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Clinical Data Scientist (Multiple Roles/Clinical Data Manager)

Job ID REQ-10029991 Dec 03, 2024 India

Summary

Internal Role Title: Clinical Data Scientist

Location: Hyerabad #LI-Hybrid

About the Role:

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: -

- As Clinical Data Scientist, provide data management input on Clinical Trial teams. May have the role of Trial Data Scientist on small low complexity trials
- Performs DM activities for startup of a study including preparing the eCRF, CCG's where needed, Data Quality plan (DQP) Data Quality Plan Module (DQPM) and performing user acceptance testing (UAT) as applicable
- Manage local lab set up for the Clinical Database as applicable. Under supervision ensures consistency of assigned trials with program level standards
- Understands third party data requirements and begins to gather an understanding of new technologies that may be used during clinical trials
- Performs ongoing review of all data generated from the clinical study including Third party and local lab data as well as SAE reconciliation where applicable
- Ensures activities that are performed are done with quality and understanding of the process. Verifies and tracks eCRF completion including Query resolution and provides data status updates as needed. With support from the Trial Data Scientist develops proposals to resolve issues that may occur during the running of assigned trials
- With support from the Trial Data Scientist gives input into Study Specification worksheets should assigned trials need to be outsourced
- Has a working knowledge of FDA and ICH guidelines. Has proven ability to use the tools available to generate listings for data review and where necessary provides these to the study teams. Generates the

study status reports for use at Clinical trial team meetings.

Essential Requirements:-

- University or college degree in life science, computer science, pharmacy, nursing or equivalent relevant degree.
- Strong technical skills,
- Fluent English verbal and written
- Ideally 3 years' experience in Drug Development with at least 2 years in Clinical Data Acquisition & Management

Why Novartis?

Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: <u>https://www.novartis.com/about/strategy/people-and-culture</u>

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Commitment to Diversity & Inclusion:

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

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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? <u>https://www.novartis.com/about/strategy/people-and-culture</u>

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

Division Development Business Unit Innovative Medicines Location India Site Hyderabad (Office) Company / Legal Entity IN10 (FCRS = IN010) Novartis Healthcare Private Limited 2/4 **Functional Area Research & Development** Job Type Full time Employment Type Regular Shift Work No Apply to Job

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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