EUROPEAN JOURNAL OF BIOMEDICAL AND PHARMACEUTICAL SCIENCES
http://www.ejbps.com

ISSN 2349-8870
Volume: 12
Issue: 3
Year: 2025

ARTIFICIAL INTELLIGENCE IN PHARMACOVIGLANCE: AN SYSTEMATIC REVIEW

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Article Received on 04/01/2025 **Article Revised on 24/01/2025** **Article Accepted on 14/02/2025**

ABSTRACT
The healthcare sector understands the need to support the increasing volume of data gathered from individual case safety reports (ICSRs), especially in the area of pharmacovigilance. To handle this expansion, more healthcare and highly qualified professionals are required for the collection and evaluation of data. Large-scale adoption of assistive technology like artificial intelligence (AI) will be necessary to stay up with the rapidly changing world. Artificial intelligence has the potential to transform the daily work and professional development of drug safety professionals in the field of pharmacovigilance. The healthcare sector understands the need to support the increasing volume of data gathered from individual case safety reports (ICSRs), especially in the area of pharmacovigilance. To deal with this expansion, more healthcare and highly qualified professionals are required for data collection and assessment. Artificial intelligence (AI) and other assistive technologies will need to be widely deployed in order to stay up with the rapidly evolving environment. Artificial intelligence has the potential to transform the daily work and professional development of drug safety professionals in the field of pharmacovigilance. Artificial intelligence has the potential to improve the pharmacovigilance industry's qualitative and quantitative data gathering and assessment processes through the application of machine learning algorithms. Advanced medical approaches, like personalised treatment that maximises the risk-benefit ratio, are made possible by artificial intelligence. In this review we have concisely focused on benefits of applying AI techniques in PV, role of drug safety professionals using AI, role of AI in PV 21st century, challenges of using AI in pharmacovigilance and Future perspectives and recommendations for future Research and developments in AI integration with Pharmacovigilance.

KEYWORDS: Artificial intelligence, Pharmacovigilance, Drug Safety, Pharmacology.

INTRODUCTION
The study of adverse event assessment, prevention, detection and collection, and evaluation of drug-related issues is known as pharmacovigilance. Although the number of individual case safety reports can rise annually, 90% of adverse occurrences (AEs) remain unreported. Therefore, technology must be required to sustain unfavourable circumstances. Artificial intelligence facilitates decision-making in challenging circumstances. Cognitive services are intended to assess PV users' ability to make judgements. Thus, the strategy for defeating AEs with unreported data is to use AI. Another strategy is to share health-related information via social media. Patient narrative information is represented by electronic health records, or EHRs. The sources mentioned above allow AEs to identify and get better. AI can reduce human labour related to transcription and data input, allowing for a greater focus on scientific and medical evaluation of adverse events (AEs) that is better for patient health.[1]

Artificial Intelligence is described as a digital computer's capacity to accomplish tasks requiring human intelligence. Artificial Intelligence (AI) is the utilisation of machines by introducing learning technologies to them with the aid of historical data acquired to solve future problems. AI improves clinical trial success rates and aids in patient randomisation. The top three global health burdens are diabetes, cancer, and diabetic retinopathy. AI has demonstrated promising outcomes in these areas, helping to identify, prevent, mitigate, and treat these conditions. PV data is crucial to maintaining the security of continuing medicinal goods. It is anticipated that reporting will be of higher quality and accuracy after the AI has processed the PV data. Net well and Simon found the first artificial intelligence program

in 1995. Often referred to as the "Father of AI," John McCarthy. The artificial neurone model was proposed in 1943 by Warren McCulloch, Walter Pitts, and Donald Hebb, who altered the strength of the connections between the neurones. A mathematical problem was solved by an algorithm discovered by researchers in 1966.In 1980, the expert system realised that it could make decisions like a human expert. In 2011, IBM's Watson answered difficult quiz questions. Watson demonstrated the ability of computers to understand natural language. In 1972, researchers in Japan used AI to teach robots to recognise objects through machine learning.[2] Three categories of AI exist: a) Rule-based static systems: these involve automation through a predetermined set of rules; b) AI-based static systems: these involve outcomes derived from training data (supervised ML, NLP); and c) Rule-based dynamic systems: these involve updating new data (New ICSRs) for future usage.[3] By examining the applications of artificial intelligence (AI) in pharmacovigilance, this study seeks to contribute to the ongoing conversation on the ethical and effective integration of technology in the pharmaceutical and healthcare sectors, with an emphasis on enhancing patient safety and optimising treatment outcomes.

Figure 1: AI in Pharmacovigilance.

OBJECTIVES

- To ensure patient safety by monitoring for adverse drug reactions and minimising medication-related damage.
- To help protect public health by identifying and reducing potential risks associated with medication use.
- Determine how well medications balance their benefits and drawbacks in order to optimise their use and promote sound decision-making.
- Encourage responsible and cost-effective drug use to improve treatment outcomes while minimising risks.
- To enhance knowledge and proficiency in medication safety monitoring and reporting, healthcare professionals and the general public should have more opportunities to understand, learn about, and be trained in pharmacovigilance approaches.
- To help patients, healthcare professionals, and the general public make educated decisions and manage risks by providing timely and accurate pharmaceutical safety information.
- To recognise and resolve the impact of free trade and globalisation on medicine availability and distribution by coordinating cross-border pharmacovigilance initiatives.
- To approach pharmacovigilance in a proactive and flexible manner, striving for continuous system and process improvement to improve medication safety monitoring and management. This will help you seize fresh opportunities and challenges.[4]

Benefits of applying ai techniques in pv

- The most significant advantage of AI is shorter cycle times. Because of this strategy, the processing occurs spontaneously.
- Boost the information's accuracy and quality.
- AI is capable of managing and processing many types of incoming data.
- ADRs can be identified with it.
- Artificial intelligence can help lessen the burden and time required to process cases.
- AI systems gather information from adverse drug event forms and assess case validity without the need for human intervention.

- Fewer human errors: AI technologies can help reduce human mistake in detecting side effects, resulting in more accurate outcomes.
- AI reduces death rates by detecting diseases at an early stage using patients' electronic footprints.[5]

Role of drug safety professions using ai

Medication safety is a major barrier to the development of innovative medicines. Unexpected toxicities are a primary cause of clinical trial attrition, and post-marketing safety concerns result in avoidable morbidity and mortality. To handle medication safety, there are two complimentary systems. Clinical trials verify a medication's safety and efficacy for the intended application before approving it. Once a medication is on the market, it is kept under observation through AE reports to make sure the safety information is current. Nevertheless, because clinical trials have fundamental flaws, neither of these procedures is error-proof. For instance, it is not feasible to perform trials on populations big enough to identify uncommon adverse events (AEs) or to test for every possible synergistic impact. Clinical studies regarded women and the elderly as special subgroups until recently. Even while appeals for precision medicine to provide the "right drug at the right dose to the right patient" are growing, these trials have concentrated on developing medications for the average patient.[6] Pre-market medication safety has been demonstrated to benefit greatly from AI techniques, particularly in the field of toxicity evaluation. Determining the adverse effects (AEs) of chemicals on people, plants, animals, and the environment is a crucial phase in the medication design process. Toxic medications must not make it to clinical trials; pre-clinical assessments are essential. Nevertheless, high toxicity still accounts for one-fifth of clinical trial failures and two-thirds of post-market drug withdrawals, making it a major cause of drug failure. Therefore, precise toxicity assessments can aid in lowering development costs and timeframes for new drug launches while also guaranteeing medication safety. Historically, the most common method used to evaluate toxicity has been through animal research.[7]

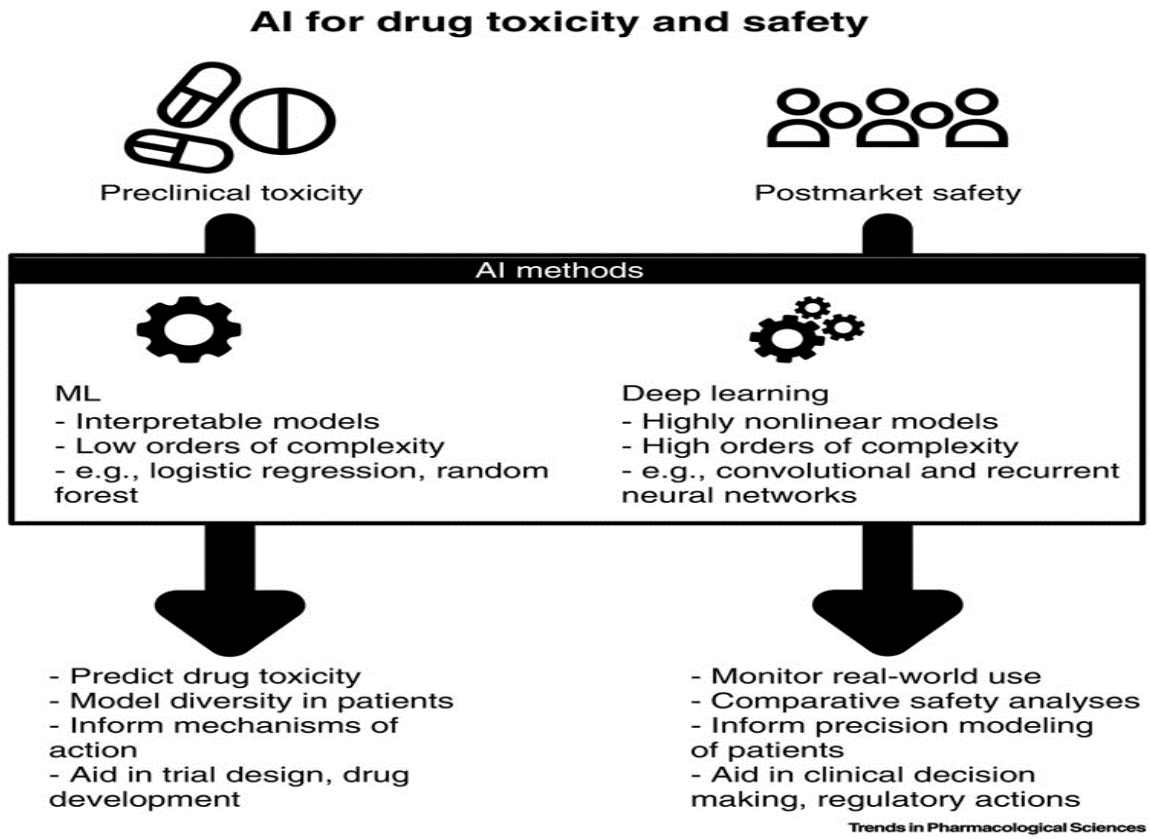

Figure 2: Drug safety professionals using AI.

Many DS team members contribute to various processes, ranging from ICSR reception to submission to regulatory bodies. Certain skills and expertise are needed for this. DS science knowledge required for competent performance as a DS practitioner is described in the drug safety pharmacovigilance core competencies. Skills in leadership, communication, analysis, and evaluation, as well as systems thinking, are other fundamental talents. A DS professional at the entry level should possess level 1 core competencies; DS associates, supervisors, and managers at the advanced and senior levels should possess level 2 core competencies; associate directors, directors, and DS organisation leaders should possess level 3 core competencies.[8]

- **Drug safety/pharmacovigilance core competencies[9]**

Table: Drug safety/pharmacovigilance core competencies.

	Level 1	Level 2	Level 3
Understanding of the sciences related to drug safety	Name important occasions in the development of drug safety history	Identifies key moments in the history of drug safety	Highlights key takeaways from drug safety history and how they are applied to the profession today.
Proficiency in analytical and assessment skills	A basic understanding of job flow, data entry, quality control, coding, and report-producing techniques inside safety databases that have been validated	Expertise in coding, work flow, and report generation inside safety databases that have been validated. Supervision of quality-control protocols by support staff, including level 1. Involvement in user acceptance testing and safety database validation.	Advanced understanding of database migrations, upgrades, change orders, and safety database validation procedures; also includes ability to communicate with database administrators and IT validation staff. Expert level 1 and level 2 practitioners use safety database workflow tools in an advanced manner when processing everyday cases.

Ai integration in pharmacovigilance

Pharmacovigilance is one of the industries that artificial intelligence (AI) has quickly revolutionised by providing more precise and effective monitoring and assessment of adverse drug responses. Predictive modelling is an example of artificial intelligence's proactive approach to spotting possible drug safety issues. By early detection of adverse events, predictive modelling improves patient safety.[10] The AI technology can also analyse unstructured data, extract text, and locate pertinent material to generate clinically viable auto-narratives and identify trends within structured and unstructured narratives, eliminating the need for routine evaluation of individual cases and laborious Identification and validation of signals.[11] The potential benefits of improving patient outcomes and medication safety outweigh the challenges of continuing research and development. A revolutionary shift in drug safety surveillance is being brought about by the combination of AI and pharmacovigilance, which enables early identification of safety issues and quick examination of adverse drug responses. Techniques for integrating AI into pharmacovigilance include NLP for extracting insights from unstructured data sources and predictive analytics for projecting adverse occurrences based on data trends. This is because integrating AI in pharmacovigilance faces challenges like data privacy issues and regulatory framework adaptation.[12] Real-world applications of AI in pharmacovigilance automate the identification and categorisation of adverse medication responses from various data sources, as well as the scanning of social media for potential safety alerts, thereby reducing time and resources required while enhancing accuracy and consistency. AI-enhanced pharmacovigilance brings both opportunities and challenges, including as addressing data privacy concerns and changing regulatory regimes. Future advances in AI-powered medication safety monitoring systems promise proactive and patient centered solutions through continuous innovation and improvement.[13] Case studies highlight the effectiveness of AI systems in detecting early warning signs and improving overall patient safety results. AI integration into pharmacovigilance ushers in a new era of proactive, data-driven methods for monitoring medication safety, with huge potential to improve patient outcomes and healthcare management.[4]

Ai implementation in pharmacoviglance

Both inpatient and outpatient settings are using artificial intelligence to increase patient safety. Additionally, it has been employed to reduce avoidable damage by utilising digital methods that facilitate patient-provider contact.[14] Traditional procedures included a number of key elements, including clinical knowledge, manual review, and retrospective analysis of data from individual case reports, epidemiological studies, and clinical trials. By analysing electronic health records, adverse event reports, medical literature, and social media posts, artificial intelligence (AI) algorithms are able to find trends, correlations, and anomalies that can point to poor responses or new safety risks.[4] There are several challenges and limitations with AI-driven automation, despite its potentially revolutionary promise. Investments in significant computing power, infrastructure, and regulatory compliance are required for using AI technology.[13] Case studies from the actual world illustrate the effectiveness and use of AI in enhancing pharmaceutical safety monitoring and regulatory decision-making processes.

AstraZeneca's AI-driven pharmacovigilance system, IBM Watson for Drug Safety, Oracle Health Sciences' Argus Safety, Adverse Health Analytics' Signal Mine, and the FDA's Sentinel Initiative are a few instances of how AI technology may change pharmacovigilance practices.[15]

Benefits of ai integration in pharmacoviglance

- Real-time analysis of incoming data streams by artificial intelligence systems can reveal emerging trends and warning signs. By continuously monitoring data from many sources, including social media platforms, healthcare databases, and regulatory reports, artificial intelligence (AI)-powered systems are able to swiftly detect any safety hazards. This makes it possible to act quickly and take preventative action to reduce risk.[16]
- Continuous patient health parameter monitoring, including vital signs, activity levels, and medication compliance, is made possible by wearable technology and artificial intelligence (AI). Wearable sensor data can be gathered in real-time by AI-enabled technologies, which can then be used to provide personalised safety monitoring tailored to each patient's needs and spot early warning signs of negative reactions.[17]
- Patient narratives and social media posts are examples of unstructured data sources that can be analysed using artificial intelligence (AI) to identify potential poor outcomes and safety concerns. NLU algorithms gather relevant information from several sources and assess text data for sentiment, context, and meaning in order to help identify and characterise negative events.[12]
- Artificial intelligence algorithms are able to predict potential drug interactions based on patient medication profiles. This helps with medication management and reduces the likelihood of polypharmacy adverse effects. By evaluating medication lists, pharmacological classifications, and pharmacokinetic characteristics, AI-powered technologies help healthcare providers increase patient safety and optimise prescription regimens by spotting possible interactions, contraindications, and adverse reactions.[18]
- Integrating AI with HIEs allows for comprehensive safety monitoring and surveillance across many care contexts by improving data exchange and interoperability across healthcare systems. AI-powered systems standardise data formats, nomenclature, and exchange protocols, allowing healthcare practitioners, pharmacies, and regulatory agencies to communicate patient data, test findings, and prescription histories more smoothly.[12]
- AI's comprehensive data analysis capabilities make signal validation methods more effective. AI-powered systems that incorporate structured and unstructured data sources, including as adverse event reports, clinical trial data, and real-world evidence, can help pharmacovigilance specialists more effectively analyse the severity and veracity of safety signals.[16]

Challenges of integration of ai in pharmacoviglance

- Why Total automation of the PV system to identify intricate patterns; inconsistent data can be deceptive and imprecise when used to make decisions.
- Ample training datasets with suitable sample sizes from various sources covering all diseases and therapeutic areas, which are reliable and valid for evaluating quality and accuracy in real-world scenarios.
- Absence of a specific methodology would result in the identification of false-positive reports that would add noise to the system and overlook potentially significant adverse events.
- Technical problems for data processing and labelling may arise from variations in the names of pharmaceuticals and conditions, descriptions of adverse pharmacological effects, diversity and issues in local languages, ambiguities, and absence of crucial information.
- Privacy and ethical issues because data is used without individuals' consent and violates the doctor-patient relationship's trust.
- The data infrastructure needed to create an extensive patient database.
- Sturdy infrastructure for education and research and development, as well as government funding for infrastructure, training, and research expenditures.
- Rules to guarantee the reliability and validity of AI tools, and to strike a balance between the financial gain and openness of tech companies and the security and welfare of customers.[11]

Role of ai in pv in 21st century

Based on real-world data, PV has to develop strategies that include AI as a component of the solution, not just for cancer but also for many other grave and potentially fatal illnesses. Patient-level data from individual customers is not always the same as validated data in the big data outcomes world since artificial intelligence (AI) is a source that electronically generates useful healthcare information. PV actions are required to update the post-marketing surveillance of biosimilar in the twenty-first century. The first use of AI in PV is to create a new epidemiological concept based on an awareness of the distinctions between the terms "biosimilar" and "generic." By producing useful data on efficacy and safety, AI will assist to fill in the gaps in the PV ecosystem that currently exist. In the framework of the artificial sciences, Herbert Simon described "design thinking" as the "Transformation of existing conditions into preferred ones."Analysing ideas with a focus on action that are generated by artificial intelligence is known as critical thinking. "We are afraid not of finding new information, but rather of being overloaded with low-quality information," stated Dr. Donald Therese at a recent conference.[19]

Future Perspective and Recommendation for future Research and Development in ai integration with pharmacoviglance

The management and observation of medication safety will change in the future thanks to the intriguing prospects presented by the application of AI in pharmacovigilance.[20] AI technology can increase the

accuracy and efficacy of adverse event identification, allowing for real-time monitoring and analysis of big datasets from numerous sources. These systems can identify patterns, trends, and potential dangers faster and more accurately than more traditional methods, which enables preventive measures to minimise harm.[4] AI integration may help improve the need for pharmacovigilance reporting and speed up regulatory compliance processes.[21] To effectively apply AI in pharmacovigilance, the following research and development recommendations have been made. By following these guidelines, pharmacovigilance stakeholders can leverage the transformative potential of artificial intelligence (AI) technology to enhance regulatory decision-making, patient care, and drug safety monitoring. As safer and more effective medications become a reality, worldwide public health will benefit from these activities.

1. XAI frameworks can help make AI-powered pharmacovigilance systems easier to understand and more transparent. These frameworks should be used to provide patients, regulators, and physicians with comprehensible explanations of AI-generated findings. For example, Stanford University's Interpretable Deep Learning for Drug-induced Liver Injury (IDILI) research aims to improve AI models' explain ability for drug-induced liver injury prediction.[22]

2. Develop AI-driven real-time monitoring systems that continuously watch streams of data about drug safety. These systems enable prompt reaction to adverse circumstances and the detection of fresh safety threats. The FDA's Sentinel Initiative, for instance, monitors real-time healthcare data from millions of patients using AI algorithms, enabling the early identification of safety signals and the enactment of regulatory actions.[4]

3. Promote the creation of frameworks for the cooperation of AI and humans in pharmacovigilance, where AI instruments enhance human knowledge rather than replace it. Make interactive AI-driven decision support tools available so that pharmacovigilance experts may collaborate to assess, refine, and comprehend AI-generated insights.[10]

4. Utilise responsible innovation and ethical AI Design principles while creating, implementing, and assessing AI-powered pharmacovigilance systems. To identify and lessen any potential biases or unintended consequences, stakeholders should be consulted in evaluating the ethical implications of AI-driven decision-making.[23]

5. Promote translational research projects that bridge the knowledge gap between outcomes driven by AI and real-world application in healthcare settings. Collaborate with academic institutions and healthcare providers to develop and assess AI-powered pharmacovigilance interventions, assessing their impact on clinical practice and patient outcomes.[4]

6. Develop state-of-the-art artificial intelligence (AI) algorithms that can identify subtle signs of adverse drug reactions (ADRs) from a range of data sources, such as social media, scholarly publications, and electronic health records (EHRs). For example, IBM Watson for Drug Safety use AI algorithms to assess millions of adverse event data and precisely pinpoint potential safety issues.[24]

CONCLUSION

For a well-defined, discrete activity like the interpretation of medical pictures, artificial intelligence (AI) in healthcare has shown great promise; nevertheless, its application to heterogeneous data is challenging. The use of AI tools in PV systems has the potential to reduce labour costs associated with human labour and increase productivity. It cannot, however, take the place of or supersede the significance of medical review and the expert opinion of qualified PV specialists for the ultimate determination of causality and signal detection. Complete PV system automation now entails a number of hazards and difficulties. More research, validation, and regulatory and medical professional approval are needed. The intricacy and difficulty of interpreting medical data is not fully understood by AI experts, nor is it fully understood by medical practitioners. Artificial intelligence (AI) should augment human intelligence, not replace human specialists. It's crucial to highlight and make sure AI improves PV more than it causes problems.

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