Cancer Research And Biostatistics
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Seattle, WA 98109-6244
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Clinical Research Project Manager — Position Number: CRPM.0522

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:
This position involves oversight and management of multiple projects related to the acquisition, design, coordination, implementation and maintenance of clinical trials and other projects. The Clinical Research Project Manager ensures that the conduct of the trial or project is in compliance with the currently approved protocol, budget and effort assumptions, project scope, GCP requirements, and other applicable regulatory requirements.

The Clinical Research Project Manager is responsible for the day-to-day duties associated with the management of clinical projects and acts as a primary point of contact between CRAB's clients and all third-party organizations as appropriate. This position requires professionalism as they interface with investigators, site coordinators, statisticians, data management personnel and other industry or federal representatives. This position reports to the Chief Operating Officer.

Primary Duties and Responsibilities:

- Works with multidisciplinary groups such as applications development staff, biostatisticians, network administrators, data coordinators and CRAB administrative and financial groups in defining requirements and recommendations to manage clinical trials and other projects at CRAB
- Collaborates with multidisciplinary groups to organize and manage larger, cross-departmental projects
- Ensures that the projects adhere to established development and documentation standards
- Applies judgment and knowledge to independently resolve project and site issues, questions, and concerns
- Collaborates with clients and CRAB functional groups to develop project scope, identify resource requirements, and define deliverables
- Interfaces with statisticians, keeping the study team appraised of trial processes that are ongoing and in development
- Assists in the generation of protocols, electronic case report forms, and other clinical trial documents
- Partners with Applications Development staff to develop client requirements for CRAB's customized web-based database for clinical trial Electronic Data Capture (EDC)
- May act as direct contact with assigned clinical sites, using judgment to assess and ensure overall integrity of study implementation and adherence to study protocol at clinical sites
- Works closely with both the CRAB Finance and the Grants and Contracts departments on a regular basis to create, develop, and price original project budgets, work orders, milestones, and pass-through expenses for proposal development
- Ensures project expenses, work orders, and pass-through expenses are accurately reported and processed in order to invoice clients and cover costs associated with changes in scope

- Works closely with Finance on project revenue recognition
- Works closely with the Quality department to ensure work is consistent with policies, processes, regulations, and guidances
- Assists with the development and implementation of clinical policies and procedures, including working guidelines, SOPs, and informal processes
- Maintains contact with internal and external study teams, engaging in the planning, implementation and management of clinical studies and other projects from initial concept through closure to ensure studies are in compliance with SOPs, regulations and ICH/GCP guidelines
- Schedules and participates in regular internal and external study team meetings and teleconferences
- Ensures immediate communication with the internal and external study teams regarding any issues that arise
- Identifies team members responsible for correcting problem(s) identified and communicates as necessary to mitigate/resolve them. When challenges persist, communicates with Chief Operating Officer, who acts as Alliance Manager on strategically important collaborations.
- Participates as a team member to support data management and project management departmental policies and goals
- Performs other duties as related to the mission, goals, and values of CRAB

Required Qualifications:

- BA/BS degree in health related field, OR a minimum five 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
- Three years of demonstrated Project Management experience in a clinical trials and/or research setting
- Detailed knowledge of the project life cycle, and ability to track project progress against contractual and financial milestones, financial control procedures (i.e. costing systems, time reporting), project management processes and proposal development
- Experience with Windows environment and Oracle database
- Excellent customer service, organizational, planning, verbal and writing skills
- Strong attention to detail and accuracy
- Experience in developing, documenting and maintaining SOPs
- Demonstrated ability to juggle multiple projects of varying priorities while meeting deadlines
- 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 and work independently
- Ability to be flexible and adapt to new systems
- Experience presenting formal and informal presentations to small and large groups
- Proficient in MS Office (Word, Excel, Outlook, PowerPoint)
- Ability to travel as required

Desired Knowledge, Skills and Abilities:

- Five years of experience in oncology clinical research
- Knowledge of anatomy/physiology, medical terminology and statistics
- Knowledge of regulatory documents and guidances as well as GCP Guidelines
- Active certification in Project Management - PMI/CPM/PMP

- Experience with regulatory requirements for clinical trials, including 21 CFR Part 11, 312, 820 Quality System Regulation (QSR), and Quality Management Systems
- Active certification in a recognized research related professional society (SoCRA, SCDM, ACRP)
- Spanish language skills a plus

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: May 20, 2022

Closing Date: Open until filled