International Journal of Pharmacology and Clinical Research

ISSN Print: 2664-7613
ISSN Online: 2664-7621
Impact Factor: (RJIF) 8.29
IJPCR 2025; 7(2): 559-562
www.pharmacologyjournal.in
Received: 13-09-2025
Accepted: 15-10-2025

JS Venkatesh
Professor, Professor, SCS College of Pharmacy, Harapanahalli, Karnataka, India

Dr. Santosh Uttangi
Assistant Professor, SCS College of Pharmacy, Harapanahalli, Karnataka, India

Aleena R Reji
Pharm D Interns, SCS College of Pharmacy, Harapanahalli, Karnataka, India

Aneeta G Jacob
Pharm D Interns, SCS College of Pharmacy, Harapanahalli, Karnataka, India

Bhoomika KS
Pharm D Interns, SCS College of Pharmacy, Harapanahalli, Karnataka, India

Dona AJU
Pharm D Interns, SCS College of Pharmacy, Rajiv Gandhi University, Harapanahalli, Karnataka, India

Corresponding Author:
Dona AJU
Pharm D Interns, SCS College of Pharmacy, Rajiv Gandhi University, Harapanahalli, Karnataka, India

Artificial intelligence and evolving pharmacovigilance strategies in oncology: Bridging clinical trials and real-world data

JS Venkatesh, Santosh Uttangi, Aleena R Reji, Aneeta G Jacob, Bhoomika KS and Dona AJU

DOI: https://www.doi.org/10.33545/26647613.2025.v7.i2g.152

Abstract
Background: In oncology, pharmacovigilance is necessary because of the narrow therapeutic window, complicated regimens and dynamic toxicities of cancer treatments. Conventional methods of pharmacovigilance based on clinical trials and spontaneous reporting fail to capture many of the adverse drug reactions that arise in real-world patient populations. Active pharmacovigilance methods and artificial intelligence present the possibility for overcoming the shortcomings.
Objective: To discuss emerging pharmacovigilance practices in oncology, with a focus on AI-enabled strategies, pharmacist-initiated interventions, and active pharmacovigilance models that supplement clinical trial data.
Methods: A narrative synthesis of the latest literature was performed, with an emphasis on targeted therapies, oral anticancer therapies, and AI-facilitated pharmacovigilance.
Results: Real-world evidence shows unreported ADRs from clinical trials, and under-reporting is still extensive. Pharmacy-led interventions raised reporting of ADRs by >120%, and AP models improved early recognition with no unnecessary discontinuations. Natural language processing (NLP) using AI has promise for the automated identification of ADRs from unstructured electronic health records (EHRs). Hybrid models combining AI, pharmacists, and AP had greater sensitivity and specificity than single-mode approaches.
Conclusion: Oncology pharmacovigilance is headed towards connected, multidisciplinary models that integrate AI, active monitoring, and the active involvement of pharmacists. Such methods can improve ADR detection, maximize treatment safety, and promote equitable cancer care.

Keywords: Pharmacovigilance, oncology, artificial intelligence, active monitoring, pharmacists, adverse drug reactions

Introduction

The treatment landscape of oncology has evolved dramatically with the development of targeted therapies, immunotherapies, and oral anticancer drugs. These agents offer improved efficacy and more personalized treatment options, but they are frequently associated with unique Adverse Drug Reactions (ADRs) that differ substantially from those observed with traditional cytotoxic chemotherapy. While randomized clinical trials remain the cornerstone for regulatory approval, they often underrepresent elderly patients, individuals with comorbidities, or those on polypharmacy, thereby underestimating the true burden of ADRs in routine practice [1, 2]. For instance, there have been reported discrepancies between trial-based safety data and real-world results, and previously unseen toxicities were detected only after extensive use across the clinical population [3-6]. These constraints underscore the imperative for strong pharmacovigilance infrastructure beyond the clinic or study that is capable of catching ADRs in larger patient populations.

While increasing emphasis is placed on pharmacovigilance, there are still many challenges to overcome. Under-reporting is common in oncology, health professionals will frequently view ADRs as unavoidable, and patients will down-play symptoms or not realize their importance [2, 7]. Attribution of causality is also challenging, since multiple-agent combinations and supportive treatments are commonly used.

Pharmacist-initiated interventions were found to enhance ADR reporting by over 120%, reveal new ADRs not mentioned in product labelling, and enhance patient compliance and satisfaction [4, 8-10]. Active pharmacovigilance (AP) programs integrating organized follow-ups, patient counselling, and monitoring devices proved to enhance ADR detection in oral anticancer drugs subject to increased monitoring, especially hematologic toxicities [11, 12]. Collectively, these results emphasize the benefit of proactive, multidisciplinary approaches to enhance oncology pharmacovigilance. At the same time, advances in Artificial Intelligence (AI) are transforming pharmacovigilance.

Natural Language Processing (NLP) methods used in electronic health records (EHRs) can pull ADR data from unstructured sources, offering earlier and more complete detection compared to conventional structured data sets [1, 13]. Systematic reviews have indicated that AI and ML models can accurately predict ADRs, although there are limitations on validation, causality attribution, and bias [14-17]. Combining AI-facilitated pharmacovigilance with pharmacist involvement and AP models is a visionary approach for monitoring oncology safety. Such a convergence system of human know-how along with technology can bridge the difference between clinical trial data and real-world practice, eventually enhancing treatment outcomes and patient safety.

Materials and Methods

This review was undertaken as a narrative review with components drawn from systematic review methodology to allow for transparency and reproducibility.

Literature was comprehensively searched between the months of January 2010 and August 2025 through PubMed/MEDLINE, Scopus, Web of Science, and Google Scholar. Further citations were tracked to identify additional references. MeSH terms and keywords used: pharmacovigilance, oncology, adverse drug reactions, targeted therapy, immunotherapy, active pharmacovigilance, pharmacists, artificial intelligence, machine learning, natural language processing.

Data Extraction and Synthesis: Data were extracted on study type, intervention/model, population, and outcomes (ADR reporting rates, ADR types, adherence, AI performance metrics). Studies were categorized thematically into: (1) Current challenges in oncology pharmacovigilance; (2) Pharmacist-led interventions; (3) Active pharmacovigilance models; (4) AI-enabled pharmacovigilance. Results were synthesized qualitatively due to heterogeneity.

Eligibility Criteria

- **Inclusion criteria:** (1) Peer-reviewed literature on ADRs or oncology pharmacovigilance. (2) AP, pharmacist intervention, or AI-based studies. (3) Adult cancer patients receiving chemotherapy, targeted, or immunotherapy. (4) 2010-2025 publications.
- **Exclusion criteria:** (1) Case reports or case series (< 5 patients). (2) Non-oncology pharmacovigilance where not applicable to AI/methods. (3) Unavailable full text.

Results

Pharmacovigilance in Oncology: Current Landscape

Oncology pharmacovigilance is particularly problematic since cancer patients can receive poly-drug regimens, including supportive care, making causality even harder. In addition, several ADRs manifest late or following cumulative exposure, like cardiotoxicity of anthracyclines or endocrinopathies related to immunotherapy [2, 5]. Patient-reported data are increasingly considered as a source of safety information. Basch *et al*. demonstrated that systematic incorporation of patient-reported outcomes in oncology trials enhanced detection of ADRs and gave more timely identification of toxicities than clinician reporting alone [5]. Observational studies validate that real-world pharmacovigilance is needed: Touma *et al*. noted more gastrointestinal and dermatologic ADRs with tyrosine kinase inhibitors in the real world than from trial data [6].

Table 1: Common ADRs of targeted therapies and monitoring strategies in oncology [2, 4, 5, 6, 9, 10, 12, 16]

Targeted Therapy Class	Common ADRs	Monitoring Strategies
Tyrosine kinase inhibitors (TKIs) (e.g., imatinib, sorafenib, erlotinib)	Rash, diarrhea, hypertension, hepatotoxicity, QT prolongation	Baseline & periodic liver function tests (LFTs), ECG for QT interval, BP monitoring, dermatological assessment
Monoclonal antibodies (e.g., trastuzumab, cetuximab, bevacizumab)	Infusion reactions, cardiotoxicity (trastuzumab), skin rash, diarrhea, proteinuria, hypertension	Echocardiogram/MUGA scan every 3-6 months (HER2 agents), urine protein monitoring, BP checks, dermatology follow-up
Immune checkpoint inhibitors (ICIs) (e.g., nivolumab, pembrolizumab, ipilimumab)	Immune-related endocrinopathies (thyroiditis, adrenal insufficiency), colitis, hepatitis, pneumonitis	Thyroid function tests, cortisol levels, LFTs, pulmonary function, colonoscopy for severe diarrhea
VEGF inhibitors (e.g., bevacizumab, sunitinib, pazopanib)	Hypertension, proteinuria, thromboembolism, hemorrhage, wound healing impairment	Regular BP monitoring, urinalysis for protein, coagulation profile, perioperative assessment
EGFR inhibitors (e.g., erlotinib, gefitinib, cetuximab)	Acneiform rash, diarrhea, interstitial lung disease (rare)	Dermatology evaluation, hydration & anti-diarrheal support, imaging if pulmonary symptoms
mTOR inhibitors (e.g., everolimus, temsirolimus)	Stomatitis, hyperglycemia, dyslipidemia, pneumonitis	Oral cavity exams, fasting glucose, lipid profile, pulmonary evaluation
CDK4/6 inhibitors (e.g., palbociclib, ribociclib, abemaciclib)	Neutropenia, fatigue, diarrhea, hepatotoxicity, QT prolongation (ribociclib)	CBC every 2 weeks for first 2 months, then monthly; LFTs; ECG monitoring
PARP inhibitors (e.g., olaparib, niraparib, rucaparib)	Anemia, thrombocytopenia, nausea, fatigue	CBC at baseline and monthly, renal & hepatic function tests

Pharmacists' Role in Detection of ADR

Pharmacists continue to be at the epicenter of real-world detection of ADR. Besides Fornasier's results of > 120% rise in ADR reporting [4], counseling interventions by pharmacists have been found to enhance medication compliance and patient satisfaction [8, 10]. Kawakami *et al*. documented that almost 40% of ADRs were identified by pharmacists alone and would have otherwise gone

undetected [9]. These roles go beyond reporting: pharmacists maximize supportive care, minimize unwarranted hospitalizations, and enhance communication with pharmacovigilance agencies. Notably, pharmacist-initiated pharmacovigilance models have proven to be sustainable in resource-poor as well as high-income countries [7].

Active Pharmacovigilance and Further Monitoring

Active Pharmacovigilance (AP) models provide systematic monitoring and prevent under-reporting. Carvalho da Silva *et al*. proved that organized AP of oral anticancer agents under further monitoring resulted in increased identification of hematological ADRs, particularly neutropenia and anemia [11]. In India, an oncovigilance project associated with national pharmacovigilance programs detected significantly enhanced ADR signal detection among targeted therapies [3]. Clemons *et al*. pointed out that nurse- and pharmacist-led phone-based AP not only detected ADRs but also prevented unnecessary treatment breaks [12]. Taken together, these studies affirm that AP is feasible and successful in oncology.

Artificial Intelligence and Real-World Data

AI and NLP are transforming how ADRs are identified. Gallifant *et al*. outlined AI-powered pipelines for oncology pharmacovigilance, prioritizing scalability and real-world use [1]. NLP for EHRs can reveal unreported ADRs and improve ADR detection sensitivity by more than 30% [13]. Hauben *et al*. listed reviews of AI/ML use cases and concluded that predictive models demonstrated strong accuracy (AUC 0.75-0.90) in detecting ADRs [14]. Social media mining has also been a new tool; Sarker *et al*. discovered initial patient-reported ADR signals for immunotherapy on social media such as Twitter, sometimes weeks prior to reporting by regulatory agencies [16]. Chen *et al*. warned, though, that AI algorithms can exacerbate disparities since training data are unrepresentative of minority groups [17].

Integrative strategies for expanded pharmacovigilance

The most encouraging outcomes come from hybrid solutions that pair AI, AP, and pharmacist engagement. Coloma *et al*. demonstrated that pharmacist validation integrated with NLP enhanced ADR signal accuracy and minimized false positives by close to 40% versus NLP only [18]. Likewise, systems where AI-flagged signals are interpreted by pharmacists have shown enhanced clinical decision-making and lower ADR treatment discontinuations [4, 8, 18]. These models illustrate the human expertise-motor-scalability complementarity of the models to ensure sensitivity and specificity of pharmacovigilance.

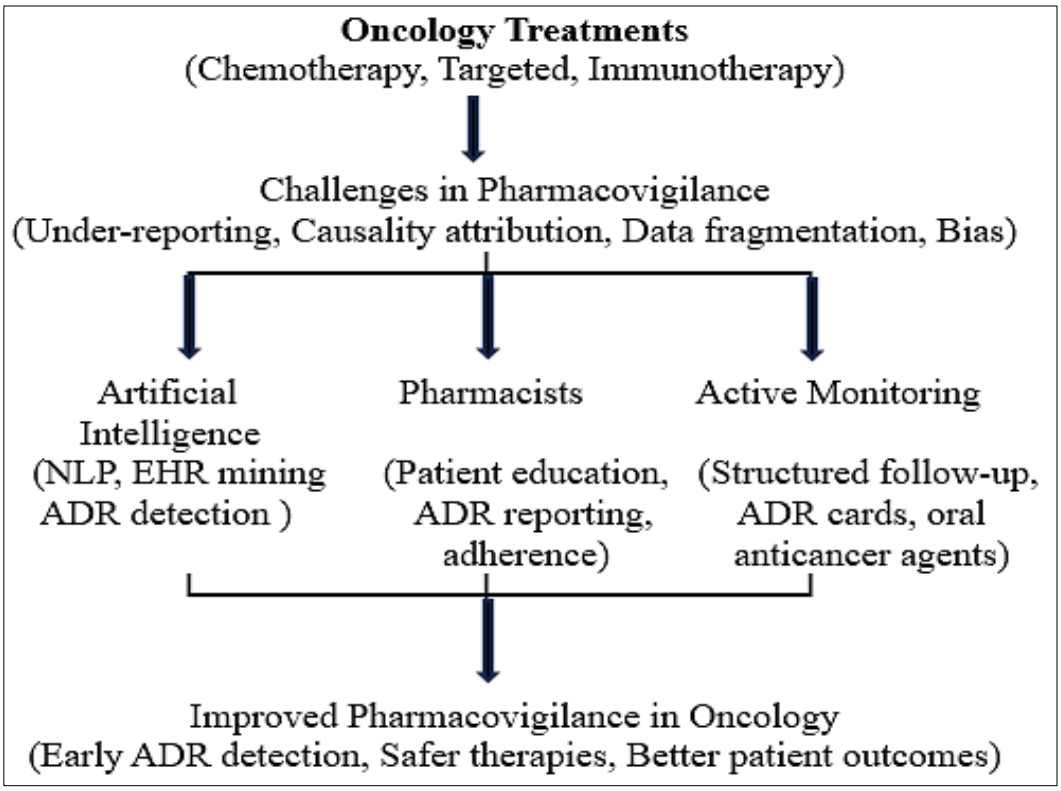

Fig 1: Flowchart showing synergy of AI, pharmacists, and active monitoring in oncology pharmacovigilance

Discussion

Pharmacovigilance is complicated by multi-drug therapy, toxicities expressed after a time delay, and lack of representation of real-world patients in clinical trials [2, 5, 6]. These factors cause under-reporting and incompleteness of safety profiles. Pharmacists are key to enhancing pharmacovigilance. Interventions have been found to increase ADR reporting over two-fold, reveal ADRs missed otherwise, and enhance patient outcomes via counselling and monitoring [4, 8-10]. Their participation helps deliver practical, on-the-ground detection and reporting.

Active pharmacovigilance (AP) programs ensure systematic ADR capture and organized follow-up.Studies verify that AP enhances hematological toxicities detection and minimizes unwarranted treatment breaks and is particularly worth it in oral anticancer treatment [3, 7, 11].

Artificial intelligence provides scalable solutions, and NLP and machine learning allow for automated ADR detection

from electronic health data and even social media [1, 13-15, 16]. Challenges, though, surround validation, bias, and equity [17]. The best strategy is hybrid: Integrating AI-powered surveillance with AP and pharmacist verification. Combined models enhance detection specificity and sensitivity while maintaining clinical applicability [18]. This dynamic model defines the future of oncology pharmacovigilance, connecting trial data and real-world safety.

Conclusion

Conventional pharmacovigilance falls short of covering the complete spectrum of ADRs in oncology. Pharmacists, AP models, and AI are supplementary approaches that, when combined, build a solid, multi-disciplinary framework for oncology safety. Directions for the future need to prioritize FAIR data, equity, and sustainability in pharmacist-led and AI-facilitated monitoring.

Acknowledgments

The authors express their gratitude to all who supported and encouraged them throughout the work.

Conflict of Interest

All authors declare that there are no conflicts of interest.

Authors Funding

The authors hereby declare that they did not obtain any financial support from any source for the writing, or publication of this article.

References

1. Gallifant J, Atreja A, Shah NH, *et al*. Navigating the complexities of artificial intelligence-enabled real-world data collection for oncology pharmacovigilance. JCO Clin Cancer Inform. 2024;8:e2400046.
2. Baldo P, Francescon S, Fornasier G. Pharmacovigilance in oncology. Int J Clin Pharm. 2018;40(4):832-841.
3. Indian Journal of Pharmacology. Oncovigilance: Adverse drug reactions with anticancer drugs. Indian J Pharmacol. 2017;49(5):349-355.
4. Fornasier G, Francescon S, Leone R, Baldo P. Targeted therapies and adverse drug reactions in oncology: The role of clinical pharmacist in pharmacovigilance. Int. J Clin Pharm. 2018;40(4):795-802.
5. Basch E, *et al*. Patient-reported outcomes in pharmacovigilance for oncology: Lessons from clinical trials. Lancet Oncol. 2019;20(5):e274-83.
6. Touma J, *et al*. Real-world safety outcomes of tyrosine kinase inhibitors: An observational study. Eur J Cancer. 2020;136:19-27.
7. Hospital pharmacists' perspectives on ADR reporting in developed and developing countries: A comparative pilot study. Pharmacy (Basel). 2025;13(4):103.
8. Role of a designated pharmacist in reducing ADR rates in hematology-oncology: A randomized controlled trial. J Clin Oncol. 2022;40(15_suppl):e18721.
9. Kawakami J, *et al*. Impact of pharmacist interventions on adverse drug event reporting in oncology. J Oncol Pharm Pract. 2019;25(6):1356-1363.
10. Meier K, *et al*. Pharmacist-led patient education in oral anticancer therapy: Systematic review. Support Care Cancer. 2021;29(12):7605-7616.
11. Carvalho da Silva SP, Morais C, Ferreira S, *et al*. Active pharmacovigilance study: A follow-up model of oral anti-cancer drugs under additional monitoring. Curr Oncol. 2023;30(3):315-325.
12. Clemons M, *et al*. Active telephone-based pharmacovigilance for oral anticancer therapies. Curr Oncol. 2018;25(5):e425-432.
13. Wang L, McLachlan S, Gray M, *et al*. NLP for pharmacovigilance: Extracting adverse drug events from clinical narratives. Drug Saf. 2021;44(3):253-264.
14. Hauben M, Hung E, Xu Z, *et al*. Artificial intelligence and pharmacovigilance: A systematic review. Drug Saf. 2022;45(9):947-960.
15. Malmasi S, Subramani S, Abdar M, *et al*. Machine learning applications in adverse drug reaction detection: A scoping review. J Med Internet Res. 2023;25:e44573.
16. Sarker A, *et al*. Mining social media for adverse drug reaction surveillance in oncology. JMIR Public Health Surveill. 2021;7(2):e23245.
17. Chen R, *et al*. Equity in artificial intelligence-driven pharmacovigilance: Challenges and opportunities. NPJ Digit Med. 2022;5:38.
18. Coloma PM, *et al*. Integrating natural language processing and pharmacist review for pharmacovigilance in oncology. Drug Saf. 2023;46(2):123-135.