

Monitoring Excellence Head

Job ID
REQ-10045555

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India

摘要

The Monitoring Excellence Head (ME Head) is responsible for setting strategic vision, driving end-to-end functional excellence in clinical trial monitoring, fostering collaboration within the organization across global, hubs and country teams with the business across programs and trials (Clinical Trial Teams -CTTs-) for CTT-roles (SL, TDCS, CSL, CSE, SSUL) interacting with monitoring roles (CRAs, Central Monitors, CPMs).

This role ensures that monitoring activities are aligned with organizational priorities, regulatory requirements, and industry best practices, and in delivering optimized trial oversight and risk-based monitoring performance. This includes the integration of Central Monitoring (CM) and Field monitoring efforts to optimize trial monitoring (consistency and high quality), to enhance trial integrity and operational efficiency.

For Central Monitoring: The ME head establishes, builds and oversees a state-of-the-art platform, to achieve portfolio and trial quality objectives. This role sets the end-to-end central monitoring strategy in alignment with the Risk Surveillance Head and partners closely with Clinical Data Operations (CDO). CM will be implemented on our ongoing CTTs from the Development and Early Development (BR) programs and will influence the work of the CTT sub-team: the Data Quality Team.

For Field monitoring Excellence: The ME Head is a visionary and strategic leader with an enterprise view of monitoring processes, roles and accountabilities and is accountable for the overall direction of

the way monitoring is done at Novartis considering all Development functions needs and interests. The role embeds innovation, develops harmonized process standards, and implements tools and metrics. Field monitoring Excellence will support the work of the CRAs (approximately 1,200 with 40+ countries) and key roles in the Monitoring function (CPMs, CRA Managers).

Through leadership of monitoring excellence communities of practice, the ME Head cultivates an empowered, matrixed organization, promoting a culture of continuous learning and a mindset embedding risk-based management, ensuring sustained operational excellence in a dynamic and evolving clinical landscape

About the Role

- Strategy & Execution
 - Establish and implement a Monitoring Excellence function at Novartis. which includes two organizational pillars: CM and field monitoring excellence, and ensure the alignment between two pillars.
 - CM includes processes, tools, and governance frameworks to support RBQM.
 - Field monitoring Excellence defines and executes overall monitoring strategies, leveraging data analytics and centralized oversight.
 - Develop and optimize CM resourcing strategy, including hiring, onboarding, development, and retention of CM Team, and perform CM resource management in line with GCO and Development and BR priorities.
 - Establish and actively monitor CM objectives in line with GCO priorities, key metrics/KPIs and industry benchmarks. Oversees and reports on monitoring performance, challenges, and opportunities for improvement for senior leadership.
 - In the long-term, ensure CM function evolves and adjusts to remain a value-added function and to ensure compliance with latest regulations.
- Collaboration with Stakeholders
 - Coordinate cross-functional interactions between monitoring teams and key stakeholders within Development in areas such as CDO (especially with Data Analyst team to support CM 's technologies), process and compliance, quality assurance, and regulatory affairs.
 - Partner with SSO Hub Heads to harmonize monitoring roles and establish an efficient organizational framework for trial oversight.
 - Serve as the central point of contact for monitoring-related queries for HA sponsor 's inspections and group audits, coordinating preparation activities, providing expert insights, facilitating responses and follow-up actions.
- Monitoring Strategy & Practices Optimization
 - Set-up a functional center of excellence in field monitoring in line with best-in-industry practices. Ensure that monitoring Organization structure and capabilities are aligned to effectively address current needs (internals/externals).
 - In partnership with SSO Hubs and Country Leadership, establish and implement global strategies to increase and sustain high performance and quality in monitoring activities. Develop and implement frameworks for monitoring performance metrics, provide strategic leadership to field monitoring teams, establishing monitoring best practice and standards, ensuring consistency across Hubs and countries.
 - Develop, maintain and disseminate comprehensive guidance for central and field monitoring best practices, identify and address gaps or inefficiencies in monitoring

practices, fostering continuous improvement with country-level functional excellence roles.

- Own the Monitoring Job Description (CRA, CRAM, CPM, SPM, ...) and seek for capabilities improvement/upgrade.
- Single point of contact for the overall Business Continuity for Monitoring.
- Risk-Based Approaches Strategy & Implementation
 - Co-create end-to-end RBQM strategy alignment with the Risk Surveillance Head.
 - Establish solid collaboration with CDO and Clinical Development (CD) functions to consider interdependencies with other key activities relating to Data Quality and RBQM and synergized actions to drive robust operational performance within Development.
 - Partner with Process & Risk Surveillance (PRS) team to lead the operationalization of end-to-end RBQM, embedding risk assessment, risk mitigation, and data-driven decision-making into trial monitoring processes.
 - Establish clear roles and responsibilities for RBQM across central and field monitoring teams.
- Training and Development
 - In collaboration with the GCO Process, Training and Compliance (PTC) and Development Learning teams identify gap in organization capabilities design and implement training programs to enhance content knowledge and technical expertise within monitoring teams.
 - Promote learning, sharing, consistent performance standards and operational excellence across program and trial teams in Development.
- Leadership and Change Management
 - Guide the organization through the transition to a CM model, driving cultural and operational change to achieve buy-in and sustained success.
 - Act as a champion for monitoring innovation, identifying opportunities for advancements and staying ahead of industry trends.
 - Break down silos through an enterprise mindset. Focus on delivery through collaboration and bringing people together to work towards the same purpose across the organization.
 - SME for monitoring processes and work in collab with the Process team.
 - Foster a networked SSO Organization for key monitoring populations (CPMs, CRAM, MSOM, SPF).
 - Build a culture of Monitoring expertise and excellence in SSO to optimize impact.
- Business owner of Monitoring technologies
 - Oversee the deployment of technology for CM (in collaboration with CDO).
 - Build knowledge of the external environment, with peer and comparison groups to effectively identify emerging trends and best practices for monitoring in Pharma industry.
 - Business owners of monitoring tools: Site Cockpit, TMO meter and Single-point-of-contact for Enterprise tools: SENSE, Horizon, CTMS NVC.

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IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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