MAPS Public Benefit Corporation

Job description

Clinical Research Department
Version 26Apr2019

Title:	Clinical Research Associate				
		Exemption status:	Exempt	**Salary Range**	

Position duties: *(a brief summary or generic description of what the job does and why it exists)*

To ensure that clinical trials are conducted in a timely manner and in accordance with Standard Operating Procedures (SOPs), the principles of ICH/Good Clinical Practice and all applicable regulations governing the conduct of clinical trials. The CRA is responsible for managing, implementing and monitoring clinical studies in a team setting. The CRA 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, and that the conduct of the trial is in compliance with the currently approved protocol/amendment(s). CRA Monitor responsibilities include: manage assigned clinical study protocols and amendments; track deviations; manage clinical trial sites and assure timely initiation and completion of clinical studies. The focus of the CRA monitor role is acting as the point of contact for assigned clinical site(s) and monitoring the assigned site(s) under direction of the Associate Director of Clinical Operations Manager.

Minimum requirements: *(education/degrees, specific training, certification or licensing and years of experience required)*

A bio-medical related scientific degree or relevant experience with a strong interest in clinical research. Minimum of Bachelor degree preferred. The amount of experience and years of experience will determine the amount of responsibility of the CRA. A minimum of 1 years CRA experience or 2 years CRA experience is required. Knowledge of medical practice/techniques and terminology. Knowledge of European regulations governing clinical trials.

Additional Competencies:

- Ability to work independently and within a team
- Open and clear communicator
- Excellent written and verbal communication skills
- Confident and influential approach
- Self-motivating, able to prioritize and take initiative
- Make informed decisions based on guidance from manager and take responsibility for actions
- Possess sound judgment, discretion and be detail orientated
- Able to lead, motivate and understand the needs of others
- Strong organizational skills with attention to details and timelines
- Able to work quickly in a remote virtual setting
- Computer skills, facility with word-processing and spreadsheet applications.
- Coordination and planning of tasks and time management
- Recognize potential obstacles and work within set timelines
- Conscientious and precise delivery of work even when under pressure
- Be proactive in problem solving

Description of Responsibilities:

General CRA Responsibilities

- Provide assistance, where directed by management, in tasks relating to preparation and review of protocol and protocol related documents.
- Assist in design of Protocols, ICFs, CRFs, Source Records
- Assist in study supply planning
- Assist with preparation of regulatory submissions
- Assist clinical sites with IRB/IEC submissions and ensure collection of required essential documents for study start-up and throughout conduct of study.
- Maintain effective communication with other members of the clinical team and management.

- Assist in identifying sites, conduct pre-study meetings and advise the team of suitability of sites.
- Conduct study initiation, monitoring and close-out visits as specified in the monitoring plan and protocol to ensure subject safety. Prepare training material as appropriate.
- Liaise with investigators on conducting the trial under the guidance of the clinical team.
- Provide a report, as required, of the status assigned studies, and make any necessary recommendations for contingency planning.
- Ensuring each centre has the trial materials and training the site staff to trial-specific industry standards.
- Verify that data entered into the electronic CRFs is consistent with participant source documents, known as Source Document Verification (SDV).
- Regularly review study data and assist with cleaning and locking clinical trial databases.
- Archive study documentation and correspondence.
- Assist the team in preparing final reports.

Specific Monitoring Responsibilities- Travel is required as needed by the study enrollment rate.

- Ensure all personnel at study sites are appropriately informed and trained at study initiation and that it is adequately maintained throughout the study. This will include orientation, training and monitoring of:
  - -Protocol details including any special efficiency or safety measurements
  - -Source Document Verification requirements
  - -Adverse Event (AE) and Serious Adverse Event (SAE) reporting
  - -Case Record Form completion
  - -Participant Information Sheets and Informed Consent
  - -Ethical Committee requirements
  - -Supplies, storage and drug accountability
  - -Video equipment and handling of recordings
  - -Good Clinical Practice
- Act as the main line of communication between the sponsor and the investigator. Make regular contact with investigators or site staff during the course of studies, to ensure protocols are proceeding in an appropriate manner.
- Lead meetings with sites as needed providing meeting notes and follow through on action items.
- Verify that the investigator follows the approved protocol and all GCP procedures. Maintain familiarity of local regulatory requirements, MPBC SOPs, guidelines and ICH Good Clinical Practice.
- Write visit reports, meeting timelines outlined in the Monitoring Plan.
- File, collate and track documentation for the Trial Master File.
- Review, track and resolve any data queries/protocol deviations prior to database lock.
- Ensure AEs, SAEs, reactions, concomitant medications, and inter current illnesses are reported in accordance with the protocol on the CRFs and the SAE Database.
- Ensure timely reporting of important AEs and SAEs
- Track study progress using tracking tools, ensuring timely and quality updates.
- Communicate deviations from the protocol, SOPs, GCP, and the applicable regulatory requirements.
- Ensure all unused trial supplies are accounted for.
- Close down study centers upon completion of the trial.