NOVARTIS

Central Monitor

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REQ-10070501
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Индия

Сводка

About the role
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: o Implement and execute centralized monitoring strategies to support clinical trial oversight. Conduct ongoing central monitoring analysis of clinical trial data to detect trends and signals. Work with Data Analysts team in reviewing CM technology outputs and performing an initial investigation of identified risks (e.g., atypical data patterns) to assess their scope and nature in preparation for review with study teams. As needed, provide input into the data domains required for central monitoring as per the monitoring strategy. Ensure adherence to risk-based monitoring plans, SOPs, and industry best practices.
- Risk Identification and Management: Perform data surveillance via the CM platform, identifying potential sites or trial risks in alignment with the IQRMP. Collaborate with Lead CM and study teams to refine and implement risk-based monitoring plans. Provide insights and recommendations to enhance trial efficiency and mitigate risks. Support root cause analysis for identified issues and suggest corrective actions.
- Generate and summarize findings within the CM platform and lead the communication of results to study teams and RSL. Contribute to GCO understanding of impact of findings. Support DQT in assessing the criticality and potential root causes of the findings and in defining . Support study teams in adopting an approach to clinical trial monitoring that utilizes data and site level information to drive monitoring interventions that have the most potential to impact patients' safety and data quality. Document findings, escalate critical risks, and support follow-up actions. Ensure timely documentation of monitoring activities and findings.
- Collaborate with cross-functional study teams, including RSLs, Study Leaders, Data Managers, and Clinical Scientific Leaders, to ensure robust risk mitigation plans are in place and effectively executed. Participate in study team meetings as CTT member and provide data-driven recommendations. Act as a single point of contact for CM activities for relevant stakeholders for allocated studies and ensure timely communication and coordination. Act as a key interface between CM, Clinical Study Teams. The CM develop the Trial Monitoring Plan, ensuring the plan addresses standard as well as trial-specific risks.
- Advise on the design and optimization of KRIs and thresholds to enhance the efficacy of Central Monitoring efforts. Continuous Improvement and Compliance: Support the continuous improvement of centralized monitoring methodologies. Ensure adherence to regulatory requirements, SOPs, and GCP guidelines. Contribute to training and knowledge-sharing initiatives within the Central Monitoring team.

Essential Requirements

- University degree in life science, business or operations Fluent in both written and spoken English
- ≥ 5 years of recent pharmaceutical industry experience, with previous experience in clinical research, in a Pharmaceutical Industry or CROs. Strong clinical experience with excellent understanding of clinical trial development and risk management processes and the management of clinical trials. Specific central monitoring / monitoring experience are strongly preferred.
- ≥ 3 years comprehensive experience in monitoring (central, site), additional experience in clinical data analytics, data management activities or equivalent is preferable.
- Specific Central monitoring / monitoring experience (hands-on experience with KRIs review, centralized monitoring and quality tolerance limits -QTLs-) are strongly preferred. Knowledge of Risk-Based Quality Management (RBQM) and adaptive monitoring principles. Knowledge of overall clinical trial management process, understanding of the protocol, study associated risks and their significance, and the risk management process.
- Thorough understanding of the international aspects of drug development process, including expert knowledge of international standards (GCP/ICH), health authorities, and Novartis standards.
- Critical thinking and analytical skills to understand/analyze complex data and provide insight into risk signaling, trends, and outliers in data. Strong analytical and critical thinking skills with the ability to interpret complex clinical and operational data, recognize patterns, and identify potential risk

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

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

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