NOVARTIS

Senior Clinical Research Associate

Job ID
REQ-10075873

4月 14, 2026

India

摘要

Monitors patient data & study-related information related to clinical study sites and clinical trial participation. Ensures the investigator adheres to research protocols, regulatory requirements and good clinical practices and provides input into data validation plan. Provides timely and accurate monitoring of patient data and study-related information from source documents, research records, and site visits where applicable. May monitor study sites and audit facility selection.

About the Role

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The Senior Clinical Research Associate (sCRA) plays a pivotal site - facing role, responsible for ensuring high - quality, compliant, and timely execution of clinical trials. The role focuses on proactive site oversight, strong site partnerships, and effective risk management to safeguard patient safety, data integrity, and inspection readiness.

Role Summary

The sCRA independently manages complex clinical trial sites across Phase I-IV studies, conducting on - site and remote monitoring activities in line with ICH/GCP, local regulations, and Novartis SOPs. Acting as the primary point of contact for sites, the role drives sustainable site performance, supports recruitment delivery, and contributes to audit preparedness and continuous improvement initiatives.

Key Responsibilities

- Serve as the primary liaison between Novartis and assigned investigational sites
- Conduct Site Initiation, routine monitoring (on - site and remote), and Close - Out visits as per Monitoring Plan
- Ensure compliance with protocol, ICH/GCP, regulatory requirements, and Novartis SOPs
- Proactively identify site risks, issues, and deviations; drive timely mitigation and resolution
- Build strong site partnerships to optimize patient recruitment, flow, and site performance
- Ensure accuracy, completeness, and timeliness of site documentation and sTMF
- Support audit and inspection readiness and implement CAPAs within agreed timelines
- Collaborate cross - functionally with CPMs, CRA Managers, Medical, MSLs, and other stakeholders

Essential Requirements

- Degree in a scientific or healthcare discipline (or equivalent relevant experience). Minimum **4 years** of pharmaceutical or clinical research experience
- Hands - on experience in site monitoring and clinical trial execution
- Strong knowledge of **ICH/GCP**, regulatory requirements, and clinical trial processes
- Ability to manage sites independently with strong decision - making capability
- Proficient written and spoken **English** and local country language
- Willingness and ability to travel extensively (including overnight travel)

Desirable Requirements

- Experience managing **complex studies** and/or **less experienced sites. Prior** involvement in **audit and inspection readiness** activities
- Strong therapeutic area knowledge. Demonstrated ability to act as a **Subject Matter Expert (SME). Experience** working in global, cross - functional clinical teams. Strong digital and systems adaptability in a fast - changing environment

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

Benefits and Rewards: Learn about all the ways we ' ll help you thrive personally and professionally. Read our handbook (PDF 30 MB)

部门
Development

Business Unit
Other

地点
India

站点
Delhi (Office)

Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Alternative Location 1
Mumbai (Head Office), India

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work

No

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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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