NOVARTIS

Central Monitor (Data Surveillance Lead)

Job ID
REQ-10089008
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Индия

Сводка

The Central Monitor (CM) plays a key role for Data Surveillance by overseeing and supporting clinical trials through centralized monitoring activities. This role ensures data quality, identifies potential risks, and enhances trial oversight by leveraging data analytics and risk-based monitoring strategies. The CM collaborates with cross-functional teams to ensure compliance with study protocols, regulatory requirements, and Good Clinical Practice (GCP) guidelines. The CM will play a vital role in the study Risk-Based Quality Management process. This role is key to detect any study related risk/issue(s) within the scope of study RBM strategy. The CM will be involved early during clinical trial lifetime, working alongside the Risk Surveillance Lead (RSL) and others to support risk identification, risk assessment, definition of risk oversight measures (ex: Key Risk Indicators - KRIs). The role will have a key responsibility in connecting with the Data Analysts team, ensuring that the Central Monitoring technology is appropriately configured. During trial execution, the CM is responsible for ongoing aggregate Data Surveillance utilizing Central Monitoring technology to monitor data quality, patient safety, and relevant risks, interpreting and contextualizing risk signals for communication to the Clinical Trial Teams (CTTs) as well as to field monitoring teams and Risk Surveillance Team.

About the Role

Key Responsibilities

Central Monitoring Execution

- Execute centralized monitoring strategies to support clinical trial oversight.
- Perform ongoing review and analysis of clinical trial data to identify trends, risks, and signals.
- Collaborate with Data Analysts to review technology outputs and investigate identified risks.
- Provide input into data requirements and monitoring strategies.
- Ensure adherence to RBM plans, SOPs, and industry best practices.

Risk Identification and Management

- Conduct data surveillance through Central Monitoring platforms.
- Identify potential site and study-level risks in alignment with the Integrated Quality Risk Management Plan (IQRMP).
- Support the implementation and refinement of risk-based monitoring plans.
- Provide risk-based recommendations to improve trial quality and efficiency.
- Contribute to root cause analyses and corrective action discussions.

Data Review and Reporting

- Generate and communicate Central Monitoring findings and insights.
- Support Data Quality Teams in assessing the significance and root causes of findings.
- Document monitoring activities, findings, and risk escalations.
- Ensure timely follow-up and resolution of identified issues.

Collaboration and Stakeholder Engagement

- Partner with Risk Surveillance Leads (RSLs), Study Leaders, Data Managers, Clinical Scientists, and other stakeholders.
- Participate as an active Clinical Trial Team (CTT) member.
- Serve as the primary point of contact for Central Monitoring activities within assigned studies.
- Contribute to the development and maintenance of Trial Monitoring Plans.

Continuous Improvement and Compliance

- Support advancement of centralized monitoring methodologies and tools.
- Ensure compliance with GCP, regulatory requirements, and Novartis standards.
- Contribute to knowledge sharing, training, and best practice development across the Central Monitoring organization.

Essential Requirements

- University degree in Life Sciences, Business, Operations, or a related discipline.
- Minimum 5 years of experience in clinical research within the pharmaceutical industry or CRO environment.
- Minimum 3 years of monitoring experience (central or site monitoring).
- Strong understanding of RBQM, centralized monitoring, KRIs, QTLs, and clinical trial risk management.
- Working knowledge of ICH-GCP and international drug development standards.
- Strong analytical, critical thinking, and problem-solving skills.Experience interpreting complex clinical and operational data.
- Excellent communication, stakeholder management, and cross-functional collaboration skills.Experience working within a global matrix organization.
- Proficiency with clinical data systems, analytics platforms, and digital tools.Strong project management and organizational skills.

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)

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Business Unit
Development
Место
Индия
Сайт
Hyderabad (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

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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