NOVARTIS

Lead Central Monitor

Job ID
REQ-10071370
апр 15, 2026
Великобритания

Сводка

LOCATION: London, Dublin, Barcelona
ROLE TYPE: Hybrid Working, #LI-Hybrid

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 capability at Novartis in Global Clinical Operations (GCO). The Lead CM is responsible for managing a team of CMs, 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 sit at the GCO sub-team of the respective programs.

The Lead CM may 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 (ex: 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. 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) to monitor data quality, patient safety, and relevant risks. The lead CM will oversee the process whereby 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 oversight of CM's detection of study-related risk/issue(s) within the scope of study RBM strategy.

About the Role

Job Responsibilities:

- 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 and to RSL for Critical to Quality (CtQ) risk management, ensuring clear communication and alignment on risk management priorities.
- Ensure that CTT risk review meetings are performed in a timely and quality manner within the assigned DU, and ensure stakeholders are informed of key risks, actions, and resolutions.
- Participate in the periodic CtQ risk review meeting led by the RSLs
- Partner closely with the Data Analysts to ensure the CM technology is appropriately configured on trial level.
- The Lead CM is accountable for 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 and lessons learned to improve the RBQM (QbD and CM) mitigation strategy. Meaning at the IQRMP development using the lessons learned to improve and suggest additional or more effective mitigation strategy linked to CM.
- 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.
- Contribute to the improvement of RBQM (both QbD and CM) mitigation strategy. Contribute to IQRMP development using the lessons learned to improve mitigation strategy linked to CM
- 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.

Job Requirements:

Education:

- University degree in life science, business or operations; Advance degree preferred

Experience:

- ≥ 7 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 (including trial design, protocol development, study start-up, patient recruitment and study close-out).
- Specific Central monitoring / monitoring experience (hands-on experience with Key Risk Indicators -KRIs- review, centralized monitoring and quality tolerance limits -QTLs-) are strongly preferred,
- Experience in implementing or working within Risk-Based Quality Management (RBQM) and adaptive monitoring frameworks
- ≥ 3 years of recent experience in people management and/or team leadership. Strong leadership and people management skills in global setting and proven ability to develop high performing teams and diverse profiles including manager of manager experience.
- ≥ 5 years comprehensive experience in monitoring (central, site), clinical data analytics, data management activities or equivalent.
- Knowledge of overall clinical trial 'planning and execution process, understanding of the protocol, study associated risks and their significance, and the risk management process.
- Proven experience in developing, implementing, and maintaining quality control documentation for remote/central monitoring activities, ensuring data integrity, completeness, and accuracy.
- Thorough understanding of the international aspects of drug development process, including expert knowledge of international standards (GCP/ICH), health authorities, and Novartis standards.
- Advanced critical thinking and analytical skills to understand/analyze/interpret complex clinical and operational data and provide insight into risk signaling, trends, and outliers in data
- Ability to interpret study protocols, assess study-associated risks, and understand operational and quality implication.
- Excellent communication and coordination skills.
- Strong capability in working in a global and country matrixed environment. Organizational awareness, including significant experience working cross-functionally.
- Strong technical, analytical and quantitative problem-solving skills. Technical ability to use the relevant technology and risk-based tools/platforms effectively.
- Proven experience in issue identification and resolution, with a proactive and collaborative approach. Data and Digital expertise: experience working with e-databases, clinical and/or project management planning and reporting and analytics systems.
- Strong project management skill with demonstrated ability to manage priorities and to meet timelines.
- Understanding team dynamics: recognizing the diverse talents, personalities, and working styles within a team to create a connected and productive work environment.
- Experience in transformation, leveraging AI and analytics
- Ability to understand and navigate diverse cultural contexts. This includes fostering inclusive environments and developing talents across different countries.
- Extensive knowledge of appropriate therapeutic area preferred

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.

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)

Дивизион
Development
Business Unit
Development
Место
Великобритания
Сайт
London (The Westworks)
Company / Legal Entity
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.
Alternative Location 1
Barcelona Barberà, Испания
Alternative Location 2
Dublin (NOCC), Ирландия
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No

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