NOVARTIS

Sr Principal Clin Data Stds Specialist

Job ID
REQ-10008932
Mai 27, 2024
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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

Your responsibilities include, but are not limited to:

• Lead and contribute to Clinical Data Standards planning, 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.
• Serves as the primary contact for global data acquisition and tabulation, analysis or data submission standards for core global and/or assigned Therapeutic Area ensuring timely and quality deliverables.
• 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.
• Accountable for driving the efficient, high quality and timely implementation of new standards and/or updates to standards; In collaboration with representatives across Data Operations disciplines and key stakeholder and partner functions within GDO and across Global Drug Development, lead the accurate translation of scientific and analytical requirements into efficient, compliant standards.
• 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.
• 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. 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.

Role Requirements:

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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Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

Division
Development
Business Unit
Innovative Medicines
Standort
Indien
Site
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.

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