

Principal Statistical Programmer

Job ID

REQ-10031209

Apr 01, 2025

India

Summary

The Principal Statistical Programmer is responsible for all statistical programming aspects of a large/pivotal study, several studies or project-level activities (incl. submission activities). The position is a key collaborator with biostatistics in ensuring that pharmaceutical drug-development plans are executed efficiently with timely and high quality deliverables in Novartis Global Drug Development

About the Role

Major accountabilities:

- 1. Lead statistical programming activities as Trial Programmer for either a large/pivotal study or several studies, or act as a Lead/Program Programmer for a small to medium sized project in phase I to IV clinical studies in Novartis Global Drug Development.
- 2. Co-ordinate activities of all programmers either internally or externally assigned to the study/project work, mentor other programmers in functional expertise and processes. Make statistical programming decisions/recommendations at study or project level.
- 3. Build and maintain effective working relationship with cross-functional teams, able to summarize and discuss status of deliverables and critical programming aspects (timelines, scope, resource plan), e.g. as member of the extended Clinical Trial Team (CTT).
- 4. Review eCRF, discuss data structures and participate in data review activities as member of the extended CTT.
- 5. Comply with company, department and industry standards (e.g. CDISC) and processes, assess and clarify additional programming requirements at project-level, review and develop programming specifications as part of the analysis plans.
- 6. Provide and implement statistical programming solutions; ensure knowledge sharing.
- 7. In consultation with the Statistician, responsible for development of programming specifications of analysis datasets and pooled datasets.
- 8. Ensure timely and quality development and validation of datasets and outputs for CSRs, regulatory submissions/interactions, safety reports, publications or exploratory analyses (as required) in the assigned drug development study/project according to specifications.
- 9. Responsible for quality control and audit readiness of all assigned statistical programming deliverables as well as accuracy and reliability of statistical analysis results.
- 10. Maintain up-to-date advanced knowledge of programming software (e.g. SAS) as well as industry requirements (e.g. CDISC SDTM/ADaM, eCTD, Define.xml), attend functional meetings and trainings.
- 11. Establish successful working relationship on individual studies with external associates according to agreed contract and internal business guidance

- 12. As assigned, act as subject matter expert (SME) or contribute to process improvement/nonclinical project initiatives with a focus on programming and analysis reporting procedures.

Key performance indicators:

- 1. Quality and timeliness of statistical programming deliverables and contributions as assessed by internal and external customers, including the Clinical Trial Team, Lead/Program Statistician and the functional/operational manager.
- 2. Adequate representation of the Statistical Programming function as Trial/Lead/Program Programmer in the Clinical Trial Team(s). Effectiveness of communication and team behaviors as assessed by the team members.
- 3. Ability and effectiveness in training, mentoring and coordinating internal and external programmers assigned to the same study/project as assessed by the functional/operational manager.

Minimum Requirements:

Ideal Background (State the preferred education and experience level) Education (minimum/desirable): BA/BS/MS or international equivalent experience in statistics, computer science, mathematics, life sciences or related field Languages: Fluent English (oral and written). Experience/Professional requirement:

- 1. Advanced SAS experience and proven skills in the use of SAS within a Statistical Programming environment to develop and validate deliverables**
- 2. Advanced experience in contributing to statistical analysis plans and/or constructing technical programming specifications**
- 3. Good knowledge of industry standards including CDISC data structures as well as a solid understanding of the development and use of standard programs**
- 4. Good understanding of regulatory requirements relevant to Statistical Programming (e.g. GCP, study procedures).**
- 5. Good communications and negotiation skills, ability to work well with others globally**
- 6. Experience as Trial Programmer, including coordination of internal or external programmers on a given study/project**
- 7. Ideally 5+years of work experience in a programming role preferably supporting clinical trials/ or in pharmaceutical industry**

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Division

Development

Business Unit

Innovative Medicines

Location

India

Site

Hyderabad (Office)

Company / Legal Entity

IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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