Manager, Clinical Operations

POSITION SUMMARY

The Manager, Clinical Operations is responsible for managing the operations of a clinical research study or multiple clinical studies including oversight of third-party vendors.

ESSENTIAL FUNCTIONS AND RESPONSIBILITIES

- Responsible for and/or support delivery of a clinical study within timelines, budget, and regulatory requirements.
- Liaise with the Clinical 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.
- Perform oversight activities of the CRO and third-party vendor as defined in study plans.
- 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.
- Serve as Clinical Operations subject matter expert in cross functional initiatives such as data review, protocol deviations review, process improvements, etc.
- 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
- Provide support to Clinical Study Operations Lead/Director in the day-to day management of a clinical study(is); and take on additional oversight tasks as needed
- Manage and provide adequate oversight on a clinical study or multiple studies simultaneously, with good prioritization and time management skills
- Employ expertise in study center selection, pre-study qualification, initiation, routine monitoring, and close-out, and ability to complete these responsibilities in compliance with company SOPs
- 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

JOB QUALIFICATIONS

Education, Certifications, Experience

- BA or BS preferably in sciences
- At least 6 years of pharmaceutical industry experience, including monitoring clinical studies and clinical trial management
- Oncology or rare diseases 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.