



PANACEA

CLINICAL RESEARCH

Clinical Research Solutions

In today's highly competitive, cost-conscious medical development landscape, companies are pushed to bring new, better products to market faster, and with far fewer resources. They require carefully managed, streamlined clinical trials that meet regulatory and ethical requirements, demonstrate safety and are cost-effective. Sponsor companies need clinical research partners that share this core approach. Panacea Clinical Research is that partner.

Panacea Clinical Research is a comprehensive clinical research organization that provides investigational trial support to pharmaceutical, biotechnology, and medical device companies for the discovery and development of novel therapeutic products and new indications for marketed products.

Panacea is headquartered outside of Boston, MA (USA) and has a broad network of clinical research professionals located throughout the U.S. Our global support is fortified with strategic alliances in Canada, South America, and India. Our clinical trial experience includes Phase I-IV pharmaceutical studies and pilot, pivotal, and post market device studies in a multitude of therapeutic arenas.

Whether you need an individual point-of-service or a complete project team, Panacea's unmatched scientific, regulatory, and project management expertise ensures a high quality, integrity-driven process that is completed with accuracy, on time and on budget.

Committed to Excellence, Panacea Clinical Research, through its network of highly experienced professionals and investigators, seeks to preserve the integrity of clinical research by assuring that ethical obligations and regulatory requirements central to our industry are met.



Services

Panacea offers an expansive suite of CRO services. And as part of these services, Panacea's experienced team identifies cost cutting measures for Sponsors while maintaining the highest quality standards and ensuring timely completion of client projects. Panacea's commitment to Sponsors is evident through every step of every project, with a focused, flexible approach to our customers that is unmatched.

Project Management

Panacea's Project Managers boast years of experience running highly successful clinical trials. Our Project Managers understand that detail-oriented oversight as well as clear, timely communication are critical. Their tasks include:

- Assuring quality, on-time deliverables and on-budget performance.
- Providing operational management for domestic and international clinical trial programs.
- Coordinating activities of multidisciplinary project teams and external vendors.
- Securing compliance with Sponsor and project requirements.
- Performing ongoing project status and budget tracking.
- Developing and administering clinical project plans.
- Negotiating investigator agreements and administer investigator payments.

Clinical Trial Monitoring

With an average of 10 years of experience, Panacea's monitors are second to none. They have experience in Phase I-IV trials in a wide array of inpatient and outpatient clinical trial settings. We have monitors throughout the United States, in addition to strategic alliances for monitoring in Canada, India and South America. All of our monitors adhere to the same high standards that have been Panacea's trademark. Monitoring includes:

- Qualifying, initiating, monitoring, and closing clinical trial sites to assure adherence to protocol, SOPs, and GCP/ICH and other applicable regulations.
- Conducting source document review and verify accuracy of collected study data .
- Assessing regulatory compliance and essential document maintenance at clinical trial sites.
- Maintaining investigational product accountability.
- Documenting accurate and timely Sponsor/site communications and site visit reports.
- Liaising with Data Management to assure complete and accurate resolution of queries, and to review data listings.
- Assuring site reporting of serious/unexpected adverse events.

Quality Assurance/GCP Auditing

Panacea offers a staff of highly experienced clinical auditors that are well versed in the FDA regulations and ICH guidelines that govern clinical research. We understand the importance of quality assurance at each step in the process to ensure clinical data integrity as well as regulatory compliance. Our auditing services include:

- Conducting GCP audits at client offices and at investigational sites.
- Developing and implementing audit plans in collaboration with the Sponsor's quality assurance policies and personnel.
- Providing timely, comprehensive audit reports.
- Mediating corrective actions as appropriate.

Site Management

Panacea supports its field monitoring team with in house site managers that complement the support of site monitors, facilitate project start up, and assure seamless project maintenance. We offer regulatory experts to expedite and even beat timelines for study initiation. We proactively request, collect, review and submit quality regulatory data using streamlined data collection and tracking processes that result in faster IRB and Regulatory submission and approval rates. Panacea's experience and focus results in a smooth, efficient, and accurate work flow that will endure throughout your program. Our site management services include:

- Providing in-house support to investigational sites.
- Collecting, reviewing, and maintaining essential documents.
- Assuring sufficient site inventory of investigational product and other supplies.
- Coordinating collection and reporting of site screening and enrollment activity.
- Facilitating communications between the site and Monitor, Project Manager, and/or Sponsor.
- Fielding site queries and disseminating information and responses to/from the monitor, Project Manager, and Sponsor as appropriate.

Investigator and Subject Recruitment

Panacea possesses an extensive network of investigational sites throughout US. Our investigators practice in university/teaching facilities, site management organizations (SMOs), and community private practice settings. Investigators and coordinators have proven track records of protocol/regulatory compliance and successful subject recruitment/enrollment. Panacea understands that expeditious recruitment of eligible study subjects is critical to protocol success. We work closely with strategic partners with proven track records of analyzing recruitment patterns, developing recruitment strategies, and creating recruitment materials. Our specialists strive to develop customized solutions to address unique challenges of investigational sites.

“Operation Rescue”

There are occasions when an active trial requires intervention. If enrollment is lagging, the Sponsor/CRO needs additional support, investigator compliance requires realignment, or the Sponsor is not satisfied with a current provider, Panacea’s experience and flexibility has proven invaluable in trial intervention. We have success in stepping into highly complex and intense protocols, analyzing its status and unique challenges, and then making necessary changes to move the trial forward towards meeting its objectives.

Medical Advisory

Panacea offers a fleet of industry seasoned MD’s, RN’s and Ph.D’s. that offer the following services:

- Designing and developing protocols and investigator brochures.
- Writing annual progress reports, clinical study reports, and safety reports.
- Providing pharmacovigilance and safety monitoring services.
- Reviewing of Serious Adverse Events.

Process Development

Panacea’s staff is experienced in process development and quality systems implementation. Whether you require review and analysis of your current Standard Operating Procedures (SOPs) or development of new SOPs, instructions or guidelines for a particular trial, Panacea will work with you throughout the process. We will ensure that your processes are FDA compliant and that they meet the trial’s efficiency and consistency objectives. Panacea can work with you to develop and review:

- Standard Operating Procedures (SOPs)
- Work Instructions
- Quality Manuals
- Data handling guidelines
- Monitoring tools and guidelines
- Study reference materials

Strategic Alliances

Panacea has developed strong strategic alliances with companies that offer expertise that complement our own services. Through these alliances, Panacea provides the full range of clinical trial services critical to a successful study. They include

- Data Management
- Web-based data entry
- Regulatory strategy development and regulatory agency liaising
- Statistics

In addition, Panacea has built monitoring partnerships in Canada, India and South America, creating a truly global reach for our company.

Therapeutic Experience

Panacea boasts deep experience in a wide range of clinical research areas.

	Drug	Biologic	Device	Vaccine	Diagnostic
Anesthesiology	✓				
Cardiology	✓	✓	✓		
Dermatology		✓	✓		
Endocrinology	✓		✓		
Gastroenterology	✓				
Hematology/Oncology	✓	✓		✓	✓
HIV/AIDS	✓	✓			
Infectious Disease	✓	✓	✓		
Metabolism	✓	✓			
Orthopedics	✓		✓		
Neurology	✓	✓			
Nuclear Medicine					✓
OB/GYN	✓		✓		
Ophthalmology		✓			
Pain Management	✓				
Psychiatry	✓				
Respiratory	✓	✓	✓	✓	
Rheumatology	✓	✓			
Transplant	✓		✓		
Urology	✓				

Contact Us

If you are a potential sponsor, investigator or consultant looking for more information about how Panacea can help you, please contact us directly at the following:

info@panaceaclinical.com

Tel: +1.508.620.2293

Fax: +1.508.620.0213

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www.panaceaclinical.com