



Biomedical Challenge to Warfighter, Veteran and Civilian: Emerging Infectious Diseases – A Global Challenge

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UNCLASSIFIED





Mission

Provide leading edge medical capabilities to deter and defend against current and emerging biological threat agents

Vision

To be the leader in the advancement of medical biological defense with world renowned experts dedicated to protecting our military forces and the nation



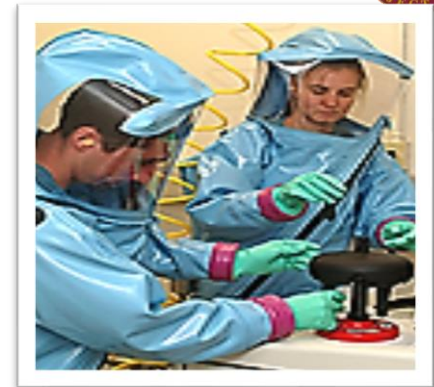
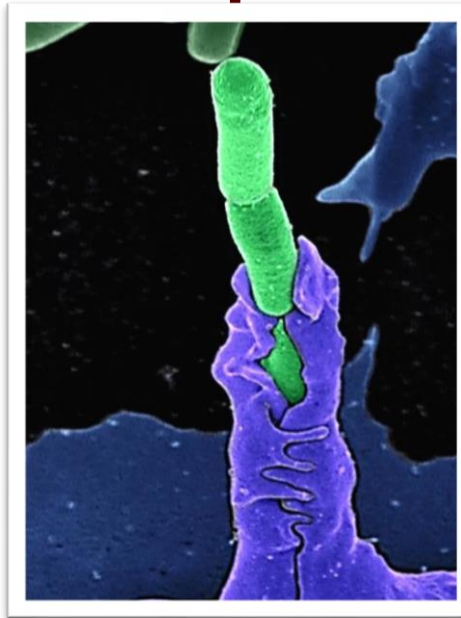
Medical Biodefense Insurance Policy for the Nation



Core Competencies



Prepare for Uncertainty



Rapidly Identify Biologic Agents

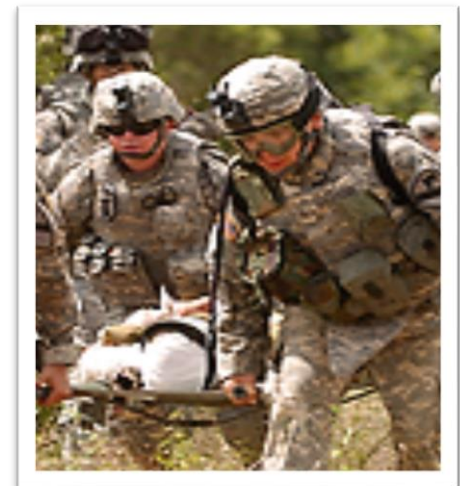


Develop, Test & Evaluate Medical Countermeasures

Provide World Class Expertise in Medical Biological Defense



Biosafety & Biosecurity



Train & Educate the Force



COLLABORATIVE AGREEMENTS

(Total: approx. 700; A few examples shown below:)

- **IAA** (Interagency Agreements)
 - BARDA
 - MCS
 - CDC
 - DHS
 - FDA
 - NIAID
 - USDA
- **MTA** (Material Transfer Agreements)
 - Emory University School of Medicine
 - VaxDesign Corporation
 - Xoma Corp.
 - Boston University
 - Albert Einstein College of Medicine
- **CRADA** (Cooperative Research and Development Agreements)
 - Sarepta Therapeutics
 - Columbia University
 - Gilead
 - Harvard University
 - Bayer
 - Novartis Vaccines and Diagnostics
 - University of Texas Medical Branch
- **IA** (International Agreements)
 - Public Health Agency of Canada
 - Institut Pasteur
 - Vivalis S.A.
 - University of Madras
 - Dstl Porton Down

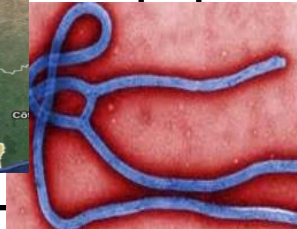
Key conduit to new technologies for the CBDP



Ebola Outbreak Support

Cooperative Biological Engagement Program

- Host nation support in Sierra Leone & Liberia prior to Operation United Assistance
- Diagnostic and genomic capabilities at the Liberian Institute for Biomedical Research



Operation United Assistance

- 38 Mobile Training Teams – short notice training and education to 4800 personnel deployed to West Africa



Subject Matter Expertise

- Armed Forces Medical Examiner Staff training
- Animal studies to determine Ebola infectivity after death
- 24/7 consultation supporting operational and command requests



Medical Countermeasures (MCM)

- Developed and/or evaluated leading Ebola MCM candidates
- FDA Emergency Use Authorization for Ebola Zaire diagnostic test
- Diagnostic test adapted for Military Working Dogs
- Laboratory Response Network Ebola diagnostic support
- Clinical trial support for leading Ebola MCM candidates



Rapid mobilization of high-impact capabilities



ACCOMPLISHMENTS

- **Trained Liberian Institute for Biomedical Research (LIBR) personnel to safely conduct Ebola virus diagnostic testing**
 - Prior to successful transition, USAMRIID maintained organic staff since the start of the outbreak
 - Part of the Defense Threat Reduction Agency's Cooperative Biologic Engagement Program
- **Established first forward-deployed genomic sequencing capability at LIBR to support Ebola outbreak response.**
 - Allows near real-time monitoring of viral evolution as the outbreak progressed and continues today
 - Sequencing data obtained through LIBR confirmed first sexual transmission case of Ebola virus: New England Journal of Medicine in the 2015 report, "Molecular evidence of sexual transmission of Ebola virus."



ACCOMPLISHMENTS

- **Developed DoD EZ-1 Ebola virus diagnostic assay**
 - First Ebola diagnostic assay to be given Emergency Use Authorization (EUA) by FDA during the Ebola virus outbreak
 - Administered qualification and proficiency testing for all DoD and state Public Health laboratories
 - Developed at USAMRIID
- **Pre-positioned data packages for 73 other diagnostic assays in the event of another declared emergency**
- **Provided Ebola diagnostic testing support for all Ebola patients treated at the National Institutes of Health, Special Clinical Studies Unit in Bethesda, MD**



ACCOMPLISHMENTS

- **Rapidly advanced Gilead Sciences GS-5734 small-molecule therapeutic from conception to initiation of Phase I clinical trials in only 9 months for treatment of Ebola virus infection**
 - Used on compassionate basis to treat Scottish nurse infected with Ebola virus while working in Sierra Leone
- **Successfully tested single monoclonal antibody Ebola therapy**
 - 100% effective against lethal Ebola virus challenge in monkeys
 - Multiple-antibody "cocktails" used to treat Ebola virus infection
 - Studies support development of a single antibody therapy
 - Could considerably shorten regulatory review and approval timelines



ACCOMPLISHMENTS

- **Completed pivotal animal efficacy studies to meet FDA “Animal Rule” requirements for treatment of inhalational and bubonic plague, and inhalational anthrax using the already-licensed drug moxifloxacin**
 - Drug repurposing for additional treatment options maximizes use of government resources and significantly shortens acquisition timelines

- **Established BSL-4 Good Laboratory Practice (GLP) testing & evaluation capability at USAMRIID**
 - USAMRIID is the only lab with this capability



**Uniquely prepared to support
our military forces and the nation**