

# Senior Principal Clinical Data Standards Specialist

Job ID REQ-10026403

9月 02, 2025

India

## 摘要

-Provide expert support and functional and technical knowledge to ensure the scientific integrity/validity for clinical development, early development, and/or research projects. Participate in the full lifecycle of producing key data and/or reports in support of data review reporting development including evaluation of requirements, design specifications, interface to programmers, report programming, coordinate validation and rollout activities along with providing quantitative analytical support. Provide statistical support for regulatory submissions including planning, analysis and reporting of clinical safety and efficacy summaries. May also provide statistical support to research or other R&D areas. -Responsible for advising/leading the planning, development & implementation of Industry (CDISC and regulatory) compliant, high quality, clinical data standards, infrastructure or automation technologies. Providing expert support and stellar customer focus to business users and teams on their use, including: -Data standard collection tools in EDC (CRFs, edits checks, derivations, core configurations) -Data transfer specifications -Analysis data/TFL standards/Define -Automation solutions / technologies -Business infrastructure, business rules and guidelines.

#### About the Role

### Major accountabilities:

- Drive the implementation of data analytics reports and dashboards for optimal data review by working with the users to establish robust user specifications and with programmers to implement the optimal output -Translate business requirements into logical models and provide direction to the development team to translate business logic.
- Lead authoring of the user requirements document, functional specifications and functional testing scripts -Proactively identify or address needs for optimal data review working with users and programmers as appropriate.
- Implement and execute robust project plans for delivery, ensuring customer needs are addressed in a timely manner.
- Provide coordination between the project resources so that deadlines are met on deliverables.
- Drive development of appropriate user training.
- Drive all necessary change management activities related to implementation of new data review tools / reports as related to data cleaning, review and visualization.
- Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt -Distribution of marketing samples (where applicable)

## Key performance indicators:

 Timely execution of of projects & data requests -Feedback from project sponsors and key stakeholders -Adherence to Novartis policy and guidelines -Metrics and Adherence to KPIs

#### Minimum Requirements:

Work Experience:

- Functional Breadth.
- Cross Cultural Experience.
- Managing Crises.
- Collaborating across boundaries.
- Operations Management and Execution.

## Skills:

- Automation.
- · Biostatistics.
- · Clinical Trials.
- Computer Programming.
- Metadata Management.
- Statistical Analysis.

#### Languages:

• English.

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部门 Development

Business Unit Innovative Medicines

地点 India

站点 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
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