Cancer Research And Biostatistics
1505 Westlake Ave N, STE 750
Seattle, WA 98109-6244
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http://www.crab.org

Central Monitor **Position Number: CeM.1022**

Cancer Research And Biostatistics (CRAB) is a non-profit organization whose purpose is to help conquer cancer. The tools and expertise we bring to clinical trials development include biostatistical principles, oncology clinical trials expertise, data management and monitoring capabilities, electronic data capture solutions, education, support, and training.

Position Summary:
With the introduction of centralized monitoring in the FDA's Guidance for Industry, central monitoring has become a key and important role in a new risk-based monitoring approach. The central monitor reviews the source data against what is submitted in the electronic data capture system in close to real time to identify possible risks or site issues. They ensure that the conduct of the trial is in compliance with the currently approved protocol, with GCP as well as with applicable regulatory requirements. Position requires professionalism as they interface with site coordinators, statisticians, data management personnel and other industry or federal representatives. This position may require occasional clinical monitoring responsibilities. This position reports to the Project Manager, Clinical Monitor. Occasional travel may be required for this position. Both clinical monitoring responsibilities and travel have the potential to increase as needed.

Primary Duties and Responsibilities:
- Performs central monitoring at CRAB office in accordance with the monitoring plan and clinical trial contract or agreement; applies judgment and knowledge to independently resolve site issues, questions and concerns
- Verifies that source data are accurate, complete and maintained
- Ensures that documentation from investigators and investigational sites meets FDA/ICH-GCP requirements
- Reviews study research records including eCRFs, consent forms, AE's/conmeds and other clinical trial forms to reconcile Case Report Forms against the source documents and site medical records for transcription accuracy. Ensures that all queries are resolved in a timely fashion
- Submits documentation of central monitoring or clinical monitoring activities e.g. risk/issues/findings following each clinical site data review. Ascertains and recommends appropriate follow-up response to issues at clinical sites including potential deficiencies in documentation, communication, and the need for additional training
- Serves as a resource to site coordinators, investigators, and other staff members regarding protocols
- Acts as direct contact with assigned clinical sites. Uses judgment to assess and ensure overall integrity of study implementation and adherence to study protocol at clinical sites
- Participates in data management tasking and special projects
- Participates as a team member to support data management departmental policies and goals
- May travel to clinical sites for clinical monitoring and/or mentoring
- Performs other duties as assigned

Required Qualifications:
- BA/BS degree in health related field, OR a minimum of four years of experience in a clinical trials research setting as a data manager/CRA/CRC/regulatory specialist/other

similar title. Graduation from a professional/continuing education program with a certificate related to clinical trials and/or healthcare regulations will be considered
- Ability to travel as required

Desired Knowledge, Skills and Abilities:

- Oncology and clinical experience preferred
- Comprehensive knowledge of and proficiency using EDCs/EHRs
- Significant knowledge of anatomy/physiology, medical terminology and statistics
- Knowledge of regulatory documents and guidance's as well as GCP Guidelines
- Experience with on-site monitoring or co-monitoring
- Excellent written and verbal communication skills
- Excellent presentation skills
- Expert planning and organization skills
- Strong attention to detail
- Certification in a recognized research related professional society (SoCRA, SCDM, ACRP) preferred
- Ability to use sound judgment and diplomacy while interacting with team members, sponsors, and participating investigative sites
- Ability to work well as part of a team or work independently
- Proficient in MS Office (Word, Excel, Outlook, PowerPoint)
- Ability to be flexible and adapt to new systems
- Qualifies for rental car contract
- Valid driver's license
- Fluency in Spanish is highly desired

This is a full-time position and is Exempt from state and federal overtime regulations.
Employment authorization is required.
Travel/relocation expenses will not be provided for this position.
CRAB is an Equal Opportunity Employer.

In your cover letter, describe how your skills and experience match the qualifications for the position.

To apply, submit resume and cover letter with position number via mail, fax or email to:
Cancer Research And Biostatistics
Attn: Hiring Coordinator
1505 Westlake Ave N, Suite 750
Seattle, WA 98109-6244
Fax: (206) 342-1689
crabjobs@crab.org

Posting Date: 10/06/2022

Closing Date: open until filled