Animal Model Resources for MCM Development

Judy Hewitt, Ph.D.
Chief, Research Resources Section, OBRA
Division of Microbiology and Infectious Diseases
NIAID, NIH, DHHS

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BARDA Industry Day
Resources for Researchers

Product Development Pathway

Basic Research
- Hypothesis Development and Testing

Preclinical Development
- Discovery
- IDE- and IND- Enabling Activities

Clinical Evaluation
- Trials

Research Tools and Technologies

Diagnostics, Vaccines, Therapeutics

► Funding opportunities
► Research tools and technologies
► Preclinical and clinical services to facilitate product development

Resources for Researchers
Preclinical Services for MCM Development

Product Development Pathway

Basic Research
- Hypothesis Development and Testing

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Research Tools and Technologies

Diagnostics Vaccines Therapeutics

In Vitro Assessments of Antimicrobial Activity
- Animal Models of Infectious Diseases
- Therapeutic Development Services
- Vaccine Development Services
Animal Models of Infectious Diseases

• Provision of a broad range of *in vivo* models
  • small animal
  • non-human primate
  • non-traditional models
• Development of novel models
• Refinement of existing models
• Screening of products
• Efficacy testing to support FDA submissions
  – Supplemental NDA for approved drugs
# DMID Animal Model Program

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Accomplishments

- Support of significant product investments
  - Vaccines for anthrax, smallpox
- Product neutral animal model development
  - Approved broad spectrum antibiotics, for \textit{Y. pestis}
  - Novel anthrax antitoxins
  - Novel smallpox antivirals
- Gap-filling to move products/concepts forward
Animal Model Development Path

Model

Product

Qualification

Product:
- independent
- dependent
- specific

Product neutral
DMID Animal Model Qualification Plans

• Near term, primary/major role:
  – Anthrax therapeutics – BARDA lead
  – Plague antibiotics
  – Tularemia antibiotics – BARDA support

• Willing to partner on:
  – Burkholderia
  – Filovirus

• Other ??
NIH/NIAID Radiation Nuclear Countermeasures Program

Achievements

- Five GLP animal facilities
- Rodent/NHP models of HE-ARS and GI-ARS
- Rodent/canine models for radionuclides

Next Steps

- MCM screening, optimization, and IND-enabling studies
- Characterization and qualification of animal models
  Rodent/NHP animal model qualification for HE-ARS and GI-ARS
DAIT Product Development Support Services Contract: Animal Models

- **Hematopoietic:**
  - Mouse: Indiana University (C. Orschell)
  - Dog: CiToxLAB (S. Authier)
  - NHP: UMB (T. MacVittie), CiToxLAB (S. Authier)

- **Gastrointestinal:**
  - Mouse: Epistem (C. Booth)
  - NHP: UMB (T. MacVittie)

- **Lung:** UMB (Z. Vujaskovic)

- **Radionuclide:** Lovelace Respiratory Research Institute (R. Guilmette)

- **Other support:**
  - Statistics
  - Pharmacokinetics
  - Document management
  - QA/GLP
Thank You!

jhewitt@nih.gov