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Medical Safety Leader

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Company: Oxford Global Resources

Location: Mechelen

Category: architecture-and-engineering

Job Description

As a Medical Safety Leader, you are responsible for global pharmacovigilance activity of dedicated investigational products portfolio, including review and analysis of safety data from non-clinical and clinical trials, quality control of ICSRs, identification and management of safety signals, management of benefit-risk profile of the assigned compounds, scientific review of internal and external documents.

Responsibilities

- Ensure that all operational processes, regarding pharmacovigilance, are followed in assigned project
- Manage the external service providers delivering pharmacovigilance services, up to industry standards as per regulations and guidelines, including financial follow up, quality control of the ICSRs, PSURs and any other Safety related documents, compliance with regulatory requirements (timely submission of expedited and periodic reports)
- Perform medical review and provide medical advice on safety-related aspects associated with the assigned compounds

Chair regular meetings of the Safety Management Teams overseeing the compound Safety profile

Review and validate ICSRs from ongoing clinical studies and collaborate with the External service provider to process the ICSR, ensure expedited reporting requirements are met

Review of a study-specific Safety Project Plan for assigned clinical studies across the portfolio, and ensure oversight on the activities executed accordingly

Integrate the safety scientific component to build up a strategic framework for clinical development plans

Contribute to the creation and review of the Safety parts of certain clinical study related documents - Clinical Study Synopsys/Protocols, Clinical Study Report

Contribute to the creation and review of the Safety parts of certain compound related documents - Investigator's Brochure, dRMP, …

Initiate, author, oversight and collaborate with the Regulatory Leader to create and submit the Development Safety Update Report (DSURs)

Requirements

MD degree or equivalent (eg, DO or MB) required

7 years or more of clinical experience and/or Industry experience, with at least 3 years of these in patient safety or pharmacovigilance

Previous experience in phase 1 to 3 clinical trials strongly preferred

Prior Oncology experience strongly preferred, either in clinical practice or drug safety

Immunology experience would also be beneficial plus

Experience with interactions with major Regulatory Agency is preferred

Effective team member who takes ownership

Demonstrated attention to detail, strategic thinking and problem solving skills

Able to work under stress, demonstrating initiative and flexibility

Existing right to work in Europe is required

Benefits

Fulltime position

Remote

A balanced salary package based on your capabilities and experience, including extra legal benefits

Vacancy number: 24460

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