NOVARTIS

Senior Principal Statistical Programmer - Advanced Quantitative Sciences

Job ID
REQ-10022575
Sep 19, 2024
USA

Summary

This position will be located at the East Hanover, New Jersey or Cambridge, MA site and will not have the ability to be located remotely.

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 (SP) aspects of several studies, a medium to large sized program or program-level activities (incl. submission and post- marketing activities). You will be a key collaborator and strategic partner with cross-functional team members within the clinical trial/program, ensuring the integrated/ clinical development/ evidence plans are executed efficiently with timely and high-quality deliverables.

About the Role

Your Key Responsibilities:

- Lead SP activities as a trial programmer for one or multiple trial(s) or as a Lead/ Program Programmer for a program or an indication.
- May coordinate activities of internal/ external programmers. Make SP decisions and propose strategies at study, program or indication/ disease level.
- May act as functional manager of associates including providing supervision and guidance to these programmers on operational / functional expertise and processes.
- 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 SP representative in study- or program-level team.
- Review eCRF, data structures, and ensure program-level standardization for effective pooling and efficient case record tabulation (CRT) production.
- Comply with company, department and industry standards (e.g. CDISC) and processes, assess and clarify additional programming requirements, review, develop and influence programming specifications as part of the analysis plans (incl. program-level strategies).
- Provide and implement statistical programming solutions; ensure knowledge sharing. Act as programming expert in problem-solving aspects.
- Ensure timely and quality development and validation of datasets and outputs for clinical study reports (CSRs), regulatory submissions/interactions, safety reports, publications, post-marketing activities or

exploratory analyses (as required) in the assigned drug development studies/program.
- Responsible for quality control and inspection 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, R) as well as industry requirements (e.g. CDISC, eCTD, Define.xml). May act as subject matter expert (SME) on process improvement/non-clinical initiatives with a focus on programming

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

Role Requirements:

Essential Requirements:

- BS degree in statistics, computer science, mathematics, life science or equivalent relevant degree and 7+ years of work experience in a programming role preferably supporting clinical trials/ or in pharmaceutical industry
- Experience as Trial/Lead/Program Programmer for several studies or project-level activities, including coordination of team of internal or external programmers on a given study/program, ability to transfer own knowledge to others
- Expert SAS/R experience and proven skills in the use of SAS/R within a Statistical Programming environment to develop and validate deliverables, proven experience in development of advanced MACROs
- Advanced experience in contributing to statistical analysis plans and/or constructing technical programming specifications
- Advanced 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)
- Proven communications and negotiation skills, ability to work well with others globally and influence

Desirable Requirements:

- MS degree in statistics, computer science, mathematics, life science, or equivalent

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/network

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

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

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.

Accessibility & 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 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.

Division
Development
Business Unit
Innovative Medicines
Location
USA
Site
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
Apply to Job
iframe{ width: 100%; margin-top: 3rem; } @media screen and (max-width: 767px){ iframe{ height: 30vh !important; } } @media screen and (min-width: 768px){ iframe{ height: 34vh !important; } }
Job ID
REQ-10022575

Senior Principal Statistical Programmer - Advanced Quantitative Sciences

Apply to Job

Source URL: *https://prod1.id.novartis.com/careers/career-search/job/details/req-10022575-senior-principal-statistical-programmer-advanced-quantitative-sciences*

List of links present in page

1. https://www.youtube.com/watch?v=vUAhCMIZbys
2. https://www.novartis.com/about/strategy/people-and-culture
3. https://www.novartis.com/careers/benefits-rewards
4. https://talentnetwork.novartis.com/network
5. https://www.novartis.com/about/strategy/people-and-culture
6. https://talentnetwork.novartis.com/network
7. https://www.novartis.com/careers/benefits-rewards
8. mailto:us.reasonableaccommodations@novartis.com
9. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/East-Hanover/Senior-Principal-Statistical-Programmer---Advanced-Quantitative-Sciences_REQ-10022575
10. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/East-Hanover/Senior-Principal-Statistical-Programmer---Advanced-Quantitative-Sciences_REQ-10022575