

# Clinical Data Scientist

Job ID  
REQ-10029991  
Nov 17, 2024  
India

## 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

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## Role Requirements

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Division

Development

Business Unit

Innovative Medicines

Location

India

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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