

Senior Statistical Programmer

Job ID REQ-10032794 Dec 08, 2024 Japan

Summary

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About the Role

- 1. Lead statistical programming activities as Trial Programmer for phase I to IV clinical studies or assigned project-level activities.
- 2. Co-ordinate activities of all programmers either internally or externally assigned to the study/project work. Make statistical programming recommendations at study level. Contribute to project level standards
- 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), e.g. as member of the Clinical Trial Team (CTT).
- 4. Review eCRF, discuss data structures and participate in data review activities.
- 5. Comply with company, department and industry standards (e.g. CDISC) and processes, review and develop programming specifications as part of the analysis plans.
- 6. Provide input into statistical programming solutions and/or ensure their efficient implementation.
- 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 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. Contributes to assigned parts of process improvement, standardization and other non-clinical initiatives

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. Good SAS experience and proven skills in the use of SAS within a Statistical Programming environment to develop and validate deliverables
- 2. Good 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. Proven ability to produce timely and quality deliverables under guidance (at least 1 year)
- 7. Ideally 4+years of work experience in a programming role preferably supporting clinical trials/ or in pharmaceutical industry (2 years for MS Statistics/Computer Science graduates)

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Division

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Business Unit

Innovative Medicines	
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Japan	
Site	
Toranomon (NPKK Head Office)	
Company / Legal Entity	
JP05 (FCRS = JP005) Novartis Pharma K.K.	
Functional Area	
Research & Development	
Job Type	
Full time	
Employment Type	
Regular	
Shift Work	
No <u>Apply to Job</u>	
r.japan@novartis.com	midcareer-
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REQ-10032794	
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