

Senior Principal Statistical Programmer

Job ID
REQ-10008227
Jun 25, 2024
India

Summary

That's how many patients participate in our clinical trials at any given time. Novartis' powerhouse of Global Clinical Operations, redesigned to enable faster trial recruitment and enhanced trial delivery resulting in more timely access for patients to potential novel treatments. Every day, we are the link between science and medicine – imagine the impact you could have as [Role]! The Senior Principal Programmer is responsible for all statistical programming aspects of several studies, a medium to large sized project or project-level activities (incl. submission and post-marketing activities) The position is a key collaborator and strategic partner with biostatistics in ensuring that pharmaceutical drug-development plans in Novartis Global Drug Development are driven efficiently with timely and high quality deliverables.

About the Role

The Senior Principal Programmer is responsible for all statistical programming aspects of several studies, a medium to large sized project or project-level activities (incl. Submission and post-marketing activities) The position is a key collaborator and strategic partner with biostatistics in ensuring that pharmaceutical drug-development plans in Novartis Global Drug Development are driven efficiently with timely and high quality deliverables.

Your responsibilities include, but are not limited to:

- Lead statistical programming activities as Trial Programmer for several studies or as a Lead/ Program Programmer for a medium to large sized project in phase I to IV clinical studies in Novartis Global Development Organization.
- Co-ordinate activities of programmers either internally or externally. Make statistical programming decisions and propose strategies at study or project level. May act as functional manager for local associates including providing supervision and advice to these programmers on 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 project-level team.
- Review eCRF, discuss data structures and review activities, ensure project-level standardization which allows pooling and efficient CRT production.
- Align 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. CSPD and other project-level strategies).
- Provide and implement statistical programming solutions; ensure knowledge sharing. Act as programming expert in problem-solving aspects. 1/3

- Ensure timely and quality development and validation of datasets and outputs for CSRs, regulatory submissions/interactions, safety reports, publications, post-marketing activities or exploratory analyses (as required) in the assigned drug development studies/project.
- Responsible for quality control and audit 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) as well as industry requirements (e.g. CDISC SDTM/ADaM, eCTD, Define.xml), attend functional meetings and trainings.
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Commitment to Diversity & Inclusion:

We are committed to building an outstanding, inclusive work environment and diverse teams representative of the patients and communities we serve.

Role Requirements :

- Ideally 7+ years of work experience in a programming role preferably supporting clinical trials/ or in pharmaceutical industry
- BA/BS/MS or international equivalent experience in statistics, computer science, mathematics, life sciences or related field
- Expert SAS experience and proven skills in the use of SAS 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
- Experience as Trial/Lead/Project Programmer for several studies or project-level activities, including coordination of team of internal or external programmers on a given study/project, ability to transfer own knowledge to others

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>

Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to hear 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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<https://talentnetwork.novartis.com/network>

Division

Development

Business Unit

Innovative Medicines

Location

India

Site

Hyderabad (Office)

Company / Legal Entity

IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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