

# Artificial Intelligence-Driven Pharmacovigilance 5.0: A Systematic Review and Future Framework for Predictive Drug Safety Surveillance Using Machine Learning and Digital Health Technologies

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**Abstract-** Pharmacovigilance is a critical component of healthcare systems responsible for ensuring medicine safety through detection, assessment, understanding, and prevention of adverse drug reactions. Conventional approaches based on spontaneous reporting and manual evaluation face challenges including under-reporting, delayed signal detection, fragmented healthcare information, and limited predictive capability. This review explores the transformative role of Artificial Intelligence (AI) in Pharmacovigilance 5.0 by integrating machine learning, deep learning, natural language processing, predictive analytics, and real-world evidence. AI-driven systems have demonstrated potential in adverse drug reaction detection, safety signal identification, risk prediction, and regulatory decision support. The manuscript discusses emerging opportunities, technological frameworks, regulatory challenges, and future perspectives for establishing intelligent, predictive, and patient-centric drug safety surveillance systems.

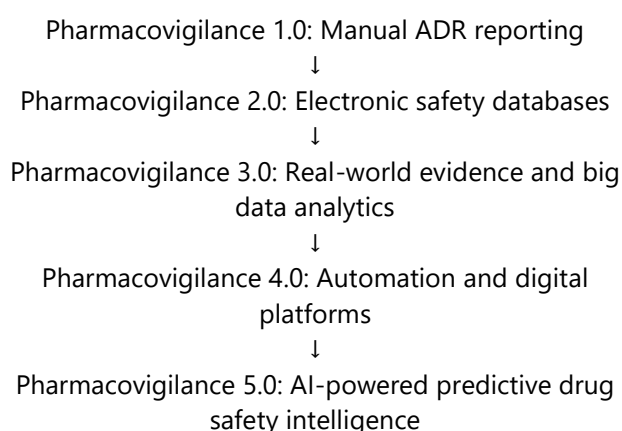
**Keywords—** Artificial Intelligence; Pharmacovigilance 5.0; Machine Learning; Deep Learning; Adverse Drug Reactions; Drug Safety Surveillance; Natural Language Processing; Predictive Analytics; Digital Health; Explainable AI; Regulatory Science

## I. INTRODUCTION

Pharmacovigilance has evolved from traditional spontaneous reporting systems towards advanced data-driven approaches. The increasing complexity of medicines and expansion of healthcare data require innovative methods capable of real-time safety monitoring.

Artificial Intelligence provides advanced computational capabilities for analysing large healthcare datasets, identifying hidden patterns, and predicting potential medicine-related risks. Pharmacovigilance 5.0 represents a future-oriented framework combining AI technology, regulatory expertise, and clinical intelligence.

## II. EVOLUTION OF PHARMACOVIGILANCE



### III. AI TECHNOLOGIES IN PHARMACOVIGILANCE

Machine Learning: ADR prediction, risk modelling, and signal prioritization.

Natural Language Processing: Extraction of safety information from clinical notes, literature, and patient-generated data.

Deep Learning: Analysis of complex healthcare datasets for improved safety prediction.

Explainable AI | Transparent decision making | Regulatory trust

#### Challenges and Future Perspectives

Major challenges include data privacy, algorithm transparency, ethical concerns, regulatory acceptance, standardization, and clinical validation.

Future opportunities include digital twins, blockchain-based safety systems, wearable monitoring, generative AI, and personalized pharmacovigilance.

### IV. AI APPLICATIONS IN DRUG SAFETY

- Automated adverse drug reaction detection
- Intelligent safety signal management
- Real-world evidence analysis
- Social media pharmacovigilance
- Predictive risk assessment
- Regulatory decision support

### VII. CONCLUSION

Artificial Intelligence-driven Pharmacovigilance 5.0 represents a major transition from reactive safety monitoring towards predictive, preventive, and personalized drug safety management. Responsible AI implementation can strengthen global medicine safety and improve patient outcomes.

### V. PROPOSED AI PHARMACOVIGILANCE 5.0 FRAMEWORK

#### Healthcare Data Sources

(EHRs, Clinical Trials, Databases, Wearables)



AI Processing Layer

(ML, DL, NLP, Predictive Analytics)



Safety Intelligence Layer

(ADR Prediction, Signal Detection, Risk Assessment)



Human and Regulatory Decision Layer

(Healthcare Professionals and Authorities)

### VI. COMPARATIVE ANALYSIS OF AI TECHNOLOGIES

Technology | Application | Major Advantage

Machine Learning | ADR prediction and classification  
| Pattern recognition

Natural Language Processing | Literature and clinical  
text mining | Automated information extraction

Deep Learning | Complex data analysis | High  
predictive capability

### REFERENCES

1. World Health Organization. Pharmacovigilance and digital health initiatives.
2. Liang L et al. Artificial Intelligence-Based Pharmacovigilance. Drug Safety. 2022.
3. Topol EJ. High-performance medicine: convergence of human and artificial intelligence. Nature Medicine. 2019.
4. Rajkomar A et al. Machine Learning in Medicine. New England Journal of Medicine. 2019.
5. Beam AL, Kohane IS. Big Data and Machine Learning in Health Care. JAMA. 2018.
6. Vamathevan J et al. Applications of Machine Learning in Drug Discovery and Development. Nature Reviews Drug Discovery. 2019.