

Senior Principal Statistical Programmer - Advanced Quantitative Sciences

Job ID
REQ-10022575

11月 07, 2024

USA

摘要

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.

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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>

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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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