Associate Director, Statistical Programming

Job ID
REQ-10036181
jan 28, 2025
Royaume-Uni de Grande-Bretagne et d'Irl. du Nord

Résumé

The Early Development, Associate Director, Statistical Programming , is responsible for all statistical programming aspects of one or more drug development programs or indication programs with Early Development space.

As a program lead, the Associate Director ensures cross-functional collaboration within and outside AQS and decision-making for assigned trials/programs in drug life cycle management. They ensure that the assigned trials/programs 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, 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

- Lead SP activities for multiple clinical trials within a program or an indication /disease area. **Experience in one of the TA areas: Immunology, Cardiovascular & Metabolic Diseases and Neuroscience is must.**
- Coordinate activities of internal / external programmers. Make statistical programming decisions and propose strategies at program or indication/disease level. Develop scientific documentation for the program(s) or indication/disease area together with the Biostatistician(s).
- Responsible for allocating resources within a program 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 (Early Development) at indication or program-level, in audits/inspections and Health Authority (HA) meetings, and on technical programming aspects in external conferences or consortiums (e.g. CDISC).

Experience:

- 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 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 early development experience, ideally in Oncology
- 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 6-15 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).

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