GRAVITAS MEDICAL, INC.

101 Mississippi St
San Francisco, CA 94107

Job Description: Sr Clinical Research Associate

COMPANY DESCRIPTION

Gravitas Medical is revolutionizing enteral feeding with smart feeding tubes, monitors, and pumps. See https://www.gravitasmedinc.com/ for more information.

POSITION DESCRIPTION

The Sr Clinical Research Associate will be the lead CRA for Gravitas clinical research studies and products and will make clinical research strategy recommendations. This role manages investigative sites, including interviewing/screening investigators and monitoring/auditing regulatory documents to ensure compliance with company SOPs, GCPs, and applicable regulatory requirements. The role also assists in the hiring, training, and managing of CRAs and identify and manage CROs, vendors and consultants.

ESSENTIAL FUNCTIONS

- Writes and reviews clinical protocols and provides input from an operational perspective.
- Assists in the identification, assessment and management/oversight of contracts, CROs, vendors, EDC decisions and implementation, and program-related consultants. Facilitates development of and reviews study-related documents, including informed consent forms, case report forms, clinical study reports, and departmental SOPs.
- Participates in identification and evaluation of investigators.
- Finalizes training materials and participates in investigator and study staff training.
- Manages subject enrollment, adherence to inclusion and exclusion and ensures sites are following protocol procedures.
- Manages and participates in monitoring/co-monitoring investigative sites and CRFs to ensure data quality and integrity.
- Manages clinical study protocol(s)/program(s), including the review and approval of monitoring reports.
- Processes for review and approval informed consent documents.
- Reviews and provides preliminary approval of monitoring reports of other Theranova staff to ensure that potential issues are identified, escalated as necessary and appropriately resolved.
- Conducts ongoing review of regulatory document files.
- Monitors/co-monitors and/or audits clinical studies to ensure data quality and integrity.
- Ensures adequate investigational clinical trial supplies and devices are maintained at the site.
- Manages and reports study site and overall program progress.

- Respond to audits conducted at selected study sites.
- Assists with the selection, hiring, training, and supervision of CRAs, as necessary.
- Participates in review/execution of Clinical Trial Agreements.
- Assists Clinical and Regulatory Manager and President/CEO in short/long term planning.
- Organizes and participates in study team and investigator meetings.
- Responsible for device accountability
- Ensures SOPs are followed and current.
- Thorough understanding of GCP

REQUIREMENTS

- Minimum of a bachelor's degree
- Minimum of 5-10 years medical device or pharmaceutical industry clinical research or clinical research site based experience. Any equivalent combination of education, training, and/or experience that fulfills the requirements of the position will be considered.
- Startup experience preferred

To apply, please send your resume to hr@gravitasmedinc.com