Clinical Trial Associate
Job Description

Title: Clinical Trial Associate
Reports to: VP of Clinical Operations
Department: Research
Location: Norwalk, CT

Position Overview: The Clinical Trial Associate (CTA) will provide the Clinical Operations Team with administrative and project specific support. This includes accurately update and maintain clinical systems file, and archive clinical documentation and reports including maintaining the clinical trial management systems (CTMS); and maintain relevant tracking information. The CTA may act as a central contact for the clinical team for designated project communications, correspondence, and associated documentation. Provide management and oversight MMRC's INDs. The CTA will be responsible for 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).

Essential Functions

Specific Job functions/Responsibilities:

- Adhere to Clinical Standard Operating Procedures and Good Clinical Practice ICH Guidelines. Assists the Clinical Operations team in the completion of all required tasks to meet departmental and project goals.
- Support the Clinical Operations team with ongoing conduct of studies.
- Assist in the coordination of study initiation documentation materials.
- Maintain and update trackers for enrollment, contracts, invoice and budgets
- Assist in contacting investigator sites to provide study specific information.
- Coordinate distribution and shipment of study related materials.
- Coordinate investigator site payments as needed.
- Assist with preparation of presentation materials.
- Maintain central registry of contact information for clinical sites, contract research organizations, vendors.
- Obtains appropriate signatures for Participation Agreements from sub-sites when MMRF/C multi-party clinical trial agreements are being used.
- To attend project team meetings and generate meeting minutes.
- Ability to manage complex protocols within a matrix environment.
- Oversee Contract Research Organizations (CROs) and other external vendors as required.
- Drive clinical trial activities: i.e. study start-up and conduct, regulatory obligations, adverse event reporting, drug ordering, budgeting.
- Provides study-specific training 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.).
- 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).
- Review study protocols, informed consents and amendments for consistency.
- Ensures SAEs /SUSARs are managed and reported according to the study safety plan.
- Other duties as assigned.

Qualifications

- Bachelor's Degree (BA, BS) in scientific or healthcare discipline preferred.
- 5+ years of pharmaceutical, biotech or CRO related/clinical research, oncology or research experience.
- Good organizational skills, ability to manage multiple tasks and meticulous attention to detail.
- Good written and verbal communication skills.
- Computer literacy required (MS word, MS excel, MS PowerPoint and MS Project)