Central Monitoring Head

Job ID
REQ-10038756
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Inde

Résumé

Welcome to the new and exciting Central Monitoring Head role - we are open for applications! The incumbent will be a: visionary, strategic leader and thrive in driving functional excellence in clinical trial monitoring. The new 2025 regulations means that you will be building-up and overseeing state-of-the-art Central Monitoring capabilities while advancing field monitoring. This opportunity is about building new processes, growing a team, solidifying relationships in a global matrix environment, overseeing data trends and incorporating new technologies. Therefore, to be a successful applicant you will need to have excellent communication skills, embrace innovation, collaborative, agile, empathetic, empower, manage resistance, and have a superior clinical trial knowledge with a thorough understanding of field monitoring landscape.

About the Role

- **Major accountabilities but not limited to:**
- **Strategy & Execution:**
  - Establish and implement a Clinical Monitoring function at Novartis, including processes, tools, and governance frameworks.
  - Define and execute Clinical Monitoring strategies, leveraging data analytics and centralized oversight.
  - Develop and optimize Clinical Monitoring resourcing strategy, including hiring, onboarding, development, and retention of Clinical Monitoring Team, and perform resource management in line with Development
  - Establish and actively monitor objectives in line with GCO priorities, key metrics/KPIs and industry benchmarks.
  - Update senior leadership on CM monitoring performance, challenges, and opportunities for improvement.
  - In the long-term, ensure CM function evolves and adjusts to a 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.
  - Act as a key connector between CM, global Risk Surveillance team, and field monitoring functions.
  - Partner with SSO Hub Heads to integrate central monitoring into existing monitoring ecosystem and adjust central and field monitoring roles accordingly.
- **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 CM 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.
- **Key performance indicators:**
- Successful build-up, deployment and integration of the CM function and technology platform, achieving alignment with trial monitoring workflows.
- Improved monitoring performance metrics, such as data completeness, protocol compliance, and reduction of critical findings in audits and inspections.
- Consistently high quality of monitoring deliverables, including adherence to data quality standards, risk identification, and timely issue resolution across trials.
- Achievement of monitoring milestones within defined timelines across the global portfolio, including risk-based monitoring (RBM) targets and KPIs for centralized data surveillance.
- Successful harmonization of field and CM efforts, leading to enhanced trial oversight and reduced operational variability

- ## Your Experience:

- University degree in life science, business or operations. An Advanced degree is preferred.
- ≥ 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.
- ≥ 6 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, 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).
- Strong technical, analytical and quantitative problem-solving skills.
- Ability to articulate the bigger picture to foster confidence and trust.
- Fluent in English
- **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

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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

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