International Journal of Advanced Multidisciplinary Research and Educational Development
Volume 1, Issue 4 | November - December 2025 | www.ijamred.com
ISSN: 3107-6513

A Short Overview of Using Artificial Intelligence in Pharmacovigilance

Dr. Joydeep Singh
Department of Pharmacy Practice, School of Pharmaceutical Sciences,
Shri Guru Ram Rai University, Dehradun, Uttarakhand-248001, India
Email: singhjoydeep738@gmail.com

Abstract:

Artificial Intelligence (AI) is transforming pharmacovigilance by enhancing the detection, assessment, and prevention of adverse drug reactions (ADRs). Leveraging technologies such as Machine Learning (ML), Natural Language Processing (NLP), and Robotic Process Automation (RPA), AI enables the analysis of vast datasets from diverse sources, including electronic health records, social media, and clinical trials . AI automates routine tasks like case processing, medical coding, and report generation, significantly reducing manual effort and human error. For instance, NLP algorithms can extract relevant information from unstructured data, transforming it into structured formats for analysis . Additionally, ML models can identify patterns and predict potential ADRs, facilitating early detection and proactive risk management .The integration of AI in pharmacovigilance leads to improved efficiency, accuracy, and compliance with regulatory standards. AI-powered systems ensure timely and consistent reporting of ADRs, enhancing patient safety and optimizing resource utilization .However, challenges remain, including data quality, algorithm transparency, and the need for human oversight in complex cases. Despite these hurdles, AI continues to revolutionize pharmacovigilance, offering a more proactive and data-driven approach to drug safety monitoring.

Keywords— Artificial Intelligence, Pharmacovigilance, Adverse Drug Reactions, Machine Learning, NLP

1.0 INTRODUCTION

Pharmacovigilance (PV) is the science focused on spotting, understanding, and preventing side effects or any harmful effects that medicines might cause(1). It's a key part of drug development and safety, aimed at closely monitoring patterns of adverse events (AEs) linked to specific drugs.The main goal of PV is to quickly identify these adverse drug reactions (ADRs) and take steps to reduce their impact, helping to protect public health throughout a drug's entire life cycle-from clinical trials to post-marketing use(2). To do this, PV brings together several important activities, including reviewing clinical trial data, analyzing medical literature, managing potential risks, and reporting individual cases of adverse reactions (2).On the flip side, artificial intelligence (AI) is proving to be a real game-changer in pharmacovigilance. By automating routine tasks like case processing, Al can significantly cut down on costs and boost the efficiency of drug safety activities. At its core, Al is about teaching computers to think and learn like humans helping them tackle problems, recognize patterns, and make smart decisions. Unlike traditional systems, AI is built with this kind of problem-solving ability from the ground up. That's why it's becoming especially valuable in fields like life sciences, pharmacovigilance, and medical information. It's not just about saving time and money-it's about making smarter, faster, and more accurate decisions that ultimately benefit patients. Artificial Intelligence (AI) is transforming the world of pharmacovigilance by making it faster, smarter, and more efficient. With the help of machine learning, natural language processing (NLP), and advanced algorithms, Al can now process huge amounts of real-world data in ways that were never possible before (3). Al-powered systems are capable of scanning everything from social media posts and adverse event reports to medical journals and electronic health records. By analyzing all this information, they can detect patterns, spot unusual trends, and even uncover early signs of potential safety issues or unexpected side effects often much faster than traditional methods.

ISSN: 3107-6513

2.0 NEED OF ARTIFICIAL INTELLIGENCE IN PHARMACOVILANCE

The number of suspected adverse event (AE) reports in pharmacovigilance databases has skyrocketed in recent years. With this surge comes the huge challenge of making sense of all that data. It's like trying to find needles in a haystack— especially when the information comes from so many different sources. For key players like pharmaceutical companies, regulators, medical professionals, and those managing national pharmacovigilance programs, keeping up with this flood of information is no easy task.Traditionally, processing each individual case safety report (ICSR) requires collecting some core details: information about the patient, the person reporting the event, what exactly happened, the medications involved (both suspected and other drugs), and the outcome. Doing this manually for thousands sometimes millions-of reports can be overwhelming. When a case is being processed, several things need to be checked. Experts look at whether the adverse event (AE) is something already expected based on the drug's official prescribing info. They also assess how likely it is that the drug actually caused the event, how serious or severe the reaction is, and whether all the necessary information is included to make the report valid for regulatory submission. This whole process involves a mix of manual work and human judgment. It requires trained professionals and technical know-how, which makes it both costly and time-consuming. With the growing number of reports, there's been a lot of interest and excitement around using Al to help automate these tasks and reduce the pressure on human teams. Opportunities and benefits. Al tools are being seen as really helpful when it comes to handling Al tools can take over a lot of routine tasks in pharmacovigilance, like automatically coding medical terms using the Medical Dictionary for Regulatory Activities (MedDRA), spotting duplicate reports, and sorting cases into those reported by doctors versus consumers. They can also flag serious reports and filter out the non-serious ones. What's really impressive is that Al can even work with messy, unstructured data—like free-text notes— pulling out the important details to create clear, clinically sound case narratives. It can recognize patterns in both structured and unstructured data, which means there's less need for people to manually review each individual case. On top of all that, Al can also pull safety information from a wide range of sources, including medical literature, case reports, drug reviews on social media, free-text clinical notes in electronic health records, and even hospital discharge summaries. It's a powerful way to stay on top of potential safety issues across all kinds of data.

3.0 AI TECHNOLOGIES USED IN PHARMACOVIGILANCE

A range of Al technologies is being applied in pharmacovigilance to enhance the way drug safety data is collected, analyzed, and acted upon. Machine learning (ML) algorithms are commonly used for pattern recognition and predictive modeling, helping identify potential adverse drug reactions (ADRs) earlier than traditional methods. Natural language processing (NLP) plays a key role in extracting meaningful information from unstructured sources such as clinical notes, social media posts, and spontaneous reports. Deep learning, a subset of ML, is particularly useful in handling large-scale, complex datasets and improving the accuracy of signal detection. Additionally, robotic process automation (RPA) is being used to streamline repetitive tasks like data entry and case processing, significantly reducing the workload on pharmacovigilance teams. Together, these technologies enable a more proactive, efficient, and scalable approach to monitoring drug safety. Natural Language Processing (NLP) is already making an impact in pharmacovigilance, especially in creating ICSR (Individual Case Safety Report) narratives. These tools can take structured data—like patient info, adverse events, and drug details and turn it into written or unstructured data.Looking ahead, the same NLP technology could be expanded to automate more complex and time-consuming reports, like PSURs (Periodic Safety Update Reports) and DSURs (Development Safety Update Reports). These are long, data-heavy documents that require careful summarization of trends, safety signals, and case series. There's also exciting potential for using LG in signal management.

Machine Learning and Deep Learning

Machine learning (ML) is an application of Al that provides computerized systems with the ability to automatically learn and improve from experience without being explicitly programmed. Some implementations of machine learning use neural networks. ML focuses on the development of computer programs that can access data and use it to learn for themselves and adapt over time. The computer programs apply historic understanding to predict

ISSN: 3107-6513

accurate outcomes from current inputs. Machine learning has the potential to support many areas of pharmacovigilance, including ICSR processing, aggregate report generation, risk management, signal detection, and quality management systems (QMS). It can help automate tasks, find patterns in data, and improve decision-making across the safety workflow. Robotic Process Automation (RPA) uses software "bots" to handle tasks that are usually repetitive, high-volume, and rule-based-like parts of adverse event case processing. These bots follow set rules and work with structured data, doing the same steps a human would, just faster and without needing a break. Basically, RPA takes care of the routine stuff so teams can focus on more complex, decision-heavy work.

4.0 APPLICATIONS OF ARTIFICIAL INTELLIGENCE IN PHARMACOVIGILANCE

Al is being used in pharmacovigilance to automate case processing, detect safety signals, analyse unstructured data, predict risks, and streamline literature screening, ultimately improving the speed and accuracy of drug safety monitoring. These applications collectively enhance the ability to ensure safer use of medicines and faster response to potential risks. Adverse Drug Reactions (ADRs) and Adverse Drug Events (ADEs) Detection. Artificial Intelligence can help with key safety tasks like detecting adverse drug reactions (ADRs), monitoring safety trends, and supporting signal detection. One real-world example is using ML to automatically identify and classify first-person reports of side effects shared on social media. This helps safety teams keep an eye on what patients are experiencing in real time-without having to read through thousands of posts manually and detect ADRs that may not be captured by medical professionals. As patients are dealing with multiple health conditions, taking several medications, and experiencing different side effects, the automation in machine learning is becoming more and more helpful. It can sort through complex data faster and more accurately than manual methods, making it easier to spot potential safety concerns from early clinical trials all the way through to post-marketing safety monitoring. Artificial intelligence can also make a big difference in managing specific diseases like diabetes. For example, a tool called HypoDetect uses natural language processing (NLP) to read blood glucose data, show it in a clear visual format, and spot signs of hypoglycemia early using smart algorithms. This helps healthcare providers act quickly and start treatment sooner, improving patient safety and outcomes.

Case Processing :

Al tools are making a big difference in how we handle case processing, especially when it comes to spotting and managing adverse events. Instead of going through countless safety reports manually, these tools can quickly scan through large volumes of data, picking out important details and organizing them in a way that makes sense. They're particularly good at identifying potential adverse drug reactions with a level of accuracy that helps reduce human error. Managing individual Case Safety reports (ICSRs) has been one of the most frequently flagged areas during inspection. That's why there's a growing focus on how automation and Al can help. By bringing these technologies into the process, teams can work more efficiently and consistently, reduce errors, and maintain high-quality standards across case management, narrative writing, and quality checks. It also means being better prepared for future inspections, with cleaner, more reliable data and processes.

Clinical Trials :

Bringing a new drug to market is a long and complex journey, it typically takes around 10 to 12 years, and nearly half of that time is spent in the clinical trial phase. One of the biggest hurdles during this stage is finding the right patients and selecting the best trial sites. If this isn't done efficiently, it can slow everything down or even cause the trial to fail altogether. To tackle these challenges, more pharmaceutical companies are turning to Al. It's not just about cutting research and development costs. Al also helps avoid expensive mistakes. By digging into massive amounts of data, Al can pinpoint specific groups of patients who are more likely to benefit from a particular trial. That means smarter, faster recruitment, and a better shot at successful outcomes. Al-powered monitoring systems help keep clinical trials on track by making sure everything runs smoothly. They're designed to uphold the integrity of the trial and ensure that all activities follow important regulatory standards, like the ICH-GCP guidelines.

Causality assessment :

Figuring out whether a drug actually caused a reported side effect is something called causality assessment, is a key part of drug safety. It's not always clear-cut, and that's where Al can really help. Using advanced models, Al looks at patterns and probabilities to gauge how likely it is that the drug caused the adverse event.

ISSN: 3107-6513

This kind of insight is incredibly valuable for managing risks and staying on top of regulatory requirements. It also helps make the call on whether a side effect is truly linked to the drug or just happened by coincidence.

Regulatory Compliance :

Al-powered systems are helping take the pressure off when it comes to safety reporting.They make sure reports are submitted on time, are thorough, and meet all the necessary global regulatory standards. By automating these tasks, there's less room for human errors in documentation and more consistent reporting. In the end, that means safer medicines for patients and better compliance for the companies behind them.

Signal Detection and Risk Management :

In drug safety, spotting early warning signs is known as signal detection, is incredibly important. Al is making this process much more powerful by digging through huge amounts of data to find patterns that might otherwise go unnoticed. It can analyse everything from structured clinical trial data to less straightforward sources like medical journals or even social media posts. Al can help identify potential risks linked to a pharmaceutical product much earlier, giving a head start in keeping patients safe.

Performing Analysis :

In today's digital world, the amount of safety data available is growing fast, and Al is helping companies make the most of it. By using machine learning and advanced data techniques, Al can quickly analyse complex datasets to uncover patterns and solve challenging problems. This includes identifying how a drug affects different people, linking compounds to specific genes, or even spotting new uses for existing medications. Ultimately, it leads to better understanding of diseases, earlier detection of risks, and improved patient safety.

5.0 BENEFITS OF ARTIFICIAL INTELLIGENCE IN PHARMACOVIGILANCE

Al is transforming pharmacovigilance by making the process of detecting and managing drug safety issues faster, more accurate, and more efficient. With the ability to analyze massive amounts of data from sources like clinical trials, electronic health records, and even social media, Al can identify patterns and potential adverse drug reactions much earlier than traditional methods. It also helps reduce the manual workload for safety professionals by automating routine tasks like case processing and literature screening, allowing teams to focus more on complex decision-making. Ultimately, Al supports a more proactive approach to patient safety, helping ensure that risks are caught and addressed sooner. Adverse Event Prediction: Al can be used to develop predictive models that identify patients at risk of adverse drug reactions and pinpoint groups needing closer monitoring after treatment. This helps reduce adverse events and enhances overall drug safety. Al can process vast amounts of data from electronic health records, social media, clinical trials, and scientific literature to detect signals of adverse drug reactions (ADRs) faster than manual methods. Enhancing Data Collection and Analysis: Al and intelligent automation help manage the overwhelming volume of pharmacovigilance data by quickly extracting relevant information from multiple sources and using machine learning to detect patterns that may signal side effects or drug interactions. Al can identify patients at higher risk for specific ADRs, helping in risk minimization and targeted post-marketing surveillance. Faster Case Processing: Al is transforming drug safety case processing by automating tasks like data entry, case triage, and causality assessment. Using natural language processing (NLP), Al can extract key details from free-text reports, saving time, reducing costs, and improving the accuracy and completeness of safety data, ultimately supporting better patient outcomes and regulatory compliance. Natural Language Processing (NLP) can quickly extract relevant information from unstructured text (like clinical notes or patient narratives), speeding up Individual Case Safety Report (ICSR) processing.

Real-Time Signal Detection: Al enhance signal detection by analysing large datasets like electronic health records and social media to identify potential adverse drug effects. These tools use statistical algorithms and machine learning to detect and prioritize signals based on severity and likelihood, helping pharmacovigilance teams focus on the most critical safety issues efficiently.

Cost Reduction: By automating routine pharmacovigilance tasks, organizations can reduce labor costs while freeing up safety experts to concentrate on more meaningful work—like complex case evaluations and making strategic decisions that truly impact patient safety.

Improved Accuracy and Consistency: Al models reduce human error and variability in data entry and

ISSN: 3107-6513

case assessment, improving the consistency of adverse event reporting and evaluation.
Scalability: Al systems can handle growing volumes of safety data efficiently, making it easier to manage pharmacovigilance activities as new drugs enter the market.

Case Management and Prioritization: Al can support case triage by prioritizing adverse event reports based on severity and potential impact, helping teams allocate resources more effectively and address urgent cases faster.

Data Quality Assurance: Al help improve pharmacovigilance data quality through cleaning, duplication, and standardization, ensuring accurate and reliable data for better analysis and decision-making.
Enhanced Regulatory Compliance: Al and IA tools support regulatory compliance in pharmacovigilance by automating tasks like adverse event reporting and safety updates, while also enabling real-time monitoring and alerts to help teams respond quickly and manage risks effectively.
Literature Screening and Data Mining: Al can help take the pressure off by automatically screening and reviewing scientific literature for important safety information. With the help of natural language processing (NLP), it can pull useful data from research articles, clinical trials, and case reports, making it easier to spot potential safety issues early on. Al can dig through large pharmacovigilance databases to uncover patterns and connections that might be hard to spot using traditional methods. This can lead to the discovery of previously unknown drug interactions, unexpected side effects, and early safety signals that might otherwise go unnoticed.

6.0 CHALLENGES & LIMITATIONS

It's clear that bringing new and innovative Al technologies into the field of pharmacovigilance isn't just a trend, it's becoming a necessity to keep up with the growing demands of monitoring drug safety. While we've already seen some impressive advancements, we're still facing a number of challenges. To truly make the most of what Al has to offer, we need to better understand the complexities behind these technologies and work through their limitations.

Data Quality and Quantity: High-quality data is at the heart of any successful Al model, and this is especially true in pharmacovigilance. The information used to track and predict drug safety comes from many places-like electronic health records, patient reports, and clinical trials. But working with this data isn't always straightforward. It can be messy, incomplete, or contain mistakes. Sometimes, patients or doctors don't report everything, or they may report things in different ways, which makes the data harder to trust. Plus, when it comes to rare side effects or newly approved drugs, there often just isn't enough information to build strong Al models. All of these challenges can affect how accurate and useful Al predictions really are :
Data Integration and Standardization: In pharmacovigilance, one big challenge is that data comes from all over the place-different systems, databases, and formats. It's often scattered and doesn't always speak the same language. Trying to bring all this information together and make it consistent is no small feat. Different terms, coding standards, and ways of recording things can make it really tough for systems to understand each other. Without standardization, it's hard to get a clear, unified view of what the data is actually saying. But to get meaningful insights— and to make Al truly useful-we need to pull all that fragmented data into one cohesive picture.
Regulatory Compliance: Pharmacovigilance is heavily regulated, and any Al tools used in this space have to meet strict standards set by agencies like the FDA or EMA. Making sure these systems follow the rules isn't easy, it takes a lot of time, effort, and resources. From keeping detailed documentation to validating the Al's performance and ensuring everything can be audited later, the process can be challenging and complex for any organization.
Interpretable Models: In pharmacovigilance, being able to understand how an Al model makes its decisions is incredibly important, after all, these decisions can directly impact people's health and safety. The problem is, many of the most powerful Al models, like deep learning systems, work in ways that are hard to explain. They're often seen as "black boxes," where it's not clear why they came to a particular conclusion. Finding the right balance between accuracy and transparency remains a tough but essential challenge in this field.
Class Imbalance: When it comes to detecting adverse drug events, one big challenge is that these events are pretty rare compared to the huge amount of data on regular drug use. This imbalance can make it hard for

ISSN: 3107-6513

Al models to learn how to spot the rare but important cases. As a result, the system often gets really good at recognizing the common, non-problematic outcomes, but struggles to catch the rare, harmful ones. To fix this, researchers use techniques like oversampling the rare events, undersampling the common ones, or choosing smarter evaluation methods that don't just reward overall accuracy, but focus on how well the model does with the rare, high-risk cases.

Resource and Expertise Constraints: Using Al in drug safety monitoring (pharmacovigilance) isn't as simple as just plugging in a system—it takes a lot of resources. You need strong computing power, solid data systems, and skilled people who understand both Al and the complexities of drug safety. For smaller pharma companies or healthcare providers, this can be a real hurdle. On top of that, the field is constantly evolving, so staying up to date with the latest tools, methods, and regulations takes ongoing effort and expertise. I's not just about having the tech it's about having the right people and support to use it effectively.

Data Privacy: Using patient data to improve drug safety is incredibly valuable- but it also comes with serious responsibilities. Al models need large amounts of information to work well, and that often includes personal health details. Naturally, this raises concerns about privacy. It's crucial that any system handling this kind of data follows strict rules, like those set out in the GDPR, to make sure people's health information stays protected. The goal is to harness the power of Al without ever putting patient confidentiality at risk.

Ethical Considerations: When we use machine learning in drug safety, it's not just about protecting privacy-ethics go much deeper. We have a responsibility to make sure these tools don't unintentionally favor one group over another or leave anyone out. That means being careful with how data is collected, how models are trained, and how decisions are made. At the end of the day, the goal is to use technology in a way that's fair, respectful, and focused on improving people's health-without introducing new risks or inequalities.Even though there are real challenges to using Al in drug safety, the benefits are hard to ignore. With the right teamwork-bringing together experts in healthcare and Al—and by tackling issues like data quality and fairness, we can unlock AI's full potential. It can help us catch problems earlier, improve patient safety, and stay on top of regulatory demands. In the end, it's about using technology not just because it's powerful, but because it can truly make a difference in how we care for people.

7.0 RESULT & DISCUSSION

Al applications in pharmacovigilance enhance drug safety monitoring by using large datasets and advanced analytics to identify potential risks more effectively. This includes early detection of adverse drug reactions (ADRs), more accurate risk assessments, and the identification of new safety signals.

Results of Al in Pharmacovigilance:

Improved Signal Detection: Al algorithms can analyze vast amounts of data from diverse sources (e.g., electronic health records, social media, clinical trials) to identify subtle patterns and correlations that might be missed by human analysts, leading to earlier detection of ADRs.

Enhanced Risk Assessment: Al can automate tasks like case triaging, data extraction, and causality assessment, freeing up human experts to focus on more complex cases and strategic decision-making.

Faster and More Efficient Processes: Al-powered systems can streamline pharmacovigilance workflows, reducing processing time and improving the speed of safety information dissemination, according to the International Journal of Pharmaceutical Sciences.

Personalized Safety Assessments: Al can be used to tailor safety assessments to specific patient populations, considering individual characteristics and medical history, potentially leading to more effective and targeted risk management strategies.

Discussion on challenges:

Data Quality and Biases: Al model performance depends greatly on the quality and completeness of the data they learn from. If the training data is inconsistent, incomplete, or biased, it can lead to inaccurate or unfair predictions.

Regulatory Framework: Regulatory agencies must develop clear standards for validating Al algorithms to ensure patient safety, as existing regulations may not fully account for the unique aspects of Al technologies.

Transparency and Explainability: Understanding how Al models make decisions is essential for building trust and allowing human oversight. When Al lacks transparency, it becomes harder to interpret and integrate into current pharmacovigilance processes.

Ethical Considerations: Using Al in pharmacovigilance brings ethical challenges, including protecting patient privacy, ensuring data security, and addressing

ISSN: 3107-6513

algorithmic bias that could unfairly impact certain populations.

8.0 CONCLUSION :

Recently, there's been a lot of talk about how to best use Al in pharmacovigilance, with much of the focus on tackling the challenge of case intake, which has long been a costly and time-consuming task for safety teams. But the potential of Al goes far beyond that. The future of Al in pharmacovigilance is much more expansive, with opportunities to improve many other areas, from detecting risks earlier to making safety processes more efficient. Al is changing the game in drug safety and clinical research. It's helping us process data faster, make better decisions, and speed up drug development. From our experience, these technologies have made a real difference in boosting both the speed and accuracy of monitoring drug safety and running clinical trials. As Al continues to grow, it's important that regulations keep up to ensure these tools are used responsibly and ethically. Looking ahead, Al has the potential to do even more, not just by making research more efficient, but by improving long-term drug safety and patient care. With its ability to detect side effects earlier, tailor treatments to individuals, and manage risks more precisely, Al is paving the way for a smarter, more personalized, and patient-focused future in healthcare.

REFERENCES:

1. Definition of Pharmacovigilance

World Health Organization. The safety of medicines in public health programmes: pharmacovigilance an essential tool. WHO; 2002. ISBN 92 4 159391 1.

World Health Organization. Pharmacovigilance: ensuring the safe use of medicines. WHO; 2004.(ReferenceWHO/EDM/2004.8) pubmed.ncbi.nlm.nih.gov+3who.int+3en.wikipedia.org +3who.int

2. Goals & Activities in the Drug Life Cycle

Indian Pharmacopoeia Commission; Pharmacovigilance Programme of India. PvPI toolkit; WHO–IPC; 2018. (Defining PV as “science relating to detection, assessment, understanding and prevention of adverse effects…”) ipc.gov.in+1who.int+1

3. Rise in AE Reporting & Role of AI

Frontiers in Drug Safety and Regulation. Rudolph G, Kassekert R, et al. “An industry perspective on the use of machine learning in drug and vaccine safety.” Frontiers; 2023. (Over 1.8 million new safety reports following COVID-19 vaccines; interest in ML, NLP, RPA across PV activities) journals.stmjournals.com+2frontiersin.org+2link.springer.com+2

TransCelerate BioPharma Inc. “Automation opportunities in pharmacovigilance: An industry survey.” Pharmaceutical Medicine; 2019. (Growth in reports due to new therapies, patient programs, social media; RPA, ML, NLP flagged as key technologies) link.springer.com+7link.springer.com+7link.springer.com+7

4. AI Technologies & Their Benefits in PV

Mohd. Wasiullah, Piyush Yadav, Satish K. Yadav & Rishabh Chauhan. “Artificial Intelligence in Pharmacovigilance: Improving Drug Safety.” RRJoCB 14(1):1–16; 2025. (Review of ML, NLP, big data, and challenges like interpretability, compliance) journals.stmjournals.com

Kompa B, Hakim JB, Palepu A, et al. “Artificial Intelligence Based on Machine Learning in Pharmacovigilance: A Scoping Review.” Drug Saf. 2022;45:477–491. DOI:10.1007/s40264-022-01176-1 pubmed.ncbi.nlm.nih.gov+2link.springer.com+2link.springer.com+2

5. AI Applications like NLP & Deep Learning

Li Y, Viswaroopan D, He W, et al. “Artificial intelligence-powered pharmacovigilance: A review of machine and deep learning in clinical text-based adverse drug event detection for benchmark datasets.” J Biomed Inform. 2025;163:104789. DOI:10.1016/j.jbi.2025.104789 pubmed.ncbi.nlm.nih.gov+1link.springer.com+1

Murphy RM, Klopotowska JE, de Keizer NF, et al. “Adverse drug event detection using natural language processing: A scoping review of supervised learning methods.” PLoS One. 2023;18(1):e0279842. DOI:10.1371/journal.pone.0279842 pubmed.ncbi.nlm.nih.gov

Dai X, Karimi S, Sarker A, et al. “MultiADE: A Multi-domain benchmark for Adverse Drug Event extraction.” J Biomed Inform. 2024;160:104744. DOI:10.1016/j.jbi.2024.104744 pubmed.ncbi.nlm.nih.gov

Trajanov D, Trajkovski V, Dimitrieva M, et al. “Review of Natural Language Processing in Pharmacology.” arXiv:2208.10228; Aug 2022. arxiv.org

6. Challenges & Limitations (Data, Interpretability, Ethics)

ISSN: **3107-6513**

Kompa B, Hakim JB, Palepu A, et al. Drug Saf. 2022 scoping review highlighting data quality, transparency, and ethical constraints of AI systems link.springer.com Mohd. Wasiullah et al. RRJoCB 2025; discussing challenges like model transparency, regulatory issues, data privacy

7. Markey J and Traverso K. The untapped potential of Al & Automation Pharmacovigilance. ISPE. Pharmaceutical Engineering. August 2020, Accessed 18 August 2022.

8. Taylor K, May E, Powell D, et al. Intelligent post-launch patient support. Deloitte insights. 27 July 2022. Accessed 19 August 2022. https://www2.deloitte.com/us/en/insights/industry/life-sciences/artificial-intelligence-in-healthcare-pharmacoviligance.html

9. Danysz K, Cicirello S, Mingle E, et al. Artificial Intelligence and the Future of Drug Safety Professional. Drug Saf. 2019;42(4):491-497. doi: 10.1007/s40264-018-0746-Z

10. Zurawski D. Enter Al: How technology is changing the pharmaceutical industry for the better. Pharmacy Times. June 26, 2020. Accessed 17 August 2022. https://www.pharmacytimes.com/view/enter-ai-how-tecinology-is-changing-the-pharmaceutical-industry-for-the-better

11. Murali K, Kaur S, Prakash A, and Medhi B. Artificial intelligence in pharmacovigilance: Practical utility. Indian J Pharmacol. 2019;51(6):373-376. doi: 10.4103/jp.IJP 814 19

12. Streefland MB. Why are we still creating individual case safety reports? Clin Ther. 2018;40(12):1973-1980. doi:10.1016/j.clinthera.2018.10.012.

13. Avenga Team. Artificial intelligence and machine learning in pharmacovigilance: current use cases and future opportunities. 18 May 2022.Accessed 19 August 2022.

14. Fornasier G, Francescon S, Leone R, et al. An historical overview over pharmacovigilance. Int J Clin Pharm. 2018; 40: 744- 747. https://doi.org/10.1007/s11096-018-0657-1.

15. Abatemarco D, Perera S, Bao SH, et al. Training augmented intelligent capabilities for pharmacovigilance: applying deep-learning approaches to individual case safety report processing. Pharmaceut Med. 2018;32(6):391- 401. doi:10.1007/s40290-018-02519.

16. Mintz Y and Brodie R: Introduction to artificial intelligence in medicine. Minim Invasive Ther Allied Technol. 2019;28(2):73-81. doi: 10.1080/13645706.2019.1575882

17. Ball R and Dal Pan G. "Artificial intelligence" for pharmacovigilance: ready for prime time?. Drug Saf. 2022;45: 429 438. https://doi.org/10.1007/s40264-022-01157-4.

18. Linger N and Karia S. Using AI to accelerate clinical trials. Deloitte. 2022 February. Accessed 18 August 2022. https://www2.deloitte.com/us/en/blog/health-care blog/2022/using-ai-to-accelerate-clinical-trials.html.

19. Mcgrail S. Al in the pharma industry: current uses, best cases, digital future. Pharmanews Intelligence. 2021 April. Accessed 21 August