Clinical Research Services

Conducting efficient, innovative clinical research from initial planning to closeout

WHY LEIDOS LIFE SCIENCES?

- Leidos has expertise supporting all product development phases for vaccines, drugs, and biotherapeutics
- Leidos understands the need to control clinical project scope, timelines, and cost while remaining flexible amidst shifting research requirements
- Leidos remains vendor-neutral while fostering and managing collaborations with the right clinical research partner(s) for your study

In addition to developing large-scale technology programs for U.S. federal agencies with a focus on health, Leidos provides a broad range of clinical services and solutions to researchers, product sponsors, U.S. government agencies, and other biomedical enterprises, hospitals, and health systems.

Our broad research experience enables us to support programs throughout the development life cycle: from concept through the exploratory, development, pre-clinical, and clinical phases, as well as with product manufacturing and launching. Leidos designs and develops customized solutions that support groundbreaking medical research, optimize business operations, and expedite the discovery of safe and effective medical products. We apply our technical knowledge and experience in selecting institutions, clinical research organizations, and independent research facilities to meet the specific needs of each clinical study. We also manage team integration, communication, and contracts throughout the project.

Finally, Leidos has a proven track record of ensuring that research involving human subjects is conducted in compliance with U.S. and international regulations and guidelines, and we bring this important skillset to the table when developing and implementing clinical approaches for our clients.

Leidos Capabilities

Planning	Startup	Initiation	Conduct	Closeout
• Regulatory submissions • Statistical analysis planning • Study document development: protocol, manual of procedures, informed consent, etc. • Outsourcing coordination • Safety planning • Study design • QC method/formulation development, clinical-grade manufacturing, labeling	• Clinical site assessment • IT infrastructure setup • Trial master file setup • Case report form development • Data management plan • Laboratory quality management plan • Clinical site budgets and agreement • Data Safety and Monitoring Board creation/management	• GCP, GDMP, GCLP training • Site initiation • Clinical team integration • Clinical trial supplies and logistics	• Project management • Site management • Subject recruitment plan development • Investigational New Drug maintenance • Clinical quality assurance • Site monitoring • Scientific meeting planning • Biospecimen management • Auditing • Safety monitoring/reporting • Data management	• Site closeout • Project closeout • Database lock/transfer • Clinical study report

- **Clinical Trial Management.** Our experience planning, monitoring, and executing clinial studies allows us to lead operations and help mitigate risks while keeping the entire team informed of project progress.
- **Comprehensive Regulatory Affairs Document Production.** Leidos provides a coordinated approach to document preparation and submission, including FDA electronic Common Technical Document (eCTD) support. We have submitted thousands of error-free regulatory documents to the FDA, and services include preparing, reviewing, and submitting regulatory documents, reports, and other agreements, as well as maintaining databases that archive and track documentation and enable orders for clinical trial materials.
- **Pioneering Integrated Pharmaceutical Operations.** Leidos performs quality oversight as well as:
  - Portfolio/project management support for product pipeline;
  - Process development, pilot production, and formulation services to generate clinical-grade material for human trials; and
  - Product development strategies and white papers on candidate selection/prioritization, product platforms, and expression systems.
- **Data-Driven Clinical Trial Site Selection.** Leidos assists clients with defining specific site requirements for clinical trials, then utilizes the criteria to select the most appropriate clinical sites. Using private and public data, as well as our existing relationships with many well-known institutions, we provide our clients with relevant information about a potential site's suitability for the trial.
- **Enhancing Clinical Project Teams.** We tap into our existing relationships with patient foundations, advocacy groups, and nonprofits to execute the best patient-centered approach for each study.
- **Innovative Trial Operations.** Our research and technology expertise enables us to evaluate the best tools for each study, including the needs of more complex multi-site international trials. When appropriate, new approaches such as utilizing direct-to-patient trial methods can improve trial efficiency, shorten the study timeline, and lower costs.
- **Customized Biorepository Access.** Leidos helps to ensure the safe, efficient, and appropriate receipt, storage, retrieval, packaging, labeling, and shipping of biopharmaceutical products and materials. Once an appropriate biorepository is selected, Leidos develops specific SOPs and guidelines, including authorities to request and approve deposits and withdrawals and appropriate lead times for placing requests before shipment.
- **Additional Competencies.** Leidos specializes in helping government and commercial clients develop overarching clinical research policies, SOPs, and best practices. We design and conduct regulatory educational and training activities, and provide specialized knowledge, consulting, and regulatory audit support.

FOR MORE INFORMATION

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