NOVARTIS

Risk Surveillance Lead

Job ID
REQ-10017287
Aug 20, 2024
United Kingdom

Summary

Responsible for driving the adoption of 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.

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 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
- 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
- Supports a culture of continual improvement and innovation; promotes knowledge sharing
- Ability to influence without authority
- Thinks creatively; challenges the status quo

Skills:

- Risk Management.
- Risk Monitoring.
- Budget Management.
- Clinical Research.
- Clinical Trials.
- Coaching.
- Cross-Functional Teams.
- Lifesciences.
- People Management.

Languages :

- English.

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Division

Development
Business Unit
Innovative Medicines
Location
United Kingdom
Site
London (The Westworks)
Company / Legal Entity
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.
Alternative Location 1
Ireland
Alternative Location 2
Spain
Alternative Location 3
Switzerland
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
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Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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