

Associate Director- Clinical Data Standards

Job ID

REQ-10022081

Sep 13, 2024

India

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 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.

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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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>

Division

Development

Business Unit

Innovative Medicines

Location

India

Site

Mumbai (Office)

Company / Legal Entity

IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Alternative Location 1

India

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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