Senior Statistician / Principal Statistician

******Candidate will be hired commensurate with the level and experience******

Senior Statistician

Description:

Perform duties of a Trial Statistician to support trials within national or international development projects or for marketed products as required. Assure well-designed clinical trials. Provide statistical expertise necessary to support the design as well as analyze, interpret and communicate the results of clinical trials. Support other Trial Statisticians in their responsibilities. Support Project Statisticians in their responsibilities, especially in their statistical responsibilities in the planning and preparation of regulatory submissions.

As an employee of Boehringer Ingelheim, you will actively contribute to the discovery, development and delivery of our products to our patients and customers. Our global presence provides opportunity for all employees to collaborate internationally, offering visibility and opportunity to directly contribute to the companies' success. We realize that our strength and competitive advantage lie with our people. We support our employees in a number of ways to foster a healthy working environment, meaningful work, diversity and inclusion, mobility, networking and work-life balance. Our competitive compensation and benefit programs reflect Boehringer Ingelheim's high regard for our employees.

Senior Statistician
Duties& Responsibilities:

- Perform duties of a Trial Statistician to support regular clinical trials within national or international development projects or for marketed products as required. Collaborate with Trial Clinical Monitor and trial teams incl. pharmacokineticist in planning clinical protocols conforming to company and regulatory agency guidelines.
- Support other Trial Statisticians in their responsibilities. Support Project Statisticians in their responsibilities, especially in their statistical responsibilities in the planning and preparation of regulatory submissions and contribute to efforts on cross-trial planning and harmonization.
- Plan valid, efficient and cost effective clinical trials, typically based on outlines provided by Project Statisticians. Prepare Statistical Methodology sections for the protocols and the Trial Statistical Analysis Plans (TSAPs). Support other Trial Statisticians in their responsibilities.
- Analyze data from phase I to IV trials incl. responsibility for program validation. Support other Trial Statisticians in their responsibilities.
- Prepare accurate, high quality reports of clinical trials for registration of drugs and biologics, and publications. Support other Trial Statisticians in their responsibilities. Support other Trial Statisticians in their responsibilities.
- Prepare specifications for data analyses by outside vendors as required. Assure compliance with the specifications by reviewing the vendors' products.
- Review and evaluate proposed case report forms for consistency with information needs for the protocol.
- Review randomization to be used in the clinical trials.
- Support management in resource planning and tracking for assigned trials and projects.

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Senior Statistician
Requirements:

- M.S. in statistics, biostatistics, or biometry with three years of experience in
- Designing, conducting, analyzing and/or presenting routine trials/studies
- Working with a team to apply statistical methodology to a research question
- Or Ph.D. in statistics, biostatistics, or biometry (must have received Ph.D prior to start date with the Company) with graduate level course work, project, consulting or internship experience in
- Writing the statistics section a protocol or analyzing a clinical trial/case study
- Working with a team to apply statistical methodology to a research question
- Communicating basic statistical information to non-statisticians
- Publishing: at least one publication (as primary or joint author) in a statistical, mathematical or clinical journal
- Good oral and written communication skills.
- Attention to Detail – Possess a strong quality orientation. Ensure tasks are completed correctly and on time.

Principal Statistician
Requirements:

- Masters degree from an accredited institution required; Doctoral degree (PhD, MD) from an accredited institution preferred.
- Very good oral and written communication skills
- Thorough knowledge of statistical methodology, design of clinical trials and on processing clinical trial information
- Ability to pro-actively identify data issues and solutions and to interact with internal and external bodies (specialists and non-specialists) on complex statistical/methodological issues at the trial level or routine issues at the project level
- Ability to detect and challenge methodological and clinical drug development issues
- Ability to supervise scientific/technical work at the project level
- Ability to write publications (as joint author) of clinical trials or on relevant statistical topics
- In addition for PSTAT:
    - Ability to successfully plan and conduct a submission for projects with established BI experience
- In addition for PSTAT-TMCP:
    - Sound knowledge of
        - Statistical BM&PGx strategy and inferential analysis
        - Inferential analysis strategy of PK and PD data
        - Inferential analysis of ECG data
        - Stat.-math. CDP strategies, incl. statistical Go/NoGo criteria for PoCP for projects with established BI experience
        - Stat. modeling strategy of BM, PGx and PK/PD data, statistical aspects of MID3
        - BM Research Projects (e.g. Banking) supporting trials & late stage projects or informing other clinical programs
        - Ability to successfully plan and conduct PK/PD and BM related analyses for submission of substances with established BI experience

- In addition for PSTAT-MA for projects with established BI experience:
    - Ability to successfully plan and conduct statistical activities to support market access activities (including dossiers for reimbursement agencies)
    - Ability to successfully plan and conduct statistical activities to support continued safety surveillance and monitoring of the benefit-risk balance of product
    - Ability to plan and analyze non-interventional studies
- In addition for PSTAT-Asia:
    - Ability to successfully plan and conduct submissions for Asian countries including China and Japan for complex international development projects, or complex marketed products
    - Ability to successfully plan and conduct statistical activities to support market access activities, continued safety surveillance and monitoring of the benefit-risk balance of product, and non-interventional studies in China and/or Japan

Eligibility Requirements:

Must be legally authorized to work in the United States without restriction.

Must be willing to take a drug test and post-offer physical (if required)

Must be 18 years of age or older

Who We Are:

At Boehringer Ingelheim we create value through innovation with one clear goal: to improve the lives of patients. We develop breakthrough therapies and innovative healthcare solutions in areas of unmet medical need for both humans and animals. As a family owned company we focus on long term performance. We are powered by 50.000 employees globally who nurture a diverse, collaborative and inclusive culture. Learning and development for all employees is key because your growth is our growth.

Want to learn more? Visit boehringer-ingelheim.com and join us in our effort to make more health.