

Senior Clinical Research Associate

Job ID
REQ-10075873
апр 14, 2026
Индия

Сводка

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

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Business Unit
Other
Место
Индия
Сайт
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Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited
Alternative Location 1
Mumbai (Head Office), Индия
Functional Area

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

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Accessibility and accommodation

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