NOVARTIS

Associate Director, Statistical Programming

Job ID
REQ-10053012
May 23, 2025
Ireland

Summary

The Medical Affairs, Associate Director, Statistical Programming , is responsible for all statistical programming aspects of one or more Therapeutic Areas (TAs) with Medical Affairs space.

As a Therapeutic Area lead, the Associate Director ensures cross-functional collaboration within and outside Medical Affairs, Advanced Quantitative Science and decision-making for assigned Therapeutic Area in all the related Medical Affairs requests (CSRs, Regulatory submissions/Interactions, Safety reports, Pricing and Reimbursement requests, Publications, Post-Marketing activities or exploratory analyses (as required) in the assigned drug development studies/project.
They ensure that the assigned therapy areas are adequately resourced, and oversee all aspects of programming, quality, and regulatory compliance.

This key leadership position ensures the efficient execution of trial/program level plans, delivering high-quality results on time. A thorough understanding of the drug development process along with Medical Affairs experience, experience in regulatory activities, and expertise in statistical reporting, along with a proven track record in operational or functional leadership, is required.

About the Role

Key Responsibilities

- Lead SP activities for multiple clinical trials within the assigned Therapeutic Area. **Experience in one of the TA(s) : Cardiovascular & Metabolic Diseases and Neuroscience is must.**
- Coordinate activities of internal / external programmers. Make statistical programming decisions and propose strategies at TA level. Develop/review scientific documentation for the program(s) or indication/disease area within the assigned TA together with the Biostatistician(s).
- Responsible for allocating resources within a TA and ensuring resource sharing between programs to meet Advanced Quantitative Science and organizational goals.
- Recruit, mentor, and nurture statistical programmers. Conduct performance appraisal of direct reports, as applicable.
- Build and maintain effective working relationships with cross-functional team members within the clinical trial/program, and able to summarize and discuss status of deliverables and critical programming aspects with them (timelines, scope, resource plan).
- Maintain up-to-date advanced knowledge of programming software (e.g. SAS/R) as well as industry requirements (e.g. CDISC, eCTD, Define.xml), attend functional meetings and training.
- Represent SP (Medical Affairs) at TA level, in audits/inspections and Health Authority (HA) meetings, and on technical programming aspects in external conferences or consortiums (e.g. CDISC).

Essential Requirements:

- In-depth understanding of clinical trials methodology, regulatory requirements, and Good Clinical Practice (GCP). Demonstrated leadership, collaboration, and organizational skills with the ability to successfully manage and oversee multiple trials, Publication/Manuscript requests and other Exploratory Analysis simultaneously, ensuring deadlines are met.
- BS/MS degree in life science, computer science, statistics, mathematics, or equivalent relevant degree. Must also be fluent in English
- Must have some Medical Affairs experience, ideally in Neuroscience or CRM.
- Excellent interpersonal skills with a proven ability to operate effectively in a global environment, influencing and communicating across functions and with external stakeholders.
- Expert in SAS or R programming, including the development and validation of deliverables within a Statistical Programming environment, and the creation of advanced MACROs and/or functions.
- Matrix or people management of approximately 10-20 internal or external programmers. Depending on role, may act as a functional/operational manager of associates or may be an individual contributor with no direct reports.
- Advanced knowledge of industry standards, including CDISC standards, and a solid understanding of the development and use of standard programs.
- At least 2+ years of experience as a Lead/Program/Project Programmer for one or more programs/indications, including the coordination of large teams of internal and/or external programmers. Ideally, 10+ years of industry experience, with at least 6 years in a programming or statistical role. At least 3 years of line management or equivalent leadership experience, such as matrix management (applicable for people managers only)

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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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

Division
Development
Business Unit
Innovative Medicines
Location
Ireland
Site
Dublin (NOCC)
Company / Legal Entity
IE02 (FCRS = IE002) Novartis Ireland Ltd
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
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