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Review Article

Artificial Intelligence in Pharmacovigilance: A Narrative Review of Global Regulatory Perspectives, Technological Evolution, and Emerging Challenges

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ABSTRACT

Pharmacovigilance plays a key role in public health-it helps us spot, assess, and prevent adverse drug reactions throughout a drug's life on the market. This review takes a closer look at how AI is reshaping pharmacovigilance. It covers what's new in AI-driven tools, what global regulators think, where the technology stands now, and what hurdles still remain for drug safety monitoring. Review was conducted using peer-reviewed articles, regulatory reports, and official guidance from databases: PubMed, Scopus, Google Scholar, WHO, UMC, FDA and EMA. The literature was reviewed to assess AI drug safety, how regulators view these new tools, and the hurdles everyone's facing. AI, whether it's is machine learning, natural language processing or deep learning methods, is a facilitator of drug safety monitoring. Global regulatory authorities have increasingly integrated AI into PV frameworks to improve data processing efficiency and regulatory decision-making. However, challenges related to algorithmic bias, data, quality, model interpretability and causality assessment continue to limit widespread implementation. New approaches like explainable AI, federated learning, and multimodal systems have the potential to transform future PV systems and global safety surveillance. The successful integration of AI into PV requires robust regulatory frameworks, transparency, ethical governance, and continued human oversight to ensure reliable and patient-centered drug safety monitoring.

Keywords: Adverse drug reactions, Artificial intelligence, Drug safety surveillance, Explainable AI, Global health, Patient safety, Pharmacovigilance, Real-world evidence, Regulatory integration, Signal detection.

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INTRODUCTION

Pharmacovigilance, a very important aspect of protecting the health of people by detecting, evaluating, and preventing undesirable outcomes related to medicinal products (World Health Organization, 2021; Edwards and Aronson, 2000). However, the growing volume, velocity, and variety of electronic health Spontaneous Reporting Systems (SRS), Electronic Health Records (EHRs), social media, and real-world evidence have rendered traditional, PV techniques increasingly unsustainable (Harpaz *et al.*, 2012; Sarker *et al.*, 2015). Machine learning was an aspect of Artificial Intelligence (AI). AI technologies, including Machine Learning (ML), Natural Language Processing (NLP), and deep learning have rapidly evolved from supportive analytical tools into fundamental facilitators of next-generation drug safety surveillance (Kreimeyer *et al.*, 2017; Rajkomar *et al.*, 2019).

Recent publications showed that AI could greatly enhance the real-time precision and accuracy of outcomes and portability of pharmacovigilance operations (Beam and Kohane, 2018; Tatonetti *et al.*, 2012). Recent studies have provided in-depth insights into the development, implementation, and challenges of AI in PV (Nagar *et al.*, 2025). The efficiency of traditional medication safety monitoring techniques has decreased due to the growing number and complexity of PV. AI provides sophisticated methods for enhancing signal identification, real-time safety monitoring and ADR detection.

AI technologies like machine learning, natural language processing, and deep learning in PV are covered in the narrative review. It covered current challenges, and future directions of

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AI-driven pharmacovigilance systems, applications in drug safety monitoring and global regulatory viewpoints.

This goal of this review to critically assess artificial intelligences developing role in PV taking into account its technological advancements, worldwide regulatory integration, drug safety surveillance applications, and new ethical and practical issues. The article further discusses current limitations and future directions for AI-enabled pharmacovigilance systems.

METHODOLOGY

This narrative review was prepared using published peer-reviewed articles, regulatory reports, and official guidance documents related to artificial intelligence in pharmacovigilance. Relevant literature was identified from sources including PubMed, Google Scholar, Scopus, and official websites of regulatory organizations such as the World Health Organization (WHO), Uppsala Monitoring Centre (UMC), United States Food and Drug Administration (FDA), and European Medicines Agency (EMA).

The literature search included publications from January 2015 to March 2026 to capture recent developments in AI-enabled pharmacovigilance. The search strategy combined Medical Subject Headings (MeSH), free-text terms, and Boolean operators. Representative search terms included: "Artificial Intelligence," "Machine Learning," "Deep Learning," "Natural Language Processing," "Pharmacovigilance," "Drug Safety," "Adverse Drug Reactions," "Signal Detection," "Real-World Evidence," and "Regulatory Perspectives." These terms were combined using Boolean operators such as AND and OR. A representative search strategy was: ("Artificial Intelligence" OR "Machine Learning" OR "Deep Learning" OR "Natural Language Processing") AND ("Pharmacovigilance" OR "Drug Safety" OR "Adverse Drug Reactions" OR "Signal Detection").

Inclusion criteria includes peer-reviewed original research articles, regulatory guidance documents, and official publications published in English. Conference proceedings, letters to the editor, duplicate publications, non-English articles, and studies not directly related to pharmacovigilance were excluded.

The initial search identified 152 records. After removing duplicate publications and screening titles and abstracts for relevance, 58 full-text articles and regulatory documents were assessed. Finally, 30 publications that were most relevant to the objectives of this review were included for narrative synthesis. Additional references were identified through manual screening of the bibliographies of eligible articles to ensure comprehensive coverage of the topic.

The selected literature was narratively synthesized to describe the technological evolution of AI in pharmacovigilance, global regulatory perspectives, current applications in drug safety surveillance, validation approaches, implementation challenges, and future directions.

GEOGRAPHICAL AND REGULATORY PERSPECTIVES ON AI IN PHARMACOVIGILANCE

Global Perspective - World Health Organization (WHO)

At the international scale, the World Health Organization (WHO) played a central role in coordinating international pharmacovigilance practices via the Uppsala Monitoring Centre (UMC). The UMC maintained VigiBase, the largest global repository of Individual Case Safety Reports (ICSRs) in the world, which is a vital backbone of global drug safety surveillance (Uppsala Monitoring Centre, 2023). To enhance the efficiency and quality of signal detections, the WHO combined AI-assisted features, such as vigiMatch, which enables duplicate report detection, and vigiRank, which enables signal prioritization, within this framework (Norén *et al.*, 2013). In this context, artificial intelligence is used to enhance the quality of the data, enhance the accuracy of the data on safety signals, and balance the pharmacovigilance data in the different national reporting systems. In terms of regulation, AI is placed as a transparent and targeted decision-support system, high global cooperation, methodological standardization, and interpretability, more than a black-box automation takes place (Wiens *et al.*, 2019).

India: low- and middle-income country perspective

In India, a Low- and Middle-Income Country (LMIC), National pharmacovigilance systems operated under substantial constraints, including limited manpower, insufficient infrastructure, and suboptimal Adverse Drug Reaction (ADR) reporting (Hazell and Shakir, 2006). In this respect, AI and big data technologies were mainly considered capacity-building tools instead of fully automated regulatory systems. These technologies are used to enhance ADR detections, enhancing signal identification, and sustaining overstretched pharmacovigilance programs (Harpaz *et al.*, 2012). Persistent challenges, such as the underreporting of ADR, fragmented and incomplete safety data and limited interoperability between healthcare databases still hamper successful monitoring. From a regulatory perspective, AI is considered to be an facilitating technology that improves the efficiency of pharmacovigilance in resource-restricted environments, with a focus on scalable and cost-effective solutions that augments the current manual reporting mechanisms.

France: national public health emergency use

In France, national health authorities deployed AI-supported pharmacovigilance systems during large-scale immunization programs conducted under public health emergencies. AI technologies were used to monitor vaccine safety signals, process high volumes of post-marketing safety reports, and support rapid regulatory decision-making (European Medicines Agency, 2021). AI-enabled analytical tools facilitate near real-time surveillance of vaccine-related adverse events, demonstrating the feasibility of

deploying AI at the national level during crisis situations. From a regulatory standpoint, AI was positioned as a surveillance acceleration and crisis response tool, supporting but not replacing expert regulatory judgment.

United states

In the United States, artificial intelligence is extensively integrated intopharmacovigilance within an advanced regulatory supervised by the Food and Drug Administration (FDA). Core safety monitoring infrastructures, including the Food and Drug Administration's Adverse Event Reporting System (FAERS) and the Sentinel System is an active surveillance system that underpins AI-enabled drug safety (Food and Drug Administration, 2023; Platt *et al*., 2018). AI was treated as a near-routine regulatory capability and automated signal identification, risk stratification, and analysis of real-life evidence gathered from large healthcare databases (Tatonetti *et al*., 2012). The validation of AI in regulatory oversight is given a strong focus, continuous post-deployment performance monitoring, maintenance of human-in-the-loop decision-making processes. From a regulatory perspective, AI systems were expected to be able to prove the reliability, transparency and auditability until they can become routine pharmacovigilance practice.

European Union

In the European Union, pharmacovigilance regulations follow a collaborative and network-based model that relies on close coordination among member states (European Medicines Agency, 2023). The implementation of artificial intelligence is in line with long-range regulatory science plans and greater digital transformation goals across the region. AI technologies support signal detection, real-world evidence-based on large-scale data analytics, automation of document processing, and regulatory workflow (European Medicines Agency, 2022). Ethical AI practices, transparency, and explainability of models are given a strong regulatory understanding to be trusted and held accountable (European Commission, 2019). EudraVigilance is a centralized database used to perform core safety monitoring and contains information on adverse drug reactions. Furthermore, AI-based initiatives have been undertaken by the European Medicines Regulatory Network during distinct Big Data and AI work plans. On the national level, states such as Germany use AI to monitor signals and regulatory text mining, Sweden uses AI-based systems to detect serious adverse drug reactions, and Switzerland uses automated literature screening tools to improve the detection of adverse drug reactions.

Japan

In Japan, artificial intelligence has been integrated into pharmacovigilance in an advanced regulatory ecosystem monitored by the Pharmaceuticals and Medical Devices Agency (PMDA). AI technologies are applied to enhance the assessment of safety indicators and aid post-marketing surveillance exercises (Pharmaceuticals and Medical Devices Agency, 2022). The Japanese regulatory approach focuses on adherence to international pharmacovigilance and regulatory standards to ensure consistency with safety monitoring developed globally. Instead of substituting conventional pharmacovigilance procedures, AI is positioned as a complementary analytical tool that enhances the existing regulatory framework and supports more efficient and data-driven safety assessments while preserving regulatory accountability.

Africa

Pharmacovigilance systems in Africa are under the supervision of national medicine regulatory authorities, and most countries are members of the WHO Programme of International Drug Monitoring. The most common type of reporting system is spontaneous adverse drug reaction reporting; however, the contribution to safety databases globally is low due to underreporting, poor infrastructure, and lack of resources (Hazell and Shakir, 2006). Artificial intelligence is now regarded as a strategic resource to enhance pharmacovigilance capacity by improving data processing, strengthening signal detection, and integrating disparate reporting systems (Harpaz *et al*., 2012). Regulatory-wise, AI is seen as a capacity-building and efficiency-enhancing strategy, rather than a substitute for human regulatory functions, and as an increased focus on regional harmonization, shared safety databases, and sustainable digital solutions.

China

In China, artificial intelligence is actively encouraged as a prerequisite for smart drug policies and digital governance. The national strategies are highly favorable for the incorporation of AI technologies in the entire drug life cycle, starting with development and approval to post-marketing safety surveillance. The application of AI in adverse drug reaction monitoring, risk early warning systems, regulatory inspections, approval processes, and complete chain drug traceability is used to ensure drug safety and quality (National Medical Products Administration, 2022). The National ADR Monitoring System is a pharmacovigilance activity that has been improved using AI and big data analytics. The system is supplemented by cloud-based regulatory systems and AI-based tools for signal detection and safety measurements. Another aspect of China's regulatory framework is the focus on alignment with international reporting standards, such as ICH-compliant forms, to facilitate global harmonization and cross-border data exchanges.

South Korea

In South Korea, pharmacovigilance and drug safety are supervised by the Ministry of Food and Drug Safety (MFDS), which has engaged in the active use of artificial intelligence as

part of its general digital health and smart regulation agenda. The regulatory perspective in South Korea focuses on the application of AI to improve the efficiency, accuracy, and timeliness of drug safety monitoring, with the government exercising high levels of oversight (Ministry of Food and Drug Safety, 2022). National policies espouse the incorporation of AI in regulatory review, post-marketing surveillance, and risk management activities.

Pharmacovigilance uses artificial intelligence to facilitate Adverse Drug Reaction (ADR) monitoring, early detection of safety signals, and real-world healthcare data analysis at scale. AI -driven methods are used for automated case processing, signal detection, and risk prediction, allowing regulators to handle the increasing volumes of safety data more efficiently. AI can also be used in regulatory decision-making through enhanced planning of inspections, prioritization of reviews, and post-marketing risk assessment.

In South Korea, drug safety reporting is assisted by the national adverse event reporting systems under the management of the MFDS and the integrations of electronic health records and real-world data sources. The systems are becoming more AI-based analytics and cloud-enabled platforms to become more accurate signal detectors and provide better data quality. The South Korean regulatory system is consistent with global pharmacovigilance requirements, such as ICH standards, and has set AI as a regulated and transparent decision-support system, but not as an independent regulatory body (Table 1).

Evolution of artificial intelligence in pharmacovigilance

The use of AI in PV can be traced back to the late 1990s, With the introduction of disproportionality-based statistical data mining methods, such as the Bayesian confidence Propagation Neural Network (BCPNN) and Multi-item Gamma Poisson Shrinker (MGPS). These initial attempts enhanced signal detection in large spontaneous report databases but had inadequate capability in manipulating unstructured data, rare ADRs, and complicated drug-drug interactions (Harpaz *et al.*, 2012; Bate and Evans, 2009).

Advances in Natural Language Processing NLP demonstrated that it is possible to extract the safety information from free text materials, such as clinical narratives, biomedical literature, and social media (Kreimeyer *et al.*, 2017). A paradigm change from passive to proactive and active surveillance systems has recently been made possible by deep learning architectures, knowledge graghs, and multimodal AI models that enable the integration of diverse data sources (Rajkomar *et al.*, 2019).

AI-DRIVEN DRUG SAFETY SURVEILLANCE

Adverse Drug Reaction Detection

ADR detection has been greatly improved using AI in a variety of data sources. According (Sarker *et al.* 2015), NLP-based models have successfully extracted ADR mentions from social media and EHRs, making it easier to find patient-reported outcomes that physicians typically miss when following formal reporting processes. Drug-ADR relationships from extensive PV databases have been successfully identified using deep learning and transformer-based models, including BERT variations (Devlin *et al.*, 2019; Kreimeyer *et al.*, 2017).

Knowledge graph-based approaches have also been demonstrated to increase ADR detection by modeling the intricate relationships among drugs, adverse events, molecular properties, and patient characteristics (Tatonetti *et al.*, 2012). These methods provide better predictive accuracy, although data quality, interpretability, and generalizability should be cautiously considered.

Signal Detection And Active Surveillance

Signal detection is one of the foundations of PV. AI and ML models, such as neural networks and gradient boosting machines, outperformed conventional disproportionality studies under some circumstances (Harpaz *et al.*, 2012; Norén *et al.*, 2013). Additionally, it has been demonstrated that multimodal signal detection frameworks detect Spontaneous Reporting System (SRS) data substantially earlier when paired with claims databases, biological literature, and web search logs.

AI is rapidly being used by active suevelliance systems, including regulatory programs like the FDA sentinel system and vaccine safety monitoring programs, to automate data processing, outcome validation, and risk categorization. Early regulatory interventions are made possible by these systems support for near real time safety assessment (Platt *et al.*, 2018).

Real-Time Monitoring

The continuous monitoring of EHRs, patient registries, and digital health enables the dynamic assessment of evolving drug safety profiles (Beam and kohane, 2018). Real-time surveliance systems powered by AI assist in early warning systems; however, they face challenges related to concerning false - positive notifications, model drift, and adherence to clinical and regulatory workflows (Wiens *et al.*, 2019).

Validation And Performance Evaluation Of Ai Tools

The successful implementation of Artificial Intelligence (AI) in pharmacovigilance depends on rigorous validation to ensure reliability and regulatory acceptance. AI models are commonly validated using internal validation techniques, such as cross-validation, and external validation with independent datasets to assess their generalizability. Model performance is

Table 1: Comparative Summary of AI Use in Pharmacovigilance.

Aspect	LMIC and Global Public Health Systems	High-Income and Advanced Regulatory Systems
Main country focus	India, Africa, WHO (Global)	European Union, and the United States. Japan, South Korea, China
Regulatory perspective	Public health-oriented, capacity strengthening	Regulatory science-driven, enterprise-level governance
WHO / UMC involvement	Strong emphasis through VigiBase, vigiMatch, vigiRank	Strong emphasis through alignment with WHO and ICH standards
National regulators (FDA, EMA, PMDA, MFDS, NMPA)	Limited direct AI deployment, supportive role	Extensive integration of AI within regulatory workflows
Reporting systems	Spontaneous ADR reporting, limited interoperability	Advanced systems (FAERS, Sentinel, EudraVigilance, national ADR platforms)
AI role	Capacity building, data quality improvement, signal support	Routine decision-support, signal detection, real-world data analytics
Use during emergencies	Selective national deployment (e.g., vaccine safety)	Systematic, scalable deployment with validation frameworks
Ethical and legal focus	Feasibility, scalability, affordability	Explainability, transparency, bias mitigation, auditability
Human oversight	Essential due to limited automation	Mandatory via human-in-the-loop regulatory models
Setting	Resource-limited, fragmented, global public health	High-income, digitally mature regulatory ecosystems

evaluated using metrics including accuracy, precision, recall (sensitivity), specificity, F1-score, and Receiver Operating Characteristic Area Under the Curve (ROC-AUC). Among these, recall is particularly important in pharmacovigilance because it minimizes missed adverse drug reactions, while precision helps reduce false-positive safety signals. In addition to statistical performance, regulatory agencies emphasize model transparency, explainability, and continuous human oversight before AI systems are routinely integrated into pharmacovigilance practice (Rajkomar *et al.*, 2019; Wiens *et al.*, 2019; CIOMS Working Group XIV, 2025).

Regulatory Integration Of Ai In Pharmacovigilance

Effective regulatory integration is essential for routine adoption of AI in PV. Transparency data integrity, validation, and human oversights in AI - enabled systems have been highlighted by regulatory bodies worldwide, including the FDA, EMA, and UMC (Uppsala Monitoring Centre, 2023; European Medicines Agency, 2023; Food and Drug Administration 2023.). the Vigimatch and VigiRank tools from UMC are notable from UMC are notable examples of how some ML applications may be successfully included into the regular tasks of regulatory PV operations. To standardize AI adoption throughout the PV lifetime, collaborative initiatives like Transcelerate and the CIOMS working XIV are actively creating frameworks for validation and guidance.

Additioanlly, AI enhances regulatory intelligence by making it possible to automatically analyze safety communications, labeling revisions and regulatory papers (Rajkomar *et al.*, 2019).

Real-World Implementation Of AI In Pharmacovigilance: Case Studies

Case Study 1: WHO-Uppsala Monitoring Centre (VigiBase)

The World Health Organization (WHO), through the Uppsala Monitoring Centre (UMC), has successfully integrated artificial intelligence into global pharmacovigilance activities. VigiBase, the world's largest repository of Individual Case Safety Reports (ICSRs), incorporates AI-based tools such as vigiMatch for duplicate report detection and vigiRank for signal prioritization. These tools assist pharmacovigilance experts by improving data quality, prioritizing clinically relevant safety signals, and reducing manual workload while maintaining expert oversight (Caster *et al.*, 2017; Uppsala Monitoring Centre, 2023).

Case Study 2: FDA Sentinel Initiative

The U.S. Food and Drug Administration (FDA) Sentinel Initiative represents another successful implementation of AI-supported pharmacovigilance. The Sentinel System utilizes real-world healthcare data, including electronic health records, insurance claims, and pharmacy databases, to support active surveillance of drug safety. Machine learning and advanced analytics facilitate early detection of potential adverse drug reactions and enable more timely regulatory decision-making. During COVID-19

vaccine surveillance, AI-assisted analytical approaches supported continuous safety monitoring while complementing expert clinical assessment (Platt *et al.*, 2018; Food and Drug Administration, 2023).

These examples demonstrate that AI has progressed beyond experimental research and is now being successfully integrated into routine pharmacovigilance practice. Rather than replacing human experts, AI serves as a decision-support technology that enhances the efficiency, accuracy, and timeliness of drug safety surveillance.

CHALLENGES AND LIMITATIONS

Algorithmic Bias And Data Representativeness

When applied to different populations, a non-representative dataset used to create AI models runs the risk of bias (Chen *et al.*, 2019). The need for diversified, high-quality training data, missing safety, and mitigation techniques may be highlighted by the underrepresentation of particular categories of people.

Temporal Dynamics And Model Drift

Over time, drug safety profiles evolve. In order to remain stable and complaint with regulations, AI systems must continue to learn and be able to adjust to new information (Chen *et al.*, 2019).

Causality In Polypharmacy

Although AI proved effective at identifying correlations, it is still difficult to demonstrate causal linkages, particularly in polypharmacy cases (Wiens *et al.*, 2019). For the purpose of developing practical regulatory insights, it is crucial to use causal inference frameworks such as propensity score approaches and causal graphs.

Explainable AI And Trust

Advanced AI systems operate as "black-box" systems which create major challenges that prevent regulators from accepting their use. Although Explainable AI (XAI) technique like SHAP and LIME, improve transparency but still have drawbacks in extremely complicated models. For model performance and regulatory trust to be balanced, context-specific explainability must be defined (Lundberg and Lee, 2017; Ribeiro *et al.*, 2016).

Ethical And Legal Considerations

The ethical deployment of AI in PV requires safeguarding patient privacy, ensuring fairness, minimizing bias, and maintaining accountability (Chen *et al.*, 2019; European Commission, 2019). It is crucial to abide by data protection laws (such as GDPR and HIPAA) and implement privacy-preserving strategies like federated learning. Human-in-the-loop governance models are essential for ensuring patient-centric decision-making (European Union, 2018; U.S. Department of Health and Human Services, 2022).

The full potential of AI in drug safety surveillance will be achieved through regulatory framework development which needs to proceed together with these technological advancements.

CONCLUSION

Artificial intelligence has become a revolutionary technology that allows modern pharmacovigilance systems to handle the increasing complexities and massive worldwide drug safety databases. AI systems improved adverse drug reaction detection, signal detection and real-time monitoring while reinforcing human supervision and regulatory accountability. The current challenges of bias and interpretability, causality assessment, and ongoing advances in explainable, federated and multimodal AI, aligned with developing a regulatory framework, position AI as a credible and an indispensable component of future drug safety surveillance systems. Future researchers need to work on building AI that are explainable, federated, and can handle multiple types of data. Setting regulatory frameworks and ethical guidelines, together, these step make AI-based Pharmacovigilance systems more reliable, transparent, and easier to use worldwide.

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ABBREVIATIONS

ADR: Adverse Drug Reaction; **AI**: Artificial Intelligence; **BCPNN:** Bayesian confidence Propagation Neural Network; **EHRs:** Electronic Health Records; **EMA:** European Medicines Agency; **FAERS:** Food and Drug Administration's Adverse Event Reporting System; **FDA:** Food and Drug Administration; **GDPR:** General Data Protection Regulation; **ICSRs:** Individual Case Safety Reports; **LMIC:** Low- and Middle-Income Country; **MeSH:** Medical Subject Headings; **MFDS:** Ministry of Food and Drug Safety; **MGPS:** Multi-item Gamma Poisson Shrinker; **ML:** Machine Learning; **NLP:** Natural Language Processing; **NMPA:** National Medical Products Administration; **PMDA:** Pharmaceuticals and Medical Devices Agency; **PV:** Pharmacovigilance; **ROC-AUC:** receiver operating characteristic area under the curve; **SRS:** Spontaneous Reporting Systems; **UMC:** Uppsala Monitoring Centre; **WHO:** World Health Organization; **XAI:** Explainable AI.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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