Title: Clinical Trial Manager
Reports to: Director, Clinical Operations
Location: Redwood City, CA

Position Overview

The Clinical Trail Manager (CTM) 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 the protocol(s), 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, including but not limited to clinical site monitoring activities and co-monitoring as needed.

Responsibilities

- Manage the operational aspects of clinical trials
- Participate in and facilitate CRO/vendor selection process for outsourced activities
- Manage the study project plan, including timeline, budget and resources
- Manage CRO and vendor interactions, including sponsor oversight of operational functional activities (e.g., study management, monitoring, site management, project master files) to ensure compliance with the contracted study specifications and applicable SOPs
- Participate in protocol, CRF and strategy development, Clinical Study Report preparation, NDA submission, as appropriate
- Prepare metrics and updates for management, as assigned
- Proactively identify potential study issues/risks and recommend/implement solutions
- Work with CRO to develop and revise scope of service agreements, budgets, plans and detailed timelines, and ensure that performance expectations are met
- Prepare and/or review/approve study-related documents (e.g., Monitoring Plan, Laboratory Manual, Patient Diary, Clinical Site Procedures Manual, Pharmacy Manual, and CRF Completion Guidelines)
- Manage clinical monitoring activities ensuring compliance with Good Clinical Practices (GCP) and applicable regulations
- Participate in the development, review and implementation of departmental SOPs and processes
- Recommend and implement innovative process ideas to impact clinical trials management
- Organize and manage internal team meetings, investigator meetings and other trial-specific meetings
- Review site study documents (informed consent template and study tools/worksheets), investigator contracts, and site payments
- Participate in the selection, training and evaluation of study personnel (contract and internal) to ensure the efficient operation of the function
- Supports inspection readiness and ensures implementation of corrective actions within specified timelines
- May manage clinical operations staff

Requirements

Education and/or Experience:

- A Bachelor of Science degree required
- A minimum of 6 years (CTM) of related clinical trial management experience
- Rare Disease experience preferred
- Experience in managing outside vendors (e.g., CROs, central laboratories, and other vendors)
- Strong knowledge with advanced concepts of clinical research and able to work effectively in a team environment
- Strong knowledge and experience with 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 hr@soleno.life.