

Principal Statistical Programmer

Job ID

REQ-10037374

Feb 27, 2025

India

Summary

The Principal Statistical Programmer is responsible for the design, execution, and quality control of computer programs to produce statistical outputs for Medical Affairs (MA) studies, Interventional or observational studies, non-interventional studies (NIS), and scientific analytic studies and the provision of programming consulting services, the training and mentoring of other programmers, and supporting project operational excellence.

About the Role

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Location – Hyderabad #LI Hybrid

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Key Responsibilities:

- Determine an efficient project programming strategy that utilizes organization 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 required 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.
- Proactively drive continuous improvements to departmental processes, standards and utilities. Support and Participate in Process initiatives/enhancements across Biometrics.
- Ensure that timelines are adhered and lead statistical programming team to successful completion of studies within given timelines .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 Biometrics to an approved vendor in accordance with Scientific Services vendor management procedures.

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.

Essential Requirements:

- Graduation/Post graduation or equivalent experience in mathematics, statistics, computer science, or health sciences/related field.
- 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 with excellent understanding of CDISC SDTM and ADaM standards).
- Advanced knowledge of / experience with SAS and/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)

Desirable Requirements:

- Good understanding of global clinical trial / project practices, procedures, methodologies.
- Good understanding of regulatory requirements relevant to statistical programming (e.g. Good Clinical Practice).

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Division

Operations

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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