

Job Title:	Clinical Study Manager
Reports To:	Vice-President, Clinical Affairs
Location:	900 Long Lake Road, Suite 300, New Brighton, MN 55112
Date:	2021 Nov 18

Purpose/Role

A brief description of the primary responsibilities for which the employee is accountable

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

Position Description

A listing of the deliverables to be accomplished, including specific duties/activities that make up the job

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
- Assists in the development of 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 study personnel are trained on the protocol
- Oversees and participates in clinical site qualification, activation and initiation processes, including review and approval of site activation documentation
- Participates in negotiation of agreements with clinical sites
- Supervises and provides input into the planning of, preparing materials for, and presenting at investigator and coordinator meetings
- Oversees and participates in the study protocol training for investigators, research coordinators, and other study personnel
- Provides ongoing updates regarding the progress of clinical studies, e.g., subject screening and enrollment, data collection, 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
- 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 Standard Operating Procedure (SOP) development and review
- Responsible for ensuring study is audit-ready at all times
- Conducts regular meetings with the study team
- Coordinates, participates in the preparation for, and attends, CEC and DSMB meetings
- Provides support for regulatory submissions and preparation for meetings with regulatory agencies
- May participate as a member of a 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

Represents the desired qualifications but may not reflect the employee's existing qualifications

Education:

- Bachelor's degree in health sciences or related field

Experience:

- 3-5 years of clinical research experience, including 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
- Expertise with Good Clinical Practice (GCP)
- Professional demeanor and appearance

Other:

- Position requires approximately 30% travel; additional travel may be needed during periods of the study such as site activation
- Sit or stand for 8-10 hours per day
- Able to lift up to 25 lbs.

Please note that only candidates local to the Twin Cities, Minnesota will be considered for this position.