NOVARTIS

Associate Director- Clinical Data Standards

Job ID
REQ-10022081
Set 13, 2024
India

Sommario

Strategically and tactically supports Director Clinical Data Standards. 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. May lead global teams.

About the Role

Major accountabilities:

- Ensuring alignment with the CDS strategy; Responsible for Clinical Data Standard/automation solution planning, definition, development, validation and support
- Serves as the primary contact for global / TA data standards and/or technologies ensuring timely and quality deliverables.
- Responsible for driving efficient, high quality and timely implementation of new standards and/or technologies.
- Ensure efficient governance and approval of global clinical data standards / technologies liaising with governance boards as needed.
- Lead the technical review and assessment of industry and regulatory standards and technologies supporting regular gap/impact analysis and implementation of action plans where needed.
- 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.
- Act as primary 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.
- Provide mentoring and technical guidance to Clinical Data Standards associates; Contributes to the effectiveness and development of talent.

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

Work Experience:

- Managing Crises.
- Functional Breadth.
- Project Management.
- Collaborating across boundaries.
- Representing the organization.

Skills:

- Automation.
- Biostatistics.
- Clinical Trials.
- Computer Programming.
- Cross-Functional Teams.
- Data Analytics.
- Decision Making Skills.
- 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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

Divisione
Development
Business Unit
Innovative Medicines
Posizione
India
Sito
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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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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