Job Description

Position: Clinical Trial Manager

Role description
The Clinical Trial Manager (CTM) is responsible for leading or participating in one or more cross-functional study teams to advance and deliver clinical trials on time, within budget and with good quality. The individual will participate in all components of clinical trials from protocol inception through CSR completion. The individual will effectively communicate with the entire project team, vendors, and investigative sites. All work will be completed in compliance with the Standard Operating Procedures (SOPs), Good Clinical Practice (GCP)/International Conference on Harmonisation (ICH) guidelines and other applicable regulations.

Location
This role will be based in Ann Arbor, MI

Hours
This is a full-time role

Responsibilities
- Manages independently and/or supports study team operations in all aspects of study execution, including project budget and timeline
- Participates in vendor/CRO selection and interfaces with vendors as required
- Coordinate the development and review of study documents including protocols, informed consent forms and study manuals with Medical Directors, Director Clinical Operations and CROs
- Prepares site budget templates and assists with negotiation of such
- Manages and supports site feasibility assessment, site selection and subject recruitment
- Manages and/or performs initial essential document collection and review
- Supports finalization of Clinical Study Agreements
- Reviews site grant payments for approval
- Communicates project status to the project team and escalates site performance issues as appropriate
- Facilitates and participates in internal and external team meetings, taking minutes and providing status updates as required
- Assumes additional roles on the team as necessary

Requirements
- College graduate, preferably with a healthcare or life science degree
- Minimum of 5 years of experience in clinical research; familiar with both U.S. and E.U. regulations (GCP/ICH guidelines)
- Experience working collaboratively and cross-functionally in a team environment
- Strong written, verbal, and interpersonal communication skills
- Strong computer skills, including Microsoft Office
- Exceptional attention to detail and highly organized
- Able to exercise judgment within defined procedures and practices and to determine appropriate action independently
- Able to work in a dynamic, changing environment

Reporting relationships
This position reports into the Vice President, Clinical Operations; works closely with the other Clinical Operations team members as well as Project Management; and is a member of the Development Team.