Statistician, Medtronic

Plymouth, MN

Together, we can change healthcare worldwide. At Medtronic, we push the limits of what technology can do to help alleviate pain, restore health and extend life. We challenge ourselves and each other to make tomorrow better than yesterday. It is what makes this an exciting and rewarding place to be.
We can accelerate and advance our ability to create meaningful innovations – but we will only succeed with the right people on our team. Let’s work together to address universal healthcare needs and improve patients’ lives. Help us shape the future.

POSITION DESCRIPTION:

To participate in the planning, design, and implementation of clinical trial protocols using sound statistical methodology. To evaluate clinical studies in terms of safety, efficacy, and marketability through statistical analysis. To participate in the documentation of study results in clinical reports for various regulatory submissions. To participate in the preparation of abstracts, oral and poster presentations, and publications relating to the study results. Works under general direction.

POSITION RESPONSIBILITIES:

- Work with cross-functional teams to develop and refine study objectives to establish the safety and efficacy of medical device therapies and diagnostics.
- Participate in development and documentation of study protocols with responsibility for scientific soundness sections, which include statistical hypotheses, sample size calculations, and analysis methods for meeting the study objectives, in collaboration with others.
- Perform analyses of study data including documentation and justification of the statistical methods, analyses, and results in clinical reports, abstracts, and manuscripts.
- Respond to statistical questions from FDA or other regulatory agencies.
- Remain current on state-of-the-art statistical methods useful in clinical trial design and analysis. Share knowledge with other statisticians.
- Contribute to the development of policies and procedures for the department and the statistics group.
- Develop statistical programs (e.g., using SAS, R, WinBUGS) for data extraction, statistical analysis, and report generation.
- Perform statistical program validation in accordance with departmental Standard Operating Procedures.
- Identify potential threats to study credibility and validity, and work with study teams to prevent, track, and manage potential problems.
- Write and implement statistical analysis plans.
- Provide guidance to study teams and investigators in the preparation of abstracts, oral and poster presentations, and publications relating to the results of clinical studies.
- Participate in the design of case report forms and ensure consistency between the data collected and the objectives of the study.
- Work with the information systems staff and the clinical study team to develop specifications for the database design that assure the quality, integrity, and timely availability of the data for monitoring and analysis purposes.
- Participate in investigator meetings.
- Manage multiple, varying sized projects concurrently.
IN ORDER TO BE CONSIDERED FOR THIS POSITION, THE FOLLOWING BASIC QUALIFICATIONS MUST BE EVIDENT ON YOUR RESUME

BASIC QUALIFICATIONS:

- M.S. in Statistics, Biostatistics, or related field.
- Programming skills in SAS and/or R
- Experience with clinical trial methods and execution in a regulated environment.

DESIRED/PREFERRED QUALIFICATIONS:

- Ph.D. in Statistics or Biostatistics.
- Experience applying Bayesian methods to clinical trials.
- Experience in medical device, biotechnology, or pharmaceutical industries.
- High level of competency in Windows environment and with Microsoft Office Tools (e.g., Word, Excel).
- Demonstration of excellent oral and written communication skills, including experience presenting clinical trial results and statistical methods.
- Specialized training and experience with group sequential designs, adaptive designs, Bayesian hierarchical models, design of experiments, statistical sampling, pharmacoepidemiology, or statistical de-identification.

https://www.statsjobs.com/jobs/12321/