Sr. Clinical Research Associate, Clinical Operations

POSITION SUMMARY:

The Sr. Clinical Research Associate (Sr. CRA), Clinical Operations is responsible for supporting the management of the operations of a clinical research study or multiple clinical studies, this includes oversight of third-party vendors. This role is also responsible for oversight activities as it relates to Contract Research Organization (CRO), Vendors and Clinical Sites. The Sr. CRA provides oversight of biological samples collected for clinical trials, including vendor management.

ESSENTIAL FUNCTIONS AND RESPONSIBILITIES

- Manage biological samples collected for the purposes of clinical trials, manage clinical laboratories, and develop and manage end to end clinical sample management processes.
- Participate in oversight visits, remotely or in person, with contracted monitors and implement training as need to ensure compliance with the protocol, CRF, SOPs and GCPs.
- Participate in the selection and management of 3rd party vendors, which may include but not limited to contract monitors, CROs, laboratories and others.
- Maintain communication with clinical department, investigators and clinical sites and contract clinical monitors.
- Perform oversight activities of the CRO and third-party vendor such as but not limited to: oversight monitoring visits, trial master file QC, review of monitoring reports, tracking of key performance indicators and other oversight tasks as defined in study plans.
- Assist in the creation and revision of model informed consents, case report forms, instruction manuals, and monitoring tools.
- Liaise with the Contract Research Organization (CRO) and other third-party vendor to ensure contractual obligations are being maintained.
- Contribute to selection, oversight of CROs, Contract Laboratories, IRT and other ancillary vendors associated with the conduct of a study.
- Drive and/or oversee contract and budget negotiation with US clinical sites.
- Develop and/or oversee development of study plans alongside the CRO and third-party vendor and ensure study plans are followed through the duration of clinical studies.
- Act as Vendor Lead for assigned vendors.
- Ensures compliance with good clinical practices (GCP), relevant standard operating procedures (SOP), and regulatory guidelines.
- Ensures coordination of the activities of functional groups that comprise the clinical study team including, but not limited to, clinical monitoring, data management, and CMC to ensure proper conduct and timely completion of all projects.

- Represent the company at clinical sites and external project meetings and develop and delivery training to CRO and/or site staff as needed.
- Ensure cross-functional team activities are aligned with clinical development plans
- Manage and provide adequate oversight on a clinical study or multiple studies simultaneously, with good prioritization and time management skills
- Propose and implement innovative process ideas that impact clinical trials management and cost efficiency
- Manage and maintain clinical and regulatory files
- Perform co-monitoring visits as needed
- Interact and establish relationships with clinical trial investigators and key opinion leaders
- Propose and implement innovative process ideas that impact clinical trials management and cost efficiency
- Perform other study-related activities as assigned by management

JOB QUALIFICATIONS

Education/Experience, Knowledge, Skills Required:

- BA or BS preferably in sciences
- At least 6 years of pharmaceutical industry experience, including monitoring clinical studies.
- Oncology or CNS diseases study management experience highly preferred
- Prefer experience with global Phase 3 or larger global Phase 2 studies
- Project leadership experience
- Good understanding of clinical study implementation process.
- Excellent organizational, analytical and project management skills
- Excellent interpersonal skills
- Excellent knowledge of GCP compliance issues
- Experience with oversight activities implementation and execution

Knowledge, Skills and Abilities

- Knowledge of Windows, MS office products including MS Project, Outlook, Word, Excel, and PowerPoint as well as EDC/IRT database platforms
- Ability to work independently and ability to prioritize
- Ability to resolve issues timely and recognize when escalation is necessary
- Work comfortably within a fast-paced and dynamic work environment, with a high level of autonomy, and ability to embrace change

SPECIAL WORKING CONDITIONS

- Willingness and ability to travel in the US and internationally frequently during some periods of trial execution

Please note this job description is not designed to cover or contain a comprehensive listing of activities, duties or responsibilities that are required of the employee for this job. Duties, responsibilities and activities may change at any time with or without notice.