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Job Title:	Senior Clinical Research Associate - Reducer
Reports To:	Clinical Study Manager
Location:	900 Long Lake Road, New Brighton, Minnesota
Date:	2021 Apr 20

Purpose/Role

The Senior Clinical Research Associate (CRA) is responsible for assisting with the execution of high quality clinical studies and will focus on the oversight and monitoring of investigational sites to ensure compliance and assist with study management activities.

Position Description

- Assists with the development and management of study related documents including clinical protocols, informed consent forms, case reports forms, monitoring plans, study manuals, and other study related tools
- Participates in the site qualification, activation and initiation process, including contract management and review of site activation documentation
- Assists in the planning of, and preparing materials for, investigator and coordinator meetings
- Assists with study training for investigators and coordinators, clinical research organization (CRO), Data and Safety Monitoring Board (DSMB), Clinical Events Committee (CEC), or core labs
- Establishes and maintains regular contact with investigative site personnel to ensure compliance and assessment of accrual rates
- Tracks and reports the progress of clinical studies (e.g., subject screening and enrollment, data collection, protocol deviations, and adverse event documentation)
- Oversees conduction of monitoring visits at investigational sites to ensure compliance to the clinical protocol, regulations, and timely receipt of data including source document verification, writing or reviewing monitoring reports and follow up letters, and device accountability
- Assists in data management with query generation and resolution, and reporting of adverse events and protocol deviations
- Assists with the development and implementation of site corrective actions as needed to address any compliance issues
- Assists the clinical management by providing input to sections of the protocol, clinical reports, regulatory submissions, study summary reports, and abstracts/manuscripts/presentations
- Assists with core lab and CRO management including contract management
- Assists with safety committee meeting preparation and support (e.g., DSMB, CEC)

- Contributes to ongoing Standard Operation Procedure (SOP) development and review
- Assists in audit preparedness (sites and internal)
- Provides input for study budget projections
- Coordinates and may schedule and conduct telephone site close-out visits at investigational sites, if applicable, including educating sites regarding record retention requirements
- Acts as mentor for less experienced CRAs

Qualifications

Education:

- Bachelor's degree in health sciences or related field or 5-10 years of experience as a CRA

Experience:

- 3-5 Years of clinical monitoring experience
- Experience in cardiovascular/heart valve disease is highly desired
- Experience with medical device clinical studies, US and/or OUS

Skills:

- Able to communicate effectively, both orally and in writing, with excellent interpersonal and diplomacy skills
- Proficient computer skills (Electronic Data Capture, Microsoft Word, Excel, PowerPoint, etc.)
- Good organizational and problem-solving skills
- High attention to detail and degree of accuracy
- Works independently and in a team environment
- Experience coordinating, prioritizing, setting timelines, and multi-tasking
- Knowledge and understanding of medical terminology
- Expertise with medical device regulations and compliance guidelines for clinical studies (e.g., 21 CFR 812, HIPAA, ISO 14155, GDPR)
- Expertise with Good Clinical Practice (GCP)
- Experience with Trial Master File management
- Professional demeanor and appearance

Other:

- Travel not required
- Sit or stand for 8-10 hours per day
- Able to lift up to 25 lbs

PLEASE NOTE THAT ONLY APPLICANTS LOCAL TO THE TWIN CITIES AREA WILL BE CONSIDERED.