Senior Clinical Research Associate / Lead CRA (In-House) Job Description

Title: Senior Clinical Research Associate /Lead CRA (In-House)
Reports to: VP of Clinical Operations
Department: Research
Location: Norwalk, CT

Position Overview: The Clinical Research Associate III/ Lead CRA will provide management and oversight for MMRC's INDs and responsible for all aspects of study conduct and CRO oversight. The Clinical Research Associate III/ Lead CRA is the CRO's primary point of contact for clinical study project management and communications. Experience and knowledge of end-to-end management of clinical trial conduct, knowledge of the pharmaceutical industry and an understanding of clinical drug development, clinical trials operations and regulatory components is essential.

Essential Functions

Specific Job Functions/Responsibilities:

- Ability to manage complex protocols within a matrix environment.
- Experience in working with and overseeing Contract Research Organizations (CROs) and other external vendors is required.
- Demonstrated ability to drive clinical trial activities: i.e. experience in all aspects of study start-up and conduct, regulatory obligations, adverse event reporting, budgeting.
- Report on all aspects of the study progress to MMRC/F management
- Provides study-specific training and leadership to clinical research staff, including CRO, sites and other contract personnel.
- Oversees the following activities across the trial program: clinical supplies, DM, outsourcing and vendor alliance management.
- Prepare and present project reports as required. Plans, executes, and leads study-specific meetings as needed (e.g., Study Management Meetings, site calls etc.).
- Study budget management and oversight of vendor and site payments. Review and approve clinical invoices against approved budgets.
- Ability to identify and manage or escalate risks.
- Review and sign off on monitoring reports, ensure study issues and action items are addressed and closeout appropriately and in compliance with study management plans.
- Daily interaction with study CRO project manager, the MMRC medical monitor and other members of the cross-functional study team.
- Contribute in the design of clinical trials, and review trial documents.
- Prepares and/or reviews study-related documents (e.g., Study Operations Plan, Monitoring Plan, Pharmacy Manual, Informed Consent, Laboratory Manual, CRF Completion Guidelines, study tools/worksheets and other study-specific documents or manuals).
- Ensures audit-ready condition of clinical trial documentation including central clinical files.
- Write and review study protocols, informed consents and amendments.
- Ensures SAEs /SUSARs are managed and reported according to the study safety plan.
- Report to the VP of Clinical Operations
- Excellent working knowledge GCP, FDA and ICH Guidelines. Ensures the assigned clinical trials are executed in compliance with FDA and ICH GCP guidelines/regulations and SOPs.
- Comfortable multi-tasking in a fast-paced small company environment and able to adjust workload based upon changing priorities.
- Excellent team player; willingness and ability to fill functional gaps in a small organization.

Qualifications

- Minimum degree requirements of a Bachelor's Degree (BA, BS) in scientific or health care discipline preferred.
- Demonstrated ability to multi-task and manage high performance demands
- 5 + years of pharmaceutical, biotech or CRO related/ oncology clinical research experience.
- Excellent organizational skills, ability to manage multiple tasks and meticulous attention to detail.
- Effective oral, written and interpersonal communication skills.
- Computer literacy required (MS word, MS excel, MS PowerPoint and MS Project)
- Hematology oncology Therapeutic Experience preferred.
- CRO oversight experience
- Study Management (CRO/Pharma) preferred
- Strong organizational skills
- Report to the VP of Clinical Operations
- Ability to travel as necessary (approximately 5-10%)

This is a non-profit organization.

The MMRF/C is an equal opportunity employer. All employment decisions are made without regard to race, color, age, gender, gender identity or expression, sexual orientation, marital status, pregnancy, religion, citizenship, national origin/ancestry, physical/mental disabilities, military status or any other basis prohibited by law. EOE, M/F/D/V