

Senior Statistical Programmer Analyst - Medical Affairs - SAS

Job ID: 00413343

Job Function

Biometrics / Biostatistics

Schedule

Full-time

Location

United States-California
South San Francisco

Job type

Regular Employee

Company/Division

Pharmaceutical

Job Level

Experienced

Who We Are

At the Roche Group, about 80,000 people across 150 countries are pushing back the frontiers of healthcare. Working together, we've become one of the world's leading research-focused healthcare groups. A member of the Roche Group, Genentech has been at the forefront of the biotechnology industry for more than 30 years, using human genetic information to develop novel medicines for serious and life-threatening diseases. The headquarters for Roche pharmaceutical operations in the United States, Genentech has multiple therapies on the market for cancer and other serious illnesses. Please take this opportunity to learn about Genentech, where we believe that our employees are our most important asset and are dedicated to remaining a great place to work.

The Position

Job Summary

The Senior Statistical Programmer Analyst (Senior SPA) works with cross-functional teams in Medical Affairs and external vendors and leads the activities in the planning, design, development, implementation and management of software and data to fulfill reports and summarized information required in support of post-marketing clinical trials, registration studies, investigations and assessments of claims databases, including health economics and outcomes research projects for Genentech and Roche products. The Senior SPA also supports internal and external requests for input into relevant documentation and materials, such as manuscripts, conference posters and presentations.

Job Responsibilities:

- The Senior SPA provides expert guidance and direction regarding statistical programming design to support timely, targeted and accurate reporting and outcomes from assigned medical affairs projects.
- He/she works closely and collaboratively with internal cross-functional partners to ensure thorough representation and alignment of cross-functional programming, data and reporting needs and objectives.
- He/she expertly manages external vendor partners supporting software developments,

enhancements, maintenance and reporting to ensure consistently on-time, on-target, and accurate deliverables.

- He/she provides timely, accurate and adequate responses and inputs to/internal and external questions, medical affairs documentation and materials.
- He/she competently and independently develops, manages, and maintains software analysis data and reporting deliverables for assigned Genentech and Roche products.
- The Senior SPA provides technical solutions to a wider range of problems with higher level of complexity, independently determines and develops approach to solutions, and recommends technical and process solutions that can be used or developed to increase efficiency of project work.
- The Senior SPA also effectively represents the department, as assigned, on cross-functional projects or work teams, and also helps on-board new team members, as appropriate, and completes special projects as assigned.

Who You Are

Job Qualifications:

- BS or MS degree in computer science, statistics, mathematics, biology, or other related disciplines in the analytical sciences.
- Seven (7) or more years' SAS statistical programming experience with four (4) or more years' clinical trial experience in a pharmaceutical or CRO setting; advanced knowledge of SAS programming techniques, such as complex SAS macros and advanced SAS/Graph, would be a plus.
- Knowledge of statistical concepts, such as p-values, rates and proportion, frequencies, confidence intervals, survival analysis, non-parametric analysis. Capable of implementing these ideas in clear, efficient SAS codes for the purpose of data analysis and reporting.
- Familiarity with relevant operating systems (e.g., UNIX).
- Intermediate experience with Oracle Clinical or equivalent data management systems and relational database theory, and 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, along with experience working on FDA submissions, are pluses.
- Basic knowledge of FDA/ICH (International Conference on Harmonisation 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.

Overall Requirements:

- Prepares summarized statistical information for study team members
- Leads statistical programming activities at study level or part of project
- Responsible for accuracy and reliability of results. Builds and monitors quality in every aspect of job activities
- Contribute to user aspects of technical infrastructure or business process initiatives with a focus on statistical programming, data process and analysis reporting procedures
- Adapts to changing circumstances, policies, work assignments, and/or team

membersDevelops strategies that will allow consistency or continuity of subsequent tasks (e.g., multiple studies or registries)

- Develops strategies that allow multi-tasking or efficient implementation to reduce execution time to meet deadlines in fast-paced environment
- Contributes to the development of department-level standards, tools and templates
- Determines technical objectives and direction for projects; develops timelines for SPA component of the study
- Prioritizes and delegates 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 SPA, or management); identifies, communicates and overcomes technical and interpersonal obstacles
- Provides technical solutions to a wider range of problems **with higher level of complexity**. Independently determines and develops approach to solutions
- Recommends technical and process solutions that can be used or developed to increase efficiency of project work
- Negotiates effectively within project teams and working groups for reasonable timelines and scope; also negotiates alternative timelines based on resourcing / priority constraints

Qualities and Abilities

- 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.

Genentech is an Equal Opportunity Employer.