



8TH ANNUAL BIODEFENSE VACCINES & THERAPEUTICS

June 14-17, 2010 | Almas Temple Club | Washington DC

Animal Model Forum

Tuesday, June 15, 2010, 9:00 AM – 5:00 PM

Agenda

- 8:00 – 9:00 Registration and Networking Breakfast
- 9:00 – 9:10 **Welcome and Opening Remarks**
Robert House, MSPH, Ph.D., *President, DynPort Vaccine Company LLC and Member of the Board of Directors, Alliance for Biosecurity*
- 9:10 – 9:45 **Presentation: Update on the Status of Animal Model Development Efforts**
This joint presentation will provide an update on the Alliance for Biosecurity and the Medical Countermeasures Against Radiological Threats (MCART) consortia on status of animal models development efforts to date. Dr. Snow will highlight findings of the Alliance for Biosecurity’s first “State of Industry” survey. Dr. MacVittie will summarize the status of animal model development efforts in support of medical countermeasure (MCM) approval against radiological and nuclear threats. Specific knowledge gaps will be identified and discussed in the context of FDA “animal rule” criteria. The animal rule includes the need for well-characterized models that anchor the development of a validated data base requisite for the definition of dose-, severity- and time-dependent relationships for the major organ-specific sequelae of the acute radiation syndrome.
- Thomas MacVittie, Ph.D.**, *Professor and Director, PreClinical Research Laboratory, MCART, Department of Radiation Oncology, University of Maryland School of Medicine*
Doris Snow, Ph.D., *Director, Regulatory Affairs, DynPort Vaccine Company LLC and Member of the Vaccines Subgroup, Alliance for Biosecurity*

9:45 – 11:00

Panel Discussion: Key Challenges in Efficacy Studies Using Animals and Strategies for Addressing Challenges

There are many scientific and resource challenges to the successful development of efficacy tests, including availability of biosafety lab space, funding, availability of analytical and immunological tools to interpret data from animal models, oversight of the use of animals in biocontainment environment involving infectious agents and infrastructure issues. The panelists will share their observations of these challenges and what resources are expected to be available to help industry succeed.

Co-Moderators:

Thomas MacVittie, Ph.D., *Professor and Director, PreClinical Research Laboratory, MCART, Department of Radiation Oncology, University of Maryland School of Medicine*

Doris Snow, Ph.D., *Director, Regulatory Affairs, DynPort Vaccine Company LLC and Member of the Vaccines Subgroup, Alliance for Biosecurity*

Panelists:

Thomas M. Dreier, Ph.D., *Senior Program Manager, Biomedical Advanced Research and Development Authority (BARDA), Office of the Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services (DHHS)*

Judith Hewitt, Ph.D., *Chief, Biodefense Research Resources Section, Office of Biodefense Research Affairs, Division of Microbiology and Infectious Diseases, National Institute of Allergy and Infectious Diseases (NIAID), NIH*

Bert Maidment, Ph.D., *Associate Director for Product Development, National Institute of Allergy and Infectious Diseases (NIAID), NIH*

Rosemary Roberts, M.D., *Director, Office of Counter-Terrorism and Emergency Coordination, Center for Drug Evaluation and Research, U.S. Food and Drug Administration*

Jim Swearingen, DVM, DACLAM, DACVPM, *Comparative Medicine Veterinarian, National Biodefense Analysis and Countermeasures Center (NBACC)*

11:00 – 11:30

Morning Networking Break

11:30 – 12:00

Presentation: Where are the Countermeasures? Protecting America's Health From CBRN Threats – A Report of the National Biodefense Science Board

America faces grave danger from a wide range of chemical, biological, radiological, and nuclear (CBRN) weapons and from the emergence and spread of infectious diseases. Whether intentional or natural, CBRN agents have the potential to incapacitate society and severely damage the economy. The need

to develop MCMs makes the Secretary of HHS and her agencies responsible for critical elements of national security. On December 1, 2009, HHS Secretary Kathleen Sebelius called for a comprehensive review of the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). In turn, the Department tasked the NBSB with leading this review, emphasizing an examination of the related strategic management, leadership and accountability structure, and asking for a report synthesizing the issues and challenges facing the PHEMCE. On March 26, 2010, the NBSB publicly presented its report with 23 major recommendations to consider in the reassessment of MCM responsiveness. These 23MCM-related recommendations center on the urgent need for a unified national biodefense strategy, centralized leadership and adequate and sustained funding.

John Grabenstein, RPh, Ph.D., *Senior Medical Director, Adult Vaccines, Merck Vaccines*

12:00 – 12:30

Presentation: Correlating Human and Animal Data to License an Anthrax Vaccine

This talk will discuss specific criteria that the FDA requires regarding animal models and correlates of immunity in order to illustrate the regulatory expectation and provide the context specifically for licensure of an anthrax vaccine. Specifically, essential data elements of an animal model and the development of these efficacy models for anthrax will be presented in terms of the approach taken, some of the specific difficulties encountered and how the human and animal data are being correlated to each other.

Gary Nabors, Ph.D., *Vice President, Product Development & Site Operations, Emergent BioSolutions, Inc.*

12:30 – 1:30

Group Luncheon

1:30 – 2:45

Panel Discussion: Animal Model Gaps with Respect to Human Disease and Impact on Product Development Using the Animal Rule

Do current animal models and associated critical prophylactic/therapeutic endpoints for pathogens reflect human diseases such that product development using the animal rule can succeed? If there are gaps, what are they? How might these gaps be addressed to facilitate development of products using the Animal Rule for approval of medical countermeasures?

Moderator

Ed Nuzum, DVM, Ph.D., *Chief, Biodefense Vaccines and Other Biological Production Section, Office of Biodefense Research*

Affairs (OBRA), Division of Microbiology and Infectious Diseases, National Institute of Allergy and Infectious Diseases (NIAID), NIH

Panelists

Claire R. Croutch, Ph.D., *Principal Scientist and Toxicology Group Leader, Midwest Research Institute*

Boris Ionin, Ph.D., *Director, In Vivo Testing Unit, Product Development Division, Emergent BioSolutions, Inc.*

Jason Mott, DVM, Ph.D., *Associate Director, BBRC, Battelle Memorial Institute*

Louise M. Pitt, Ph.D., *Director, Center for Aerobiological Sciences, United States Army Medical Research Institute for Infectious Diseases*

Robert Sherwood, Ph.D., *Director for Applied Life Sciences & Toxicology, Senior Scientist, Lovelace Respiratory Research Institute*

Peter Silvera, Ph.D., *Program Leader, Drug & Vaccine Research - Animal Models, Department of Infectious Disease Research, Southern Research Institute*

Chris Sinclair, Ph.D., MBA, *Senior Director, Clinical Development, Cangene Corporation*

2:45 – 3:15

Presentation: Standardization of Challenge Agents Used for Development of Medical Countermeasures for Biological Threats

Evaluation of medical countermeasures to the expanding array of biological threats requires the development animal challenge models representative of the human response following exposure to the threat agent. The use of standardized challenge agents in these animal models is essential for ensuring consistent interpretation of results among laboratories. Approaches for standardized preparation and storage of different classes of biological threat agents (toxin, bacteria and virus) will be presented. Methods for verifying identity, purity and potency (strength) of challenge agents will be discussed along with plans for monitoring challenge agent stability. The use of standardized preparations of challenge agent, from discovery through advanced development, will improve the efficiency of medical countermeasure development.

Jamie Austin, *Researcher, BBRC, Battelle Memorial Institute*

3:15 – 3:45

Presentation: Addressing Challenges of Animal Model Development Through Collaboration for Biologicals

This presentation will discuss creative approaches being developed to streamline animal model development and reduce hurdles to licensure through collaborative efforts for biologicals. The current status of the Alliance for Biosecurity's efforts to work with government and academic partners to create a centralized, shared database of animal model data relevant to therapeutic countermeasures will be discussed. Issues

surrounding the collection of sensitive data, including IP rights, access issues, and standardization of data will be presented.

Elizabeth Leffel, Ph.D., *Director, Non-Clinical Science*, PharmAthene, Inc.

3:45 – 4:00

Afternoon Networking Break

4:00 – 4:30

Presentation: Addressing Challenges of Animal Model Development Through Collaboration for Rad/Nuc

The University of Maryland, School of Medicine at Baltimore (UMB) Consortium, Medical Countermeasures Against Radiological Threats (MCART) is a successful, enabling enterprise focused on medical countermeasure (MCM) development via the criteria of the FDA “animal rule” (AR) for FDA approval to treat personnel exposed to potentially lethal doses of radiation. It is composed of 15 academic, clinical and commercial partners representing every functional area required for MCM development. The overarching goal of MCART is to develop MCM for the treatment of the major syndromes and organ injury of the acute radiation syndrome and the delayed effects of acute radiation exposure. The consortium has developed an animal model research platform focused on performing studies concordant with FDA AR criteria and adherence to a clear developmental path for candidate products to achieve FDA approval.

Thomas MacVittie, Ph.D., *Professor and Director, PreClinical Research Laboratory, MCART, Department of Radiation Oncology*, University of Maryland School of Medicine

4:30 – 5:00

Presentations: Perspectives on the Challenges of Meeting the Animal Model Rule

This talk will share perspectives on challenges to understanding and meeting the requirements of the animal model rule and considerations for study design and developing a regulatory strategy in order to attempt to effectively manage uncertainty.

Sally Bolmer, Ph.D., RAC, *Senior Vice President, Development and Regulatory Affairs*, Human Genome Sciences, Inc.

5:00

Forum Adjourns