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Detection and evaluation of drug safety signals in post marketing phase

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The safety of all the medicinal products needs to be monitored throughout the product life cycle. The primary function of pharmacovigilance is to detect early warnings (potential signals) with regard to Adverse Drug Reactions which were previously unknown or unquantified. The concept of a drug safety signal is not new. Indeed, it has been the cornerstone of pharmacovigilance activities for about forty years. However, as more medicines are authorised for marketing each year, and as increasing numbers of persons are taking medicines this has resulted in an increase in the number of adverse events reported to manufacturers and to regulators. The life cycle of drug safety signal includes signal detection, signal prioritization and signal evaluation. If the evaluation of a drug safety signal establishes a new Adverse Drug Reaction, then this stage of the signal's life cycle will lead to an update of the product's prescribing information and, possibly, other regulatory actions including further risk communications and risk minimisation efforts. There are different methods for signal detection which include traditional methods (qualitative) and data mining methods (quantative). The manual review of paper based reports that provided the foundation of early productive pharmacovigilance systems is simply no longer practical. Modern pharmacovigilance systems, which received several hundred thousand reports each year and which have databases containing several million adverse event reports, must be able to detect, prioritize and evaluate signals in an efficient and proactive manner. To do so requires a systematic approach that couples statistical and analytic methods with sound clinical judgement.

Biography

Neha Vala is an MBBS doctor with 9 years of clinical experience including 5 years in Pharmacovigilance domain, having key expertise in signal detection and risk management activity. Currently, she is working as Operations Manager in pharmacovigilance department of Lambda Therapeutic Research Limited and handling different teams of case processing, aggregate reports, risk management, signal detection, medical review, submission and medical information system. She has also handled multiple regulatory and client audits successfully.

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