

Associate Statistical Scientist

Job ID: 201812-129528

Job Function

Biometrics

Schedule

Full time

Location

United States of America - California
South San Francisco

Job type

Regular

Company/Division

Pharmaceuticals

Job Level

Individual contributor

The Position

The Associate Statistical Scientist is responsible for providing high-quality statistical expertise to assigned Clinical Development studies or nonclinical projects. He/she looks beyond the purely statistical aspects, collaborating actively to promote rigor in the planning, conduct, and analysis of experiments, and in the interpretation of results. The Associate Statistical Scientist typically requires regular guidance from management and works under the direction of a senior statistician operating at the project level.

In the clinical setting the Associate Statistical Scientist works closely with study team partners from biometrics, clinical science, safety science, operations, pharmacology, and regulatory. They collaborate to create of strategies to address drug development needs and design and execute appropriate studies. This includes input to protocols, review of case report forms, developing data analysis plans, and supporting the execution and interpretation of planned analyses. Effective collaboration with Operations, Data Management, and Statistical Programming personnel is essential.

Key Responsibilities & Accountabilities

Clinical Development:

- A member of cross-functional Study Management Teams
- Study Planning: With assistance of senior statistical scientists, reviews study protocols, authors statistical sections of protocols
- With assistance of senior statistical scientists develops independent data monitoring and endpoint committee charters.
- Develops the statistical and data analysis plans, and prepares the study randomization
- Study Conduct: Reviews case report forms to ensure protocol objectives are met and project standards are maintained. Develops statistical programs as necessary to perform analyses, Review and approve analyses produced by statistical programming, ensuring the accuracy and validity of results.
- Analysis & Reporting: Contributes to authoring the clinical study report, and with

assistance of senior scientists and cross-functional team members provides input into global health authority documents and regulatory response for health authority submissions

- Contributes to study publications and presentations, and provides analytical support for exploratory activities such as personalized healthcare biomarker development and PK/PD modelling.
- Understand and apply business requirements and processes. Participates in functional training.
- Keep abreast of new developments in statistics, drug development, and regulatory guidance through literature review, conference attendance, etc.

Required Technical Qualifications, Experiences, and Competencies

- MSc or PhD in statistics, biostatistics, mathematics or similar areas of academic discipline.
 - Good knowledge of English in a business environment.
 - Experience in using statistical software.
 - Good knowledge of theoretical and applied statistics
 - Developing knowledge and experience applying statistical methods to drug development
 - Developing understanding of regulatory guidelines in a pharmaceutical research setting
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- Understands and applies Business requirements and processes
 - Understands and respects cultural differences when interacting with colleagues in the global work place
 - Accomplishes responsibilities with supervision
 - Good Communication and Collaboration Skills (including statistical consulting skills, interpersonal skills to contribute effectively in cross-functional team settings, ability to influence others without authority, ability to build strong collaborative relationships with scientific and non-scientific partners)
 - Evident Project management skills (including ability to manage scope and effectively delegate to other functions, staff, contractors and external vendors)
 - Evident Strategic Agility (including problem-solving and critical thinking skills, ability to drive drug development strategies, agility that extends beyond statistical aspects)
 - Evident Drive for Results (Demonstrates interest and ability to learn new things, takes initiative, welcomes problems as challenges; finds solutions to technical problems)

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Who We Are

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