Risk Surveillance Lead

Job ID
REQ-10055475
Jun 19, 2025
United Kingdom

Summary

More than 100,000 people across 140 countries are working for Novartis to discover, develop, and successfully market innovative products to prevent and cure diseases, ease suffering, and enhance the quality of life.

The Risk-Based Quality Management (RBQM) Risk surveillance Lead is responsible driving the adoption of RBQM practice at trial level and oversee the implementation, and continuous improvement. Risk Surveillance Lead works within a matrix environment and has overall account-ability for the surveillance of the quality risks across the assigned trials and program, enabling a comprehensive clinical quality (GCP) risk governance. The role demonstrates leadership in influencing and improving clinical trial quality through the expert understanding of clinical trial protocols, processes, regulatory requirements, and quality management principles.

This role can be based in London, Dublin or Barcelona. On site expectation of three days in the office.

About the Role

Major Accountabilities:

- Facilitate trial protocol risk assessment across multiple cross-functional domains (clinical, operational, data management, vendors, regulatory etc.) associated to critical-to-quality (CtQ) data and processes, including definition of quality tolerance limits (QTLs), evaluation of risks based on likelihood, detectability, impact, and ensures mitigation strategy / plans are defined
- Responsible for drafting, maintaining, and archiving the study specific documentation of risk management activities e.g., Integrated Quality Risk Management Plan (IQRMP)
- Partners with the RBQM system configuration team to ensure risk indicators, quality tolerance limits and other analytics/visualizations are programmed and functioning per operational requirements in the RBQM system
- Conduct of periodic central surveillance of the aggregate data at the study and potentially program level, leveraging available analytics/visualizations in the RBQM system, to identify emerging risks and/or issues
- Facilitate risk review meetings and discussions with study and potentially program team members to effectively communicate and discuss the findings, support, and encourage robust root cause identification and mitigation strategies
- Supports and participates in internal and external audits and inspection
- Collaborate with training departments to support training initiatives and aid in the adoption of the RBQM approach.
- Identifies and shares lessons learned, best practices, successes, case studies, failures, and process

improvement opportunities to promote continuous improvement and consistency with RBQM processes
- Acts as a change agent, champion, subject matter expert and point of contact of RBQM methodology, leading study teams to understand and follow the best practices to achieve maximum benefit

Experience:

Bachelor's Degree in a health-related, life science area, or equivalent combination of education, training, and work experience

- Minimum of 4 years of experience in the pharmaceutical or CRO industry
- Preferred minimum of 1 years of experience in Risk Based Quality Management
- Robust understanding of the drug development process and clinical trial execution
- Knowledge of industry regulatory standards including 21 CFR Part 11, ICH E6, ICH E8 (GCP)
- Experience in risk management, sponsor audits and health authority inspections, root cause analyses and mitigation strategies as well as Corrective Actions Preventive Actions
- Knowledge of RBQM IT systems or other data analytic systems
- Demonstrated ability to analyze data, identify patterns and make recommendations for improvement
- Demonstrated ability to effectively lead cross functional team meetings
- Experience forming cross-functional collaborations; strong interpersonal skills
- Supports a culture of continual improvement and innovation; promotes knowledge sharing
- Ability to influence without authority
- Thinks creatively; challenges the status quo

Languages:

English: fluent written and spoken

Why Novartis? Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

You'll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. https://www.novartis.com/careers/benefits-rewards

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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

Division
Development
Business Unit
Universal Hierarchy Node
Location
United Kingdom
Site
London (The Westworks)
Company / Legal Entity
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.
Alternative Location 1
Barcelona Gran Vía, Spain
Alternative Location 2
Dublin (NOCC), Ireland
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
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