NOVARTIS

Lead Central Monitor

Job ID
REQ-10047951
Apr 09, 2025
India

Summary

The Lead Central Monitor (Lead CM) supports the Central Monitoring Head to drive excellence in clinical trial monitoring by establishing and delivering a state-of-the-art Central Monitoring (CM) capability at Novartis in Global Clinical Operations (GCO).
The Lead CM is responsible for managing a team of Central Monitors, for developing central and site monitoring strategies, ensuring that the configuration of the CM platform aligns with strategic needs, is consistent with identified indications, program, and study risks, in alignment with the IQRMP, to ensure appropriate trial data surveillance in order to deliver quality and integrity of the trials' clinical data
The Lead CM will be responsible for a portfolio of programs and related trials within a Development Unit (DU). The role will be responsible for building DU knowledge in the CM team to set adapted strategies for CM. The lead CM will seat at the GCO sub-team of the respective programs.
The Lead CM will also have trial's role:
• During trial start-up, this role will be involved for the protocol development process to support risk identification, risk assessment, risk oversight (Key Risks Indicators -KRIs-) in partnership with the Risk Surveillance Lead (RSL). This role may also contribute to the establishment of trial-specific KRIs, as needed. The role will have a key responsibility in connecting with the Data Analysts team, ensuring the CM platform is appropriately configured.
During trial execution, the Lead CM will also be responsible for overseeing the CMs' ongoing risk review, checking of the study data, and detection of risks utilizing technology (the CM platform) in partnership with the Data Analyst (DA), to monitor data quality, patient safety, and relevant risks. The lead CM will ensure that those data are translated into signals and insights and communicated to the Clinical Trial Teams (CTTs) for review and decision making to investigate and act appropriately. This role is critical for the detection of study-related risk/issue(s) within the scope of study RBM strategy.

About the Role

- **CM Establishment**
  - Support the establishment and implementation of a CM function at Novartis, including processes, tools, and governance frameworks to support RBQM.
  - Contribute to the CM resourcing strategy, including hiring, onboarding, development, and retention of CM Team.
  - Contribute to the Establishment and actively monitoring of CM objectives.
- **Team Leadership and Oversight:**
  - Manage and mentor a team of CMs, fostering professional development, ensuring alignment with CM processes, and maintaining high performance across the team.
  - Serve as the primary escalation point for CMs, providing guidance on complex risk signals and ensuring timely resolution of critical study-related risks.

- **Strategic Input and Coordination:**
  - Partner with the CM Head to set, refine and implement the CM strategy, contributing to the continuous improvement of Risk-Based Monitoring (RBM) processes across the organization.
  - Lead efforts to harmonize CM practices across studies, ensuring consistency in risk detection, assessment, and escalation protocols.
  - Set, refine and implement CM strategy tailored to the associated risks within the assigned DU.
- **Risk Management and Analytics Leadership:**
  - Oversee the analysis and interpretation of CM dashboards and data visualization tools to identify and contextualize risk signals and ensure accurate root cause analysis and mitigation actions
  - Collaborate with cross-functional study teams, including RSL, Study Leaders, Data Managers, and Clinical Scientific Leaders, to ensure robust risk mitigation plans and issue resolutions are in place and effectively executed.
- **Protocol and Study Design Support:**
  - Provide strategic input during protocol development and study setup to ensure comprehensive risk identification and alignment with RBQM objectives and processes.
  - Advise on the design and optimization of KRIs and thresholds to enhance the efficacy of CM efforts.
- **Data integrity and quality through Collaboration:**
  - Ensure appropriate trial data surveillance to deliver quality and integrity of the trials' clinical data
  - Act as the primary liaison between the CM team and CTTs, ensuring clear communication and alignment on risk management priorities.
  - Ensure that CTT risk review meetings are performed in timely and quality manner within the assigned DU, and ensure stakeholders are informed of key risks, actions, and resolutions.
  - Partner closely with the Data Analysts to ensure the CM technology is appropriately configured on trial level.
  - The Lead CM will also play a critical role in the development of the Trial Monitoring Plan, ensuring the plan addresses standard as well as trial-specific risks.
- **Performance Tracking and Continuous Improvement:**
  - Monitor and report on the effectiveness of CM activities, identifying opportunities for process improvements and driving implementation of enhancements.
  - Share insights and lessons learned across teams to build organizational capability in RBQM.
- **Documentation and Compliance:**
  - Ensure comprehensive documentation of CM activities, including risk identification, escalation, and resolution, to meet regulatory and internal quality requirements.
  - Oversee audit readiness of CM processes and outputs, supporting inspections and ensuring compliance with regulatory standards.
- **Technology and Innovation Leadership:**
  - Act as a key stakeholder in the evaluation, adoption, and improvements of the CM tools and technologies, ensuring effective integration into workflows.
  - Drive innovation in the use of analytics, visualization, and data-driven techniques to enhance risk identification and monitoring capabilities.

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Employment Type
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Shift Work
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