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

Quality Assurance Coordinator — Position Number: QAC.1220

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:
Under supervision of the Data Management Department, the Quality Assurance Coordinator (QAC) coordinates and executes quality control procedures for Data Coordinators (DC) in support of CRAB research. Acts as liaison and reference resource to participating institutions' Clinical Research Associates (CRAs) and other project personnel. Performs quality review and evaluation of study data. Interacts with Biostatisticians and other study team personnel, participating in activities necessary to enhance and maintain data management functions for specific scientific committee(s) and/or projects as assigned.

The QAC works independently to address quality issues by creating and executing Quality Assurance plans and documenting their results in order to demonstrate the validity of study results. Functions as a collaborating member of the management team and provides feedback to DCs and management on DC work quality. Tact is used in communicating with other team members regarding problems uncovered during testing. The QAC is also an active Clinical Research Data Coordinator, therefore responsible for items outlined in the DC I-II-III job descriptions. This position reports to a Clinical Research Data Operations Supervisor, Therapeutic Studies.

Primary Duties and Responsibilities:

- Acts as liaison and reference resource to institutional CRAs, nurses and investigators
- Uses established Quality Control procedures for data management
- Participates as a team member within specific scientific committee(s) and/or study teams
- Maintains contact with clinical investigators and staff to ensure compliance with protocols and overall study objectives
- Engages in the planning, implementing and managing clinical studies from initial concept through closure to ensure studies are in compliance with SOPs, regulations and ICH/GCP guidelines
- Participates in the design and development of clinical trial protocols and case report forms
- Provides coding and procedural guidance to internal staff and external customers
- Assists in the development and revision of departmental operating procedures
- Participates in internal system audits and vendor assessments at the discretion of upper Management
- Evaluates DC work quality against existing standards. Documents discrepancies according to standardized formats/procedures
- Reviews and assesses completed design, development and support documents related to data quality assurance
- Identifies team members responsible for correcting any problem(s) identified and communicates as necessary to mitigate/resolve them
- Provides internal QA training sessions
- Functions as a resource for DCs
- Pilots new DC projects with a view to establishing requirements
- Liaises with personnel and customers
- Assists with regulatory and safety issues as requested or required

- May also have responsibilities for one or more complex clinical trials
- Performs other duties as assigned

Required Qualifications:

- BA/BS in health, life sciences, similar field, or four years of experience in clinical trials research setting
- PLUS an additional six years of clinical trials research experience. Graduation from a research related certification program or certification in a recognized research related professional society (SoCRA, SCDM, ACRP) may be substituted for three of the additional six years of clinical trials research experience
- Comprehensive knowledge of and proficiency using electronic data capture systems
- Experience mentoring/training other, less senior staff
- Significant knowledge of anatomy/physiology, medical terminology, ICH/GCP Guidelines and AJCC TNM staging
- Solid familiarity in statistics
- Excellent written and oral communication skills
- Good interpersonal skills
- Demonstrated understanding of computer-based systems and ability to learn new software

Desired Knowledge, Skills and Abilities:

- Spanish language skills highly desirable
- Experience with both industry and government funded clinical trials
- Familiarity with validation requirements to register a study with the FDA
- Working knowledge of Structured Query Language (SQL)
- Experience writing scripts to create lists and reports utilizing Oracle SQL Developer
- Demonstrated organizational skills with an attention to detail
- Proven ability to use sound judgment and diplomacy while interacting with staff and participating study sites
- Graduation from a research related certification program
- Certification in a recognized research related professional society

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This is a full-time position and is Non-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, STE 750
Seattle, WA 98109-6244
Fax: (206) 342-1689
crabjobs@crab.org

Posting Date: December 7, 2020

Closing Date: open until filled