



USAMRIID



Animal Models and Efficacy Studies

M. Louise M. Pitt, Ph.D.

**United States Army Medical Research Institute of
Infectious Diseases**

BARDA Industry Day

USAMRIID: Biodefense Solutions to Protect our Nation

USAMRIID spearheads research to develop medical solutions—vaccines, drugs, diagnostics, and information—to protect our military service members and the nation from biological threats.

Specialized Capabilities

- **Biosafety Level 3 and Level 4 laboratories**
- **World-class expertise in the generation of biological aerosols for testing candidate vaccines and therapeutics**
- **Fully accredited animal research facilities.**
- **Subject Matter Experts**

Aerosol Capabilities



- **State of the art bioaerosol facility**
- **GLP compliant**
- **BSL-3 and BSL-4**
- **Aerosol animal models**
- **Animal rule efficacy studies**
- **Leaders in aerosol science**

GLP Capability

- **Sustained GLP capability in BSL-2 and BSL-3**
 - FDA inspections with minimal findings (2003, 2008, 2011, 2012)
 - 74 GLP studies completed since 1997

- **GLP studies in BSL-4**
 - First completed in FY 12
 - 3 Supporting GLP assay validation studies ongoing
 - 6 nonhuman primate studies planned for FY 13

BSL-4 GLP MCM– T & E Capability

- **Recommendation: Establish Test and Evaluation capability using 50% of USAMRIID’s BSL-4 space with some minor alterations in New USAMRIID to improve efficiencies**

- **Concurrence from:**
 - **Commanding General, US Army Medical Research and Materiel Command**
 - **Joint Program Executive Officer for Chemical and Biological Defense**
 - **Deputy Assistant Secretary of Defense for Chemical and Biological Defense**
 - **Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs**
 - **Senior Director for Preparedness Policy, National Security Staff**

USAMRIID formally assigned the BSL-4 GLP T&E mission in October 2012

USAMRIID BSL-4 GLP MCM-T&E Capability

Mission: Perform test and evaluation on leading biodefense medical countermeasure candidates and provide the essential data packages to support US Food and Drug Administration approval.

Vision: A flexible and sustainable test and evaluation capability to facilitate US Food and Drug Administration approval of biodefense medical countermeasures to protect the Warfighter and the Nation

Animal Model Development

- **Telemetry**
- **Veterinary Surgery**
- **Veterinary Clin Path**
- **Aerobiology**
- **Pathology**
- **GLP – BSL-2, BSL-3, and BSL-4**
- **Regulated Studies Support**
 - Assay development and validation
 - Study Coordination
- **Study Reagents**
 - Well Characterized Challenge Material
 - Standardized assay reagents
 - Positive and negative Standards

Animal Models

- **Mature: Used in animal rule studies / GLP**
 - Pneumonic plague (NHP)
 - Inhalational anthrax (Rabbit & NHP)
 - Monkeypox (NHP)
- **Moderately Mature: Used to evaluate vaccines and/or therapeutics**
 - Filovirus, Ebola and Marburg (NHP)
 - Alphaviruses, VEE,EEE, WEE
 - Tularemia
 - Glanders
 - Melioidosis
 - Botulinum toxins
 - Ricin
- **Early : Dose response / Natural History**
 - Lassa Fever
 - Rift Valley Fever

Funding

- **Basic and Applied Research**
 - DTRA – JSTO
- **Advanced Development**
 - JPEO (BSL-4 GLP T&E core capability)
 - JPM-TMT
 - JPEO-JVAP
- **Inter-Agency Agreements**
- **Grants**
- **Contracts**
- **Industry Agreements**

Collaboration with MCM developers

- **Multiple agency efforts**
 - eg. FANG, Anthrax animal model working group
- **Direct government funding to USAMRIID (JPEO, TMT, JVAP, JSTO)**
 - Contract USAMRIID – Company
- **Subcontractor to funded Company**
 - Company funded by Government agency

Collaborative Mechanisms to Work with USAMRIID

- **Informal**

- Investigator based exchange of non proprietary information
- Contact through meetings, publications, working groups, etc.

- **Formal**

- Nondisclosure Agreement (NDA)
- Cooperative Research And Development Agreement (CRADA)
- Material Transfer Agreement (MTA, UBMTA)
- Commercial Test Agreements (CTA)
- License Agreement (BML, PLA)
- Educational Partnership Agreement
- Grant & Cooperative Agreement (BAA, SBIR, STTR)
- Contract (FAR based, Research Services)

- **POC: USAMRIID Business Plans & Programs Office**

- **Mr. Dan Coffman, Chief, Office of Research & Technology Applications**
- **301-619-6886, Dan.Coffman@US.Army.Mil**

CRDA – Leverage Lab's R&D Consistent with Mission

- ◆ Between one or more federal labs and one or more nonfederal parties
- ☞ Not a procurement contract, sub-contract or grant, but is a legally enforceable document
- ☞ Lab can commit people, facilities, equipment, IP & other resources, but NO FUNDS
- ◆ Collaborator can commit people, facilities, equipment, IP & other resources and funds
- ◆ Provides Collaborator an option to negotiate an exclusive license to the Government's rights in inventions made solely or jointly
- ☞ CRADA information is considered CONFIDENTIAL, not FOIAble
- ◆ Very flexible agreement, allows for negotiation, can be executed with relative speed (1-3 weeks)