Senior Biostatistician

Apply rigorous scientific and ethical standards to ensure our medical devices and supplies are safe, have real clinical benefits and help reduce costs in the healthcare system.

SUMMARY OF POSITION:

As a key member of the team representing Corporate Biostatistics, this person has the following responsibilities:

- Provide statistical expertise to project teams in the design, analysis and interpretation of clinical studies.
- Main responsibility includes developing Statistical Analysis Plans, performing interim and/or final analysis and supporting ongoing needs for publications and ad-hoc analyses.
- Provide technical support within a central group of biostatisticians, SAS programmers and consultants to ensure successful completion of statistical tasks to agreed timelines and quality.
- Perform statistical data analysis (Tables, Listings, Graphs) for clinical studies using SAS and other valid software.
- Develop Statistical Analysis Plans (SAP) working with the Clinical Project Manager and team for various types of clinical studies (Feasibility, Pre-Market, Post-Market).
- Provide strong technical knowledge across multiple areas of statistical practice (e.g. experimental design, clinical trial design, linear statistical models, generalized linear models, mixed models, logistic regression, categorical data analysis, survival analysis, and nonparametric statistics).
- Assist in the protocol development for clinical studies to ensure that a valid sample size is chosen to test the hypothesis adequately and to ensure that proper statistical methods are employed.
- Present statistical results in graphs, tables, reports and manuscripts as needed at the time of interim or final analysis, abstract submissions and/or ad-hoc requests.
- Use statistical techniques to monitor data quality and perform ad-hoc analysis on clinical study data as needed.
- Provide review and input in Oracle Clinical study design as needed with respect to defining Data Extract Views, SAS names etc.
- Develop SOPs, work instructions and templates for Statistical Analysis Plans (SAP), Review checklists, Good programming practices etc.
- Responsible for developing Quality Control (QC) and Review procedures related to application of statistical analysis tools. Help on QC of the work provided by vendors as well as internal teams.
May need to prepare and/or present for FDA panel review meetings.

Interaction with upper management as well as principal investigators/clinicians may be required for data presentations and manuscript review.

Interaction with vendors and outside statisticians will be required at times.

May have to work on legacy studies to run ad-hoc analysis and/or data pooling etc.

Depending on qualifications, may assist in special projects to develop and apply modern statistical methodology for key programs.

Qualifications

MINIMUM REQUIREMENTS:

Education and Experience: M.S. degree with at least 4 years or Ph.D. with at least 2 years related experience. Education in Biostatistics / Statistics / Epidemiology or related fields preferred. At least 3 years of experience with data collection/statistics for clinical trials in the medical device and/or pharmaceutical industry required.

Skills/Qualifications:

- Strong skills in statistical analysis methods/tools and SAS programming

- Excellent communication skills (oral and written), with the ability to work effectively with technical and non-technical persons alike

- Advanced coursework, research, or hands on experience in the areas of pharmacoepidemiology, signal detection, sampling, or statistical de-identification would be a plus

- Demonstrated ability to perform complex univariate and multivariate statistical analysis using statistical models

- Ability to perform meta-analysis a plus (for literature review)

- Computer literacy in MS Word, Excel, PowerPoint etc.

- Oracle Clinical system knowledge a plus

- Ability to prioritize and multitask

- Excellent organizational skills and attention to detail.
• Ability to speak, write and understand English to comply with written procedures, instructions, SOPs and other documents

• Ability to redact statistical reports (including statistical results interpretation)

• Ability to work as a team and with autonomy will be appreciated

Competencies:
• Customer Focus

• Ethics and Values

• Functional/Technical Skills

• Priority Setting

• Problem Solving

ORGANIZATIONAL RELATIONSHIPS/SCOPE:

Will work primarily within Clinical Affairs but may interact with the Quality and Regulatory Affairs staff. Scope will include multiple clinical studies at a time across diverse business units.

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 more than 85K employees in more than 160 countries.

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.

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