Biostatistician III

The Duke Clinical Research Institute, part of the Duke University School of Medicine, is the world’s largest academic clinical research organization. We conduct innovative research to deliver on our mission to share knowledge that improves the care of patients around the world. The Duke Clinical Research Institute (DCRI) is known for conducting groundbreaking multinational clinical trials, managing major national patient registries, and performing landmark outcomes research. The Clinical Trials Statistics group within DCRI supports research projects from conception to regulatory submission. Currently our groups consists of approximately 60 dedicated faculty, lead statisticians, and statistical programmers. We are looking to fill two positions: one Biostatistician II and one Biostatistician III.

Occupational Summary

Manages trial/project responsibilities independently. Handles multiple competing projects and deadlines, and coordinates all the statistical needs of each clinical trial/project. Performs intermediate and advanced statistical analysis and programming for multi-center phase I-IV clinical trials and/or clinical research projects

Work Performed

- With minimal or no guidance, prepares statistical analysis plans and performs and interprets basic and complex analyses. Uses statistical and medical understanding to propose and perform additional analyses appropriately and independently. Learns new statistical methods and applies new skills to future projects.
- Documents analyses, creates summaries, and presents results in written and verbal form to requestors. Writes statistical text for study reports and clinical publications. Prepares methods sections and analysis plans for incorporation in abstracts, manuscripts, grants.
- Discusses analytic issues related to other findings within a clinical trial/project. Understands how clinical trial/project results fit in the context of results from similar clinical trials/projects in the broader field.
- Designs analysis data set specifications and provides input on those prepared by junior statisticians or statistical programmers.
- Writes own SAS and/or S-plus code, finds errors, corrects, and validates output and results. Performs complex programming efficiently, uses complicated SAS procedures and options. Programs analysis datasets using SAS and/or reviews those programmed by others to ensure quality products; combines multiple disparate raw databases and derives analysis variables accurately. Considers alternative programming approaches to improve quality and/or efficiency.
- Collaborates effectively with statistical programmers that support clinical trial/projects. Identifies potential data problems from analytic queries and takes appropriate initiative to guide the process of resolution. Demonstrates thorough understanding of clinical trial/project data collection processes and data sets and shares knowledge with collaborators, fellow statisticians, and programmers. Helps less experienced programmers and/or statisticians with programming skills.
- Participates in all statistical aspects of a trial/project with minimal guidance. Collaborates with project leader, principal investigator, other clinical investigators, and external government or industry representatives to affect significant decisions regarding the trial/project, and to jointly achieve objectives and timelines. Represents the functional group in project team meetings and contributes constructively to project discussions.
- Understands the contracted scope of work and forecasts monthly hours expected to complete each trial/project. Proactively identifies potential out-of-scope activity and brings to the attention of project leader. Creates timelines for statistical project management with minimal or no assistance.
- Contributes to the thought process of endpoint selection and study design. Calculates samples sizes, power calculations, and interim stopping guidelines, with guidance. Provides review and approval of data collection tools, data correction criteria and procedures, identification of critical data fields, and endpoint collection documents. Understands study data and the intricacies of the process through which it is being collected.
- Collaborates closely with investigators, sponsors, and other trial leadership to ensure that trial/project results and conclusions are presented accurately and without bias. Leads the statistical team responsible for designing and validating analysis data sets, programs, and statistical output products (tables, listings, figures).
- Adheres to standard operating procedures of the functional department as they apply to documentation and validation of clinical research statistics. Understands and remains abreast of guidelines from the FDA, ICH, EMEA, or other regulatory agency as they apply to statistics and programming. Demonstrates a solid understanding of the clinical drug and/or device development process.
Perform other related duties incidental to the work described herein.

The above statements describe the general nature and level of work being performed by individuals assigned to this classification. This is not intended to be an exhaustive list of all responsibilities and duties required of personnel so classified.

**Minimum Qualifications**

**Education**

Position requires a minimum of a Doctoral degree in (bio) statistics or related field and no relevant experience, or a Master's degree in (bio) statistics or related field and 2 years relevant experience, or a Bachelor's degree in (bio) statistics or related field and 4 years relevant experience.

**Experience**

OR AN EQUIVALENT COMBINATION OF RELEVANT EDUCATION AND/OR EXPERIENCE Contribution to analysis of clinical trials and/or clinical research projects, and/or participation in preparation of academic manuscripts or other written summaries of analysis results, thorough experience with SAS, and solid command of the English language is required. Desirable experience includes prior role as a lead statistician on clinical trials and/or clinical research projects that have delivered the agreed-upon end products on time, and prior guidance of lower level or less experienced staff.