

Principal Statistical Programmer

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REQ-10086654
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Индия

Сводка

-Responsible for all statistical programming/data review reporting and analytics development aspects of several studies, a medium to large sized project or project-level activities. Acts as a key collaborator and strategic partner in ensuring that drug-development plans are executed efficiently with timely and high quality deliverables. Complies with project / study standards and specifications following internal and regulatory guidelines. Oversees programming style, quality of statistical reporting & compliance with timelines.

About the Role

Major Accountabilities:

- 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 relationships 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. Understand Git-based version control workflows and their role in supporting collaborative, traceable, and reproducible programming activities.
- 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. Champion reproducibility, documentation, and code quality across programming activities; establishes best practices for code development, review, testing, and maintenance.
- Maintain up-to-date advanced knowledge of statistical programming languages (e.g. R, SAS) as well as industry requirements, support and guide the application of modern programming practices in assigned studies or projects (e.g. CDISC SDTM/ADaM, eCTD, Define.xml) and attend functional meetings and training.
- Establish successful working relationship with individual studies with external associates according to agreed contract and internal business guidance.
- Learn and apply emerging tools, standards; act as subject matter expert (SME) or contribute to improvement/non-clinical project initiatives with a focus on programming and analysis reporting procedures.
- Lead development of high-quality graphical outputs and advise on visualization approaches for complex analyses to support interpretation and decision-making.

Essential Requirements

- Strong experience and proven skills in Statistical programming languages (e.g., R, SAS, or Python) to lead the development and validation of deliverables. Strong practitioner and guide of the appropriate use of R packages (e.g. Tidyverse), R Shiny Applications, AI-enabled tools etc. to support data visualization, version control (e.g. Git-based), and reproducible workflows.
- Advanced experience in contributing to statistical analysis plans and/or constructing technical programming specs.
- Good knowledge of industry standards including CDISC data structures as well as a solid understanding of the development and use of standard programs.
- Good understanding of regulatory requirements relevant to Statistical Programming (e.g. GCP, study procedures).
- Good communications and negotiation skills, ability to work well with others globally.
- Experience as Trial Programmer, including coordination of internal or external programmers on a given study/project.
- Ideally 7 to 11 years of work experience in a programming role supporting clinical trials or in pharma industry.
- BS/MS degree in statistics, computer science, mathematics, data science, life science or equivalent relevant degree.

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Business Unit
Development
Место
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Сайт
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Company / Legal Entity

IN10 (FCRS = IN010) Novartis Healthcare Private Limited
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No

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.india@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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