

Monitoring Excellence Head

Job ID
REQ-10045554
Apr 07, 2025
Switzerland

Summary

We have an exciting opportunity as a Monitoring Excellence Head. In this role, you will be leading the strategic vision, drive end-to-end functional excellence in clinical trial monitoring, foster collaboration within the organization across global, hubs and country teams with the business across programs and trials for clinical trial teams-roles interacting with monitoring roles (CRAs, Central Monitors, CPMs).

Apply today and we can thrive together!

This role will be based in Basel, Switzerland in a hybrid working approach.

About the Role

Major accountabilities but not limited to:

- Establish and implement a Monitoring Excellence function at Novartis, which includes two organizational pillars: central monitoring and field monitoring excellence and ensure the alignment between two pillars.
- Establish and actively monitor central monitoring objectives in line with Global Clinical . 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 central monitoring function evolves and adjusts to a remain a value-added function and to ensure compliance with latest regulations.
- Coordinate cross-functional interactions between monitoring teams and key stakeholders within Development in areas such as Clinical Data Operations (especially with Data Analyst team to support Central Monitoring's technologies), process and compliance, quality assurance, and regulatory affairs.
- 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.
- 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 Site and Study Operations 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.
- Establish solid collaboration with Clinical Data Operations and Clinical Development functions to consider interdependencies with other key activities relating to Data Quality and RBQM and synergized actions to

drive robust operational performance within Development.

- Guide the organization through the transition to a Central Monitoring model, driving cultural and operational change to achieve buy-in and sustained success.
- Oversee the deployment of technology for Central Monitoring, in collaboration with Clinical Data Operations.

Video Link <https://www.youtube.com/watch?v=ggbnzRY9z8w>

Essential Requirements:

- University degree in life science, business or operations. An Advanced degree is preferred with 10+ years of recent pharmaceutical industry experience, with previous experience in clinical research, in a Pharmaceutical Industry or CROs. Strong clinical and budgeting/finance experience with excellent understanding of clinical trial development and risk management processes and the management of clinical trials. Specific central monitoring / monitoring experience preferred.
- 8 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.
- Thorough understanding of the international aspects of drug development process, including expert knowledge of international standards (GCP/ICH), health authorities (FDA/EMA), local/National Health Authorities regulations and Novartis standards.
- Strong capability in working in a Global/Country matrixed environment. Organizational awareness, including significant experience working cross-functionally.
- Proven track record in study operations process set-up and/or improvement(s).
- Exceptional technical, analytical and quantitative problem-solving skills.
- Strong strategic thinking and ability to articulate the bigger picture to foster confidence and trust.
- Experience in building-up a new organization: building a new capability (or transformation significantly an existing capability) with demonstrated adaptability and by embracing change and new approaches.
- Proven experience in prioritizing transformation, leveraging AI and analytics, and focusing on transformative investments.

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>

Commitment to Diversity & Inclusion:

Novartis is committed to building an outstanding, inclusive work environment and diverse team's representative of the patients and communities we serve.

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Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: <https://www.novartis.com/careers/benefits-rewards>

Division

Development

Business Unit

Innovative Medicines

Location

Switzerland

Site

Basel (City)

Company / Legal Entity

C028 (FCRS = CH028) Novartis Pharma AG

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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