Project Manager/Senior Project Manager/Director, Clinical Operations

REPORTS TO: Vice President, Clinical Operations

STATUS: Full-time employee, Exempt, Onsite

JOB SUMMARY: The Project Manager/Senior Project Manager/Director will oversee the company's clinical research programs. The job will require a candidate who can organize, execute, and oversee all aspects of clinical initiatives including protocol drafting/approval, informed consent drafting/approval, Investigator Brochure drafting/approval and oversight of CROs and third-party vendors. This individual will work closely with other functions of the company including Quality Assurance, Medical Affairs, Regulatory Affairs, and Manufacturing.

ESSENTIAL DUTIES AND RESPONSIBILITIES:

- Responsible for management and oversight of clinical trials, ensuring cost, quality, and adherence to timelines
- Responsible for creating/maintaining clinical operation department goals, budget, and study priorities.
- Provide leadership for successful project management and completion of clinical trials with study teams using CROs, vendors, and internal resources.
- Assist with vendor selection and contracting for assigned studies.
- Provide efficient updates on trial progress to internal stakeholders
- Write and edit clinical protocols, informed consents, and investigator brochures.
- Oversee maintenance and quality review of study TMF
- Ensure effective project plans are in place for each trial and work proactively with CRO project teams to ensure adherence to the plans.
- Monitor the quality of vendor deliverables, address quality issues with the appropriate project team members and identify opportunities to improve execution and quality control across the project team.
- Ensure potential study risks are escalated to internal stakeholders when appropriate
- Build collaborative relationships with key internal stakeholders to support clinical programs.
- Act as single point of contact for CRO and project team and facilitate responses to questions and observations
- Maintain communication with internal departments/functional team members, management, and vendors as well as external corporate partners (as applicable) to ensure clear and consistent messaging is relayed to all relevant stakeholders involved in our clinical trials
- Work with the Chief Medical Officer and Chief Scientific Officer to draft and finalize study-related documents such as clinical study protocols, investigator brochures, and informed consent forms.
- Collaborate with KOLs for feedback on study protocols and development plans
- Support Regulatory Affairs department with regulatory filings.

QUALIFICATIONS:

- Strong attention to detail and deadlines
- Knowledge of FDA regulations, ICH Guidelines, and GCPs governing the conduct of clinical trials
- A good decision-maker, with proven problem solving skills and success at making timely decisions that keep the organization moving forward.
- Proficient in reading and understanding clinical proposals (RFPs) and legal agreements
- Ability to hold yourself and others accountable to achieve goals and live up to commitments.
- Thorough understanding of drug development process and the pharmaceutical industry.
- Ability to work independently with minimal supervision.
- Excellent verbal and written skills to analyze, define and convey difficult and complex issues in a way that accurately and persuasively communicates the issues to internal and external stakeholders.
- Ability to work effectively in a high-energy environment and adapt to emerging issues
- A Bachelor's degree is required; an advance degree is preferred.
- Five or more years of professional experience in clinical trial management within the pharmaceutical industry; Sponsor experience preferred
- Ability to use office technology tools to include Apple, Word, Excel, PowerPoint, Outlook, Zoom, among others.
- Must be eligible to legally work in the United States

PHYSICAL REQUIREMENTS AND WORKING CONDITIONS:

Essential functions require telephone, meetings, and other desk work approximately 70-90 percent of time. The position requires that employee must be able to meet with employees and others who have business with the Company. Regularly required to stand while making presentations. Visual acuity and manual dexterity required to proofread a high volume of documents and operate various technologies. Must be able to hear and speak clearly and distinctly to provide information in person or on the telephone. Employee must be able to operate general office equipment including familiarity with MacOS.

The above assignments are intended to describe the general nature and level of work being performed by people assigned to this job. They are not intended to be an exhaustive list of all responsibilities, duties and skills required. Cingulate Therapeutics is an employer which recruits, hires, trains and promotes persons in all positions and does not discriminate. We are not able to provide sponsorship to work in the United States.