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Senior Clinical Research Associate-Remote Based-Eastern Region

Hiring organization
BioLink 360

Employment Type
Full-time, Contractor, Temporary

Industry
Life Sciences

Job Location
Morristown, NJ
Remote work possible

Date posted
January 27, 2023

Description

Location: Remote Based with Regional Travel
Travel: Up to 65% regional travel
Position type: Contract or Direct Hire
Salary Range: 85K-120K
Position Reports to: Line Manager

Our client is a Contract Research Organization that is hiring CRA's due to business growth and clinical expansion for studies across the Eastern region. This is a mid-sized full-service clinical research organization (CRO) headquartered in the Bay Area, CA, with clinical operations personnel globally. Since their launch in 1996 as a woman-owned business, their goal was straightforward: to provide clients with a team of highly experienced, dedicated, and detail-oriented clinical research professionals.

They work with sponsors in the pharmaceutical, biotechnology and medical device industries to deliver high-quality clinical operations services such as study management, investigative site monitoring, grant services, project and program management, biometrics including biostatistics, pharmacovigilance, and associated clinical development services.

Job Description

The Clinical Research Associate plays a vital role in the Clinical Operations team. Through responsibilities like monitoring studies, reviewing data, and engaging with sites, the CRA will ensure the success of clinical trial operations and management. The CRA may be based from home, while traveling to sites to provide monitoring of Phase 1-4 clinical trials, assuring adherence to Good Clinical Practice (GCP).

Responsibilities

• Monitoring clinical studies of investigational and approved products that have been determined to satisfy a medical need and/or offer a commercial benefit. This may include the following site visits: qualification, initiation, interim, and close out
• Managing and training of site personnel on therapeutic area, protocol requirements, proper source documentation, and case report form completion
• Managing, preparing, sending, tracking, and returning investigational supplies at individual sites
• Monitoring and documenting investigational product dispensing, inventory, and reconciliation
• Monitoring and documenting laboratory sample storage and shipment
• Monitoring trial by reviewing and reporting on the following: site enrollment and termination updates, monitoring visits, protocol deviations/exceptions, serious adverse events, and laboratory abnormalities
• Reviewing source data and case report forms for accuracy, completeness, and integrity of the data, and identifying and resolving ongoing data issues
• Reviewing data queries and listings, and working with the study centers to resolve data discrepancies

• Reviewing regulatory documentation for accuracy and completeness, and supporting study centers with regulatory issues
• Maintaining complete and accurate study files and reviewing files to ensure all appropriate documentation is present
• Maintaining consistent and timely contact with the study centers, investigators, coordinators, client personnel, and other individuals involved in clinical trials.
• Following Good Documentation Practices, completing Visit Reports and site correspondence in accordance with SOPs

Qualifications

- Bachelors and/or advanced degree in biological sciences or related field, or equivalent combination of relevant experience, education or training
- 2 years of prior experience as a Clinical Research Associate preferred
- Site Management or equivalent experience in clinical research, with understanding of clinical trials methodology and terminology.
- Ability to perform all clinical monitoring activities independently.
- Must have valid drivers license.
- Must be US Citizen or Greencard holder.