

GeoSera Executive Summary

The catalyst to drug development



Contract Clinical Research Support

- GeoSera is a contractual team that embeds ourselves within pharma/biotech companies
- Medical writing, statistics and programming, clinical leadership, clinical program managers, GxP auditing, clinical research associates
- Oversee and responsible for the key clinical deliverables
- Provide Functional Service Providers (FSPs) at a reduced cost



Mission statement

- Provide pharma and biotech companies with experienced, high-quality drug development support in a cost-efficient manner



Why Us

- Our team is formed by industry veterans all who have decades of experience in industry
- Our contractual model allows for financial flexibility by increasing or decreasing the scope of services based on company needs
- Sponsors can delegate clinical development task to the “do-ers” whose success is measured by achieving milestones
- No project is too small for our team to fill in gaps within the lifecycle of a drug



Achievements

- GeoSera was formed in 2017 and has expanded to 22 contractors and project-based staff
- Supports global trials, clients and vendors
- Experienced staff has been involved with countless INDs through NDAs/BLAs



Target Client

- Small pharma and biotech
- Companies seeking floating or task/project-based support



Services

- Responsible for deliverables of all external parties (CROs, sites, vendors and contractors)
- Day-to-day project management of individual trials and communication external parties
- Lead cross-functional teams to facilitate communication across internal and external vendors
- Overall site management including site feasibility, identification and selection, query resolution, site training
- Medical writing of INDs, ICFs, IBs, protocols, regulatory agency communications, support NDAs/BLAs, briefing books, SAE narratives, CSRs
- Statistical study design creation and validation, sample size calculation
- Create Statistical Analysis Plans



Our Core Team

John Carlos Diaz: Clinical Leadership, 25 years exp.

Medical Writing: Pharm D., 28 years exp.

Statistics: PhD, MBA, 30 years exp.

CRAs: 10-30+ years exp., East, Central, West Coast

Project Management: Team Members with 10+ years exp

Medical Monitoring: MD, 30+ years exp.

GxP Auditing: 23+ years exp.

Regulatory Consulting: 20+ years exp.

Contact Us



Virtually based with colleagues across the United States



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+1.484.568.3952
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