

# Principal Statistical Programmer

Job ID  
REQ-10008688  
Nov 29, 2024  
India

## Summary

About the role: The number of New Molecular Entities (NMEs) approvals of potential blockbusters, which Novartis obtained in 2019 alone. We advanced a breath of early programs in our pipeline that addresses significant unmet needs and are looking for passionate and enthusiastic Statistical Programmers with expertise in SDTMs, ADaMs & TFLs, and experience in Regulatory Submissions. As a part of the Statistical Programming unit, you will play a key role in supporting a growing pipeline across multiple therapeutic areas, with emphasis on regulatory submissions. An excellent opportunity to work end-to-end programming from CRF collections through Regulatory submission, you will have an exciting opportunity to learn new technologies (like R) and endorse Statistical Programming as a key contributor in driving the #GO-Digital vision of Novartis.

## About the Role

### Major accountabilities:

- Responsible for managing project level activities within Product Lifecycle Services (PLS). Act as the programming functional lead on customers' project teams. Participate in project team meetings. Determine an efficient project programming strategy that utilizes customers' standards and procedures. Develop project-level programming specifications for analysis datasets and pooled datasets for a project.
- Lead the production of statistical outputs for clinical study reports, publications, and market promotions. Ensure the quality control of all programs, specifications and statistical outputs within a study project.
- Ensure that programming-related documents are consistent, and comply with Data Science's and customers' standards, by reviewing case report forms, statistical analysis plans, data structures specifications, and specifications for tables, listings and figures. Archival of project programs and associated documentation.
- Mentor programmers in the functional expertise required for project support. Support the development of, and the training of users in, new programming applications.
- As required, participate in process improvement initiatives or other non-clinical project activities.
- Develop advanced, general-purpose programming functions for deployment across multiple projects. Maintain advanced knowledge of programming languages (e.g., SAS and R).
- Manage the outsourcing of programming activities from Data Science to an approved vendor in accordance with Scientific Services vendor management procedures.

### Role Requirements :

### Key Essentials:

- Graduation/Post graduation or equivalent experience in mathematics, statistics, computer science, or health sciences/related field with at least 8 years' work experience in a programming role preferably supporting clinical trials/ or in the pharmaceutical industry (5 years for MS Statistics / Computer Science graduates).

Advanced knowledge of / experience with SAS, or R, and other relevant programming software.

- Proven experience in development of advanced programming functions with high programming efficiency; strong programming and problem-solving skills
- Proven experience in leading programmer support for multiple clinical trials and submission activities (or equivalent). Proven knowledge of database design/structures and basic statistics. Working experience in pooling analysis datasets across multiple clinical studies (or equivalent)
- Good understanding of global clinical trial / project practices, procedures, methodologies. Good understanding of regulatory requirements relevant to statistical programming (e.g. Good Clinical Practice).
- Good knowledge of office tools.

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>

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You'll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook.

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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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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](mailto: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.

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