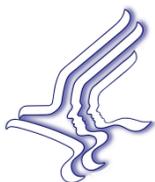


Division of Clinical Studies

Biomedical Advanced Research and Development Authority (BARDA)

Jo Ellen Schweinle, MD

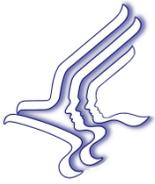
**Acting Director
HHS/ASPR/BARDA**



Division of Clinical Studies



- **June/July 2010 created**
 - Two physicians
 - One regulatory/clinical trial expert
- **August/September four part-time team members borrowed**
 - Regulatory and Quality Assurance
 - CBRN Diagnostics
 - Broad Spectrum Antibiotics
 - Administrative Assistant
- **Resources going forward**
 - Statistician
 - Physician
 - Interdisciplinary Scientist

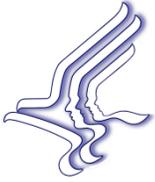


Commitment to Influenza



– Seasonal and Pandemic Influenza

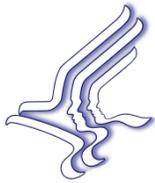
- Vaccines
 - Egg based with adjuvants
 - Cell culture based +/- adjuvants
 - Recombinant +/- adjuvants
- Antiviral medications
- Diagnostic devices
- Safety
 - Safety reports
 - VAMPSS



Commitment to CBRN



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

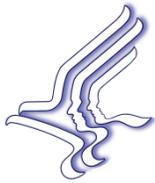


Commitment to CBRN



- **Radiological/Nuclear**

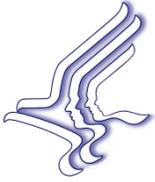
- Mitigation of acute radiation syndrome
 - Organ systems focus
 - Hematopoietic
 - Gastrointestinal
 - Epidermal
- Therapeutic agents
- Biologics
- Small molecules
- Oxygen radical scavengers



Other Responsibilities



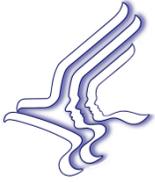
- **BARDA Clinical Representation**
 - CDC Disaster Preparation Exercises
 - National Commission on Children and Disasters
 - Federal Immunization Safety Task Force (VSRAWG)
 - All Hazards Science Response Working Group (NBSB)
 - Participate with multiple government agencies and other stakeholders to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



Aspirations

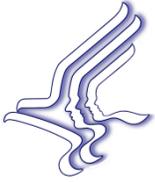


- **Strengthen partnerships with industry**
 - Clinical development plans
 - Protocols
 - Safety
- **Prepare for disasters**
 - Protocols ready
 - Relationships with healthcare/governments of other countries in place
 - Pre EUAs prepared
- **More attention to groups at special risk**



Programmatic Responsibilities

Corrina Pavetto, MS, RAC



Programmatic Responsibilities



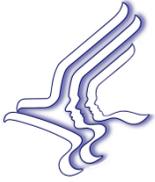
- **Initial Responsibilities**

- Pre-Award

- Contribute clinical input on BARDA solicitations
- Critical review of all technical and business proposals received by BARDA that involve clinical studies
- Participate on technical evaluation panels

- Post-Award

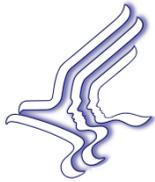
- Attend kick off meetings and become an integral member of the project coordination team for each BARDA contract
- Offer guidance on the development of clinical programs
- Review costs and budgets regarding clinical trials



Programmatic Responsibilities



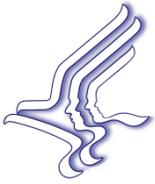
- **Ongoing Regulatory Input from a Clinical Perspective**
 - Review and comment on regulatory strategy
 - Review FDA briefing packages
 - Attend meetings with FDA
 - Review FDA correspondence
 - Review clinical sections of regulatory submissions



Programmatic Responsibilities



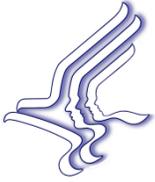
- **Ongoing Clinical Support for Contracts**
 - Review of safety data
 - Serious Adverse Event (SAE) reports
 - Safety monitoring procedures and minutes from data safety monitoring boards
 - Any potential safety signals
 - Review of efficacy data
 - Early data reports
 - Ongoing IND submissions
 - Annual reports
 - Interim data
 - Clinical study reports



Programmatic Responsibilities

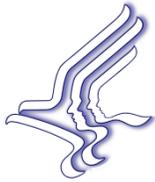


- **Clinical Guidance for Licensure or Approval**
 - Participate in preparatory meetings with the contractor
 - Attend pre-BLA or pre-NDA FDA meetings
 - Participate in post-meeting assessments
 - Review clinical summaries of BLA or NDA filings



Expertise

Jim King, MD



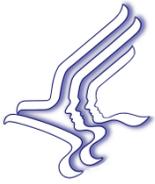
Team Members

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

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



- Infectious diseases
- Cholestatic liver disease
- Stomach ulcers
- Osteoarthritis
- Sickle cell disease
- Hypercholesterolemia
- ADHD
- Vaccines
- Exocrine pancreatic insufficiency
- Inflammatory bowel disease
- Urinary incontinence
- Diabetes
- Alzheimer's Disease
- Hemostasis



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 for over 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

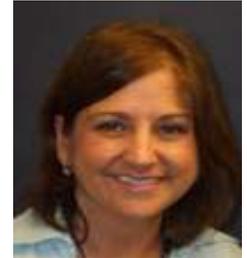




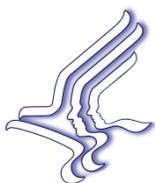
Team Members



- **Corrina Pavetto, MS, RAC - Program Manager**



- 3 years experience working on influenza contracts
- Prior pharmaceutical industry and CRO experience
- Over 15 years experience in managing Phase I through IV clinical trials in the following therapeutic areas:
 - Infectious disease
 - Oncology
 - Cardiovascular disease
 - CNS
 - Women's Health
- Prior experience as a clinical research coordinator
- Certified in regulatory affairs



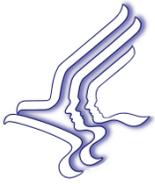
Team Members



- **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





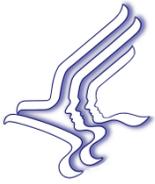
Team Members



- **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





Team Members



- **Terrie Kolodziej, RN, BSN, MS - Interdisciplinary Scientist**



- BARDA Project Officer proposal technical evaluator
- Previous associate PI on Phase 1 clinical trials in adults
- Member International Working Group on Human Subject Protection
- Conducted NIH intramural clinical studies in hypertension and diabetes
- Primary academic interest metabolic syndrome
- Over 10 years of grant and contract experience

