Sr. Clinical Research Associate

Job ID
REQ-10036188

1月 14, 2025

India

摘要

This is a site relationship management role to ensure sustainable trial execution at Site. Performs on-site and remote monitoring activities related to initiation, conduct and timely completion of Phase I-IV Global Drug Development (GDD) trials within the country in adherence with monitoring procedures and processes in accordance with International Council for Harmonisation of Technical Requirements of Pharmaceuticals for Human Use (ICH) / Good Clinical Practice (GCP), local regulations and Standard Operating Procedures (SOPs). Proactive site performance management (recruitment & quality) and early identification of real site needs and issues as the single best point of contact (internally & externally) for all sites. (From issue management to risk identification).

About the Role

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Key Responsibilities:
Your responsibilities include, but are not limited to:
- Frontline liaison between Novartis and sites to ensure successful collaboration, meeting Novartis expectation on achievement and deliverables with true ownership attitude.
- 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. Performs continuous training for amendments and new site personnel as required. Re-trains site personnel as appropriate
- Conducts continuous site monitoring activities (onsite and remote). Implements' site management activities to ensure compliance with protocol ICH / GCP, global and local regulation including Health Authorities, Institutional Review Board (IRB) / Ethics Committee (EC), data privacy requirements, global and local processes as applicable. Documentation according to Good Development Practice (GDP) and Novartis standards.
- Promotes a compliance culture advocating adherence to the highest standards and ethical integrity, ensuring human subject protection and reliability of trial results at all times.
- Performs Site Closeout activities per SOPs and applicable regulations to ensure that site is aware of any follow-up activity and archiving requirements.
- Proactively collaborates with the Site & Study Operations (SSO) Clinical Project Managers (CPM) and CRA Managers as well as Medical Science Liaisons, Clinical Research Medical Advisors (CRMA) and medical advisors to ensure optimal recruitment, site development and data quality.
- 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

Commitment to Diversity & Inclusion: :

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

Role Requirements :

Minimum Requirements:
- Degree in scientific or healthcare discipline
- 4 years pharmaceutical industry experience or other relevant experience
- Central/in-house monitoring or field monitoring experience
- Knowledge of international standards (GCP/ICH, Food & Drug Administration (FDA), European Medicines Agency (EMA)
- Understanding the purpose of the CRA (Patient Safety; Data Integrity; Principal Investigator (PI) Oversight; GCP/ICH & Protocol Compliance)

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

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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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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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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