

Title of Job: Region Manager

Description: The Region Manager must adequately understand protocol designs, study objectives, study procedures and study related timelines. Will assist with the identification of operational, logistical and regulatory challenges, while overseeing their resolution. The Region Manager manages multiple clinical research sites under the delegation of their principal investigators, whose research activities are conducted under Good Clinical Practice (GCP) Guidelines and within CRA's SOPs. Works within and across sites to monitor patient status and safety; collects and organizes research data; schedules and/or attends study specific training and site in-services to train staff on protocols, GCP guidelines, SOPs, possible side effects and complications, has overall operational responsibilities for assigned sites. Ensures that the sites are running smoothly and efficiently. Region Managers typically perform tasks such as:

- Oversees multiple locations and works to ensure sites' preparation
- Responsible for oversight, training and recruitment of employees
- Assist in daily study activities
- Completing and ensuring the quality of case report forms
- Ensuring quality care to patients
- Ensuring quality data at sites
- Schedules and organizes study related meetings, generates agendas, maintains and distributes meeting minutes and study team contact lists
- Generates study status reports, data tables, presentations and correspondence
- Coordinates the purchase, receipt, inventory and distribution of study equipment
- Assists with development and distribution of study communication
- Provides oversight and direction of recruitment at the sites

Educational Qualifications: BA/BS; RN, BSN preferred, plus 4 or more years related experience. Specific clinical research experience may be substituted for education. CPR Certification. Certification (CCRC/CCRP) is required.

Experience/Training:

- 4 years minimum experience as CRC in Phase II-IV trials;
- Phlebotomy and ECG experience;
- Strong understanding of HIPAA, GCP guidelines and FDA/ICH regulations;
- Computer competency with various programs (MS Word, Excel);
- Completion of CRA's proficiency exams;
- Ability to develop accurate study related documents with minimal supervision; and
- Demonstrated organizational skills and the ability to prioritize multi-tasks.

Licenses. etc: Must obtain the Certified Clinical Research Coordinator (CCRC) certification and maintain that certification during employment. HAZMAT and CPR certification. Maintain RN License (if applicable).

Status and Scope: Reports to the VP of Clinical Operations and/or the COO.

FLSA Status: Exempt

Essential Job Duties:

1. Excellent written, oral, interpersonal communication skills, strong organizational talents with attention to detail;
2. Ability to multi-task and juggle multiple protocols and staff at several locations.
3. Become familiar with the protocols, case report forms, informed consents, source documentation, patient diaries (when applicable), and study medication(s) for their assigned research sites;
4. Adhere to and ensure site compliance to GCP, ICH, HIPAA, FDA Regulations, SOPs, policy & procedures, and maintaining ongoing regulatory documents;
5. Establishes rapport with sponsor representatives and maintains frequent face-to-face, written and telephone contact with various persons involved in the study, including but not limited to the patients, relatives/friends of the patients, doctors, pharmaceutical sponsors and all levels of the company;
6. Manage onsite research protocol activities and assist staff in organization to ensure study protocol procedures and good clinical practices;
7. Manages and participates in study recruitment to reach patient recruitment goals;
8. Able to perform basic lab procedures and have knowledge of the process at each site, such as: blood specimen collection, centrifuge operation, storing and shipping of lab specimens, accountability of specimens and notification of courier for specimen pick-up, schedules patients, obtains informed consent, administers study medications;
9. Able to perform appropriate research protocol procedures which may include, but are not limited to: vital signs, pregnancy tests, blood collection and processing, ECGs and pulmonary function tests;
10. Responsible for quality assurance of source documents, case report forms, ensuring accuracy of data and timely reporting of serious adverse events to sponsor;
11. Ensures study related reports and patient results are reviewed by an investigator in a timely manner;
12. Able to dispense investigational product and instruct subjects on usage and potential drug interactions. Ensure site is following CRA SOPs for drug accountability and inventory of study related supplies;
13. Thorough knowledge of document processes and reporting of SAEs, 1572s, CRFs, ICFs, etc.;
14. Prepares presentations for physicians, nurses and staff on research protocol;
15. Generates and tabulates reports for the VP of Clinical Operations;
16. Maintains accountability of own ongoing professional growth and development;
17. Performs and oversees necessary functions as approved by Clinical Research Advantage, for the conduct of clinical research;
18. Ensures that sites maintain strict confidentiality of patients, employees and company information at all times and adheres to HIPAA Guidelines;
19. Maintain contact and interact with monitors and sponsors;

20. Work closely with principal investigator at each site;
21. Monitor the quality control and overall integrity of all source documents from inception to study completion;
22. Ensure timely, accurate transcription of data from the source document to the subject CRFs and timely completion of queries;
23. Ensures smooth and efficient day-to-day functioning of each site;
24. Evaluate and interpret regulations and standards to determine applicability to study protocols;
25. Perform routine audits and inspections to ensure compliance;
26. Ensure issues of critical non-compliance are handled efficiently;
27. Participate in and manage external audits;
28. Assist in the development and implementation of quality assurance compliance policies and procedures applicable to sites;
29. Oversee all the studies running simultaneously to assure they are conducted and enrolled in the most efficient manner;
30. Ensure proper final disposition of finished products and materials;
31. Oversees and may conduct pre-study, initiation, monitoring and close-out visits with the study monitors/sponsor representative;
32. Ensures all Coordinators and Assistants have completed mandatory training in a timely manner. May need to organize training sessions from an external source;
33. Tracks, monitors and reviews site's timecards;
34. Administer document control systems including original SOPs, Policies and Procedures, and training manuals;
35. May attend investigator meetings;
36. Works with all employees within sites to assure staff is performing necessary duties; and
37. May perform other duties not specifically listed in this job description as assigned by their immediate supervisor.

Leadership Traits

High Standard of Personal Ethics - *Decisions made under pressure and/or temptation separate the great ones from the impostors.*

High Energy - *Great leaders are not exhausted by dealing with petty issues. These people know right from wrong as well as the difference between what's truly important and what's merely interesting.*

The Ability to Work Priorities - *The difference between setting priorities and working them through is the difference between a dreamer and a doer.*

Courage - *The willingness to take risks and accept responsibility for the outcome is a consistent quality among effective leaders. Either you or your fears will control everything you do. An organization will be no bolder than the leader.*

Committed and Dedicated - *Hard working leaders will eventually develop dedicated and hard working organizations regardless of who they start with or the experience they bring to the job.*

Creativity – *Effective leaders are innovators who bore easily and prefer shaping tomorrow to repeating yesterday.*

Goal Orientation to Make Tough Decisions - *Goal orientation produces a drive and energy that shield us from the pain of the task. Keeping an organization focused increases efficiency.*

Inspired Enthusiasm - *Genuine enthusiasm is contagious. People look to their leaders for enthusiasm. The inspiration level of the organization is directly proportionate to the enthusiasm of the leader--be it high or low.*

Level-Headed - *Good leaders respond to problems rather than simply react. A leader who can stay cool under pressure inspires confidence among those in the organization and empowers them to do the same.*

Help Others Succeed – *This is the mark of a truly great leader. Synergy is created when a leader truly invests his or her efforts in the success of others.*