Senior Principal Statistical Programmer

Job ID
REQ-10031208

6月 12, 2025

India

摘要

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

About the Role

Major accountabilities:

- 1. Lead statistical programming activities as Trial Programmer for several studies or as a Lead/ Program Programmer for a medium to large sized project in phase I to IV clinical studies in Novartis Global Development Organization.
- 2. Co-ordinate activities of programmers either internally or externally. Make statistical

programming decisions and propose strategies at study or project level.

- 3. May act as functional manager for local associates including providing supervision and advice to these programmers on functional expertise and processes.
- 4. 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 SP representative in study- or project-level team.
- 5. Review eCRF, discuss data structures and review activities, ensure project-level standardization which allows pooling and efficient CRT production.
- 6. Comply with company, department and industry standards (e.g. CDISC) and processes, assess and clarify additional programming requirements, review, develop and influence programming specifications as part of the analysis plans (incl. CSPD and other project-level strategies).
- 7. Provide and implement statistical programming solutions; ensure knowledge sharing. Act as programming expert in problem-solving aspects.
- 8. Ensure timely and quality development and validation of datasets and outputs for CSRs, regulatory submissions/interactions, safety reports, publications, post-marketing activities or exploratory analyses (as required) in the assigned drug development studies/project.
- 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. Act as subject matter expert (SME) or, as assigned, lead process improvement/non-clinical 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.
- 2. Adequate representation of the Statistical Programming function as Trial/Lead/Program Programmer in the Clinical Trial Team/ project level meetings. 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.
- 4. Ability and effectiveness as a programming representative on non-clinical initiatives.

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. Expert SAS experience and proven skills in the use of SAS within a Statistical Programming environment to develop and validate deliverables, proven experience in development of advanced MACROs

2. Advanced experience in contributing to statistical analysis plans and/or constructing technical programming specifications

3. Advanced 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. Proven communications and negotiation skills, ability to work well with others globally and influence

6. Experience as Trial/Lead/Project Programmer for several studies or project-level activities, including coordination of team of internal or external programmers on a given study/project, ability to transfer own knowledge to others

7. Ideally 7+ years of work experience in a programming role preferably supporting clinical trials/ or in pharmaceutical industry.

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Innovative Medicines

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Hyderabad (Office)

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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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representative of the patients and communities we serve.

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