30 June 2018

Hart Clinical Consultants P.O.
P.O. Box 202
Deland, FL 32721-0202

Position/Title: **Project Manager**

Reports to: **TBD**

Position Summary:

The Clinical Project Manager (CPM) position performs a wide variety of activities to support the startup, management, and completion of clinical research studies, and may supervise other clinical operations personnel. An experienced project manager with a sound skill set and process discipline systematically applies knowledge, skills, tools, and techniques to project-based activities to meet project requirements.

The CPM is responsible for the management of all aspects of Clinical Trial Team activities for assigned project(s). The CPM, in concert with the Clinical Program Director (CPD), is accountable for achieving successful delivery of HCC clinical team activities at the project level by meeting Sponsor and regulatory requirements according to time, quality/scope and budget constraints.

The CPM acts as the bridge between all teams and stakeholders on the project, is the functional link between HCC and the sponsor-client, the point person for all related tasks and materials, and the link between strategy and execution. The clinical project manager bridges the gap between the strategists (stakeholders and business leaders who communicate the vision and the objective) and actual project execution with the team members that are working to accomplish those goals.

HCC senior management assigns the CPM to the specific clinical trial.

Job Description:

- Manages clinical projects from concept through clinical study report completion
- Assesses the operational feasibility of studies and recommends execution and risk mitigation plans
- Drafts project proposals in accordance with provided project synopsis; drafts responses to Requests for Proposal (RFP)
- Ensures effective project plans (e.g., Monitoring Plan, Quality Plan, Safety Plan) are in place and operational for each trial
- Organizes and leads the clinical project team. Achieves study objectives by working with team members to set project priorities and milestones and resolve project conflicts
- Proactively manages project level operational aspects of clinical trial team including the trial timeline, budget, resources, vendors and quality metrics
- Provides timely updates on trial progress to designated sponsor personnel in addition to HCC Clinical Program Director (CPD) and/or Clinical Operations Officer (COO), with respect to vendor selection, project plans, trial budget and timeline management, quality standards and risk mitigation
- Demonstrates thorough knowledge of FDA, ICH 6(R2) and ISO14155 GCP guidelines, and applicable regulatory requirements for clinical trial management

- Ensures GCP and regulatory compliance is maintained across all study activity in anticipation of regulatory or sponsor inspection
- Leads the development of study-related documents, including study protocols and case report form design (if applicable), informed consent documents, study manuals and plans, trial master files, etc.
- Co-monitors as needed
- Assigns roles and responsibilities within the project group, for example, the Lead CRA, in collaboration with HCC management
- Leads regularly scheduled cross-functional study team meetings with internal and external resources
- Participates in vendor selection, negotiation and management, including monitoring of associated budgets and contracts
- Participates in meetings with investigative sites, key opinion leaders and consultants, as needed
- Plays a part in the analysis, summary, and reporting of clinical data through the course of the study
- Proactively identifies and resolves issues, and participates in process improvement initiatives as required
- Responds promptly and appropriately to study questions and issues raised by investigative sites, vendors, monitors, senior management, sponsors and consultants
- Reviews and approves invoices from study vendors, investigators, consultants, etc. in collaboration with Accounting personnel to ensure investigator payments occur in a timely manner
- Evaluates monitoring reports with significant findings to confirm appropriate conclusions and actions taken
- Reviews serious adverse events and other pertinent data with the medical monitor and drug safety personnel to identify safety trends and potential risks
- Reviews protocol deviations data to identify and analyze non-compliance trends, and recommend and supervise implementation of mitigations
- Maintains professional expertise through familiarity with therapeutic area and clinical research literature
- Leads sponsor study project initiation process, including but not limited to conduct of the Trial Kick-off meeting, the set-up of trial master file (TMF), site selection, and finalization of site and vendor Clinical Trial Agreements and budgets
- Works proactively with the clinical trial team to set priorities in accordance with applicable project plans, company standard operating procedures (SOPs), ICH/ISO GCP guidelines and domestic/regional regulatory requirements
- Ensures potential study risks are escalated to the attention of the Clinical Program Director and Sponsor-client when appropriate, as per the trial-specific Monitoring Plan
- Chairs trial-specific team meetings and vendor status update meetings and ensures meeting minutes are completed, distributed to team members and filed in the Trial Master File (TMF) in a timely manner
- Monitors the quality of vendor deliverables, addresses quality issues with the appropriate team member(s) and identifies opportunities to improve training, execution and quality control across the clinical team
- Reviews vendor responses to quality assurance audits for appropriateness, timeliness and accordance with company SOPs and regulatory requirements
- Ensures all project level study documentation is filed in the TMF in accordance with company SOPs and all regulatory requirements, and provides oversight to the clinical team regarding TMF filing,

maintenance and archival procedures
- Effectively provides support to CRAs/clinical site manager(s) in the conduct of the trials
- Other duties as assigned

Skills

- A thorough knowledge of clinical research concepts and practices, FDA regulations and ICH/ISO GCP Guidelines regarding drug and device development, and data management methods
- General business skills, such as communication, time management, and computer/software competencies
- Conscientious, influential person with an outstanding work ethic and strong personal discipline
- Excellent organizational, leadership and problem-solving skills
- Excellent written and verbal communication skills
- Experience in leading cross-functional teams to meet goals and metrics
- Experience in writing clinical study protocols, reports, informed consent forms, and other clinical documents
- Success at managing global studies a plus

Experience:

Minimum Qualifications: At least five (5) years of clinical operations experience, with increasing levels of responsibility, and a minimum of two (2) years project-lead or management experience in the pharmaceutical, biotechnology, medical device and/or CRO industry is required, or an equivalent combination of education and work experience.

Preferred Qualifications: At least eight (8) years of clinical operations experience, with expert understanding of clinical research and clinical project management experience at a sponsor or CRO company, or an equivalent combination of education and work experience. Therapeutic experience in cardiology and/or vascular disease is a plus.

Education/Certification:

Minimum Qualifications: Bachelor's degree in scientific or biological sciences or healthcare field, at minimum

Preferred Qualifications: Bachelor's or advanced degree in scientific or biological sciences or healthcare field; Project Manager Professional certification; Clinical Research Certification (ACRP, SoCRA)

Physical Demands/Work Environment:

Position is home based, requires extended time on computer and phone.
30% - 50% domestic travel is anticipated, however, international travel may be required on occasion