Lead Central Monitor, Associate Director

Job ID
REQ-10047948

4月 13, 2025

Switzerland

摘要

The Lead Central Monitor 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

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This role will be based in Basel, Switzerland, Dublin, Ireland or London, UK in a hybrid working approach.

About the Role

Major accountabilities but not limited to:

- Support the establishment and implementation of a CM function at Novartis, including processes, tools, and governance frameworks to support RBQM.
- Manage and mentor a team of CMs, fostering professional development, ensuring alignment with CM processes, and maintaining high performance across the team.
- 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.
- 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
- Provide strategic input during protocol development and study setup to ensure comprehensive risk identification and alignment with RBQM objectives and processes.
- Ensure appropriate trial data surveillance to deliver quality and integrity of the trials ' clinical dat
- 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.

Education & Experience:

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

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部门
Development

Business Unit
Innovative Medicines

地点
Switzerland

站点
Basel (City)

Company / Legal Entity
C028 (FCRS = CH028) Novartis Pharma AG

Alternative Location 1
Dublin (NOCC), Ireland

Alternative Location 2
London (The Westworks), United Kingdom

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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