Title: Clinical Trial Manager / Sr. Clinical Trial Manager
Reports to: VP of Clinical Operations
Location: Redwood City, CA

Position Overview

The CTM / Sr. CTM, Clinical Operations will work closely with various internal team members and vendors as well as clinical study sites to ensure that clinical trials are conducted in a timely fashion and in a manner compliant with SOPs, ICH/GCP/regulatory guidelines, company goals, and budgets. This person may have line management responsibilities. This person is able and willing to perform all duties or functions of subordinates.

Responsibilities

- Manages the operational aspects of clinical trials
- Manages the study project plan, including timeline, budget and resources
- Manages CRO interactions, including sponsor oversight of operational functional activities (e.g., study management, monitoring, site management, project master files)
- Participates in protocol, CRF and strategy development, Clinical Study Report preparation, NDA submission, as appropriate
- Prepares metrics and updates for management, as assigned
- Proactively identifies potential study issues/risks and recommends/implements solutions
- Participates in and facilitates CRO/vendor selection process for outsourced activities
- Works with CRO to develop and revise scope of service agreements, budgets, plans and detailed timelines, and ensure that performance expectations are met
- Prepares and/or reviews/approves study-related documents (e.g., Monitoring Plan, Laboratory Manual, Patient Diary, Clinical Site Procedures Manual, Pharmacy Manual, and CRF Completion Guidelines)
- Manages clinical monitoring activities ensuring compliance with Good Clinical Practices (GCP) and applicable regulations
- Participates in the development, review and implementation of departmental SOPs and processes
- Recommends and implements innovative process ideas to impact clinical trials management
- Organizes and manages internal team meetings, investigator meetings and other trial-specific meetings
- Reviews site study documents (informed consent template and study tools/worksheets), investigator contracts, and site payments
- Participates in the selection, training and evaluation of study personnel (contract and internal) to ensure the efficient operation of the function
- May manage clinical operations staff

Requirements

Education and/or Experience:

- A Bachelor of Science degree required
- A minimum of 6 years (CTM) and 8 years (Sr. CTM) of related clinical trial management experience
- Rare Disease experience preferred
- Experience in managing outside vendors, e.g., CROs and other vendors
- Strong knowledge with advanced concepts of clinical research and able to work effectively in a team/matrix environment
- Strong knowledge and experience of clinical research operations, including interpretation and implementation of FDA regulations/ICH guidelines, is required
- Ability to provide clinical development expertise in a specified product area or project
- Excellent written and verbal skills required. Must display strong analytical and problem-solving skills. Attention to detail required.
- Proficient in MS Suite
- Must be willing to travel up to 25% time

Competencies and Attributes:

- Demonstrated leadership to drive results that are needed to achieve company objectives -
- Must possess excellent interpersonal skills
- Must have the ability to build and maintain positive relationships with management, peers, and direct reports
- Ability to deal with time demands, incomplete information or unexpected events

Please submit resume to Soleno Therapeutics, Inc., hr@soleno.life

Local candidates only, please.