Risk Surveillance Lead

Job ID
REQ-10037509

Feb 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 Surveillance Lead is responsible for driving the adoption of Risk-based Quality Management (RBQM) practice at trial level, oversee the implementation, and continuous improvement. The Risk Surveillance Lead works within a matrix environment and has overall accountability 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 under-standing 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 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/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 inspections
- 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
- May perform line management of other (junior) staff within RBQM Team

Key performance indicators:

- Adoption rate of RBQM across trial portfolio
- Effectiveness in risk identification, assessment, and mitigation (number of risks identified, assessed, and successfully mitigated)
- Stakeholder satisfaction measured through structured feedback and surveys conducted periodically
- Insights generated from metrics leading to Process and Quality Risks improvements

Minimum Requirements:

Work Experience:

- Minimum of 6 years of experience in the pharmaceutical or CRO industry
- Minimum of 2 years managerial and supervisory experience
- 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

Education

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

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

Commitment to Diversity and Inclusion:

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

Accessibility and accommodation

Novartis is committed to working with and providing reasonable accommodation to all individuals. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to receive more detailed information about the essential functions of a position, please send an e-mail to diversity.inclusionch@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message

Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here: https://talentnetwork.novartis.com/network

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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

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

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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

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

部門
Development

部門
Universal Hierarchy Node

国
United Kingdom

勤務地
London (The Westworks)

Company / Legal Entity
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.

Alternative Location 1
Barcelona Gran V í a, Spain

Alternative Location 2
Dublin (NOCC), Ireland

Functional Area
Research & Development

職種
Full time

雇用形態
CDI

Shift Work
No

Apply to Job.

Job ID
REQ-10037509

Risk Surveillance Lead

Apply to Job.

Source URL:
https://prod1.novartis.com/jp-ja/careers/career-search/job/details/req-10037509-risk-surveillance-lead-fr-fr

List of links present in page

1. https://www.novartis.com/about/strategy/people-and-culture
2. mailto:diversity.inclusionch@novartis.com
3. https://www.novartis.com/about/strategy/people-and-culture
4. https://talentnetwork.novartis.com/network
5. https://www.novartis.com/careers/benefits-rewards
6. https://www.novartis.com/about/strategy/people-and-culture
7. https://talentnetwork.novartis.com/network
8. https://www.novartis.com/careers/benefits-rewards
9. https://novartis.wd3.myworkdayjobs.com/fr-FR/NovartisCareers/job/London-The-Westworks/Risk-Surveillance-LeadREQ-10037509-1
10. https://novartis.wd3.myworkdayjobs.com/fr-FR/NovartisCareers/job/London-The-Westworks/Risk-Surveillance-LeadREQ-10037509-1