



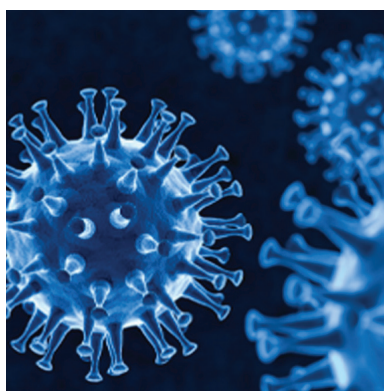
Medical and Health Preparedness

Patricio Enterprises is dedicated to assisting the Federal Government and its partners in developing improved health outcomes for infectious diseases, emerging infectious diseases, and potential chemical, biological, radiological, and nuclear events to protect our nation, our people, and our allies. We are fully engaged in national and international efforts to prevent and reduce the effects of naturally occurring and manufactured threats through ongoing research, science and technology activities, and acquisition support.



Product Compliance

- Food and Drug Administration (FDA) Regulated Non-Clinical, Product Manufacturing and Testing Subject Matter Expertise
- Good Clinical Practice (GCP), Good Laboratory Practice (GLP) and Good Manufacturing Practice (GMP) Subject Matter Expertise
- Clinical and Non-Clinical Studies Regulatory Compliance
- Research Protocol Development and Review
- Assay Development and Validation
- Contract Research Organization (CRO) Oversight



Clinical Data Management

- Protocol Review
- Data Management Essential Documentation
- Database Development, Testing, Validation, and Maintenance
- Statutory, Regulatory, Policy Compliance
 - FDA
 - Army Regulations
 - Clinical Data Acquisition Standards and Harmonization (CDASH)
 - Good Clinical Data Management Practices (GCDMP)
 - Good Clinical Practices (GCP)



Statistical and Regulatory Oversight

- Technology and Advanced Development Program Technical Assistance
- Statistical Analysis Plans
- Statistical Programming Validation Plans
- Position Papers