JOB DESCRIPTION

Job Title: Clinical Research Associate II / Senior Clinical Research Associate

Department: Clinical Operations **FLSA Status:** Exempt

SUMMARY OF ESSENTIAL FUNCTIONS:

Responsible for providing support to clinical trial teams in vendor oversight, site management and other trial related activities, including trial start-up, interim monitoring as well as closeout activities. Monitors progress of clinical trials at the site level and works to ensure that clinical standard operating procedures (SOPs), protocols, and documentation are followed as per the International Conference on Harmonization Good Clinical Practice (ICH GCP)/ Code of Federal Regulations (CFR).Has the responsibility to verify that the rights and well-being of human subjects are protected and that the reported trial data are accurate, complete, and verifiable from source documents. The CRA, in partnership with the Clinical Trial Manager or designee, will also ensure that Clinical Operations' leadership team is aware of all monitoring metrics and related site critical issues. This position will review relevant study documents, trip reports, monitoring trends, track monitoring deliverables, and recommend potential solutions to identified issues. In addition, mentors junior Clinical Research Associates and Clinical Trial Assistants.

SPECIFIC DUTIES, ACTIVITIES AND RESPONSIBILITIES INCLUDE, BUT ARE NOT LIMITED TO:

- Supports in the efficient management of trials in all phases (Phase 1-3) including assisting in recruitment of potential Investigators, preparation of Independent Ethics Committee/ Institutional Regulatory Board (IEC/IRB) submissions, organization of meetings and other tasks as instructed by the Clinical Trial Manager or Director, Clinical Operations.
- Performs pre-trial contact visits, initiation, routine monitoring visits and closeout visits.
- Builds and maintains strong relationships with investigators and study site staff.
- Trains, with the support of the medical monitor, investigators and other trial staff on the protocol and data collection methods to ensure collection of subject data is accurate, complete, and conforms to protocol requirements, in accordance with local regulations, ICH-GCP and Soleno SOPs.
- Ensures site adherence to protocol, accurate data collection via comprehensive source document verification according to trial specific monitoring plan.
- Drives site performance and engagement through regular communications and by setting clear expectations, providing feedback, and, in conjunction with the Lead CRA and CTM, developing action plans for remediation when needed.
- Communicates effectively with site personnel, including the Principal Investigator (PI), and Sponsor management to relay protocol/study deviations and ensure timely implementation of corrective actions
- Confirms investigational medicinal product (IMP)/biological samples/supplies accountability is accurate and site has sufficient quantities of IMP and other study supplies necessary to perform the trial.
- Monitors data in an Electronic Data Capture (EDC) system in a timely manner and in accordance with trial specific guidelines and monitoring plan.
- Identifies and processes Serious Adverse Events (SAEs) according to the procedures defined by the study team.

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- Clearly documents within the timeframes specified in the trial specific monitoring plan the activities performed during site visits in monitoring reports and follow-up letters.
- Supports with all aspects of interaction with central IRB/EC and ensures collection and review of required essential study documents and report.
- Establishes, updates, tracks, and maintains study specific trial management tools/systems, and status reports.
- Collects essential regulatory documents from sites and ensures that Trial Master Files for assigned projects are in adherence to global regulations and guidelines, company quality standards and departmental SOPs.
- May assist in the negotiation of the investigator budgets and the execution of site contracts.
- Supports with all aspects of interaction with central IRB/EC and ensures collection and review of required essential study documents and reports.
- May assist in development of protocols, informed consents, case report forms, monitoring plans, edit specifications, and other trial related documents.
- Involved in initial review of study documents, e.g., protocol, CRFs, informed consent forms, IXRS manuals, laboratory manuals, vendor manuals (not all inclusive).
- Participates in study-specific meetings, teleconferences, and trainings.
- Participates in meetings or conference calls with CROs, CRAs and cross-functional study teams.
- Interact with central laboratory vendors, ensuring logistical support for sites, tracking, and resolution of CRF and central laboratory queries.
- Assists in the review of routine data and preparation of safety, interim, and final study reports, and resolution of data discrepancies.
- Supports regulatory inspection activities as required.
- Ensures adherence to federal regulations and applicable local regulations, ICH-GCP, SOPs, Monitoring Plans, and to quality standards in conducting clinical research.
- Stays abreast of new and/or evolving local regulations, guidelines and policies.

POSITION REQUIREMENTS:

- Bachelor's degree or higher preferably in a biologic/scientific discipline.
- A minimum of 3 years' experience as a Clinical Research Associate preferably in a small pharmaceutical / biotech company.

KNOWLEDGE AND SKILLS:

- Must possess detailed knowledge of FDA regulations and GCP/ICH guidelines as they apply to the conduct of clinical research.
- Must have excellent interpersonal, written, verbal communication and administrative skills.
- Excellent computer skills in the following programs: MS Word, PowerPoint, and Excel.

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WORK ENVIRONMENT:

The work required for this position is to be performed on site in a formal office setting. Significant travel is required (~30%).