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Review

Artificial Intelligence in Pharmacovigilance: Advances in Automation, Deep Learning, Signal Detection, and Real-World Data Analytics

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	Abstract
Published on: 17.03.2026	Artificial intelligence (AI) is reshaping pharmacovigilance (PV) by improving the detection, evaluation, and prevention of adverse drug reactions. Traditional PV processes are limited by manual case handling and delayed signal detection, whereas modern AI methods machine learning, deep learning, and natural language processing enable rapid analysis of large, complex, and unstructured real-world data. These technologies enhance automation of case processing, improve extraction of safety information from electronic health records and social media, and uncover subtle patterns that support earlier and more accurate signal detection. Despite these advances, challenges remain related to data quality, model transparency, regulatory expectations, and integration into existing PV workflows. This review summarizes recent progress, applications, and future directions of AI in pharmacovigilance, emphasizing its growing role in automation, deep learning, signal detection, and real-world data analytics.
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ARTIFICIAL INTELLIGENCE (AI) IN PHARMACOVIGILANCE (PV)

Artificial intelligence (AI) has become an important technological tool for improving pharmacovigilance (PV) activities by increasing

operational efficiency and reducing the cost associated with manual safety case processing. Traditional pharmacovigilance systems rely heavily on manual review of large volumes of safety reports, which can be time-consuming and resource

intensive.¹ The integration of AI technologies enables automated processing, faster data analysis, and improved accuracy in safety monitoring. By applying advanced computational models, pharmacovigilance systems can identify safety signals more efficiently and support timely regulatory decision-making. AI technologies are widely used in healthcare for several purposes including disease diagnosis, clinical decision support, treatment optimization, and predictive health analytics. In modern healthcare environments, AI algorithms can process large and complex datasets derived from electronic health records, clinical trials, insurance claims databases, and patient-reported outcomes. These intelligent systems can identify hidden patterns within large datasets and generate insights that may not be easily detectable through traditional analytical methods. In pharmacovigilance, AI systems employ sophisticated machine learning algorithms, natural language processing techniques, and deep learning architectures to extract relevant safety information from both structured and unstructured data sources.² These technologies enable automated extraction of adverse event information from clinical narratives, medical literature, regulatory databases, and social media platforms. Because AI models are capable of continuous learning and self-improvement through exposure to new data, they can progressively enhance the accuracy and reliability of pharmacovigilance analyses.

The adoption of AI in pharmacovigilance has expanded rapidly in recent years, with applications across multiple safety monitoring processes. Key areas where AI technologies are increasingly applied include:

- **Individual Case Safety Report (ICSR) Processing** – automated intake, duplicate detection, data extraction, and case triage from structured and unstructured safety reports.
- **Safety Operations Management** – optimization of workflow activities such as case prioritization, medical coding, quality review, and regulatory reporting.
- **Signal Detection and Risk Assessment** – identification of potential safety signals through advanced data mining and predictive modeling techniques.
- **Identification of Target Populations** – detection of patient subgroups that may have increased susceptibility to specific

adverse drug reactions based on demographic, genetic, or clinical characteristics.³

Furthermore, AI-driven pharmacovigilance systems are increasingly incorporating **real-world data analytics, predictive safety modeling, and large language models (LLMs)** to support proactive drug safety surveillance. These advanced technologies have the potential to transform pharmacovigilance from a reactive reporting system into a **predictive and data-driven safety monitoring framework**, ultimately improving patient safety and supporting more effective risk management strategies

MACHINE LEARNING

Machine learning (ML), a major branch of artificial intelligence, plays a crucial role in modern pharmacovigilance by enabling automated analysis of large volumes of drug safety data. Unlike traditional rule-based systems, machine learning algorithms can learn patterns from historical datasets and improve their performance over time without being explicitly programmed.⁴ In pharmacovigilance, this capability is particularly valuable because safety data originate from diverse and complex sources such as clinical trials, spontaneous reporting systems, electronic health records, scientific literature, and patient-reported outcomes. The growing volume of Individual Case Safety Reports (ICSRs) submitted to regulatory databases has made manual processing increasingly challenging. Machine learning models help address this challenge by automating several steps within pharmacovigilance workflows.⁵ These systems can rapidly analyze large datasets, detect patterns associated with adverse drug reactions (ADRs), and support faster identification of potential safety signals. As a result, ML contributes significantly to improving the efficiency, consistency, and scalability of pharmacovigilance operations. Machine learning techniques used in pharmacovigilance can generally be categorized into supervised learning, unsupervised learning, and reinforcement learning approaches. Supervised learning algorithms such as support vector machines, logistic regression, and random forests are commonly applied for classification tasks, including identifying adverse events, categorizing medical terms, and prioritizing safety cases. Unsupervised learning methods, including

clustering and association rule mining, are useful for discovering hidden relationships between drugs and adverse events within large safety databases.⁶ These methods help detect unexpected safety signals that may require further investigation. Another important application of machine learning in pharmacovigilance involves natural language processing (NLP) techniques that extract relevant safety information from unstructured text sources. Clinical narratives, discharge summaries, regulatory reports, and scientific publications often contain valuable safety data that cannot be easily analysed using traditional structured data methods.⁷ Machine learning-based NLP models can automatically identify drug names, adverse reactions, patient characteristics, and temporal relationships within these documents, significantly reducing manual review time. Machine learning is also increasingly used in predictive pharmacovigilance, where models analyze historical safety data to estimate the likelihood of adverse drug reactions occurring in specific patient populations. By incorporating demographic variables, comorbidities, genetic information, and medication histories, ML models can identify individuals who may be at higher risk of experiencing certain adverse reactions. This capability supports personalized medicine approaches and helps healthcare professionals make safer prescribing decisions.⁸

In addition to improving signal detection, machine learning contributes to drug-drug interaction prediction, safety signal prioritization, duplicate report detection, and automated case triage. These capabilities allow pharmacovigilance teams to focus their efforts on clinically significant safety issues rather than routine administrative tasks. Overall, the integration of machine learning into pharmacovigilance systems represents a major advancement in drug safety monitoring. By enabling automated data analysis, improved signal detection, and predictive safety assessment, machine learning technologies have the potential to transform pharmacovigilance into a more efficient, proactive, and data-driven discipline.⁹

INTEGRATING ARTIFICIAL INTELLIGENCE AND MACHINE LEARNING IN PHARMACOVIGILANCE SYSTEMS

The integration of Artificial Intelligence (AI) and Machine Learning (ML) into pharmacovigilance (PV) systems has significantly improved the

efficiency and effectiveness of drug safety monitoring. Traditional pharmacovigilance processes often depend on manual evaluation of safety reports and large datasets, which can delay the identification of potential adverse drug reactions (ADRs). AI and ML technologies enable automated data processing, rapid analysis of complex datasets, and improved detection of safety signals. By incorporating intelligent algorithms into PV workflows, healthcare organizations and regulatory agencies can enhance drug safety surveillance and support more timely risk management decisions.¹⁰ Modern pharmacovigilance platforms integrate AI tools with existing regulatory databases, electronic health records, and real-world data sources. These systems allow continuous monitoring of drug safety information, automated extraction of relevant safety data, and predictive assessment of potential adverse reactions. The following subsections highlight key areas where AI and ML technologies contribute to pharmacovigilance systems.

1.Role of Algorithms in Drug Safety Monitoring

Algorithms play a central role in AI-driven pharmacovigilance systems by enabling automated analysis of large safety datasets. These computational models can analyze complex relationships between drug exposure and adverse events, helping to identify potential safety signals earlier than traditional statistical methods. Machine learning algorithms can detect unusual patterns in safety databases by comparing observed adverse event frequencies with expected values. These models also support classification and prioritization of safety cases based on severity, causality, and clinical relevance. By continuously learning from updated safety data, AI algorithms improve their predictive accuracy over time.¹¹

Furthermore, algorithm-based monitoring systems can assist regulatory agencies and pharmaceutical companies in maintaining proactive surveillance of marketed medicines. This capability allows early identification of potential drug safety issues and supports more effective risk mitigation strategies.

2.Predictive Analytics for Identifying Adverse Drug Reactions

Predictive analytics is an important application of AI and ML in pharmacovigilance. These techniques use historical pharmacovigilance data to forecast potential adverse drug reactions before they become widespread clinical problems.¹² Predictive

models employ various machine learning approaches such as regression analysis, decision trees, random forest algorithms, and neural networks to identify patterns associated with adverse drug reactions. These models analyze multiple patient-related variables including age, gender, medical history, genetic factors, and concurrent medications. By evaluating these factors simultaneously, predictive analytics can help identify populations that may be more susceptible to certain adverse drug reactions. This information supports targeted monitoring strategies and contributes to the development of personalized medicine approaches that improve patient safety.¹³

3. Deep Learning for Pattern Recognition in Safety Data

Deep learning represents an advanced subset of machine learning that uses artificial neural networks to analyze large and complex datasets. In pharmacovigilance, deep learning models are particularly useful for recognizing hidden patterns in multidimensional healthcare data. These models can process information from various sources such as clinical notes, laboratory results, prescription records, and spontaneous adverse event reports.¹⁴ Deep learning techniques can identify subtle relationships between drug exposure and adverse effects that may not be detected through conventional analytical approaches. Another advantage of deep learning models is their ability to improve continuously as more data become available. This adaptive learning capability allows pharmacovigilance systems to become increasingly accurate in detecting emerging safety signals and predicting potential adverse reactions.¹⁵

4. Natural Language Processing for Safety Data Extraction

A significant portion of pharmacovigilance data exists in unstructured text formats such as clinical narratives, medical literature, regulatory documents, and patient-reported reports. Natural Language Processing (NLP), a specialized area of AI, enables automated extraction and interpretation of safety information from these textual sources algorithms can identify drug names, adverse event terms, dosage information, and temporal relationships within large text datasets. By converting unstructured information into structured safety data, NLP tools significantly reduce manual data entry and review efforts. These technologies are

particularly valuable for analyzing social media discussions, online health forums, and scientific publications, which can provide early indications of emerging safety issues related to pharmaceutical products.¹⁶

5. AI-Assisted Decision Support in Pharmacovigilance

AI-based decision support systems assist pharmacovigilance professionals in evaluating complex safety information and prioritizing regulatory actions. These systems integrate data from multiple sources and apply advanced analytical models to generate actionable safety insights. Decision support tools can help determine the seriousness of adverse events, assess potential causality between drugs and reported reactions, and identify cases that require urgent medical or regulatory attention. By providing automated recommendations and risk assessments, AI systems help safety experts make faster and more informed decisions.¹⁷

6. Integration with Real-World Data Sources

Another important advancement in AI-enabled pharmacovigilance is the integration of real-world data (RWD) sources such as electronic health records, insurance claims databases, wearable health devices, and patient registries. AI algorithms can analyze these large datasets to generate real-world evidence about drug safety and effectiveness.¹⁸ This integration enables continuous monitoring of medication in real clinical settings and helps identify long-term safety trends that may not be observed during controlled clinical trials. As a result, AI-driven pharmacovigilance systems contribute to a more comprehensive understanding of drug safety throughout the product lifecycle.

ROLE OF ARTIFICIAL INTELLIGENCE IN ICSR CASE PROCESSING AND SIGNAL DETECTION

Artificial Intelligence (AI) has become an important technological tool in pharmacovigilance for improving the processing and evaluation of Individual Case Safety Reports (ICSRs) and enhancing the detection of potential safety signals. The number of safety reports submitted to regulatory authorities has increased significantly due to the expansion of global drug use, post-marketing surveillance requirements, and digital reporting systems. Manual processing of these large

volumes of reports can be time-consuming and may lead to inconsistencies in safety evaluation.¹⁹ AI technologies, including machine learning, natural language processing (NLP), and deep learning, provide automated methods for managing safety data more efficiently and accurately. AI-driven pharmacovigilance platforms can analyze structured and unstructured safety data, identify relevant clinical information, and support safety professionals in assessing adverse drug reactions. These systems are designed to assist rather than replace human expertise, and therefore many modern pharmacovigilance workflows adopt a “human-in-the-loop” model, where AI performs automated data extraction and preliminary assessment while trained safety experts validate the results. This approach improves efficiency while maintaining regulatory compliance and quality assurance.²⁰

Categories of AI Applications in ICSR Processing

AI applications in ICSR management can broadly be classified into two major categories: data ingestion and information extraction, and AI-assisted decision support.

1. Data Ingestion and Extraction from Structured and Unstructured Sources

ICSR data originate from multiple formats including structured electronic reports and unstructured

documents such as medical narratives and literature reports. AI technologies enable efficient ingestion and

processing of these diverse data sources.

- Safety information may be submitted in formats such as XML files, PDF documents, electronic forms, emails, scanned images, or word-processing files.
- Natural Language Processing (NLP) techniques allow automated extraction of critical safety information such as patient details, suspected drugs, adverse reactions, and event timelines from textual narratives.
- Machine learning models can standardize extracted data and map medical terms to standardized dictionaries such as MedDRA, improving data consistency.
- Optical Character Recognition (OCR) technologies can convert scanned documents and images into machine-readable text for further analysis.

Through these technologies, pharmacovigilance systems can transform unstructured information into structured datasets that can be efficiently analyzed and submitted to regulatory authorities.²¹

2. AI-Assisted Decision Support in Safety Evaluation

Another important application of AI in pharmacovigilance is supporting safety professionals in the evaluation of ICSRs. Safety reports often contain incomplete or inconsistent information, making manual assessment challenging. AI algorithms can assist by identifying patterns, prioritizing cases, and highlighting potential safety concerns.

- Machine learning models can assist in classification of adverse events and drug-event relationships.
- AI-based tools can identify duplicate reports and reduce redundancy within safety databases.
- Algorithms can support causality assessment and seriousness classification by analyzing historical safety data.
- Predictive models can help detect emerging safety signals by identifying unusual reporting patterns.

These tools improve efficiency by prioritizing high-risk cases and enabling pharmacovigilance experts to focus on clinically significant safety issues.²²⁻²⁵

AI IN SIGNAL DETECTION AND SAFETY SURVEILLANCE

Signal detection is a fundamental objective of pharmacovigilance, aimed at identifying previously unknown associations between drugs and adverse events. AI-based signal detection systems combine traditional statistical methods with machine learning algorithms to analyze large safety databases and detect potential signals earlier than conventional approaches. AI-driven signal detection methods may use Bayesian data mining, disproportionality analysis, clustering algorithms, and neural networks to identify unusual reporting patterns. These technologies can analyze large datasets from multiple sources including spontaneous reporting systems, electronic health records, scientific literature, and real-world healthcare databases. Early identification of safety signals allows regulatory authorities and pharmaceutical

companies to take timely risk management actions.²⁶

AI-SUPPORTED ICSR CASE PROCESSING WORKFLOW

The processing of Individual Case Safety Reports typically involves several key activities. AI technologies are increasingly integrated into each of these stages to improve workflow efficiency.

1. Case Intake

During case intake, pharmacovigilance systems must verify the presence of the four minimum reporting elements required for a valid safety report:

- Identifiable patient
- Identifiable reporter
- Suspected medicinal product
- Suspected adverse event

AI tools can automatically screen incoming reports, identify these elements, and categorize the report for further processing.

2. Case Evaluation

In this stage, safety professionals assess the clinical significance of the reported adverse event. AI-based systems can assist by automatically coding medical terms, evaluating seriousness criteria, and comparing reported reactions with known safety information.

3. Follow-Up

Many ICSRs require additional information to ensure complete evaluation. AI-based systems can automatically identify missing data elements and generate follow-up requests to reporters or healthcare professionals.

4. Case Distribution and Regulatory Submission

After evaluation, ICSRs must be transmitted to regulatory authorities according to established reporting timelines. AI-enabled systems can automate the preparation and validation of electronic reports, ensuring compliance with regulatory data standards.²⁷

CURRENT REGULATORY FRAMEWORKS SUPPORTING AI IN PHARMACOVIGILANCE

The adoption of AI technologies in pharmacovigilance must comply with regulatory guidelines established by international health authorities. Several regulatory frameworks support the integration of digital technologies into drug safety monitoring systems.²⁸

E2B(R3) Standard for Electronic Reporting

The E2B(R3) standard developed by the International Council for Harmonisation (ICH) provides a structured format for electronic transmission of Individual Case Safety Reports. This standardized data structure facilitates automated data exchange between pharmaceutical companies and regulatory agencies and supports the integration of AI-based data processing tools.

FDA Regulatory Guidance for AI and Digital Health Technologies

The U.S. Food and Drug Administration (FDA) has issued guidance documents related to software as a medical device (SaMD) and artificial intelligence applications in healthcare. These guidelines outline principles for validation, transparency, and lifecycle management of AI-based systems used in clinical and safety monitoring applications.

European Medicines Agency Big Data Strategy

The European Medicines Agency (EMA) has established initiatives such as the Big Data Steering Group to promote the use of advanced data analytics and machine learning in regulatory decision-making. These initiatives aim to improve drug safety monitoring by leveraging large healthcare datasets and modern computational tools.²⁹⁻³⁰

FUTURE OUTLOOK

As pharmacovigilance systems continue to evolve, the integration of AI, real-world data analytics, and advanced predictive models will play an increasingly important role in drug safety surveillance. Emerging technologies such as large language models, explainable AI, and federated learning are expected to further enhance the accuracy and transparency of safety signal detection. Although AI technologies offer significant advantages, expert oversight remains essential to ensure that automated analyses are clinically meaningful and compliant with regulatory requirements. A collaborative approach that combines advanced computational tools with professional pharmacovigilance expertise will be critical for building reliable and effective AI-enabled drug safety systems.

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