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"Next-Generation Pharmacovigilance - The Role Of AI In Adverse Drug Reaction Monitoring"

V. Sravan Kumar [1*], V. Prasanthi[1], Ch. Madhurika[1], D. Haseena[1], Ch. Alekhya[1], Sk. Jameela[1], P. Srinivas Babu[2].

1.Department of Pharmaceutical Chemistry, Vignan Pharmacy College, Vadlamudi, 522213, Andhra Pradesh, India.

2. Department of Pharmaceutics, Vignan Pharmacy College, Vadlamudi,522213, Andhra Pradesh, India.

Abstract:

The increasing complexity of pharmaceutical treatments necessitates robust systems for monitoring adverse drug reactions (ADRs) to ensure patient safety. This paper explores the integration of artificial intelligence (AI) into pharmacovigilance, highlighting its potential to enhance ADR detection and reporting. By leveraging machine learning algorithms and natural language processing, AI can analyze vast datasets from diverse sources—such as electronic health records, social media, and clinical trial reports—yielding real-time insights into drug safety profiles. This innovative approach not only improves the accuracy and speed of ADR identification but also facilitates proactive risk management. Case studies demonstrate AI's capability to uncover hidden patterns and correlations that traditional methods may overlook, ultimately leading to more effective regulatory responses and improved patient outcomes. The findings underscore the transformative role of AI in modern pharmacovigilance, advocating for its broader adoption to safeguard public health in an increasingly complex pharmaceutical landscape. Pharmacovigilance (PV) plays a pivotal role in ensuring drug safety by detecting, assessing, and preventing adverse drug reactions (ADRs). However, conventional PV approaches, which rely heavily on manual reporting and retrospective analyses, often fall short in capturing early safety signals, particularly in the context of modern data-intensive healthcare systems.

Keywords – Pharmacovigilance, Clinical trials, Artificial Intelligence, Pharmacovigilance, Adverse Drug Reactions, Machine Learning, Natural Language Processing, Drug Safety, Signal Detection.

1. Introduction:

Pharmacovigilance (PV) is a critical discipline in drug safety, concerned with detecting, assessing, and preventing adverse drug reactions. The traditional PV process is heavily reliant on spontaneous reporting systems (SRS) and retrospective data analysis, which suffer from underreporting, delays, and limited coverage. With the rise of digital healthcare systems, AI offers a transformative opportunity to revamp PV by integrating real-time, automated, and predictive safety surveillance.

Artificial intelligence is a revolutionizing pharmacovigilance by enhancing drug safety through advanced technologies like machine learning and natural language processing. These innovations enable efficient, accurate detection of adverse drug reactions, timely interventions and comprehensive data analysis, despite challenges. Pharmacovigilance refers to the science of detecting, assessing, understanding, and preventing adverse effects or any other drug-related problems. The increasing complexity of drug safety monitoring, alongside the sheer volume of data generated by healthcare systems, has highlighted the limitations of traditional pharmacovigilance systems.

Pharmacovigilance (PV) ensures drug safety by detecting and evaluating ADRs. Traditional methods are often reactive and slow.

AI transforms PV by:

- ❖ Automating data collection from diverse sources.
- ❖ Enabling real-time monitoring.
- ❖ Enhancing decision support systems.

2. Objectives

1. Early detection of Adverse drug Reactions (ADR).
2. Efficient data analysis.
3. Enhance predictive capabilities.
4. Increase in precision of ADR.
5. Cost and time efficiency.
6. Real time monitoring.
7. Regularity compliance and reporting.
8. Improvement in public health outcomes.

3. Opportunities with AI

- High-throughput data processing.
- Extraction of safety signals from unstructured text.
- Enhanced real-time monitoring.
- Predictive modeling for risk stratification.

4. Data Sources for AI-Based ADR Detection

AI models utilize diverse datasets, including:

- ✓ Electronic Health Records (EHRs).
- ✓ Spontaneous Reporting Systems (FAERS, VigiBase).
- ✓ Social Media and Online Forums.
- ✓ Medical Literature and Clinical Trial Data.
- ✓ Insurance and Claims Data.

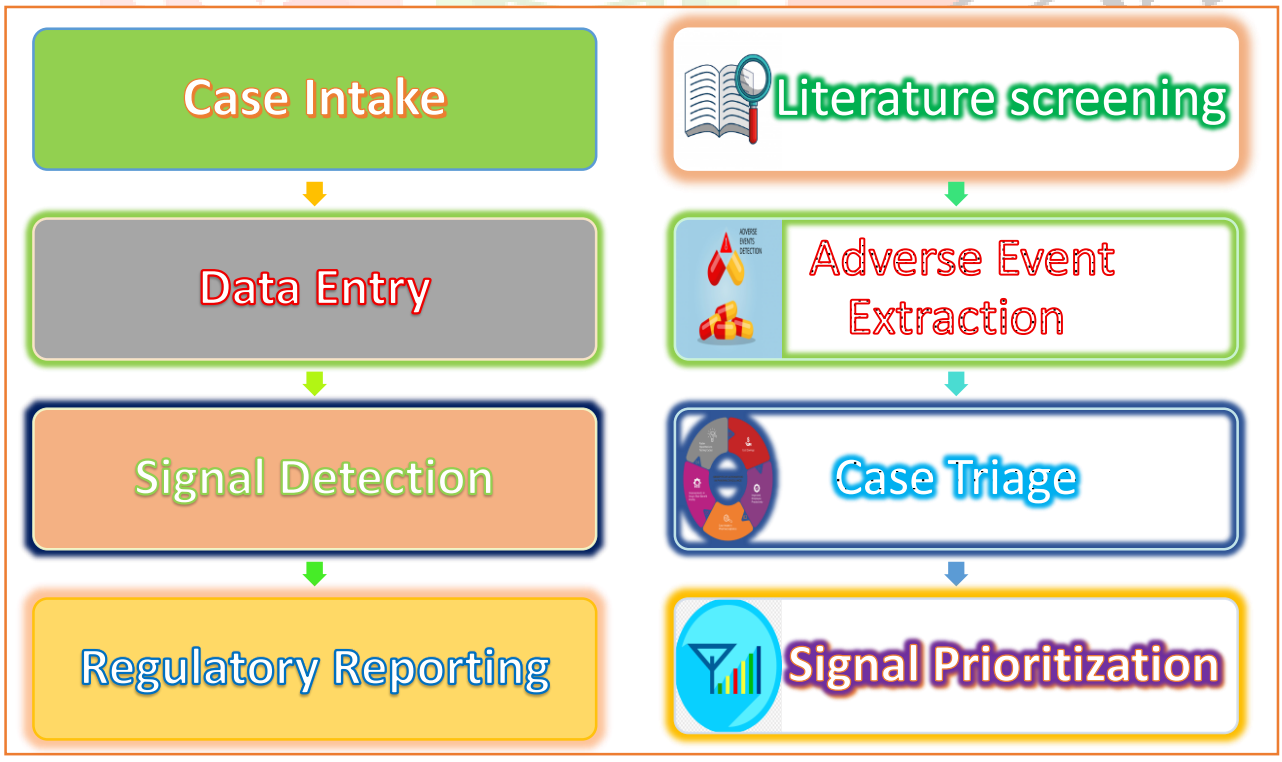

fig.1 illustration of traditional vs. ai-powered pharmacovigilance workflows.

5. Leveraging AI in Pharmacovigilance

- Machine learning models to detect signals.
- Natural Language Processing (NLP) to extract insights from unstructured data.
- Integration of multimodal data (structured + text + image).
- Benefit: Identifying hidden signals earlier than traditional systems.

6. Advantages of AI in ADR Detection

- Enhanced Signal Detection: Hidden patterns uncovered via ML
- Faster Responses: Reduces latency in identifying new ADRs
- Improved Regulatory Compliance: Supports evidence-based safety decisions
- Scalability: Handles vast, growing datasets
- Pattern Recognition and Risk Stratification.
- Deep learning models can uncover subtle correlations between drugs, genetic markers, comorbidities, and ADRs.
- Automated Causality Assessment.
- AI can be used to model causality using frameworks like the Bradford Hill criteria or Bayesian networks.
- Automated systems can handle vast data volumes at lower marginal costs than traditional manual review.

7. Core AI Technologies in Pharmacovigilance

7.1. Machine Learning

ML algorithms can be trained on large datasets to identify complex patterns and predict the likelihood of ADRs. Techniques such as supervised learning (e.g., support vector machines, decision trees) and unsupervised learning (e.g., clustering) are used extensively.

7.2. Natural Language Processing

NLP facilitates the extraction of meaningful insights from clinical notes, case reports, scientific literature, and social media. Named entity recognition (NER) and sentiment analysis can be used to detect ADR mentions and sentiments associated with drugs.

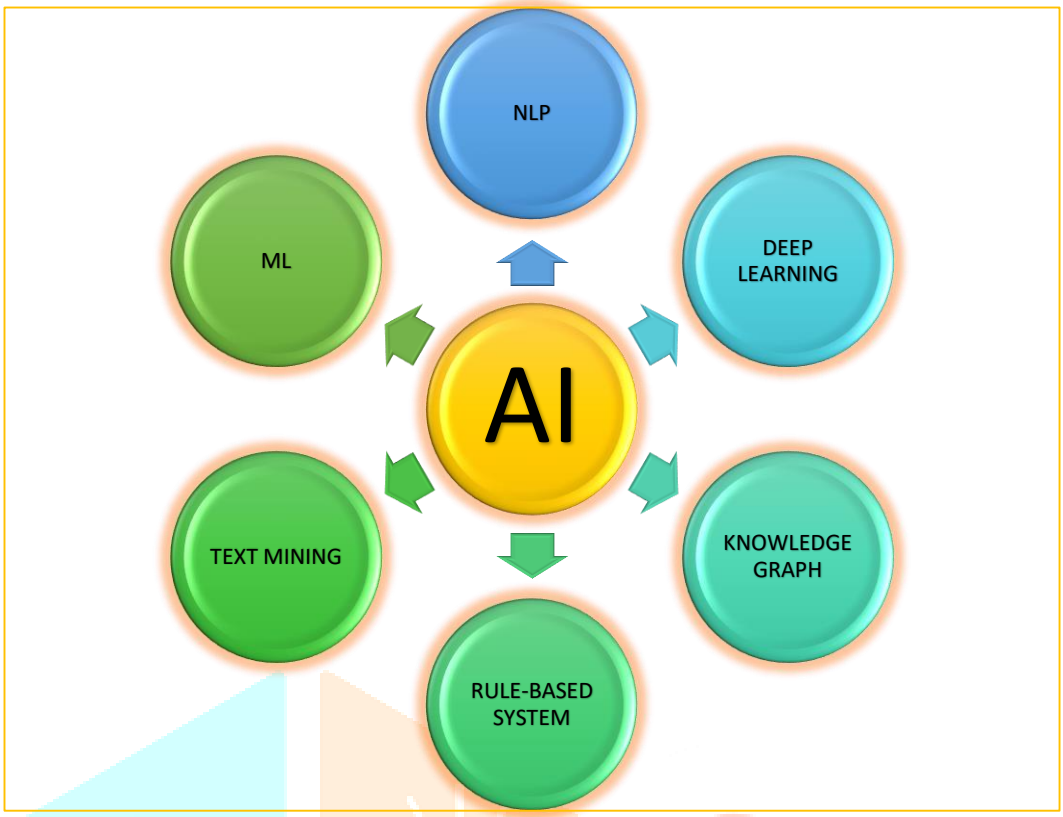

fig.2 overview of ai techniques used in pharmacovigilance.

8. Background and Need for Next-Generation Pharmacovigilance

Pharmacovigilance (PV) is the science and practice of monitoring, evaluating, and preventing adverse drug reactions (ADRs) and other drug-related problems. As therapeutic agents become more complex and widely used, the demand for efficient, real-time drug safety monitoring systems has intensified. Traditional PV systems, which rely heavily on spontaneous reporting, literature review, and manual data processing, face critical challenges such as underreporting, delayed signal detection, and data fragmentation[1]. These limitations can lead to delayed regulatory action and, more importantly, compromised patient safety.

9. Artificial Intelligence: A Disruptive Technology in Pharmacovigilance

Artificial Intelligence (AI), particularly machine learning (ML), deep learning, and natural language processing (NLP), has emerged as a transformative tool in pharmacovigilance[2]. These technologies can process vast amounts of structured and unstructured data from diverse sources including electronic health records (EHRs), social media, biomedical literature, and spontaneous adverse event reports. AI systems can identify hidden patterns and correlations, enabling earlier detection of ADR signals and improving the prediction of drug safety profiles. One particularly promising application is NLP, which can extract clinically relevant information from free-text clinical narratives, case reports, and patient forums[3]. AI models have demonstrated success in identifying rare and serious ADRs earlier than traditional methods by continuously mining real-time data.

10. Automating and Enhancing Pharmacovigilance Workflows

In addition to signal detection, AI is automating several pharmacovigilance functions, including adverse event coding (using MedDRA), case triage, causality assessment, and literature screening[4]. These automations can significantly reduce the manual burden on PV professionals while improving consistency and accuracy. Furthermore, AI-driven decision-support tools are being piloted by regulatory authorities to assist in benefit-risk evaluation and expedite regulatory review cycles.

11. Current Challenges and Ethical Considerations

Despite its potential, AI in PV faces several challenges. These include data privacy concerns, lack of standardized data formats, biases in training datasets, limited interpretability of deep learning models, and the need for regulatory alignment5. Ensuring transparency, ethical use of patient data,

and adherence to legal frameworks such as GDPR and HIPAA is paramount for building trust and achieving widespread adoption.

12. Outlook: Toward Predictive and Personalized Drug Safety

The integration of AI into pharmacovigilance is poised to revolutionize drug safety surveillance by enabling predictive, real-time, and patient-centered monitoring. AI will not replace PV professionals but will augment their capabilities by providing more precise, scalable, and actionable insights. As healthcare ecosystems become increasingly digital, AI-powered pharmacovigilance will be vital in ensuring safe and effective medication use.

13. Applications of Artificial Intelligence in Pharmacovigilance

13.1. Signal Detection and Management

One of the primary applications of AI in pharmacovigilance is in signal detection—the identification of new, rare, or serious adverse drug reactions. Traditional signal detection relies on disproportionality analysis in spontaneous reporting systems (e.g., VigiBase or FAERS). However, AI enables more sophisticated methods that incorporate time-series analysis, clustering, and anomaly detection to identify emerging trends in large, dynamic datasets[1].

Deep learning algorithms have demonstrated superior performance in predicting ADRs from historical case reports and adverse event databases. These models can continuously learn and refine signal thresholds, minimizing false positives and improving precision[2].

13.2. Natural Language Processing (NLP) in Case Processing

NLP is increasingly used to extract structured information from unstructured text sources such as clinical notes, product labeling, regulatory reports, and patient narratives on forums or social media[3]. Key NLP tasks include named entity recognition (e.g., identifying drug names, reactions), sentiment analysis, and relation extraction (e.g., linking a drug to an adverse event). For example, NLP models can classify and summarize narrative descriptions in Individual Case Safety Reports (ICSRs), enabling faster triage and assessment. Some platforms also employ NLP for real-time monitoring of social media (e.g., Twitter, Reddit) to detect patient-reported ADRs that are not captured in formal reports[4].

13.3. Automated Case Triage and Prioritization

AI algorithms are being developed to prioritize cases based on urgency and clinical significance. Machine learning classifiers trained on historical data can predict the likelihood that a case involves a serious ADR or requires expedited reporting. This enables more efficient resource allocation and improves regulatory compliance[5].

Some systems integrate AI with rule-based logic (hybrid models) to automatically route cases to appropriate safety reviewers or escalate complex cases to human experts.

13.4. Literature Mining and Signal Validation

Automated literature mining tools, powered by AI, assist pharmacovigilance professionals in identifying relevant case reports and studies in scientific publications. These tools can scan thousands of abstracts daily and rank articles based on relevance, novelty, and clinical impact[6].

AI can also assist in signal validation by correlating information across multiple sources (e.g., EHRs, post-marketing surveillance, clinical trials) and providing a probabilistic estimate of causality using models like Bayesian inference networks.

13.5. AI in Post-Marketing Surveillance and Real-World Data Analysis

Real-world data (RWD), such as data from EHRs, insurance claims, and patient registries, provide rich insights into the safety and effectiveness of medications post-approval. AI models are uniquely positioned to handle the volume, variety, and velocity of RWD.

For instance, AI can analyze longitudinal EHRs to detect ADRs with delayed onset, stratify risk across subpopulations, and identify drug-drug interactions that may not emerge during clinical trials[7].

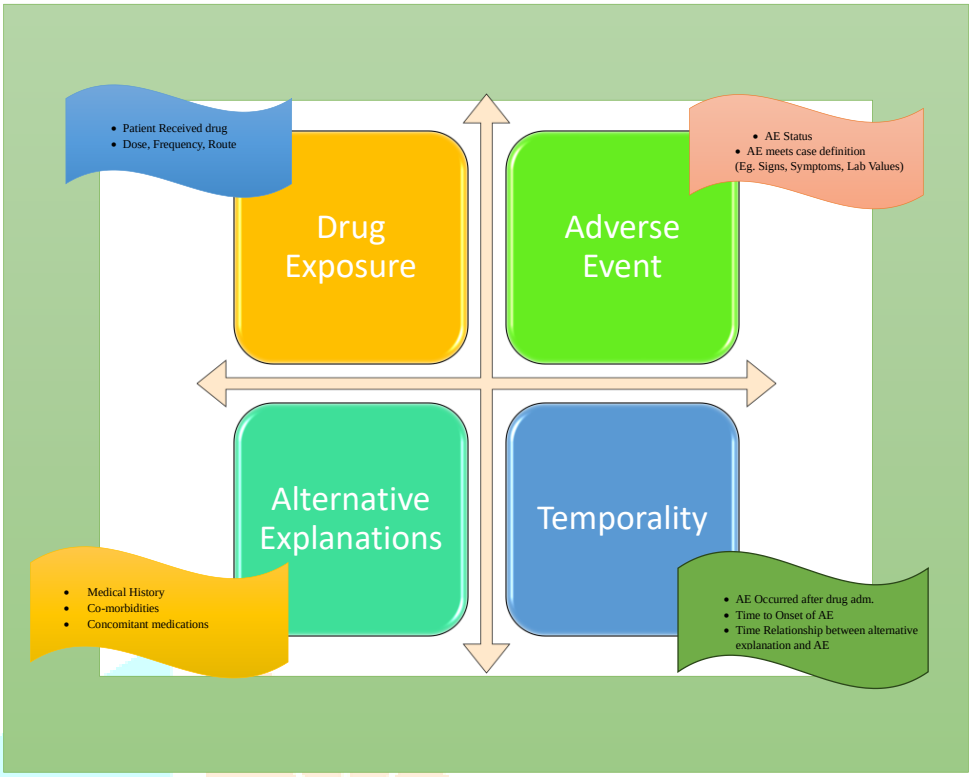

fig.3 Evaluation of drug history through Pharmacovigilance

Table-1 key applications of ai in pharmacovigilance

AI Technology	Application Area	Benefit
Machine Learning	Signal detection	Predictive modeling of ADR patterns
Natural Language Processing	Case processing, literature review	Efficient handling of unstructured data
Deep Learning	Social media monitoring	Early detection of patient-reported events
Rule-based AI	Case triage and workflow automation	Improved efficiency and accuracy
Hybrid Systems	Post-marketing surveillance	Real-world insights and risk stratification

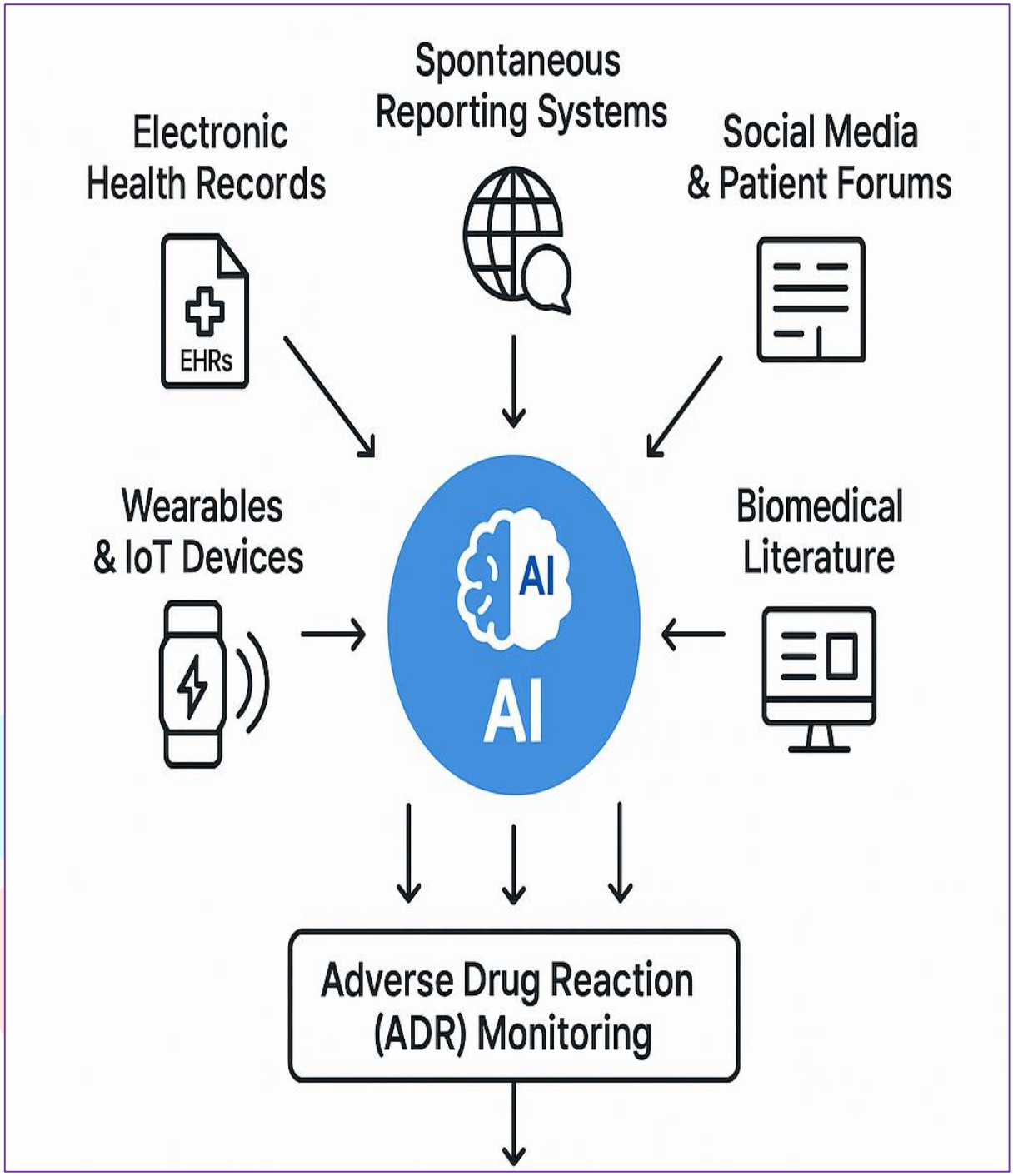

fig.4 ai integration with multi-modal sources for pv

14. Limitations of Conventional PV

- Manual data processing is time-consuming.
- Underreporting in SRS leads to incomplete safety profiles.
- Retrospective analysis delays intervention.
- Limited capacity to analyze unstructured data.

15. Opportunities with AI

- High-throughput data processing.
- Extraction of safety signals from unstructured text.
- Enhanced real-time monitoring.
- Predictive modeling for risk stratification

16. AI requires diverse and high-quality data to be effective:

Table-2 Data Sources for AI-Driven ADR Detection

Source	Description
Electronic Health Records (EHRs)	Structured and unstructured patient data
Spontaneous Reporting Systems	e.g., FAERS, VigiBase
Social Media & Forums	Twitter, Reddit, patient networks
Scientific Literature	PubMed, clinical trial reports
Claims & Insurance Data	Reimbursement patterns

17. Challenges and Limitations

- Data Quality and Availability: Variability across sources
- Ethical Concerns: Privacy, patient consent, and data use
- Regulatory Hurdles: Lack of standardized validation frameworks
- Model Interpretability: Black-box algorithms are hard to explain Despite its promise, AI in pharmacovigilance faces several challenges:
- Data Quality and Heterogeneity: Inconsistent formats, missing values, and bias in training data affect model reliability.
- Interpretability: Black-box models like deep learning lack transparency, limiting clinical trust.
- Regulatory Hurdles: No universally accepted standards for AI validation in PV.
- Ethical and Privacy Concerns: Patient data use must comply with regulations like GDPR and HIPAA.

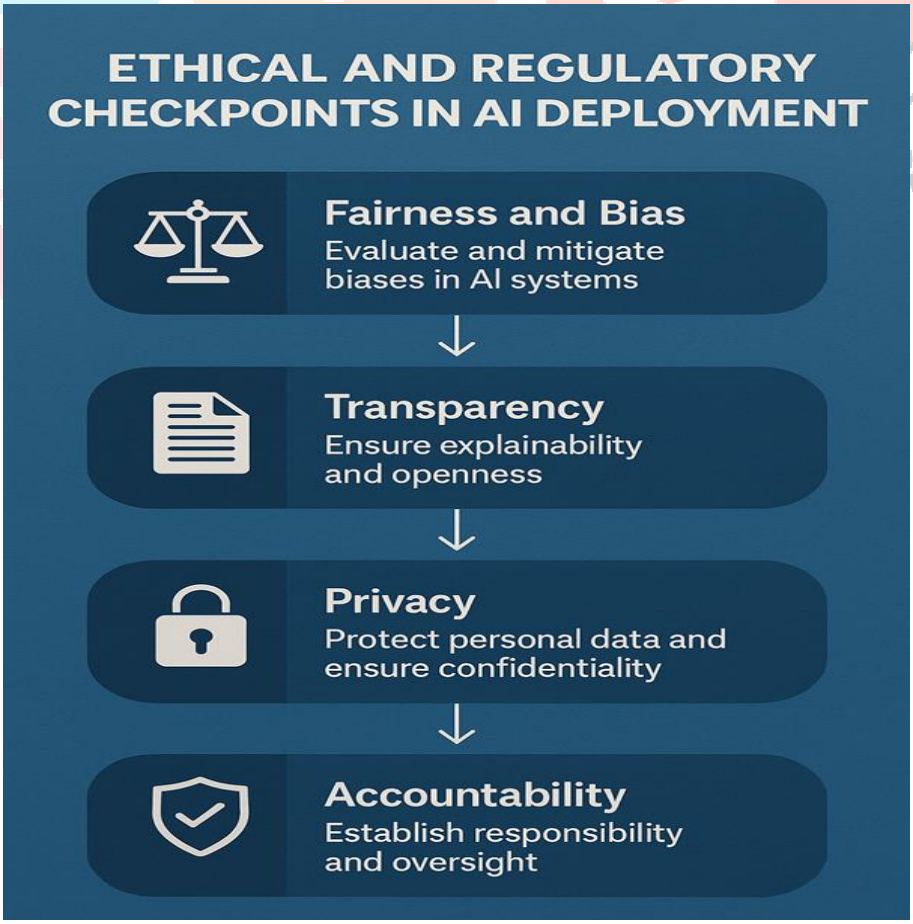

fig.5 ethical and Regulatory checkpoints in AI deployment.

18. Case Studies and Applications

- FDA Sentinel Initiative: The Sentinel System uses advanced data mining and AI to monitor the safety of marketed drugs across millions of EHRs.
- AstraZeneca deployed NLP to extract ADRs from internal safety reports and medical literature, improving both speed and accuracy.
- Social Media Monitoring: AI uncovers ADRs from real-time conversations
- AI models have successfully identified previously unreported ADRs by analyzing public sentiment and discussions on platforms like Twitter.
- Methods:
  We reviewed current literature and case studies on the application of AI—including machine learning (ML), deep learning, and natural language processing (NLP)—in pharmacovigilance processes such as signal detection, case processing, literature mining, and post-marketing surveillance. Challenges such as data quality, algorithmic bias, interpretability, and regulatory considerations are also addressed.

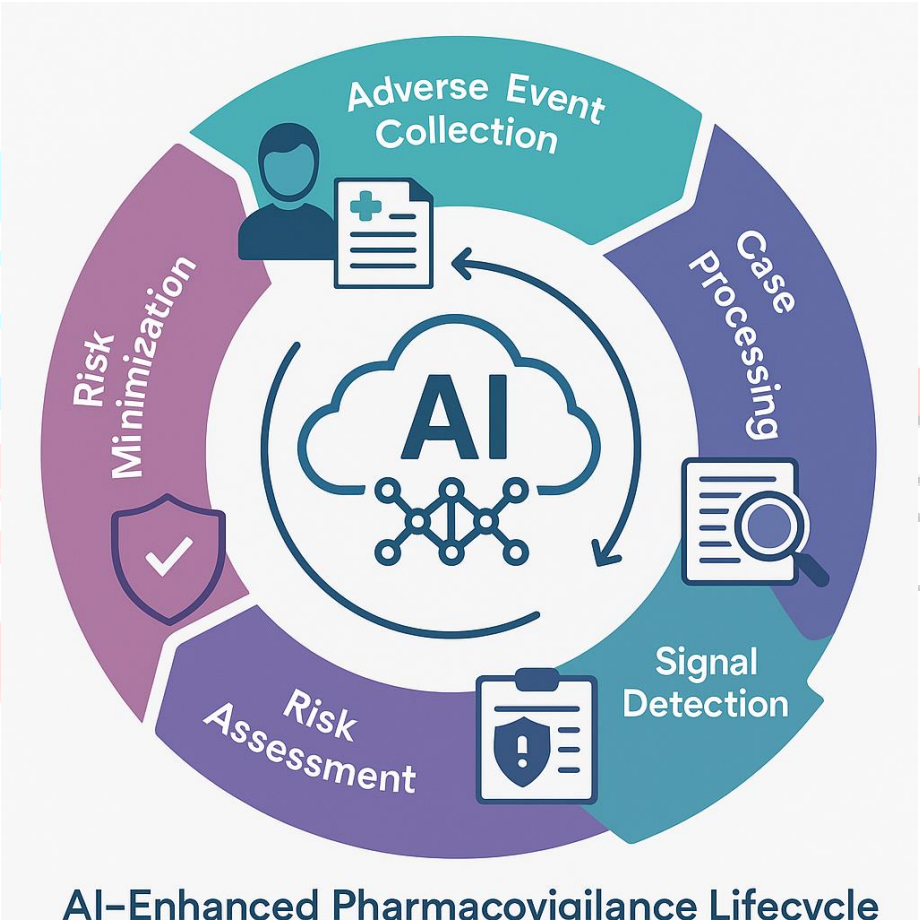

Fig.6 Infographic summarizing the AI-enhanced pharmacovigilance lifecycle.

19. Future Perspectives

The future of AI in pharmacovigilance lies in:

- Federated Learning: Enables model training on decentralized data without compromising privacy.
- Explainable AI (XAI): Enhances interpretability and trust in model decisions.
- Integration with Genomics: Personalized risk profiling based on pharmacogenomics.
- Real-World Evidence (RWE): Continued growth of real-world data will fuel better AI models.
- Integration with genomics, federated learning, and explainable AI to further enhance pharmacovigilance.

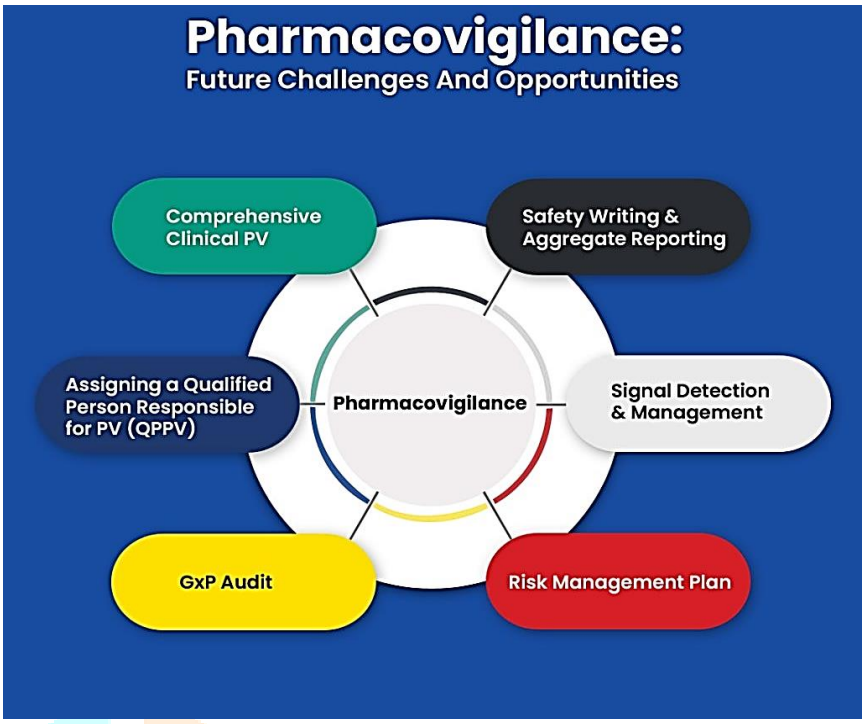

fig.7 future challenges and opportunities

20. Discussion:

- AI systems enhance the scalability and precision of ADR detection by automating the analysis of large volumes of structured and unstructured data, including spontaneous reports, electronic health records, and social media. These technologies facilitate earlier signal detection, reduce manual workload, and support regulatory decision-making.
- AI is poised to transform pharmacovigilance, offering unprecedented opportunities to enhance drug safety.
- By leveraging technologies such as machine learning, natural language processing, and data mining, AI can improve the efficiency, accuracy, and timeliness of pharmacovigilance activities.
- The full potential of AI in this field requires addressing challenges related to data quality, regulatory compliance, system integration, and human-AI collaboration.
- As the technology continues to advance, AI-driven pharmacovigilance will play a crucial role in ensuring the safety and efficacy of drug therapies, ultimately improving patient outcomes and public health.
- The advantage of an AI-based PV system includes automatic detection, an evidence generation network, multiple data source integration, AI algorithms optimization, and concept standardization, which could largely help to minimize the human labor workload and facilitate development of PV.
- By embracing the capabilities of AI, the pharmacovigilance community can proactively identify and mitigate drug-related risks, paving the way for safer and more effective medical treatments in the age of technology.

21. Conclusion

AI is reshaping the pharmacovigilance landscape by enabling faster, more accurate, and predictive detection of adverse drug reactions. While challenges remain, the integration of AI into PV processes offers transformative potential in safeguarding patient health. Regulatory agencies, healthcare providers, and industry stakeholders must work collaboratively to ensure AI adoption is ethical, effective, and evidence-based. The integration of AI into pharmacovigilance represents a paradigm shift toward predictive and personalized drug safety. While challenges persist, AI-driven systems have the potential to transform PV into a more agile and efficient discipline, ultimately improving patient outcomes and public health.

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CONFLICTS AND INTERSTATEMENT

All authors declare that there do not have any conflicts of interest.

References

1. Jaltotage, B., Ihdayhid, A. R., Lan, N. S., Pathan, F., Patel, S., Arnott, C., ... & Dwivedi, G. (2023). Artificial intelligence in cardiology: an Australian perspective. Heart, Lung and Circulation, 32(8), 894-904.
2. AL-Shareef, E. K., Khan, L. M., & Alsieni, M. Detection of Adverse Drug Reactions in COVID-19 Hospitalized Patients at Royal Commission Medical Center in Yanbu, Saudi Arabia: A retrospective Study by ADR Prompt Indicators.
3. Chatterjee, A., Gerdes, M., Prinz, A., & Martinez, S. (2021). Paper B Human Coaching Methodologies for Electronic Coaching..... Technology: Systematic Review. Automatic Generation of Personalized Recommendations in eCoaching, 23(3), 153.
4. Xie, W., Xu, J., Zhao, C., Li, J., Han, S., Shao, T., ... & Feng, W. (2024). Transformer-based Named Entity Recognition for Clinical Cancer Drug Toxicity by Positive-unlabeled Learning and KL Regularizers. Current Bioinformatics, 19(8), 738-751.
5. Choudhary, A., & Surbhi, A. (2024, October). AI arbitration–Charting the ethical and legal course. In AIP Conference Proceedings (Vol. 3220, No. 1). AIP Publishing.
6. European Medicines Agency. (2017). Guideline on good pharmacovigilance practices (GVP). Module VI–collection, management, and submission of reports of suspected adverse reactions to medicinal products (Rev 2).
7. Sharma, P., Joshi, R. V., Pritchard, R., Xu, K., & Eicher, M. A. (2023). Therapeutic antibodies in medicine. Molecules, 28(18), 6438.
8. Path, P. (2020). Previous issues. Inflammatory bowel diseases, 18, 2.
9. Li, Y., Tao, W., Li, Z., Sun, Z., Li, F., Fenton, S., ... & Tao, C. (2024). Artificial intelligence-powered pharmacovigilance: A review of machine and deep learning in clinical text-based adverse drug event detection for benchmark datasets. Journal of Biomedical Informatics, 104621.
10. Feng, Y., Wang, A. Y., Jun, M., Pu, L., Weisbord, S. D., Bellomo, R., ... & Gallagher, M. (2023). Characterization of risk prediction models for acute kidney injury: a systematic review and meta-analysis. JAMA Network Open, 6(5), e2313359-e2313359.
11. Grissette, H., & Nfaoui, E. H. (2022). Affective concept-based encoding of patient narratives via semantic computing and neural networks. Cognitive Computation, 14(1), 274-299.
12. Yang, S., & Kar, S. (2023). Application of artificial intelligence and machine learning in early detection of adverse drug reactions (ADRs) and drug-induced toxicity. Artificial Intelligence Chemistry, 100011.
13. Saxena, R. R. (2024). Examining Reactions about COVID-19 Vaccines: A Systematic Review of Studies Utilizing Deep Learning for Sentiment Analysis. Authorea Preprints.
14. Vora, L. K., Gholap, A. D., Jetha, K., Thakur, R. R. S., Solanki, H. K., & Chavda, V. P. (2023). Artificial intelligence in pharmaceutical technology and drug delivery design. Pharmaceutics, 15(7), 1916.
14. Grouin, C., & Grabar, N. (2023). The year 2022 in Medical Natural Language Processing: Availability of Language Models as a Step in the Democratization of NLP in the Biomedical Area. Yearbook of Medical Informatics, 32(01), 244-252.

15. Vora, L. K., Gholap, A. D., Jetha, K., Thakur, R. R. S., Solanki, H. K., & Chavda, V. P. (2023). Artificial intelligence in pharmaceutical technology and drug delivery design. Pharmaceutics, 15(7), 1916.
16. Zitnik, M., Li, M. M., Wells, A., Glass, K., Gysi, D. M., Krishnan, A., ... & Milenković, T. (2023). Current and future directions in network biology. arXiv preprint arXiv:2309.08478.
17. Bouazizi, S., & Ltifi, H. (2024). Enhancing accuracy and interpretability in EEG-based medical decision making using an explainable ensemble learning framework application for stroke prediction. Decision Support Systems, 178, 114126.
18. Han, R., Yoon, H., Kim, G., Lee, H., & Lee, Y. (2023). Revolutionizing medicinal chemistry: the application of artificial intelligence (AI) in early drug discovery. Pharmaceuticals, 16(9), 1259.
19. Dhudum, R., Ganeshpurkar, A., & Pawar, A. (2024). Revolutionizing Drug Discovery: A Comprehensive Review of AI Applications. Drugs and Drug Candidates, 3(1), 148-171.
20. Wang, X. (2024). Customization of Large Language Models for Causal Inference and Data Quality (Doctoral dissertation, University of Arkansas at Little Rock).
21. Mistry, S., & Wang, L. (2022, April). Efficient prediction of heart disease using cross-machine learning techniques. In 2022 IEEE Asia-Pacific Conference on Image Processing, Electronics, and Computers (IPEC) (pp. 1002-1006). IEEE.
22. Yang, X., Huang, K., Yang, D., Zhao, W., & Zhou, X. (2024). Biomedical big data technologies, applications, and challenges for precision medicine: A review. Global Challenges, 8(1), 2300163.
23. Vardhan, S., & Sahoo, S. K. (2022). Computational studies on the interaction of SARS-CoV-2 Omicron SGp RBD with human receptor ACE2, limonin, and glycyrrhizic acid. Computers in biology and medicine, 144, 105367.
24. Shortliffe, E. H., Peleg, M., Combi, C., Chang, A. C., & Vinci, J. (2021). Publishing artificial intelligence research papers: a tale of three journals. Journal of Biomedical Informatics, 115, 103708-103709.
25. Rak, R. R. (2023). Internet of healthcare (law): privacy and data protection aspects in an internet of everything.
26. Dagan, M., Kolben, Y., Goldstein, N., Ben Ishay, A., Fons, M., Merin, R., ... & Nachman, D. (2022). Advanced hemodynamic monitoring allows recognition of early response patterns to diuresis in congestive heart failure patients. Journal of Clinical Medicine, 12(1), 45.
27. Wu, D., An, J., Yu, P., Lin, H., Ma, L., Duan, H., & Deng, N. (2021). Patterns for patient engagement with the hypertension management and effects of electronic health care provider follow-up on these patterns: cluster analysis. Journal of Medical Internet Research, 23(9), e25630.
28. Curtis, L. H., Sola-Morales, O., Heidt, J., Saunders-Hastings, P., Walsh, L., Casso, D., ... & Quek, R. G. (2023). Regulatory and HTA Considerations for Development of Real-World Data Derived External Controls. Clinical Pharmacology & Therapeutics, 114(2), 303-315.
29. Husby, A., Pottegård, A., & Hviid, A. (2021). Association between inhaled corticosteroid use and COVID-19 outcomes. Pharmacoepidemiology and Drug Safety, 30(11), 1486-1492.
30. Massey, H., Gorczynski, P., Harper, C. M., Sansom, L., McEwan, K., Yankouskaya, A., & Denton, H. (2022). Perceived impact of outdoor swimming on health: a web-based survey. Interactive Journal of Medical Research, 11(1), e25589.
31. Nasir, S., Khan, R. A., & Bai, S. (2024). Ethical framework for harnessing the power of AI in healthcare and beyond. IEEE Access, 12, 31014-31035.
32. Vishwakarma, L. P., Singh, R. K., Mishra, R., & Kumari, A. (2023). Application of artificial intelligence for resilient and sustainable healthcare system: Systematic literature review and future research directions. International Journal of Production Research, 1-23.
33. Kumar, A., & Kumar, L. (2024). Navigating the Future: The Ethical, Societal and Technological Implications of Artificial Intelligence. Journal homepage: https://gjrpublication. com/gjrecs, 4(02).

34. Dr. Asutosh Pramanik, Dr. Gunaseelan.C, Dr. Shakeel Ahmad, Dr. Hari Narayan Singh, & Dr. Sukanta Bandyopadhyay. (2024). The role of ai in predicting adverse drug reactions: enhancing patient safety in pharmaceutical practice. *Journal of Population Therapeutics and Clinical Pharmacology*, *31*(11), 80-89.
35. Desai MK. Artificial intelligence in pharmacovigilance - Opportunities and challenges. Perspect Clin Res. 2024 Jul-Sep;15(3):116-121. doi: 10.4103/picr.picr_290_23. Epub 2024 Mar 27. PMID: 39140015; PMCID: PMC11318788.
36. Andrew Bate, Jens-Ulrich Stegmann, Artificial intelligence and pharmacovigilance: What is happening, what could happen and what should happen?, Health Policy and Technology, Volume 12, Issue 2, 2023.
37. Topol EJ. High-performance medicine: the convergence of human and artificial intelligence. Nature medicine. 2019 Jan;25(1):44-56.
38. Hendrix N, Veenstra DL, Cheng M, Anderson NC, Verguet S. Assessing the economic value of clinical artificial intelligence: challenges and opportunities. Value in Health. 2022 Mar 1;25(3):331-9.
39. Schwartz WB, Patil RS, Szolovits P. Artificial intelligence in medicine. New England Journal of Medicine. 1987 Mar 12;316(11):685-8.
40. Ball R, Dal Pan G. "Artificial intelligence" for pharmacovigilance: ready for prime time?. Drug safety. 2022 May;45(5):429-38.
41. Norén GN, Orre R, Bate A, Edwards IR. Duplicate detection in adverse drug reaction surveillance. Data Mining and Knowledge Discovery. 2007 Jun;14:305-28.
42. Zou M, Barmaz Y, Preovolos M, Popko L, Ménard T. Using statistical modeling for enhanced and flexible pharmacovigilance audit risk assessment and planning. Therapeutic Innovation & Regulatory Science. 2021 Jan;55:190-6.
43. Cherkas Y, Ide J, van Stekelenborg J. Leveraging machine learning to facilitate individual case causality assessment of adverse drug reactions. Drug Safety. 2022 May;45(5):571-82.
44. Bate A, Lindquist M, Edwards IR, Olsson S, Orre R, Lansner A, De Freitas RM. A Bayesian neural network method for adverse drug reaction signal generation. European journal of clinical pharmacology. 1998 Jul;54:315-21.
45. Caster O, Norén GN, Madigan D, Bate A. Large-scale regression-based pattern discovery: the example of screening the WHO global drug safety database. Statistical Analysis and Data Mining: The ASA Data Science Journal. 2010 Aug;3(4):197-208.
46. Caster O, Juhlin K, Watson S, Norén GN. Improved statistical signal detection in pharmacovigilance by combining multiple strength-of-evidence aspects in vigiRank: retrospective evaluation against emerging safety signals. Drug safety. 2014 Aug;37:617-28.
47. Basile AO, Yahi A, Tatonetti NP. Artificial intelligence for drug toxicity and safety. Trends in pharmacological sciences. 2019 Sep 1;40(9):624-35.
48. Sessa M, Liang D, Khan AR, Kulahci M, Andersen M. Artificial intelligence in pharmacoepidemiology: a systematic review. part 2–comparison of the performance of artificial intelligence and traditional pharmacoepidemiological techniques. Frontiers in Pharmacology. 2021 Jan 14;11:568659.
49. Zhao Y, Yu Y, Wang H, Li Y, Deng Y, Jiang G, Luo Y. Machine learning in causal inference: Application in pharmacovigilance. Drug Safety. 2022 May;45(5):459-76.
50. Kompa B, Hakim JB, Palepu A, Kompa KG, Smith M, Bain PA, Woloszynek S, Painter JL, Bate A, Beam AL. Artificial intelligence based on machine learning in pharmacovigilance: a scoping review. Drug Safety. 2022 May;45(5):477-91.
51. Stergiopoulos S, Fehrle M, Caubel P, Tan L, Jebson L. Adverse drug reaction case safety practices in large biopharmaceutical organizations from 2007 to 2017: an industry survey. Pharmaceutical Medicine. 2019 Dec;33(6):499-510.

52. Streefland MB. Why are we still creating individual case safety reports?. Clinical Therapeutics. 2018 Dec 1;40(12):1973-80.
53. Lee I, Lee TA, Crawford SY, Kilpatrick RD, Calip GS, Jokinen JD. Impact of adverse event reports from marketing authorization holder-sponsored patient support programs on the performance of signal detection in pharmacovigilance. Expert Opinion on Drug Safety. 2020 Oct 2;19(10):1357-66.
54. Danysz K, Cicirello S, Mingle E, Assuncao B, Tetarenko N, Mockute R, Abatemarco D, Widdowson M, Desai S. Artificial intelligence and the future of the drug safety professional. Drug safety. 2019 Apr 5;42:491-7.
55. Basile AO, Yahi A, Tatonetti NP. Artificial Intelligence for Drug Toxicity and Safety. Trends Pharmacol Sci. 2019 Sep;40(9):624-635. doi: 10.1016/j.tips.2019.07.005. Epub 2019 Aug 2. PMID: 31383376; PMCID: PMC6710127.
56. Yin Y, Shu Y, Zhu J, Li F, Li J. A real-world pharmacovigilance study of FDA Adverse Event Reporting System (FAERS) events for osimertinib. Sci Rep. 2022 Nov 15;12(1):19555. doi: 10.1038/s41598-022-23834-1. PMID: 36380085; PMCID: PMC9664039
57. Bauer TM, Felip E, Solomon BJ, Thurm H, Peltz G, Chioda MD, Shaw AT. Clinical Management of Adverse Events Associated with Lorlatinib. Oncologist. 2019 Aug;24(8):1103-1110. doi: 10.1634/theoncologist.2018-0380. Epub 2019 Mar 19. PMID: 30890623; PMCID: PMC6693708.
58. Laville SM, Gras-Champel V, Moragny J, Metzger M, Jacquelinet C, Combe C, Fouque D, Laville M, Frimat L, Robinson BM, Stengel B, Massy ZA, Liabeuf S; Chronic Kidney Disease-Renal Epidemiology and Information Network (CKD-REIN) Study Group. Adverse Drug Reactions in Patients with CKD. Clin J Am Soc Nephrol. 2020 Aug 7;15(8):1090-1102. doi: 10.2215/CJN.01030120. Epub 2020 Jul 1. PMID: 32611662; PMCID: PMC7409761.
59. Montastruc JL, Sommet A, Lacroix I, Olivier P, Durrieu G, Damase-Michel C, Lapeyre-Mestre M, Bagheri H. Pharmacovigilance for evaluating adverse drug reactions: value, organization, and methods. Joint Bone Spine. 2006 Dec;73(6):629-32. doi: 10.1016/j.jbspin.2006.09.002. Epub 2006 Oct 12. PMID: 17110152.
60. Kumar A. Pharmacovigilance: Importance, concepts, and processes. Am J Health Syst Pharm. 2017 Apr 15;74(8):606-612. doi: 10.2146/ajhp151031. Epub 2017 Feb 24. PMID: 28235869.
61. Härmark L, van Grootheest AC. Pharmacovigilance: methods, recent developments and future perspectives. Eur J Clin Pharmacol. 2008 Aug;64(8):743-52. doi: 10.1007/s00228-008-0475-9. Epub 2008 Jun 4. PMID: 18523760.
62. Zhou S, Jia B, Kong J, Zhang X, Lei L, Tao Z, Ma L, Xiang Q, Zhou Y, Cui Y. Drug-induced fall risk in older patients: A pharmacovigilance study of FDA adverse event reporting system database. Front Pharmacol. 2022 Nov 29;13:1044744. doi: 10.3389/fphar.2022.1044744. PMID: 36523498; PMCID: PMC9746618.
63. Liu M, McPeek Hinz ER, Matheny ME, Denny JC, Schildcrout JS, Miller RA, Xu H. Comparative analysis of pharmacovigilance methods in the detection of adverse drug reactions using electronic medical records. Journal of the American Medical Informatics Association : JAMIA. 2013 May 1;20(20). 420-6. PMID: 23161894 [PubMed] PMCID: PMC3628053
64. Kim HR, Sung M, Park JA, Jeong K, Kim HH, Lee S, Park YR. Analyzing adverse drug reaction using statistical and machine learning methods: A systematic review. Medicine (Baltimore). 2022 Jun 24;101(25):e29387. doi: 10.1097/MD.0000000000029387. PMID: 35758373; PMCID: PMC9276413.
65. Del Rio-Bermudez C, Medrano IH, Yebes L, Poveda JL. Towards a symbiotic relationship between big data, artificial intelligence, and hospital pharmacy. J Pharm Policy Pract. 2020 Nov 9;13(1):75. doi: 10.1186/s40545-020-00276-6. PMID: 33292570; PMCID: PMC7650184
66. Yue QX, Ding RF, Chen WH, Wu LY, Liu K, Ji ZL. Mining Real-World Big Data to Characterize Adverse Drug Reaction Quantitatively: Mixed Methods Study. J Med Internet Res. 2024 May 3;26:e48572. doi: 10.2196/48572. PMID: 38700923; PMCID: PMC11102038.

67. Upadhyay, J., Nandave, M., Kumar, A. (2024). Role of Artificial Intelligence in Pharmacovigilance. In: Nandave, M., Kumar, A. (eds) Pharmacovigilance Essentials . Springer, Singapore. https://doi.org/10.1007/978-981-99-8949-2_17
68. World Health Organization. (2002). The Importance of Pharmacovigilance. WHO Publications.
69. Harpaz, R., et al. (2014). Data mining in pharmacovigilance. *Clinical Pharmacology & Therapeutics*, 95(5), 563–566.
70. Wang, L., et al. (2018). Detecting ADRs from EHRs using NLP. *Journal of Biomedical Informatics*, 86, 76–89.
71. Sarker, A., et al. (2020). Mining health-related data from social media. *Annual Review of Public Health*, 41, 135–150.
72. Tatonetti, N. P., et al. (2012). Detecting drug interactions from adverse event reports. *Science Translational Medicine*, 4(125), 125ra31.
73. Bate, A., & Evans, S. J. W. (2009). Quantitative signal detection using spontaneous ADR reporting. *Drug Safety*, 32(4), 289–301.
74. Liu, X., et al. (2019). Deep learning for pharmacovigilance: a review. *Briefings in Bioinformatics*, 20(1), 179–190.
75. Kreimeyer, K., et al. (2017). Natural language processing systems for capturing and standardizing unstructured clinical information. *Journal of Biomedical Informatics*, 73, 14–29.
76. Sarker, A., & Gonzalez, G. (2015). Portable automatic text classification for adverse drug reaction detection. *Journal of Biomedical Informatics*, 53, 196–207.
77. Vilar, S., et al. (2017). Machine learning approaches for the detection of drug–drug interactions. *Expert Opinion on Drug Metabolism & Toxicology*, 13(7), 745–758.
78. Yu, Y., Wang, L., & Rastegar-Mojarad, M. (2019). Literature mining to improve drug safety. *Drug Discovery Today*, 24(4), 1050–1055.
79. Kadri, H., et al. (2020). Real-world data in pharmacovigilance: promise and challenges. *Therapeutic Advances in Drug Safety*, 11, 2042098620938595.
80. Ogbuagu OO, Mbata AO, Balogun OD, Oladapo O, Ojo OO, Muonde M. Artificial intelligence in clinical pharmacy: Enhancing drug safety, adherence, and patient-centered care. International Journal of Multidisciplinary Research and Growth Evaluation. 2023 Jan;4(1):814-22.
81. Sharmila KS, Chandra KR. Predicting Adverse Interactions: A Comprehensive Review of AI-Driven Drug-Drug Interaction Models for Enhanced Patient Safety. In2024 International Conference on IoT Based Control Networks and Intelligent Systems (ICICNIS) 2024 Dec 17 (pp. 1098-1102). IEEE.
82. Yang S, Kar S. Application of artificial intelligence and machine learning in early detection of adverse drug reactions (ADRs) and drug-induced toxicity. Artificial Intelligence Chemistry. 2023 Dec 1;1(2):100011.
83. Shamim MA, Shamim MA, Arora P, Dwivedi P. Artificial intelligence and big data for pharmacovigilance and patient safety. Journal of Medicine, Surgery, and Public Health. 2024 Aug 1;3:100139.
84. Sopromadze Z, Shashiashvili N, Simonishvili B. Enhancing Medication Safety in Hospital Setting Through Artificial Intelligence. Georgian Scientists. 2025 Jun 13;7(2):446-58.
85. Mishra HP, Gupta R. Leveraging Generative AI for Drug Safety and Pharmacovigilance. Current Reviews in Clinical and Experimental Pharmacology. 2025 May;20(2):89-97.
86. Sumayli AA, Daghriry AI, Sharahili MA, Alanazi AA, Alanazi AA, Alharbi IF, Alghamdi FN, Alqarni KA, Aljohani NM, Alfaqir AM, Shajiri IM. An In-Depth Examination of Drug-Drug Interaction Databases: Enhancing Patient Safety through Advanced Predictive Models and Artificial Intelligence Techniques. Journal of Medical and Life Science. 2024 Dec 16;6(4):553-65.
87. 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 Jan;23(1):23-33.

88. Mendoza JA, Fernandez MV, Fernandez AP, Alvarez JG. Current perspectives on the use of artificial intelligence in critical patient safety. Medicina Intensiva (English Edition). 2025 Mar 1;49(3):154-64.
89. Khan O, Parvez M, Kumari P, Parvez S, Ahmad S. The future of pharmacy: how AI is revolutionizing the industry. Intelligent Pharmacy. 2023 Jun 1;1(1):32-40.
90. Saha K, Okmen N. Artificial Intelligence in Pharmacovigilance: Leadership for Ethical AI Integration and Human-AI Collaboration in the Pharmaceutical Industry.
91. Khirfan R, Kotb H, Atiyeh H. Utilizing Artificial Intelligence to Improve Patient Safety: Innovations, Obstacles, and Future Paths. Research Journal of Pharmacy and Technology. 2024 Sep 1;17(9):4630-6.
92. Kandhare P, Kurlekar M, Deshpande T, Pawar A. A review on revolutionizing healthcare technologies with AI and ML applications in pharmaceutical sciences. Drugs and Drug Candidates. 2025 Mar 4;4(1):9.
93. Majekodunmi EA. Strengthening Drug Safety and Public Health Surveillance in the United States: The Role of Artificial Intelligence in Pharmacovigilance. Available at SSRN 5181179. 2025 Mar 16.
94. Farrokhi M, Taheri F, Moeini A, Farrokhi M, Khouzani PJ, Ghadirzadeh E, Varmazyari S, Ghaneiyan M, Mohebbi S, Mogharari Z, Rezaei V. Artificial Intelligence for Drug Development, Personalized Prescriptions, and Adverse Event Prediction. Kindle. 2024 Feb 29;4(1):1-80.
95. Abbasi N, Nizamullah FN, Zeb S. AI in healthcare: integrating advanced technologies with traditional practices for enhanced patient care. BULLET: Jurnal Multidisiplin Ilmu. 2023 Jun 13;2(3):546-56.
96. Rashmi R, Kaur V, Kumar A, Srivastava H, Kumar S, Babu A. AI-Powered Pharmacovigilance: Revolutionizing Drug Safety for Tomorrow. Available at SSRN 5086737. 2024 Nov 15.
97. Upadhyay J, Nandave M, Kumar A. Role of Artificial Intelligence in Pharmacovigilance. InPharmacovigilance Essentials: Advances, Challenges and Global Perspectives 2024 Apr 4 (pp. 347-363). Singapore: Springer Nature Singapore.
98. Kumar RK, Velusamy S. Harnessing Artificial Intelligence for Enhanc
99. Challen R, Denny J, Pitt M, Gompels L, Edwards T, Tsaneva-Atanasova K. Artificial intelligence, bias and clinical safety. BMJ quality & safety. 2019 Mar 1;28(3):231-7.
100. Solaiman M, Tisha SJ, Dawood M. Artificial Intelligence in the Field of Pharmacogenomics. International Journal of Engineering Technology Research & Management (IJETRM). 2025;9(04).
101. Ou Q, Jiang X, Guo Z, Jiang J, Gan Z, Han F, Cai Y. A Fusion Deep Learning Model for Predicting Adverse Drug Reactions Based on Multiple Drug Characteristics. Life. 2025 Mar 10;15(3):436.
102. Badria FA, Elgazar AA. Optimizing Pharmacovigilance in an Era of Accelerating Innovation. Pharmacovigilance-Facts, Challenges, Limitations and Opportunities: Facts, Challenges, Limitations and Opportunities. 2025 Apr 30:3.
103. Usman US, Ahsan F, Alanjiro M, Bataba SY, Dallatu JA, Mahmood T, Bano S, Ansari JA, Parveen S. The role of artificial intelligence in pharmacy: Revolutionizing drug development and beyond. Journal of Intelligent Medicine. 2025.
104. Osheba A, Abou-El-Ela A, Adel O, Maaod Y, Abuhmed T, El-Sappagh S. Leveraging Large Language Models for Smart Pharmacy Systems: Enhancing Drug Safety and Operational Efficiency. In2025 19th International Conference on Ubiquitous Information Management and Communication (IMCOM) 2025 Jan 3 (pp. 1-8). IEEE.
105. Mohan HR, Bora G, Kalita JK. 18 ARTIFICIAL INTELLIGENCE (AI) IN PHARMACY PRACTICE: FROM DIAGNOSIS TO TREATMENT. INNOVATIVE RESEARCH.:125.
106. Al Kuwaiti A, Nazer K, Al-Reedy A, Al-Shehri S, Al-Muhanna A, Subbarayalu AV, Al Muhanna D, Al-Muhanna FA. A review of the role of artificial intelligence in healthcare. Journal of personalized medicine. 2023 Jun 5;13(6):951.