Senior Clinical Research Associate

About Gregor Diagnostics

Gregor Diagnostics Inc. is a Madison, WI based, venture-backed, early-stage molecular diagnostics company developing novel molecular diagnostics for improved prostate cancer detection and patient management.

Summary of Major Responsibilities

The Sr. Clinical Research Associate (CRA) will be involved in all aspects of sponsor clinical trial development and management at Gregor Diagnostics. The Sr. CRA will work directly with sites, physicians, CROs, and other contracted groups to manage all daily and developmental aspects of current and future clinical trials. The Sr. CRA will report to the Director of Clinical and Regulatory at Gregor.

Essential Duties and Responsibilities

1. Assist in the coordination of clinical operations required to initiate, execute, and complete clinical trials to drive on time delivery of clinical trial milestones.
2. Create and organize relevant clinical documents, including study protocols, data collection documents, regulatory compliance documents, monitoring plans, training documents, standard operating procedures.
3. Maintain communication between the sponsor and all existing and future sites, PIs, and contractors.
4. Participate in updates to stakeholders and executive management regarding study progress, enrollment updates, and data management updates.
5. Involved in selection of investigational sites and service providers.
6. Main contact for Electronic Data Capture (EDC) database and lead ongoing reporting requirements for studies.
7. Ongoing clinical data review to ensure quality and consistency.
8. Participate in data management of clinical and safety databases.
9. Other duties as assigned.

Qualifications

Education and industry experience

- Bachelor's degree preferably in Life Sciences or related field
- Minimum of 5 years of clinical trial experience
- Strong working knowledge and experience in clinical trial management, clinical operations, study enrollment, database management and study planning for multiple national sites.

- Experience working with clinical databases, EDC systems, and reporting; Experience in REDCap is preferred.
- Understanding of IRB processes, submissions, and requirements.
- Industry sponsor experience in vitro diagnostics (IVD) and/or medical device sponsor(s) strongly preferred.
- Clinical or research experience in oncology, ideally in diagnostic product development.
- Strong verbal and written communication skills including documentation and regulatory compliance.
- Strong analytical, problem solving and decision-making skills.
- Ability to work in a team environment and adapt to changing plans and circumstances.
- Ability to travel up to 25% as required

Physical Requirements

- Ability to work for up to 8 hours a day in an office environment.
- Ability to work up to 6 hours a day in a laboratory environment.
- Ability to lift and move up to 40 pounds on an occasional basis.

Gregor Diagnostics is an equal employment opportunity employer. All qualified applicants will receive consideration for employment without regard to age, color, creed, disability, gender identity, national origin, protected veteran status, race, religion, sex, sexual orientation, and any other status protected by applicable local, state, or federal law.