Principal Statistical Programmer

Job ID
REQ-10031209

4月 01, 2025

India

摘要

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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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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