Cancer Research And Biostatistics
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Clinical Research Data Coordinator I — Position Number: CRDC-I.0920

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:
Under supervision of the Data Management department, the Clinical Research Data Coordinator I (DCI) performs quality review and evaluation of study data, reviews study-specific protocols, contributes to overall study management tasks and participates in special projects as directed.

The DCI acts as liaison and reference resource to participating institutions' Clinical Research Associates (CRAs), investigators, and clinical monitoring staff. Interacts with Biostatisticians and other study team personnel, participating in activities necessary to enhance and maintain data management functions for specific disease site or research committee(s) and/or projects as assigned.

After appropriate and extensive training, the DCI works with supervisory and/or study team guidance and is expected to execute sound judgment within the framework of data management policies and procedures to fulfill position responsibilities. Receives direct supervision in performing work assignments and refers non-routine decisions to his/her supervisor.

Primary Duties and Responsibilities:

- Acts as liaison and reference resource to institutional CRAs, nurses and investigators
  - Develops and maintains effective working relationships with Biostatisticians, study team personnel and institutional research sites
  - Provides training to research sites in using the Electronic Data Capture (EDC) system including, but not limited to: presenting formal or web-based training, site initiation visits (SIV), triage helpdesk requests for assistance
  - Initiates, maintains and responds to open communication with research institutions and their affiliated study sites through oral, written, and electronic methods to ensure compliance with protocols and overall study objectives
- Uses established Quality Control procedures for data management
  - Monitors and evaluates incoming patient data for protocol and procedural compliance
  - Performs patient data evaluations to summarize overall eligibility, adverse events during and after protocol intervention, response to study treatment, patient reported outcomes (PROs), protocol compliance and deviations
  - Implements corrective action as required by requesting missing data and/or data clarifications
  - Maintains and updates study specific data base tables for use in interim and final study analyses
- Participates as a team member within specific scientific committee(s) and/or study teams
  - Develops working knowledge of medical terminology, anatomy, physiology and cancer disease processes as related to specific disease sites and research areas
  - Reviews and edits proposed research protocols and participates in the development of new clinical trial protocols, case report forms and edit checks

- Assists in the activities of planning, implementing and managing clinical studies from initial concept through closure to ensure studies are in compliance with SOPs, regulations and ICH/GCP guidelines
- Conducts user acceptance testing (UAT) for EDC forms and online enrollment programs prior to study activation
- Participates in and facilitates training in workshops as relevant
- Completes routine data management tasks and special projects as assigned
- Works to support the policies, procedures and goals of the Data Management department and CRAB

Additional Responsibilities:

- Provides practical and/or theoretical training at the SWOG Cancer Research Network Group Meeting at minimum once per year
- Sets up and maintains user accounts within the CRAB EDC
- Assists clinical monitoring staff by performing requested remote monitoring tasks
- On occasion, may be asked to present as a formal speaker
- Assists with the enrollment and/or randomization process of research participants as needed
- Develops working knowledge of CRAB computer resources, applications, and programs
- Performs other duties as assigned

Required Qualifications:

- BA/BS in health, life sciences or similar field or four years of experience in clinical trials research setting
- Knowledge of medical terminology
- Basic understanding of ICH/GCP guidelines
- Familiar with EDC systems
- Out of state travel is required

Desired Knowledge, Skills and Abilities:

- Spanish language skills highly desirable
- Excellent written and oral communication skills
- Competent in Microsoft Word, PowerPoint and Outlook
- Familiar with statistics
- Demonstrated organizational skills with an attention to detail
- Proven ability to use sound judgment and diplomacy while interacting with staff and participating Study Sites
- Excellent interpersonal/teamwork skills for effective collaboration
- Experience working with commercial EDC software
- EDC form design, study build, and study management

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, Suite 750
Seattle, WA 98109-6244
Fax: (206) 342-1689
crabjobs@crab.org

Posting Date: September 23, 2020

Closing Date: open until filled