Principal Statistical Programmer

Job ID
REQ-10032347
déc 04, 2024
Royaume-Uni de Grande-Bretagne et d'Irl. du Nord

Résumé

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

Our Development Team is guided by our purpose: to reimagine medicine to improve and extend people's lives.

To do this, we are optimizing and strengthening our processes and ways of working.

We are investing in new technologies and building specific therapeutic area and platform depth and capabilities – all to bring our medicines to patients even faster.

We are seeking key talent, like you, to join us and help give people with disease and their families a brighter future to look forward to.

Apply today and welcome to where we thrive together!

The Role

The Principal Statistical Programmer is responsible for all statistical programming aspects of a large/pivotal study, several studies or project-level activities (incl. submission activities). The position is a key collaborator with biostatistics in ensuring that pharmaceutical drug-development plans are executed efficiently with timely and high-quality deliverables in Novartis Global Drug Development.

This role offers hybrid working, requiring 3 days per week in our Basel office.

Key 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 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.

Your experience:

- BA/BS/MS or international equivalent experience in statistics, computer science, mathematics, life sciences or related field
- Ideally 5+ years of work experience in a programming role preferably supporting clinical trials/ or in pharmaceutical industry
- Advanced SAS experience and proven skills in the use of SAS within a Statistical Programming environment to develop and validate deliverables
- Advanced experience in contributing to statistical analysis plans and/or constructing technical programming specifications
- 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

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

Commitment to Diversity & Inclusion:

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

Join our Novartis Network:

Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

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Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

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Business Unit
Innovative Medicines
Emplacement
Royaume-Uni de Grande-Bretagne et d'Irl. du Nord
Site
London (The Westworks)
Company / Legal Entity
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.
Functional Area
Recherche & Développement
Job Type
Full time
Employment Type
Regular
Shift Work
No
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