STM JOURNALS

Research & Reviews: Journal of
Computational Biology

https://journals.stmjournals.com/rrjocb/

ISSN: 2319-3433 (Online)
ISSN: 2349-3720 (Print)
Volume 15, Issue 1, 2026
January–April
DOI (Journal): 10.37591/RRJoCB

Review RRJoCB

Modernizing Pharmacovigilance: Leveraging AI, Automation, and Real-World Data for Drug Safety

Yash Prakash Rathod[1,*], Pranav Dattatray Farate[1], Dilan Philip Kurian[1], Ashlesha Shripad Mandale[1], Himalay Prassan Shende[1], Priya Shekhar Daingade[2], Vaishali Ganesh Mundhe[2], Tushar Treembak Shelke[3]

Abstract

Pharmacovigilance, or PV, is "the pharmacological science relating to the detection, assessment, understanding, and prevention of adverse effects, mainly long term and short-term adverse effects of medicines." PV's specific objectives are to increase patient care and safety when using medications and all medical and paramedical therapies; assist in evaluating the benefits, drawbacks, efficacy, and risks of medications, ensuring their safe, prudent, and more effective use; and promote clinical training, education, and pharmacovigilance, as well as its successful public dissemination. Pharmacovigilance (PV) is the main and most important component of clinical research that aims to lower the risk of drug-related accidents for patients. The aim of this article is to give a brief overview regarding the value of the practice of PV to determine and maintain the rational use of medications in the field of pharmacotherapy. Pharmacovigilance (PV) is crucial for public health, mainly for monitoring and assessing adverse drug reactions to ensure patient health. Artificial intelligence (AI) integration is transforming PV by enabling massive data analysis, automating processes, and enhancing the detection of safety signals. This increased capability results in the implementation of more extensive and proactive risk management. An essential "sunshade" of medication safety, pharmacovigilance (PV) guarantees smooth and efficient drug relation, clinical practice, and public health initiatives around the world by monitoring and evaluating the adverse drug reactions (ADRs). PV provides solutions to major drug safety issues which may affect public health across borders. Although many PV centers around the world are now monitoring drug safety, the start of the millennium presented major challenges to enhance drug safety and surveillance. This article discusses drug safety, the function and limitation of global PV centers, and future PV thinking in healthcare. The pharmaceutical industry concentrates on case management, signal detection, and benefit-risk management. These are essential for post-marketing surveillance, product safety, and appropriate medical use through risk management.

***Author for Correspondence**
Yash Prakash Rathod
E-mail: rathodyash0214@gmail.com

[1]Student, Department of Pharmacy, Genba Sopanrao Moze College of Pharmacy, Wagholi, Pune, Maharashtra, India.
[2]Assistant Professor, Department of Pharmacy, Genba Sopanrao Moze College of Pharmacy, Wagholi, Pune, Maharashtra, India.
[3]Principal, Department of Pharmacy, Genba Sopanrao Moze College of Pharmacy, Wagholi, Pune, Maharashtra, India.

Received Date: September 12, 2024
Accepted Date: February 07, 2026
Published Date: March 07,2026

Citation: Yash Prakash Rathod, Pranav Dattatray Farate, Dilan Philip Kurian, Ashlesha Shripad Mandale, Himalay Prassan Shende, Priya Shekhar Daingade, Vaishali Ganesh Mundhe, Tushar Treembak Shelke. Modernizing Pharmacovigilance: Leveraging AI, Automation, and Real-World Data for Drug Safety. Research & Reviews: Journal of Computational Biology. 2026; 15(1): 12–21p.

Keywords: Adverse drug reaction (ADR), artificial intelligence (AI), biomarkers, genomic study, pharmacovigilance, wearable devices

INTRODUCTION

The Latin word vigilare and the Greek word pharmakon are the roots of the word pharmacovigilance. Pharmacovigilance (PV) refers to "the pharmacological science related to the recognition, assessment, understanding, and prevention of adverse effects, particularly long term and short-term adverse effects of medicines." The World Health Organization (WHO) started a program to record every drug-related adverse and toxic event. The profession and science of PV have grown due to the increased knowledge of hazardous medication responses [2]. PV, a crucial component of healthcare systems worldwide, is concerned with the monitoring and assessment of medication product safety. Its capacity to identify and assess ADRs and ensure the overall safety and effectiveness of medications makes it significant for public health. Clinical experience, manual assessment, investigation, and examination of data from individual case reports, epidemiological studies, and clinical trials have historically been the pillars of pharmacovigilance [3]. The various industries that use pharmacovigilance are depicted in Figure 1.

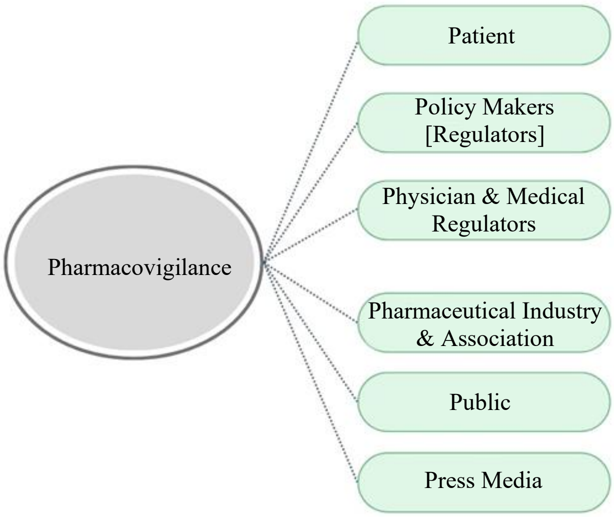

Figure 1. Pharmacovigilance in different sectors.

Identification, measurement, and reporting of drug-related issues that lead to drug-related injuries are just a few of the important functions that PV plays. Additionally, the National PV Program (NPP) was started, and it has a big impact on raising public knowledge of medication safety. The five-year roadmap for India's PV program began in 2010 and progressed through consolidation, maintenance, and optimization before reaching the pinnacle of perfection in the year 2015 with the creation of the Asia-Pacific Center of excellence for Pharmacovigilance [1]. PV and medication safety are dynamic clinical and scientific practices. The WHO has defined pharmacovigilance as "the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem." It is necessary to ensure that both the patient and the doctor have sufficient information to make an informed decision regarding the drug of choice for treatment [4]. For research and the creation of pertinent guidelines that support safe and effective use, systematic PV is necessary to collect trustworthy data for the safety of all category medications. In essence, it involves identifying and assessing safety signs. Table 1 provides definitions for a few of the commonly used terms [6].

Table 1. Definitions of terms related to pharmacovigilance [6].

Term	Definition
Adverse event (AE)	Any unpleasant medical event that occurs during medicine treatment but may not always have a connection to its use is considered an AE.
Adverse drug reaction (ADR)	When a drug is given to a person for prevention, diagnosis, therapy, or pharmacological change of a physiological function, an ADR is a dangerous, undesired, and unintentional side effect.
Post marketing surveillance (PMS)	PMS refers to monitoring a pharmaceutical device or drug's safety once they have been placed into their respective markets.
Clinical trials	To produce safety and efficacy data (or information about adverse reactions to medication and adverse effects to other interventions) for health interventions (e.g., medications, tests for diseases, implants, treatment protocols), clinical trials are a series of experiments carried out under medical research and pharmaceutical development.
Safety signals	A safety signal is an indication that there are more adverse events than would be expected to be linked to the use of a product. These signals can come from post-marketing data, pre-clinical data, and events that are specific to different products in each pharmacological class.

OBJECTIVES OF PHARMACOVIGILANCE

- To establish a patient safety reporting system throughout the nation [2].
- To find and study the new indicator (ADR) in the cited cases [2].
- To safeguard patients from drug-induced harm and adverse reactions through cautiousness [3].
- To determine to what extent drugs offset their benefits and risks in trying to maximize their use and enable informed decision-making [3].
- To determine new facts concerning drug-related risks [6].
- To determine risk factors and potential mechanisms of adverse reactions [6].
- One can create a public patient safety reporting system through making reports [7].
- Describe the amount of effort needed to automate, and anticipated degrees of benefit of automating, each step of ICSR procedures [8].

FUNDAMENTALS OF PHARMACOVIGILANCE

PV is a process in which the safety of all biological products, including vaccines, pharmaceuticals, and complementary and herbal treatments, is being monitored. Pharmacovigilance is the process of detecting, assessing, understanding, and preventing the side effects and other drug-related problems. It is important for patient care as well as for the responsible use of medications. Other names for it include ADR monitoring, drug safety surveillance, side effect monitoring, PMS, and spontaneous reporting. The numerous steps in the pharmacovigilance process are depicted in Figure 2 below [3].

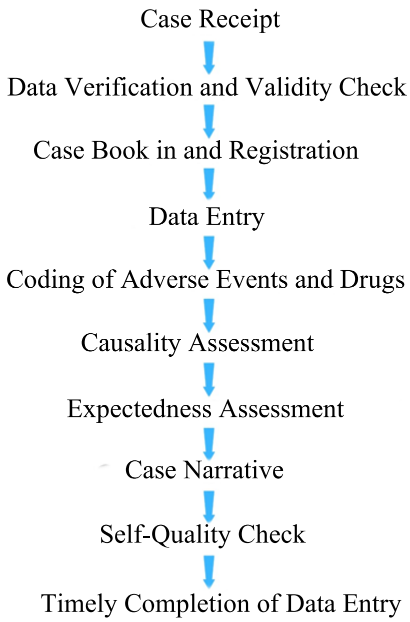

Figure 2. Overview of pharmacovigilance process [3].

Pharmacovigilance Program of India (PvPI)

The Pharmacovigilance Program of India (PvPI) was launched by the Government of India on July 14, 2010, with its National Coordination Center for Indian Adverse Drug Reactions (ADRs) surveillance to ensure protection of public health being AIIMS, New Delhi. During 2010, as a part of this scheme, 22 ADR monitoring centers with AIIMS, New Delhi, were established. Government of India, Ministry of Health & Family Welfare, Central Drugs Standard Control Organization (CDSCO), & Directorate General of Health Services is launching a state-wide pharmacovigilance program with a collaborative effort by Indian Pharmacopeia Commission, Ghaziabad, which secures the patient health through drug safety. The role of National Coordinating Center (NCC) for this program is given to the Indian Pharmacopoeia Commission located in Ghaziabad. The activities at this center will be governed by a steering group [2].

ROLE OF ARTIFICIAL INTELLIGENCE IN PHARMACOVIGILANCE

Artificial intelligence (AI) is ushering in a new era. Unbeknownst to us, technology has permeated every part of our lives, from home to the street, and is currently influencing scientific research, the healthcare system, and pharmacovigilance (PV) [12]. The main reason PV was developed was to safeguard patients who are only partially exposed to therapeutic drugs while they are undergoing clinical trials and research. This makes it possible to use and monitor pharmacological profiles over an extended period [11]. The two facets of AI are Machine Learning (ML) and Natural Language Processing (NLP). Structured data, such as genetic and imaging data, are analyzed using machine learning algorithms. NLP may be able to recognize free and unstructured text forms since it can recognize and analyze human language [5]. Among other applications, AI is used in search engines and in clinical settings for diagnosis, treatment, detection, and outcome prediction. When properly monitored in the healthcare industry, it can be used to prevent issues with human health. VigiFlow, VigiBase, VigiAccess, and VigiLyze are some of the databases that the PV uses. AI is utilized for diagnosis, therapy, detection, and result prediction in clinical settings as well as in search engines, among other places. It is also used in the healthcare sector to avoid problems with human health when properly monitored. Among the databases used by the PV are VigiFlow, VigiBase, VigiAccess, and VigiLyze. For international drug monitoring, the Uppsala Monitoring Center (UMC) was founded in Uppsala, Sweden, in 1978, it acts in collaboration with WHO [15].

Need for Artificial Intelligence in Pharmacovigilance

PV is still a novel idea and is not very popular in developing nations. Countries all around the world are voicing concerns about the necessity of mechanisms to keep an eye on the security of medications after they are marketed. The two primary techniques for reporting ADRs are spontaneous reporting and pharmacoepidemiological processes, which use systematic collection and analysis of AEs connected to drug usage. To address emerging problems, record warning indicators, and communicate to lessen or prevent harm, ADR Monitoring Centers and Marketing Authorization Holder (MAH) businesses also take this action [11]. There are now a lot more potential adverse effects (AEs) in the PV database. The analysis of the massive amount of data from multiple sources, making sense of it, and separating the "shots out of the grain" (European Medicines Agency, 2020) is carried out by the important stakeholders like the pharmaceutical industry, regulatory bodies, medical, and PV specialists, and National Pharmacovigilance Project managers [15].

Applications for AI in Pharmacovigilance

- *Detection of Adverse Events:* To identify ADRs, AI analyzes both structured and unstructured data sources, which includes social media, regulatory databases, and electronic health records.
- *Detection of Signals and Risk Assessment:* ML models that can identify subtle connections can be used to augment traditional disproportionality analysis in datasets such as VigiBase and FAERS.
- *Automatic Case Processing:* Categorizing and prioritizing ADR reports, reducing the need for human intervention, and speeding up case processing can be done automatically using the help of AI systems.
- *Post-Marketing Surveillance:* To identify late-emerging ADRs, AI models analyze empirical data from patient forums, insurance claims, and medical records [14].

GENOMIC STUDY

Adverse Drug Reactions

Adverse reactions or drug related side effects are undesirable drug side effects. They vary in severity, predictability, prevalence, and reported injury. Most drug users in varied clinical settings have an adverse drug response (ADE), which is a predictable side effect. ADEs do not cause disability or endanger life [17].

Pharmacogenomics

The science of pharmacogenomics uses a patient's genetic map as a guide to give the correct medication to the exact person at the correct dose. By providing treatment that is tailored to each patient, genomics testing aims to increase drug effectiveness. Personalized medicine is the aim or advantage of pharmacogenomics. The discovery of DNA was decades before which marked beginning of pharmacogenomics. Researchers shifted their focus in the middle of the 1980s. Using a buccal swab of saliva for DNA analysis, genetic test is a non-recurring method. All the general information is recorded on the swab. A certified/qualified genomics testing laboratory receives this swab kit and data to test the relevant information. The test results, which include the patient's phenotype, alleles, and SNPs, are returned in a few days.

Psychiatric medicine: Treatment of mental illnesses is complicated for both the patient and the doctor. In common, psychiatric medicine is associated with high rates of polypharmacy, underuse, and overuse when compared to pharmacological efficacy. Lethal adverse drug reactions (ADRs) are most common with prescription opioids and benzodiazepines. They exceed the fatal overdose rates from cocaine or heroin [17].

ADVERSE DRUG REACTIONS (ADRs)

ADRs are unintended or negative side effects of drugs at therapeutic doses for treatment, prevention, or diagnosis. They are typically classified as:

- *Type A (Augmented):* Dose-dependent and expected (e.g., insulin-induced hypoglycemia).
- *Type B (Bizarre):* Atypical, unpredictable, and often immunologic or genetic (e.g., Stevens–Johnson Syndrome).
- *Type C (Chronic):* Through long-term use (for example, corticosteroid adrenal suppression).
- *Type D (Delayed):* Consequences after prolonged exposure (e.g., carcinogenesis).
- *Type E (End of Use):* During eviction (like after quitting narcotics).
- *Type F (Failure):* Unexpected failure to be effective [28].

Hazardous drug reactions go unreported because medical teams cannot detect adverse drug events or attribute them to clinical, biochemical, or radiological abnormalities. Therefore, biochemical testing and diagnostic tools can identify many ADRs and have a significant role in PV. According to the current examination, reporting, training, feedback, and direct interactions with prescribers are all areas where the optimum use of the human resource – pharmacology residents – can be made. For obvious reasons, the performance of this human resource in terms of ADR reporting is significantly impacted by summers, major festivals, postgraduate exams, and the submission of theses and synopses. These activities and periods were associated with low reporting, as our data shows. To guarantee consistency in ADR monitoring and reporting, these factors must be foreseen, and prompt action must be taken. To increase the number of ADRs reported, more active participation by physicians (interns, house officers), nurses, pharmacists, and residents is required. The influence of undesirable side effects upon healthcare industry is depicted in Figure 3 below.

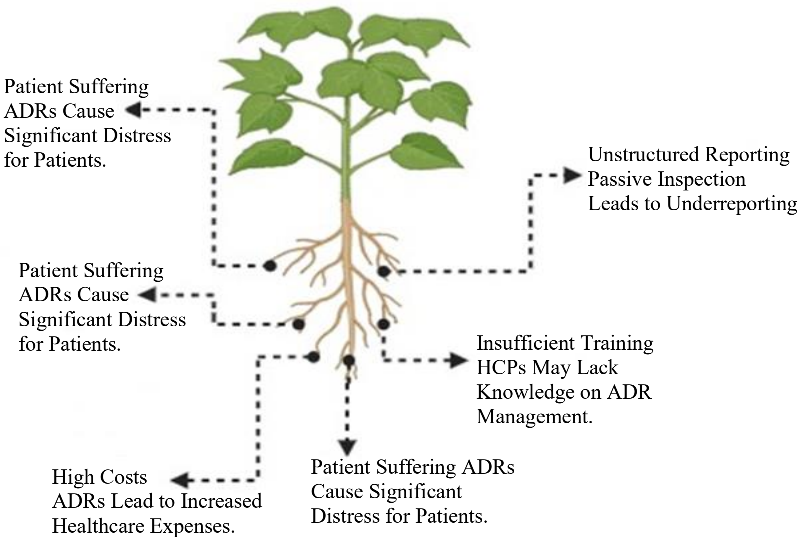

Figure 3. Influence of undesirable effect of drug on medical care [15].

Numerous tactics have been put forth to improve recording such as the establishment of an ADR recording network within the hospital, patient education and encouragement, and mandatory ADR reporting by nurses. According to Trustbusters, doctors' attitudes and expertise on ADR reporting need to be improved. ADR reporting could become intense even with sporadic phone intervention. Sending doctors recurring emails or SMS reminders is a great and cost-effective way to remind them of the need of spontaneous ADR reporting. Ongoing, dynamic, and continuous efforts are necessary since, as the current study also demonstrates, the effects of interventions have been demonstrated to decrease after they are discontinued. WHO's public health initiatives, such as the integration of data from primary care electronic medical records, active surveillance, stimulated reporting, have been found to improve spontaneous reporting. In PvPI, the effects of such therapies have not yet been investigated. ADR reporting is influenced by human behavior, motivation, knowledge, and attitudes. Interventions targeted at changing such factors could enhance UR. UR is highly linked to certain attitudes that educational interventions may be able to change. According to the study's findings, UR was caused by several reasons, including workload, insufficient PV training, complacency, apathy, insecurity, laziness, and ignorance about PvPI. In a similar study, UR was linked to 95% of participants' ignorance, 72% to their diffidence, 77% to their lethargy, 67% to their apathy and uneasiness, and 47% to their complacency. Factors that encourage ADR reporting, such as years of work experience and participation in educational programs related to the detection and treatment of drug-associated disorders, have not been evaluated in the current study. Some of the issues that discourage reporting include amnesia, difficulties reporting prior bad drug responses, lack of time, and uncertainty about informal connection of drugs along undesired side effects. Only a small portion of undergraduate and graduate pharmacology courses include PV. The outcomes of the most recent study are comparable as well. The Medical Council of India and the relevant stakeholders in nursing and pharmacy education should, therefore, require that the curriculum include pertinent interventions to incorporate ADR reporting and PV in a suitable format. The center only published two occasional case reports during the research period. Physicians may be encouraged to report PV by the publication of rare and atypical ADRs as well as other research findings related to ADRs. However, because practitioners frequently conceal significant and deadly ADRs during the recommended time limit, some of these ADRs remain unreported. Convincing therapists that disclosing ADRs carries no legal consequences is crucial. It is recommended to check for the ADRM number or ID generated in the Vigibase to verify the authenticity of case reports submitted for publication in journals. Additionally, this ensures that the reports are part of the data provided from India in Vigibase [18, 19, 20].

BIOSIMILARS

With at least five biosimilar applications pending approval from the US Food and Drug Administration (FDA), 2015 marks a significant turning point in the evolution of medical innovation. For the first time, several manufacturers will develop a variety of novel medications that are comparable but distinct for the US market. This new era began in March 2015 with the approval of the first biosimilar, Zarxio [filgrastim-sndz], in the United States [21].

Brand Names

When reporting adverse events, brand names are frequently the first identifier used. When ordering a medication for prescription or patient record documentation, about half of the 376 US prescribers surveyed used the brand name. Biologics brand names in SRSs might differ depending on the product class and region. For example, in the United States, 84% of insulin brand names are correctly used, whereas in the European Union (EU), 99% of epoetins were attributed to specific products. The EU implemented a requirement in 2010 to guarantee that trade names appear in adverse event reports and medical records for biological pharmaceuticals. Amgen did not link a particular brand name to 21% of spontaneous filgrastim notifications it received from the EU between April 2012 and December 2014, notwithstanding this restriction. Similarly, the code "filgrastim (not specified)" was included in 42% of reports submitted to Australia's Therapeutic Goods Administration public database between March 2011 and November 2014. These findings demonstrate that when reporting adverse events, a sizable portion of reporters utilize the non-proprietary word rather than the brand name. AS simply provides billing codes for provided products; brand names are rare in medical benefit claims and are not receptive to AS [21].

Non-Proprietary Names

In the United States, generic names are also known as non-proprietary names, established names, US Adopted Names [USAN], International Non-proprietary Names [INN], or active ingredients, are most used because brand names are not required for goods or prescription medications. According to a survey, generic names accounted for 21% of prescriptions. The non-proprietary name is a vital tool for worldwide pharmacovigilance of nonbiologic drugs and is commonly used in adverse event reports [21].

EMERGENCE OF BIOMARKERS AS A TOOL FOR SAFETY ASSESSMENT

With the aid of molecular biomarkers, pharmacovigilance has become a vital tool that holds the potential for a more accurate safety assessment. They can also help identify individuals who are susceptible to ADRs by looking at their metabolomic, proteomic, or genetic profiles. Early drug toxicity identification, early adverse event management, and customized treatment plans are all made possible by biomarkers. Recent research has shown how crucial biomarkers are for elucidating the mechanism of drug-induced toxicity to conduct more thorough risk assessment and management. Thus, genetic biomarkers of medication responses, for example, can assist physicians in determining a patient's likelihood of adverse reactions and, consequently, in treatment decision-making. Utilizing biomarkers in a proactive rather than reactive pharmacovigilance process can be facilitated by integrating biomarker data into pharmacovigilance systems [23].

Information Extraction as a Pharmacovigilance Methodology

With the aid of molecular biomarkers, pharmacovigilance has emerged as a significant technique that holds the promise of a more precise safety assessment. Depending on their genetic, proteomic, or metabolomic profiles, they can also help in the recognition of the people who are at the verge of developing ADRs. Biomarkers are used to help with early drug toxicity diagnosis, early adverse event management, and customized therapy plans. The importance of biomarkers for clarifying the mechanism of drug-induced toxicity for more comprehensive risk assessment and management has been demonstrated by recent studies. Genetic biomarkers of drug reactions, for instance, can help physicians assess patients' risk of adverse reactions and, in turn, aid in treatment decision-making. Applying biomarkers to pharmacovigilance processes that are proactive rather than reactive can be facilitated by integrating biomarker data into pharmacovigilance systems [25].

Emerging Technologies in Patient Monitoring

Wearable Devices

Smartphones, smart wrist bands, and health monitors are examples of wearable gadgets that collect data in real time to discover and detect negative situations. They allow for the scheduling of medications and the monitoring of physiological signs. Technology makes it easier to make healthcare adjustments in real time rather than waiting for test results by providing real-time information that care professionals may access on different devices [27]. Wearables include gadgets that track biometrics and vital signs, including Fitbit, Apple Watch, Oura Ring, and more recent models like the CGM from Dexcom. Continuous or semi-continuous data can be captured by these technologies and usually sent to cloud-based systems accessible to pharmacists and medical experts [30].

Remote Patient Monitoring and Telepharmacy

The COVID-19 pandemic and subsequent investments in digital health solutions have led to a record and exponential growth in RPM technology. Pharmacists may now remotely monitor patient trends and act when specific thresholds are achieved thanks to telepharmacy models. For example, they can act when a patient's blood pressure reaches 160 millimeters of mercury despite taking antihypertensives [30].

CHALLENGES AND OPPORTUNITIES

The caliber of training data affects how well machine learning (ML) models perform. It is challenging to obtain representative, high-quality training data for pharmacovigilance (PV). Reliability, timeliness, correctness, and completeness are all components of data quality. Errors led to inaccurate conclusions, thus accurate data is crucial. Completeness is crucial since incomplete information might skew forecasts. Timeliness – having current data that reflects the most recent trends – is crucial because outdated data might mislead drug safety models. Data consistency across time without bias is encouraged by reliability. Data annotation is also crucial; accurate labeling requires in-depth PV knowledge. Errors and biases may arise from the time-consuming task. Furthermore, varied patient populations must be represented in databases to avoid making skewed predictions about certain populations. Managing unstructured data, including patient records and clinical notes, is one of PV's most difficult tasks. Such data can yield valuable information for natural language processing (NLP), but the effectiveness of NLP depends on how well-chosen and representative the training data is [34].

FUTURE PERSPECTIVES FOR RESEARCH AND DEVELOPMENT WITH PHARMACOVIGILANCE

The utilization of AI in PV creates a chance at revolutionizing drug precaution monitoring and management in the future. By using real-time analysis and monitoring of huge data from several sources, AI technology helps in improving the precision and effectiveness of AE detection. The quicker and precise detection of trends, patterns, and emerging hazards by these technologies allow for preventive loss reduction. Regulators and healthcare experts can also respond quickly and efficiently to new safety concerns with predictive AI-powered analytics. AI implementation is further set to automate pharmacovigilance reporting obligations and expedite regulatory procedures for adherence. Taken together, the application of AI in PV offers a ground-breaking paradigm to enhance medication safety monitoring and protect health of the public. To fully utilize artificial intelligence in pharmacovigilance, the following recommendations have been made for further research and development. Pharmacovigilance stakeholders can take use of the groundbreaking capability of artificial intelligence (AI) technology for enhanced patient care, systematic decision-making, and drug safety surveillance by heeding this advice. These efforts will improve community health globally as safer and more efficient drugs become accessible [3]. To maximize ADR reporting and show efficacy, high-quality, intervention-based studies in this population must be created and carried out quickly. To get over the sometimes-changeable obstacles, a variety of patient-focused communication, instructional, and promotional tactics must be created and implemented. One effective way to get beyond the obstacles would be to provide training and information about online platforms with interactive, straightforward, and easy-to-understand content [20].

CONCLUSION

Pharmacovigilance (PV) is a necessity for pharmaceutical welfare and community well-being, especially as drugs get more complex. AI has the potential to revolutionize PV, an area where it has typically fallen short in terms of offering user-friendly information for choosing medications. Technology can help with conducting drug safety monitoring in near real time and automating cases management to boost identification of side effects. The deployment of AI is, however, contingent upon resolution of algorithmic bias and data privacy and regulatory compliance issues. The future drug safety system will rely upon explainable AI, blockchain, and federated learning breakthroughs. Molecular biomarkers are also significantly enhancing early drug toxicity detection and pharmacovigilance.

REFERENCES

1. Dol HS, Shinde VR, Vijaykumar Mali J, Navnath Khakal N. Pharmacovigilance: A practical approach for reshaping patient safety. Innovare J Med Sci. 2017;5(2):1–4.
2. Kumar DA, Reddenna L, Basha SA. Pharmacovigilance programme of India. Innov Pharm. 2015;6(1).
3. Ahire YS, Patil JH, Chordiya HN, Deore RA, Bairagi VA. Advanced applications of artificial intelligence in pharmacovigilance: Current trends and future perspectives. J Pharm Res. 2024;23(1):23–33.
4. Jeetu G, Anusha G. Pharmacovigilance: A worldwide master key for drug safety monitoring. J Young Pharm. 2010;2(3):315–20.
5. 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. 2019;105(4):954–61.

6. Sumit K, Ashish B. Pharmacovigilance in India: Perspectives and prospects. J Drug Deliv Ther. 2013;3(4):237–46.
7. Vishwakarma R, Rai V, Singh S. A review paper on pharmacovigilance: an overview. 2024;4:60–70.
8. Ghosh R, Kempf D, Pufko A, Barrios Martinez LF, Davis CM, Sethi S. Automation opportunities in pharmacovigilance: An industry survey. Pharm Med. 2020;34:7–18.
9. Hans M, Gupta SK. Comparative evaluation of pharmacovigilance regulation of the United States, United Kingdom, Canada, India and the need for global harmonized practices. Perspect Clin Res. 2018;9(4):170–4.
10. Kompa B, Hakim JB, Palepu A, Kompa KG, Smith M, Bain PA, et al. Artificial intelligence based on machine learning in pharmacovigilance: A scoping review. Drug Saf. 2022;45(5):477–91.
11. Murali K, Kaur S, Prakash A, Medhi B. Artificial intelligence in pharmacovigilance: Practical utility. Indian J Pharmacol. 2019;51(6):373–6.
12. Desai MK. Artificial intelligence in pharmacovigilance–Opportunities and challenges. Perspect Clin Res. 2024;15(3):116–21.
13. Dimitsaki S, Natsiavas P, Jaulent MC. Applying AI to structured real-world data for pharmacovigilance purposes: Scoping review. J Med Internet Res. 2024;26:e57824.
14. Baby A. Leveraging artificial intelligence in pharmacovigilance: Enhancing drug safety through data-driven approaches.
15. Shukla D, Bhatt S, Gupta D, Verma S. Role of artificial intelligence in pharmacovigilance. J Drug Discov Health Sci. 2024;1(04):230–8.
16. Choi YH, Han CY, Kim KS, Kim SG. Future directions of pharmacovigilance studies using electronic medical recording and human genetic databases. Toxicol Res. 2019;35:319–30.
17. McCorvey A, Hale C. Advancing personalized medicine: Has genomic testing enhanced pharmacovigilance to improve drug efficacy? J Interprof Educ Pract. 2017;7:65–71.
18. Moride Y, Haramburu F, Requejo AA, Begaud B. Under-reporting of adverse drug reactions in general practice. Br J Clin Pharmacol. 1997;43(2):177–81.
19. Tandon VR, Mahajan V, Khajuria V, Gillani Z. Under-reporting of adverse drug reactions: A challenge for pharmacovigilance in India. Indian J Pharmacol. 2015;47(1):65–71.
20. Costa C, Abeijon P, Rodrigues DA, Figueiras A, Herdeiro MT, Torre C. Factors associated with underreporting of adverse drug reactions by patients: A systematic review. Int J Clin Pharm. 2023;45(6):1349–58.
21. Grampp G, Felix T. Pharmacovigilance considerations for biosimilars in the USA. BioDrugs. 2015;29:309–21.
22. Garcia-Gancedo L, Bate A. Digital biomarkers for post-licensure safety monitoring. Drug Discov Today. 2022;27(11):103354.
23. Farid F, Ferdouszzaman M, Khan T, Sharma D. Advances in molecular biomarkers for pharmacovigilance: Early detection of drug toxicity. World J Biol Pharm Health Sci. 2025;21:71–81.
24. Liu F, Jagannatha A, Yu H. Towards drug safety surveillance and pharmacovigilance: Current progress in detecting medication and adverse drug events from electronic health records. Drug Saf. 2019;42(1):95–7.
25. Segura-Bedmar I, Martínez P. Pharmacovigilance through the development of text mining and natural language processing techniques. J Biomed Inform. 2015;58:288–91.
26. Zakari N, Al-Razgan M, Alsaadi A, Alshareef H, Alotaibi S. Blockchain technology in the pharmaceutical industry: A systematic review.
27. Aher S, Mahajan M, Upaganlawar A, Upasani C. Pharmacovigilance in the digital age. Int J Pharm Sci. 2024;2(4):691–711.
28. Anestina N, Obiageli C, Anthony O, Alade A, Mustapha A, Oluwaferanmi A. Ensuring drug safety: Comprehensive pharmacovigilance strategies for public health.
29. Singh A, Twomey K, Baker R. Global pharmacovigilance regulations: Call for reharmonization. Clin Trials. 2018;15(6):631–2.
30. Gettman D. Proactive pharmacovigilance: Leveraging predictive analytics and wearable health tech to manage medication-related risks in high-risk patient population. 2015.
31. Bahk CY, Goshgarian M, Donahue K, Freifeld CC, Menone CM, Pierce CE, et al. Increasing patient engagement in pharmacovigilance through online community outreach and mobile reporting

applications: An analysis of adverse event reporting for the Essure device in the US. Pharm Med. 2015;29:331–40.
32. Silva L, Pacheco T, Araújo E, Duarte RJ, Ribeiro-Vaz I, Ferreira-da-Silva R. Unveiling the future: Precision pharmacovigilance in the era of personalized medicine. Int J Clin Pharm. 2024;46(3):755–60.
33. Getov I, Panayotova D, Dobrev S, Dimitrova M, Petkova V. Opportunities for implementing digital applications to monitor the impact of risk-minimization measures within the pharmacovigilance process: Scoping review of published literature. Pharmacia. 2025;72:1–6.
34. Yang J, Li F. The impact of technological progress on pharmacovigilance. Pharmacovigilance-Facts Challenges Limitations Opportunities. 2025:43.

