NOVARTIS

Central Monitor

Job ID
REQ-10047972

4月 13, 2025

Switzerland

摘要

The Central Monitor (CM) plays a key role in 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 and others to support risk identification, risk assessment, definition of risk oversight measures (Key Risk Indicators - KRIs).

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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:

- 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.
- Perform data surveillance via the CM platform, identifying potential site or trial risks.
- Collaborate with Lead Central Monitor and study teams to refine and implement risk-based monitoring plans.
- Generate and summarize findings within the CM platform and lead the communication of results to study teams.. Contribute to GCO understanding of impact of findings to data quality.
- Ensure timely documentation of monitoring activities and findings.
- Document findings, escalate critical risks, and support follow-up actions.
- Collaborate with cross-functional study teams, including Risk Surveillance Leads, Study Leaders, Data Managers, and Clinical Scientific Leaders, to ensure robust risk mitigation plans are in place and effectively executed.
- Advise on the design and optimization of KRIs and thresholds to enhance the efficacy of Central Monitoring efforts.
- Support the continuous improvement of centralized monitoring methodologies.
- Ensure adherence to regulatory requirements, SOPs, and Good Clinical Practice (GCP) guidelines.
- Contribute to training and knowledge-sharing initiatives within the Central Monitoring team.

Education & Experience:

- University degree in life science, business or operations
- $\geq$ 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.
- $\geq$ 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 signals or issues. Strong understanding of clinical metrics and trend analysis; experience managing operational insight at site level.
- Excellent communication and coordination skills.
- Strong capability in working in a Global/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.
- Data and Digital expertise: experience working with e-databases, clinical and/or project management planning and reporting and analytics systems.
- 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.
- Fluent English languages skills

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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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