JOB DESCRIPTION

Position: Senior Clinical Trial Assistant

Reports to: Senior Director, Clinical Operations

Responsibilities Overview:

The Senior Clinical Trial Assistant supports the efforts of Clinical Operations and performs a variety of administrative assignments such as “in house” management of site essential documents, study tracking tools and metrics, and the set up/maintenance of the Trial Master Files.

Tasks and Responsibilities:

Study-Specific Activities:

- Establish, maintain, and archive the Trial Master File (i.e., hard copy, as needed and electronic folder set-up, filing, tracking, archiving) in compliance with SOPs, ICH and GCPs. Ensure proper naming conventions are followed.
- Coordinate distribution of documents to sites as well as monitors/CROs.
- Collect, track and review regulatory documents and notify sites and/or monitors/CRO of missing documents or documents that need updating.
- Develop and maintain spreadsheets and other documents to track critical study milestones
- Track and report project/study information regarding subject and site status, metrics, lab sample shipments and discrepancies, and other needs as appropriate.
- Assists with the preparation and review of study related materials as it pertains to CTA processes (e.g. study reference manual, clinical trial material requests, and Investigator Site File).
- May participate in team review of data listings and clinical study reports.

Communication and Coordination

- Perform assigned administrative activities in support of clinical studies from design to completion.
- Actively participates in the planning and conduct of CRO and study related meetings; creating an agenda and draft minutes as appropriate.
- Effectively and professionally communicate to internal and external team members (e.g., vendors, site personnel, and consultants) to ensure adequate distribution of information.

Other Departmental Activities:

- May track and process vendor or site invoices, and ensure accurate accrual records are kept.
- Maintain up-to-date knowledge of current regulations and guidelines to ensure compliance.
- Provide general administrative support to the clinical team as assigned.
- Other duties as deemed necessary.

Preferred educational background and skill required:

- Bachelor’s Degree and/or equivalent with at least 5 years of CTA experience in the biopharmaceutical industry

- Past experience in development of tools and other tracking documents that support clinical research.
- Working knowledge of FDA regulations and ICH guidelines regarding GCPs.

Knowledge, Skills and Attributes:

- Proven ability to multi-task and prioritize.
- Well-organized, detail-oriented, possess a sense of urgency
- Team-oriented with very good communication and interpersonal skills.
- Excellent computer skills in the following programs: MS Outlook, MS Word, PowerPoint, Excel, and WebEx.

Special Considerations

Some travel may be required to sites or to study-related meeting.