Principal Clinical Data Standards Specialist

Job ID
REQ-10053259

May 30, 2025

India

Summary

-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.

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

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部門
Development

部門
Innovative Medicines

国
India

勤務地
Hyderabad (Office)

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

Functional Area
Research & Development

職種
Full time

雇用形態

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.

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