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Advancements In Pharmacovigilance: The Role of Technology in Drug Safety Monitoring

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ABSTRACT: Pharmacovigilance (PV) has evolved significantly with the integration of technology in drug safety monitoring. This review explores recent technological advancements—from computational signal detection and semantic frameworks to social media mining and real-time surveillance systems. We analyze how diverse data sources such as electronic health records (EHRs), spontaneous reporting systems (SRS), and patient-generated content enhance the detection of adverse drug reactions (ADRs). The discussion also addresses regulatory perspectives, challenges in data integration, and the future of pharmacovigilance in a tech-driven healthcare ecosystem.

KEYWORDS: Pharmacovigilance, Technology, Signal Detection, Drug Safety, Social Media, Semantic Integration.

I. INTRODUCTION

Pharmacovigilance refers to the science and activities associated with detecting, assessing, understanding, and preventing adverse drug reactions (ADRs). Initially reliant on manual and spontaneous reporting, modern pharmacovigilance has embraced technologies that offer enhanced scalability, real-time data processing, and integrated data analysis. These advancements are essential to address the complexity of drug safety in a rapidly evolving pharmaceutical landscape.

II. LITERATURE REVIEW

The scope of pharmacovigilance has broadened through technological developments. Signal detection using structured longitudinal data and spontaneous reporting systems (SRS) has revealed limitations in underreporting and delays. Semantic technologies, such as the PharmacoVigilance Signal Detectors Ontology (PV-SDO), facilitate integration of heterogeneous sources and analysis methods. Text mining of social media and EHRs enables the identification of ADRs outside traditional clinical reporting. Furthermore, computational approaches, including disproportionality analysis, case-control designs, and self-controlled methods, allow high-throughput processing for ADR detection.

III. DISCUSSION

While technology brings immense potential to pharmacovigilance, it also introduces challenges. Data heterogeneity, bias, and privacy concerns persist. For example, social media data require advanced NLP algorithms to extract meaningful ADR insights due to informal language. Integration of multiple data sources enhances sensitivity but requires standardization and semantic mapping. Regulatory efforts, such as those by EMA, FDA, and WHO, aim to ensure data quality and traceability of biosimilars and biologics. A combined approach involving structured databases, patient reports, and real-world evidence may become the gold standard in future pharmacovigilance frameworks.

IV. CONCLUSION

Technological integration in pharmacovigilance offers a promising avenue for enhancing drug safety monitoring. By leveraging computational tools, semantic frameworks, and big data analytics, stakeholders can achieve more comprehensive and timely identification of drug-related risks. Continued regulatory collaboration and technical innovation will be critical in shaping an efficient, responsive, and evidence-based pharmacovigilance ecosystem.

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