Principal RWE Research Analyst

Job ID
389390BR

Jun 06, 2024

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 and 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.
- Provide understandable and actionable reports on clinical data and monitoring of clinical data for key stakeholders.
- CDS Role 1.
- Lead and contribute to Clinical Data Standards definition, development, validation and support within assigned standards discipline (domain) including the development and maintenance of associated metadata, documents, business rules and guidelines where applicable.
- 2.
- Define and deliver to robust, priority driven standards development plans for assigned area to ensure agreed deliverables are met and assigned resources are fully and effectively utilized.
- 3.
- Responsible for driving the efficient, high quality and timely implementation of new standards and/or updates to standards for:a.
- Data Acquisition and Tabulation standards Or/and; b.
- Analysis and Reporting Data Standards4.
- In collaboration with representatives across Data Operations disciplines and key stakeholder and partner functions within GDO and across Global Drug Development, ensure the accurate translation of scientific and analytical requirements into efficient, compliant standards.
- 5.
- Support and ensure the appropriate and efficient governance and approval of global and project/study specific clinical data standards liaising with governance boards as needed.
- 6.
- Contribute to the technical review and assessment of industry and regulatory standards and guidelines supporting regular gap/impact analysis & implementation of action plans where needed.
- 7.
- Communicate an

Key performance indicators:

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

Minimum Requirements:
Work Experience:

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

Skills:

- NA.

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
Operations

部門
Universal Hierarchy Node

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

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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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