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Integration of Real-World Evidence in Post-Marketing Pharmacovigilance: A Systematic Review of Global Regulatory Practices

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ABSTRACT

The integration of real-world evidence (RWE) into post-marketing pharmacovigilance has significantly transformed modern drug safety monitoring. Unlike randomized clinical trials, which are conducted under controlled conditions with limited populations, real-world data (RWD) provide insights into the actual use, effectiveness and safety of medicines across diverse patient groups and long-term clinical settings[1,2]. This systematic review evaluates the role of RWE in post-marketing pharmacovigilance from 2014 to 2024, with emphasis on major data sources, analytical methodologies, regulatory frameworks, practical applications and existing challenges[3,4]. A structured literature search was conducted using PubMed to identify peer-reviewed studies related to RWD and pharmacovigilance. The review highlights the contribution of electronic health records, administrative claims databases, patient registries, spontaneous reporting systems, digital health technologies and social media platforms in detecting and validating adverse drug reactions [5-8]. Key case studies, including rofecoxib, rosiglitazone, canagliflozin and COVID-19 vaccine-associated myocarditis, demonstrate the growing importance of RWE in regulatory decision-making and risk assessment [9,12]. The review also discusses challenges such as confounding bias, data standardization, privacy concerns and the need for methodological transparency [13,14]. Overall, the findings suggest that RWE serves as a valuable complement to traditional clinical trials by strengthening lifecycle drug safety surveillance and supporting evidence-based pharmacovigilance practices worldwide.

Keywords: Real-world evidence, Pharmacovigilance, Post-marketing surveillance, Drug safety, Electronic health records**,** Adverse drug reactions.

1.INTRODUCTION

Pharmacovigilance plays a critical role in ensuring the safety of medicines throughout their lifecycle by identifying, assessing and preventing adverse drug reactions after market approval[1,3]. Although randomized controlled trials (RCTs) remain the gold standard for establishing the efficacy and initial safety of pharmaceutical products, their controlled environments, restricted patient populations and limited duration often fail to capture rare, delayed or population-specific adverse events[2,4]. As a result, continuous post-marketing surveillance has become essential for evaluating the real-world safety profile of medicines across broader and more diverse healthcare settings[5].

The rapid expansion of digital healthcare systems has led to the generation of vast amounts of real-world data (RWD) from sources such as electronic health records, insurance claims databases, patient registries, pharmacy dispensing records, wearable devices and spontaneous adverse event reporting systems[6-9]. When systematically analyzed using epidemiological and statistical methods, these data generate real-world evidence (RWE), which provides valuable insights into drug utilization patterns, long-term safety outcomes, treatment effectiveness and patient-specific risk factors under routine clinical practice conditions [10,11].

Over the past decade, regulatory agencies including the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA) and World Health Organization (WHO) have increasingly recognized the importance of RWE in supporting pharmacovigilance activities and regulatory decision-making [12-15]. Real-world evidence has contributed to the identification of significant safety concerns, refinement of risk-benefit assessments, implementation of labeling changes and development of post-authorization safety studies [16,17]. Notable examples include the cardiovascular risk associated with rofecoxib, myocarditis following mRNA COVID-19 vaccination and amputation risks linked to certain sodium-glucose cotransporter-2 inhibitors [18-20].

Despite its growing importance, the integration of RWE into pharmacovigilance presents several challenges, including data heterogeneity, confounding bias, incomplete reporting, privacy concerns and the need for methodological transparency[21,22]. Ensuring the reliability and validity of observational evidence remains a major priority for researchers and regulators worldwide.

Therefore, this systematic review aims to evaluate the integration of real-world evidence into post-marketing pharmacovigilance between 2014 and 2024. The review focuses on major sources of RWD, analytical methodologies, regulatory frameworks, practical applications, current limitations and future directions in order to provide a comprehensive understanding of the evolving role of RWE in modern drug safety surveillance.

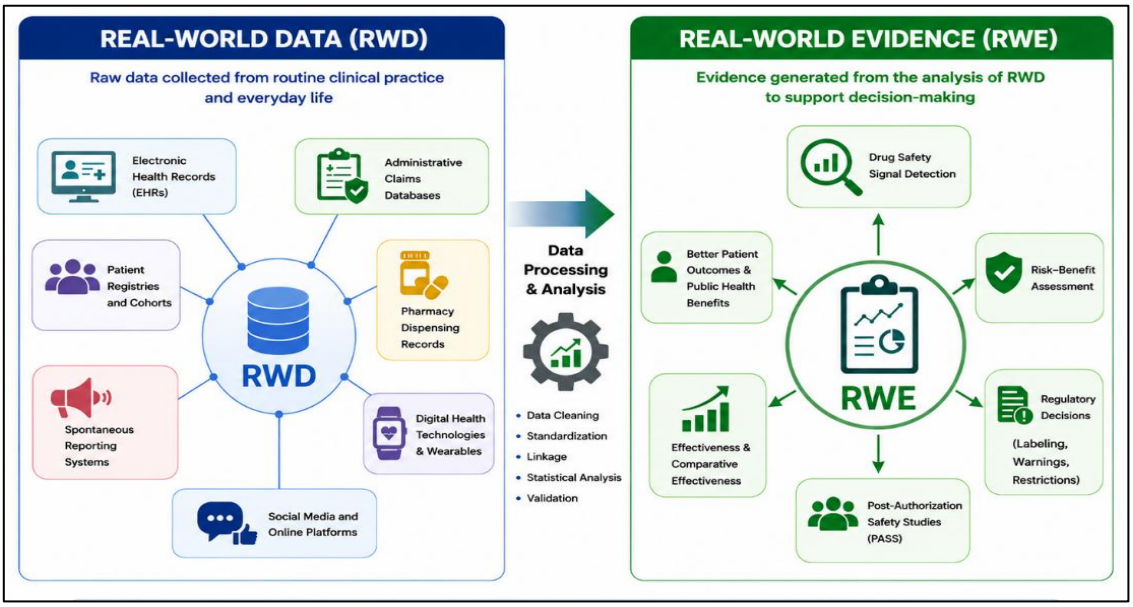

Figure 1. Transformation of real-world data (RWD) into real-world evidence (RWE) for improving pharmacovigilance and regulatory decision-making.

2. METHODS

2.1 Search Strategy and Information Sources

A systematic review of the literature was performed to evaluate the integration of real-world evidence in post-marketing pharmacovigilance. Relevant studies published between January 2014 and December 2024 were identified through a structured search of the PubMed (MEDLINE) database[23]. The search strategy was developed to capture studies focusing on real-world data applications in drug safety monitoring, regulatory pharmacovigilance and post-marketing surveillance.

The search was conducted using combinations of keywords and Medical Subject Headings (MeSH) terms including “real-world data,” “real-world evidence,” “pharmacovigilance,” “drug safety,” “post-marketing surveillance,” “electronic health records,” “administrative claims,” “signal detection,” “post-authorization safety study,” “FDA,” and “EMA.” Boolean operators such as AND and OR were used to combine search terms and improve retrieval of relevant studies.

2.2 Eligibility Criteria

Studies were included in the review if they met the following criteria:

- Published in peer-reviewed journals between 2014 and 2024,
- Focused on the application of real-world data or real-world evidence in pharmacovigilance,
- Discussed post-marketing drug safety surveillance, regulatory decision-making or safety signal evaluation,
- Included observational studies, methodological studies, regulatory reports or systematic reviews.

- And were available in the English language.

Studies were excluded if they:

- Focused solely on preclinical, animal or in vitro research,
- Were conference abstracts without complete full-text access,
- Consisted only of editorials, commentaries or opinion-based articles without scientific evidence
- Or lacked relevance to post-marketing pharmacovigilance.

2.3 Study Selection Process

All records identified through database searching were screened initially based on title and abstract. Duplicate records were removed prior to screening. Articles considered potentially relevant were assessed through full-text evaluation according to the predefined inclusion and exclusion criteria [24]. Studies fulfilling the eligibility criteria were included in the final qualitative synthesis.

2.4 Data Extraction and Organization

Data from the selected studies were collected and organized systematically. Information extracted from each study included author details, year of publication, country or region, source of real-world data, pharmacovigilance application, methodological approach, regulatory significance and major findings related to drug safety monitoring.

The extracted information was categorized into major thematic areas including:

- Sources of real-world data
- Analytical approaches for real-world evidence generation
- Regulatory frameworks
- Practical pharmacovigilance applications
- Challenges associated with real-world data
- And future directions in pharmacovigilance.

2.5 Data Analysis

Considering the heterogeneity among the included studies with respect to study design, data sources, methodologies and outcome measures, statistical meta-analysis was not performed[25]. Instead, the findings were analyzed qualitatively through narrative synthesis. The selected studies were critically reviewed to identify common trends, methodological advancements, regulatory perspectives and emerging challenges related to the use of real-world evidence in pharmacovigilance.

2.6 Reporting Standards

The overall review process was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines to ensure transparency, consistency and methodological rigor in study identification, selection and reporting.

3. RESULTS

Recent pharmacovigilance research indicates a significant expansion in the use of real-world evidence for post-marketing pharmacovigilance between 2014 and 2024. The findings highlighted the growing importance of real-world data sources, advanced analytical approaches and regulatory acceptance of real-world evidence in improving drug safety surveillance and decision-making.

3.1 Sources of Real-World Data in Pharmacovigilance

The reviewed literature identified multiple sources of real-world data used in pharmacovigilance activities. Electronic health records were among the most widely utilized sources due to their ability to provide detailed clinical information, including diagnoses, laboratory results, medication history and longitudinal patient outcomes[26,27]. Administrative claims databases were frequently used because of their large population coverage and standardized coding systems, making them valuable for detecting rare adverse drug reactions and evaluating long-term safety outcomes [28].

Patient registries and post-authorization safety studies were also commonly employed for structured long-term monitoring of specific drug-related risks [29]. Pharmacy dispensing records contributed to accurate exposure assessment and medication adherence evaluation [30]. In addition, spontaneous reporting systems such as the FDA Adverse Event Reporting System (FAERS) and EudraVigilance continued to play a major role in early signal detection and safety monitoring [31,32].Emerging digital health technologies, including wearable devices, mobile health applications and patient-reported outcome platforms, were increasingly recognized as supplementary sources of real-world data[33]. Several studies also explored the use of social media and online patient forums for identifying previously unreported adverse drug experiences [34].

3.2 Analytical Approaches for Real-World Evidence Generation

Recent studies reported substantial advancements in analytical methods used to generate reliable real-world evidence. Observational study designs, propensity score matching, target trial emulation, inverse probability weighting and self-controlled study methods were frequently applied to minimize confounding and improve causal inference [35-37].

Multiple studies highlighted the importance of combining multiple data sources and validating findings across independent datasets to strengthen evidence reliability [38]. Machine learning and artificial intelligence-based tools were also increasingly applied for signal detection, data mining and automated pharmacovigilance activities [39]. However, the reviewed literature emphasized that algorithm-generated findings should be supported by epidemiological validation before regulatory implementation [40].

3.3 Regulatory Applications of Real-World Evidence

Regulatory agencies including the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA) and World Health Organization (WHO) increasingly incorporated real-world evidence into pharmacovigilance frameworks and regulatory decision-making processes [12-15]. The reviewed studies demonstrated that real-world evidence contributed to label modifications, safety warnings, prescribing restrictions, risk mitigation strategies and post-marketing safety evaluations [16,17].

The FDA Sentinel Initiative and EMA real-world evidence programs were frequently highlighted as important milestones in the development of structured regulatory frameworks supporting the use of real-world data in drug safety monitoring [41,42].

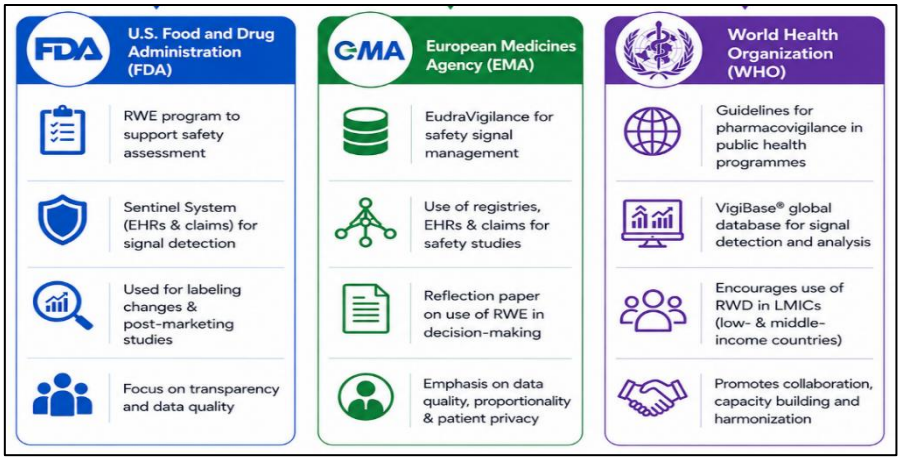

Figure 2. Regulatory frameworks established by the FDA, EMA, and WHO for the integration of real-world evidence in post-marketing pharmacovigilance and drug safety monitoring.

3.4 Challenges Identified in the Included Studies

Multiple pharmacovigilance investigations identified several challenges associated with the integration of real-world evidence into pharmacovigilance systems. Common concerns included incomplete or inconsistent data recording, confounding bias, underreporting of adverse events, lack of standardized data structures and difficulties in establishing causality in observational studies[43,44].

Privacy concerns, regulatory differences across countries and limited digital infrastructure in low- and middle-income regions were also recognized as barriers to large-scale implementation of real-world evidence-based pharmacovigilance systems[45]. Additionally, published studies highlighted the continued need for methodological transparency, standardized reporting practices and interdisciplinary collaboration to improve the reliability and acceptance of real-world evidence[46].

4. REPRESENTATIVE CASE STUDIES IN PHARMACOVIGILANCE

Table 1. Representative Case Studies Demonstrating the Role of Real-World Evidence in Pharmacovigilance

Drug / Product	Safety Concern Identified	Real-World Data Source	Evidence Generated	Regulatory Outcome	Significance
Rofecoxib (Vioxx)	Increased risk of myocardial infarction and stroke	Insurance claims databases, observational cohort studies, post-marketing surveillance reports	Observational analyses demonstrated elevated cardiovascular risk associated with prolonged rofecoxib use	Voluntary market withdrawal in 2004 and strengthening of cardiovascular safety monitoring	Demonstrated the importance of post-marketing pharmacovigilance in identifying serious adverse cardiovascular events not fully detected during pre-approval clinical trials
Rosiglitazone (Avandia)	Increased cardiovascular risk, particularly myocardial infarction	Administrative claims data, observational cohort studies, randomized trial meta-analyses	Combined real-world evidence and clinical trial analyses suggested increased cardiovascular complications	Regulatory restrictions, enhanced safety monitoring, and risk management strategies	Highlighted the role of integrated evidence in benefit–risk evaluation and regulatory decision-making
mRNA COVID-19 Vaccines	Myocarditis and pericarditis, especially among younger males	National vaccination registries, electronic health records, hospital databases	Large-scale real-world studies quantified the incidence, timing, and severity of myocarditis following vaccination	Label updates, revised vaccination recommendations, and public safety communication	Demonstrated the ability of real-world evidence systems to rapidly identify and evaluate rare adverse events during public health emergencies
Canagliflozin (SGLT2 Inhibitor)	Increased risk of lower-limb amputation	Claims databases, patient registries, post-authorization safety studies	Real-world analyses identified higher amputation risk among high-risk diabetic patients	FDA boxed warning and targeted risk mitigation measures	Showed the usefulness of long-term real-world monitoring in identifying uncommon but clinically important adverse effects
Hydroxychloroquine (COVID-19 Use)	Questionable safety and efficacy findings based on unreliable data	Proprietary multinational registry database (Surgisphere)	Published observational findings were later retracted because the underlying data could not be	Retraction of published study and reconsideration of treatment recommendations	Emphasized the importance of data transparency, auditability, and methodological rigor in real-world evidence research

			independently validated		
Hormone Replacement Therapy (HRT)	Misinterpreted cardiovascular benefits in observational studies	Large observational cohort studies including Nurses' Health Study	Observational studies initially suggested cardiovascular protection, later contradicted by randomized controlled trials	Revision of clinical guidelines and prescribing practices	Demonstrated the limitations of observational evidence and the impact of confounding bias in pharmacovigilance research

5. DISCUSSION

The findings of this systematic review demonstrate that real-world evidence has become an increasingly important component of modern pharmacovigilance systems [1-10]. The growing availability of healthcare databases, electronic health records, insurance claims data, patient registries and digital health technologies has significantly expanded the ability to monitor drug safety beyond the limitations of randomized controlled trials. Unlike pre-marketing clinical trials, which often involve carefully selected patient populations and controlled study conditions, real-world evidence provides insight into the actual use and safety of medicines in routine clinical practice across diverse populations and longer periods of observation.

Current evidence indicates that no single source of real-world data is sufficient to address all pharmacovigilance challenges. Electronic health records provide detailed clinical information but may contain incomplete documentation and inconsistencies in coding practices. Administrative claims databases offer large-scale population coverage but frequently lack detailed clinical parameters. Patient registries and post-authorization safety studies support structured long-term follow-up, whereas spontaneous reporting systems remain valuable for early signal detection despite limitations such as underreporting and reporting bias. The combined use of multiple data sources was consistently identified as an effective approach for improving the reliability and validity of safety assessments [38].

Advancements in analytical methodologies have further strengthened the role of real-world evidence in regulatory science. Approaches such as propensity score matching, target trial emulation, inverse probability weighting and self-controlled study designs have improved the ability to reduce confounding and enhance causal interpretation in observational studies[35-37]. In addition, the increasing application of machine learning and artificial intelligence has improved signal detection and large-scale data analysis. However, the reviewed literature emphasized that automated findings should always undergo epidemiological and clinical validation before influencing regulatory or clinical decisions.

Several important case studies highlighted the practical impact of real-world evidence in pharmacovigilance. The identification of cardiovascular risks associated with rofecoxib and rosiglitazone demonstrated how observational evidence can contribute to regulatory action, including prescribing restrictions and market withdrawal. Similarly, real-world evidence played a major role in evaluating myocarditis risk following mRNA COVID-19 vaccination and refining risk communication strategies during the pandemic. In contrast, the Surgisphere controversy involving hydroxychloroquine illustrated the serious consequences of using non-transparent and non-validated datasets in public health decision-making.

Despite substantial progress, multiple challenges continue to limit the widespread implementation of real-world evidence in pharmacovigilance. Data heterogeneity, missing information, confounding bias, privacy concerns, lack of interoperability and differences in regulatory standards across countries remain important barriers[43-46]. In addition, vulnerable populations such as pregnant women, pediatric patients, elderly individuals and economically disadvantaged communities are still underrepresented in many healthcare databases and observational studies.

Overall, the findings of this review suggest that real-world evidence should be considered a complementary approach rather than a replacement for randomized clinical trials. When supported by robust methodology, transparent reporting and regulatory oversight, real-world evidence has the potential to significantly strengthen post-marketing drug safety surveillance, improve regulatory decision-making and contribute to safer and more personalized healthcare practices worldwide.

6. CONCLUSION

The present systematic review highlights the growing significance of real-world evidence in strengthening post-marketing pharmacovigilance and modern drug safety surveillance. The integration of real-world data from electronic health records,

administrative claims databases, patient registries, spontaneous reporting systems and digital health technologies has substantially improved the ability to identify, evaluate and monitor adverse drug reactions in routine clinical practice[1,5].

Current evidence suggests that real-world evidence complements traditional randomized clinical trials by providing information on long-term safety, rare adverse events, treatment effectiveness in diverse populations and real-world medication utilization patterns[2,10]. Regulatory agencies such as the FDA, EMA and WHO have increasingly recognized the value of real-world evidence in supporting safety assessments, regulatory decision-making, labeling modifications and risk management strategies[12,15].

Despite these advancements, several challenges remain, including data quality issues, confounding bias, lack of standardization, privacy concerns and underrepresentation of vulnerable populations. Addressing these limitations through improved methodological rigor, transparent reporting practices, standardized data frameworks and interdisciplinary collaboration is essential for ensuring the reliability of real-world evidence in pharmacovigilance.

Overall, the integration of real-world evidence represents a major advancement in lifecycle drug safety monitoring and is expected to play an increasingly important role in future pharmacovigilance systems and regulatory science.

7. LIMITATIONS OF THE REVIEW

This review has certain limitations that should be acknowledged. First, the literature search was limited to the PubMed database and English-language publications, which may have excluded relevant studies published in other databases or languages. Second, the included studies showed considerable heterogeneity in study design, data sources, analytical methods, and outcome measures, which limited direct comparison among findings.

Additionally, because the review primarily relied on published literature, the possibility of publication bias cannot be excluded. Some unpublished negative findings or unsuccessful real-world evidence applications may not have been captured in the available literature. The rapidly evolving nature of digital health technologies and pharmacovigilance frameworks may also result in newer developments emerging after the completion of the literature search period.

Furthermore, variations in healthcare systems, regulatory practices and data accessibility across different countries may affect the generalizability of the findings presented in this review.

8. FUTURE PERSPECTIVES

The future of pharmacovigilance is expected to be increasingly driven by advanced real-world evidence generation and digital healthcare integration. The continued development of interoperable healthcare databases, common data models and federated analytics is likely to improve large-scale safety monitoring while preserving patient privacy and data security.

Artificial intelligence, machine learning and natural language processing technologies are expected to further enhance automated signal detection, adverse event prediction, and large-scale pharmacovigilance data analysis. The integration of wearable devices, mobile health applications, genomics and patient-reported outcomes may also provide more personalized and real-time approaches to drug safety monitoring.

Future pharmacovigilance systems should focus on improving data quality, methodological transparency, international collaboration, and regulatory harmonization. Greater inclusion of underrepresented populations in real-world datasets will also be important for ensuring equitable and comprehensive drug safety evaluation.

As healthcare systems continue to digitalize globally, real-world evidence is expected to become an integral component of regulatory decision-making and patient-centered pharmacovigilance practices.

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