Sr Prin Statistician

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Position Description

Design and develop methodologically sound clinical trials that support Renal Care Solutions (RCS) business’s research, development, regulatory clearance and post-regulatory approval studies. Develop strong analytical methods using state-of-the-art statistical principles and tools, to support the needs of the RCS business. Work in close collaboration with physicians and other internal stakeholders in defining hypotheses, implementing trial design and protocols and conducting analyses. Actively engage regulatory bodies to articulate clinical study findings and defend study design.

Position Responsibilities

1. Work with key opinion leaders and cross-functional teams to develop and refine study objectives to design studies to support global products approval studies.
2. 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.
3. Become proficient, by literature review and interactions with key nephrologists, in chronic kidney disease, particularly renal replacement therapy for ESRD and hemodialysis.
4. Perform analyses of study data including documentation and justification of the statistical methods, analyses, and results in clinical reports, abstracts, and manuscripts.
5. Actively engage with regulatory bodies to negotiate appropriate study designs, to articulate the quantitative results of clinical studies, and to defend the analytical approach.
6. Remain current on state-of-the-art statistical methods used in clinical trial design and analysis.
7. Develop statistical programs (e.g., using SAS, S-PLUS, R, WinBUGS) for data extraction, statistical analysis, and report generation.
8. Perform statistical program validation.
9. Identify potential threats to study credibility and validity, and work with study teams to prevent, track, and manage potential problems.
10. Write statistical analysis plans.
11. Participate in the design of case report forms and ensure consistency between the data collected and the objectives of the study.
12. 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.
13. Participate in investigator meetings, key opinion leader discussions, and regulatory body meetings.
14. Manage multiple, varying sized projects concurrently.

Please apply directly on our website at: http://goo.gl/St8zND and ensure you are applying to Req# 94710.
Basic Qualifications

- M.S. in Statistics or Biostatistics
- 8+ years of experience in the design and analysis of clinical studies (to include clinical trial methods and execution in a regulated environment), or 5+ years with a Ph.D. degree.
- Statistical programming experience
- Experience in medical device, biotechnology, or pharmaceutical industries.
- Experience with writing the following submissions: Investigational Device Exemption (IDE), Premarket Approval (PMA), Investigational New Drug (IND) and New Drug Application (NDA).
- SAS experience

Desired/Preferred Qualifications

- Ph.D. in Statistics or Biostatistics.
- High level of competency in Windows environment and with Microsoft Office Tools (Word, Excel).
- Good oral and written communication skills.
- Strong interpersonal, customer-focused and collaborative skills.
- Ability to manage multiple projects concurrently.

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