Use of Artificial Intelligence in Analyzing Electronic Health Records for Pharmacovigilance: A Comprehensive Review

Odedra Sakshi Nalinbhai[1] and Dr. Trupesh M. Pethani[2]
[1,2] *Department of Pharmaceutical Sciences, Saurashtra University, Rajkot, Gujarat, India*

Abstract: *Pharmacovigilance plays a critical role in drug safety, based on traditionally relying on spontaneous reports and manual case assessments. With the exponential growth of electronic health records, artificial intelligence (AI) has become a processing tool for the analysis of complex clinical data. This review examines the use of AI, including machine learning (ML) and natural language processing (NLP), treatment in the supervision of pharmacovigilance using electronic health records (EHR). It discusses how AI enhances adverse event detection, improves the accuracy and speed of signal detection, and supports real-time surveillance. Real-world implementations such as the FDA Sentinel Initiative, OHDSI, and the EU-ADR project are examined alongside regulatory and industry adoption. This article defines existing issues such as data confidentiality, model interpretation, and integration failures. At the same time, it emphasizes future orientations such as drug parks in the field of artificial technology or global cooperation tailored to the results. Thanks to current innovation and ethical developments, AI is committed to changing the landscape of pharmacovigilance and increasing patient safety from around the world.*

Key words: Pharmacovigilance, Artificial Intelligence, Electronic Health Records, Machine Learning, Natural Language Processing, Adverse Drug Reactions.

Introduction:

The word “pharmacovigilance” was derived from the Greek literature “pharmakon” (meaning drug) and the word “vigilare” (meaning keep watch) in Latin. The science and practices of pharmacovigilance are concerned with the identification, assessment, comprehension, and avoidance of side effects or other potential drug-related problems[1]. The European Medicines Agency states that “The objective is to improve the health of patients, healthcare providers, and the public regarding drug safety”[2]. Globally, the quality and safety of healthcare have increased because of electronic health records (EHRs). Both organized (such as demographics, vital signs, medications, and lab test results) and unstructured (like doctor's notes, progress notes, clinical notes, discharge summaries, patient narratives, and imaging reports) data are included in digital patient data[3]. Applying artificial intelligence (AI) to real-world data (RWD; such as electronic health records) has been acknowledged by pharmacovigilance as a potentially beneficial technical method[4]. By automating the pharmacovigilance process and enhancing the surveillance of known and documented adverse medication events, artificial intelligence, including machine learning (ML) techniques like natural language processing (NLP) and deep learning (DL), can identify and extract information regarding adverse drug events[5].

AI and ML technologies, including DL and NLP, present intriguing ways to improve and automate pharmacovigilance procedures. These technological advancements are transforming our understanding of medication safety and increasing the effectiveness and proactive aspects of pharmacovigilance[6]. The purpose of this study is to outline the ways in which incorporating AI—more especially, ML and NLP—into pharmacovigilance systems can enhance data collection, processing, and adverse drug reaction (ADRs) detection. Pharmacovigilance has traditionally mostly relied on spontaneous reporting systems (SRS), which, in spite of their significance, had serious drawbacks such as underestimating, delayed security signal identification, and inconsistent data quality. Therefore, the application of AI and EHRs has a significant future for expanding different kinds of drugs for more aggressive, effective, and customized physician safety monitoring.

1. Pharmacovigilance: Fundamental Ideas and Evolution

1.1 Definition and Purpose:

The science and practice of detecting, evaluating, understanding, and mitigating adverse effects or other possible issues associated with drugs is known as pharmacovigilance. Enhancing patient care and safety with regard to drug use and all medical and paramedical interventions, providing trustworthy information to support public health initiatives, assessing the risk-benefit profile of medications effectively, and fostering clinical training and knowledge in pharmacovigilance and its effective public communication are the goals[7].

1.2 Traditional Approaches:

The basis of traditional pharmacovigilance has traditionally been the spontaneous reporting mechanism. This enables patients and healthcare providers to notify local or federal authorities about adverse drug reactions. A systematic assessment of 37 research studies from 12 different countries, however, revealed a median underreporting rate of 94%, suggesting that the majority of ADRs go undetected. Under-reporting is comparable between hospital and general medical settings, even for significant ADRs. These findings point to significant shortcomings in conventional techniques as well as the necessity of enhancing awareness, training, and supplementary reporting strategies[8].

1.3 Need for Innovation:

Pharmacovigilance is becoming more aware of the need for technological developments, particularly in the areas of artificial intelligence and big data. Alongside these demands, a number of significant occasions occurred. First, sophisticated technologies are needed for efficient processing and data analysis due to the growing volume and complexity of data from several sources, including social networks, EHRs, and spontaneous reporting. Both AI and ML approaches that can automate ADR extraction and analysis are NLP and DL. By processing unstructured data and finding models that are hidden even using conventional techniques, these techniques increase the efficacy and precision of ADR detection[6].

2. Electronic Health Records:

Comprehensive electronic health records, including diagnoses, prescriptions, test results, and clinical notes, are known as EHRs. Their unstructured elements and structured elements offer a vast collection of real clinical data.

2.1. Structure and Components:

The EHRs idea included a wide variety of information systems, from files assembled in individual departments to long-term patient data collectors. EHRs were used in primary, secondary, and tertiary care. Data was entered into electronic health records by a variety of medical expert groups. Doctors have also confirmed the information that patients themselves documented. Daily charting, medication administration, physical examination, admission nursing note, referral, current complaint (e.g., symptoms), past medical history, lifestyle, physical examination, diagnoses, tests, procedures, treatment, medication, discharge, history, issues, findings, and vaccinations were among the data components recorded in EHRs. Numerous studies have demonstrated that using an information system helped medical workers document more accurately and completely[9]. The United States (US) has undergone a rapid adoption of EHRs systems by hospitals and medical practices in recent decades, leading to the creation of enormous databases of electronic patient data, both organized (disease codes, prescription codes, etc.) and unstructured (clinical narratives, such progress notes). Despite the numerous potential benefits of employing discrete data fields in clinical documentation and the growing presence of structured data entry fields in EHRs systems, physicians are still reluctant to utilize them because of the additional paperwork they must complete. Clinical narration is frequently used by doctors and other healthcare professionals as an easier way of recording patient data, including social factors that affect health and family medical histories[10].

2.2. Pharmacovigilance Using EHR Data:

EHRs' primary purpose is to efficiently store and handle patient data in contrast to paper-based health record systems. However, pharmacovigilance has gained a lot of attention, and their secondary usage is currently being extensively investigated for a variety of medical research, including illness identification and patient stratification. There are a number of data-driven approaches to using EHRs for pharmacovigilance, including using machine learning-based prediction, which is still in its early stages, grouping patients into distinct disease categories, and determining connections between medications and illnesses[11]. EHRs are a helpful tool for monitoring adverse drug events (ADEs) as well as performing overall public health observation. Pharmacovigilance integration has made it possible to access comprehensive, long-term clinical data that goes beyond the constraints of claims data and SRS. EHRs offer comprehensive patient-level data, such as vital signs, laboratory findings, and clinical free-text notes; enhance signal identification capabilities; and enhance inefficiency management when compared to claims databases. Data volatility, underutilization of EHRs components, and challenges integrating EHRs data with non-EHRs sources are some of the problems, though. Notwithstanding these challenges, there is hope for enhancing surveillance tactics and guaranteeing medication safety when EHRs and other pharmacovigilance data are combined[12].

3. Integration of AI in Pharmacovigilance:

Pharmacovigilance is using AI, such as ML and NLP, more and more to automatically identify ADRs in massive datasets like social networks and EHRs. These tools improve speed, accuracy, and real-time drug safety monitoring while resolving the shortcomings of manual methods.

3.1. Introduction to AI, ML, and NLP:

Pharmacovigilance is seeing a paradigm shift from manual, retrospective, and traditional methods to AI-enabled real-time, predictive, and automated systems. Conventional approaches are no longer sufficient for prompt and precise signal detection due to the growing volume and complexity of healthcare data, including EHRs, unplanned reports, medical literature, and patient-generated content. To solve these difficulties, AI technologies like ML, NLP, and predictive analytics provide the necessary tools[13]. Important AI, ML, and NLP. These findings hold promise for a range of clinical uses, including pharmacovigilance. One crucial aspect of detecting, evaluating, and preventing ADEs and ADRs is pharmacovigilance. NLP integration makes it possible to efficiently extract crucial information about ML and AI from clinical narratives and electronic health data. Encouraging quicker and more precise drug safety monitoring[3].

3.2. AI in Healthcare and Pharmacovigilance:

Acquisition of data, extraction of information, data mining, insights, regulatory reporting, and actionable intelligence are all parts of the pharmacovigilance value chain that are being shaped by AI and ML technologies. AI makes data collection more effective and reliable by assisting in the identification, categorization, and prioritization of pertinent information from a variety of sources, including social media, medical literature, and EHRs[14]. AI and intellectual automation can greatly increase the effectiveness of pharmacovigilance procedures. Routine processes including duplicate searches, critical regulatory information verification, and the initial verification of individual case safety reports (ICSRs), can be automated with the use of these technologies. Additionally, it can speed up signal recognition, establish priorities for further considerations, and evaluate the case's dependability. Pharmacovigilance experts can concentrate on higher-value tasks by having less work to do. Additionally, by incorporating AI into telehealth platforms, real-time pharmacovigilance can be provided by utilizing wearable device data and telehealth consultations to enable continuous monitoring and identification of adverse drug reactions in patients getting remote care[6].

4. AI Application in Pharmacovigilance Based on EHRs:

New prospects for using AI in pharmacovigilance have been made possible by the expanding use of EHRs. AI helps overcome the slow and error-prone nature of manual approaches by automating ADR detection, signal recognition, and predictive modeling. In order to manage the growing complexity of healthcare information as well as guarantee prompt medication safety.

4.1. Automatic Detection of ADRs:

It is becoming more and more possible to identify and anticipate drug-related injuries as EHRs systems gain widespread use. By aiding in the identification of potential ADEs, EHRs present a strong alternative to the time-consuming manual review of patient charts. The use of statistical models can then be used to forecast negative reactions. As a result, a growing amount of research has concentrated on ADE prediction using EHRs data[15]. AI can identify possible ADRs and signals by analyzing vast amounts of data from many sources, including social media, EHRs, and other sources. AI is also capable of real-time data analysis, which makes it possible to identify ADRs very instantly[16].

4.2. Signal Detection and Model Recognition:

AI systems are able to identify security indicators early on and take prompt action. Examine information from several sources, including clinical testing, EHRs, and side effects, to find novel patterns or links between medications and adverse occurrences. Proactive actions like label updates or investigations depend on this early discovery[17]. Large datasets, such as social media, EHRs, and other sources, can be examined by AI algorithms to find possible indications of ADRs. Patterns and correlations that might not be immediately obvious using conventional techniques can be identified by these algorithms[18].

4.3. Risk Modeling and Predictive Analytics:

Advanced predictive analytics techniques for anticipating adverse events and estimating pharmaceutical safety profiles across a range of patient populations. Integrate proteomic, genomic, and other data into AI-driven risk modeling tools to provide customized risk assessment and precision medicine solutions. One example is drug-induced liver damage (DILI) predictive biomarker panels, which use AI algorithms to identify those who are more likely to have negative consequences[19]. Early detection of ADRs and DDIs is made possible by predictive models, which are transforming pharmacovigilance. These models, which are driven by machine learning algorithms, examine extensive datasets such as clinical trials, EHRs, and spontaneous reports. Given the increasing prevalence of polypharmacy, particularly in older populations, identifying trends in patient demographics, genetic information, and pharmacological characteristics allows for a more proactive and accurate risk assessment[20].

4.4. Data Cleaning and Standardization:

EHRs data is frequently diverse, containing both unstructured information like clinical notes and organized information like test findings. Preprocessing is necessary because AI models need high-quality, standardized, and clean data. To guarantee data quality, preprocessing techniques, including text mining, normalization, and assortment of missed values, are crucial[21].

4.5. Visualization and Reporting:

By fusing analytics methods with interactive visualizations, visual analytics (VA) solutions have demonstrated great potential in tackling the issues of information overload in EHRs. By applying methods from a variety of disciplines, including statistics, machine learning, and data mining, analytics has the potential to support the clinical decision-making process of healthcare professionals. VA systems enhance the efficiency of EHR-driven processes by utilizing interactive displays and analytics methodologies[22]. This procedure is further enhanced by the use of AI systems, which forecast and display detected ADRs. By putting in place a constant feedback loop that includes validation, visualization, and updated EHRs, AI models may be continuously trained, which will result in the continuous discovery of new ADRs[23].

5. Published Studies:

Numerous published studies have effectively illustrated the use of AI in pharmacovigilance, emphasizing the incorporation of RWD in secure and regulated frameworks.

5.1. FDA Sentinel Studies:

Sentinel is a strong and adaptable tool that leverages a distributed data network with carefully selected EHRs to offer evidence on the effects of medical items while maintaining patient privacy. ML, NLP, and other technologies that can enhance the usage of EHRs or other real data sources are examples of such approaches[24]. Creating the organizational structure and putting in place the governance, harmonization, and quality assurance procedures to provide high-fidelity, appropriate data to satisfy regulatory significant inquiries is the first step in extending Sentinel's access to EHRs data. Linking EHRs to insurance claims, which capture longitudinal data regardless of the care settings, is essential to comprehending the completeness of longitudinal data because the majority of EHRs sources in the US are unable to capture data when individuals receive care outside of the contributing healthcare systems. The Sentinel Innovation Center will address important regulatory requirements in creating a query-ready distributed data network with EHRs, such as identifying the source of EHRs data with standing linkage to insurance claims and specifying the minimal data elements required to handle use cases that are currently challenging to handle. In order to enable uniform query implementation, we will also provide the concepts and methods for figuring out how to arrange the structured, semi-structured, and unstructured EHRs data as well as the insurance claims data in a single data model[25].

5.2. OHDSI (Observational Health Data Sciences and Informatics):

The OHDSI initiative is an interdisciplinary partnership with multiple stakeholders that uses large-scale analysis to determine the value of observational data. The Observational Medical Outcomes Partnership (OMOP) common data model (CDM) is used by the OHDSI program to standardize clinical patient data (electronic health records, claims, and clinical registries) in order to promote AI-based pharmacovigilance. The project offers scalable machine learning tools like electronic phenotypes and predictive patient modeling, which are crucial for identifying adverse drug reactions. Additionally, OHDSI offers open-source tools to provide consistent analysis and cohort augmentation across international datasets, greatly expanding the reach and dependability of pharmacovigilance initiatives[26].

5.3. EU-ADR Project:

The EU-ADR project was created with the goal of investigating the use of EHRs as a supplement to medication safety monitoring. The European Commission supported the EU-ADR project, "Exploring and Understanding Adverse Drug Reactions by Integrative Mining of Clinical Records and Biomedical Knowledge (EU-ADR)", which started in February 2008. The project's main goal is to design, create, and verify an automated integrative system that uses biological database and EHRs data to detect ADRs early. Extending beyond the current state-of-the-art, EU-ADR resulted in the federation of various EHRs databases, generating an unparalleled resource for drug safety monitoring in Europe (more than 30 million patients over eight databases)[27].

6. Advantages and opportunities:

For pharmacovigilance, AI provides several benefits, including improved speed, accuracy, and scalability when evaluating big datasets. It enhances the sensitivity of ADRs detection, permits real-time surveillance, and facilitates personalized risk assessment. Because of these possibilities, AI can be a useful instrument to improve regulatory and public health decision-making.

6.1. **Enhanced speed and efficiency**:

AI is faster than alternatives in processing vast volumes of data. The hazards to medication safety among patients, social networks, scientific literature, and spontaneous reporting can be swiftly identified by machine learning algorithms. This facilitates the early identification of adverse drug reactions and the prevention of extensive harm[28].

6.2. Enhanced sensitivity and accuracy:

In order to improve public health outcomes, AI has emerged as a technique to boost the precision and effectiveness of EHRs data processing. Machine learning algorithms play a key role in the analysis of EHRs data, enabling the identification of trends and the prediction of disease transmission. NLP techniques enhance EHRs analysis by gaining a deeper understanding of patients' health conditions by extracting data from unstructured text sources, such as doctor's notes. DL algorithms are increasingly being utilized to inform public health policy decisions and anticipate patient outcomes, such as hospital readmissions. These AI-driven methods enhance the sensitivity and accuracy of ADRs detection in the context of pharmacovigilance, facilitating early safety measures and more accurate signal identification[29].

6.3. Real-time surveillance:

By continuously evaluating data from many sources, such as EHRs, clinical trial data, social media, and international drug safety databases, AI and ML technologies allow for real-time drug safety monitoring[30]. Building on this tracking ability AI enables real-time pharmacovigilance, in which ongoing data gathering from regulatory databases, wearable medical technology, social media, and EHRs may be examined for new adverse drug reactions. Compared to conventional post-market surveillance systems, this real-time approach enables regulatory agencies, healthcare practitioners, and pharmaceutical corporations to identify safety risks significantly faster. AI systems that evaluate enormous volumes of real-time data can assist in identifying possible ADRs and sending out signals to relevant parties for more research, enabling speedier reaction times for addressing safety issues[31].

6.4. Post-Market Data Analysis:

AI algorithms are far more effective than human operators at identifying safety signals because they can evaluate large datasets, such as adverse event reports, electronic health records, social media conversations, and patient feedback. For example, NLP models can look for hidden adverse medication reactions in free-text medical records that are missed by traditional reporting systems. Pharmaceutical companies will therefore be able to take preventative action against a possible hazard to clinical safety through timely data analysis[32].

6.5. Characteristics of Healthcare Systems with Multi-Center:

AI-driven pharmacovigilance has a lot of potential in multi-center health systems. These settings, which include geographically dispersed research facilities amongst clinics and hospitals, produce a lot of data from various clinical research and documentation systems. These systems are used in clinics and hospitals, produce a variety of structured and unstructured data, from clinical narratives to pharmaceutical records, and offer a solid basis for AI modeling. In order to address these issues, innovative infrastructure, structural designs, and algorithms that are tailored to the distribution, security, and application of AI in pharmacovigilance must be carefully considered[33].

7. Limitations and Challenges:

Although AI has great potential, there are challenges preventing its widespread use in pharmacovigilance. Problems include inadequate data quality, a lack of transparency, integration challenges, and ethical dilemmas that need to be resolved. It's critical to acknowledge these obstacles in order to guarantee the ethical, safe, and trustworthy application of AI in medication safety monitoring.

7.1. Data Quality and Integration:

To provide precise predictions, AI and ML algorithms need high-quality, standardized data. Pharmacovigilance data, however, is frequently partial, unstructured, or inconsistent across a range of sources. In order for algorithms to acquire accurate and comprehensive data for analysis, it is a significant challenge to integrate data from several platforms such as social networks, regulatory databases, and EHRs [31]. The Observational Medical Outcomes Partnership Common Data Model (OMOP CDM) has gained popularity in research networks and AI development environments as a solution to the analytical aspect of interoperability. OMOP enables AI developers to create models that are transferable between institutions by standardizing diverse EHRs data into a uniform schema with shared vocabularies. Without necessitating the transfer of raw data, the paradigm facilitates collaborative pharmacovigilance investigations by supporting cross-site analytical consistency[33].

7.2. Explainability and Transparency:

The decisions made by AI models frequently function as "black boxes" that don't explicitly explain how they arrived at a given conclusion. Concerns are raised by this lack of transparency in crucial domains like pharmacovigilance, where medical practitioners must incorporate conversations based on AI signals. AI analysis of complicated EHRs data, where clinical variance and unstructured text further obfuscate decision-making, exacerbates this issue[34].

7.3. Work Flow Integration:

Pharmacovigilance in the future is likely to be significantly impacted by the integration of transparency AI into EHR. Because of this connection, patient data can flow continuously into artificial intelligence systems, enabling real-time analysis and capture of adverse occurrences. Pharmacovigilance operations become more accurate and swifter as a result of this integration[35].

7.4. Ethics and Privacy:

There are various ethical issues with the use of AI in pharmacovigilance. Since sensitive patient information like EHRs needs to be protected, data privacy is a significant concern. Additionally, AI has the ability to disrupt the workforce by replacing human positions. To guarantee that decisions are rational and clear, transparency in AI operations is essential. Using AI in an ethical and responsible manner is essential to upholding public confidence and guaranteeing adherence to legal requirements. The effective incorporation of AI in pharmacovigilance requires addressing these issues[36]. EHRs and genetic data are examples of healthcare data that need to be safeguarded against security breaches and misuse. To protect data integrity and adhere to laws like the General Data Protection Regulation (GDPR) and the Health Insurance Portability and Accountability Act (HIPAA), strict procedures are required[34].

7.5. Pharmacovigilance Data Complexity:

The interpretation of artificial intelligence-controlled systems is made more difficult by the heterogeneous and varied character of pharmacovigilance data, which leads to issues with data integration and analysis. The usage of EHRs data, which combines structured (lab findings) and unstructured (clinical notes, patient history) data, adds to this complexity[37].

8. Future Directions:

Future developments in AI-driven pharmacovigilance will concentrate on explainable models, EHRs system enhancement, and multimodal data integration. Predictive monitoring and personalized medicine will be further improved by international cooperation and patient-centred strategies. Establishing a strong, contemporary pharmacovigilance framework requires following these guidelines.

8.1. Data Science and AI Development:

Thanks to recent technological advancements, data science and AI have advanced significantly. A subset of automated learning called profound training offers a potent method for drawing inferences from important, complicated datasets without the requirement for overt engineering effort. NLP is another useful technique that improves communication between humans and machines. To process and analyze complicated datasets and produce more accurate prediction models, AI and data science employ a variety of models, such as ontological, statistical, hybrid, and biological models. In conclusion, new models and methods for processing and analyzing complicated data, as well as more accurate prediction models, have been introduced as a result of advances in data science and artificial intelligence[38].

8.2. Using Multi-Modal Data Integration:

Despite its emphasis on EHRs as multimodal data, an artificial intelligence-based approach to data fusion can also be used to incorporate other techniques, including multi-omics and environmental data. Numerous factors, such as lifestyle, living environment, and heredity, might contribute to the development of disease because the origins of many diseases are complicated. Thus, integrating data from several sources, such as imaging, EHRs, and multi-omics, can reveal the general areas in which personalized medicine can be applied to enhance patient outcomes[39].

8.3. Global Collaboration and Exchange of Data:

The main ways to address the issues of AI-based pharmacovigilance managing the limited resources are to enhance the EHRs system, build extensive databases, and encourage collaboration among stakeholders. Partnerships, improved stakeholder collaboration, and increased opportunities and knowledge metabolism could all assist in ensuring the effective adoption of AI-based pharmacovigilance[40].

8.4. Patient-driven and predictive pharmacovigilance:

AI in pharmacovigilance is also moving toward customized and predictive medicine. Using machine learning algorithms, AI can analyze EHRs that include patient demographics, medical histories, and genetic information to forecast how a certain prescription would affect a person. By identifying which individuals are most at risk for severe side effects, this method, called predictive pharmacovigilance, seeks to detect ADRs early on before they happen. Enhances overall patient safety by administering medication based on the individual characteristics of each patient[41].

8.5. Strengthening the AI Foundations of EHRs:

Training the staff and maintaining the integrity and quality of the system should be the main priorities when implementing EHRs in the healthcare system. Patient identification, data interchange standards, training and education, EHRs storage, and quality control are all crucial components. AI-based pharmacovigilance modeling can make use of crucial data from EHRs, including pharmaceutical orders, test findings, and medical records. According to Liu et al., inpatient laboratory test results and medication orders were useful in validating and identifying adverse drug reactions. By linking with external databases, AI-based pharmacovigilance detection performance can be further enhanced. By integrating AI algorithms into the EHRs system, pharmacovigilance signals can be continually monitored, reminders can be sent, and forms can be automatically filled out. Other methods for gathering pharmacovigilance data outside EHRs include social networks and biological literature. These pharmacovigilance signals were found to provide useful information in public health as complementary data, and this database enrichment helps AI-based pharmacovigilance by reducing the biases brought on by incomplete data[42].

9. Conclusion:

Artificial intelligence has revolutionized the field of pharmacovigilance by enabling real-time, scalable, and high analysis of EHRs. This transition from traditional manual methods to AI-based systems solved many years of problems, including underestimation, detection of delayed signals, and difficulty in processing large data sets. Tools based on machine learning and natural language processing therapy currently support faster identification of adverse eventspersonalized risk profiling, and more effective adoption of regulatory decisions. Real-world implementations, including the FDA Sentinel, OHDSI, and EU-ADR project initiatives, illustrate the growing awareness of AI in the industry and regulatory framework. However, restrictions include data confidentiality issues, transparency, and algorithm integration issues. Solutions to these barriers are important through ethical frameworks, reliable verification, and global collaboration. Although AI continues to evolve, the synergistic effect of patient-focused patient data and technology has great potential to increase drug safety observations around the world.

10. References:

[1] K. Murali, S. Kaur, A. Prakash, and B. Medhi, “Artificial Intelligence in Pharmacovigilance: Practical utility,” *Indian J Pharmacol*, vol. 51, no. 6, p. 373-376, 2019, doi: 10.4103/ijp.IJP_814_19.

[2] European Medicines Agency; Heads of Medicines Agencies, “Guideline on Good Pharmacovigilance Practices (GVP) Module I – Pharmacovigilance systems and their quality systems,” European Medicines Agency, London, UK (EMA headquarters), Guideline EMA/541760/2011, June 2012. Available: https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-gvp-module-i pharmacovigilance-systems-their-quality-systems_en.pdf (Accessed on 14 September 2025).

[3] S. Golder, D. Xu, K. O’Connor, Y. Wang, M. Batra, and G. G. Hernandez, “Leveraging Natural Language Processing and Machine Learning Methods for Adverse Drug Event Detection in Electronic Health/Medical Records: A Scoping Review,” *Drug Saf*, vol. 48, no. 4, pp. 321–337, Apr. 2025, doi: 10.1007/s40264-024-01505-6.

[4] S. Dimitsaki, P. Natsiavas, and M.-C. Jaulent, “Applying AI to Structured Real-World Data for Pharmacovigilance Purposes: Scoping Review,” *J Med Internet Res*, vol. 26, p. e57824, Dec. 2024, doi: 10.2196/57824.

[5] H. Edrees, W. Song, A. Syrowatka, A. Simona, M. G. Amato, and D. W. Bates, “Intelligent Telehealth in Pharmacovigilance: A Future Perspective,” *Drug Saf*, vol. 45, no. 5, pp. 449–458, May 2022, doi: 10.1007/s40264-022-01172-5.

[6] M. A. Shamim, M. A. Shamim, P. Arora, and P. Dwivedi, “Artificial Intelligence and Big Data for Pharmacovigilance and Patient Safety,” *Journal of Medicine, Surgery, and Public Health*, vol. 3, p. 100139, Aug. 2024, doi: 10.1016/j.glmedi.2024.100139.

[7] World Health Organization, *The Importance of Pharmacovigilance: Safety Monitoring of Medicinal Products*. Geneva, Switzerland: World Health Organization, 2002. Available: https://apps.who.int/iris/handle/10665/42493. (Accessed on 14 September 2025).

[8] L. Hazell and S. A. W. Shakir, “Under-Reporting of Adverse Drug Reactions: A Systematic Review,” *Drug Safety*, vol. 29, no. 5, pp. 385–396, 2006, doi: 10.2165/00002018-200629050-00003.

[9] K. Hayrinen, K. Saranto, and P. Nykanen, “Definition, Structure, Content, Use and Impacts of Electronic Health Records: A Review of the Research Literature,” *International Journal of Medical Informatics*, vol. 77, no. 5, pp. 291–304, May 2008, doi: 10.1016/j.ijmedinf.2007.09.001.

[10] X. Yang *et al.*, “A Large Language Model for Electronic Health Records,” *npj Digit. Med.*, vol. 5, no. 1, p. 194, Dec. 2022, doi: 10.1038/s41746-022-00742-2.

[11] J. Zhao, A. Henriksson, L. Asker, and H. Boström, “Predictive Modeling of Structured Electronic Health Records for Adverse Drug Event Detection,” *BMC Med Inform Decis Mak*, vol. 15, Supplement 4, no. S4, pp. 1–15, Nov. 2015, doi: 10.1186/1472-6947-15-S4-S1.

[12] J. V. Kim, S. E. Davis, M. E. Matheny, and J. C. Smith, “Integrating Electronic Health Records with Other Data Sources for Postmarket Drug Safety Signal Identification: A Review,” *Front. Drug Saf. Regul.*, vol. 4, p. 1428831, Nov. 2024, doi: 10.3389/fdsfr.2024.1428831.

[13] Dr. Sahana V. M. Vats, Dr. Sunil Kumar, and Dr. Tribhuvan Pareek, “From Detection to Prediction: The Evolving Role of Ai in Pharmacovigilance Systems,” *World J Pharm Res*, vol. 14, no. 13, pp. 1650–1662, 2025, doi: 10.20959/wjpr202513-37458.

[14] A. Nagar, J. Gobburu, and A. Chakravarty, “Artificial Intelligence in Pharmacovigilance: Advancing Drug Safety Monitoring and Regulatory Integration,” *Therapeutic Advances in Drug Safety*, vol. 16, p. 20420986251361435, July 2025, doi: 10.1177/20420986251361435.

[15] Q. Hu, J. Li, X. Li, D. Zou, T. Xu, and Z. He, “Machine Learning to Predict Adverse Drug Events Based on Electronic Health Records: A Systematic Review and Meta-Analysis,” *J Int Med Res*, vol. 52, no. 12, p. 03000605241302304, Dec. 2024, doi: 10.1177/03000605241302304.

[16] S. Kumar, “Revolutionizing Pharmacovigilance: The Role of Artificial Intelligence

in Enhancing Patient Safety," *CHCMJ*, vol. 14, no. 02, pp. 78–86, July 2025, doi: 10.24321/2278.2044.202527.

[17] A. Agarwal, G. Singh, S. Jain, and P. Mittal, "Beyond Boundaries: Charting the Frontier of Healthcare with Big Data and AI Advancements in Pharmacovigilance," *Health Sciences Review*, vol. 14, p. 100214, Mar. 2025, doi: 10.1016/j.hsr.2025.100214.

[18] Deepesh Chouhan, "Artificial Technology in Pharmacovigilance," *Int J Pharm Res Appl*, vol. 9, no. 2, pp. 560–565, Apr. 2024, doi: 10.35629/7781-0902560565.

[19] Y. S. Ahire, J. H. Patil, H. N. Chordiya, R. A. Deore and V. A. Bairagi, "Advanced Applications of Artificial Intelligence in Pharmacovigilance: Current Trends and Future Perspectives," *JOPCR*, vol. 23, no. 1, pp. 23–33, Mar. 2024. doi: 10.18579/jopcr/v23.1.24.

[20] R. C. Algarvio, J. Conceição, P. P. Rodrigues, I. Ribeiro, and R. Ferreira-da-Silva, "Artificial Intelligence in Pharmacovigilance: A Narrative Review and Practical Experience with an Expert-Defined Bayesian Network Tool," *Int J Clin Pharm*, vol. 47, no. 4, pp. 932–944, Aug. 2025, doi: 10.1007/s11096-025-01975-3.

[21] R. J. Chen, J. J. Wang, and A. Willie, "The Role of AI in Enhancing Electronic Health Records (EHR) for Better Clinical Decision Support," Jan. 2025. Available: https://www.researchgate.net/publication/388412306. (Accessed on 14 September 2025).

[22] N. Rostamzadeh, S. S. Abdullah, and K. Sedig, "Visual Analytics for Electronic Health Records: A Review," *Informatics*, vol. 8, no. 1, p. 12, Feb. 2021, doi: 10.3390/informatics8010012.

[23] C. R. Alexander, "Artificial Intelligence in Early Detection of Adverse Drug Reaction for Anti-psychotic drugs," *J Student Res*, vol. 12, no. 4, pp. 1–12, 2023. (Accessed on 14 September 2025).

[24] R. Platt *et al.*, "The FDA Sentinel Initiative — An Evolving National Resource," *N Engl J Med*, vol. 379, no. 22, pp. 2091–2093, Nov. 2018, doi: 10.1056/NEJMp1809643.

[25] R. J. Desai *et al.*, "Broadening the reach of the FDA Sentinel System: A roadmap for Integrating Electronic Health Record Data in a Causal Analysis Framework," *npj Digit. Med.*, vol. 4, no. 1, p. 170, Dec. 2021, doi: 10.1038/s41746-021-00542-0.

[26] J. M. Banda, "Fully connecting the Observational Health Data Science and Informatics (OHDSI) initiative with the world of linked open data," *Genomics Inform*, vol. 17, no. 2, p. e13, June 2019, doi: 10.5808/GI.2019.17.2.e13.

[27] G. Trifirò, A. Fourrier-Reglat, M. C. J. M. Sturkenboom, C. Diaz Acedo and J. Van Der Lei, "The EU-ADR Project: Preliminary Results and Perspective," in *Studies in Health Technology and Informatics*, IOS Press, 2009. doi: 10.3233/978-1-60750-043-8-43.

[28] D. Kumar, A. Kaur, Shruti, and D. Kaur, "Artificial Intelligence in Pharmacovigilance," *CUCS*, vol. 04, p. e29503779340108, June 2025, doi: 10.2174/0129503779340108241226103521.

[29] K. M. Y. Moafa *et al.*, "Artificial Intelligence for Improved Health Management: Application, Uses, Opportunities, and Challenges-A Systematic Review," *Egypt. J.*

Chem., vol. 67, no. 13, pp. 865–880, Dec. 2024, doi: 10.21608/ejchem.2024.319621.10386.

[30] . N. Patil, A. M. Kadam, S. T. Daud, M. A. Jadhav and K. S. Kanadje, “Pharmacovigilance in the Era of Artificial Intelligence and Machine Learning,” *IJIRT*, vol. 11, no. 5, pp. 1839–1847, Oct. 2024. (Accessed on 14 September 2025).

[31] Jaibhagvan, “Pharmacovigilance in the Digital Age: Using Big Data and Artificial Intelligence to Improve Drug Safety,” *Scholar’s Digest: Journal of Pharmacology*, vol. 1, no. 1, pp. 170–186, Apr. 2025. (Accessed on 14 September 2025)

[32] J. P. S. Saini, A. Thakur, and D. Yadav, “AI-Driven Innovations in Pharmaceuticals: Optimizing Drug Discovery and Industry Operations,” *RSC Pharm.*, vol. 2, no. 3, pp. 437–454, 2025, doi: 10.1039/D4PM00323C.

[33] O. C. Anthony, “AI Driven Pharmacovigilance Systems for Real-Time Detection of Adverse Drug Events in Multi-Center Health Networks,” 2025, *Unpublished*. doi: 10.13140/RG.2.2.35526.59209.

[34] J. Oluwaseyi, “AI and Pharmacovigilance: "Enhancing Drug Safety Monitoring," *https://www.researchgate.net/publication/384729469*, Oct. 2024. Available: https://www.researchgate.net/publication/384729469. (Accessed on 14 September 2025).

[35] D. S. Sadaf and S Sameer, “Pharmacovigilance and Adverse event Detection: A Comprehensive Review of Artificial intelligence applications,” *Eur J Mod Med Pract*, vol. 3, no. 12, pp. 97–104, Dec. 2023. (Accessed on 14 September 2025).

[36] R. K. S. Kumar and S. Velusamy, “Harnessing Artificial Intelligence for Enhanced Pharmacovigilance: A Comprehensive Review,” *Ind. J. Pharm. Pract.*, vol. 18, no. 2, pp. 171–179, Jan. 2025, doi: 10.5530/ijopp.20250145.

[37] M. S. Rajeshkumar, K. Anusha, M. A. Kumar, G. Rohith, K. T. P. Kalyan and K. Kalyan, “Explainable AI for Patient Safety: A Review of Application on Pharmacovigilance,” *IJHRMOB*, vol. 12, no. 2, pp. 99–105, Apr. 2024. (Accessed on 14 September 2025).

[38] M. F. Safitra, M. Lubis, T. F. Kusumasari and D. P. Putri, “Advancements in Artificial Intelligence and Data Science: Models, Applications, and Challenges,” *Procedia Comput. Sci*, vol. 234, pp. 381–388, 2024, doi: 10.1016/j.procs.2024.03.018.

[39] F. Mohsen, H. Ali, N. El Hajj, and Z. Shah, “Artificial Intelligence-based Methods for Fusion of Electronic Health Records and Imaging Data,” *Sci Rep*, vol. 12, no. 1, p. 17981, Oct. 2022, doi: 10.1038/s41598-022-22514-4.

[40] A. Madasu, S. Mukherjee, G. A. Johny, E. Jagadeesh and S. Vengadesan, “Artificial Intelligence-Driven Pharmacovigilance in Resource-Limited Settings,” *IJTSRD*, vol. 8, no. 4, pp. 593–599, Aug. 2024. (Accessed on 14 September 2025).

[41] H. G. Patil and V. S. Khairnar, “Impact of AI on Pharmacovigilance: A Systematic Review,” *IJRPAS*, vol. 04, no. 05, pp. 26–35, 2025, doi: 10.71431/IJRPAS.2025.4503.

[42] L. Liang *et al.*, “Artificial Intelligence-Based Pharmacovigilance in the Setting of Limited Resources,” *Drug Saf*, vol. 45, no. 5, pp. 511–519, May 2022, doi: 10.1007/s40264-022-01170-7.