CG ONCOLOGY

Job Description

Clinical Research Associate

Revised Date	4/25/22
Department	Clinical Operations
Reports To	Sr. Manager, Global Site Management and Monitoring
Location	US Based (Remote Eligible with Travel)
Exemption Status	Exempt
Job Code/Grade	
Manager Level	Non-Manager

POSITION SUMMARY:

The Clinical Research Associate (CRA) is responsible for the monitoring and site management of clinical sites on one or more clinical trials to ensure participant safety and rights, data integrity, and compliance to study protocol, ICH GCPs, CFRs and other local regulations, and IRB requirements. The CRA may assist the Clinical Project Manager with other duties.

ESSENTIAL FUNCTIONS:

- Perform Site Qualification, Initiation, Interim Monitoring, and Close Out Visits, in addition to site management for all assigned sites.
- Perform remote query and data review as needed to assist CDM.
- Present updates at team meetings as needed (i.e., Clinical Trial Team Meeting, Project Team Meeting, Investigator Meeting, project training, etc.).
- Collect and review essential documents from investigational sites.
- Support CTAs with TMF set-up, maintenance, ongoing quality review, and final reconciliation of study documents.
- Participate in study specific tasks such as investigator identification, recruitment, collection of regulatory documents and site activation.
- Contribute to the development/review of study specific Monitoring Plans; tracks timing/planning of site visits to ensure compliance.
- Contribute to the development of study materials, case report forms (CRFs), informed consent documents for clinical studies.
- Assist in the preparation and review of site reference materials (i.e., screening/enrollment logs, Delegation of Site Responsibilities form, Site Monitoring Log, etc.).
- Assist Clinical Project Manager with oversight of study vendors (CRO, Drug Supply, Central Lab) as required.
- Support Clinical Project Manager to execute study milestones against study timelines.
- Tracking of key deliverables during start-up, study maintenance and close-out; generate, review, and distribute reports from internal tracking at requested intervals (Site Status, Enrollment, Dosing).
- Collaborate with the Clinical Project Manager to develop/review certain study-specific plans and/or processes.

The following competencies describe the desired behaviors, skills and attributes that will facilitate success at CG Oncology:

1. COMMUNICATION - Expresses ideas clearly and constructively (written and spoken, upward and downward, one-on-one and with groups). The ability to display decisiveness and good judgment in clinical and business situations is required.
2. COLLABORATION – Is politically savvy and able to tactfully navigate scientific, procedural, and cultural differences and competing concerns to maintain productive relationships to work proactively with others to streamline work and achieve mutual goals timely.
3. CLINICAL DEVELOPMENT EXPERTISE: Demonstrated understanding of the required steps to progress a new biologic through the stages necessary to allow it to be tested in human clinical trials; ability to ensure high quality in the design, development, execution, statistical analysis, clinical interpretation, and reporting of clinical studies.
4. PROFESSIONALISM - Treats others with respect; abides by the institutional and cultural values; displays a positive and cooperative attitude; adheres to the standards of conduct and compliance policies. Able to present oneself in a professional manner displaying executive presence, approachability, confidence, and credibility.
5. RESILIENCE - Must be resilient and able to manage around constraints and challenges to develop solutions that will most likely involve establishing consensus from parties subject to different international regulatory standards.
6. TECHNICAL ACUMEN – Demonstrates a strong understanding of Clinical Research Operations, and key terms, processes, compliance, and timelines as they relate to advancing Biotechnology research through the pre-clinical to clinical phases.
7. CULTURAL ACUMEN – Demonstrates understanding of different cultures to facilitate and effectively communicate, collaborate, and advance the scientific process in a balanced and compliant manner.
8. GOOD CLINICAL PRACTICE (GCP) - Demonstrated ability to ensure an investigation is conducted according to GCP regulations and internal control documents to protect the rights, safety, and well-being of subjects and the accuracy and validity of the trial data.
9. MANAGEMENT/TEAMWORK - Balances team and individual responsibilities; gives and welcomes feedback; contributes to building a positive team spirit; puts success of team above own interests; supports everyone's efforts to succeed. Contributes to building a positive team spirit; shares expertise with others.
10. CLINICAL DATA STEWARDSHIP - Demonstrated understanding of the critical importance of rigorous data generation and disciplined stewardship of the data.
11. TRAINING - The ability to plan, create and deliver formal training presentations (large and small groups) at the trial sites or remotely.

POSITION QUALIFICATIONS

Minimum Education	Bachelor's degree (relevant discipline preferred) or Experience may substitute for minimum educational requirements
Minimum Experience	• Minimum of three (3) years in clinical research, biopharmaceutical, or Clinical Research Organization (CRO) • Experience in scientific discipline and oncology therapeutic area highly preferred • Thorough understanding of all applicable FDA, ICH and GCP/GxP regulations and guidelines
Requirements: Other	• Ability to proactively perform and complete duties with minimal supervision in an accurate and timely manner • Ability to travel for site visits and meetings
Preferred Education	BSN, MSN or science degree is preferred
Preferred Experience	• Five (5) years in clinical research, biopharmaceutical, or Clinical Research Organization (CRO) • Demonstrated experience in the biopharmaceutical industry and/or supporting scientific organizations • Organization of similar size and scale to CG Oncology is preferred
Skills: Other	• Effective interpersonal, written, and verbal communication skills • Effectively collaborates with Study Team members • Exceptional organizational skills with the ability to multi-task and prioritize • Ability to work with distributed team members and outside vendors
Pref. Certification/Licensure:	• SOCRA or other related CRA certification preferred
Preferred Experience	•
Software	Proficient in MS Office (Word, Excel, and PowerPoint) Cloud-based programs
Machines/Equipment	Audiovisual equipment Calculator Phone/Fax Personal Computer Photocopier
Working / Environmental Conditions	Subject to interruptions Subject to varying and unpredictable situations

	Handles multiple tasks simultaneously Handle pressure due to multiple calls and inquiries Handle pressure due to deadline requirements Requires judgment that could affect image of CG Oncology
Physical Demands	Light physical effort (lift/carry up to 10 lbs.) Mostly sedentary work Occasional standing/walking Occasionally lifts supplies/equipment Occasional reaching, stooping, bending, kneeling, crouching Manual dexterity and mobility Works at PC involving focused concentration Extensive telephone activity Occasionally copies and sorts lengthy material Works at computer tasks involving hand/wrist coordination Frequent repetitive motion
Communication	Excellent verbal communication and telephone skills Excellent written communication skills

Employee: _____ Date: _____

Dept. Head/Administrator: _____ Date: _____

The above statements are intended to describe the general nature and level of work being performed. They are not intended to be construed as an exhaustive list of all responsibilities, duties and skills required of personnel so classified.