Senior CRA, 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.

ESSENTIAL FUNCTIONS AND RESPONSIBILITIES

- 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
- Interact and establish relationships with clinical trial investigators and key opinion leaders

JOB QUALIFICATIONS

Education, Certifications, Experience

- BA or BS preferably in sciences

- At least 6 years of pharmaceutical industry experience, including monitoring clinical studies
- Oncology or CNS study management experience highly preferred
- Prefer experience with global Phase 3 or larger global Phase 2 studies
- Project leadership experience
- Experience with oversight activities implementation and execution

Knowledge, Skills and Abilities

- Good understanding of clinical study implementation process.
- Excellent organizational, analytical and project management skills
- Excellent interpersonal skills
- Excellent knowledge of GCP compliance issues
- 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

- Physical Activities: On a continuous basis, sit at desk for a long period of time; intermittently answer telephone and write or use a keyboard to communicate through written means. The noise level in the work environment is usually low to moderate. The physical demands described above are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.
- Willingness and ability to travel 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.