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Job Details

CLINICAL RESEARCH ASSOCIATE

Position: Full time
Open date: March 2008
Location: Rockville, Maryland
Required degrees: BS or MS in a scientific or health care field
Experience required: One to three years experience
Relocation: Not indicated

Position Description:

The Clinical Research Associate is key participant in the design, implementation and monitoring of clinical trials, preparation of integrated medical reports, INDs, Investigational Device Exemptions (IDE), periodic reports, New Drug Applications (NDAs) and Biological License Applications (BLAs), etc. Participates in design and writing of protocols, case report forms and informed consent forms for clinical trials. Productive in recruitment/selection of new investigators, contract research organizations and outside vendors. Responsible for planning and implementing all activities required to conduct and monitor complex clinical trials and ensures that Good Clinical Practices (GCP) are followed. Conducts site visits pre-study, at study initiation, at regular intervals during the study and at study closeout. Monitors investigator performance and adherence to protocol, and proactively addresses conduct issues and enrollment problems, as necessary. Ensures that Case Report Forms (CRF) are reviewed in a timely fashion and submitted to the data management group. Involved in the compilation/writing of integrated medical reports and clinical sections of INDs, IDEs, New Drug Applications (NDAs) and Biological License Applications (BLAs)), etc. Assists in preparation of presentations and manuscripts of scientific meetings and technical journals. Attends scientific/professional meetings and training courses as appropriate.

Responsibilities Include:

- Participates in the identification of potential investigators and clinical sites, conducts prestudy site visits, collects and reviews data, and prepares evaluative reports; participates in the final selection of investigators and study sites
- Assists in the identification of centralized services such as clinical laboratories; assesses qualifications and experience in relation to proposed research activities, and participates in final selection

- Assists with the development and implementation of study-specific monitoring and reporting procedures, methods, guidelines, and tools; participates in the establishment of baseline parameters and edit check specifications, and in the development of subject tracking systems
- Conducts clinical trial site initiation visits; advises and trains site personnel on sponsor and regulatory requirements for study conduct; participates and/or conducts site meetings and multicenter investigator meetings and prepares reports
- Conducts site monitoring visits and follow-up to identify significant problems and issues and to ensure that all clinical aspects of studies are being carried out in accordance with state and federal regulations, guidelines and policies
- Reviews on-site files and records, case report forms, and source documents for completeness, accuracy, consistency, and compliance; identifies deficiencies and discrepancies, and provides remedial training and/or initiates corrective action as required
- Ensures appropriate transmission of clinical case data to the data management centers; reviews case report queries and problems, and clarifies and/or obtains changes to data as appropriate
- Assists in the termination of clinical studies by identifying items and issues for review and/or follow-up; assembles necessary documents, conducts site termination visits to include test article reconciliation and disposition, review of completeness and accuracy of files, and retrieval of relevant codes and documents; prepares study termination reports.
- Performs miscellaneous job-related duties as assigned

Education and Experience

- Requires a BS or MS in a scientific or health care field (e.g., nursing, pharmacy, physician's assistant)
- Demonstrated the ability to manage multiple tasks
- Five to eight years of direct hands on experience in the pharmaceutical or device industry including relevant clinical research experience
- Demonstrated strong ability to work successfully in a team environment requiring matrix management skills
- Knowledgeable in all aspects of the Federal (FDA) regulations and requirements governing the conduct of clinical trials including, but not limited to, GCP and ICH requirements
- Demonstrated ability to make effective presentations in public settings

Contact Information

Send resume today to join our fast growing team with ground floor opportunities to:

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