

Principal Statistical Programmer - Medical Affairs

[Vertex Pharmaceuticals](#) - Greater Boston Area

Posted 13 days ago

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About this job

Job description

The Principal Statistical Programmer works with Clinical Development, Biostatistics, Medical Affairs, Health Economics and Outcomes Research and with external vendors if applicable to support activities in the planning, design, development, implementation, and management of data to fulfill reports and summarize information required in support of ad hoc requests in post-marketing clinical trials, investigations, and assessments of claims databases, including health economics and outcomes research projects, for Vertex Pharmaceuticals products. The Principal Statistical Programmer also supports internal and external requests for input into relevant documentation and materials, such as manuscripts, conference posters, and presentations.

Key Responsibilities:

- Provides expert support and direction regarding statistical programming design to ensure timely, targeted, and accurate reporting and outcomes from assigned projects and ad hoc requests.
- Provides timely, accurate, and adequate responses and inputs for internal and external questions, medical affairs documentation, and materials.
- Develops, manages, and maintains analysis data and reporting deliverables for assigned Vertex Pharmaceutical products.
- Effectively represents the Biometrics department, as assigned, on cross-functional projects or study teams, and also helps to on-board new team members, as appropriate, and completes special projects as assigned.
- Works with biostatisticians, develops or reviews programming specifications for the ad hoc request.

- Knowledge of statistical concepts, such as p-values, rates and proportions, frequencies, confidence intervals, survival analysis, non-parametric analysis, repeated measures analysis. Capable of implementing these ideas in clear, efficient SAS code for the purpose of data analysis and reporting.
- Familiarity with relevant operating systems (e.g., Windows).
- Solid understanding of data collection and database concepts including data collection processes in clinical trials.
- Proficiency in problem solving, along with debugging skills to resolve issues with other programmers' or vendors' code and/or system macro code, is highly desirable.
- Experience with pharmaceutical industry data standards, such as CDISC/SDTM and ADaM data models.
- Basic knowledge of FDA/ICH (International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use) guidelines, the software development lifecycle and 21 CFR Part 11 and other FDA regulations.
- Additionally, experience working with data from electronic medical records (EMRs), registry databases, external insurance claims databases (i3, GE, etc.) for health outcomes research as well as epidemiology background or experience would be pluses.
- Proven SAS statistical programming experience in a pharmaceutical or CRO setting
- Supports statistical programming activities for Medical Affairs and health Economics and Outcomes Research
- Responsible for accuracy and reliability of results. Builds and monitors quality in every aspect of job activities
- Adapts to changing circumstances, policies, work assignments, and/or team members and develops strategies that will allow consistency or continuity of subsequent tasks (e.g., multiple studies or registries)
- Contributes strategies that allow multi-tasking or efficient implementation to reduce execution time to meet deadlines in fast-paced environment
- Development and maintenance of tracking systems, folder systems and archival of analysis
- Supports tasks based on the importance of the deliverable and awareness of overall timelines in order to efficiently produce high quality deliverables

- Proactively addresses project uncertainties to minimize risk and alerts or escalates the issue to the appropriate person (project team member, lead biostatistician, or management); identifies, communicates and overcomes technical and interpersonal obstacles

Desired Skills and Experience

Minimum Qualifications:

- B.S. and 10+ years of statistical programming work experience in Biotech, Pharmaceutical or Clinical Research Organizations
- M.S. and 8+ years of statistical programming work experience in Biotech, Pharmaceutical or Clinical Research Organizations.

Preferred Qualifications:

- Good interpersonal and negotiation skills, to complete deliverables by working effectively with others internally and externally; willingness to partner and collaborate with others in team or inter-functional settings.
- Good verbal and written communication skills along with effective business presentation skills.
- Sound project management skills, to prioritize multiple tasks and goals to ensure the timely, on-target and within-budget accomplishment of deliverables.
- Good judgment and decision-making skills; knows how to make trade-off decisions while balancing ethics and effectiveness.
- Outstanding attention to detail to ensure accuracy and reliability of results; builds and monitors quality in every work activity.

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Vertex is committed to equal employment opportunity and non-discrimination for all employees and qualified applicants without regard to a person's race, color, gender, age, religion, national origin, ancestry, disability, veteran status, genetic information, sexual orientation or any characteristic protected under applicable law. Vertex will make reasonable accommodations for qualified individuals with known disabilities, in accordance with applicable law.

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