

(Senior) Principal Statistical Programmer

Job ID
REQ-10040720

Feb 13, 2025

China

Summary

负责几项研究, 中型到大型项目或项目级活动的所有统计编程/数据审查报告和分析开发方面。作为关键合作者和战略合作伙伴, 确保药物开发计划得到有效执行, 并及时和高质量的可交付成果。符合内部和监管指南的项目/研究标准和规范。监督编程风格, 统计报告的质量以及时间表的遵守情况。

About the Role

Key Responsibilities :

- 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.
- 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.

- 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).
- Review eCRF, discuss data structures and participate in data review activities as member of the extended CTT. 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. Provide and implement statistical programming solutions; ensure knowledge sharing.
- In consultation with the Statistician, responsible for development of programming specifications of analysis datasets and pooled datasets.
- 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. Responsible for quality control and audit readiness of all assigned statistical programming deliverables as well as accuracy and reliability of statistical analysis results.
- 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. Establish successful working relationship on individual studies with external associates according to agreed contract and internal business guidance
- As assigned, act as subject matter expert (SME) or contribute to process improvement/non-clinical project initiatives with a focus on programming and analysis reporting procedures.

Commitment to Diversity and Inclusion / EEO:

Novartis is committed to building an outstanding, inclusive work environment and diverse team 's representative of the patients and communities we serve.

Essential Requirements:

- Bachelor Degree and above
- Fluent English (oral and written). Mandarin Chinese is desirable but not required

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients ' lives. Ready to create a brighter future together? <https://www.novartis.com/about/strategy/people-and-culture>

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Accessibility and Accommodation:

Novartis is committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to diversityandincl.china@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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部門
Development

部門
Innovative Medicines

国

China

勤務地

Shanghai (Shanghai)

Company / Legal Entity

CN14 (FCRS = CN014) China Novartis Institutes for BioMedical Research Co., Ltd.

Functional Area

Research & Development

職種

Full time

雇用形態

正式

Shift Work

No

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