



## Developing solutions to expedite the discovery and safe development of medical treatments and scientific advances

### WHY LEIDOS LIFE SCIENCES?

- ▶ Extensive expertise in vaccine and drug development and testing, human clinical trials, and regulatory compliance and documentation
- ▶ In-depth experience with the entire grants management process from pre-award through award set-up and grant close-out
- ▶ A 25-year history providing biomedical research and development support, including program/portfolio management and strategic planning, to a long list of federal customers

The Leidos Life Sciences team employs a broad range of Doctoral and Masters level scientific and analytical professionals who execute a diverse portfolio of biopharmaceutical, medical science, program management, and peer/program review contracts. From improving program processes to optimizing business operations, we design and deliver customized solutions that help our customers perform more efficiently and overcome their most difficult challenges

Long-term customers include the U.S. Army Medical Research and Materiel Command (25 years), the National Institute of Allergy and Infectious Diseases (13 years), and the Department of Homeland Security (DHS) (11 years). Additional clients comprise domestic and international pharmaceutical and biotechnology companies seeking drug development, regulatory affairs, and current Good Manufacturing Practice (GMP)/Good Laboratory Practice (GLP) compliance support.

Our newest clients are public and private funders of biomedical research, where we provide support through our Health Research Management Practice (HRMP) for mission and vision support, patients/stakeholder engagement, and business operations.



## We Succeed in Three Markets

### ► Global Health

- Production and testing of experimental malaria vaccines
- Programmatic review for the DoD Congressionally Directed Medical Research Programs
- Peer review and technical reports for the Patient-Centered Outcomes Research Institute
- Vaccine development guidance for the National Breast Cancer Coalition
- Comprehensive regulatory affairs services for the NIAID Division of Microbiology and Infectious Diseases Office of Regulatory Affairs
- Compliance and consulting for the NIAID Vaccine Research Center

### ► Defense Medical

- Diverse scientific, administrative, program, and communications support for Headquarters, USAMRMC
- Program planning and coordination support for the Military Infectious Diseases Research Program
- Analytical support for the Clinical and Rehabilitative Medicine Research Program
- Regulatory strategy development for the Army's Hantaan/Puumula vaccine effort
- Expertise and support for the USAMRMC Enterprise Information Technology Project Management Office

### ► Threat Reduction

- Development of therapeutics for biodefense and emerging infectious diseases
- Scientific support to DHS agricultural and biodefense threat research
- Preparation of the first Bioterrorism Risk Assessment Report for DHS in 2007

## Accomplishments

- Evaluated 17 preclinical malaria vaccine concepts since 2000, 4 of which were advanced to human clinical testing. Pipeline of 10 additional candidates in progress.
- Assisted DHS with development and licensure of foot and mouth disease vaccine suitable for use in the United States. Received formal recognition from the Under Secretary for Science and Technology.
- Received a NIAID Special Recognition Award for performance during the 2009/2010 H1N1 influenza pandemic.
- Provided scientific and management support to plan and develop new systems biology capabilities for USAMRMC.
- Researched, wrote, and printed the book *USAMRMC: 50 Years of Dedication to the Warfighter* in 2008 for the Command's 50th anniversary.
- Conducted a comprehensive assessment of DoD biomedical research and development, which played a key role in the Department's decision to establish a new ~\$300M/year medical research program.
- Assisted DHS with stand-up of its Science and Technology Directorate and launch of the National Biodefense Analysis and Countermeasures Center.

## FOR MORE INFORMATION

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## SERVICE OFFERINGS

### Translational Science

- Medical product development plans
- Virtual pharma for product life-cycle support
- Process research and development and GMP production
- Outsourcing management and coordination
- Regulatory strategy and compliance
- FDA electronic submissions

### Health Science Support

- Research program management
- Grants management
- Peer and program review
- Technical analysis and reports
- DoD acquisition documentation
- Custom tool and COTS product implementation
- Scientific staffing

### Communications

- Document writing and editing
- Desktop publishing and graphic design
- Multimedia and video production
- Conference planning and logistics

