

Senior Clinical Data Scientist(Multiple Roles/Senior Clinical Data Manager)

Job ID REQ-10029993 Dec 03, 2024 India

Summary

Internal Role Title: Senior Clinical Data Scientist

Location: Mumbai #LI-Hybrid

About the Role:

Senior Clinical Data Scientist is responsible of using advanced data management tools and techniques, provide professional and lean execution of Data Management products and milestones with respect to cost, quality and timelines for all assigned trials within Clinical Data Acquisition and Management. Ensure consistently high-quality data available for analysis and reporting.

About the Role

Key Responsibilities: -

- Provides DM leadership across assigned trial(s) Acts as the Trial Data Scientist where needed ensuring strong DM representation across the CTT.
- Demonstrates a business understanding of the compound(s) profile and data strategy to identify and assist in successful application of data management processes and documentation across assigned trials.
- Ensures alignment with the TA level data strategy as defined by the TA Data Strategy Director.
 Competent in relevant CDISC or other recognized industry standards and how these impact the programming team.
- Provides accelerated feedback to assure well written, stable protocols and amendments. Recognize and resolve protocol issues.
- Performs DM activities for study start up including preparing the architecture and performing user
 acceptance testing (UAT). Manage local lab data flow and set up for the Clinical Database as applicable.
 Performs DM hands on activities during the course of the study, with a strong emphasis on quality,
 integrity and on-time delivery.
- Disseminates study level information to the Clinical Trial Team (CTT) and Program Clinical Data Scientist (PCDS). Supports and assists Junior staff for assigned trials
- Ensures Third party and other necessary reconciliation activities are performed for the study in a timely manner. Provides effective input into DM initiatives and innovations for quality, efficiency and continuous improvement in scientific and operational excellence

• Tracks and reports status and progress for assigned trials, indications or programs. Ensures adherence to ICH GCP, DM standards, SOPs/WPS and process guidelines.

Essential Requirements:-

- Timing and quality of database locks affecting submissions to regulatory authorities.
- University or college degree in life science, computer science, pharmacy, nursing or equivalent relevant degree.
- Ability to work under pressure demonstrating agility through effective and innovative team leadership.
 Excellent interpersonal skills and proven ability to operate effectively in a global environment. Ability to influence and communicate across functions and to external stakeholder
- Proven ability to interrogate and view data though various programming/GUI techniques
- Excellent problem-solving skills, verbal and written skills
- Ideally 5 years' experience in Drug Development with at least 4 years' in Clinical Data Management.

Why Novartis?

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Division
Development
Business Unit
Innovative Medicines
Location
India

Site

Mumbai (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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