

***The qualified candidate will be hired at the appropriate level commensurate with education/experience.***

**Description:**

Perform duties of a Trial Statistician to support complex clinical trials within national or international development projects or for marketed products as required. Assure well-designed clinical trials. Provide statistical expertise necessary to design, analyze, interpret and communicate the results of complex clinical trials. Provide statistical input for publications on clinical trials. Either support Project Statisticians on complex projects or act as a Project Statistician for early projects, backup projects, or projects with established BI experience. Act as a team leader for a complex project or mega-trial.

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.

**Duties & Responsibilities:**

- Perform duties of a Trial Statistician to support complex clinical trials within national or international development projects or for marketed products as required. Collaborate with members of Clinical Research and Marketing, Trial Clinical Monitor and trial teams incl. pharmacokineticist in planning clinical trials and protocols conforming to company and regulatory agency guidelines and/or marketing and publication strategies.
- Act as Project Statistician for early projects, backup projects, or projects with established BI experience.
- Support Project Statisticians of high profile international projects 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.
- Analyze data from phase I to IV trials incl. responsibility for program validation. Perform exploratory analyses in collaboration with the Project Statistician.
- Prepare accurate, high quality reports of complex clinical trials for registration of drugs and biologics, publications and management.
- Prepare specifications for data analyses by outside vendors as required. Assure compliance with the specifications by reviewing the vendors' products.
- Participate on assigned international teams to promote harmonization efforts for clinical drug development.
- Support management in resource planning and tracking for assigned trials and projects.
- Act as a team leader for a complex project or mega-trial who
- Ensures team members adhere to the SOPs, guidelines and local working instructions.
- Attends all the meetings related to the trial/project needing a statistical input (or send delegates) and send minutes to the team members
- Assist the Head of programming and Head of statistics with the working of vendors, contractors in establishing procedures for programming and validating statistical analysis (writes the scope of work, prepare documents to be sent to the contract research organization (CRO). From a statistical perspective, is the primary contact for CROs (programming validation)
- Acts as a Trial or Project Statistician (TSTAT or PSTAT) for the trial/project. In particular, develops report and programming specifications in a Trial Statistical Analysis Plan (TSAP) and update this document as often as needed.

- Collaborate with the programming group and the data management group to submit very detailed timelines for the trial/project to clinicians. Meeting agreed upon timelines are essential to the success of the clinical trial/project team objectives
- From a statistical perspective, is the primary contact for medical writing (or choose a designee)
- Ensures that protocol objectives are met and project standards are maintained (also responsible to update the project statistical analysis plan when necessary)
- Ensures achievement of major statistical deliverables and milestones in coordination with other functions including Clinical Research, Safety, Statistical Programming, Data Management and Medical Writing
- Provides and organizes statistical support for regulatory meetings, questions and submissions.
- Informs management that hours allocated to TSTAT by the capacity algorithm should be updated (follow up the amount of hours entered in the time recording system and related to the trial/project)
- Ensures efficient work within the team by setting priorities and avoiding overlaps between team members
- Works directly and proactively with the Trial, Project or Substance team.
- Assumes responsibility for the coordination of all relevant statistical activities for a Trial, Project or Substance.
- Receives broad operating instructions in performing a majority of duties from manager and keeps manager abreast of programming status. Alerts management in case of resources issues, timelines problems or conflicts within the team
- In collaboration with the statistical expert group member, maintain expertise in therapeutic area, by keeping abreast of new publications with the purpose of increasing the overall efficiency or effectiveness in the department.

#### **Sr. Biostatistician Requirements:**

- M.S. in statistics, biostatistics, or biometry with three years of experience in: designing, conducting, analyzing and/or presenting routine trials/studies, and working with a team to apply statistical methodology to a research question
- Or a 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, and working with a team to apply statistical methodology to a research question, and 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 Biostatistician Requirements:**

- Masters' degree from an accredited institution required and 6 years' experience within the pharmaceutical industry, CROs, regulatory authorities, or academic institutions, or Doctoral degree (PhD, MD) from an accredited institution with 3 years' experience within the pharmaceutical industry, CROs, regulatory authorities, or academic institutions.
- Ability to interact with authorities on statistical issues at the trial level.
- Thorough knowledge of statistical methodology, processing clinical trial information and the drug development process.
- Ability to communicate statistical information to non-statisticians.
- Ability to write publications (as joint author) in clinical trials.

- Excellent oral and written communication skills.
- Ability to manage project from a statistical perspective.
- Demonstrated ability to design, conduct and analyze a complex trial
- Evidence of strong teamwork in order to successfully work with a trial team and project level team members

**Sr. Principal Biostatistician Requirements:**

- Ph.D. in statistics, biostatistics, or biometry; at least 6 years' experience in pharmaceutical clinical trial experience, preferably in the pharmaceutical industry and/or Regulatory Authorities, or M.S. in the above mentioned areas with 10 years of similar experience.
- Ability to work on local/global project teams in order to come to resolution on a project.
- Ability to mentor, motivate, teach a scientific/technical staff.
- Offer scientific insight to projects.
- Excellent interpersonal skills with the ability to interact effectively with people, internally and externally at all levels of the organization.
- Must have exceptional oral and written presentation skills.

**Sr Principal Biostatistician Desired Experience, Skills and Abilities:**

- Record of publications (principal author) in methodological research.
- Extensive knowledge of scientific area of responsibility; ability to ask critical scientific questions and to critique devised hypotheses, experimental designs and results interpretation
- Demonstrated ability to successfully plan and conduct a statistical analysis on research.
- Demonstrated ability in supervising scientific/technical work.

**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

**Our Culture:**

Boehringer Ingelheim is one of the world's top 20 pharmaceutical companies and operates globally with approximately 50,000 employees. Since our founding in 1885, the company has remained family-owned and today we are committed to creating value through innovation in three business areas including human pharmaceuticals, animal health and biopharmaceutical contract manufacturing. Since we are privately held, we have the ability to take an innovative, long-term view. Our focus is on scientific discoveries and the introduction of truly novel medicines that improve lives and provide valuable services and support to patients and their families. Employees are challenged to take initiative and achieve outstanding results. Ultimately, our culture and drive allows us to maintain one of the highest levels of excellence in our industry. We are also deeply committed to our communities and our employees create and engage in programs that strengthen the neighborhoods where we live and work. Boehringer Ingelheim, including Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim USA, Boehringer Ingelheim Animal Health USA, Inc., Merial Barceloneta, LLC and Boehringer Ingelheim Fremont, Inc. is an equal opportunity and affirmative action employer committed to a culturally diverse workforce. All qualified applicants will receive consideration for employment without regard to race; color; creed; religion; national origin; age; ancestry; nationality; marital, domestic partnership or civil union status; sex, gender identity or expression; affectional or sexual orientation; disability; veteran or military status, including protected veteran status; domestic violence victim status; atypical cellular or blood trait; genetic information (including the refusal to submit to genetic testing) or any other characteristic protected by law.

Boehringer Ingelheim is firmly committed to ensuring a safe, healthy, productive and efficient work environment for our employees, partners and customers. As part of that commitment, Boehringer Ingelheim conducts pre-employment verifications and drug screenings.

Use the following link to submit your resume for consideration:

<https://tas-boehringer.taleo.net/careersection/global+template+career+section+28external29/jobdetail.ftl?job=1811399&tz=GMT-05%3A00>