Clinical Trial Project/Study Manager Job Description

Title: Clinical Trial Project/Study Manager
Reports to: VP of Clinical Operations
Department: Research
Location: Norwalk, CT

Position Overview: The Clinical Trial Manager will provide management and oversight MMRC's INDs. The CTM will be responsible for all aspects of study conduct and CRO oversight and the primary point of contact for clinical study project management, communications, and decisions for the clinical INDs being held by the Multiple Myeloma Research Consortium (MMRC). 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.
- Manage all clinical aspects of the study, including responsibility for oversight of study execution, develop and manage comprehensive study timelines and metrics; management/oversight of external vendor deliverables reports and budgets.
- 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 groups 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. Liaise with MMRF's finance group on budget expense projections and payment reconciliation. 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.
- 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).
- Tracking of all CDA, MSA, Agreements and other legal documentation as required for new and returning sponsors, vendors and suppliers.
- 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.
- 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
- 8 + 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
- Project Management (CRO/Pharma) required
- Strong leadership skills
- Strong organizational skills
- Ability to travel as necessary (approximately 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