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Recent Advances in Pharmacovigilance: Artificial Intelligence, Real-World Evidence, and Global Harmonization

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Abstract: ***Pharmacovigilance (PV) has transitioned from reactive spontaneous reporting to a proactive, predictive science that integrates artificial intelligence (AI), real-world evidence (RWE), and global harmonization frameworks. Recent advances include machine learning algorithms for signal detection, natural language processing for case triage, and clinical decision support systems (CDSS) that flag drug–drug interactions at the point of care. Expanded surveillance for biologics, biosimilars, oncology agents, and pediatric medicines has intensified the need for tailored monitoring strategies and traceability. Regulatory bodies such as the EMA and FDA are driving harmonization through centralized reporting platforms and standardized coding systems (e.g., MedDRA), enabling cross-regional data sharing. Despite these innovations, challenges such as underreporting, heterogeneous data quality, algorithmic bias, and ethical concerns regarding transparency and privacy persist. Literature suggests hybrid human-AI models, risk-tiered CDSS, and globally harmonized infrastructures as future directions to balance innovation with ethical responsibility and patient safety [1–3].***

Keywords: Pharmacovigilance, Artificial Intelligence, Real-World Evidence, Signal Detection, Clinical Decision Support Systems, Biologics, Global Harmonization, Drug Safety

1. Introduction

Pharmacovigilance encompasses systematic efforts to identify, evaluate, and mitigate adverse drug reactions, ensuring safer therapeutic use. Traditionally, PV relied on spontaneous reporting systems such as FDA's FAERS and EMA's EudraVigilance [4–6]. However, globalization of pharmaceutical markets, increasing therapeutic complexity, and the availability of diverse data sources have necessitated modernization of PV practices. Recent advances emphasize proactive surveillance, predictive analytics, and harmonized infrastructures to ensure patient safety in an era of precision medicine.

2. Review of Literature

1) Artificial Intelligence and Machine Learning

AI/ML algorithms enhance signal detection by analyzing large datasets from electronic health records (EHRs), registries, and social media [4–9]. Natural language processing supports automated case triage and MedDRA coding. Predictive models improve sensitivity and specificity of ADR detection, though validation and explainability remain challenges. While AI accelerates signal detection, its reliance on historical datasets risks perpetuating reporting biases, highlighting the need for continuous model recalibration[22–24, 27–28].

2) Real-World Evidence Integration

RWE from EHRs, registries, and patient-reported outcomes complements clinical trial data [7–12]. Social media mining provides early signals but requires robust filtering. Wearables and digital health tools enable continuous monitoring of physiological parameters [19, 25–27].

3) Clinical Decision Support Systems

CDSS embedded in hospital systems flag drug–drug interactions and contraindications in real time [10–14]. Pharmacists play a pivotal role in implementing and optimizing CDSS. Alert fatigue necessitates adaptive, risk-tiered alert systems.

4) Advances in Therapeutic Areas

Biologics and biosimilars require enhanced traceability and immunogenicity monitoring [13–18]. Pediatric PV frameworks emphasize caregiver engagement and age-specific monitoring. Oncology and rare disease therapeutics demand genomic data integration and registry-based surveillance [29–30].

5) Global Harmonization

Regulatory bodies (FDA, EMA, WHO-UMC) promote harmonization through centralized reporting platforms Standardized coding (MedDRA, ICH guidelines) ensures interoperability. Collaborative networks enable cross-regional signal validation and coordinated regulatory action[1–3, 16–21, 34–36, 49–50].

Pharmacovigilance (PV) has undergone a significant transformation over the past few decades. Traditional PV systems were primarily reactive, relying heavily on spontaneous reporting mechanisms, manual case processing, and paper-based documentation. In contrast, modern PV leverages advanced technologies such as artificial intelligence (AI), natural language processing (NLP), and real-world evidence (RWE) to enable proactive and predictive safety surveillance [1–3].

Traditional PV systems relied on spontaneous reporting and manual case processing, which limited scalability. Traditional PV systems, such as the U.S. Food and Drug Administration's (FDA) Adverse Event Reporting System (FAERS), depend

on voluntary reporting by healthcare professionals and patients. These systems often suffer from underreporting and delays in signal detection [4–6]. Manual case processing and paper-based systems further limit the scalability and efficiency of traditional PV [7]. Regional databases, while useful, often operate in silos, hindering global signal detection and harmonization [5].

Modern PV systems, exemplified by the European Medicines Agency's (EMA) EudraVigilance platform, incorporate AI-driven signal detection algorithms and NLP tools to automate case triage and MedDRA coding [8,9]. These systems utilize data from electronic health records (EHRs), patient registries, and even social media to enhance the sensitivity and specificity of adverse drug reaction (ADR) detection [10–12]. The integration of global harmonized networks and standardized coding systems such as MedDRA and ICH guidelines facilitates cross-regional data sharing and coordinated regulatory action [31–33, 37–44].

Figure 1 provides a tabular comparison of key features distinguishing traditional and modern pharmacovigilance approaches. As illustrated, the shift from manual, region-specific systems to automated, globally harmonized platforms marks a paradigm shift in drug safety monitoring.

Comparative Analysis of Traditional and Modern Pharmacovigilance

3. Discussion

The literature underscores a shift from reactive to predictive pharmacovigilance. AI and RWE integration promise earlier detection of ADRs, while CDSS enhances prevention at the point of care. However, persistent challenges—underreporting, data heterogeneity, algorithmic bias, and ethical concerns—demand robust governance. Hybrid models combining AI-assisted analytics with expert medical review are emerging as the optimal approach. Global harmonization initiatives further strengthen PV by ensuring consistency and interoperability across regions.

4. Conclusion

Pharmacovigilance is entering a data-centric, globally harmonized, and AI-enabled era. Innovations in analytics, decision support, and therapeutic monitoring are reshaping drug safety practices. Success depends on balancing technological advances with ethical safeguards, regulatory compliance, and human expertise. Future directions emphasize hybrid human–AI models, pediatric-specific frameworks, and globally harmonized infrastructures to advance patient safety.

Figure 1: Comparative Table of Traditional vs. Modern Pharmacovigilance

Traditional Pharmacovigilance	Modern Pharmacovigilance
Spontaneous reporting	AI-driven signal detection
Manual case processing	Automated NLP triage
Limited to clinical trials	Real-world data integration
Paper-based systems	Digital platforms and EHRs
Regional databases	Global harmonized networks

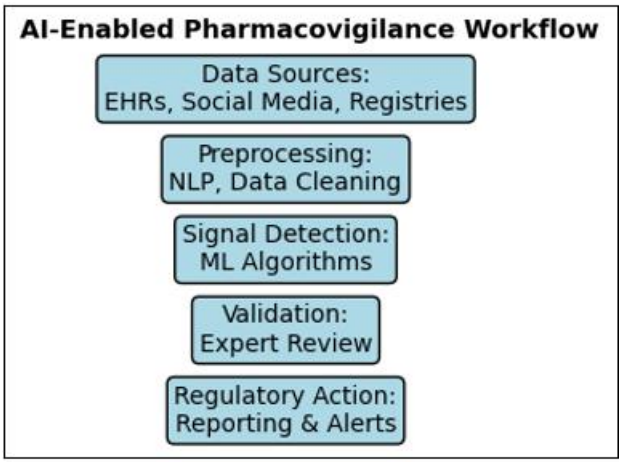

Figure 2: AI-Enabled Pharmacovigilance Workflow

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