NOVARTIS

Clinical Research Associate

Job ID
REQ-10054048

6月 11, 2025

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

Key Responsibilities

- Frontline liaison between Novartis and sites to ensure successful collaboration, meeting Novartis expectation on milestone and deliverables with true ownership mindset. Manages assigned study sites, conducting phase I-IV protocols according to the Monitoring Plan and Novartis procedures

- Performs Site Initiation Visit, ensures site personnel is fully trained on all trial related aspects. Perform continuous training for amendments and new site personnel as required. Re-trains site personnel as appropriate. Conducts continuous site monitoring activities (onsite and remote). Implement site management activities to ensure compliance with protocol, ICH/GCP, global and local regulation including Health Authorities, IRB/EC, data privacy requirements, global and local processes as applicable. Documentation according to GDP and Novartis standards.
- Identifies deficiencies in site processes and monitor site processes performed outside the site, works in close collaboration with site on risks mitigation and process improvements. Promotes a compliance culture advocating adherence to highest standards and ethical integrity, ensuring human subject protection and reliability of trial results at all times
- Identify deficiencies in site process, work in close collaboration with site on risk mitigation. Establish a strong partnership and true collaboration with the site, to increase patient density and decrease issues at site. Early engagement with site on patient inventory and patient flow in advance of SIV in close collaboration with global and local study team. Performs Site Closeout activities per SOPs and applicable regulations to ensure that site is aware of any follow up activity and archiving requirements
- Attends onboarding-, disease indication and project specific training and general CRA training as required. Proactively collaborates with the SSO Clinical Project Manager (CPM) and CRA Manager as well as MSL, CRMA and medical advisor to ensure optimal recruitment, site development and data quality
- Ensures that relevant site insights are shared with internal stakeholders such as site partnership manager, medical advisor, MSL and CRMA etc. to improve one Novartis approach to sites. Participates in audit organization and inspection readiness activities for monitoring and site related activities as required and ensures implementation of corrective actions within specified timelines
- Collaborates with internal stakeholders and site personnel to manage data query resolution process and to ensure timely and accurate data entry. Ensures the site Investigator Folder is up to date. Responsible for collecting essential documents from site and accountable to keep sTMF(s) up to date

Essential Requirements

- Degree in scientific or healthcare discipline (or, for United States: 4-year degree plus relevant, related healthcare experience*).*

- Fluent in both written and spoken English and country language

Desirable Requirements

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: 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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

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/benefits-rewards

部门
Development

Business Unit
Innovative Medicines

地点
India

站点
Mumbai (Head 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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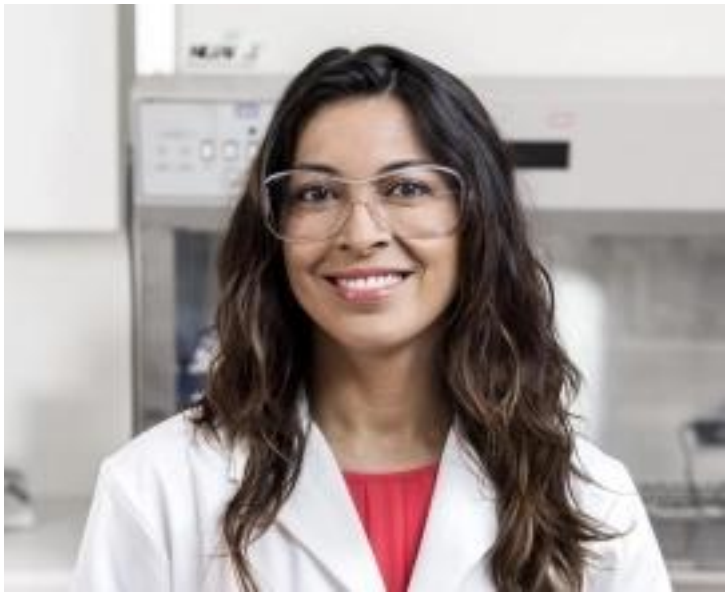

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