Journal of Chemical Health Risks

www.jchr.org

JCHR (2026) 16(2), 2451-2463 | ISSN:2251-6727

Integrating AI in Pharmacovigilance: A New Era of Drug Safety and Risk Management

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(Received: 16 January 2026 Revised: 25 February 2026 Accepted: 30 March 2026)

KEYWORDS:

Pharmacovigilance, Artificial Intelligence, Drug Safety, Adverse Drug Reaction, Machine Learning, Natural Language Processing, Predictive Modelling, Healthcare Technology..

ABSTRACT:

Traditional pharmacovigilance methods are becoming less and less effective at controlling medication safety as a result of the growing complexity of healthcare systems and the proliferation of real-world data. This review discusses how pharmacovigilance is changing from a reactive process to a proactive and predictive strategy for tracking adverse drug reactions (ADRs) with the help of Artificial Intelligence (AI). By using technologies like Machine Learning (ML), Natural Language Processing (NLP), and deep learning, artificial intelligence (AI) can quickly analyze various data sources, including wearable technology, social media, and electronic health records, to find safety issues earlier and more accurately. This innovation promises improved risk-benefit analysis, faster decision-making, and better patient outcomes. The adoption of AI-driven pharmacovigilance systems has advanced significantly in nations like the US, EU, China, and India; nevertheless, issues with data quality, transparency, regulatory alignment, and workflow integration still exist. The review also covers the useful applications of AI, like risk-benefit analysis, automating case processing, and creating predictive models for ADR detection. Despite encouraging developments, we must resolve ethical issues, understandability limitations, infrastructure deficiencies, and bias in AI models to ensure safe and fair adoption. To fully utilize AI in pharmacovigilance, a well-rounded, cooperative strategy involving developers, data scientists, regulators, and physicians is essential. In the end, AI is a strong complement to human-led drug safety initiatives rather than a substitute.

Introduction

Pharmacovigilance (PV) involves the collection, monitoring, examination, interpretation, and assessment of relevant data to reduce the occurrence and severity of adverse reactions. Pharmacovigilance and drug safety remain dynamic clinical and research disciplines [1],[2]. According to the World Health Organization (WHO), pharmacovigilance is defined as 'the science and activities concerning the detection, evaluation, comprehension, and prevention of adverse effects or any other drug-related issues'. It plays a vital role in safeguarding public health, guiding clinical practices, regulating medications, and preventing potential harms linked to approved drugs. In Low- and Middle-Income Countries (LMICs), PV systems often face constraints. Various explanations exist for this. Human resource availability is insufficient, and the workload on healthcare professionals (HCPs) tends to be significantly high [3].

The need for routine pharmaceutical safety monitoring was highlighted in 1848 when a young girl named Hannah Greener passed away after chloroform anesthesia, sparking the start of pharmacovigilance. However, pharmacovigilance did not receive much attention until the 1960s. Effective mechanisms for monitoring drug safety are essential, as demonstrated by the thalidomide disaster, in which the medication caused serious birth deformities (phocomelia) in thousands of infants [4]. Globally, this led to the creation of regulatory frameworks and official

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JCHR (2026) 16(2), 2451-2463 | ISSN:2251-6727

pharmacovigilance systems. The World Health Organization (WHO) launched the International Drug Monitoring Program in 1968. The program established a global network for exchanging ADR data. The program's operating center, the Uppsala Monitoring Centre (UMC) in Sweden, gathered and examined adverse event information from participating nations. Over the decades, pharmacovigilance has evolved from a reactive, post-marketing activity to a proactive, integrated process that spans the entire drug lifecycle [5].

Worldwide, pharmacovigilance methods vary, yet they all aim to ensure drug safety. The European Medicines Agency (EMA), which offers services and methods to enhance pharmaceutical safety monitoring, coordinates pharmacovigilance efforts within the European Union [6]. Pharmacovigilance in the United States is supervised by the Food and Drug Administration (FDA) through its MedWatch program, which promotes consumers' and healthcare providers' voluntary reporting of adverse events [7]. Other countries have implemented their own systems, often in collaboration with the WHO's Uppsala Monitoring Centre, a global drug safety information repository.

The third-biggest pharmaceutical market in the world is Asia, which is home to 4.3 billion people and 60% of the world's population. The largest drug markets are in China and Japan, followed by those in India, Korea, Hong Kong, Singapore, Malaysia, Indonesia, Thailand, the Philippines, and Vietnam [8]. Asian countries have experienced rapid growth recently due to the expansion of new markets. As it shifts toward a trend of higher quality requirements, its more stringent regulations are changing the pharmaceutical industry's quality standards and showing strong growth [9]. Pharmacovigilance (PV) and drug safety are receiving more attention in this area as a result of the rising demand. While the SFDA and MOH collaborate to establish regulations and procedures, the SFDA is primarily in charge of administering statewide ADR oversight in China [10].

Pharmacovigilance (PV) in India developed relatively late, with no traditional medicine surveillance system. Although despite the introduction of the concept, the initial ADR monitoring program with 12 regional centers failed due to a lack of awareness and funding. In 1997, India joined the WHO ADR Monitoring Program, establishing three monitoring centers at AIIMS (New Delhi), KEM Hospital (Mumbai), and JLN Hospital (Aligarh) [11]. However, due to poor implementation, these centers remained nonfunctional. CDSCO launched the WHO and World Bank-funded National Pharmacovigilance Program (NPVP) in 2005. It established two zonal centers (Mumbai and New Delhi), five regional centers, and 24 peripheral centers, with objectives to foster ADR reporting, involve healthcare professionals, and become a global benchmark. Despite these efforts, the program failed due to ineffective execution [12].

In 2010, the Indian Pharmacopoeia Commission (IPC) established the Pharmacovigilance Program of India (PvPI). The program aims to ensure the safety of medicines by collecting, analyzing, and disseminating ADR data from healthcare professionals and patients [13]. PvPI operates through a network of Adverse Drug Reaction Monitoring centers (AMCs) across the country. These centers report ADRs to the National Coordination Center (NCC), which collaborates with the WHO Program for International Drug Monitoring. Despite its successes, PvPI faces challenges such as underreporting, lack of awareness among healthcare providers, and limited resources [14].

Pharmacovigilance (PV) relies heavily on data collection, management, and analysis from various sources to ensure drug safety. One of the primary data types in PV is Individual Case Safety Reports (ICSRs)—records of suspected adverse events gathered from multiple channels. These include electronic health records (EHRs), chatbot interactions, published literature, patient registries, support programs, and even direct patient reports through social media. Since these reports come from diverse global sources, they vary in format, language, and healthcare system characteristics [15].

The key challenge in PV is effectively sorting through this vast and complex data to identify potential safety issues with medicines and vaccines. The goal is to quickly detect safety signals—early warnings of adverse drug reactions—that require further investigation and regulatory action [16]. With recent advancements in artificial intelligence (AI) and machine learning (ML), many experts believe these technologies could revolutionize PV [17]. AI has the potential to process

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JCHR (2026) 16(2), 2451-2463 | ISSN:2251-6727

massive datasets efficiently, recognize patterns, and identify safety concerns faster than traditional methods—helping healthcare professionals find critical "needles in the haystack" with greater accuracy and speed. Beginning in the early 1990s, the use of these techniques to gather data on human safety has been gradually growing since the 2000s [18].

Machine learning models based on pharmacogenomics can help predict unwanted reactions to drugs. The technique is a promising way to tailor medicine and improve drug safety. By analyzing large amounts of data, these models provide valuable insights into the risk of adverse drug reactions. These models can assist healthcare providers in making better decisions about medications and patient monitoring. Ultimately, such monitoring can result in improved patient outcomes and minimize the healthcare costs [19].

While the performance of various models can be evaluated using training data, understanding the overall effect of AI/ML on healthcare safety is still difficult. Advances in NLP models, better access to training data, potential cost savings, and the urgent need for improved pharmacovigilance have led to the quick creation of new predictive models [20]. However, real-world implementation challenges persist, as highlighted by the limited adoption of ML models in hospital-based ADR monitoring systems. These challenges include concerns about explainability, interoperability with existing healthcare systems, and the need to follow strict regulation [21].

1. An overview of AI and its need for pharmacovigilance

1.1 Definition and Categorization of AI

Artificial intelligence falls under the domains of engineering, statistics, and computer science. Artificial intelligence refers to the ability of machines to perform tasks typically associated with human intelligence by replicating the structure and function of the human brain, such as reasoning, exploration, and learning from prior experiences. Common AI models include ML and DL. ML, a branch of artificial intelligence [22], represents a group of techniques designed to train AI systems, improving their efficiency in tasks through the use of data [23]. ML involves the study and implementation of algorithms that automatically refine decisions or predictions through experience and training data interaction. This encompasses methods such as deep neural networks, K-nearest neighbors, random forests, and decision trees [24]. DL, a division of ML, replicates cognitive processes related to how the human brain learns and addresses complex data-based problems. It primarily differs from ML in terms of the size of data required and the intricacy of models. Typically, DL suits large-scale data processing and employs advanced models like deep neural networks (DNNs), convolutional neural networks (CNNs), and recurrent neural networks (RNNs) [25].

1.2. History of AI and the Rise of AI in Pharmacovigilance

The origins of AI trace back to the 1950s when Alan Turing introduced the concept of the "Turing Test" to assess a machine's level of intelligence [26]. The evolution of artificial intelligence can be broadly categorized into four distinct stages. AI officially emerged in 1956 during the conceptualization era (1940–1960s) [27]. During the expert system era (1960–1980s), the focus shifted from general intelligence to replicating human expert knowledge [28]. A notable example is the MYCIN system, which successfully applied a rule-based framework for medical diagnosis and therapeutic recommendations [29]. In the ML phase (1980–2000s), the training of deep neural networks largely relied on the backpropagation method introduced by Paul Werbos in 1988, which facilitated effective learning in multi-layered neural networks [30]. Deep belief networks (DBNs) served as a foundation for the widespread application of DL during the deep learning era (2006–2019). One well-known instance is the AlphaGo system, which triumphed over Go World Champion Lee Sedol, showcasing a major breakthrough in deep learning for complex decision-making and strategic games [31].

A surge in research focusing on the integration of AI into pharmacovigilance took place in the years leading up to 2017. Early investigations primarily focused on applying natural language processing (NLP) to extract adverse event details from unstructured data in sources such as social media and electronic health records. For instance, researchers demonstrated that NLP could efficiently identify adverse drug reaction (ADR) references within clinical texts, thereby improving traditional surveillance mechanisms. The use of machine

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learning techniques significantly enhanced the capability to predict ADRs based on patient profiles and historical records. Currently, ChatGPT, an AI chatbot developed by OpenAI, represents a generative large-scale language model that has attracted worldwide interest for its ability to reshape how we view education, employment, and daily life. Today, DeepSeek-R1, a semi-open-source reasoning model, exhibits problem-solving abilities that rival OpenAI's most advanced language model, GPT-4o [32].

PERIOD	PHASE	SPECIFICATION
1940-1960	Formation of AI Concepts	The idea of AI was first talked about at the Dartmouth Conference in 1956. This was the start of AI as a field [33].
1960-1980	Exploration phase	Expert systems, which could mimic how human experts make decisions to solve problems in certain areas, became the focus of AI research [34].
1980-2000	Formation of ML and Neural networks & rising of Bayesian methods	In 1988, Paul Werbos came up with the backpropagation method, which was very important for training DNNs and made it possible to train multilayer neural networks well. In the 1990s, Bayesian methods, including disproportionality analyses like the Proportional Reporting Ratio (PRR) and the Reporting Odds Ratio (ROR), became widely used to analyze large data sets and identify links between medications and unexpected results [35].
2000- Present	The accelerated advancement phase of deep learning and NLP	Geoffrey Hinton et al. suggested DBNs in 2006. These broke through long-standing problems in the development of neural networks and made a huge step forward in machine learning. In the year 2017, researchers demonstrated that NLP could successfully detect ADR mentions in clinical narratives, thereby enhancing conventional reporting systems. By 2017, the convergence of advanced data analytics, digital health developments, and emerging regulatory science established a solid basis for a revolutionary period in pharmacovigilance [36].

1.3 Artificial intelligence's necessity for pharmacovigilance

To ensure drug safety, pharmacovigilance (PV) is crucial for identifying, evaluating, and preventing adverse drug reactions (ADRs). PV is still a new concept that doesn't get much attention in developing nations. Worldwide, countries are raising concerns about the need for systems to monitor the safety of drugs post-marketing. Nevertheless, conventional PV systems encounter considerable constraints in the contemporary data-centric healthcare environment [37].

1.31 Underreporting and Data Gaps Impact on Signal Detection

In pharmacovigilance, underreporting adverse drug reactions (ADRs) is one of the most enduring problems. It is believed that the foundation of traditional pharmacovigilance, spontaneous reporting systems (SRS), only records 5–10% of real ADR cases [38]. This

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JCHR (2026) 16(2), 2451-2463 | ISSN:2251-6727

significant reporting gap greatly hinders the ability of regulatory bodies and pharmaceutical corporations to identify early warning signs of drug safety risks. The natural tendency in clinical practice is for medical professionals to focus on reporting serious or life-threatening

events means that milder, less obvious, or delayed side effects of drugs are often ignored or considered less important, which contributes to this lack of reporting. Because of this, important safety signals could be overlooked until they develop into more extensive clinical effects [39].

1.32 Inaccuracy and inefficiency in manual pharmacovigilance operation

The manual processing of case reports is yet another significant drawback. Traditional pharmacovigilance systems require many slow tasks, such as entering data, coding with MedDRA (Medical Dictionary for Regulatory Activities), assessing causes, and summarizing reports. These tasks, which frequently include subjective judgment and time restrictions, increase the possibility of human mistakes at different phases of case handling. [40]. The quality and reliability of safety databases can be impacted by mistakes in medical coding, misunderstandings of clinical stories, and uneven data entry, which can harm the accuracy of signal detection and regulatory decisions. This manual dependency slows down the processing pipeline and adds to the already limited resources of pharmacovigilance teams. [41].

1.33 Exponential Growth in the Volume of Safety Data

The proliferation of digital health data has brought about a significant change in the pharmacovigilance scene. With almost 30 million records, the World Health Organization's VigiBase, the largest global database for individual case safety reports (ICSRs), is nearly impossible to manually analyse. [42]. Modern data ecosystems also go much beyond conventional ICSRs. Pharmacovigilance practitioners now have to take into account a wide range of unstructured data sources, including wearable device outputs, social media interactions, mobile health apps, and electronic health records (EHRs) [43]. Because of their volume, complexity, and variability, these new data streams provide substantial analytical hurdles even though they are full of real-world insights. Such high-dimensional and heterogeneous data cannot be efficiently processed and interpreted by traditional pharmacovigilance tools and procedures, which causes delays and lost chances for proactive action.

1.34 Delays in drug safety signal detection

One of the biggest threats to patient safety is the incapacity of conventional pharmacovigilance techniques to promptly identify safety warnings. Patients may continue to be exposed to potentially dangerous drugs for months or even years before a signal is detected based on a retrospective study of case reports. A well-known example is the widespread prescription of the COX-2 inhibitor rofecoxib (Vioxx) before the discovery of its cardiovascular hazards [45]. The medicine was eventually taken off the market after causing significant harm to patients, even though evidence had been gathered over a number of years. This emphasizes how urgently more technologically advanced, flexible, and responsive pharmacovigilance systems that can identify signals in real-time or almost real-time are needed [46].

2. The Role of AI in Advancing Pharmacovigilance

AI includes technologies like deep learning, natural language processing (NLP), and machine learning (ML), which can optimize and automate several PV procedures. By using these technologies, vast amounts of data may be processed efficiently, enabling the identification of ADRs and enhancing the general quality of safety studies [47].

Tasks such as data entry, identifying drug-drug interactions, detecting adverse drug events (AEs), and reviewing cases are among the routine and repetitive duties that AI has been suggested to handle [47]. Additionally, AI can convert handwritten notes and unstructured, free-text data related to drug safety into formats that machines can process [48],[49]. The technology is capable of spotting serious cases, excluding non-serious ones, checking for duplicate submissions, assigning them to either consumer or healthcare provider categories, and autonomously applying Medical Dictionary for Regulatory Activities coding. The AI system can recognize patterns within both structured and

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unstructured content, retrieve and analyze text from unstructured inputs, and generate clinically accurate automated narratives by extracting pertinent details. This capability removes the necessity for manual signal detection, validation, and repetitive case assessments [50].

Moreover, it may gather ICSR data from several published papers including medical literature, case reports, social media drug reviews, free-text clinical notes in electronic health records, and discharge summaries [51]. A recently released survey shows that the application of artificial intelligence technologies processes the data very fast, speeds up computations that were not before possible, and saves scientists time and money [52]. The use of artificial intelligence techniques will help to lower the work, time, and cost of case processing, enhance data quality, and maybe be a game changer for PV activities given the vast volume of drug safety data being kept electronically [53].

3. Application and Technologies of AI in Pharmacovigilance

One of the most significant developments in pharmacovigilance is the use of AI-powered automation. This has fundamentally altered the way that safety signals and adverse events are recognized, assessed, and addressed in the pharmaceutical and healthcare sectors. By using sophisticated algorithms, machine learning methods, and natural language processing (NLP) to quickly and effectively understand enormous volumes of real-world data sources, artificial intelligence integration is poised to completely transform pharmacovigilance [54]. AI integration improves the compilation of reports of pharmaceutical side effects from various sources. By aggregating data from multiple sources, we attain a more thorough comprehension of the potential risks and benefits associated with a medication. It allows us to process substantial amounts of information quickly. Therefore, we may analyze several reports and identify patterns or trends more rapidly [55].

Predictive modeling methods powered by artificial intelligence (AI) are used to calculate the probability of adverse effects linked to particular medications or their combinations. These models assist in identifying possible high-risk circumstances by examining historical data, such as previous drug exposures, patient demographics, and recorded adverse events. This knowledge facilitates well-informed decision-making at every stage of the drug lifecycle, from clinical application to regulatory review and drug development. In the end, predictive modeling strengthens pharmacovigilance's proactive safety monitoring and risk reduction initiatives [56].

Pharmacovigilance has taken on a new dimension with the combination of wearable technology and artificial intelligence (AI), which allows for continuous, real-time health monitoring. Vital signs, physical activity, and medication adherence can all be tracked by wearable technology, producing enormous amounts of data unique to each patient. AI-enabled technologies process this real-time data to immediately identify potential adverse drug interactions. These technologies can improve the accuracy and responsiveness of post-marketing surveillance by providing customized safety alerts and adaptive monitoring plans based on the requirements of each patient [57].

In pharmacovigilance, artificial intelligence (AI) greatly improves the standard and comprehensiveness of risk-benefit analyses. AI systems can combine many different types of information, like what patients prefer, how well treatments work, how serious the illness is, and individual patient characteristics, unlike traditional methods that often depend on limited clinical trial data. Artificial intelligence-powered systems facilitate more thorough and individualized assessments by compiling and evaluating data from a variety of sources, including observational studies, clinical trials, real-world data, and patient-reported outcomes. Ultimately, this holistic approach aligns therapeutic approaches with clinical effectiveness and patient-centered care by empowering regulators and healthcare practitioners to make more informed judgments about the safety and effectiveness of medications and interventions [58].

Pharmacovigilance systems rely heavily on artificial intelligence (AI) to drive ongoing quality improvement. Artificial Intelligence (AI) tools can detect inefficiencies, minimize errors, and provide opportunities for operational optimization by evaluating process-level data. To identify best practices and address bottlenecks, these systems evaluate critical performance metrics like workflow timings, data completeness, and

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JCHR (2026) 16(2), 2451-2463 | ISSN:2251-6727

reporting accuracy. Consequently, pharmacovigilance teams might make specific enhancements that boost system dependability, expedite case processing, and guarantee better safety data. In the end, insights powered by AI help create a pharmacovigilance system that is more adaptable, efficient, and responsive [58].

Pharmacovigilance's reach has been greatly expanded by the combination of artificial intelligence (AI) and health information exchanges (HIEs), which allow for thorough safety monitoring in various healthcare environments. By standardizing how data is formatted, named, and shared, AI-powered platforms make it easier for pharmacies, regulatory bodies, and healthcare providers to share important information like patient histories, test results, and medication records. A more coordinated and proactive approach to medication safety is supported by this networked infrastructure. More and more people are using AI algorithms to predict potential drug interactions based on the medication profiles of individual patients [59]. AI can instantly detect interactions and contraindications by examining drug classes, pharmacokinetic characteristics, and current prescriptions. In addition to helping medical practitioners optimize treatment plans, this skill lowers the possibility of polypharmacy-related adverse events, which eventually improves patient outcomes and medication safety [60]. The examples of some key technologies and applications are given below the table.

Examples of implementing AI in pharmacovigilance

IBM Watson Health for Drug Safety	It has used natural language processing (NLP) and machine learning (ML) methods to analyse various structured and unstructured data from EHRs and social media to identify potential harmful adverse drug reactions (ADR). It helps to identify and monitor drug safety and decision-making. It needs a high initial investment as well as potential algorithmic bias [61].
AstraZeneca predictive Modeling for drug safety	AstraZeneca uses AI-driven systems to find adverse events and signals. This helps them follow the rules, but it requires skilled workers and infrastructure investments, and it's possible that they miss real adverse events [62].
Advera Health Analytics Signal Mine	Advera Health Analytics' SignalMine platform is a powerful AI-powered tool for optimizing risk assessment and adverse event monitoring processes. The technology improves safety signal detection processes' accuracy and efficiency by utilizing machine learning methods. However, issues with system integration and scalability could affect how effective it is. Additionally, the platform's overall performance and dependability in pharmacovigilance applications are greatly influenced by the caliber and accessibility of the input data [63].
Oracle Health Sciences Argus Safety	Oracle's Argus Safety is a complete pharmacovigilance platform that uses AI and machine learning to detect signals and automatically report adverse occurrences. Benefit: It detects signals and automatically reports negative situations. Cons: It is quite expensive to set up and maintain. Limitation: The program must be constantly reviewed and observed [64].
Bayer's AI-Driven Risk-Benefit Analysis	Bayer analyzes real-world data, such as adverse event reports and clinical trial results, using AI platforms to continuously evaluate the benefit-risk profile of its medications. These techniques facilitate proactive, data-driven pharmacovigilance and aid in the early detection of new safety issues. This speeds up regulatory judgments and guarantees the safety of medications for all patient groups [64].

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JCHR (2026) 16(2), 2451-2463 | ISSN:2251-6727

4.Challenges in implementing Artificial Intelligence (AI) in Pharmacovigilance

Even if artificial intelligence (AI) has a lot of potential to transform pharmacovigilance (PV), there are several major obstacles in the way of its application. The transition from conventional human-led approaches to AI-driven pharmacovigilance necessitates cautiously navigating obstacles related to technology, ethics, regulations, and infrastructure. The problem of data standardization and quality is among the most urgent ones. High-quality, organized data is essential for AI systems to identify safety signs and generate precise predictions [56]. However, the data used in PV is frequently inconsistent, unstructured, and incomplete, especially when it comes to data from social media, spontaneous adverse event reporting systems, and electronic health records (EHRs). Training robust and generalizable machine learning (ML) models is challenging due to this heterogeneity. Also, it's harder to combine data and scale models because there are no standard data formats and classifications used in different pharmacovigilance systems and regions [65].

The lack of explainability and transparency in AI algorithms, particularly deep learning (DL) models, is another significant worry. These models frequently function as "black boxes," which makes it difficult for regulators and medical practitioners to comprehend how a certain output or safety alert was produced. In crucial medication safety situations, this opacity erodes confidence and calls into question the dependability and accountability of AI-driven decisions. Interpretability is even more important for pharmacovigilance systems, which have a direct impact on public health [66].

Significant obstacles are also presented by ethical and legal considerations. Concerns about patient privacy, data ownership, and informed consent arise when AI is used in PV to process sensitive personal health data. Furthermore, strict anonymization and data governance procedures are required in order to comply with data protection rules like the General Data Protection Regulation (GDPR) in the European Union. This problem is made more difficult by the absence of globally uniform regulatory frameworks for the use of AI in healthcare, which frequently leaves pharmaceutical companies and health authorities unsure of how to operationalize and validate these technologies within the bounds of the law [67].

A major change in organizational culture and professional skills is also required for the integration of AI technologies into current pharmacovigilance workflows. The majority of pharmacovigilance teams are typically made up of regulatory experts, pharmacists, and doctors who might not have the computational literacy needed to work with AI systems efficiently. Significant investment in multidisciplinary training and the creation of intuitive AI interfaces that assist decision-making without overwhelming users are necessary to close this gap in human-AI collaboration [68].

The effectiveness of AI models is further constrained by bias and generalizability problems. When used in different demographic or clinical contexts, algorithms that were trained on datasets from particular demographics or geographical areas could not function as intended. This may lead to false alarms or missed adverse event signals, endangering patient safety and taxing medical resources. Although they are technically and operationally challenging, ensuring algorithmic fairness and creating systems to track and address prejudice are crucial [69].

Finally, the implementation of AI is practically hampered by infrastructure and financial limitations. High levels of financial investment, a strong IT infrastructure, and continuous technical assistance are necessary for the creation and upkeep of complex AI systems. These standards can be unaffordable for regulatory agencies in underdeveloped nations, smaller pharmaceutical businesses, and healthcare facilities with limited resources. Therefore, disparities in global pharmacovigilance capacity and drug safety monitoring may be worsened by the digital divide [70]. In a broader sense, however artificial intelligence (AI) presents a potent supplement to conventional pharmacovigilance systems; its use is rife with complex difficulties. To overcome these obstacles and create reliable, just, and long-lasting AI-driven pharmacovigilance systems, technologists, medical experts, regulators, and legislators must work together.

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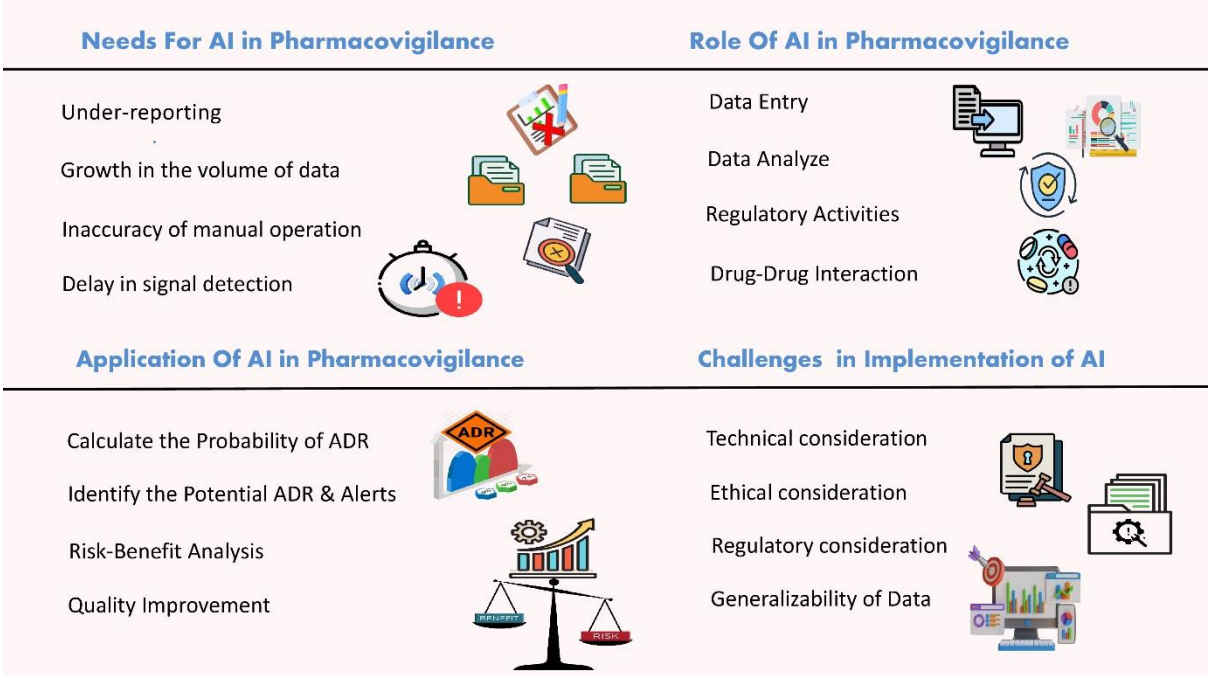

Discussion

The introduction of AI in pharmacovigilance represents a paradigm shift from conventional reactive tactics to proactive, predictive, and real-time surveillance mechanisms. This review highlights how using AI tools can enhance the detection of safety signals, speed up the handling of adverse drug reactions (ADRs), and support better decisions by regulators. Artificial intelligence (AI) leverages techniques such as natural language processing, machine learning, and neural networks to extract valuable insights from large-scale data sources, including social media platforms, electronic health records, and spontaneous reporting systems. This allows AI to find hidden patterns and safety signals that might otherwise go overlooked.

Despite the immense potential of technology, there remain barriers to its effective implementation. To ensure that AI helps improve drug safety instead of putting it at risk, we need to address issues like different types of data, unclear algorithms, ethical concerns, and uncertain regulations. Additionally, human monitoring is still required to comprehend insights generated by AI and to maintain the integrity and contextual relevance of pharmacovigilance protocols. Multidisciplinary collaboration between doctors, data scientists, regulatory agencies, and software engineers is crucial to achieving the goal of AI-augmented pharmacovigilance.

The creation of globally defined data formats and regulatory requirements should also be a top priority for future plans. Funding healthcare workers' education to understand and use AI technologies will further facilitate effective adoption. Pilot initiatives must give way to long-term, scalable solutions that can be verified in many healthcare contexts as AI technology advances.

Conclusion

Artificial intelligence (AI) has emerged as a disruptive force in pharmacovigilance due to its powerful ability to enhance risk management and pharmaceutical safety monitoring. AI has the potential to alleviate a number of the drawbacks of conventional pharmacovigilance techniques, from facilitating real-time decision-making to enhancing adverse event identification. But achieving this promise will involve overcoming formidable obstacles pertaining to explainability, ethics, data quality, and regulatory approval. Stakeholders can make the most of AI to create a new era of proactive and patient-focused drug safety monitoring by promoting teamwork across different fields, supporting new regulations, and ensuring that AI systems are clear and fair.

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JCHR (2026) 16(2), 2451-2463 | ISSN:2251-6727

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