Senior Principal Statistical Programmer

Job ID
REQ-10043834

3月 25, 2025

India

摘要

We are in search of a Senior Principal Statistical Programmer, with expertise in HTA and Pricing and Reimbursement activities. This role offers the chance to provide statistical programming solutions to HTA problems. The successful candidate will work closely with International Value & Access and HEOR teams to shape ways of working for Joint Clinical Assessment in Europe to ensure high-quality deliverables.

-The Senior Principal Statistical Programmer will be responsible for all statistical programming aspects of several studies, a medium to large sized project or project-level activities. Acts as a key collaborator and strategic partner in ensuring that drug-development plans are executed efficiently with timely and high quality deliverables. Complies with project / study standards and specifications following internal and regulatory guidelines. Oversees programming style, quality of statistical reporting & compliance with timelines.

About the Role

Major accountabilities:

- 1. 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.
  2. Co-ordinate activities of programmers either internally or externally. Make statistical programming decisions and propose strategies at study or project level.
  3. May act as functional manager for local associates including providing supervision and advice to these programmers on functional expertise and processes.
  4. 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.
  5. Review eCRF, discuss data structures and review activities, ensure project-level standardization which allows pooling and efficient CRT production.
  6. 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. CSPD and other project-level strategies).
  7. Provide and implement statistical programming solutions; ensure knowledge sharing. Act as programming expert in problem-solving aspects.
  8. 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.
  9. Responsible for quality control and audit readiness of all assigned statistical programming deliverables as well as accuracy and reliability of statistical analysis results.
  10. 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.
  11. Establish successful working relationship on individual studies with external associates according to agreed contract and internal business guidance
  12. Act as subject matter expert (SME) or, as assigned, lead process improvement/non-clinical project initiatives with a focus on programming and analysis reporting procedures.

Key performance indicators:

1. Quality and timeliness of statistical programming deliverables and contributions as assessed by internal and external customers,
2. Adequate representation of the Statistical Programming function as Trial/Lead/Program Programmer in the Clinical Trial Team/ project level meetings. Effectiveness of communication and team behaviors as assessed by the team members.
3. Ability and effectiveness in training, mentoring and coordinating internal and external programmers assigned to the same study/project as assessed by the functional/operational manager.
4. Ability and effectiveness as a programming representative on non-clinical initiatives.

Minimum Requirements:

Education (minimum/desirable): BA/BS/MS or international equivalent experience in statistics, computer science, mathematics, life sciences or related field

Languages: Fluent English (oral and written).

Experience/Professional requirement:
1. Strong programming skills in R and Python and SAS. Demonstrated knowledge of data visualization, exploratory analysis.
2. Advanced experience in contributing to statistical analysis plans and/or constructing technical programming specifications
3. Advanced knowledge of industry standards including CDISC data structures as well as a solid understanding of the development and use of standard programs
4. Good understanding of regulatory requirements relevant to Statistical Programming (e.g. GCP, study procedures)
5. Proven communications and negotiation skills, ability to work well with others globally and influence
6. 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
7. Ideally 7+ years of work experience in a programming role preferably supporting clinical trials/ or in pharmaceutical industry

8. Experience in HTA /HEOR is preferable

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

部门
Development

Business Unit
Innovative Medicines

地点
India

站点
Hyderabad (Office)

Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Alternative Location 1
Mumbai (Office), India

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

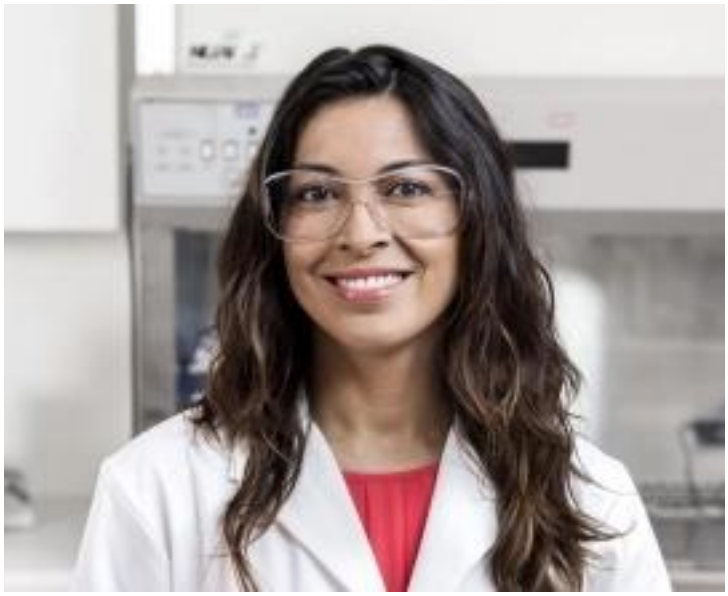
Apply to Job

Accessibility and accommodation

Novartis is 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 recruitment process, or in order to perform the essential functions of a position, please send an e-mail to diversityandincl.india@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

Novartis is committed to building an outstanding, inclusive work environment and diverse teams'

representative of the patients and communities we serve.



Job ID
REQ-10043834

Senior Principal Statistical Programmer

Apply to Job

Source URL:
https://prod1.novartis.com.cn/careers/career-search/job/details/req-10043834-senior-principal-statistical-programmer

List of links present in page

1. https://www.novartis.com/about/strategy/people-and-culture
2. https://talentnetwork.novartis.com/network
3. https://www.novartis.com/careers/benefits-rewards
4. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Hyderabad-Office/Senior-Principal-Statistical-ProgrammerREQ-10043834
5. mailto:diversityandincl.india@novartis.com
6. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Hyderabad-Office/Senior-Principal-Statistical-ProgrammerREQ-10043834