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

— Areas of CBRN Focus

• 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
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 though 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
• DCS looks forward to working collaboratively with contractors to develop important MCMs for the public

Questions ?