WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
Coden USA: WJPRAP Impact Factor 8.63
Volume 15, Issue 18, 421-437. Review Article ISSN 2277–7105

APPLICATION OF ARTIFICIAL INTELLIGENCE IN PHARMACOVIGILANCE FOR AUTOMATED ADVERSE DRUG REACTION DETECTION AND REGULATORY COMPLIANCE

Tippareddy Narendra*, B. Ramarao, M. Prasada Rao

Department of Pharmaceutical Regulatory Affairs, M. A. M College of Pharmacy, Kesanupalli, Narasaraopet, Palnadu District, AndhraPradesh, India, 522601.

Article Received on 16 August 2026,
Article Revised on 05 September 2026,
Article Published on 16 Sept. 2026,

https://doi.org/10.5281/zenodo.22768803

***Corresponding Author**

Tippareddy Narendra

Department of Pharmaceutical Regulatory Affairs, M. A. M College of Pharmacy, Kesanupalli, Narasaraopet, Palnadu district, AndhraPradesh, India, 522601.

How to cite this Article: Tippareddy Narendra*, B. Ramarao, M. Prasada Rao. (2026). Application of Artificial Intelligence In Pharmacovigilance For Automated Adverse Drug Reaction Detection and Regulatory Compliance. World Journal of Pharmaceutical Research, 15(18), 421–437.

ABSTRACT

Pharmacovigilance is essential for continuous monitoring of medicine safety and prevention of adverse drug reactions. Traditional pharmacovigilance approaches depend mainly on spontaneous reporting and manual evaluation, resulting in underreporting, delayed signal identification and difficulties in managing large healthcare datasets. Artificial intelligence (AI) has emerged as a powerful technology for improving drug safety surveillance through automated data processing, pattern recognition and predictive analysis. Machine learning, deep learning and natural language processing enable efficient extraction of safety information from structured and unstructured sources including electronic health records, clinical trials, scientific literature, social media and regulatory databases. AI-based pharmaco vigilance systems support automated adverse drug reaction detection, individual case safety report processing, signal prioritization and regulatory compliance. Major databases such as FAERS, Vigi Base and Eudra Vigilance provide important resources for AI model development and validation. However, challenges related to data quality, transparency, privacy, algorithm validation and regulatory acceptance must be addressed for reliable implementation. This review discusses AI applications in pharmacovigilance, data sources, regulatory considerations, limitations and future opportunities for developing proactive and intelligent drug safety systems.

KEYWORDS: Artificial Intelligence; Pharmacovigilance; Adverse Drug Reaction Detection; Machine Learning; Natural Language Processing; Signal Management; Drug Safety; Regulatory Compliance.

1. INTRODUCTION[1-4]

Pharmacovigilance (PV) is an essential component of healthcare systems that focuses on the detection, assessment, understanding, and prevention of adverse drug reactions (ADRs) and other medicine-related problems. The primary objective of pharmacovigilance is to ensure the continuous evaluation of the benefit–risk profile of medicines throughout their entire lifecycle, beginning from clinical development and extending to post-marketing surveillance. Although extensive preclinical and clinical evaluations are conducted before regulatory approval, many safety concerns may remain unidentified due to limitations associated with clinical trial populations, restricted study durations, and controlled experimental conditions. Therefore, continuous monitoring of medicines after approval is critical for identifying rare, delayed, or long-term adverse effects. Adverse drug reactions represent a major public health concern worldwide, contributing significantly to patient morbidity, mortality, prolonged hospitalization, and increased healthcare expenditure. ADRs may occur due to pharmacological effects, drug–drug interactions, genetic variability, inappropriate use, or unpredictable immune-mediated mechanisms. Conventional pharmacovigilance systems primarily depend on spontaneous reporting mechanisms, where healthcare professionals, patients, and pharmaceutical companies submit suspected ADR reports to regulatory databases. Although these systems have successfully identified numerous important safety signals, they are associated with several limitations, including underreporting, incomplete information, reporting bias, delayed signal recognition, and extensive manual workload. The rapid expansion of pharmaceutical development, increasing global medicine utilization, and the emergence of complex therapeutic modalities have resulted in an exponential increase in pharmacovigilance data. Modern drug safety monitoring involves the evaluation of multiple heterogeneous data sources, including Individual Case Safety Reports (ICSRs), electronic health records (EHRs), clinical trial databases, medical literature, patient registries, social media platforms, and other real-world evidence (RWE) sources. These datasets are often characterized by large volume, high velocity, diverse formats, and significant amounts of unstructured information. Traditional analytical approaches are often insufficient to efficiently process such complex datasets, creating the need for advanced computational technologies. Artificial intelligence (AI) has emerged as a transformative technology capable

of addressing several challenges associated with conventional pharmacovigilance practices. AI refers to the simulation of human intelligence by computer-based systems capable of learning from data, identifying patterns, performing reasoning, and supporting decision-making. In healthcare, AI technologies have demonstrated significant potential in diagnosis, personalized medicine, clinical decision support, and biomedical research. Within pharmacovigilance, AI provides opportunities to improve ADR detection, automate case processing, enhance signal management, and support regulatory decision-making.

Machine learning (ML), one of the most widely applied branches of AI, enables computer systems to learn from historical datasets and develop predictive models without explicit programming. ML algorithms such as decision trees, random forests, support vector machines, gradient boosting methods, and neural networks have been investigated for ADR classification, safety signal detection, and risk prediction. These models can analyze large pharmacovigilance databases and identify complex relationships between medicines, patient characteristics, and adverse outcomes that may not be easily recognized through conventional methods. Deep learning (DL), an advanced subset of machine learning, utilizes multilayer artificial neural networks to process complex and high-dimensional datasets. Deep learning models such as convolutional neural networks (CNNs), recurrent neural networks (RNNs), and long short-term memory (LSTM) networks have shown potential in extracting hidden patterns from clinical narratives, medical records, and other complex safety datasets. More recently, transformer-based models and large language models (LLMs) have further expanded AI capabilities by enabling advanced language understanding, information extraction, and automated generation of safety-related documents.

Natural language processing (NLP) represents another important AI technology in pharmacovigilance because a significant proportion of safety information exists in unstructured textual formats. Clinical notes, case narratives, scientific publications, regulatory documents, and patient communications contain valuable safety information that requires extensive manual review. NLP techniques such as named entity recognition, text classification, sentiment analysis, and relation extraction enable automated identification of drug names, adverse events, patient characteristics, and drug-event relationships. These approaches significantly reduce manual workload and improve the efficiency of pharmacovigilance operations. AI-driven pharmacovigilance also supports regulatory compliance by improving the accuracy, consistency, and timeliness of safety reporting.

Regulatory authorities including the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), World Health Organization (WHO), and International Council for Harmonisation (ICH) emphasize the importance of reliable safety monitoring systems. AI-based solutions can assist in automated Individual Case Safety Report processing, MedDRA coding, duplicate detection, signal prioritization, periodic safety report preparation, and risk management activities. Despite its considerable advantages, implementation of AI in pharmacovigilance requires careful consideration of several challenges. Data quality, standardization, algorithm transparency, explainability, privacy protection, cybersecurity, and regulatory validation remain critical concerns. Many advanced AI models operate as "black-box" systems, making it difficult to understand how specific predictions are generated. Therefore, explainable artificial intelligence (XAI), human oversight, and robust validation frameworks are essential for ensuring reliable and ethical implementation.

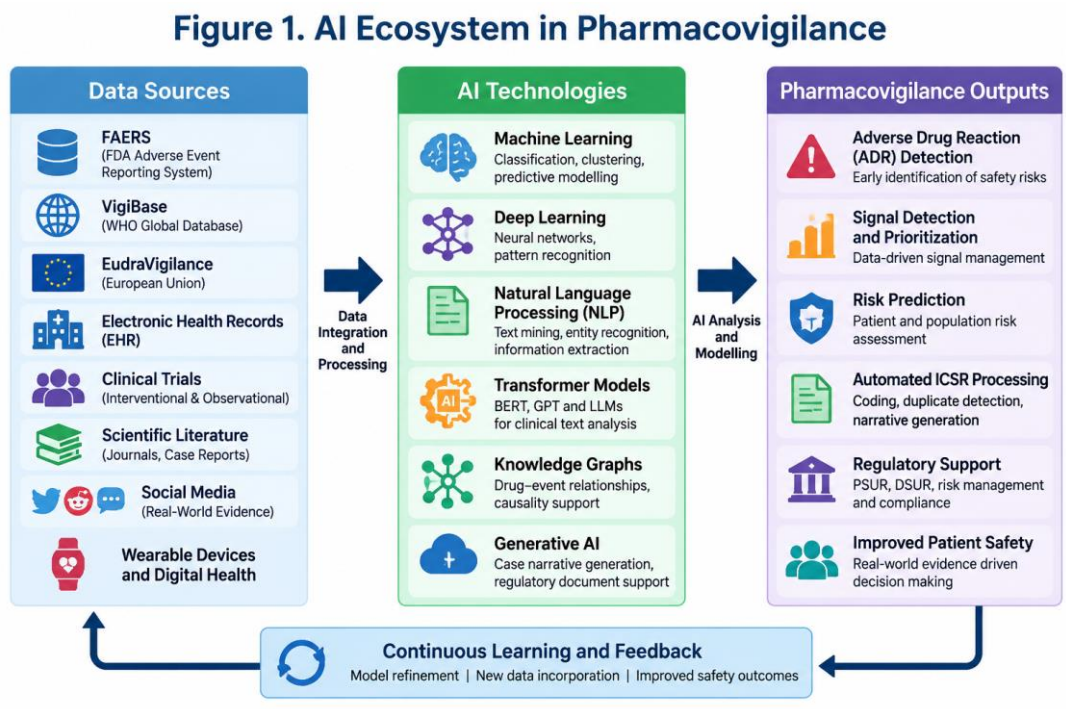

Figure 1: Integrated AI ecosystem showing data sources, AI technologies and pharmacovigilance outputs.

Table 1: Comparison of Conventional and AI-Based Pharmacovigilance.

Parameter	Conventional PV	AI-Based PV
Data processing	Manual	Automated
Signal detection	Delayed	Near real-time
Data handling	Limited	Large-scale
Analysis	Statistical	Predictive AI models

2. AI Technologies Used in Pharmacovigilance[5-10]

Artificial intelligence (AI) has emerged as a transformative technology in pharmacovigilance by enabling automated analysis of large-scale healthcare datasets, improving adverse drug reaction (ADR) detection, accelerating safety signal identification, and supporting regulatory decision-making. Pharmacovigilance activities involve the analysis of heterogeneous data obtained from spontaneous reports, clinical trials, electronic health records (EHRs), scientific literature, social media, and real-world evidence (RWE). The complexity, volume, and diversity of these datasets exceed the capabilities of conventional manual approaches, creating a need for advanced computational methods.

AI technologies used in pharmacovigilance mainly include machine learning (ML), deep learning (DL), natural language processing (NLP), transformer-based models, knowledge graphs, and generative artificial intelligence (Generative AI)**.** These technologies can analyze structured and unstructured safety data, identify hidden relationships between drugs and adverse events, predict potential risks, and improve the efficiency of pharmacovigilance workflows.

2.1 Machine Learning in Pharmacovigilance

Machine learning (ML) is one of the most widely applied AI approaches in pharmacovigilance. ML algorithms enable computer systems to learn from historical pharmacovigilance datasets and identify patterns associated with adverse drug reactions without requiring explicit programming. These models improve continuously as additional safety data become available.

ML techniques are broadly categorized into

1. Supervised Learning

Supervised learning algorithms are trained using labeled datasets containing known examples of ADR and non-ADR cases. The model learns relationships between input variables and outcomes and subsequently predicts new safety events.

Common supervised learning algorithms include

- Logistic regression
- Decision trees
- Random forest
- Support vector machines (SVM)

- Gradient boosting algorithms
- Artificial neural networks

Applications in pharmacovigilance include

- ADR classification
- Case prioritization
- Seriousness assessment
- Drug-event association prediction
- Patient risk prediction

For example, ML models can analyze patient demographics, drug exposure information, clinical characteristics, and previous adverse events to estimate the probability of developing a specific ADR.

2. Unsupervised Learning

Unsupervised learning identifies hidden patterns and relationships within datasets without predefined labels. This approach is particularly useful for exploring large pharmacovigilance databases where unexpected safety signals may exist.

Major techniques include

- Clustering algorithms
- Principal component analysis (PCA)
- Association rule mining

Applications include

- Identification of unknown ADR patterns
- Patient subgroup analysis
- Detection of unusual drug-event combinations
- Discovery of emerging safety concerns

Unsupervised approaches can complement traditional statistical signal detection methods by identifying previously unrecognized relationships.

3. Reinforcement Learning

Reinforcement learning is an advanced ML approach where algorithms learn through interactions with an environment and optimize decisions based on feedback.

Potential applications in pharmacovigilance include

- Automated prioritization of safety cases
- Adaptive monitoring strategies
- Optimization of regulatory workflows

2.2 Deep Learning in Pharmacovigilance

Deep learning (DL) represents an advanced form of machine learning based on artificial neural networks with multiple computational layers. Unlike traditional ML methods, deep learning models can automatically extract important features from raw data without extensive manual feature engineering.

Deep learning is particularly valuable for pharmacovigilance because safety information is often complex, high-dimensional, and unstructured.

Major deep learning architectures include

1. Artificial Neural Networks (ANNs)

Artificial neural networks mimic biological neural systems by processing information through interconnected computational nodes.

Applications

- ADR prediction
- Risk assessment
- Classification of safety reports
- Pattern recognition

2. Convolutional Neural Networks (CNNs)

CNNs are mainly used for image-based and spatial data analysis but have also been applied for extracting patterns from complex medical datasets.

Potential pharmacovigilance applications

- Analysis of medical images associated with drug reactions
- Identification of visual biomarkers
- Clinical data classification

3. Recurrent Neural Networks (RNNs)

RNNs are designed for sequential data analysis and are useful for evaluating time-dependent information.

Applications

- Longitudinal patient records
- Temporal ADR patterns
- Drug exposure sequences

4. Long Short-Term Memory Networks (LSTM)

LSTM networks are advanced RNN models capable of remembering long-term dependencies within sequential data.

Applications

- Analysis of patient histories
- Prediction of delayed ADRs
- Monitoring disease progression after drug exposure

2.3 Natural Language Processing (NLP) in Pharmacovigilance

A large proportion of pharmacovigilance information exists in unstructured text formats, including:

- Individual case safety reports (ICSRs)
- Clinical narratives
- Electronic health records
- Scientific publications
- Regulatory documents
- Patient forums and social media

Natural language processing (NLP) enables computers to understand, interpret, and extract meaningful information from human language.

Important NLP techniques include

1. Named Entity Recognition (NER)

NER identifies important entities from text documents.

Examples:

- Drug names

- Adverse events
- Diseases
- Patient characteristics
- Laboratory findings

2. Text Classification

NLP-based classification models categorize documents according to predefined criteria.

Applications:

- Serious vs non-serious ADR classification
- Expected vs unexpected events
- Medical review prioritization

3. Sentiment Analysis

Sentiment analysis evaluates patient-generated content from:

- Social media
- Patient communities
- Online health platforms

Applications

- Identification of patient-reported adverse effects
- Understanding patient experiences
- Early safety signal generation

4. Information Extraction

NLP automatically extracts relationships between:

- Drug
- Dose
- Duration
- Reaction
- Outcome

This supports automated ICSR processing and reduces manual workload.

2.4 Transformer-Based Models and Large Language Models (LLMs)

Recent advances in AI have introduced transformer-based architectures that have significantly improved natural language understanding.

Examples

- BERT (Bidirectional Encoder Representations from Transformers)
- BioBERT
- ClinicalBERT
- GPT-based large language models

Applications in pharmacovigilance include

Automated case processing

- Extraction of patient information
- ADR identification
- Narrative summarization

Literature monitoring

- Automated screening of publications
- Identification of relevant safety information

Regulatory documentation support

- Safety narrative generation
- Periodic report assistance
- Regulatory intelligence

Transformer models provide improved contextual understanding compared with conventional NLP methods.

2.5 Knowledge Graphs in Pharmacovigilance

Knowledge graphs represent relationships between different entities such as:

- Drugs
- Diseases
- Adverse events
- Genes
- Biological pathways

They create interconnected networks that support advanced safety analysis

Applications

- Drug-event relationship identification
- Mechanism-based ADR prediction

- Causality assessment
- Drug interaction analysis

Knowledge graphs can integrate information from multiple sources, including literature databases, clinical records, and regulatory databases.

2.6 Generative Artificial Intelligence in Pharmacovigilance

Generative AI represents a new generation of AI systems capable of producing human-like text and supporting knowledge-based tasks.

Applications include

Automated ICSR Narrative Generation

AI can assist in preparing standardized safety narratives from collected case information.

Literature Review Automation

Generative AI can

- Screen scientific publications
- Extract relevant safety information
- Summarize evidence

Regulatory Support

Potential applications include

- Preparation of safety reports
- Regulatory document assistance
- Risk management documentation

However, human review and validation remain essential because generated information must comply with regulatory requirements.

Table 2: Summary of AI Technologies Used in Pharmacovigilance.

AI Technology	Principle	Major Applications
Machine Learning	Pattern learning from data	ADR prediction, classification, signal detection
Deep Learning	Neural network-based analysis	Complex data processing, risk prediction
NLP	Text understanding and extraction	Literature mining, ICSR processing
Transformers	Context-based language modelling	Clinical text analysis, report generation
Knowledge Graphs	Relationship mapping	Drug-event association,

		causality support
Generative AI	Content generation	Narratives, regulatory documentation

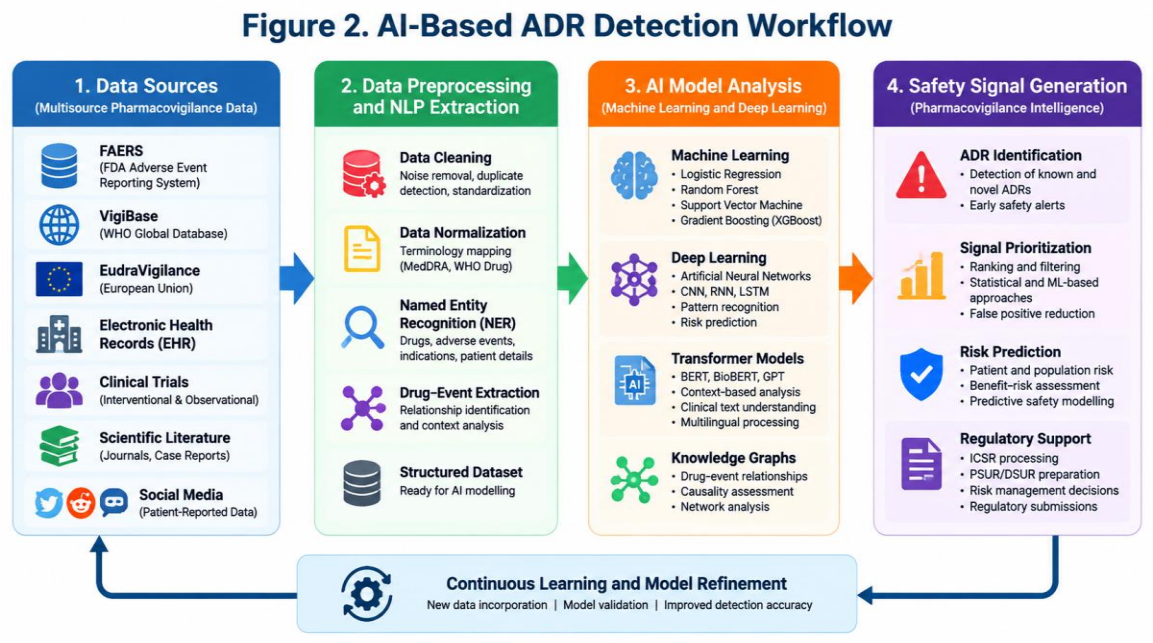

Figure 2: AI-Based ADR Detection Workflow.

3. Pharmacovigilance Data Sources and Management[11-15]

Pharmacovigilance (PV) is a data-intensive discipline that depends on the systematic collection, processing, analysis, and interpretation of safety information associated with medicinal products. The effectiveness of pharmacovigilance systems largely depends on the availability, quality, completeness, and reliability of safety data. With the rapid expansion of healthcare digitalization, pharmacovigilance has evolved from traditional spontaneous reporting systems toward integrated data-driven approaches involving artificial intelligence (AI), machine learning, and real-world evidence (RWE) analytics.

Modern pharmacovigilance systems utilize multiple heterogeneous data sources, including spontaneous adverse event reports, clinical trial databases, electronic health records (EHRs), scientific literature, regulatory databases, patient registries, social media platforms, and digital health technologies. These diverse datasets contain valuable information regarding drug exposure, patient characteristics, adverse events, treatment outcomes, and potential safety signals.

However, pharmacovigilance data are often complex due to variations in reporting formats, incomplete information, duplicate records, inconsistent terminology, and large volumes of

unstructured text. Therefore, effective data management involving data cleaning, standardization, integration, and advanced analytical methods is essential for generating reliable safety intelligence.

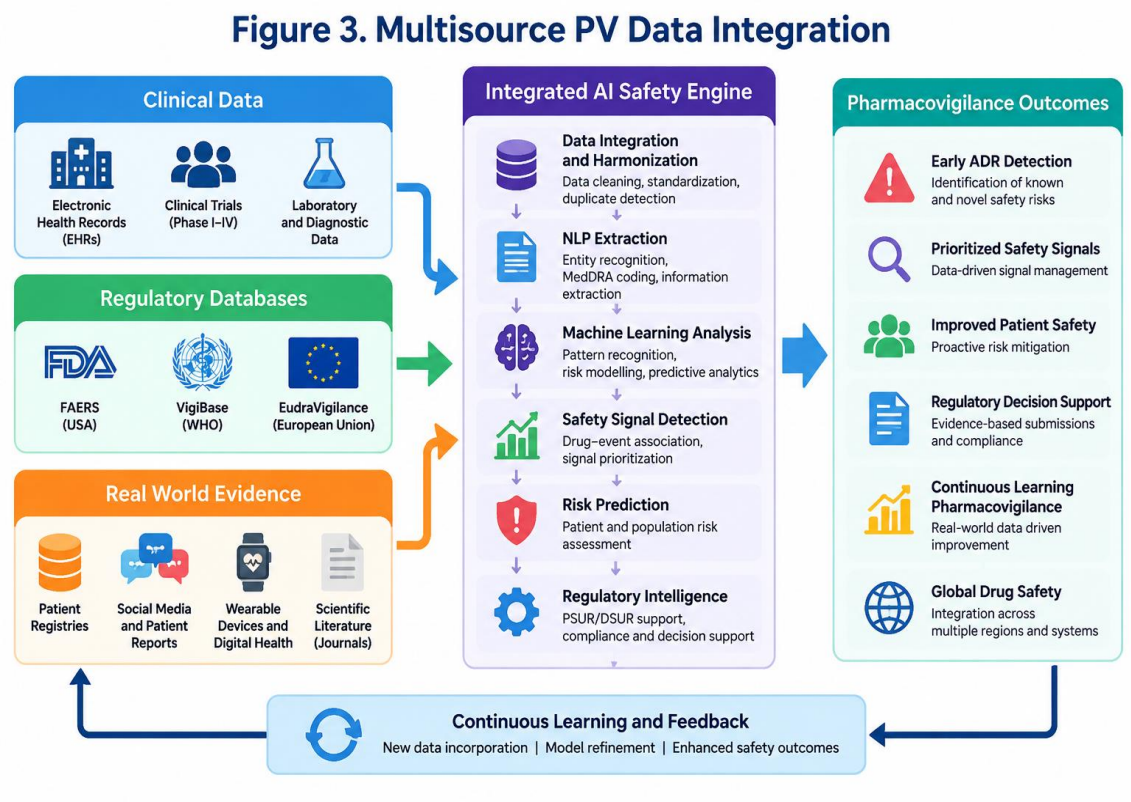

Figure 3: Multisource Pharmacovigilance Data Integration Model.

4. Regulatory Compliance and Future Perspectives[16-20]

Regulatory compliance is a fundamental component of pharmacovigilance (PV) systems because drug safety activities must follow internationally accepted guidelines to ensure accurate reporting, reliable safety assessment, and protection of public health. The increasing adoption of artificial intelligence (AI) in pharmacovigilance has created new opportunities for improving regulatory processes through automation, advanced analytics, and real-time safety monitoring. However, successful implementation of AI requires alignment with existing regulatory expectations related to data integrity, model validation, transparency, cybersecurity, and human oversight.

Regulatory agencies including the **U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), World Health Organization (WHO), and International Council for Harmonisation (ICH)** have emphasized the importance of maintaining scientifically valid, transparent, and reproducible pharmacovigilance processes. AI-based

systems must therefore complement existing pharmacovigilance frameworks rather than replace expert evaluation and regulatory decision-making.

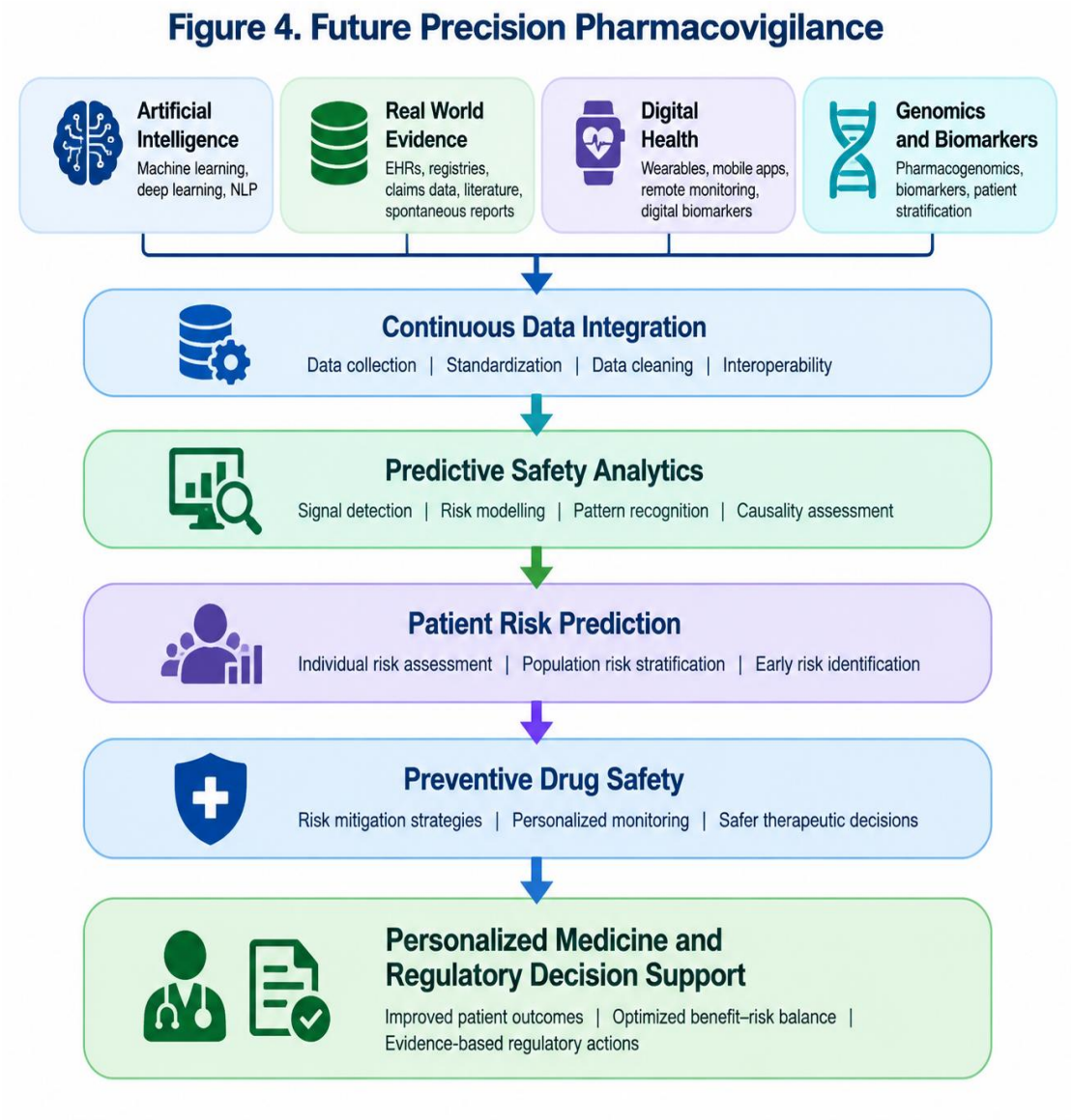

Figure 4: Future Precision Pharmacovigilance Framework.

5. CONCLUSION

Artificial intelligence is rapidly transforming pharmacovigilance by enabling a shift from traditional reactive safety monitoring approaches toward proactive, predictive, and patient-centered drug safety systems. The integration of machine learning, deep learning, natural language processing, transformer-based models, knowledge graphs, and generative AI has significantly improved the ability to process large and complex pharmacovigilance datasets derived from spontaneous reports, electronic health records, clinical trials, scientific literature, regulatory databases, and real-world evidence sources. AI-based approaches

provide valuable support in multiple pharmacovigilance activities, including automated adverse drug reaction (ADR) detection, individual case safety report (ICSR) processing, signal identification, risk prediction, literature surveillance, and regulatory documentation. By integrating multisource healthcare data and applying advanced analytical models, AI systems can enhance early detection of potential safety concerns, improve signal prioritization, reduce manual workload, and support evidence-based regulatory decision-making. Despite these advantages, successful implementation of AI in pharmacovigilance requires addressing important challenges related to data quality, algorithm transparency, model validation, privacy protection, cybersecurity, and regulatory acceptance. Explainability and human oversight remain essential to ensure that AI-generated insights are scientifically reliable and clinically meaningful. Regulatory frameworks must continue evolving to establish standardized approaches for validation, monitoring, and lifecycle management of AI-based pharmacovigilance systems.

The future of pharmacovigilance will be driven by the integration of AI with real-world evidence, digital health technologies, wearable devices, and precision medicine approaches. Future AI-enabled platforms are expected to provide continuous safety monitoring, personalized risk prediction, early ADR prevention, and improved benefit–risk assessment throughout the medicine lifecycle. Therefore, responsible adoption of artificial intelligence, supported by regulatory harmonization and interdisciplinary collaboration, has the potential to create a smarter, more efficient, and globally connected pharmacovigilance ecosystem that ultimately improves patient safety and healthcare outcomes.

5. REFERENCES

1. World Health Organization. **WHO Guidelines on Safety Monitoring of Medicinal Products: Pharmacovigilance Systems and Their Role in Public Health.** Geneva: World Health Organization, 2004.
2. World Health Organization. **The Importance of Pharmacovigilance: Safety Monitoring of Medicinal Products.** Geneva: WHO, 2002.
3. U.S. Food and Drug Administration (FDA). **FDA Adverse Event Reporting System (FAERS): Database and Safety Reporting System.** Silver Spring, MD: FDA, 2024.
4. European Medicines Agency (EMA). **Guideline on Good Pharmacovigilance Practices (GVP): Modules I–XVI.** Amsterdam: European Medicines Agency, 2024.

5. International Council for Harmonisation (ICH). **E2A: Clinical Safety Data Management—Definitions and Standards for Expedited Reporting.** Geneva: ICH, 1994.
6. International Council for Harmonisation (ICH). **E2B(R3): Clinical Safety Data Management—Data Elements for Transmission of Individual Case Safety Reports.** Geneva: ICH, 2012.
7. International Council for Harmonisation (ICH). **E2C(R2): Periodic Benefit-Risk Evaluation Report (PBRER).** Geneva: ICH, 2012.
8. Bate A, Evans SJW. **Quantitative signal detection using spontaneous ADR reporting.** Pharmacoepidemiol Drug Saf., 2009; 18(6): 427-436.
9. Harpaz R, DuMouchel W, Shah NH, Madigan D, Ryan P, Friedman C. **Novel data-mining methodologies for adverse drug event discovery and analysis.** Clin Pharmacol Ther., 2012; 91(6): 1010-1021.
10. Hauben M, Bate A. **Decision support methods for the detection of adverse drug reactions.** Drug Discov Today, 2009; 14(7-8): 343-357.
11. Yang CC, Yang H, Jiang L, Zhang M. **Social media mining for drug safety surveillance.** J Biomed Inform, 2015; 58: 202-210.
12. Sarker A, Gonzalez G. **Portable automatic text classification for adverse drug reaction detection using machine learning.** J Biomed Inform, 2015; 53: 187-196.
13. Wang L, Liu J, Fang H. **Natural language processing for pharmacovigilance: extracting adverse drug reactions from biomedical literature and clinical data.** Drug Saf., 2020; 43: 1-15.
14. Wu Y, Xu J, Zhang Y, et al. **Biomedical natural language processing and its applications in pharmacovigilance.** Brief Bioinform, 2021; 22(5): bbab123.
15. Harrer S. **Attention is not all you need: the complicated case of ethically using large language models in healthcare.** Patterns, 2023; 4(4): 100730.
16. Beam AL, Kohane IS. **Big data and machine learning in health care.** JAMA, 2018; 319(13): 1317-1318.
17. Brahmaiah Bonthagarala, Lakshmi Prasanthi Nori, Maddala Lohitha, Rama Rao Vadapalli, Venkateswara Raju Kalidindi, Revolutionizing Healthcare: The Impact of AI on Precision Medicine, International Journal of Pharmaceutical Investigation, Apr-Jun, 2025; 15(2).
18. Brahmaiah Bonthagarala, Lakshmi Prasanthi Nori, Jyothirmai Malla, Rama Rao Vadapalli2, Praveen Kumar Dannaram, Kalidindi Venkateswara Raju, Exploring the

Healing Paths: Navigating Complementary and Alternative Medicine, International Journal of Pharmaceutical Investigation, Jul-Sep, 2025; 15(3).

19. Topol EJ. **High-performance medicine: the convergence of human and artificial intelligence.** Nat Med., 2019; 25: 44-56.
20. Rajkomar A, Dean J, Kohane I. **Machine learning in medicine.** N Engl J Med., 2019; 380: 1347-1358.