Ensuring Drug Safety beyond Trials: "The Promise of Real-World Evidence."

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Abstract:

Introduction

Drug safety is an important patient; clinician and regulatory agencies concern which is closely associated with ADR and drug interaction. Pharmacovigilance plays a critical role in ensuring medication safety and efficacy through the detection, assessment, understanding, and prevention of adverse effects and other drug-related problems. This is achieved with the help of RWE which tells us what actually happen when drug is used by uncontrolled population However, pharmacovigilance continues to face challenges such as underreporting of ADRs, heterogeneity of data sources, and the increasing demands associated with accelerated drug approvals. To address these issues, real-world evidence (RWE) has emerged as a valuable contributor, offering deeper insights into drug safety and efficacy. Analysing this data helps us to creating real world evidence which helps doctor, companies and regulators to know about safety and efficacy of drugs.

Methods

RWE strengthens pharmacovigilance practices by utilizing data from multiple real-life sources including electronic health records, patient registries, and social media platforms. Through big data analytics and artificial intelligence, these diverse datasets are processed to detect, monitor, and analyse ADRs more effectively. This approach facilitates a more comprehensive evaluation of drug safety and supports timely decision-making by regulatory agencies. Integration of RWE into existing pharmacovigilance systems provides an enhanced model that complements traditional clinical trial data and enriches safety monitoring throughout the product lifecycle.

Conclusion

Pharmacovigilance is a scientific method based on real world data and real world evidence. It helps in early detection and better understanding of adverse drug reactions. It allows more accurate safety monitoring, which ensures drug safety beyond clinical trials.

Keywords: pharmacovigilance, real world evidence, adverse drug reaction

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