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Job Title:	Clinical Study Manager
Reports To:	Director, Clinical Affairs
Location:	900 Long Lake Road, New Brighton, Minnesota
Date:	2021 Apr 20

Purpose/Role

The Clinical Study Manager is responsible for the execution of high quality clinical studies (US and/or OUS) and will focus on study management activities to meet study objectives.

Position Description

PRINCIPAL DUTIES AND RESPONSIBILITIES:

- Supervises and provides input to the development and management of study related documents including clinical protocols, case report forms, monitoring plans, study manuals, and other study- related tools
- Develops the study budget and updates as needed throughout the study including oversight to ensure spending remains within budget guidelines
- Oversees training of CRAs and ensures all members of the study team, or anyone conducting study-specific duties, are trained on the protocol and applicable study activities
- Oversees and participates in clinical site qualification, activation and initiation processes, including review and approval of site activation documentation
- Negotiates, or supervises negotiation of agreements with clinical sites and other study vendors (e.g., core lab, safety committees)
- Supervises and provides input into the planning of, preparing materials for, and presenting at investigator and coordinator meetings
- Oversees and/or participates in the study training activities for investigators, research coordinators, other study personnel, CROs, monitors, safety committees (as applicable)
- Provides ongoing updates regarding the progress of clinical studies, e.g., subject screening and enrollment, data collection, protocol deviations, and adverse event management
- Ensures adequate monitoring is conducted and may conduct monitoring visits at investigational sites as needed
- Evaluates clinical data and provides oversight for data management, query generation, and resolution and reporting of adverse events
- Evaluates protocol deviations and assists with development and implementation of site corrective actions as needed to address any compliance issues
- Oversees completion of clinical reports, study summary reports, and provides input for abstracts/manuscripts/presentations in conjunction with the clinical team and investigators
- Manages core laboratories and contract research organizations (CROs) involved in the study
- Contributes to ongoing clinical Operating Procedure (COP) development and review

- Responsible for ensuring study is audit-ready at all times
- Conducts regular meetings with the study team
- Ensures adequate preparation for CEC and DSMB meetings
- Provides support for regulatory submissions and preparation for meetings with regulatory agencies
- May participate as a member of a cross-functional Project Team representing Clinical Affairs, as assigned
- Supervises direct reports including interviewing and hiring, ensuring training, work assignments, evaluating their performance on an ongoing basis and providing feedback on day-to-day performance, and conducting annual performance reviews

Qualifications

Education:

- Bachelor's degree in health sciences or related field

Experience:

- 3-5 years of clinical research experience, preferably including monitoring experience and 1-3 years of experience managing projects
- Experience in cardiovascular/heart valve disease is highly desired
- Experience with medical device clinical studies

Skills:

- Advanced communication skills, both orally and in writing, with excellent interpersonal and diplomacy skills
- Proficient computer skills (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)
- Professional demeanor and appearance

Other:

- Position may require approximately 30% travel; additional travel may be needed during periods of the study such as site qualification, activation, or closeout
- 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.