Associate Director Clinical Operations

POSITION SUMMARY

The Associate Director Clinical Operations is a key leadership role within the Clinical Operations department under the supervision of an Executive Director, and is responsible for the execution planning and conduct of clinical trials. The trials are to be executed on time, on budget, compliant with all relevant regulatory and ethical requirements, and of the quality required to support submission to relevant authorities for drug approval.

ESSENTIAL FUNCTIONS AND RESPONSIBILITIES

- Develop timelines and for assigned clinical trials and programs
- Drive study subject enrollment to completion according to company timelines
- Drive all other study milestone completion according to company timelines
- Lead and inspire cross-functional Clinical Trial teams to successful execution of assigned trials
- Lead early feasibility efforts and country/site selection
- Develop clinical trial/program budgets and liaise with Finance/Accounting in communicating budget forecasting and accruals
- Develop Request for Proposals (RFPs) and define scope of services for outsourced clinical activities
- Oversee CRO/vendor selection process activities, seeking input from other internal functional groups
- Ensure qualification of CROs, vendors and service providers in accordance with Denovo Biopharma policy and process
- Partner with CROs to inspire superior performance and develop long-term partnerships to the mutual benefit of Denovo Biopharma and our service partners
- Manage CRO/vendor agreements, ensuring change orders and budgets meet defined clinical operations specifications
- Drive team to completion of all deliverables such as protocol ICF, manauls, etc.
- Review proposed site contract/agreement templates and budget templates
- Supervise the negotiation of investigator agreements and grants appropriate to the clinical programs. Review and approve any variations to the proposed agreement and/or grant.
- Review protocol deviations and evaluate trends across studies
- Ensure clinical data are collected and managed in accordance with the study monitoring plan and data quality standards
- Contribute to the clinical content of Investigator's Brochure (IB), Development Safety Update Report (DSUR), etc.
- Prepare high-quality reports for management on program status and issues
- Ensure clinical trials are conducted in compliance with applicable ICH-GCP guidelines, SOPs and local regulatory guidelines or regulations
- Monitor trial conduct for potential GCP violations, and report to Denovo Biopharma management appropriately. Participate in any corrective and preventative action (CAPA) plans as appropriate
- Perform co-monitoring visits as needed
- Interact and establish relationships with clinical trial investigators and key opinion leaders
- Participate in the development and review of departmental SOPs and working practices
- Manage, mentor, and train clinical staff as appropriate

JOB QUALIFICATIONS

Education, Certifications, Experience

- Bachelor of Science or related field, Master's degree preferred
- At least 10-years clinical trial experience
- Oncology or CNS experience preferred
- Experience overseeing CROs and other vendor partners
- Excellent organizational, analytical, planning, and project management skills
- Demonstrated excellent communication skills and cross-functional collaboration skills
- Excellent working knowledge of Good Clinical Practices, ICH guidelines, trial initiation and management practices and procedures
- Excellent management and leadership skills
- Excellent written and oral communication skills. Communication style should be diplomatic and direct, but not confrontational. Must work well in a collaborative team environment.
- Ability to independently manage multiple studies

Knowledge, Skills and Abilities

- Ability to communicate, verbal, analytical and organizational skills, project management, management, and computer expertise.
- Possess a strong commitment to quality and accuracy.
- A self-starter and a team-player who thrives in a fast-paced environment.

SPECIAL WORKING CONDITIONS

- 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.