Lead Principal CDS Specialist

Job ID
REQ-10022085

9月 15, 2024

India

摘要

The Lead Principal Clinical Data Standards Specialist is responsible for multitasking and managing multiple assignment along with overseeing the planning, development and implementation of Industry (CDISC and regulatory) compliant Clinical Data Standards, providing expert support to business users and teams on their use and in line with the Clinical Data Standards strategy.

They work with members of the clinical data standards specialist to 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

Lead multiple standards development activities across assigned Therapeutic Area (TA) For development of clinical data standards for assigned TA('s)

- Contribute towards Implementation of various assets
- Support with impact analysis or change management
- Ensure e2e standards development by following processes
- Ensure quality by performing peer review
- Ensure regulatory, system and quality requirements are met during the development
- Create/Review guidance and train stakeholders and drive adoption of developed standards
- Oversee process and quality adherence
- Monitor compliance and utilization, present metrics
- Collaborate with Governance, internal and external stakeholders for approval/endorsement
- As an SME provide expert opinion in matters relating to standards development.
- Support with internal and external audits

Lead or Represent CDS in special projects (Non Drug Projects) and improvement initiatives as part of functional or wider Novartis initiatives and ensure smooth execution. Accountable for analyzing metric related to standards adoption and present the same to leadership and governance boards

Accountable for overseeing & 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.

Or/and;

Analysis and Reporting Data Standards

- Compliant analysis and reporting standards (ADaM and TFL)
- Use advanced programming knowledge to support specification of new analysis and reporting tools (incl. standard macros)
- Data models to support data analysis (ADaM) and reporting (TFL) standards (including associated metadata).
- Processes, tools and guidelines relating to the submission of standardized analysis data supporting regulatory submission.

Lead the technical review and assessment of industry and regulatory standards and guidelines supporting regular gap/impact analysis and implementation of action plans where needed.

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.

Lead and contribute to the development, maintenance and training of relevant clinical standards systems and processes.

Provide mentoring and technical guidance to Clinical Data Standards associates; Contributes to the effectiveness and development of talent.

Maintain up-to-date, advanced knowledge of relevant technologies (EDC, software languages, applications etc.), Industry Standards (e.g. CDISC, define.xml, eCTD etc.) and regulatory guidelines.

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.

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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部门
Development

Business Unit
Innovative Medicines

地点
India

站点
Mumbai (Office)

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

Alternative Location 1
Hyderabad (Office), India

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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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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