IJBPAS, October, 2025, 14(10): 5636-5647

ISSN: 2277–4998

International Journal of Biology, Pharmacy and Allied Sciences (IJBPAS)

'A Bridge Between Laboratory and Reader'

www.ijbpas.com

COMPREHENSIVE REVIEW ON ROLE ARTIFICIAL INTELLIGENCE: A GAME CHANGER FOR PHARMACOVIGILANCE?

AGRAWAL P[1], PARMAR K[1] AND PATEL P[1*]

1: Parul Institute of Pharmacy and Research, Faculty of Pharmacy, Parul University, Vadodara, Gujarat-391760

***Corresponding Author: Ms. Pratima Patel: E Mail: pratima.patel21166@paruluniversity.ac.in**

Received 26th April 2024; Revised 29th Aug. 2024; Accepted 21st Oct. 2024; Available online 1st Oct. 2025

https://doi.org/10.31032/IJBPAS/2025/14.10.9526

ABSTRACT

This review explores the transformative potential of artificial intelligence (AI) in pharmacovigilance (PV), the field of ensuring medication safety. AI promises to significantly improve risk management, adverse drug event (ADE) detection, and signal identification. The ever-increasing volume of data from individual case safety reports (ICSRs) necessitates new approaches. Traditional methods struggle to keep pace, highlighting the critical need for AI-powered solutions.

AI has the potential to revolutionise the daily work of PV professionals and accelerate career advancement. It can enhance both qualitative and quantitative aspects of PV, leading to more effective drug safety practices. By enabling advanced medical strategies like personalized treatment, AI can optimize the risk-benefit balance for patients. Additionally, AI can significantly improve signal evaluation, validation, and prioritization within PV.

However, challenges remain. Legal restrictions, ethical considerations, and data quality issues require careful attention. Despite these hurdles, the future of PV is undoubtedly intertwined with AI. As AI integration progresses, we can expect substantial improvements in patient safety and pharmaceutical development.

Keywords: Drug safety, Cognitive service, Pharmacology, Pharmacovigilance, Artificial Intelligence

INTRODUCTION:

The Latin word "vigilare," which means "keep watch," and the Greek word "pharmakon," which means "drug," are the sources of the English phrase

"pharmacovigilance." The World Health Organisation (WHO) established the pharmacovigilance (PV) system in 1961 to monitor drugs worldwide, in response to the thalidomide catastrophe. PV refers to the techniques and studies used in the identification, assessment, comprehension, and mitigation of pharmaceutical side effects as well as any other potential drug-related problems. Processing the massive amounts of data that PV collects every day is a difficult task on a global scale. Herb vigilance, hemovigilance, materiovigilance, blood products, medical devices, conventional and alternative pharmaceuticals, and other topics are now being covered by the research effort **[1]**.

Pharmacovigilance involves the study and assessment of adverse events, as well as the prevention, detection, collection, and evaluation of drug-related issues.90% of adverse occurrences (AEs) go unreported, despite the possibility of an annual increase in the number of individual case safety reports. As a result, technology must be needed to endure adverse conditions. Artificial intelligence makes difficult situations easier to make decisions in. The purpose of cognitive services is to assess the decision-making abilities of PV users. Applying AI is indeed a promising strategy for overcoming adverse events by analyzing unreported data. Another effective approach is to leverage social media platforms to disseminate health information and raise awareness about drug-related issues. These strategies can play a significant role in advancing pharmacovigilance efforts. Electronic health records (EHRs) serve as a representation of patient narrative information, enabling authorized entities to recognize and improve patient care and outcomes. By reducing human labour associated with transcription and data entry, artificial intelligence (AI) can improve patient health by enabling a greater emphasis on the scientific and medical examination of adverse events (AEs) **[2]**.

HISTORY OF PHARMACOVIGILANCE:

169 years ago, a 15-year-old girl named Hannah Greener passed away, which marked the beginning of pharmacovigilance. On the contrary, the 1961 Thalidomide incident marked a significant change in the pharmacovigilance procedure, with the reporting of adverse drug reactions becoming a crucial aspect of drug safety monitoring. Reactions becoming time-sensitive, spontaneous, and systematic. It was essential to consistently monitor the pharmaceuticals being sold to safeguard the health and safety of the public. The medical community is required to report any blatantly obvious adverse pharmacological reaction that is identified through signals. Furthermore, signal detection has emerged as the main area of concentration for

pharmacovigilance, based on documented occurrences **[3]**.

PHARMACOVIGILANCE GOALS:

Pharmacovigilance aims to safeguard against harm resulting from unfavourable human Rapidly educating patients, healthcare providers, and the general public about the safety of medical products aims to enhance responses to the use of medicinal products, both within and beyond the scope of their marketing authorizations and throughout their life cycles **[4]**. pharmacovigilance aims to promote the safe and effective use of medicinal goods. As such, pharmacovigilance is an endeavour that advances patient safety and upholds public health **[5]**.

ADVERSE EVENTS:

Adverse events are any physical side effects a patient may have from a medication or possible pharmacological molecule. A significant adverse event is a side effect that endangers the patient's life and may cause hospitalisation, impairment, irreversible damage, or, in the worst cases, patient death. Clinical research investigators must record adverse occurrences, even if they are purely hypothetical. The technique of detecting adverse effects that extend a medication's therapeutic window is known as pharmacovigilance. Put another way, weighing the benefits and drawbacks of a certain course of treatment for a particular illness **[6, 7]**.

ROLE OF ARTFICIAL INTELLEGANCE IN PHARMACOVIGILANCE:

The ability of a digital machine to perform tasks that require human intelligence is known as artificial intelligence (AI). AI involves utilizing learning technologies to enable machines to solve future problems by leveraging previously collected data. a fast-evolving technology, has enormous potential for pharmacovigilance. As artificial intelligence advances, it will become increasingly crucial for monitoring drug safety and spotting negative occurrences. AI in pharmacovigilance offers a number of benefits, including enhanced clinical trial prioritisation, precise dosage recommendations, and quicker adverse event identification. The use of artificial intelligence in pharmacovigilance, which involves monitoring the safety of medicines, is expanding. Machine learning algorithms trained on extensive real-world trial datasets play a crucial role in enhancing pharmacovigilance **[8]**.

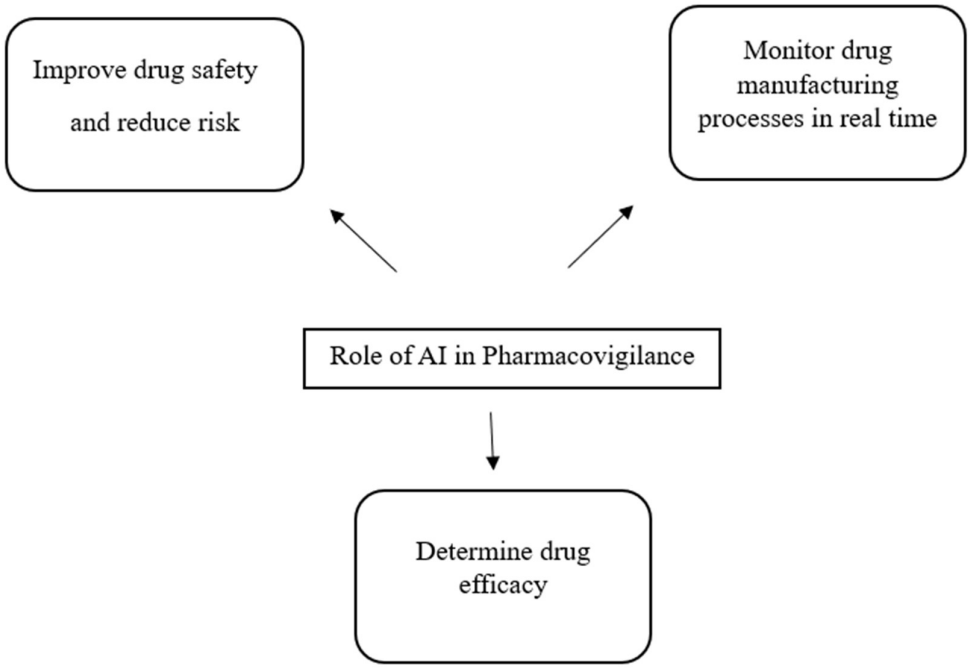

Figure 1: Role of AI in Pharmacovigilance

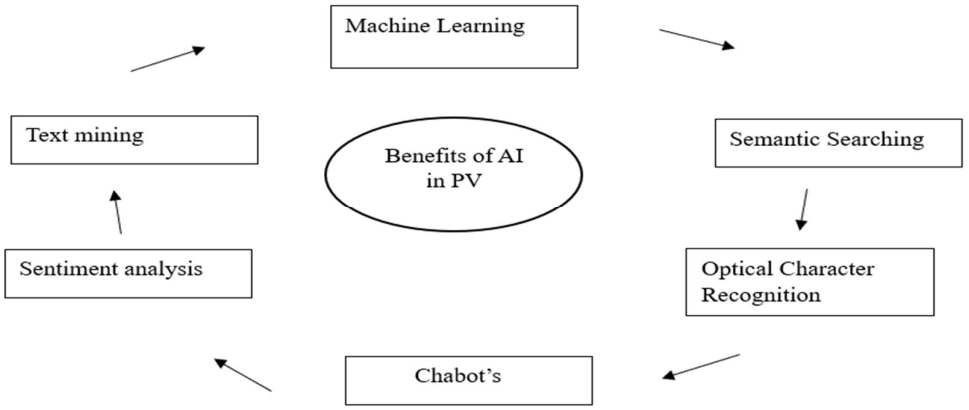

Figure 2: The benefits of applying artificial intelligence techniques in pharmacovigilance

The use of artificial intelligence (AI) in medication development and life cycle management, including pharmacovigilance (PV), has garnered significant attention. According to the US Food and Drug Administration, pharmacovigilance (PV) encompasses "all scientific and data collection activities related to the detection, evaluation and understanding of adverse events." This broad definition by the FDA includes various scientific research methodologies, registries, clinical pharmacology studies, individual case

safety reports (ICSRs), and other related activities **[11]**.

Management of individual case safety reports (ICSRs) and the requirements of pharmacovigilance:

The FDA has mandated that pharmaceutical companies implement an ICSR. ICSRs are shared with important parties, The text below highlights the involvement of regulatory agencies and pharmaceutical companies to guarantee public safety. A PV specialist is necessary to evaluate the case's legitimacy before the ICSR process may commence. Four conditions must be satisfied for the ICSR to be deemed genuine **[12]**.

1. A distinct provider
2. Patient identification
3. Possible drug use
4. Expected negative outcome

After gathering these data, the PV specialist creates an ICSR that complies with FDA guidelines. To complete this task, it is important to gather adverse event (AE) cases systematically, thoroughly research and understand each case, input the AEs into a database, use accepted medical terminology to code the AEs, and categorize them into groups such as expected versus unexpected, serious versus non-serious, and related versus unrelated **[13]**.

The primary source of inefficiency in pharmacovigilance is the creation and management of individual case safety reports (ICSRs) to ensure regulatory compliance. There is concern that the substantial increase in adverse events (AEs) reported annually may make the development of ICSRs as a means of conducting pharmacovigilance assessments obsolete **[14]**.

The increasing rate of ICSRs has been shown in the figure below.

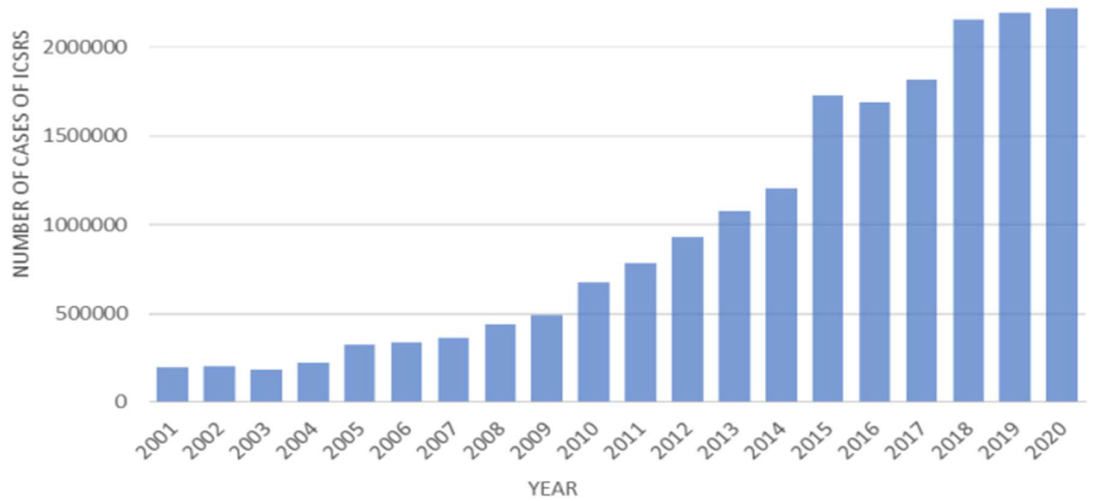

Figure 3: Individual case safety reports received by the FDA's adverse event system provide important information about potential drug or medical device-related adverse events

ROLE OF DRUG SAFETY PROFESSIONALS IN AI:

Experts in drug safety must be capable of systemic thinking, communication, analytical evaluation, and leadership **[15]**. Drug safety professionals need to have undergone extensive soft skill training. Retraining and updating algorithms provide the biggest hurdles for drug safety specialists **[15, 16]**.

ROLE OF AI IN 21st CENTURY:

Drawing from empirical data, PV must devise tailored strategies, with AI contributing to the resolution of numerous other severe and potentially lethal illnesses in addition to cancer. In the realm of big data outcomes, patient-level data from individual consumers may not always match validated data since artificial intelligence (AI) is a source that electronically provides valuable healthcare information. Post-marketing surveillance of biosimilars needs to incorporate pharmacovigilance (PV) steps to stay current with the advancements of the twenty-first century. By utilizing AI in PV for the first time, a new epidemiological concept is being developed to distinguish between "generic" and "biosimilar. “By creating pertinent safety and efficacy evidence, AI is already in use in many healthcare settings to manage drugs in electronic health records and treatment regimens. In genomics and genetics, AI has the most influence on the identification of patterns, mutations, and linkage diseases. However, in order to be actionable, our knowledge must demonstrate the analytical process in order to draw a conclusion, but this is limited because of access to private data **[17]**.

The importance of AI for assessing drug toxicity and safety cannot be overstated:

AI for Safer Drugs: Why it Matters

Traditional methods struggle to keep up with the rapid increase in new drugs and adverse event reports. AI offers a powerful solution:

Machine learning helps predict drug toxicity before they reach patients.

Natural language processing analyses vast amounts of medical data to identify safety risks.

AI tools like TargeTox and PrOCTOR speed up toxicity prediction.

By using AI, pharmacovigilance (PV) can ensure safer drugs reach patients faster **[18]**. AI goes beyond basic prediction with different techniques for various stages:

Pre-clinical: Simple models like logistic regression analyze data to understand a drug's mechanism and potential toxicity.

Following the release of a drug, complex models such as CNNs and RNNs are utilized to analyze extensive real-world data to identify safety risks during the post-marketing phase.

Structured data: Easily analyzed data like medication codes and diagnoses help predict adverse drug reactions (ADRs) **[19]**.

Novel techniques in AIPV: Since not all adverse events were identified during clinical trials, AEs were evaluated by PV professionals. AIPV supports the gathering and evaluation of both quantitative and qualitative data using machine learning algorithms. AI utilized in PV significantly impacted the biological world and the Industrial Revolution. Drug-related adverse events (AEs) are documented in ICSR patients, and all medication-related data is gathered and compiled by PV professionals. DL can sum together the information to produce logical output **[20]**. The Global Drug Safety and Risk Management (GDSRM) programme at Celgene was established to leverage innovative ML algorithms in pharmacovigilance (PV). Electronic Medical Records (EMR), with their digital signature and encryption capabilities, serve as a valuable source of information for automating critical thinking processes based on action-oriented concepts. AI is utilized in PV to analyze historical data and detect Adverse Events (AE), to minimize risks **[21][22]**.

The eight types of autonomous intelligence that form an individual include verbal-linguistic, visual-spatial, mathematical-logical, kinaesthetic physical, and interpersonal, as described by psychologist Gardner. Computer science commonly encompasses artificial intelligence (AI), which encompasses DL and ML. The three categories of machine learning are supervised, unsupervised, and reinforcement learning. An example of machine learning is seen in grey literature **[23][24]**.

Table 1: Contrasting Characteristics of Machine Learning (ML) and Non-Machine Learning Models

ML (Machine learning)	Non-ML (Statistical analyses, models)
Divide the data into segments for categorization, prediction, testing, and signification.	Analyze the dataset by indicating interference, calculating p-values, and interpreting variable relationships.
Design for external hyperparameters before training, rather than using guessed data.	When a parametric distribution occurs in a Bayesian model, the model parameter is calculated directly.
Organise large data with millions of parameters.	Utilize a limited number of parameters to organize small to medium-sized datasets.
Display the automated function.	Represent the manual feature.
There are numerous ways to optimise performance, including running time and hyperparametric tuning.	Performance improves with larger sample sizes.

APPLICATION OF AI:

AI has the potential to reduce mortality by identifying diseases at an early stage by analyzing patients' electronic records. However, the risk of cyber-attacks causing serious health issues, such as hacking cardiac stimulators, underscores the importance of establishing regulatory frameworks to ensure the safe and reliable implementation of AI in healthcare **[25]**.

ADVANTAGES OF AIPV:

- Utilization of GPS (Gamma Poison Shrinkage) for detecting spontaneous reporting signals.
- The information component can be used for signal detection purposes.
- Collection of data for cognitive services from various sources such as healthcare professionals, dentists, physicians, patients, literature reviews, and social media.
- Implementation of the spontaneous reporting system (SRS) for the rapid electronic detection of data items that are challenging to identify through manual research **[26]**.

CHALLENGES OF AI IN PHARMACOVIGILANCE:

The application of artificial intelligence (AI) in pharmacovigilance is still in its early stages, presenting several challenges. One of the most significant obstacles is the need for structured and selected data to effectively train the algorithms in identifying potential pharmaceutical safety issues. Additionally, the use of AI in pharmacovigilance raises privacy concerns, as there is a risk that data may be utilized for unrelated purposes without the knowledge or consent of the individuals involved **[27]**.

Barriers in automation in pharmacovigilance

1) Trust Factor: Life sciences companies are interested in AI and machine learning, but they are concerned that automation would not give the same results as traditional case processing methods.
2) Uncertainty: Because they are unable to fully comprehend the potential that automated PV reporting systems could bring to their operations, many health sciences businesses struggle to define demanding standards for their own developers and to carefully evaluate vendors and platforms in the market **[28]**.
3) Lack of industry expertise: Despite nearly adapting an existing platform for such applications, pharmaceutical companies may choose to hire technology experts rather than industry experts, only to find out later that these partners are ignorant of the complex rules and regulations governing international pharmacovigilance practises.
4) The extent to which undeveloped and developing nations employ technology: In certain countries, utilising current technologies may be challenging due to a lack of accessibility, dependability, sufficient handling knowledge, and adoption of technical usage **[29]**.

Opportunities for Artificial Intelligence in pharmacovigilance

Artificial intelligence (AI) has a significant impact on pharmacovigilance. In the realm of drug safety, AI can enhance the quality of data collected from drug research, leading to improved decision-making. Advances in image identification and natural language processing have enabled this progress. As big data analytics and cloud-based pharmacovigilance platforms advance, larger datasets can be studied with greater sophistication.

CONCLUSION:

Artificial intelligence can be used to treat a variety of illness states and facilitates the processing and analysis of vast volumes of data. The use of automation and machine learning models can streamline pharmacovigilance procedures, providing a more effective way to analyze safety-related data. However, further research is necessary to determine the impact of these improvements on the quality of safety evaluations. Given its importance in predicting side effects and adverse drug reactions, its use is anticipated to rise shortly.

Now, AI techniques will be useful for finding and initiating a hidden relationship for accurate PV ICSR processing. AI awareness is still growing in PV. This awareness might be impacted by IT businesses working with pharmaceutical companies, which would help both pharmaceutical and medical device companies by improving regulatory compliance and obtaining cost savings, among other benefits. Data entry and case intake still require manual labour, even with the availability of IT systems that automate ADR reporting and case processing these days. AI can automate every step of the process, from receiving the case to reporting.

These processes will reduce expenses and improve quality and accuracy. Raising knowledge about artificial intelligence (AI) in PV is crucial, as the majority of people were ignorant of it until 2017. A few AI web applications are accessible to the general public, such "VigiAccess" for ADR data. Using AI techniques to automate data entry for PvPI could reduce the amount of effort required across the entire process, from receiving cases to reporting. These processes will reduce expenses and improve quality and accuracy. Global standardisation of the automatic statistics allows UMC Sweden to monitor the data collected by different PV centres.

The application of AI techniques may make medication safety protocols more complicated. In relation to PV, more study in the field of AI is required. While AI, database, and tool research is still in its early stages, it has the potential to significantly transform solar technology.

REFERENCE:

[1] Artificial intelligence in pharmacovigilance: Practical utility. Kotni Murali, Sukhmeet Kaur, Ajay Prakash, and Bikash Medhi.

[2] Mockute R, Desai S, Perera S, Assuncao B, Danysz K, Tetarenko N, *et al*. Artificial Intelligence Within Pharmacovigilance: A Means to Identify Cognitive Services and the Framework for their Validation. Pharmaceut Med 2019;33(2):109–20.

[3] Pinnow E, Amr S, Bentzen SM, *et al*. Postmarket safety outcomes for new molecular entity (NME) drugs approved by the Food and Drug Administration between 2002 and 2014. Clin Pharmacol Ther, 2018; 104: 390–400.

[4] Arnaud M, Bégaud B, Thurin N, Moore N, Pariente A, Salvo F. Methods for safety signal detection in healthcare databases: a literature review. Expert Opin Drug Saf, 2017; 16: 721–32.

[5] The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, E2D(R1), Final Concept Paper for E2D(R1), 2021.

[6] Artificial Intelligence‖ for Pharmacovigilance: Ready for Prime Time? Robert Ball & Gerald Dal Pan.

[7] Evans HP, Anastasiou A, Edwards A, Hibbert P, Makeham M, Luz S, *et al*. Automated classifcation of primary care patient safety incident report content and severity using supervised machine learning (ML) approaches. Health Inf J, 2019; 26(4): 3123–39.

[8] NagaRavi Kiran T, Suresh Kumar N, Lakshmi GVN, Naseema S, Bhargav SB MS. Artificial Intelligence in Pharmacy. Der Pharm Lett. 2021;13(5):6–14.

[9] Huysentruyt K, Kjoersvik O, Dobracki P, Savage E, Mishalov E, Cherry M, et al. Validating Intelligent Automation Systems in Pharmacovigilance: Insights fromGood Manufacturing Practices. Drug Saf 2021;44(3):261–72.

[10] The Use of Artificial Intelligence in Pharmacovigilance: A Systematic Review of the Literature. Maribel Salas1· Jan Petracek · Priyanka Yalamanchili · Omar Aimer · Dinesh Kasthuril. Sameer Dhingra· Toluwalope Junaid· Tina Bostic.

[11] Laves M-H, Ihler S, Ortmaier T, Kahrs LA. Quantifying the uncertainty of deep learningbased computer-aided diagnosis for

patient safety. Curr Dir Biomed Eng, 2019; 5: 223–6

[12] The Evolving Role of Artificial Intelligence in Pharmacovigilance. Written by Janne Bate. Principal Consultant at SRG.

[13] Future of Pharmacovigilance: Emerging role of AI. Prasanthi Sadhu, Editor, Pharma Focus Asia

[14] Danysz K, Cicirello S, Mingle E, Assuncao B, Tetarenko N, Mockute R, *et al*. Artificial Intelligence and the Future of the Drug Safety Professional. Drug Saf 2019;42(4):491–7.

[15] Article R, Babu A. ARTIFICIAL INTELLIGENCE: AN INNOVATIVE APPROACH IN. World J Pharm Res. 2020;9(13):569–79.

[16] Pitts PJ. 21st Century Pharmacovigilance: Intuition, Science, and the Role of Artificial Intelligence. J Commer Biotechnol. 2017;23(1):3–6.

[17] Kalaiselvan V, Sharma A, Kumar S. "Feasibility test and application of AI in healthcare"—with special emphasis in clinical , pharmacovigilance and regulatory practices. Health Technol(Berl) 2020;(0123456789).

[18] Aarushi, Naveen Nandal and Anuradha, Satyam Computers Scam-Pre and Post Analysis, International Journal of Psychosocial Rehabilitation, Volume 24, Issue 6, pp. 1817-1824.

[19] Sreenivasa Rao VeerankI,"A Hybrid Cloud and Cluster Computing Paradigm for Life Science Applications",International Conference on Soft Computing and Intelligent Technologies [ICSCIT–2021]",ISBN:978-93-91535-15-5,24

[20] . Wang X, Hripcsak G, Markatou M, Friedman C. Active Computerized Pharmacovigilance Using Natural Language Processing, Statistics, and Electronic Health Records: A Feasibility Study. J Am Med Informatics Assoc 2009;16(3):328–37

[21] Bousquet C, Henegar C, Louët AL Le, Degoulet P, Jaulent MC. Implementation of automated signal generation in pharmacovigilance using a knowledge-based approach. Int J Med Inform. 2005;74(7–8):563–71.

[22] Anna O. Basilea, Alexandre Yahia NPT. Artificial Intelligence for Drug Toxicity and Safety. Physiol Behav. 2019;40(9):624–35.

[23] Basile AO, Yahi A, Tatonetti NP. Artificial Intelligence for Drug Toxicity and Safety. Trends Pharmacol Sci. 2019;40(9):624–35.

[24] Schmider J, Kumar K, LaForest C, Swankoski B, Naim K, Caubel PM. Innovation in Pharmacovigilance: Use of Artificial Intelligence in Adverse Event Case Processing. Clin Pharmacol Ther. 2018;105(4)

[25] Ghosh R, Kempf D, Pufko A, Barrios Martinez LF, Davis CM, Sethi S. Automation Opportunities in Pharmacovigilance: An Industry Survey. Pharmaceut Med 2020;34(1):7–18.

[26] Tricco AC, Zarin W, Lillie E, Jeblee S, Warren R, Khan PA, *et al*. Utility of social media and crowd-intelligence data for pharmacovigilance: a scoping review. BMC Med Inform Decis Mak. 2018; 18:1–14.

[27] Hauben M, Hartford CG. Artificial Intelligence in Pharmacovigilance: Scoping Points to Consider. Clin Ther 2021;43(2):372–9.

[28] Salas, M., Petracek, J., Yalamanchili, P., Aimer, O., Kasthuril, D., Dhingra, S., Junaid, T., & Bostic, T. (2022). The Use of Artificial Intelligence in Pharmacovigilance: A Systematic Review of the Literature. Pharmaceutical medicine, 36(5), 295–306

[29] Gupta J, Patrick J, Poon S. Clinical safety incident taxonomy performance on C4.5 decision tree and random forest. Stud Health Technol Inform, 2019; 266: 83–8.

[30] Ma C, Zhang HH, Wang X. Machine learning for big data analytics in plants. Trends Plant Sci, December 2014; 19: 796e806.