

Manager, Clinical Sciences

Job ID REQ-10056217 Jun 26, 2025 India

Summary

Clinical Sciences Manager is responsible and accountable for the Operational Planning and Execution of IITs, RCs and NIS.

About the Role

Location - Hyderabad #LI Hybrid

Major Responsibilities:

- Accountable for the accuracy and timeliness of trial information in all trial databases and tracking systems. Facilitates MRC and SRC review of concepts
- Interfaces with the disease area(s), global and US clinical team members, regulatory affairs, drug supply, data management, finance and other relevant functional areas
- Preparation of trial related documentation, TMF maintenance: project files including ethics committee
 approvals; curricula vitae of investigators and study personnel; clinical investigators brochure; protocols;
 case report forms instructions; consent documents; clinical trial material shipping orders; start-up meeting
 attendance documentation; letters of agreement; lab reference ranges; all investigator and site
 correspondence; and schedules of payment.
- Ensures key processes and documents are maintained/updated on time (e.g. TPSR, ICF Clinical Review, TMF). Ensures TPSR & Pubs Review. Initiation of IND x-ref letter and IN & IB distribution. Establishes charters for and support management of SC and EO. Conducts Pre-RC alignment and Ensure EPRM and TPIAT completion for RCs (internal and external interface management)
- Responsible for the initial and subsequent drug supply across trials within a therapeutic area in
 collaboration with the Local Clinical Supply Manager. Contributes to the preparation and review of clinical
 program documents (PowerPoint presentations, IND annual report, regulatory documents, clinical study
 reports, (CSR) and submissions) and other study related documents assuring quality and consistency.
- Supports the management and tracking of trial budgets including payments working closely with the appropriate partners. Study close out execution, including financial reconciliation & creating closure letters. Prepares for and supports quarterly review meetings with TA teams
- Understands and complies with company SOPs and GCPs; contributes to continuous improvement in SOPs and local Working Practices. Any other clinical activities as assigned

Minimum Requirements:

Bachelor's degree in a science related field or a Registered Nursing certification or equivalent certification/licensure from an appropriately accredited institution.

Experience Required:

- Significant clinical research or research monitoring experience (comparable to 5 years) that provides the required knowledge, skills and abilities and experience mentoring or training others.
- In some cases, an equivalent combination of education, professional training, and experience that provides the required Knowledge, Skills and Abilities may be considered.

Technical Knowledge/Competencies:

- Ability to evaluate medical research data and proficient knowledge of medical terminology.
- Effective oral and written communication skills, with the ability to communicate effectively with medical personnel.
- Strong customer focus.
- Ability to utilize problem-solving techniques applicable to constantly changing environment.
- Good computer skills: good knowledge of Microsoft Office and the ability to learn appropriate software.
- Effective presentation skills.
- Conducts above activities with minimal oversight, ability to work independently. Mid to High-level competency for above activities.
- Ability to mentor and train other clinical associates in a positive and effective manner.
- Effective organizational and time management skills.
- Proven flexibility and adaptability.
- Excellent team player with team building skills.

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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/benefita-rewards

Division

Finance

Business Unit

Universal Hierarchy Node

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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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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