Biostatistician II

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

Performs intermediate-level statistical analysis and programming for multi-center phase I - IV clinical trials and/or clinical research projects. Collaborates closely with a cross-functional trial project team, physicians, and external government or industry representatives with regard to statistical aspects of each clinical trial project. Coordinates the statistical needs of each clinical trial project.

Work Performed

- With appropriate guidance, prepares statistical analysis plans. Independently generates descriptive and basic test statistics, analysis of basic data requests and generates statistical modeling results. Learns new statistical methods as needed, and applies new skills to future projects.
- Documents analyses, creates summaries, and presents results in written and verbal form to requestors. Able to work on any phase of a manuscript project, from initial meeting with an investigator to final review of a manuscript prior to submission for publication, with guidance. Builds documentation and organizational skills to effectively return to a trial or manuscript project after long intervals during which no progress was made by other members of the project team. Contributes meaningfully to discussions of analyses and identifies next steps for analyses.
- Designs analysis data set specifications through writing own SAS and/or S-plus code, finds errors, corrects, and validates output and results. Performs complex programming such as data transposition and macrocs. Programs analysis datasets using SAS; combines multiple disparate raw databases and derives analysis variables accurately. Uses complicated SAS procedures and options and programs with increasing efficiency.
- Collaborates effectively with statistical programmers that support their clinical trial/projects. Identifies potential data problems from analytic queries and brings them to the attention of the team. Demonstrates understanding of clinical trial/project data collection processes and data sets and shares knowledge with collaborators.
- Participates in most statistical aspects of a clinical trial/project, with consultation or assistance when needed. 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. Creates timelines for statistical project management, with assistance from project leader and statistical managers.
- Drafts statistical sections for study synopses and protocols, with guidance of senior or faculty statistician. Generates project randomization sequences and random study drug kit numbers; provides input and review of telephone-based or internet-based randomization system specifications. Provides input regarding data collection tools and data correction criteria and procedures.
- Understands study data and the intricacies of the process through which it is being collected. Handles and secures highly confidential and sensitive analyses and documentation. Supports the preparation of Data and Safety Monitoring Board reports and final statistical and study reports, including those intended for regulatory submission, and collaborates with medical writers as needed. Collaborates closely with investigators, sponsors, and other trial leadership to ensure that trial/project results and conclusions are presented accurately and without bias.
- Leads or participates actively in the statistical team responsible for designing and validating analysis data sets, programs, and statistical output products (tables, listings, figures). Adheres to standard operating procedures (SOPs) of the functional department as they apply to documentation and validation of clinical research statistics. Understands guidelines from the FDA, ICH, EMEA, NIH, or other regulatory agency as they apply to statistics and programming expectations for each project.
- Collaborates effectively with a variety of types of individuals: programmers, statisticians (both junior and senior), medical personnel, and representatives within the business community. Develops leadership and communication skills and shares them with others.
Manages project responsibilities with decreasing levels of supervision or regular support and takes initiative to complete project-specific responsibilities with minimal supervision. Demonstrates progress in ability to multi-task.

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

Work requires a minimum of a Master's degree in (bio)statistics or related field and no relevant experience, or a bachelor's degree in (bio) statistics or related field and 2 years relevant experience, or an equivalent combination or relevant education and/or work experience.

Experience

OR AN EQUIVALENT COMBINATION OF RELEVANT EDUCATION AND/OR EXPERIENCE Prior contribution to analysis of research projects, a working knowledge of SAS, and solid command of the English language is required.