🕛 NOVARTIS

Associate Director, Statistical Programming

Job ID REQ-10022579 Nov 07, 2024 USA

About the Role

Your Key Responsibilities:

- Lead statistical programming activities for multiple clinical trials within a program or an indication /disease area, or development program.
- Accountable for timely and quality development and validation of all statistical programming components on assigned program(s). Responsible for audit readiness of all assigned statistical programming deliverables as well as accuracy and reliability of statistical analysis results.
- 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 AQS and organizational goals.
- May act as an operational and/or functional manager of associates including providing supervision and guidance to these programmers on operational / functional expertise and processes.
- Recruit, mentor, and develop statistical programmers.
- 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 statistical programming 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).
- Offer expert technical and professional recommendations, thought leadership for the SP function at the indication/ program level or for non-clinical initiatives.

Video Link Meet the Data Analytics team (youtube.com)

Role Requirements:

Essential Requirements:

- BS/MS degree in life science, computer science, statistics, mathematics, or equivalent relevant degree and 6+ years in a programming or statistical role.
- 3+ years experience in a line management or equivalent leadership experience, such as matrix management (applicable for people managers only). Demonstrated leadership, collaboration, and 1/4

organizational skills with the ability to successfully manage and oversee multiple trials simultaneously, ensuring deadlines are met.

- In-depth understanding of clinical trials methodology, regulatory requirements, and Good Clinical Practice (GCP)
- 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.
- Significant experience in contributing to statistical analysis plans and developing technical programming specifications.
- 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.
- Excellent interpersonal skills with a proven ability to operate effectively in a global environment, influencing and communicating across functions and with external stakeholders.

Desirable Requirements: Aim for 2 bullet points

• 10+ years experience in a programming or statistical role.

Why Novartis:

Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: <u>https://www.novartis.com/about/strategy/people-and-culture</u>

You'll receive:

You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook.

https://www.novartis.com/careers/benefits-rewards

Commitment to Diversity & Inclusion: Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

Accessibility and Reasonable Accommodations: The Novartis Group of Companies are 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 application process, or in order to perform the essential functions of a position, please send an e-mail to <u>tas.nacomms@novartis.com</u> call +1(877)395-2339 and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to learn more about Novartis and our career opportunities, join the Novartis Network here: https://talentnetwork.novartis.com/networ

Role Requirements

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 USA Site East Hanover Company / Legal Entity U014 (FCRS = US014) Novartis Pharmaceuticals Corporation Alternative Location 1 USA **Functional Area** Research & Development Job Type Full time **Employment Type** Regular Shift Work No Apply to Job

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