Cancer Research And Biostatistics
1730 Minor Ave STE 1900
Seattle, WA 98101-1468
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http://www.crab.org

Clinical Monitor — Position Number: CM.0918

Cancer Research And Biostatistics (CRAB) is a non-profit organization whose purpose is to help conquer cancer and other diseases through the application of biostatistical principles and data management methods.

Position Summary:
With minimal direct supervision, the Clinical Monitor has responsibility to verify that the well-being and rights of human subjects are protected and that clinical trial data reported from source documents are accurate, complete, and verifiable. She/he ensures 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 she/he interfaces with investigators, site coordinators, statisticians, data management personnel and other industry or federal representatives. This position reports to the Clinical Monitor Manager. Travel is required for this position (up to 70%).

Primary Duties and Responsibilities:

- Travels to, and manages, multiple clinical sites
- Performs on-site visits 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 all research staff and facilities have adequate qualifications and resources and that such conditions remain adequate throughout the trial
- Verifies that the investigator follows the approved protocol and all GCP requirements such as training. Ensures site adherence to all protocol requirements, including, but not limited to, eligibility confirmation and the prompt submission of data
- Verifies that source data, regulatory files, and other trial records are accurate, complete and maintained
- Ensures that documentation from investigators and investigational sites meet 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 routine Monitoring Reports following each site visit within an agreed-upon time frame
- 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 investigational products and 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
- Ensures immediate communication with team regarding any issues that arise at a site
- Participates in data management tasking, special projects, and other duties as assigned
- Participates as a team member to support data management departmental policies and goals

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 may substitute for degree
- Work experience must include a minimum three years of experience in clinical monitoring or as a CRA in the pharmaceutical industry
- Ability to travel as required (up to 70%)
- Required to work in Seattle office, except during site monitoring visits and travel
- Must qualify for rental car contract
- Valid driver's license

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
- Excellent written and verbal communication skills
- Expert planning and organization skills
- Strong attention to detail
- Certification in a recognized clinical trials program, healthcare regulations, or other research related professional society (SoCRA, SCDM, ACRP)
- 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
- Valid U.S. Passport
- 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
1730 Minor Avenue, Suite 1900
Seattle, WA 98101-1468
Fax: (206) 342-1689
crabjobs@crab.org

Posting Date: September 20, 2018

Closing Date: open until filled