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Leveraging Real-World Evidence in Pharmacovigilance Reporting

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Abstract

The real-world evidence (RWE) has emerged as significant to strengthen the pharmacovigilance reporting and to understand the safety and efficacy profile of the drugs in the uncontrolled populations other than trial participants. This article focuses on the possibilities of using RWE to enhance the analysis of monitored drugs' safety and the decision-making of the regulatory agencies. And highlights the use of information from the electronic health records, patient registries and social media to better detect and study ADRs. Through the use of big data analysis and AI, RWE makes it possible for the identification of ADRs that may not manifests itself during the clinical trial period. From this article, concerns related to RWE are also discussed with regard to data quality, privacy, and the necessity for the consistency of methods and protocols in the use of RWE on the field of pharmacovigilance practices. In addition, it emphasises that RWE can be valuable in enabling risk management and directing the actions of the regulators to improve patient safety. This review therefore supports the integration of real-world evidence into the structure of pharmacovigilance in order to have a more progressive model to the existing safety program. The application of real data by the health care providers and regulators can therefore assist in coming up with the correct measures to protect the public.

Keywords: Adverse Drug Reactions, Data Quality, Machine Learning, Patient Safety, Real-World Data, Regulatory Decision-Making.

1 INTRODUCTION

There is a remarkable shift to the world of reporting of pharmacovigilance with the incorporation of real-world evidence. This transfer influences the role and responsibility that the healthcare professionals and the regulatory agencies play in evaluating the risks related with the drug. Substantial advancements are also identified on data mining, electronic health records, and other real-world data resources as improving the detection and assessment of ADRs beyond traditional approaches. Real-world evidence is now influencing the disposition of clinical trials and interpretation of those trials' results, by offering insights into outcomes of drug use in different populations. This approach to pharmacovigilance gives a broader perspective of the performance of the drugs in conditions that may

not be easily rotined under research circumstances. Since the regulatory agencies are starting to pay attention to the value of real-world data, there is the need to find out how such data could be useful in enhancing patient safety as well as the drug development processes (Gallifant et al., 2024).

2 THE RISE OF REAL-WORLD EVIDENCE

Real-world evidence (RWE) has proved to be of great value for reporting in the domain of pharmacovigilance beyond conventional randomized controlled trials (RCTs) by overcoming some of their downsides. Consequently, it has implications on how health care practitioners and pharma regulatory apply drug safety and efficacy across different patients' populations. Figure 1 displays the Rise of Real-World Evidence.

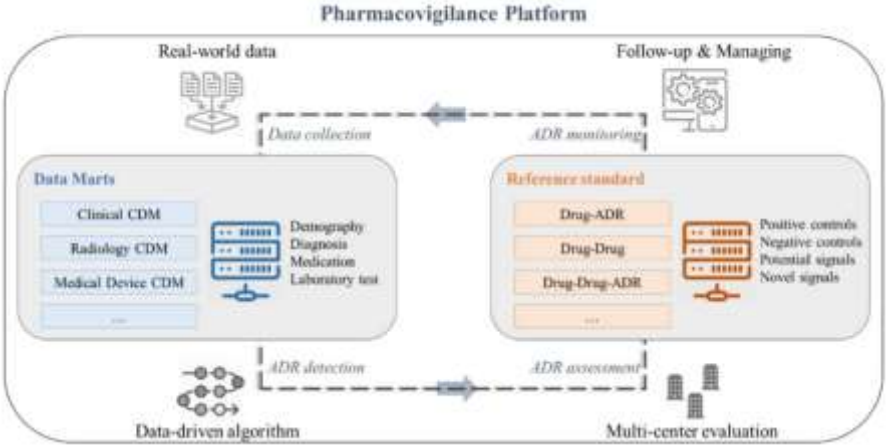

Figure 1: The Rise of Real-World Evidence

Limitations of RCTs

Although RCTs are widely used as the research model to assess drug efficacy, the trial has several drawbacks when applied to the question of drug safety and representative effectiveness. RCT applies random patient populations to treatment with carefully prescribed periods of treatment. In particular, drugs are administered to so many more extensive schedules by patients with several chronic conditions at a time in the real world.

It is a feature of RCTs to sample for efficacy, and yet are usually under-sampled for harm, especially in situations where such harm is relatively rare. This limitation assumes special importance for broadly used medications applied for the management of frequent illnesses, in which distributions of uncommon side effects may be critical.

Besides, RCTs runs the risk of including a relatively homogenous sample of participants who may not necessarily be representative of the population at large. The trials that investigate lipid-lowering therapy show that women are less likely to be involved than their representation in coronary events suggest. Older people are also excluded from trials for drugs that treat ischemic heart disease, though this problem is widespread in this age group. There are also large racial and ethnic disparities and therefore limited ways to address potential future harm for certain groups (Patadia et al., 2024).

Definition of RWE

Real-world evidence (Figure 2) is clinical evidence on a medical product's safety and efficacy realised using real-world data, which is derived from normal clinical practice. Thus, RWD comprises all data that are collected within daily practice and in contrast to RCTs in daily practice, e.g. EHRs, claims and billing processes, product and disease registries as well as data from mobile devices of patients.

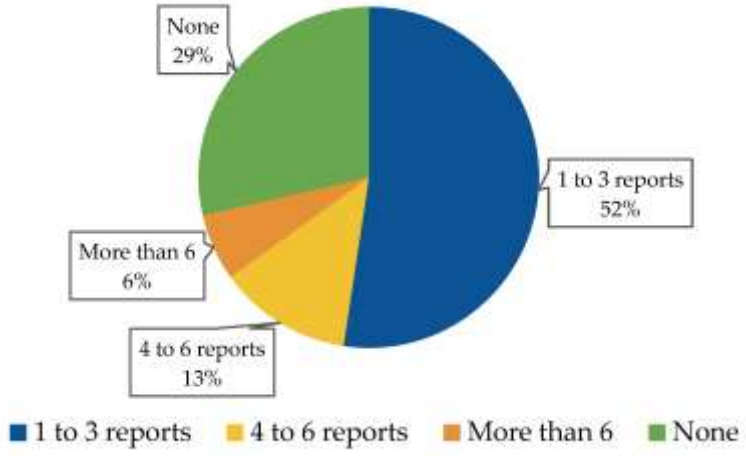

Figure 2: Definition of RWE

Thus, according to the U. S. Food and Drug Administration (FDA), the definition of RWE is "the clinical data about utilization and therapeutic value or threat of a medical product being derived from RWD." This evidence can be generated through different study designs, including prospective and retrospective cohort studies, case-control studies, and pragmatic clinical trials.

Potential Applications

RWE has numerous potential applications throughout the drug development and approval cycle. It has been extensively used in post-marketing surveillance to generate pharmacovigilance data. Recently, its applications have expanded to other stages of drug development and approval.

- Optimizing RCT Design: RWE can be used to optimize the design of RCTs, potentially leading to shorter trial durations and cost savings.
- Complementing RCT Findings: RWE can fill gaps in existing clinical knowledge by providing insights into drug performance in diverse, real-world settings.
- Regulatory Decision Support: Increasingly, RWE is being utilized to support clinical and regulatory decisions, including new drug approvals, supplementary approvals, and label revisions.
- Exploring Various Health Aspects: RWE studies have been used to investigate epidemiology, disease burden, treatment patterns, safety, treatment outcomes, long-term outcomes, and patient-reported outcomes such as satisfaction, quality of life, and medication adherence.

- Identifying Unexpected Side Effects: Data from EHRs and patient-generated sources, while more challenging to analyze, can potentially reveal more unfiltered information about unexpected side effects of medical products.

While RWE provides valuable insights, it's important to note that it complements rather than replaces RCT findings. RCTs remain the gold standard for assessing drug safety and efficacy in controlled settings. However, RWE represents the outcome of variable treatment patterns in real-world scenarios, thus enhancing the overall evidence base for medical products.

The increase in RWE affects the pharmacovigilance reporting by enriching them with additional information from various population subsets as well as scenarios. This paper highlights the rationale for understanding how various stakeholders can harness the potential of RWE effectively and optimise the use of this approach in enhancing patient safety and optimising drug development processes as the above-mentioned regulatory agencies already acknowledged the importance of the concept (Choong et al., 2024).

3 SOURCES OF REAL-WORLD DATA

Real world data (RWD) is enormously important for pharmacovigilance reporting as the data source in addition to clinical trials. These sources include but are not limited to the following; It comprises different patients' views about their experiences during treatment and the results that they obtained.

Electronic Health Records

Electronic Health Records (EHRs) have lately have provided substantial information type of RWD (Figure 3). Empowering these digital records we get huge patient data such as demographics, diagnosis, medications, operations, lab tests, and essential signs. EHR records reflect patients' complete data, and, therefore, using the patients cohort reaching millions, researchers can collect data of different populations.

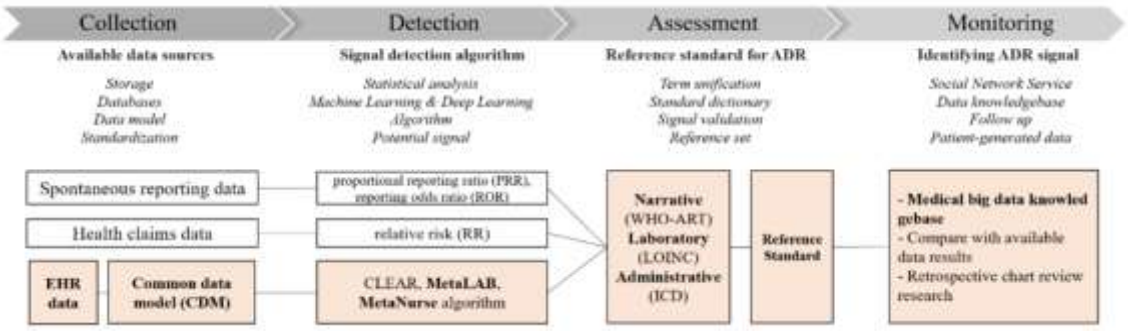

Figure 3: Sources of Real-World Data

That is why there is a stimulus, for example, The Health Information Technology for Economic and Clinical Health (HITECH) Act, which has contributed to the increase in the use of EHRs. This has resulted into the formation of large databases which can be utilized for pharmacovigilance functions. EHRs offer several advantages:

- Longitudinal data collection
- Recording of unscripted ‘ambulatory care’ visits and admissions
- More diversified group of patients
- Detailed clinical information (displays in figure 4)

This fall provides a direction on how to apply EHR data, but several challenges are observed: data quality problem, variability in documentation, unstructured data/semantically rich clinical notes, and methods of extracting valuable data from the EHR.

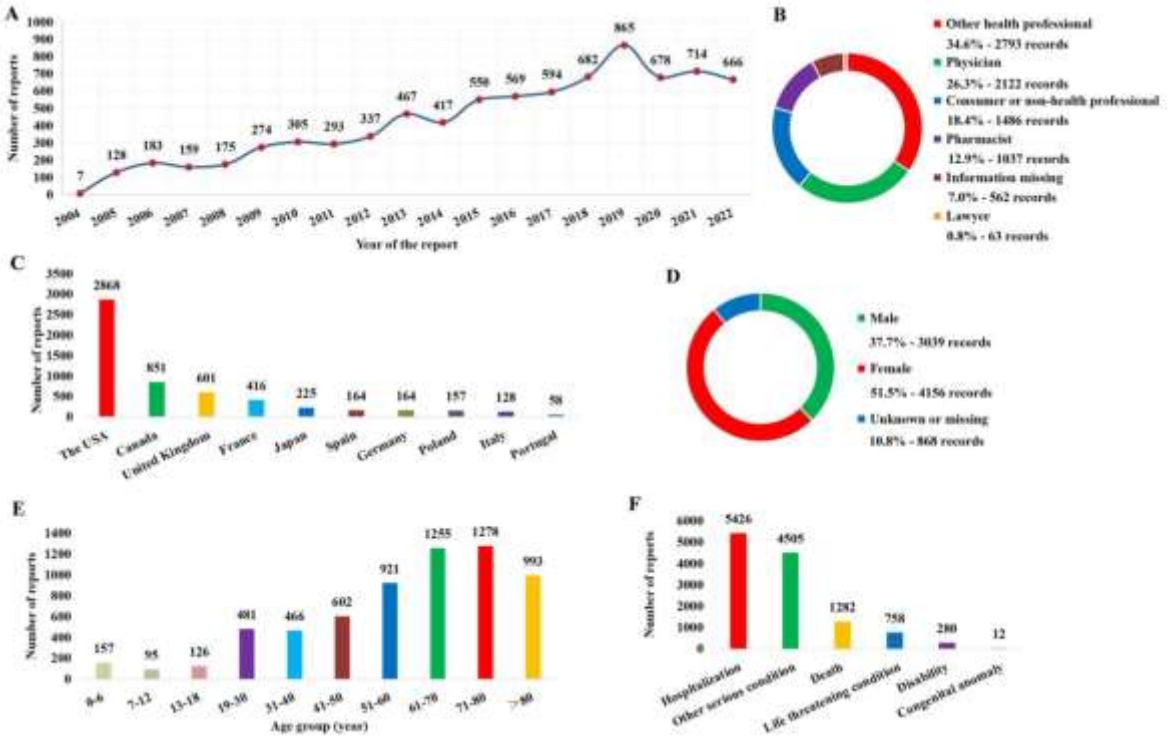

Figure 4: Detailed Clinical Information

Claims Databases

Another valuable source of RWD is claims database as well as billing and administrative data sources and health insurers. These databases helps to learn about the long-term patient profiles and treatment practices, healthcare usage, and results encompassing extensive number of patients.

Key features of claims databases include:

- In particular, it is worth mentioning the permissive approach to the definition of patient populations.
- Long-term follow-up data
- Data on health care expenditure and consumption

The U. S. Food and Drug Administration’s Sentinel Initiative uses claims data for safety monitoring to show the value of this data in safety decisions.

Wearables and Apps

Wearable devices and mobile health application technologies have added a new dimension in collection of RWD. They provide data that is otherwise hard to obtain concurrently with continuous and real time monitoring of different health factors within different clinical settings.

Wearables and apps offer several advantages:

- Intermittent and systematic data gathering and analysis in the real-world contexts
- Patient-generated health data
- Forecast for the possibility of early diagnosis of undesirable outcomes
- Better patients' involvement into their treatment

As with most promising tools, there are concerns about data admissibility, patients' privacy issue, and how to fit these data into conventional healthcare systems.

Patient Registries

Patient registries are assemblies of data that can be systematically gathered and arranged on particular patient populations as they progress chronologically. They are formed to give more information in regards to diseases and its evolution, the efficacy of certain therapies, and survivorship profiles.

Key characteristics of patient registries include:

- As much as possible, present a disease-specific view on child health.
- Standardized data collection
- Long-term follow-up
- Potential for international collaboration

For example, the European Cystic Fibrosis Society (ECFS) Registry is collecting data on cystic fibrosis patients across Europe and contributes to epidemiological studies as well as to public health planning.

All these sources have their specific strengths, however, they also have their specific limitations when used for data integration, quality control and analysis. This shows that utilization of the presented various forms of the RWD sources influence the improvement in the reporting of pharmacovigilance and hence patient safety as well as better informed regulation decision making (Bansal).

4 METHODOLOGIES FOR RWE GENERATION

The real-world evidence generation encompasses a number of approaches that seeks to turn real-world information into usable information for clinical practice. These approaches affect the way in which outcomes of data that is gathered from ordinary health care delivery is examined and analyzed.

Three primary methodologies have emerged as key tools in RWE generation: there are observational researches, pragmatic trials, and synthetic control groups.

Observational Studies

Observational studies play a crucial role in RWE generation by analyzing data from sources such as electronic health records, claims databases, and patient registries. These studies do not involve preassigned interventions or exposures, allowing researchers to examine real-world treatment patterns and outcomes. Figure 5 displays the observational studies.

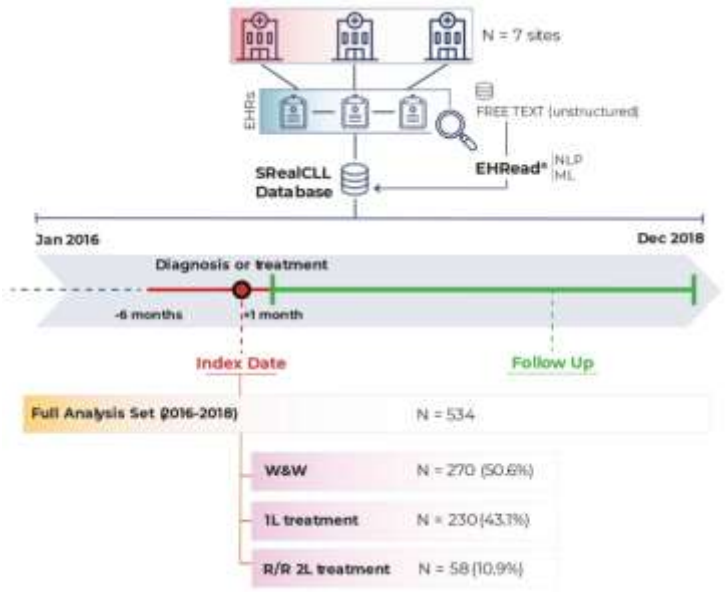

Figure 5: Observational Studies

There are several types of observational studies:

- Cross-sectional studies: These assess exposure and outcome at once in a given population at a given period of time. They are particularly valuable in the assessment of prevalence and moreover, hypothesized causes of diseases.
- Case-control studies: Normally cross-sectional, such studies satisfy case definition by enlisting persons with a given result (cases) and contrasted with those without the result. Researchers then have to go back in time in order to search for possible causes.
- Cohort studies: These assess the extent to which exposure or risk factors are related with the occurrence of the disease in the future. Cohort studies can be of two types the prospective or concurrent and retrospective or non-concurrent which monitors groups of exposed and unexposed people over a certain period of time.

One consider the following; the observational study is capable of dealing with large number of patients, it does give long-term follow-up and doesn't restrict the patients to be of a homogenized group. But they are accompanied by some issues concerning data quality, bias potentiality, and high-order statistical analysis in order to control confounding.

Pragmatic Trials

Pragmatic randomized controlled trials (RCTs) are attempted to address the gap that exist in between, the concept RCTs and clinical practice RCTs. These trials explore the interventions in real-life settings therefore maximizing on external validity while the randomization of the participants' ensures some internal validity.

Key features of pragmatic trials include:

- The eligibility criteria should be general so that they are applicable to the different patient populations across various settings.
- Choice of flexible implementation approaches and compliance to the programme intervention
- Application to PRM of clinically meaningful outcomes
- Little interferences with the habitual patients' care approaches
- What makes the process less pragmatic is the multifactorial PRECIS-2 tool that enables the researchers to assess the extent of pragmatism in trials in nine dimensions that are scaled from 1 as very explanatory to 5 as highly pragmatic. This tool is used in the design of trials that seek to capture real life scenarios while at the same time ensuring the controlled environment requisites of science.

Interactive trials operate at the level of choices and shape the choice of pragmatic management strategies based on data on comparative effectiveness of clinical options in real-world conditions. They are of particular relevance when the efficiency of the existing therapies is at the center of attention, as well as when the corresponding policies must be determined.

Synthetic Control Arms

Synthetic control arm is another novel method of RWE generation, which may be especially helpful in cases when the classic approach to designing control group is problematic. This methodology takes historical or external data to form comparator group probably minimizing the use of placebo arm in clinical trials.

Key aspects of synthetic control arms include:

- Use of real-life data from EHRS, claims repositories and historical trials data Full Name of resource:
- Sophisticated analytical and mathematical tools for the identification of the study population with outside information
- Opportunity to optimize the time needed for developing the drugs and receiving permissions for the usage in the case of the oriented disease states, on which there are no effective treatments.

Synthetic control arms are another significant point of concern which has attracted attention of the regulatory agencies in recent times. For instance, there are Single-Arm Trials supported by Synthetic Comparator Data that make the FDA approve drugs. A positive effect is realized in aspects of trial cost, development time and bringing about of therapy to patients.

But some issues are still present: how to guarantee dataset's quality, how to control some potential selection biases, and how to establish unified criteria for assessment of synthetic control arms? This methodology is bound to gradually develop over time; therefore, engagment from the involved stakeholders will be vital for the determination of its effectiveness and ideal application in RWE generation (Lee et al., 2024).

5 RWE IN DRUG SAFETY MONITORING

Real-world evidence (RWE) affects the improvement of drug safety in a medicinal product's entire life cycle shows in figure 6. Because knowledge about a medicine accumulates in pre-clinical, clinical, and post-marketing stages, pharmacovigilance systems are aimed to search for such 'signals' using various information sources.

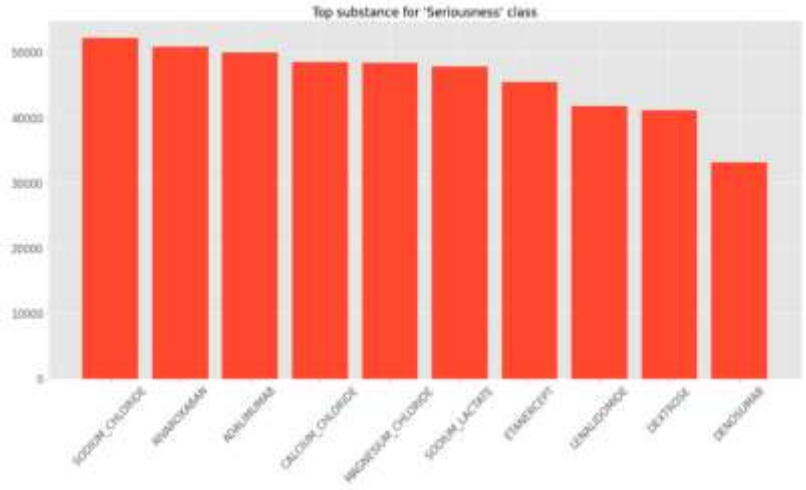

Figure 6: RWE in Drug Safety Monitoring

Post-Marketing Surveillance

Pharmacovigilance data has therefore frequently been collected using post-marketing surveillance. What has come to light is that RCTs insufficient for understanding the safety profile of a medical product. Effects which are not evident in trials are usually experienced in normal clinical practice. From this realization, the regulatory authorities have required manufacturers to gather safety related information after marketing approval through Phase IV or post-marketing surveillance (PMS) studies that are basically RWE studies.

Real-World Data source (RWD) including electronic health records (EHRs) and Patient Reported Outcomes Measure (PROMs) have broadened Post Marketing Surveillance. Though these sources can be characterised as unstructured data compared to structured data, they are equally easier to interpret

and may provide more raw, unadulterated data about adverse effects of medical products. For example, a research done in 2019 extracted information obtained from social media to capture cutaneous adverse drug reactions to cancer drugs about seven months earlier than their documentation in the news. This study also proffered new side effects which have not been observed by other present day studies (Sun et al., 2024).

Signal Detection

In the context of pharmacovigilance signal detection is very important and RWE has introduced new methods for it. Originally, signals for most of the marketed drugs and vaccines have been mainly generated by SRS that have been in existence since the 1960s. However, these systems are not without their drawbacks, some of which have been known to include, under reporting, stimulated reporting and others.

To overcome these shortcomings, new new measures, referred to as quantitative, or measures of disproportionality, emerged at the beginning of the new millennia. These procedures offer a scientific way of passing through the vast drug-event pairs and directing clinical scrutiny onto the concepts that are likely to be the remaining new 'signals of a suspected causality'.

Thus, RWD, especially from source electronic healthcare databases including insurance claims and EHRs is another technique to signal detection besides SRS. These longitudinal healthcare databases offer a vast source of data on the utility of a medical product and its risks or otherwise accrued systematically on millions of patients over years. They offer several advantages over spontaneous reports, including:

- The probability of risk estimates was considered to be the most important competency.
- Baseline assessment of patient and the assessment conducted after exposure to the targeted stimuli that has to be captured.
- Data on comparators to be used for matching or statistical control.
- Error-free data capture for systemically variable data.

Nonetheless, such potential advantages have not made the routine utilization of RWD for systematic signal detection frequent. Nevertheless, the conditions for testing signal detection in RWD have never been better due to the availability of data and improvement in computing and analytics.

Risk Evaluation

It will be seen that RWE has implications on advancing risk assessment in pharmacovigilance. In light of this, real-world data offers benefits in assessing risks with the possibility of enabling evaluations of vast amounts of information then the current method. This is particularly important when seeking to detect low incidence complications, event that may affect a subgroup of the patients or those that may manifest after prolonged drug use.

The usage of EHRs and insurance claims data, social media data has provided for a more efficient and effective approach to risk assessment. For instance, the FDA's Sentinel System uses EHRs and insurance claims data in distributed data networks of participating institutions to expand the Agency's pharmacovigilance infrastructure.

In addition, those in the clinical trial field can learn from RWE on how to enhance study design and manage the processes of patient recruitment. RWD, and especially EHR data, have the potential of helping in the identification of untapped clinical needs, and in attracting clinical populations that are most likely to benefit from new treatments. These have an effect on enhancing the actuality as well as the efficiency of the clinical trials and thus improving the evaluation of risk.

Consequently, RWE has offered a fresh approach in managing drug safety in that it offers a clearer picture of the position of a product in broader community scenarios. In the development of this new field, the combinations of RWE in PV reporting play role in the development of patient safety and improved decision by the regulators (Wei et al., 2024).

6 REGULATORY LANDSCAPE FOR RWE

The standards of the use of RWE are still developing, and all major regulatory agencies around the world have acknowledged the value of RWE at various stages in a medicine's lifecycle. The shift affects how the regulatory authorities think regarding the development of drugs, approval of the drugs and even post-marketing regulation.

FDA's RWE Program

It can be noted that the U. S. Food and Drug Administration (FDA) has also made efforts to incorporate RWE as one of the key aspects for the regulation of drugs and medical devices. The agency has set up the RWE program to analyze involving real-world data (RWD) with a view of bringing about evidence for regulatory choices. This program is designed to assess the ability of RWE strengthen deficiency of clinical trial and contribute to the assessment of drug safety and efficacy in the various populations.

EMA's Initiatives

EMA has also grown in its ability to integrate RWE into its approval procedures over the past several years. The agency has set up a coordination centre known as the Data Analysis and Real World Interrogation Network (DARWIN EU), which offers timely accurate evidence on the utilisation, safety and efficacy of medicinal products from real world health care databases in European Union. With regards to this initiative, there are effects on increasing the EMA's capacity in obtaining and processing RWD from different sources.

Now in its second year, the DARWIN EU network has increased from 10 to 20 partners, providing access to patient data of roughly 130 million via thirteen European nations. This growth has an effect

on the broadening of the range of additional RWD and their further diversification, which in turn opens up new opportunities for more detailed studies.

International Collaboration

Being aware of the international character of drug development and regulation, international cooperation has become an important aspect in the RWE field. Therefore, the International Coalition of Medicines Regulatory Authorities (ICMRA) has significantly contributed towards enhancing collaboration of regulatory bodies globally.

Is on June 2022, ICMRA conducted a workshop in which experience outcomes of getting and employing RWE in medicine appraisal and what resulted from the communication were briefs. From this event, participants were drawn to appreciate the need to achieve consistency in the use of RWE across the various regulatory regions.

In order to advance this aim, the ICH already issued a reflection paper in June 2024. The purpose of this paper is to align the RWE terminology and to provide the overarching guiding principles for planning and reporting of studies using RWD for informing regulatory decisions internationally.

Secondly, the guideline M14 matching strategy: Non-interventional pharmacoepidemiological studies for safety assessment of medicines Draft prepared for Consultation is available until August 30, 2024. This guideline influences the world-wide provision of recommendations and ideals in pharmacoepidemiologic studies employing real-world data.

Still, some barriers can be still seen when it comes to incorporating RWE in to the regulatory sphere. These include the requirements for other types of data, including the secondary care database, claims database and registries from other parts of Europe. There is also identified disparity in the level of RWE generation capability and capacity in the regulatory agencies and the rest of the healthcare stakeholders.

In the future, the cooperation with the RWE agencies and other industry's members and healthcare providers will be essential to create the more effective and solid framework for the implementation of the pharmacovigilance reporting and RWE in the regulatory decision-making.

7 CHALLENGES IN LEVERAGING RWE

The availability of the real-world data (RWD) along with their diversity presents new possibilities to gain real-world evidence (RWE). Nevertheless, there are several difficulties that do not allow the effective use of RWE for filling out PV reports and for making regulatory decisions.

Data Quality and Standardization

Some of the issues, which arise in the process of using RWE, are related to the data quality and their comparison with the data from other sources. Despite the fact that health care is situated in digital environment and majority of data are electronic health records, most of these databases represent health care better for administrative and billing purposes than for researchers and RWE generation.

Consequently, they are usually not comprehensive, and may contain bias inherent to the chosen methodology. Due to the peculiarities of the data sources including EHRs, claims data base and patient registries it is challenging to qualify the data with a certain level of certainty.

Appraisal of RWD is difficult, time consuming, and costly mainly because there is little visibility into the data set and its quality until after it has been purchased. Such lack of transparency can result to ineffectiveness in the procurement and use of data in decision making. Also, studying various types of data obtained even when using protocols makes the reliability and validity of data arising out of RWD questionable.

To overcome these problems, some firms have even more developed the superior capabilities to evaluate and purchase RWD. The more complex methods, as for example the outlier detection or the automated gap analyses with dashboards, will point at data quality and missing values. Current data pre-processing techniques such as natural language processing (NLP) and semantic ontology are being employed in removing noise in UDTs especially in EHR considering that different physicians have different ways of documenting their observations.

Bias and Confounding

Several issues arise in RWE studies as far as bias and confounding are concerned. As opposed to randomized controlled trials in which treatment allocation is done at random, many observational studies based on RWD are vulnerable to confounding by indication. This is perhaps because treatments tend to be allocated according to the characteristics of the patients which makes the study non-randomised.

Thus, adjustment by frailty affects real-world evidence based on PBM, especially among older adults. There may be potential source of bias due to a permitted enrolment of participants to the cohort at some time during the course of treatment hence immortal-time bias.

To avoid such biases, researchers should apply proper study design and analyte methods of data collected in the study. Nevertheless, it should be stressed that, even advanced approaches may not include all types of bias in observational researches.

Privacy and Ethics

Several privacy and ethical issues are endemic to the application of RWD for research and regulatory objectives. In addition, the privacy of patients can be at high risk as various databases including EHRs, Smartphones, wearables, and insurance databases are interrelated.

Caring for the privacy of patients is an important responsibility that is assigned to representatives of academic research and medical facilities. They need to be at a position to protect the identities of the patients in the data they share with the industry partners, other institutions, and researchers. This means putting in place sound mechanisms on sharing of data, de identification and consent.

As with most retrospective kinds of study utilizing archived data, it often may not be easy or even feasible to seek consent from the participants. In such cases, an ethics committee may allow the exclusion of the informed consent condition on certain grounds such as when conducting research present negligible risk to the participants and the research cannot proceed without exclusion of the condition.

Solving these issues poses a question of sharing the tasks among the researchers, clinicians, regulatory authorities, and patients. As RWE expands in use the construction of standardized guidelines for data quality assurance, data bias minimization and ethical data utilization affects the increase in the credibility and acceptability of RWE in pharmaceutical reporting and regulatory decision making.

8 BEST PRACTICES FOR RWE IN PHARMACOVIGILANCE

Real world evidence (RWE) in pharmacovigilance should be governed and analysed through data and analytical strategies and should engage all stakeholders. These best practices effects the improvement of the value of RWE into the evaluation and decision making of the drug safety concern.

Data Governance

The reliability and credibility of generated measurements depends on the efficiency and effectiveness of maintained data governance (DG) policies that are reflected in utilizing real-world data (RWD) for pharmacovigilance. The path towards creating modern data environments should be based on the establishment of business functions replaced by operationalized data lakes. This approach enables user to get a centralized source of a broad array of data sets.

To achieve this, organizations should:

- A similar change of approach must be done toward data catalogs according to business values and a clear map of RWE sources.
- Use the concept of pipelines and develop processes which can be easily reusable to extract, transform and load data assets.
- Create and own insights by connecting data assets that can be applied organisation-wide.
- Develop a set of automated procedures for tracking and handling frameworks of data access, metadata, data lineage, and compliance that are industrialized.

These practices support identification of operational patterns that guarantee the quality and reproducibility of the workflows and provide full traceability of data in all analyses based on RWE when realised in large projects.

Advanced Analytics

The introduction of the advanced analytics techniques affects the realisation of RWE in pharmacovigilance in the following manner. Machine learning algorithms are able to screen real world data for a number of feared adverse events continually, and detect new safety issues effectively.

Key applications of advanced analytics include:

- Identifying rare diseases and getting fresh knowledge concerning the therapy outcomes and potential side effects.
- The incorporation of large unstructured data into a knowledge system that ideally cannot be processed algorithmically.
- Adding labels and tags to clinical case reports along with categorising them according to the level of importance in the current review cycle.
- Developing causality evidence to augment the risk assessment of known safety risks to cater for different patients.

To build upon these capabilities, companies need to establish industrialized benefit/risk platforms in which Hy algorithms are integrated into reliable data--engineering pipelines. These platforms can be generalized for various datasets and processed on standard automated intervals, thus offering PV teams ready access to the near-real-time standardized potential signal views of the asset portfolio.

Stakeholder Engagement

Effective stakeholder engagement has an impact on maximizing the value of RWE in pharmacovigilance. This involves collaboration between various teams within the organization and external partners.

Best practices for stakeholder engagement include:

- Establishing a global expert group to oversee RWE enterprise strategy, capability building, and governance.
- Creating a new role to work between RWE, key business areas, and R&D, identifying opportunities and shaping a portfolio of work.
- Building a network of relationships with strategic data providers to secure privileged access to data and develop proprietary enriched data sets.
- Integrating medical, clinical, epidemiological, and business expertise into every process to ensure the relevance and applicability of RWE insights.

By implementing these best practices, pharmaceutical companies can transform RWE from a source of insights into a foundational pillar of corporate strategy and a key part of the value chain. This has a role in moving organisational transformation, from the product centred view to the patient centred perspective, to enhance patient experience and create considerable value for shareholders.

9 CONCLUSION

The use of real-life data in pharmacovigilance reporting also presents the effect on the improvement of drug safety and quantitative policy making. Holding such data leads to better understanding of drug performance in real life scenarios using other ARM approaches so that both the pharmaceutical

companies as well as the regulatory agencies enhance their knowledge. It also plays an impact on the aspect of enhancing patient safety, enhancing clinical trial designs and design a faster route map for the drug development process. Three factors should therefore be considered when undertaking RWE: Quality of data, Bias and ethic issues. Therefore, with the help of strong data governance, effective application of analytics approaches, as well as cooperation of several departments and external stakeholders, RWE may become the basis for companies' strategies. The fact that the field has been advancing means improvements in the best practices mean it holds a role in gradually changing a more patient-oriented approach within drug development and monitoring safety amongst its side effects.

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