

CLINICAL RESEARCH ASSOCIATE

JOB SUMMARY

Responsible for all aspects of clinical trial monitoring including initiating, investigating and monitoring data collected. Analyzes and documents results. Adheres to FDA, NIH Office of Biotechnology Activity and central/local Institutional Review Board and Institutional Biosafety Committee requirements. 25-30% travel to field sites required.

ESSENTIAL FUNCTIONS

Monitoring Duties:

- Conduct evaluation, initiation, routine monitoring and close-out visits at each assigned study site.
- Instruct investigator and clinical site staff in their responsibilities and ensure compliance with GCP and ICH guidelines and FDA regulations.
- Review source documentation to confirm subject eligibility for the clinical trial, to confirm that the correct informed consent process has been followed.
- Review case report forms to ensure that data is accurate and legibly entered.
- Review of regulatory binders. Notify clinical sites of document discrepancies and follow-up.
- Generate and follow-up of data queries/discrepancies.
- Monitor study drug dispensing and accountability; work with project teams to ensure that sites have adequate study drug and supplies.
- Identify and resolve site related issues.
- Review of nursing and medical records for AE/SAE information and follow-up, ensure timely reporting, and follow-up.
- Promptly bring any potential safety problems or significant protocol deviations to the attention of clinical team management
- Author and monitoring reports per standard operating procedures and monitoring plan

General Duties:

- Prepare and ship clinical study supplies to investigational sites (e.g., reference manuals, binders, reference tools and forms, Quality of Life questionnaire)
- Provide training for new clinical site staff, as needed. Document the training provided.
- Maintain database of collected and outstanding regulatory documents.
- Review study documents for completeness, accuracy and compliance with protocol and appropriate regulations. Investigate missing documents.
- Attend routine meetings in relation to clinical trials. Keep up-to-date with information.
- Prepare status reports, as needed.
- Provides administrative support, not limited to, word processing, photocopying, managing and maintaining departmental records or files consisting of memos, letters, documents, reports, tables, and graphs.
- Understand clinical protocols in order to answer site questions correctly or with supervisory assistance.
- Monitor own workload and provide feedback to Director of Clinical Trials of workload shortfalls, as necessary.
- Other duties as assigned.

Position Requirements

- Must be able to travel 25-30% time each month.
- Bachelor's degree preferred.
- Minimum of 1 year experience in biotech or pharma preferred.
- Prior oncology experience preferred.
- Regard for patient privacy essential.
- Knowledge of medical terminology, clinical pharmaceutical standards, FDA, GCP/ICH guidelines, required.
- Excellent interpersonal skills required for working with sponsor and clinical site staff.
- Ability to work independently with only general supervision as well as in a collaborative small group environment
- Organizational skills and ability to prioritize tasks in order to meet deadlines.
- Willingness to be reassigned to different tasks in a fast-paced research environment.
- Ability to train others.
- Broad range of skills in the use of computer software, such as, but not limited to word-processing, spreadsheets, electronic communications, and graphics.
- Strong oral/written communication skills and attention to detail required.

Complies with company safety policies and minimizes risk to self, others and the environment, consistent with the community and industry standards.