

# Principal Statistical Programmer

Job ID

REQ-10031239

Jun 12, 2025

India

## Summary

The Principal Statistical Programmer is responsible for all statistical programming aspects of a large/pivotal study, several studies or project-level activities (incl. submission activities). The position is a key collaborator with biostatistics in ensuring that pharmaceutical drug-development plans are executed efficiently with timely and high quality deliverables in Novartis Global Drug Development.

## About the Role

### Major accountabilities:

- 1. Lead statistical programming activities as Trial Programmer for either a large/pivotal study or several studies, or act as a Lead/Program Programmer for a small to medium sized project in phase I to IV clinical studies in Novartis Global Drug Development.
- 2. Co-ordinate activities of all programmers either internally or externally assigned to the study/project work, mentor other programmers in functional expertise and processes. Make statistical programming decisions/recommendations at study or project level.
- 3. 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 member of the extended Clinical Trial Team (CTT).
- 4. Review eCRF, discuss data structures and participate in data review activities as member of the extended CTT.
- 5. Comply with company, department and industry standards (e.g. CDISC) and processes, assess and clarify additional programming requirements at project-level, review and develop programming specifications as part of the analysis plans.
- 6. Provide and implement statistical programming solutions; ensure knowledge sharing.
- 7. In consultation with the Statistician, responsible for development of programming specifications of analysis datasets and pooled datasets.
- 8. Ensure timely and quality development and validation of datasets and outputs for CSRs, regulatory submissions/interactions, safety reports, publications or exploratory analyses (as required) in the assigned drug development study/project according to specifications.
- 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. As assigned, act as subject matter expert (SME) or contribute to process improvement/nonclinical project initiatives with a focus on programming and analysis reporting procedures.

**Key Performance Indicators (Indicate how performance for this job will be measured) :**

- 1. Quality and timeliness of statistical programming deliverables and contributions as assessed by internal and external customers, including the Clinical Trial Team, Lead/Program Statistician and the functional/operational manager.**
- 2. Adequate representation of the Statistical Programming function as Trial/Lead/Program Programmer in the Clinical Trial Team(s). 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.**

**Job Dimensions (Indicate key facts and figures) Number of associates:**

**No direct reports. Coordination of 5+ internal and external programmers. Financial responsibility: (Budget, Cost, Sales, etc.) None Impact on the organization:**

- 1. Timely, high quality and efficiently produced statistical programming deliverables included in study and project level documents (incl. submissions)**
  - 2. Reliable and compliant statistical analysis results presented externally (incl. submissions)**
  - 3. Innovative technical solutions to support timely and efficient drug development deliverables**
- Ideal Background (State the preferred education and experience level)**  
**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. Advanced SAS experience and proven skills in the use of SAS within a Statistical Programming environment to develop and validate deliverables**
- 2. Advanced experience in contributing to statistical analysis plans and/or constructing technical programming specifications**
- 3. Good 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. Good communications and negotiation skills, ability to work well with others globally**

**6. Experience as Trial Programmer, including coordination of internal or external programmers on a given study/project**

**7. Ideally 5+years of work experience in a programming role preferably supporting clinical trials/ or in pharmaceutical industry**

**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>

Division

Development

Business Unit

Innovative Medicines

Location

India

Site

Mumbai (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

[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](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.

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

representative of the patients and communities we serve.

Job ID

REQ-10031239

## Principal Statistical Programmer

[Apply to Job](#)

---

**Source URL:** <https://prod1.id.novartis.com/id-en/careers/career-search/job/details/req-10031239-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/Novartis\\_Careers/job/Mumbai-Office/Principal-Statistical-Programmer\\_REQ-10031239](https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Mumbai-Office/Principal-Statistical-Programmer_REQ-10031239)
5. <mailto:diversityandincl.india@novartis.com>
6. [https://novartis.wd3.myworkdayjobs.com/en-US/Novartis\\_Careers/job/Mumbai-Office/Principal-Statistical-Programmer\\_REQ-10031239](https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Mumbai-Office/Principal-Statistical-Programmer_REQ-10031239)