

Job Advertisement for Senior Clinical Research Associate (Oncology)

Progen Pharmaceuticals Inc. in the United States is currently seeking a Senior Clinical Research Associate in the Raleigh, NC area to oversee and monitor one of its key Oncology Studies. This individual will be responsible for managing and monitoring clinical trial sites, assisting with project specific management, and providing leadership to less experienced staff / contractors. This position requires a degree in the medical field / and a MINIMUM of 3 years Oncology monitoring experience.

Specific duties are as follows:

- Independently manages/monitors investigative sites to ensure that all their clinical trial activities conform to the protocol plus all applicable GCP/ICH guidelines, regulations, statutes and SOPs.
- Independently creates project specific documents and tools – e.g., Monitoring Guidelines, Meeting materials/manuals, tracking spreadsheets/databases, training tools/materials, etc.
- Develops and presents Investigator Meeting materials.
- Assists with site selection as directed by team leaders.
- Conducts study qualification visits for the purpose of assessing the site's ability to affectively conduct the trial as per SOPs and study guidelines.
- Attends Investigator or Study Coordinator meetings.
- Conducts study initiation visits for the purpose of reviewing and training site personnel as per SOPs and study guidelines.
- Assists in planning and coordinating the efforts of the CRAs in development and evaluation of patient enrollment strategies.
- Ensures proper storage, dispensation and accountability of clinical trial supplies at study site.
- Provides appropriate verbal and written feedback to site, listing overall site performance, deficiencies and corrective action required.
- Completes monitoring report to document monitoring results, listing deficiencies and corrective action required according to company timelines.
- Produces monitoring reports requiring minimal corrections.
- Maintains responsibility for management of the clinical trial site and adherence to standard operating procedures and agreements.
- Ensures ongoing tracking and updating of regulatory documents.
- Reviews and ensures that all patient and site tracking records for assigned sites are current, complete and accurate.
- Conduct study closure visits.
- Conduct periodic audits of site files.
- Any other job that management feels appropriate based on employees skill level.

If you feel you have the skills and desire to work in a stimulating environment we look forward to hearing from you. To apply for this position please email your resume to jobs@progen-pharma.com.