

Artificial Intelligence in Pharmacovigilance: Transforming Post-Marketing Drug Safety Surveillance

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ABSTRACT

Pharmacovigilance ensures the ongoing evaluation of medicinal product safety throughout their post-marketing lifecycle. Traditional systems rely heavily on spontaneous reporting and manual case assessment, often limited by underreporting, delayed signal detection, and scalability constraints. Artificial Intelligence (AI) is redefining pharmacovigilance through automated, high-throughput analysis of heterogeneous real-world safety data. Machine learning (ML), deep learning, natural language processing (NLP), and predictive analytics enable efficient mining of spontaneous reporting systems, electronic health records, clinical trial repositories, and biomedical literature. These computational approaches enhance signal detection sensitivity, improve causality assessment, and facilitate proactive benefit-risk evaluation. AI-driven systems accelerate early identification of safety risks and support evidence-based regulatory decision-making. Despite these advancements, implementation challenges persist, including inconsistent data quality, lack of harmonized reporting standards, limited model interpretability, and regulatory validation concerns. Algorithmic transparency and infrastructure readiness remain critical determinants of clinical and regulatory trust. Continued innovation in explainable AI, standardized data governance frameworks, and collaborative engagement among academia, regulators, and industry stakeholders will be essential for sustainable adoption. The integration of AI into pharmacovigilance workflows promises to enhance proactive safety surveillance and strengthen global drug safety ecosystems.

Keywords: Signal detection, Natural language processing, Post-marketing surveillance, Benefit-risk assessment, Regulatory science

