Principal Clinical Data Standards Specialist

Job ID
REQ-10059820

8月 20, 2025

India

摘要

The Principal Clinical Data Standards Specialist is responsible for the development, maintenance and implementation of Industry (CDISC and regulatory) compliant Clinical Data Standards, providing expert support to business users and teams on their use in line with the Clinical Data Standards strategy.
They provide expert support ensuring the development, implementation and timely availability of consistent, high quality Clinical Data Standards deliverables supporting the acquisition and tabulation and/or analysis and reporting of Clinical Trial data across global libraries including;

- Data collection tools in EDC (CRFs, edits checks, derivations, core configurations) and data transfer specifications
- Analysis data/TFL standards
- Associated standard metadata, business rules and guidelines.

About the 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: Data Acquisition and Tabulation standards
- Standards in clinical systems including EDC, MDR and other global standards libraries including robust testing and validation
- Compliant data models to support the use and transformation of data acquisition, tabulation and review standards (including associated metadata).
- Use advanced database programming techniques to support the implementation of efficient data collection tools.
- Processes, tools and guidelines relating to the submission of standardized acquisition/tabulation data supporting regulatory submission.

4. 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 and implementation of action plans where needed.
7. Communicate effectively with the partners and customers; Establish and maintain strong collaborative relationships with Data Operations, Biostatistics and Clinical Development groups supporting the development and use of Clinical Data Standards.
8. Lead and contribute to the development, maintenance and training of relevant clinical standards systems and processes.

9. Act as an expert consultant providing Clinical Data Standards input to all relevant areas including; electronic data capture/database programming, edit check programming, report programming, electronic data loads, IVR technology, electronic patient reported outcomes, metadata management and/or other clinical data management or analysis data and TFL-related systems

10. Act as subject matter expert (SME) for assigned area providing support, consultation and training to end users and SME networks on implementation of standards and related tools on development programs.
11. Provide mentoring and technical guidance to Clinical Data Standards associates.
12. Maintain up-to-date, expert knowledge of relevant technologies (EDC, software languages, applications etc.), Industry Standards (e.g. CDISC, define.xml, eCTD etc.) and regulatory guidelines.
13. May represent Novartis within industry wide associations and working groups; contributing to regulatory guidelines, industry practices and professional standards development organizations such as CDISC, CFAST, PhUSE CSS, DIA etc.
14. As needed, act as a Clinical Standards representative supporting data standards governance, process improvement initiatives and/or other non-clinical projects.

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Development

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Innovative Medicines

地点
India

站点
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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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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