Clinical Research Manager

Summary

TAI Diagnostics is a growing company! We currently have an opening for a Clinical Research Manager to join our organization to support the Research team. Under the direction of Chief Laboratory Officer, a qualified candidate will assume primary clinical study management responsibilities and actively participate on cross-functional project teams responsible for the research and development of molecular diagnostic products. Strong leadership skills are needed in all aspects of cross functional relationships in order to create a cooperative work environment in support of corporate goals.

Essential Duties and Responsibilities

- Manage day-to-day activities of all aspects of clinical research for assigned projects, including study plans, data management plans, monitoring plans (as appropriate), timelines, resources, problem identification and resolution, status reports and budgets to ensure timely delivery of completed study deliverables.
- Manage all research project documentation through standardized processes following TAI Diagnostics Quality Management System.
- Coordinate with cross-functional teams to identify the goal and scope of clinical research projects.
- Manages clinical sample inventory on an ongoing basis including sample procurement and distribution.
- Manages the materials required to complete each research project including but not limited to the distribution of documents, supplies, and equipment.
- Assists in the development of supported and sponsored studies, including the development of protocols, informed consent documents (as appropriate), case report forms (CRFs), data collection documents and other study related documents.
- In conjunction with procurement, coordinates the request for information and request for proposal processes, including site feasibility and qualification assessments.
- Oversees the site approval, start-up, maintenance, and close-out processes with respect to contract review, critical document and reporting requirements and ICH/GCP, in conjunction with the project team. This includes training sites to the study protocols.
- Manage central IRBs to achieve review, approval and oversight of research activities where applicable.
- Identifies and evaluates study and project issues, and issue escalation oversight; oversees all safety reporting, documentation and follow-up.
- Provides oversight and direction to project team members and study staff for study deliverables; including training as needed,
- Manages the development and implementation of clinical research processes for execution of internal and external studies within the TAI Diagnostics Quality System.
- Assist in the management of independent consultants/vendors including but not limited to CROs, clinicians, independent CRAs, or statisticians when required by the project including selection, coordination of project specific training, and payment.
- Monitors work to ensure quality, and continuously improves clinical research processes.
- Ensure research projects are compliant with all applicable local, state, and federal regulations and TAI Diagnostics policies and procedures.

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Education and Experience

- Bachelor of Science, or RN or BSN; OR equivalent combination of education and clinical research.
- Minimum 5+ years of clinical research experience including clinical/laboratory site monitoring OR 3+ years of clinical research experience with in vitro diagnostic assays (IVDs).
- Extensive and varied clinical and laboratory monitoring experience.
- Previous industry experience highly preferred.
- Background in molecular biology/biochemistry, laboratory experience or nursing experience preferred.
- Procurement and management of clinical research samples.

Qualifications

To perform this job successfully, an individual must be able to perform each essential duty satisfactorily. The requirements listed below are representative of the knowledge, skill and /or ability required. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

- Proven clinical research management skills and study leadership abilities.
- Extensive knowledge of Good Clinical Practice and all US regulations applicable to conducting trials involving humans or specimens from humans and investigational in-vitro diagnostic devices to be marketed in the US.
- Understanding of US regulations for FDA submission of a medical device.
- Experience writing clinical research documents (e.g. protocols, reports, case report forms, monitoring plans, etc.)
- Interpersonal skills including problem recognition and solving ability.
- Ability to promote and lead teamwork in a cross-functional, dynamic, matrix organization.
- Ability to gain and share knowledge regarding changing therapeutic areas.
- Excellent verbal communication and writing skills.
- Ability to create and deliver presentations to experts in molecular diagnostics
- Ability to travel, as needed.
- Computer and administrative skills (Word, Excel, Access, PowerPoint and Microsoft Project) and understanding of project management processes.

TAI Diagnostics is an Equal Opportunity employer.