Associate Director, Statistical Programming

Job ID
REQ-10022579

9月 19, 2024

USA

摘要

This position will be located at the East Hanover, NJ or Cambridge, MA site and will not have the ability to be located remotely. This position will require 1% travel as defined by the business (domestic and/ or international).

The Statistical Programming community at Novartis comprises of approximately 350 (internal) statistical programmers and belongs to the Advanced Quantitative Sciences (AQS) organization which also includes more than 450 biostatisticians, pharmacometricians and data scientists supporting the entire portfolio of clinical projects across the Research, Development and Commercial spectrum. In this role, you will be responsible for all statistical programming aspects of one or more drug development programs or indication programs. This role may involve being a people manager, a program lead, or both. In this role, you will lead cross-functional collaboration within and outside AQS and decision-making for assigned trials/programs in drug life cycle management and efficient, timely execution of integrated/clinical development/evidence plans. You will also take on strategic technical roles across programs or at an enterprise level. This includes, but is not limited to, consulting on pooling strategies, acting as a subject matter expert (SME) at audits/inspections, and leading technical non-clinical initiatives. The AD should also engage with and influence industry working groups and organizations.

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 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: https://www.novartis.com/about/strategy/people-and-culture

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 tas.nacomms@novartis.com 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

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

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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EEO Statement:

The Novartis Group of Companies are Equal Opportunity Employers who are focused on building and advancing a culture of inclusion that values and celebrates individual differences, uniqueness, backgrounds and perspectives. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, sex, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status. We are committed to fostering a diverse and inclusive workplace that reflects the world around us and connects us to the patients, customers and communities we serve.

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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 to perform the essential functions of a position, please send an e-mail to us.reasonableaccommodations@novartis.com or 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.

部门
Development

Business Unit
Innovative Medicines

地点
USA

站点
East Hanover

Company / Legal Entity
U014 (FCRS = US014) Novartis Pharmaceuticals Corporation

Alternative Location 1
Cambridge (USA), USA

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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