(Senior) Principal Statistical Programmer

Job ID
REQ-10040720
Feb 13, 2025
China

Summary

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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

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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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