Journal of Drug Discovery and Health Sciences

journal home page : https://jddhs.com/index.php/jddhs/index

Review Article

Role of Artifical Intelligence in Pharmacovigilance

Deepika Shukla, Shubham Bhatt*, Deepika Gupta and Shikhar Verma

Maharishi School of Pharmaceutical Sciences, MUIT, Lucknow, U.P, 226013, India.

ARTICLE INFO

Article history:

Received: 05, October, 2024

Revised: 04 November, 2024

Accepted: 06 December, 2024

Published: 30 December, 2024

Keywords:

Adverse Drug Reaction, Artificial Intelligence, Signal Detection, Pharmacovigilance, Healthcare Professionals, etc.

DOI:

10.21590/jddhs.01.04.06

ABSTRACT

Pharmacovigilance (PV) focuses on detecting, assessing, understanding, and preventing adverse drug reactions (ADRs) to ensure drug safety. As the pharmaceutical industry grows, traditional methods, such as clinical trials and manual reporting, are challenged by the increasing complexity of data. Artificial intelligence (AI) and machine learning (ML) have emerged as promising tools to enhance PV by automating processes, improving signal detection, and analysing vast datasets. AI can identify hidden safety signals, predict risks, and streamline case processing, reducing the workload and enhancing efficiency. Integrating AI into PV involves careful attention to data quality, compliance, and transparency. Future advancements, such as deep learning, real-time pharmacovigilance platforms, and multi-modal data integration, will further improve predictive modelling and drug safety monitoring. Despite the challenges of data complexity and privacy concerns, AI's role in PV continues to expand, offering new opportunities to safeguard public health and improve patient outcomes. Artificial intelligence (AI) is increasingly transforming pharmacovigilance, the science of monitoring the safety of medications. Traditional methods of detecting adverse drug reactions (ADRs) rely on spontaneous reporting systems, which can be slow and underreport ADRs. AI enhances these processes by enabling more efficient data analysis and improving signal detection. One key application of AI in pharmacovigilance is the use of machine learning algorithms to analyse vast amounts of data from diverse sources, including electronic health records, social media, and clinical trial databases. These algorithms can identify patterns and correlations that may indicate potential safety issues, allowing for faster and more accurate identification of ADRs. Natural language processing (NLP) is another critical AI component that facilitates the extraction of relevant information from unstructured data. By analysing physician notes, patient reports, and online discussions, NLP can uncover insights that traditional methods might overlook, thereby enriching the understanding of a drug's safety profile.AI can also support risk assessment by predicting potential safety issues based on historical data. Predictive analytics models can forecast the likelihood of adverse events, enabling proactive risk management strategies. Moreover, AI streamlines reporting processes by automating the data entry and compliance checks, reducing the administrative burden on healthcare professionals. This increased efficiency not only speeds up the reporting cycle but also enhances data quality, ensuring that regulators receive timely and accurate information. In summary, AI significantly enhances pharmacovigilance by improving data analysis, accelerating signal detection, and facilitating risk assessment. As AI technologies continue to evolve, their integration into pharmacovigilance practices is likely to lead to more robust drug safety monitoring systems, ultimately contributing to better patient outcomes and enhanced public health safety.

INTRODUCTION

The research and practices involved in identifying, evaluating, comprehending, and averting adverse effects or any other medication-related issue are known as pharmacovigilance. Pharmacovigilance, which is essential to both the pharmaceutical industry and public

***Corresponding Author:** Shubham Bhatt

Address: Maharishi School of Pharmaceutical Sciences, MUIT, Lucknow, U.P., 226013, India.

Email ✉**:** shubhatt521@gmail.com

Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

health, includes the science and efforts devoted to the identification, evaluation, comprehension, and avoidance of side effects and other drug-related issues. As the pharmaceutical industry develops, maintaining the safety of medications that are on the market becomes critical to protecting public health. The foundation of medication safety monitoring has traditionally been traditional pharmacovigilance techniques, which rely on clinical trials, spontaneous reporting systems, and regulatory reporting (*Cireşan et al., 2011*).

Finding the "needles in the haystack," or safety signals that need escalation and triage, is a critical task for PV, and it requires making sense of vast and heterogeneous amounts of data *(Edwards, 1997)*. Many have hypothesized that these similar technologies *(Jumper et al., 2021, Chen et al., 2019)* could be applied to address the fundamental issues with PV *(Gulshan et al., 2016, Schmaltz & Beam, 2021)* in light of the emergence of artificial intelligence (AI) and machine *(Beam & Kohane, 2016)* learning (ML) during the past ten years in numerous fields of science and medicine *(LeCun et al., 2015)*.

These techniques were initially used to human safety data in the early 1990s, and since the 2000s, their application has grown steadily *(Basile et al., 2019)*. The objective of this review is to systematically identify works that characterize the present status of machine learning in PV by using ML, generally defined, for safety data *(Bate & Hobbiger, 2021)*. It also aims to shed light on how recent developments in AI and ML might be applied to enhance different aspects of pharmacovigilance *(Alvager et al., 1993)*.

The studies and procedures that deal with the detection, assessment, understanding, and prevention of side effects or all other problems related to drugs is referred to as pharmacovigilance *(Divya et al., 2022)*, or PV, in line with the World Health Organization (WHO) *(U.S. FDA)*. Adverse drug reactions are reported world in a variety of handwritten, unstructured, and multilingual formats; on average, many companies receive over 3 lakh ADRs each year. Human error is possible with manual processes, and project prices are going to increase overall *(Watson & Härmark, 2018, Adler et al., 2008)*.

Pharmacovigilance (PV) works to regulate, track, analyze, and minimize the risk of adverse drug reactions, or ADRs, that can occur from taking medicine *(Rifat et al., 2019)*. Good PV Practices, a collection of standards meant to improve the function of PV systems and/or control safety signal assessment, feeling, and program design, was an important step in PV processes *(White et al., 2016)*. The basis of PV systems is the free reporting of possible adverse drug reactions (ADRs), no matter their quality, which has been become compulsory for doctors and hospitals by law *(Khan et al., 2023)*. Patients have also submitted an increasing number of spontaneous reports for possible adverse drug reactions over the last 20 year *(Grossman et al., 2018)*.

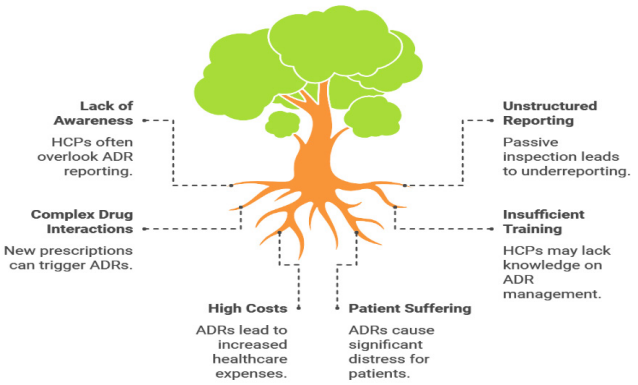

Figure 1: Impact of Adverse Drug Reaction (ADR) On Health Care

Adverse Drug Reaction in Pharmacovigilance

The concept "adverse drug reaction" (ADR) denotes to a casually negative response to drugs the fact that is occurring at stages that are usual by persons for either diseases preventative care, diagnosis, treatment, or conversion to processes of the body *(Grossman et al., 2018)*. ADR is a major healthcare condition with involves wide global influence on healthcare procedures. ADR includes a variety of adverse effects which comprises a higher possibility about passing away, drugs-related admissions to hospitals, extended hospitalizations, as well as emergency room ("ER") visits *(Andrews & Moore, 2014)* (Figure 1). Prescription cycles can happen whenever novel drugs have been prescribed to supply signs and symptoms that the have been brought about by yet another healthcare, an issue that is prevalent *(Boxtel et al., 2001)*. In healthcare facilities, prices, provisions, especially prescription medicine constitute mainly expense related to adverse drug reactions. ADRs cost as well clients and their relatives informally via in the form suffering day off from work or otherwise diseases such anxieties *(Lazarou et al., 1998)*.

ADR management or defense being an objective at pharmacovigilance (PV), an investigation which establishes related activities. Either passive as well as active inspection constitute ADR reporting the methods wrapped under PV *(Aronson, 2022)*. The naturalness and interest of these reporters—who typically involve health care professionals (HCPs)—are primarily determines the fact that unstructured reporting, sometimes referred to as passive inspection, is generally or typically selected. A PV regulation that has proved powerful has been developed upon the willingness by HCPs to ADR reporting *(Pitts, 2017)*.

Applying AI In Pharmacovigilance

Connecting AI to Pharmacovigilance involves including AI tools and technology into present processes and systems in Pharmacovigilance. This is a detailed guide:

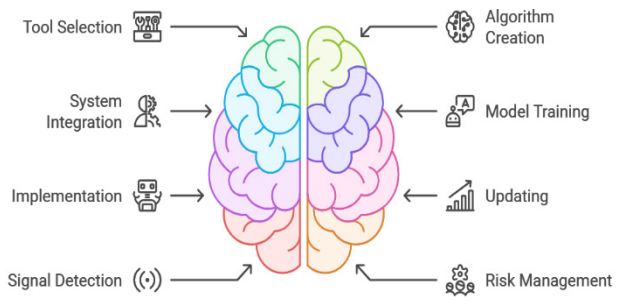

Figure 2: AI In Pharmacovigilance

List specific pharmacovigilance aims and issues that AI could assist with *(Ball & Dal Pan, 2022)* (Figure 2). For AI integration, study the quality, formats, and sources of data which is available. Make right decisions about AI tools and technologies (like software, platforms, and machine learning and natural language processing) *(Kamel Boulos & Zhang, 2021)*. Establish AI algorithms for pharmacovigilance applications (risk assessment, signal detection, etc.) or modify current ones. Link AI tools and formulations to nowadays Pharmacovigilance databases, programs, and protocols *(Thiong'o & Rutka, 2022)*. Utilize use of historical data to train AI models and verify their effectiveness. Put Pharmacovigilance solutions with AI to use while staying an eye on the way they're working. Regularly update AI models and improve their functionality in response to newly data and feedback from users *(Lindquist, 2007)*. The degree of harm caused by a pharmaceutical drug in the market-wide circulation is determined by a number of factors other than merely an adverse event, such as the adverse drug reaction (ADR), risk factor, serious reaction, and signal *(Leong et al., 2021)*. Because human lives are on the line, these aspects are extremely significant, sensitive data sources, and need to be closely examined. This is precisely where AI can be useful. From massive databases, AI models can help find new potential signals indications *(Bate & Evans, 2009)* of probable causal links between a medicine and an adverse event. These models are able to spot trends that conventional statistical techniques might overlook *(Meyer, 2020)*. Additionally, AI can be very important in risk management, automated case processing, predictive analysis, data mining, ae reporting, and clinical trial monitoring *(Kim et al., 2022)*.

Importance of Pharmacovigilance

Pharmacovigilance, is essential for recognizing and minimizing side effects, making sure drugs are used as prescribed, etc. Keeping an eye on and controlling drug-related hazards while safeguarding sizable populations, regulatory trustworthy sources of information, proactively recognizing and reducing drug-related risks & providing guidance to enhance the safety and effectiveness of upcoming pharmaceuticals *(Shmueli & Koppius, 2011)*. Healthcare Decision-Making by supplying precise safety data to enable well-informed therapy selections. Advancing knowledge of medication effects in practical contexts *(Smith, 2023)*. Quality Improvement by improving results, lowering adverse events, and strengthening medication. Encouraging candid dialogue and establishing confidence among interested parties. Preventing Harm by shielding patients from needless danger and encouraging secure and efficient medical interventions *(Esslinger et al., 2022)*.

Artifical Intelligence

The development of artificial intelligence (AI) announces a new time. obliviously tech has built it through every part of our daily lives, form residence to the paths as well as is currently used in the fields of pharmacy, healthcare, and research projects (PV). By checking stories of potential adverse effects of analyzing data on health for safety signals that are PV works to reduce the impact and harm related to using drugs as quickly as reasonable. Person case reports of safety (ICSRs) represent an arranged and systematic technique designed for collect post marketing security data on healthcare products globally using a natural submitting process (Figure 3, 4). Though unstructured material, databases, available studies in medicine, a field of study research, personal wellness documents, and yearly health assessment accounts supply valuable resources for data for normal PV functions. The one thing of data science involves artificial intelligence. An artificial intelligence platform uses a process and data storage with events to mimic human actions, such detection of speech, awareness, imagination as the process of decision *(European Medicines Agency, 2020)*.

Need of Artificial Intelligence in Pharmacovigilance

The PV database now has significantly increasing numbers of likely adverse effects (AEs). For significant interests like the pharmaceutical industries, the regulatory bodies, medical and PV specialists, and National Pharmacovigilance Project managers, analyzing the massive amount then many different sources of data, creating some sense of them, and including separating that "shots out of the grain" represents an opportunity *(European Medicines Agency, 2020)*. The procedure in ICSR experiences usually involves the following important parts: data on the individual presenting with the person reporting the case, potential adverse effects, suspect and associated pharmaceuticals, and the final result. Accurately separating adverse side effects, uncovering and disclosing adverse drug reactions, analyzing the level of severity of a situation, creating safety assessment reports, and interacting with suspected drugs are a part of PV's harshest tasks. Such procedures take a lot additional moment, particularly during the process comes to reporting ADRs, and advances in technology was required *(European Medicines Agency and Heads of Medicines Agencies, 2012)*. Thus, the pharmaceutical sector and professional services worked together to discover a new technology

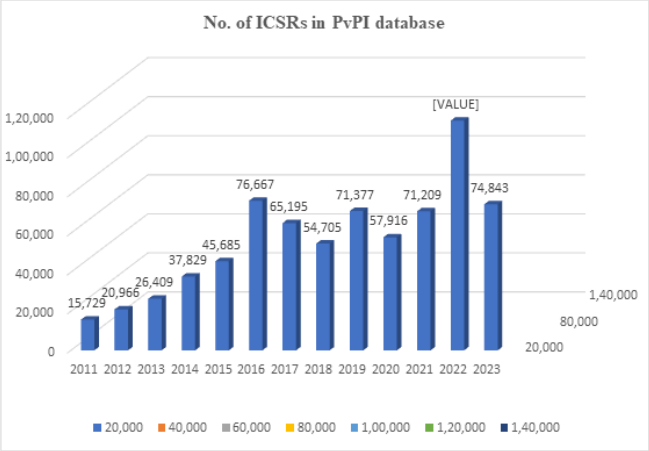

Figure 3: No. of ICSRs in PvPI database

called artificial intelligence that makes it easier to maintain and process quality and compliance guidelines. Artificial Intelligence organizes the tracking of globally available data, which previously challenging for other systems. In the fields of prescription drugs design and pharmaceutical product adverse event (AE) identification, artificial intelligence (AI) tools are crucial *(European Medicines Agency and Heads of Medicines Agencies, 2017)*.

The ICSR procedure will also be evaluated for the possible existence of a causal organization, the expectedness of adverse effects as described in the information in the medication document, their seriousness and severity criteria, as well as for thoroughness or accuracy for regulatory presentation. Importantly, it combines all manual work as imagination. In basic terms, it's expensive and takes a while as it needs staff members with skills in technology. There was a lot more anticipation and interest for using artificial intelligence for automated PV to try to manage such additional responsibilities *(European Medicines Agency and Heads of Medicines Agencies, 2017)*.

Role Of Artifical Intelligence In Pharmacovigilance

Artificial intelligence may be utilized in pharmacovigilance to assessment massive amounts of drugs information with order to find undetected patterns, estimate potential risks, ultimately at last enhance drug efficacy. During a pharmaceutical product's phases, pharmacovigilance ensures its quality and success. ADR understating are a common problem using current methods that track adverse reactions to drugs (ADRs), while they're demanding on resources. AI with adverse reaction reporting interface represents a current growth area within pharmacovigilance assessment. The idea of the present section proved to look at the various benefits of AI in PV *(Santoro et al., 2017)*. Automate in pharmacovigilance data, like signal detection, risk assessment, and requirement for regulatory compliance, can be proved by AI deep learning, as well as natural language processing devices.

Artificial Intelligence essential to pharmacovigilance as it make pharmaceutical safety control processes both successful and successful (Figure 5). These are some of the primary goals that artificial intelligence plays in pharmacovigilance Automated Case Processing: High quantity of notifications of adverse events might be quickly analyzed by AI systems, that may similarly successfully identify situations as obtain useful data. Delays are reduced and lesser work by hand will be required according to these automated. Signal Detection: A lot of data within various sources may be analyzed through machines learning methods to locate current developments of acceptable signals of safety the fact that might point toward a drug-related risk. Finding and responding fast became easy given this sudden the purpose of discovery. Predictive Analytics: Training AI models by applying previous data may be helpful when determining the possibility of unwanted situations according to particular people or issues. Such aggressive approach supports risk assessment as well as management techniques. Natural Language Processing: Natural language processing (NLP) processes based on AI have the ability to understand unstructured data including posts on social networking sites or situation accounts, can obtain significant safety data it could otherwise go unsupervised with standard techniques. The pharmaceutical industry may enhance outcomes for patients and legal compliance through the use, of artificial intelligence with pharmacovigilance to enhance their detection and reaction speeds for safety risks.

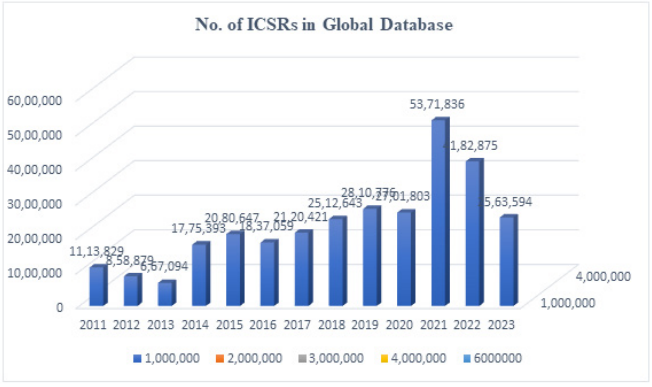

Figure 4: No. of ICSRs in Global Database

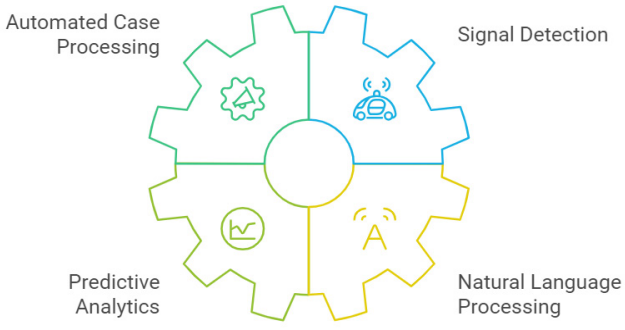

Figure 5: Role of Artificial Intelligence In Pharmacovigilance

Application of Artifical Intelligence In Pharmacovigilance

Regulatory

Although ai has yet to become mature sufficient to see wide adoption, AI is already established as used in many different types of PV applications. While new medicines went faster by the FDA's it was approval process, the COVID-19 pandemic presented the advantage of an open swift action. A five-year path for putting AI within the already existing PV structure was published by FDA previous to the global epidemic from spreading *(European Medicines Agency and Heads of Medicines Agencies, 2017)*.

Clinical

It generally requires approximately 10–12 years for a medicinal product to be officially authorized and placed in the marketplace, involving 5–6 years of clinical trials to complete. Various clinical trial processes, such patient applying and selecting the site, consume quite a bit of time and can frequently end up trial rejection for a range of situations. The pharmaceutical industry has been seeking novel technologies such as artificial intelligence (AI) to assist personal details, minimize the expense of manufacturing and research, and gain insight into million data moments.

Signal Detection

In PV, signal detection was a necessary project. (Figure 6) Data directing attention towards a unique, maybe responsible interaction or an unusual perspective to a previously established connection throughout a pharmaceutical as well as a situation will be referred to serve as signal. By basic terms, a signal signifies an issue with safety that had been in two ways unexplained otherwise unclear at the exact moment the signal was detected. Either another situation-by-situation processing as well as a method based on statistics could both be made use of to locate signals. On any given day, specialist analysis of documented instances or cases studied in community and national PV institutes could highlight an apparent unique causing causal link among a medication and an emergency. Pharmaceutical interaction combinations the fact that are reported in greater quantities than initially thought were determined using means of data mining in more comprehensive databases. For a person to be reviewed as one acceptable signal, that they must go through an in-person assessment during their detection. As transforming research with confirmed conclusions, recently established suggests might prove valuable in upcoming decades for minimizing distress for patients. Pharmacovigilance's primary trouble, though, is determining unusual as well as unwelcome signals compared to consumers with as little time to be needed. Pharmacovigilance is a critical and essential feature for the healthcare profession. In the industry, artificial intelligence

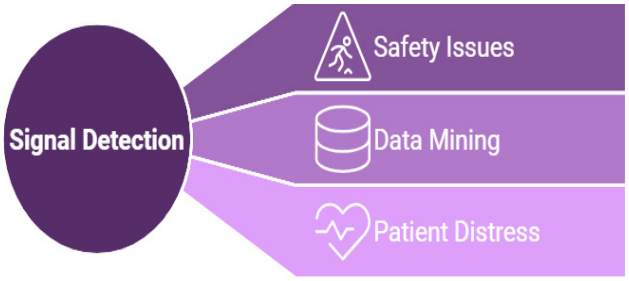

Figure 6: Signal Detection

applications remain in development or rapidly developing. The abundance of established enough curated data for software instruction to detect suspected prescription drug risks is one of several fundamental challenges toward the use of AI. Making use of AI towards pharmacovigilance also presents privacy issues considering knowledge might be repurposed during various reasons without also the authorization of the participants. Pharmacovigilance organizations can begin by means of that method after including AI to the risk dataset. The team may begin adding AI across deeper processes like creating automatic essays, absorbing individual matters or assessing information about security to stay signal detection because they are now utilizing AI in this step.

Data Mining

This had been a visible direction over the past few years through the accessibility of algorithms that use machine learning for signal acceptance in naturalistic data set, against usual equality analyses (Figure 7). In this way, a current review of systematic reviews suggested which, as soon as 2017, a greater quantity to investigate was responsible to with injustice evaluations compared from artificial intelligence techniques. In contrast, 2018, data mining algorithms served in 38.1% of the study's validity, all while common imbalances evaluate had been done on 33.4% of them as well.

Commerce, interaction economic, including firms that mark a some of the industries that the harness data mining the most frequently for analyzing the cost, client preferences, product positioning, including the effect it has on turnover, client fulfillment, and profitability for the organization. Using data mining, retail establishments may design assets and advancements attracting clientele by means of the opportunity data from patient spending decisions.

Although the likelihood is apparent additional analyses using multiple databases together with much bigger pharmaceutical interaction data sets are going to be available in the next years, so can help in assessing its actual significance during signal detection. As well, the quality of the availability related to successes using IAs is understood and their efforts are currently produced to providing data that has become more readily apparent and simpler for everyone to comprehend.

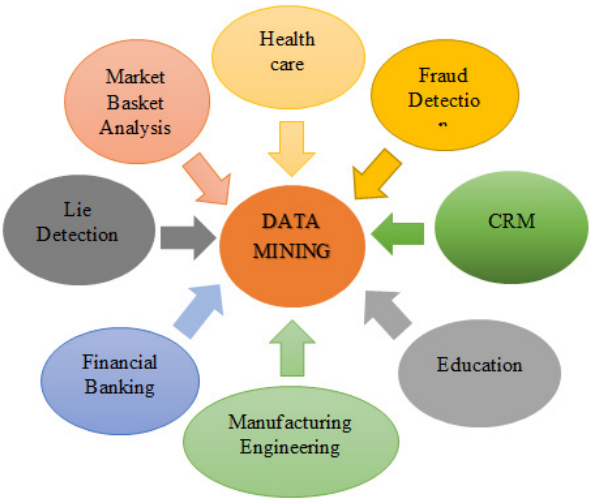

Figure 7: Data Mining

Risk assessment

A risk management plan (RMP) exists in the European Union (EU) considering making applications for the beginning publicity authorization from the organization, when applying for either a significant update to any currently publicity authorization, or when the European Medicines Agency (EMA) or an individual the State's the appropriate government agency would like it as well *(European Medicines Agency and Heads of Medicines Agencies, 2017)*. A pharmaceutical product's risk management system is described as part of RMP was the highest featuring a high value on sufficient risk assessment and planning all over all stages of the daily existence cycle. (Figure 8) To ensure to perform thus, the security of a medication profile must be recorded via an RMP, that were underscores three key areas: (1) safety concerns that depend on more assessment along with risk management; (2) pharmaceutical surveillance (PV) assignments to clarify the security risks; and (3) actions meant to avoid or reduce damage caused to patients.The Risk Management Plan (RMP) Safety The information establishes a product's safety appearance, which incorporates its Important Identified Risks (IIRs), Important Potential Risks (IPRs), and Missing Information (MI). An understood risk is identified as a potentially unnecessary clinical reaction that can be demonstrated that there seems to be adequate medical proof of a direct causal connection present in the medicinal product. A potential risk is outlined as an undesirable clinical outcome for which there is strong proof to believe in there is a prospective correlated attachment with the medicine being used, and not suitable for confirmation an association. Meanwhile, the RMP especially focuses to the others observed as well as possible risks that they should be considered vital i.e., risks that are significant that might alter the medicinal product's benefit-risk your balance or be detrimental for the safety of the public.

Figure 8: Pharmaceutical Product Risk Management

Key roles of AI in PV include

Automated case processing

AI systems can process large volumes of ADR reports, reducing manual labor and minimizing human error. These systems can extract useful information from unstructured data, improving efficiency.

Signal detection

AI can analyze data from various sources, identifying new signals or safety risks that traditional statistical methods may miss. This early detection is crucial for timely interventions.

Predictive analytics

By training AI models on historical data, it is possible to predict potential adverse events in specific patient populations, allowing for proactive risk management.

Natural language processing (NLP)

NLP tools can interpret unstructured data, such as social media posts or case reports, providing valuable safety insights that might otherwise be overlooked.

Causality Analysis and Explainable AI

AI models can assess causality between a drug and an ADR. Explainable AI, which offers transparency in decision-making, is critical for building trust with regulatory bodies and healthcare professionals.

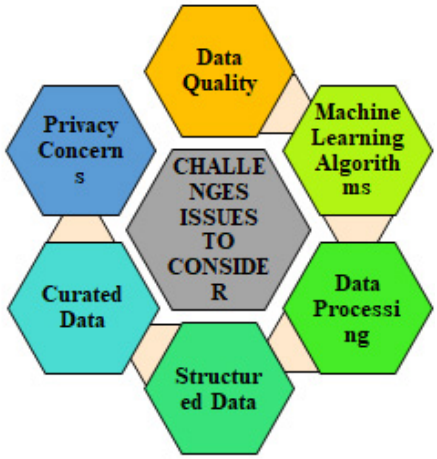

Figure 9: Challenges Issues To Consider

While AI holds promise for PV, its implementation requires careful consideration of several factors: Data Quality and Integrity: The accuracy of AI systems depends heavily on the quality of the data they process. Ensuring clean, structured, and relevant data is key.

Regulatory compliance

Adopting AI must align with existing regulatory frameworks to ensure patient safety and data privacy.

Human Oversight

Despite AI's potential, human expertise is essential for validating AI findings and interpreting complex safety data. Ongoing Training and Validation**:** AI models must continuously learn from new data to remain accurate and effective over time. The challenges and issues to consider while using AI are depicted in the Figure 9.

AI's Expectations in Pharmacovigilance in the Future

Pharmacovigilance is closely tied to the continuous improvement of Artificial Intelligence (AI) supplied the lightning-fast advancements in pharmaceutical production. AI's setting up into pharmacovigilance standards has already been demonstrated is substantially enhance their risk assessment, signal analysis, and adverse occurrence detection. Because of when it comes to pharmacovigilance, opportunities that throughout AI in the future come about to have become more urgent than ever, motivated by recent advancements, future researchers. inventions, and an unpredictable essential role in remaining the safety of pharmaceuticals. Integration of Advanced Technologies: It is believed that the utilization of AI in pharmacovigilance could go further its current ability of natural language processing (NLP) and artificial intelligence (AI). The application of deep learning, a kind amongst machine learning the fact that attracts encouragement throughout the structure and processes of the human brain, is one of many currently guaranteeing technologies. A combination pharmacovigilance storage database can be studied and analyzed more specifically and nuancedly attributable to deep learning technologies' ability to develop independently from information with hierarchical their representations. Improved Predictive Modeling: Advances in technology statistical modeling capabilities are anticipated from pharmacovigilance AI systems in the future. Health care providers and the pharmaceutical industry would both be able implement medical procedures and preventive treatments with greater proficiency if unfortunate events could have been predicted by using greater levels of accuracy and precision. By establishing a preventative approach, the possible number of unexpected incidents can be dramatically reduced, enhanced health safety for patients. Multi-Modal Data Integration: For the purposes to have cell a comprehensive understanding of drug safety, multi-modal data sources are required to be incorporated to form part of the increasingly important function of AI in pharmacovigilance. Apart from in comparison to traditional healthcare data, a better understanding is going to be offered by incorporating gene information, patient lifestyle data, and empirical evidence from mobile devices and health applications for smartphones and tablets Pharmacovigilance professionals will come able to spot previously undiscovered modifications and relations attributable to this multi-modal data integration. Real-Time Pharmacovigilance Platforms: powered by artificial intelligence immediate format pharmacovigilance internet sites are a promising idea for the future of medicine. Each of these instruments promise to deliver real-time insights into unacceptable events and completely novel safety concerns by automatically observing and analyzing healthcare data streams of water. Response times can be extremely cut short by real-time pharmacovigilance, offering encourage and focused measures to lessen risks that may exist. Explainable AI for Causality analysis: The issue of explain in AI continues to grow becoming ever more valuable, especially within challenging processes of decision-making like causality analysis. The discovery of explainable AI models is projected to receive the highest importance in pharmacovigilance applications of AI in the future. Gaining the trust you need of medical experts, agencies of government, and the general public demands that one be easily understood about how AI impacts any causal connection between a pharmaceutical as well as an adverse development.

Conclusion

The field of pharmacovigilance (PV) focuses on monitoring and preventing adverse drug reactions (ADRs) to ensure medication safety. As pharmaceutical products advance and patient safety remains paramount, PV plays a crucial role in identifying and addressing potential risks. With the increasing complexity of drug safety data and the sheer volume of ADR reports, traditional methods of PV, which rely on clinical trials and manual processes, are becoming inadequate recent years, AI and machine learning (ML) have emerged as transformative technologies across industries, including PV. These technologies offer immense potential to enhance PV processes by automating data analysis, detecting patterns, and predicting adverse events. This integration can lead to faster signal detection, better risk management, and improved decision-making regarding drug safety. The efficiency of PV systems can be substantially increased by these technologies, which can also lower human error and assist in spotting possible hazards that conventional approaches could overlook. However, to achieve efficacy, integrating AI into PV techniques necessitates constant evaluation, regulatory compliance, and careful consideration of data integrity. AI has the potential to revolutionize pharmacovigilance

systems as it advances, allowing for more proactive risk management, speedier detection of safety concerns, and eventually improved patient outcomes. The value of AI-supported pharmacovigilance goes beyond merely adhering to regulations; it protects the public's health, guides medical decisions, and promotes accountability and openness in the healthcare system. AI's ongoing development and application in PV has the potential to greatly improve drug safety monitoring and raise the standard of healthcare globally.

References

Adler, L., Denham, C. R., McKeever, M., Purinton, R., Guilloteau, F., Moorhead, J. D., & Resar, R. (2008). Global trigger tool: Implementation basics. Journal of Patient Safety, 4(4), 245-249.

Alvager, T., Smith, T. J., & Vijai, F. (1993). Neural-network applications for analysis of adverse drug reactions. Biomedical Instrumentation & Technology, 27(5), 408-411.

Andrews, E. B., & Moore, N. (Eds.). (2014). Mann's pharmacovigilance. John Wiley & Sons.

Aronson, J. K. (2022). Artificial intelligence in pharmacovigilance: An introduction to terms, concepts, applications, and limitations. Drug Safety, 45(5), 407-418.

Ball, R., & Dal Pan, G. (2022). "Artificial intelligence" for pharmacovigilance: Ready for prime time? Drug Safety, 45(5), 429-438.

Basile, A. O., Yahi, A., & Tatonetti, N. P. (2019). Artificial intelligence for drug toxicity and safety. Trends in Pharmacological Sciences, 40(9), 624-635.

Bate, A., & Evans, S. J. W. (2009). Quantitative methods in pharmacovigilance. Pharmacoepidemiology and Drug Safety, 18(3), 223-229.

Bate, A., & Hobbiger, S. F. (2021). Artificial intelligence, real-world automation and the safety of medicines. Drug Safety, 44(2), 125-132.

Beam, A. L., & Kohane, I. S. (2016). Translating artificial intelligence into clinical care. JAMA, 316(22), 2368-2369.

Boxtel, C. J. V., Santoso, B., & Edwards, I. R. (2001). Drug benefits and risks: International textbook of clinical pharmacology.

Chen, M. L., Doddi, A., Royer, J., Freschi, L., Schito, M., Ezewudo, M., & Farhat, M. (2019). Beyond multidrug resistance: Leveraging rare variants with machine and statistical learning models in Mycobacterium tuberculosis resistance prediction. EBioMedicine, 43, 356-369.

Cireşan, D., Meier, U., Masci, J., & Schmidhuber, J. (2011, July). A committee of neural networks for traffic sign classification. In The 2011 International Joint Conference on Neural Networks (pp. 1918-1921). IEEE.

Divya, P., Susmita, A., Sushmitha, P., Ch, R., & Chandini, K. (2022). Automation in pharmacovigilance: Artificial intelligence and machine learning for patient safety. Journal of Innovations in Applied Pharmaceutical Science (JIAPS), 118-122.

Edwards, I. R. (1997). Adverse drug reactions: finding the needle in the haystack: Pharmacovigilance is improving: now we need to ensure that patients benefit. BMJ, 315(7107), 500.

Esslinger, S., Quinn, L., Sampat, S., Otero-Lobato, M., Noël, W., Geldhof, A., ... & Reeder, S. J. (2022). Risk management plans: Reassessment of safety concerns based on Good Pharmacovigilance Practices Module V (Revision 2)—A company experience. Journal of Pharmaceutical Health Care and Sciences, 8(1), 14.

European Medicines Agency and Heads of Medicines Agencies. (2012). Guideline on good pharmacovigilance practices (GVP) Module V- Risk management system, EMA/838713/2011. Retrieved from https://www.ema.europa.eu/en/documents/scientific-guideline/draft-guideline-good-pharmacovigilance-practices-module-v-risk-management-systems_en.pdf

European Medicines Agency and Heads of Medicines Agencies. (2017). Guideline on good pharmacovigilance practices (GVP) Annex I – Definitions (Rev 4), EMA/876333/2011 Rev 4. Retrieved from https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-annex-i-definitions-rev-4_en.pdf

European Medicines Agency. (2020). Legal framework: Pharmacovigilance. Retrieved from https://www.ema.europa.eu/en/human-regulatory/overview/pharmacovigilance/legal-framework-pharmacovigilance

Grossman, L. V., Choi, S. W., Collins, S., Dykes, P. C., O'Leary, K. J., Rizer, M., ... & Vawdrey, D. K. (2018). Implementation of acute care patient portals: Recommendations on utility and use from six early adopters. Journal of the American Medical Informatics Association, 25(4), 370-379.

Gulshan, V., Peng, L., Coram, M., Stumpe, M. C., Wu, D., Narayanaswamy, A., ... & Webster, D. R. (2016). Development and validation of a deep learning algorithm for detection of diabetic retinopathy in retinal fundus photographs. JAMA, 316(22), 2402-2410.

Jumper, J., Evans, R., Pritzel, A., Green, T., Figurnov, M., Ronneberger, O., & Hassabis, D. (2021). Highly accurate protein structure prediction with AlphaFold. Nature, 596(7873), 583-589.

Kamel Boulos, M. N., & Zhang, P. (2021). Digital twins: From personalised medicine to precision public health. Journal of Personalized Medicine, 11(8), 745.

Khan, M. A. A., Hamid, S., & Babar, Z. U. D. (2023). Pharmacovigilance in high-income countries: Current developments and a review of literature. Pharmacy, 11(1), 10.

Kim, H. R., Sung, M., Park, J. A., Jeong, K., Kim, H. H., Lee, S., & Park, Y. R. (2022). Analyzing adverse drug reactions using statistical and machine learning methods: A systematic review. Medicine, 101(25), e29387.

Lazarou, J., Pomeranz, B. H., & Corey, P. N. (1998). Incidence of adverse drug reactions in hospitalized patients: A meta-analysis of prospective studies. JAMA, 279(15), 1200-1205.

LeCun, Y., Bengio, Y., & Hinton, G. (2015). Deep learning. Nature, 521(7553), 436-444.

Leong, C. M., et al. (2021). Artificial intelligence in pharmacovigilance: A systematic review. Drug Safety, 44(4), 359-371.

Lindquist, M. (2007). The importance of pharmacovigilance: Safeguarding public health. Drug Safety, 30(7), 613-619.

Meyer, A. (2020). Privacy and ethical considerations in the use of AI in healthcare. Journal of Medical Internet Research, 22(8), 238-242.

Pitts, P. J. (2017). 21st-century pharmacovigilance: Intuition, science, and the role of artificial intelligence. Journal of Commercial Biotechnology, 23(1).

Rifat, M. J. R., Noori, S. R. H., & Hasan, M. R. (2019, July). Pharmacovigilance study of opioid drugs on Twitter and PubMed using artificial intelligence. In 2019 10th International Conference on Computing, Communication and Networking Technologies (ICCCNT) (pp. 1-7). IEEE.

Santoro, A., Genov, G., Spooner, A., Raine, J., & Arlett, P. (2017). Promoting and protecting public health: How the European Union pharmacovigilance system works. Drug Safety, 40, 855-869.

Schmaltz, A., & Beam, A. L. (2021). Sharpening the resolution on data matters: A brief roadmap for understanding deep learning for medical data. The Spine Journal, 21(10), 1606-1609.

Shmueli, G., & Koppius, O. (2011). Predictive analytics in information systems research. MIS Quarterly, 35(3), 553-572.

Smith, J. A. (2023). The impact of data mining in commerce. Journal of Business Analytics, 12(4), 200-215.

Thiong'o, G. M., & Rutka, J. T. (2022). Digital twin technology: The future of predicting neurological complications of pediatric cancers and their treatment. Frontiers in Oncology, 11, 781499.

U.S. FDA. Good pharmacovigilance practices and pharmacoepidemiologic assessment.

Watson, S., & Härmark, L. (2018). Desogestrel and panic attacks–A new suspected adverse drug reaction reported by patients and healthcare professionals on spontaneous reports. British

Journal of Clinical Pharmacology, 84(8), 1858.
White, R. W., Wang, S., Pant, A., Harpaz, R., Shukla, P., Sun, W., ... & Horvitz, E. (2016). Early identification of adverse drug reactions from search log data. Journal of Biomedical Informatics, 59, 42-48.

HOW TO CITE THIS ARTICLE: Shukla, S., Bhatt, S., Gupta, D., Verma, S. Role of Artifical Intelligence in Pharmacovigilance. J. of Drug Disc. and Health Sci. 2024;1(4):230-238. **DOI:** 10.21590/jddhs.01.04.06