Senior Statistical Programmer

Job ID
REQ-10032794

12月 08, 2024

Japan

摘要

すべての統計プログラミング/データレビューレポートと、割り当てられた研究やプロジェクトレベルの活動の分析開発の側面を担当します。医薬品開発計画をタイムリーかつ高品質な成果物で効率的に実行するための重要な貢献者として機能します。

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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部门
Development

Business Unit
Innovative Medicines

地点
Japan

站点
Head Office (Japan) (Pharmaceuticals)

Company / Legal Entity
JP05 (FCRS = JP005) Novartis Pharma K.K.

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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利便性と合理的配慮

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