

Manager, Clinical Sciences

Job ID
REQ-10083489
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Индия
Available in: English

Сводка

#LI Hybrid

The Manager, Clinical Sciences is responsible and accountable for execution of assigned clinical research tasks related to Investigator-Initiated Trials (IITs), Research Collaborations (RCs,) and Non-Interventional Studies / Local Interventional Studies (NIS/LIS).

Manager, Clinical Sciences role is critical to support the growing complexity and volume of clinical studies (IITs & RC), evidence generation activities, and cross-functional collaborations. This position will provide dedicated clinical operations oversight to ensure high-quality study execution, timely deliverables, and compliance with regulatory and organizational standards.

About the Role

Key Responsibilities:

- Accountable for the accuracy and timeliness of trial information in all trial databases and tracking systems.
- Facilitates Medical Review Committee (MRC) and Scientific Review Committee (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, Trial Master File (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., Third Party Study Report (TPSR), Informed Consent Form (ICF) Clinical Review, TMF).
- Ensures TPSR & Pubs review.
- Initiation of Investigational New Drug (IND) x-ref letter and Investigator Notification (IN) & Investigator Brochure (IB) distribution.
- Establishes charters for and support management of Steering Committee (SC) and Executive Oversight (EO).
- Conducts Pre-Review Committee (RC) alignment and Ensure External Party Risk Management (EPRM) and Third-Party Impact Assessment Tool (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, Investigational New Drug (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 Therapeutic Area (TA) teams.
- Understands and complies with company SOPs and Good Clinical Practices (GCPs); contributes to continuous improvement in SOPs and local Working Practices.
- Leverages AI tools to streamline tasks, generate content, and support decision-making, demonstrating practical fluency in prompting, interpreting, and refining AI outputs to improve work quality and efficiency.
- Any other clinical activities as assigned.

Essential Requirements:

- Bachelor's degree in a life science related field or a Registered Nursing certification or equivalent certification/licensure from an appropriately accredited institution.
- Fluent in English. Good English language and grammar skills.
- Significant clinical research or research monitoring experience (comparable to 6 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.
- 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; Excellent interpersonal skills; Strong attention to detail.
- 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.
- Ability to work independently as required.

Commitment to Diversity and Inclusion:

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

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.

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

You'll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook <https://www.novartis.com/careers/benefits-rewards>

Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here: <https://talentnetwork.novartis.com/network>.

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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Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No

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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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