Sr Statistician, Medtronic

Fridley, MN

Together Medtronic and Covidien are working to improve how healthcare addresses the needs of more people, in more ways and in more places around the world. As one company, we can accelerate and advance our ability to create meaningful innovations – but we will only succeed with the right people on our team. This is the ideal opportunity to join us, and be part of our commitment to the health of others.

We know the combined resources of Medtronic and Covidien will be transformative, creating new methodologies and new opportunities. Whatever your specialty or ambitions, you can make a difference at Medtronic – both in the lives of others and your career.

Medtronic is a $27.8b company with 85,000+ employees in more than 160 countries.

POSITION DESCRIPTION

The Senior Statistician will be responsible for statistical aspects of study design and analysis of data from clinical studies conducted for regulatory approval or marketing purposes. This includes responsibility for design of studies, calculating of sample size and power, writing of statistical portions of protocol and statistical analysis plan, review of protocol and case report forms, analysis and interpretation of data, and preparation of relevant sections of regulatory submissions, reports, and manuscripts. Work will generally be done independently, but will be reviewed by the Manager at key time points.

POSITION RESPONSIBILITIES

- Applies statistical knowledge and experience to the design of clinical studies, ensuring that study objectives can be met. This requires calculation of sample size and power, as well as possible determination of appropriate design assumptions from published literature.
- Prepares relevant sections of protocols, especially those detailing the plans for data analysis, and justification for the sample size. Reviews entire protocol for consistency.
- Writes the statistical analysis plan for the study.
  - Identifies potential threats to study credibility and validity, and works with study team to prevent, track, and manage potential problems.
- Assists in development and review of case report forms and error-checking requirements, ensuring data will be collected efficiently and accurately.
- Uses a variety of statistical methods and software tools to analyze and display data from clinical and other studies, including more advanced methods. Methods must be appropriate for the kind of data collected, and required assumptions must be tested.
- Validates and provides clear documentation of analysis programs.
- Writes Results and Methods sections of reports and manuscripts as needed.
- Consults with other (e.g. non-clinical) staff on statistical and analysis issues.
- Interprets statistical and clinical findings, and ensures that regulatory submissions, reports, and manuscripts accurately reflect the data collected.
- Takes responsibility for responding to relevant questions from FDA.
- Attends and contributes to project and department meetings.
- Ensures personal understanding of all quality policy/system items that are personally applicable. Follows all work/quality procedures to ensure quality system compliance and high quality work.
- Remains current on state-of-the-art statistical methods useful in clinical trial design and analysis.
- Manages multiple projects concurrently.

### BASIC QUALIFICATIONS

- M.S. in Statistics or Biostatistics

### YEARS OF EXPERIENCE:

- 3+ years of experience in analysis of data from clinical studies and design of clinical trials.
- Experience with statistical programming in SAS or another statistical analysis package.
- Experience with clinical trial methods and execution in a regulated environment.

### DESIRED/PREFERRED QUALIFICATIONS

- Experience in study design in the medical device or pharmaceutical industries.
- Specific coursework in Clinical Trials or Epidemiology.
- High level of competency with Microsoft Office Tools.
- Demonstration of good oral and written communication skills.

### PHYSICAL JOB REQUIREMENTS

- The physical demands described within the Responsibilities section of this job description are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.
- While performing the duties of this job, the employee is regularly required to be independently mobile. The employee is also required to interact with a computer, and communicate with peers and co-workers.
- Ability to travel up to 10%

It is the policy of Medtronic to provide equal employment opportunity (EEO) to all persons regardless of age, color, national origin, citizenship status, physical or mental disability, race, religion, creed, gender, sex, sexual orientation, gender identity and/or expression, genetic information, marital status, status with regard to public assistance, veteran status, or any other characteristic protected by federal, state or local law. In addition, Medtronic will provide reasonable accommodations for qualified individuals with disabilities.

https://www.statsjobs.com/jobs/sr-statistician-medtronic/