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

Questions ?