



Clinical Research Manager – Pittsburgh, PA

Position Summary:

The Clinical Research Manager will assume a leadership role in the development and implementation of device clinical trials to ensure the safety of patients/subjects, the quality and integrity of data, and the proper management of study procedures according to ICH and GCP regulatory guidelines and Standard Operating Procedures. This position interfaces with R&D, Marketing, Regulatory, Legal, as well as various healthcare professionals, biostatisticians and other consultants. Responsibilities include managing contract research organizations (CROs) and other trial related vendors.

Primary Responsibilities:

- Serve as a key member of the team in planning and executing clinical trials.
- Coordinate all aspects of clinical trials from study start-up through close-out. This includes responsibilities across operations, study development, and project management.
- Manage budgets, timelines, and resources across assigned trials.
- Oversee the overall strategy of the clinical trials, and ensure that studies are developed in a professional manner to permit publication at professional conferences or in medical journals.
- Collaborate with independent clinical advisors to create regulatory and non-regulatory protocols.
- Assemble and manage Clinical Advisory Boards (CAB) and Data Monitoring Committees (DMC) as needed.
- Lead company efforts to obtain IRB approvals and monitor ongoing compliance to study protocols, FDA regulations, and IRB requirements.
- Establish and implement company Clinical Research Procedures and Policies.
- Oversee site training and in-services in addition to review of materials for clinical training sessions.
- Recruit, negotiate compensation, manage deliverables and provide feedback to sites, laboratories, and other outside vendors (CROs).
- Manage tracking of study supplies and usage, enrollment of subjects, regulatory document flow, study timelines, financial information, Adverse Events, performance metrics, data flow, etc.
- Cross functional management/participation (e.g., clinical investigators, CROs, data management, clinical science, statistics, etc) for the duration of trials.
- Develop and/or review protocols, amendments, Case Report Forms (CRFs), investigator brochures, informed consent, and other study related documents to ensure proper collection of data.



Position Requirements:

- Bachelor's degree (nursing, biology, or scientific field is preferred). Cardiology experience preferred.
- Minimum of eight (8) years direct experience in clinical study management in a sponsor setting or CRO organization, or combination thereof. (Sponsor setting is preferred.)
- Knowledge of regulatory agency reporting requirements regarding device safety, and an understanding of general device safety methodology
- Knowledge of FDA regulatory requirements is required.
- Strong experience in the management of investigational device exemption (IDE) clinical trials is required.
- Excellent written communication skills (correspondence, reports, protocols, etc).
- Proficient use of Microsoft Office Suite Applications
- Demonstrated proficiency in presenting scientific/technical data.
- Effective time management.
- Strong leadership and effective interpersonal skills are essential.
- Ability to coordinate and lead multiple projects simultaneously.
- Ability to travel up to 25%