Journal of Zoology and Allied Sciences
Online peer reviewed Journal | Published by COGNIX PRESS
Content available at www.cognixpress.in Online ISSN: XXXX-XXXX

REVIEW ARTICLE
OPEN ACCESS

BEYOND ADVERSE DRUG REACTIONS: THE EVOLVING LANDSCAPE OF PHARMACOVIGILANCE IN ENSURING MEDICATION SAFETY

NAGA SUBRAHMANYAM S*[1], MOGULURI NAGA PRAVALLIKA[1], S INDU HARINI[2]

[1]*Vishwa Bharathi College of Pharmaceutical Sciences, N.R.T Road, Perecherla, Medikonduru MD, Guntur-522006, Andhra Pradesh, India*
[2]*Departmnet of Pharmacy Practice, Koringa College of Pharmacy, Korandi, Kaninada, Andhra Pradesh, India*

Corresponding Author
Dr. Naga Subrahmanyam S

Article History: 14.03.2026 Received: 24.03.2026 Revised: Accepted: 02.04.2026

ABSTRACT
Pharmacovigilance has evolved from focusing solely on adverse drug reaction (ADR) reporting to a comprehensive, patient-centered approach that ensures medication safety throughout a drug's life cycle. It now includes the monitoring of medication errors, drug interactions, vaccine safety, materiovigilance, and continuous benefit–risk assessment. Advances in artificial intelligence, machine learning, big data, electronic health records, digital reporting, and real-world evidence have strengthened signal detection and regulatory decision-making. However, challenges such as under-reporting, poor data quality, privacy concerns, and unequal pharmacovigilance infrastructure remain. Enhancing global collaboration, increasing the involvement of healthcare professionals and patients, and adopting advanced digital technologies are essential for improving medication safety and protecting public health.

Keywords: *Pharmacovigilance, Adverse Drug Reactions, Medication Safety, Drug Safety, Signal Detection, Benefit–Risk.*

INTRODUCTIO

Burden of Adverse drug reactions worldwide:

Adverse drug reactions (ADRs) are a major cause of morbidity and mortality worldwide and remain one of the leading medication-related challenges in healthcare. They contribute significantly to hospital admissions, prolonged hospitalization, increased healthcare costs, and reduced quality of life [1]. Although medicines undergo rigorous testing before approval, rare or delayed adverse effects often become evident only after widespread use in diverse patient populations. According to the World Health Organization (WHO), unsafe medication practices and medication-related harm account for millions of preventable injuries each year, emphasizing the need for continuous monitoring of medicine safety [2].

Why medication safety is a Global priority

Medication safety is the prevention of avoidable harm while maximizing the therapeutic benefits of medicines. It is a global priority because medication-related harm is a leading cause of preventable patient injury and increased healthcare costs. Medication errors can occur at any stage of the medication-use process, particularly during polypharmacy, complex treatment regimens, and transitions of care[3]. Effective pharmacovigilance, continuous monitoring, timely reporting, and collaboration among healthcare professionals are essential to reduce preventable harm and improve patient outcomes [4].

Evolution of Pharmacovigilance

Pharmacovigilance has evolved from ADR reporting to a proactive, patient-centered approach to medication safety. It now includes medication errors, vaccine safety, materiovigilance, risk management, benefit–risk assessment, and continuous safety monitoring throughout the drug life cycle [5]. Advances in electronic health records, real-world evidence, artificial intelligence, big data analytics, and digital reporting have strengthened safety signal detection and regulatory decision-making, improving public health [6].

HISTORY AND EVOLUTION OF PHARMACOVIGILANCE

1. Historical drug disasters:

The evolution of pharmacovigilance has been largely influenced by several historical drug disasters that highlighted the need for effective drug safety monitoring. The first major incident was the chloroform disaster in 1848, in which the death of a young patient following chloroform anaesthesia raised concerns about medicine safety. Later, the Elixir Sulphanilamide disaster of 1937 resulted in the deaths of more than 100 people due to the use of the toxic solvent diethylene glycol, leading to the introduction of stricter drug safety regulations before medicines could be marketed. Another significant event was the thalidomide tragedy in 1961, where the use of thalidomide during pregnancy caused severe congenital birth defects in thousands of infants worldwide. This tragedy emphasized the importance of rigorous drug testing and post-marketing surveillance. More recently, Vioxx (rofecoxib) was withdrawn from the market in 2004 after post-marketing studies revealed an increased risk of serious cardiovascular events such as heart attack and stroke [7]. These incidents demonstrated that clinical trials alone cannot identify all drug-related risks and highlighted the importance of continuous monitoring of medicine safety throughout a drug's life cycle [8]. As a result, they laid the foundation for the development and strengthening of modern pharmacovigilance systems to protect public health [9].

2. Birth of modern Pharmacovigilance:

The thalidomide tragedy of 1961 marked the beginning of modern pharmacovigilance by highlighting the need for continuous monitoring of medicine safety after marketing. In response, regulatory authorities across the world strengthened drug approval processes and introduced stricter safety regulations[10]. To promote international collaboration in monitoring adverse drug reactions (ADRs), the World Health Organization (WHO) established the Programme for International Drug Monitoring (PIDM) in 1968. This programme encouraged member countries to collect, evaluate, and share ADR reports to improve patient safety [11]. In 1978, the Uppsala Monitoring Centre (UMC) in Sweden became the WHO Collaborating Centre for International Drug Monitoring and was entrusted with managing the global database of Individual Case Safety Reports (ICSRs). These initiatives established the foundation of modern pharmacovigilance by creating an organized international system for detecting, assessing, and preventing medicine-related risks while promoting safer use of medicines worldwide [12].

3. Major milestones:

Since its establishment, pharmacovigilance has achieved several important milestones that have strengthened medicine safety worldwide. During the 1990s, the International Council for Harmonisation (ICH) introduced harmonized guidelines for adverse event reporting and safety data management, improving consistency among regulatory agencies [13]. The establishment of the European Medicines Agency (EMA) in 1995 enhanced post-marketing surveillance and benefit–risk assessment across Europe. The launch of EudraVigilance in 2001 improved electronic reporting and signal detection of adverse drug reactions [14]. Later, the European Union Pharmacovigilance Legislation (2012) strengthened risk management, increased patient involvement in ADR reporting, and enhanced transparency in medicine safety monitoring [15]. Together, these milestones have made pharmacovigilance a more efficient and patient-centred system for ensuring the safe use of medicines [16].

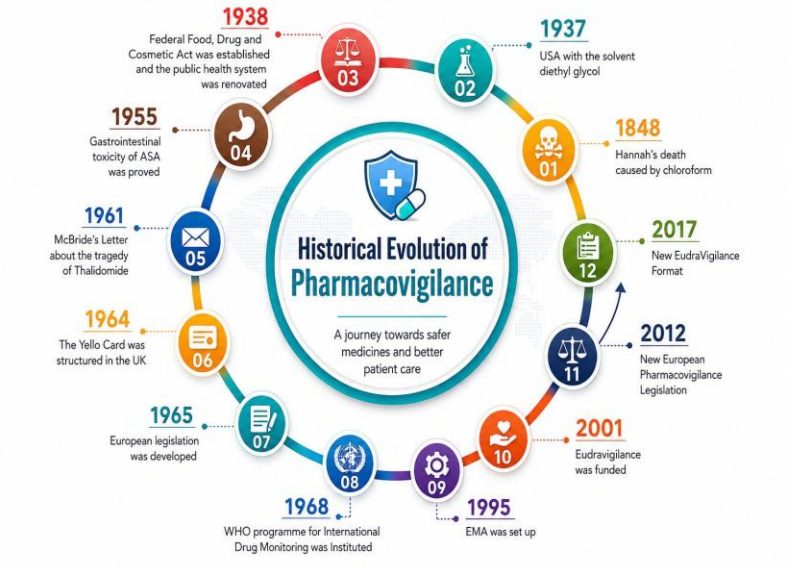

Figure 01:

FUNDAMENTALS OF PHARMACOVIGILANCE

1. **Definition:**
   Pharmacovigilance is the science and activity of detecting, assessing, understanding, and preventing adverse effects or any other drug-related problems [17].

2. **Objectives:**

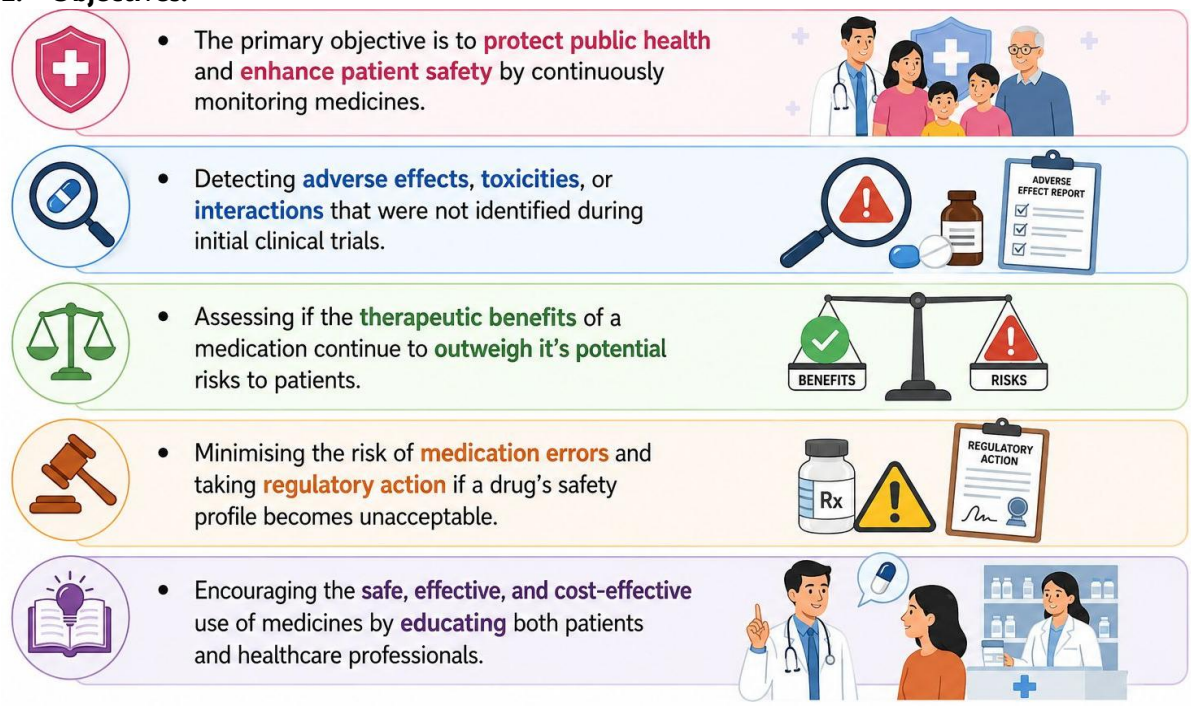

Figure 02:

3. **Scope:**
   The scope of pharmacovigilance extends beyond adverse drug reaction (ADR) monitoring to ensure medicine safety throughout the drug life cycle. It includes clinical trial safety, post-marketing surveillance, development of Risk Management Plans (RMPs), and regulatory compliance through timely reporting of safety information [18]. These activities help identify and minimize medicine-related risks, maximize therapeutic benefits, and ensure the safe and effective use of medicines while protecting public health [19].
4. **Importance in healthcare:**
   Pharmacovigilance plays a crucial role in improving healthcare by ensuring the safe and effective use of medicines. It supports real-world safety monitoring to identify rare or long-term adverse effects, helps prevent patient harm and reduce healthcare costs through early detection of medication-related risks, and contributes to safer drug development and regulatory decision-making [20]. By ensuring transparency, timely communication, and appropriate regulatory actions, pharmacovigilance also maintains public trust and promotes the rational use of medicines [21].

ADVERSE DRUG REACTIONS

1. **Definition:**
   The unintended, noxious, or harmful response to a drug that occurat normal therapeutic doses, medication errors, misuse, abuse, overdoses or off-labeluses [22].

2. Classification:

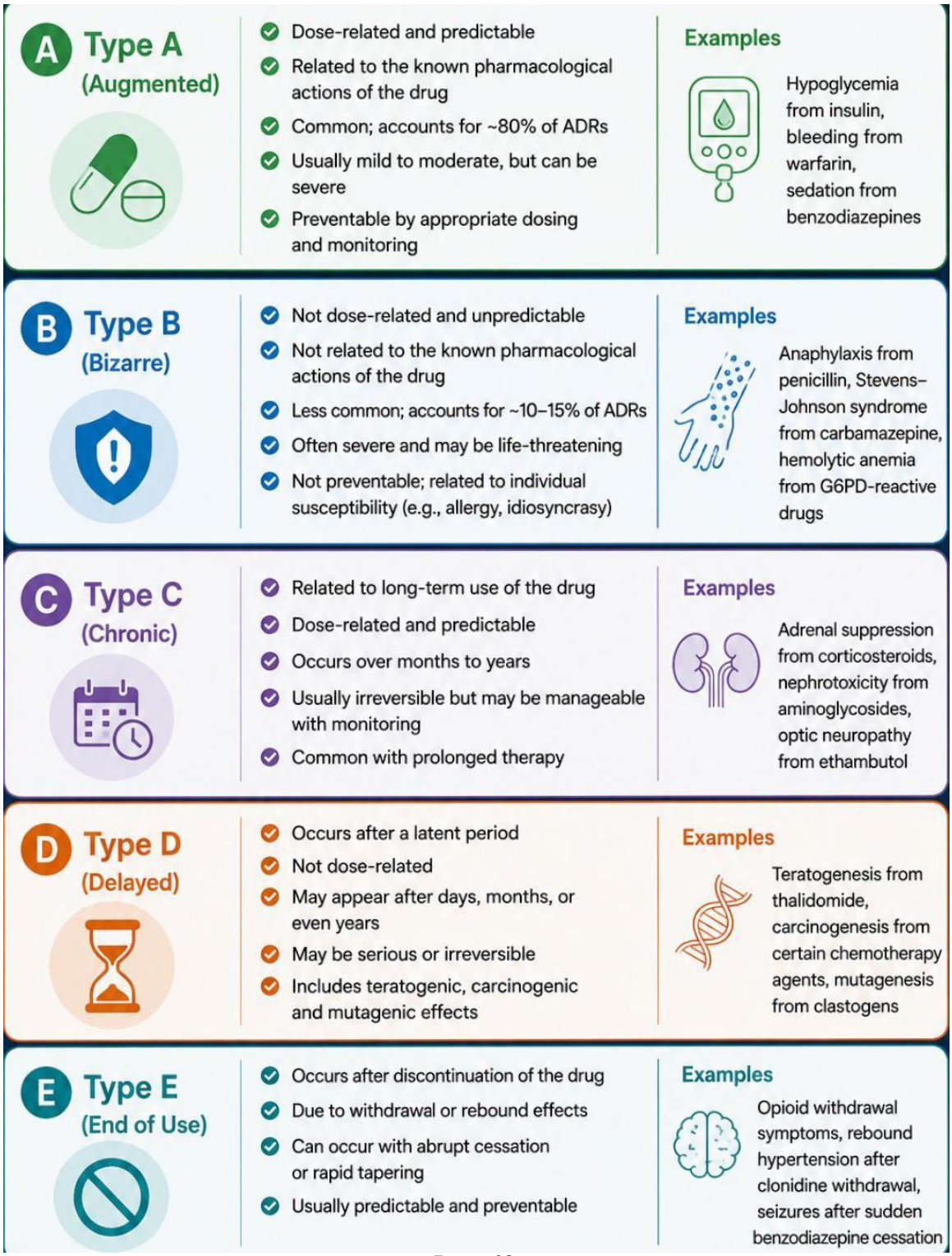

Figure 03:

3. Risk factors:

1. **Clinical impact:**

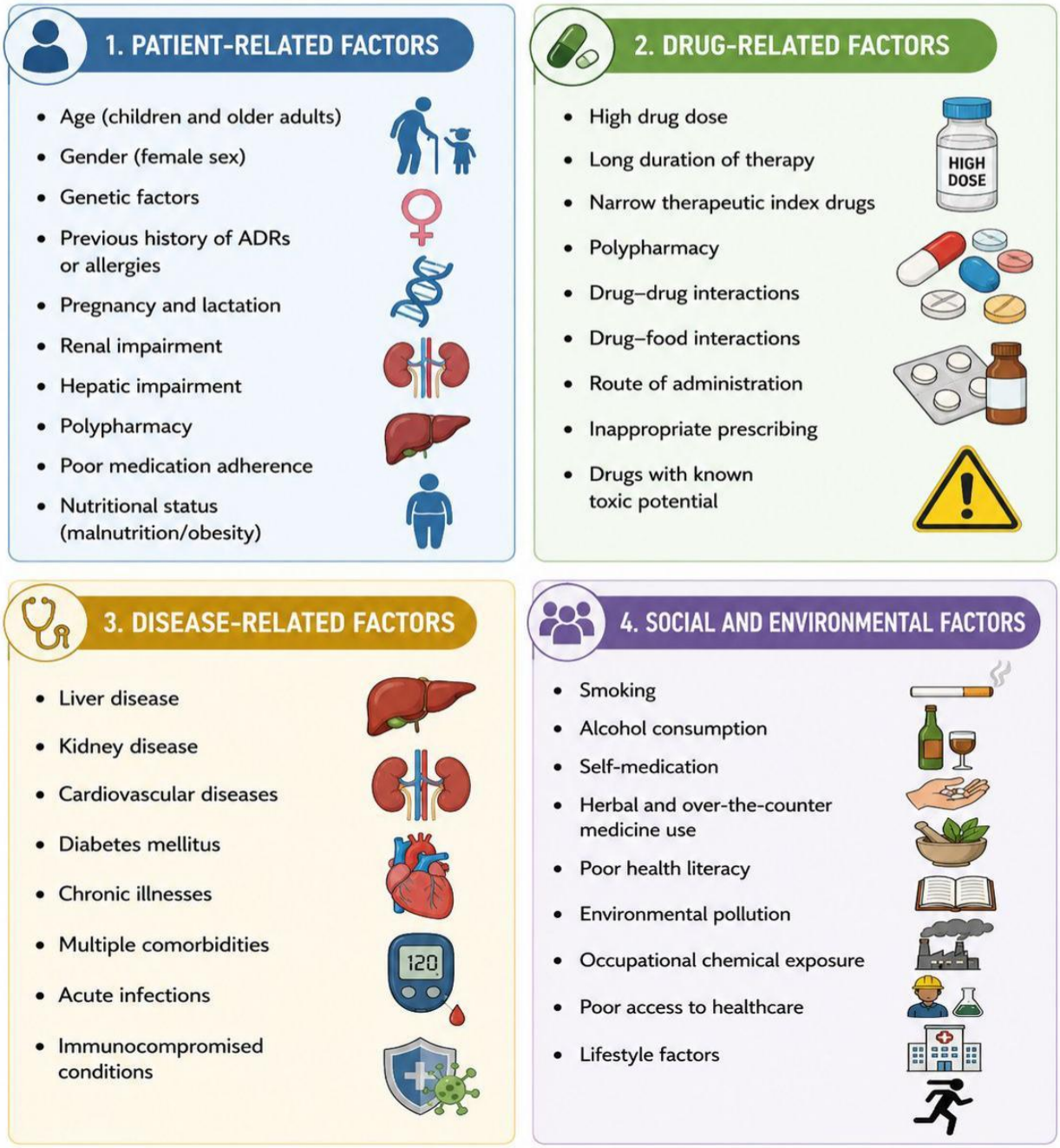

Figure 04:

- **Increased Morbidity and Mortality**: ADRs can increase disease severity, cause serious complications, and may lead to preventable deaths [23].
- **Prolonged Hospitalization**: ADRs often result in extended hospital stays, increased healthcare costs, and the need for additional medical care [24].
- **Treatment Disruption**: ADRs may require dose reduction, temporary interruption, or discontinuation of therapy, leading to reduced treatment effectiveness and poor patient outcomes [25].

DRUG SAFETY MONITORING THROUGHOUT THE DRUG LIFE CYCLE

1. **Preclinical safety:**
   Preclinical safety is the initial stage of drug safety evaluation conducted before a new medicine is tested in humans. It involves in vitro (laboratory) and in vivo (animal) studies to assess the safety profile of a drug candidate. These studies evaluate acute, subacute, and chronic toxicity, genotoxicity, carcinogenicity, reproductive and developmental toxicity, and safety pharmacology to identify any harmful effects on major organ systems [26]. Preclinical studies also help determine the No Observed Adverse Effect Level (NOAEL), which is used to estimate a safe starting dose for human clinical trials. The primary goal of preclinical safety assessment is to identify potential risks, ensure an acceptable safety margin, and support regulatory approval before clinical trials are initiated [27].
2. **Clinical trial safety:**
   Clinical trial safety is an essential part of drug development that evaluates the safety of a medicine in human participants before it is approved for marketing. Clinical trials are conducted in different phases to identify adverse events, assess the frequency and severity of adverse drug reactions (ADRs), determine a safe dosage range, and evaluate the overall benefit–risk profile of the drug [28]. Throughout the trial, participants are closely monitored, and all adverse events are documented, assessed, and reported to regulatory authorities and ethics committees. Continuous safety monitoring helps identify potential risks early, ensures participant protection, and supports decisions regarding the continuation, modification, or termination of clinical trials [29].
3. **Post-marketing surveillance:**
   Post-marketing surveillance is the continuous monitoring of a medicine after it has been approved for public use. It aims to identify rare, delayed, or long-term adverse drug reactions (ADRs) that may not have been detected during preclinical studies or clinical trials. Safety information is collected through spontaneous ADR reporting systems, patient registries, electronic health records, observational studies, and pharmacovigilance databases [30]. The collected data help identify new safety concerns, evaluate the long-term safety of medicines, update prescribing information, implement risk minimization measures, and support regulatory decisions when necessary. Therefore, post-marketing surveillance is an essential component of pharmacovigilance that ensures the continued safe and effective use of medicines throughout their life cycle [31].
4. **Continuous benefit-risk assessment:**
   Continuous benefit–risk assessment is the ongoing evaluation of whether the benefits of a medicine outweigh its potential risks after it is approved for use. As new safety information is collected from adverse drug reaction reports, clinical studies, scientific literature, and real-world clinical practice, the benefit–risk profile of the medicine is regularly reviewed [32]. If new safety concerns are identified, regulatory authorities may update prescribing information, issue safety warnings, recommend risk minimization measures, restrict the use of the medicine, or withdraw it from the market if necessary. Continuous benefit–risk assessment ensures that medicines continue to provide maximum therapeutic benefit while maintaining patient safety throughout their life cycle [33].

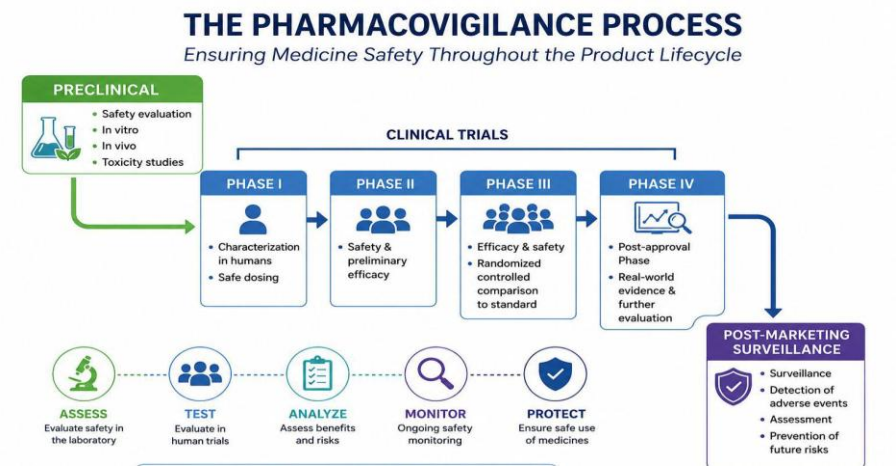

Figure 05:

PHARMACOVIGILANCE SYSTEMS AROUND THE WORLD

1. **World Health Organization programme:**
   The World Health Organization (WHO) plays a leading role in promoting pharmacovigilance globally through the WHO Programme for International Drug Monitoring (PIDM), established in 1968. The programme supports member countries in monitoring the safety of medicines by encouraging the collection, assessment, and sharing of adverse drug reaction (ADR) reports [34]. WHO develops international guidelines, promotes collaboration among national pharmacovigilance centres, and supports signal detection and risk communication to improve patient safety worldwide [35].
2. **Uppsala Monitoring Centre:**
   The Uppsala Monitoring Centre (UMC), located in Sweden, became the WHO Collaborating Centre for International Drug Monitoring in 1978. It manages VigiBase, the world's largest global database of Individual Case Safety Reports (ICSRs), received from countries participating in the WHO Programme. UMC supports signal detection, causality assessment, data analysis, training, and the development of pharmacovigilance tools such as VigiFlow, thereby strengthening global medicine safety monitoring [36].
3. **Pharmacovigilance programme of India:**
   In India, pharmacovigilance is coordinated through the Pharmacovigilance Programme of India (PvPI), which was launched in 2010 by the Ministry of Health and Family Welfare. The Indian Pharmacopoeia Commission (IPC) serves as the National Coordination Centre (NCC) and is responsible for collecting, analysing, and monitoring ADR reports received from Adverse Drug Reaction Monitoring Centres (AMCs) across the country [37]. The programme supports signal detection, benefit–risk assessment, regulatory decision-making, and communication of medicine safety information. India is also an active member of the WHO Programme for International Drug Monitoring and contributes ADR reports to the global database managed by UMC [38].

ROLE OF HEALTHCARE PROFESSIONALS

1. **Pharmacists:**
   Pharmacists play a key role in pharmacovigilance by contributing to the safe and effective use of medicines through:
   - Detecting suspected adverse drug reactions (ADRs) during routine patient care.
   - Assessing the causality, severity, preventability, and clinical significance of ADRs.
   - Reporting suspected ADRs accurately and promptly to pharmacovigilance centres or regulatory authorities.
   - Monitoring patients for medicine-related problems, particularly those receiving high-risk drugs or multiple medications [39].
   - Preventing ADRs by identifying medication errors, drug interactions, and providing medication counselling.
   - Educating patients and healthcare professionals about ADR reporting and the rational use of medicines.
   - Collaborating with physicians, nurses, and other healthcare professionals to improve medication safety and patient outcomes [40].
2. **Physicians:**
   Physicians play a central role in pharmacovigilance by:
   - Diagnosing suspected adverse drug reactions (ADRs) based on clinical evaluation.
   - Identifying medicines responsible for ADRs and evaluating possible risk factors.
   - Managing ADRs by modifying, discontinuing, or changing drug therapy when necessary.
   - Reporting suspected ADRs to national pharmacovigilance centres or regulatory authorities.
   - Prescribing medicines rationally by considering the patient's medical history and risk factors.
   - Monitoring treatment outcomes and medicine safety during follow-up.
   - Counselling patients about the benefits, risks, and possible adverse effects of medicines.
   - Contributing to pharmacovigilance programs through active participation in ADR reporting and medication safety initiatives [41].
3. **Nurses:**
   Nurses play a crucial role in pharmacovigilance by ensuring patient safety through:
   - Observing patients closely for signs and symptoms of adverse drug reactions (ADRs).
   - Recognizing and identifying unexpected or unusual reactions during treatment.

- Documenting ADRs accurately in patient records.
- Reporting suspected ADRs promptly to the physician or pharmacovigilance centre.
- Administering medicines safely by following the prescribed dose, route, and timing.
- Educating patients and caregivers about possible adverse effects and the importance of reporting them.
- Communicating ADR-related information effectively with the healthcare team.
- Supporting continuous monitoring of patients to improve medication safety and quality of care [42].

4. **Patients:**

Patients contribute to pharmacovigilance by:

- Reporting adverse drug events (ADEs) directly to pharmacovigilance centres or regulatory authorities.
- Providing patient-reported outcomes (PROs) that reflect real-world experiences with medicines.
- Supporting signal detection by reporting new, rare, or unexpected adverse drug reactions.
- Reducing blind spots in pharmacovigilance by reporting adverse effects that may not be recognized or reported by healthcare professionals.
- Sharing complete information on medicine use, symptoms, and treatment outcomes.
- Participating actively in medicine safety monitoring to improve patient care and public health [43].

MEDICATION SAFETY BEYOND ADVERSE DRUG REACTIONS REPORTING

1. **Medication errors:**

Medication errors are preventable events that may lead to inappropriate medication use or patient harm and can occur at any stage of the medication-use process. Common causes include poor communication, incorrect prescribing, look-alike or sound-alike medicines, inadequate labelling, lack of training, and system-related failures. As an important component of pharmacovigilance, identifying, reporting, and analyzing medication errors help prevent adverse events, improve medication practices, and enhance patient safety [44].

2. **Drug Interactions:**

Drug interactions occur when the effects of a medicine are altered by another medicine, food, herbal product, or disease, affecting its safety or effectiveness. They may increase adverse drug reactions, reduce therapeutic efficacy, or cause unexpected clinical outcomes. Drug interactions are classified as drug–drug, drug–food, drug–herb, and drug–disease interactions, as well as pharmacokinetic and pharmacodynamic interactions. Patients receiving multiple medications, older adults, and individuals with chronic diseases are at higher risk. Therefore, identifying, monitoring, and preventing drug interactions are essential components of pharmacovigilance to optimize drug therapy and improve patient safety [45].

3. **Medication Conciliation:**

Medication reconciliation is the systematic process of obtaining, verifying, and documenting a patient's complete medication list during transitions of care. It involves comparing current and newly prescribed medicines during admission, transfer, and discharge to identify and resolve discrepancies. This process helps prevent medication errors, drug interactions, and adverse drug events, improving patient safety through collaboration among physicians, pharmacists, nurses, and patients [46].

4. **Vaccine Pharmacovigilance:**

Vaccine pharmacovigilance involves the detection, assessment, understanding, and prevention of adverse events following immunization (AEFIs). It continuously monitors vaccine safety, identifies rare or unexpected adverse events, evaluates the benefit–risk profile of vaccines, and supports timely regulatory action. By collecting safety information through reporting systems and surveillance programs, vaccine pharmacovigilance strengthens public confidence and promotes the safe and effective use of vaccines [47].

5. **Materiovigilance:**

Materiovigilance is the systematic monitoring of the safety, performance, and quality of medical devices to identify, assess, and prevent device-related adverse events. In India, the Materiovigilance Programme of India (MvPI), launched in 2015 and coordinated by the Indian Pharmacopoeia Commission (IPC), monitors and evaluates medical device-related adverse events. Materiovigilance helps identify device-related risks, improve device performance, support regulatory decision-making, and ensure the safe and effective use of medical devices [48].

CHALLANGES IN PHARMACOVIGILANCE

Figure 06:

Despite significant advancements, pharmacovigilance continues to face several challenges that affect the effectiveness of medicine safety monitoring. These include:

Addressing these challenges through improved reporting systems, education, international collaboration, and technological advancements is essential to strengthen pharmacovigilance and ensure patient safety [49].

FUTURE PERSPECTIVES

1. **Artificial Intelligence:**
   Artificial Intelligence (AI) is transforming pharmacovigilance by enabling the rapid analysis of large volumes of safety data. AI-based tools can automate adverse drug reaction (ADR) case processing, support signal detection, assist in causality assessment, and improve benefit–risk evaluation. By reducing manual effort and improving efficiency, AI is expected to strengthen future pharmacovigilance systems and support faster regulatory decision-making [50].
2. **Big Data:**
   Big data has become an important resource for pharmacovigilance by integrating information from electronic health records, pharmacovigilance databases, insurance claims, clinical studies, and social media [51]. The analysis of these large datasets helps identify rare adverse events, detect safety trends, and improve the understanding of medicine safety in diverse populations.
3. **Real-World Evidence:**
   Real-world evidence provides information on the safety and effectiveness of medicines in routine clinical practice [52]. It is generated from sources such as electronic health records, patient registries, and healthcare databases. RWE complements clinical trial data by identifying long-term and rare adverse drug reactions, supporting regulatory decisions, and improving benefit–risk assessment [53].
4. **Digital Reporting**
   Digital reporting systems have simplified the collection and reporting of adverse drug reactions through online portals, mobile applications, and electronic reporting platforms [54]. These systems enable faster submission of safety reports, improve data quality, promotepatient participation, and facilitate timely signal detection and regulatory action.
5. **Personalized machine**
   Advances in pharmacogenomics and personalized medicine are expected to improve medication safety by tailoring drug therapy according to an individual's genetic profile, disease characteristics, and treatment response[55]. This approach helps minimize adverse drug reactions, optimize therapeutic outcomes, and support safer, patient-centeredhealthcare [56].

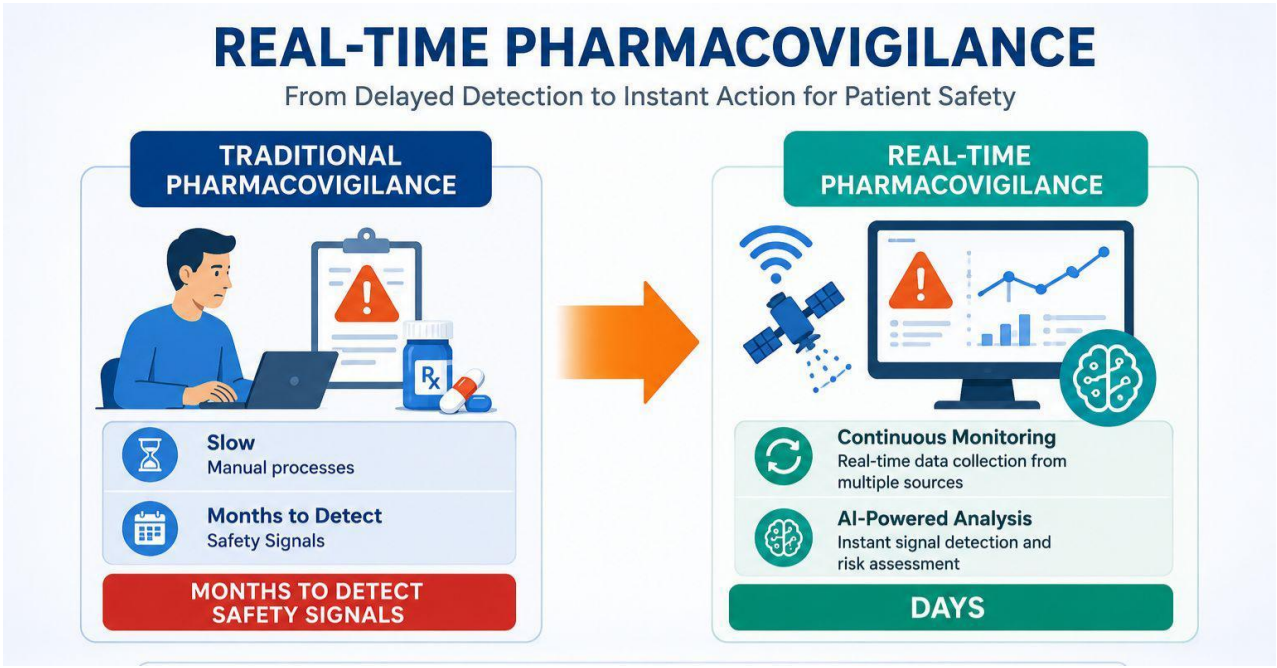

Figure 07:

CONCLUSION

Pharmacovigilance has evolved from ADR reporting to a comprehensive approach for ensuring medication safety throughout the medicine life cycle. It includes post-marketing surveillance, risk management, medication error reporting, vaccine pharmacovigilance, and materiovigilance. Advances in artificial intelligence, big data, real-world evidence, and digital reporting systems have made pharmacovigilance more proactive and efficient. Although challenges such as under-reporting and data quality remain, collaboration among healthcare professionals, regulatory authorities, pharmaceutical industries, and patients is essential to strengthen pharmacovigilance and ensure the safe, effective, and rational use of medicines.

FUNDING

Ni

INFORM CONSENT AND ETHICAL STATEMENT

Not Applicable

ACKNOWLEDGEMENT

Not Declared

AUTHOR CONTRIBUTION

All authors are contributed equally.

REFERENCES

1. Pachi, A., Bratis, D., Moussas, G., &Tselebis, A. (2013). Psychiatric morbidity and other factors affecting treatment adherence in pulmonary tuberculosis patients. *Tuberculosis Research and Treatment*, *2013*, 1–37. https://doi.org/10.1155/2013/489865
2. Al-Busafi, S. A., & Alwassief, A. (2024). Global perspectives on the Hepatitis B vaccination: challenges, achievements, and the road to elimination by 2030. Vaccines, 12(3), 288. https://doi.org/10.3390/vaccines12030288
3. Spinewine, A., Foulon, V., Claeys, C., De Lepeleire, J., Chevalier, P., Desplenter, F., De Winter, S., Dumont, C., Lacour, V., Simoens, S., Hourlay, C., & Paulus, D. (2010). Seamless care with regard to medications between hospital and home. https://doi.org/10.57598/r131c
4. Suke, S. G., Kosta, P., & Negi, H. (2015). Role of Pharmacovigilance in India: An overview. Online Journal of Public Health Informatics, 7(2), e223. https://doi.org/10.5210/ojphi.v7i2.5595

5. Convertino, I., Sansone, A., Marino, A., &Galiulo, M. (2016). 16th ISOP Annual Meeting "'Pharmacovigilance for Safer Tomorrow'" Agra, India 16–19 October, 2016. Drug Safety, 39(10), 989–1042. https://doi.org/10.1007/s40264-016-0445-6
6. Thakkar, S., Slikker, W., Yiannas, F., Silva, P., Blais, B., Chng, K. R., Liu, Z., Adholeya, A., Pappalardo, F., Da Luz Carvalho Soares, M., Beeler, P. E., Whelan, M., Roberts, R., Borlak, J., Hugas, M., Torrecilla-Salinas, C., Girard, P., Diamond, M. C., Verloo, D., . . . Tong, W. (2023). Artificial intelligence and real-world data for drug and food safety – A regulatory science perspective. Regulatory Toxicology and Pharmacology, 140, 105388. https://doi.org/10.1016/j.yrtph.2023.105388
7. Davidson, M. A. (2018). A Pharmacovigilance Approach for Assessing Cardiovascular, Osteological, and Carcinogenic Risk Associated with Thiazolidinedione Drugs Used in the Treatment of Type 2 Diabetes Mellitus. In uO Research (University of Ottawa). https://doi.org/10.20381/ruor-22317
8. Herdeiro, M. T., Roque, F., Figueiras, A., & Silva, T. M. (2021). New Insights into the Future of Pharmacoepidemiology and Drug Safety. In IntechOpen eBooks. https://doi.org/10.5772/intechopen.87642
9. Hodel, K. V. S., Fiuza, B. S. D., Conceição, R. S., Aleluia, A. C. M., Pitanga, T. N., Fonseca, L. M. D. S., Valente, C. O., Minafra-Rezende, C. S., & Machado, B. a. S. (2024). Pharmacovigilance in Vaccines: Importance, Main Aspects, Perspectives, and Challenges—A Narrative review. *Pharmaceuticals*, *17*(6), 807. https://doi.org/10.3390/ph17060807
10. Wasiullah, M. W. M., Yadav, P. Y. P., & Khan, R. A. K. R. A. (2025). Pharmacovigilance: Concept, Procedure and Information resources. International Journal of Pharmaceutical Research and Applications, 10(2), 2443–2452. https://doi.org/10.35629/4494-100224432452
11. Nousheen, A., Asra, A., Fatima, H., Nizami, N., Noureen, S., Ali, S. A., Tazneem, B. T., & Begum, S. Z. (2021). Pharmacovigilance. International Journal of Pharmaceutical Sciences Review and Research, 70(1). https://doi.org/10.47583/ijpsrr.2021.v70i01.006
12. Cascini, F. (2025). Secondary use of electronic health data. In SpringerBriefs in public health. https://doi.org/10.1007/978-3-031-88497-9
13. Chan, K. (2016). The Evolutional Development of Traditional Chinese Medicine (TCM) outside China Mainland: Challenges,Training, Practice, Research, and Future Development. World Journal of Traditional Chinese Medicine, 2(4), 6–28. https://doi.org/10.15806/j.issn.2311-8571.2016.0026
14. Kaeding, M., Schmälter, J., & Klika, C. (2017). Pharmacovigilance in the European Union: Practical Implementation across Member States. In Directory of Open access Books (OAPEN Foundation). https://doi.org/10.1007/978-3-658-17276-3
15. Khan, M. A. A., Hamid, S., Khan, S. A., Sarfraz, M., & Babar, Z. (2022). A qualitative study of stakeholders' views on pharmacovigilance system, policy, and coordination in Pakistan. Frontiers in Pharmacology, 13, 891954. https://doi.org/10.3389/fphar.2022.891954
16. Yadav, S. (2008). Status of adverse drug reaction monitoring and pharmacovigilance in selected countries. Indian Journal of Pharmacology, 40(7), 4. https://doi.org/10.4103/0253-7613.40235
17. Poluzzi, E., Raschi, E., Piccinni, C., & De, F. (2012). Data mining techniques in pharmacovigilance: Analysis of the Publicly Accessible FDA Adverse Event Reporting System (AERS). In InTech eBooks. https://doi.org/10.5772/50095
18. Raghuvanshi, S., Rahman, M. A., Posa, M. K., & Kumar, A. (2023). Identification of Novel Signals Associated with US-FDA Approved Drugs(2013) Using Disproportionality Analysis. Current Drug Safety, 19(3), 395–401. https://doi.org/10.2174/0115748863276447231108092936
19. Prevention, C. F. D. C. A. (2019). Antibiotic resistance threats in the United States, 2019. https://doi.org/10.15620/cdc:82532
20. Lu, Z. (2009). Information technology in pharmacovigilance: Benefits, challenges, and future directions from industry perspectives. Drug Healthcare and Patient Safety, 1, 35. https://doi.org/10.2147/dhps.s7180
21. Bhasale, A. L., Sarpatwari, A., De Bruin, M. L., Lexchin, J., Lopert, R., Bahri, P., & Mintzes, B. J. (2020). Postmarket safety communication for protection of Public Health: A comparison of regulatory policy in Australia, Canada, the European Union, and the United States. Clinical Pharmacology & Therapeutics, 109(6), 1424–1442. https://doi.org/10.1002/cpt.2010
22. Gawai, P. P. (2020). Introduction and evaluation of pharmacovigilance for beginners. International Journal of Scientific Reports, 6(10), 425. https://doi.org/10.18203/issn.2454-2156.intjscirep20204036
23. Anderson, N., &Borlak, J. (2011). Correlation versus Causation? Pharmacovigilance of the Analgesic Flupirtine Exemplifies the Need for Refined Spontaneous ADR Reporting. PLoS ONE, 6(10), e25221. https://doi.org/10.1371/journal.pone.0025221

24. Wu, C., Bell, C. M., &Wodchis, W. P. (2012). Incidence and Economic Burden of Adverse Drug Reactions among Elderly Patients in Ontario Emergency Departments. Drug Safety, 35(9), 769–781. https://doi.org/10.1007/bf03261973
25. Groenland, S. L., Ratain, M. J., Chen, L. S., & Gandhi, V. (2021). The right dose: from phase I to clinical practice. American Society of Clinical Oncology Educational Book, 41(41), 92–106. https://doi.org/10.1200/edbk_319567
26. Translational Research in Pharmacy: Bridging the lab and clinic. (2026). https://doi.org/10.71223/spp.book.trp
27. Beilmann, M. (2018). Optimizing drug discovery by Investigative Toxicology: Current and future trends. ALTEX, 36(2), 289–313. https://doi.org/10.14573/altex.1808181
28. Noah, B. A. (2000). Adverse Drug Reactions: Harnessing experiential data to promote patient welfare. Scholarship at Catholic Law (Catholic University of America), 49(2), 449–504. https://scholarship.law.edu/lawreview/vol49/iss2/5
29. Nunn, A., McCormack, S., Crook, A. M., Pool, R., Rutterford, C., & Hayes, R. (2009). Microbicides Development Programme: design of a phase III trial to measure the efficacy of the vaginal microbicide PRO 2000/5 for HIV prevention. Trials, 10(1), 99. https://doi.org/10.1186/1745-6215-10-99
30. 30.Duijnhoven, R. G., Straus, S. M. J. M., Raine, J. M., De Boer, A., Hoes, A. W., & De Bruin, M. L. (2013). Number of patients studied prior to approval of new medicines: A database analysis. PLoS Medicine, 10(3), e1001407. https://doi.org/10.1371/journal.pmed.1001407
31. Santoro, A., Genov, G., Spooner, A., Raine, J., & Arlett, P. (2017). Promoting and protecting public health: How the European Union Pharmacovigilance system works. Drug Safety, 40(10), 855–869. https://doi.org/10.1007/s40264-017-0572-8
32. 32.Om, D. A. O., Sarmiento, M., Gliklich, R., Leavy, M., Dreyer, N., Jacobs, V., Cutler, M., Day, J., Kirkham, J., Clarke, M., Williamson, P., Dokholyan, R., Muhlbaier, L., Falletta, J., Hammill, B., Hernandez, A., Peterson, E., Labresh, K., Gliklich, R., . . . Juarez-Garcia, A. (2020). Registries for Evaluating Patient Outcomes: A user's guide. https://doi.org/10.23970/ahrqepcregistries4
33. Cohen, I. G., Cohen, I. G., Price, W. N., II, Vokinger, K. N., Evans, B. J., Konnoth, C., Minssen, T., Biasin, E., Van Kolfschooten, H., Meszaros, J., Solaiman, B., Yu, H., Cohen, I. G., Aboy, M., Herder, M., Gerke, S., Robertson, C., Madeira, J. L., Epstein, W. N., . . . Shachar, C. (2022). The future of medical device regulation. In Cambridge University Press eBooks. https://doi.org/10.1017/9781108975452
34. 34.Shaikh, T., Surve, P. R., Wakchoure, S., Salve, S. L., Shaikh, A., & Sawant, P. A. (2026). A review article of pharmacovigilance and studies of clinical research for health care. International Journal of Pharmacy and Pharmaceutical Science, 8(4), 94–102. https://doi.org/10.33545/26647222.2026.v8.i4a.367
35. Poluzzi, E., Raschi, E., Piccinni, C., & De, F. (2012b). Data mining techniques in pharmacovigilance: Analysis of the Publicly Accessible FDA Adverse Event Reporting System (AERS). In InTech eBooks. https://doi.org/10.5772/50095
36. N, C. (2023). Pharmacovigilance in the age of Precision Medicine: Opportunities and challenges. International Journal of Science and Research (IJSR), 12(4), 1344–1348. https://doi.org/10.21275/sr23420171304
37. Maurya, V., Kumar, A., Budhiman, B., Babu, R., & Prajapati, K. (2026b). PHARMACOVIGILANCE PROGRAMME OF INDIA(PVPI): STRUCTURE, FUNCTION & IMPACT. JOURNAL OF ADVANCE AND FUTURE RESEARCH, 4(3). https://doi.org/10.56975/jaafr.v4i3.504693
38. Mssusa, A. K., Holst, L., Maregesi, S., & Kagashe, G. (2024b). Pharmacovigilance systems for safety monitoring of herbal medicines: assessment of the national regulatory authority, manufacturers and marketing authorisation holders in Tanzania. Journal of Pharmaceutical Policy and Practice, 18(1), 2438223. https://doi.org/10.1080/20523211.2024.2438223
39. Hodel, K. V. S., Fiuza, B. S. D., Conceição, R. S., Aleluia, A. C. M., Pitanga, T. N., Fonseca, L. M. D. S., Valente, C. O., Minafra-Rezende, C. S., & Machado, B. A. S. (2024c). Pharmacovigilance in Vaccines: Importance, Main Aspects, Perspectives, and Challenges—A Narrative review. Pharmaceuticals, 17(6), 807. https://doi.org/10.3390/ph17060807
40. Urbańczyk, K., Guntschnig, S., Antoniadis, V., Falamic, S., Kovacevic, T., Kurczewska-Michalak, M., Miljković, B., Olearova, A., Sviestina, I., Szucs, A., Tachkov, K., Tiszai, Z., Volmer, D., Wiela-Hojeńska, A., Fialova, D., Vlcek, J., Stuhec, M., Hogg, A., Scott, M., . . . Kardas, P. (2023b). Recommendations for wider adoption of clinical pharmacy in Central and Eastern Europe in order to optimise pharmacotherapy and improve patient outcomes. Frontiers in Pharmacology, 14, 1244151. https://doi.org/10.3389/fphar.2023.1244151
41. Valdiserra, G., Tillati, S., Lorenzoni, V., Gini, R., Turchetti, G., Giometto, S., Bartolini, C., Paoletti, O., Convertino, I., Ferraro, S., Cappello, E., Fornai, M., Lucenteforte, E., & Tuccori, M. (2021). 20thISoP Annual

Meeting "Integrated pharmacovigilance for safer patients" 8–10 November 2021 Muscat, Oman (Hybrid meeting). Drug Safety, 44(12), 1391–1470. https://doi.org/10.1007/s40264-021-01129-0
42. FIP Copenhagen 2025: Pharmacy practice research. (2025). Pharmacy Education, 25(4), 1–108. https://doi.org/10.46542/pe.2025.254.ppr.1108
43. Brahmer, J. R., Abu-Sbeih, H., Ascierto, P. A., Brufsky, J., Cappelli, L. C., Cortazar, F. B., Gerber, D. E., Hamad, L., Hansen, E., Johnson, D. B., Lacouture, M. E., Masters, G. A., Naidoo, J., Nanni, M., Perales, M., Puzanov, I., Santomasso, B. D., Shanbhag, S. P., Sharma, R., . . . Ernstoff, M. S. (2021). Society for Immunotherapy of Cancer (SITC) clinical practice guideline on immune checkpoint inhibitor-related adverse events. Journal for ImmunoTherapy of Cancer, 9(6), e002435. https://doi.org/10.1136/jitc-2021-002435
44. Hilgersom, W. J. A., & P, V. P. E. (2016). 16th ISOP Annual Meeting "'Pharmacovigilance for Safer Tomorrow'" Agra, India 16–19 October, 2016. Drug Safety, 39(10), 989–1042. https://doi.org/10.1007/s40264-016-0445-6
45. Gamil, N. M., Elsayed, H. A., Hamed, R. M., Salah, E. T., Ahmed, A. M., Mostafa, H. A., El-Shiekh, R. A., & Abou-Hussein, D. (2025). Insights from herb interactions studies: a foundational report for integrative medicine. Future Journal of Pharmaceutical Sciences, 11(1). https://doi.org/10.1186/s43094-025-00794-7
46. Glans, M., Midlöv, P., Ekstam, A. K., Bondesson, Å., & Brorsson, A. (2022). Obstacles and Opportunities in Information Transfer Regarding Medications at Discharge – A Focus Group Study with Hospital Physicians. Drug Healthcare and Patient Safety, Volume 14, 61–73. https://doi.org/10.2147/dhps.s362189
47. Kompa, P. M., Nagrale, S. N., Pondkule, A. V., Kumbhar, R. M., & Runje, S. S. (2026). Post-Marketing Surveillance and Pharmacovigilance: Regulatory responsibilities and emerging challenges. International Journal of Biological and Medical Research, 17(2). https://doi.org/10.65048/ijbmr.2026.17.2.8535.1037
48. Pashte, S., Shafeeque, A., Patil, D., & Ahire, D. (2026). An Overview of Materiovigillence in Medical Device Safety: Regulatory Framework, challenges, and Future Direction. International Journal of Innovative Research in Technology, 12(10). https://doi.org/10.64643/ijirtv12i10-194918-459
49. Crisafulli, S., Bate, A., Brown, J. S., Candore, G., Chandler, R. E., Hammad, T. A., Lane, S., Maro, J. C., Norén, G. N., Pariente, A., Russom, M., Salas, M., Segec, A., Shakir, S., Spini, A., Toh, S., Tuccori, M., Van Puijenbroek, E., Trifirò, G., & Pharmacovigilance, T. R. E. A. B. D. S. I. G. O. T. I. S. O. (2025). Interplay of Spontaneous Reporting and Longitudinal Healthcare Databases for Signal Management: Position Statement from the Real-World Evidence and Big Data Special Interest Group of the International Society of Pharmacovigilance. Drug Safety, 48(9), 959–976. https://doi.org/10.1007/s40264-025-01548-3
50. Honey, E., & Khan, A. R. (2025). Artificial Intelligence in Drug Discovery & Development. International Journal of Research and Scientific Innovation, 12(10), 1337–1349. https://doi.org/10.51244/ijrsi.2025.1210000118
51. Strom, B. L., Kimmel, S. E., & Hennessy, S. (2019). Pharmacoepidemiology. John Wiley & Sons.
52. Terry, A., Mottram, C., Round, J. A., Firman, E., Step, J., & Bourne, J. (2005). A safer place for patients: learning to improve patient safety. White Rose Research Online (University of Leeds, the University of Sheffield, University of York). http://eprints.whiterose.ac.uk/3427/1/NAO_2005_a_safer_place.pdf
53. Quality/AHRQ, A. F. H. R. A. (2014). Registries for evaluating patient outcomes: A User's Guide. Government Printing Office.
54. Al-Worafi, Y. M. (2020). Drug safety in developing countries: Achievements and Challenges. Academic Press.
55. Pharmacological breakthroughs in disease management. (2026). https://doi.org/10.71223/spp.book.pbdm
56. DiPiro, J. T., Yee, G. C., Haines, S. T., Nolin, T. D., Ellingrod, V., & Posey, L. M. (2023). DiPiro's Pharmacotherapy: A Pathophysiologic Approach, 12th Edition. McGraw Hill Professional.