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Review Article

Real World Evidence Study: A New Path Towards Drug Safety

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ABSTRACT

Real-world data (RWD) allows researchers to recognize the effectiveness of treatments in everyday situations. This data type captures factors that cannot be measured in clinical settings. Real-world data can be obtained from observational studies, clinical trials, or surveys conducted in real-world settings.

The design of real-world evidence (REW) studies is crucial to developing new health technologies. Planning for real-world evidence studies allows for seamless integration of health economics and outcomes research. Accurate World Data provides an alternative source of clinical evidence. It can also improve drug development by identifying unmet medical needs. However, real-world data is not a perfect substitute for controlled clinical trials. Unlike traditional RCTs, real-world evidence studies look at treatments in standard settings. They are based on data gleaned from electronic health records (EHR) and patient registries. These data are de-identified, which makes them an excellent source for RWE studies. T real-world data represents ninety-five percent of all patient data compared to clinical trials. Real-world studies can accompany clinical trials by providing additional insights on medication use. Real-world evidence studies can overcome some of the limitations associated with clinical trials. Real-world data can be collected from a diverse cross-section of society and be more helpful in determining whether a new treatment will work in the real world.

Real-world evidence can be invaluable in many ways, not the least of which is helping researchers develop new medicines. These data come from studies of existing drugs in the real world, not controlled trials. Although real-world evidence may be noisier, it can also inform future trials. The FDA acknowledges the value of RWE and has established criteria for assessing its quality. High-quality, real-world data must be transparent, unbiased, and codified to industry standards. It is a need for time to explore the real-world data and use it to find a new treatment.

Keywords: *Real-world Data, Real World Evidence, Health Care, Clinical trial, Safety, effectiveness*

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INTRODUCTION

Real-world data is data collected from real-world settings, like medical claims, electronic health records, patient-reported data, and registries. This data type captures factors that cannot be measured in clinical settings (Bakhai, A., et al. 2021). This data allows researchers to understand the effectiveness of treatments in everyday situations. This type of data is primarily used to develop real-world evidence. Currently, most trials are single-blinded and therefore do not incorporate real-world data. The most common use of real-

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world data is in the field of Pharmacovigilance (Swift, B., et al. 2018). This is when researchers monitor the safety of new drugs after they are launched. This requires monitoring them for more extended periods to identify patterns and trends. For example, data from the COVID-19 vaccine helped the company identify a blood clot-related adverse event that occurred post-trial, which helped minimize future cases.

Similarly, real-world data are used in regulating medicines by the U.S. FDA (Hager, A., et al. 2011). Real-world data can be obtained from observational studies, clinical trials, or surveys conducted in real-world settings. These data provide a complete picture of a drug's use in real-world settings. It can also help improve treatment and reduce costs by examining real-world conditions. Regardless of where it is collected, real-world data should be used to support medical decisions. It is imperative when rare side effects of a new drug or treatment are investigated (Nokihara, H., et al. 2022).

Real-world evidence is data representing millions of patient's health and care experiences. These studies provide complete insight into the efficiency and safety of a treatment based on data from the actual use of the product (Jahanzeb, M., et al. 2020). The results of real-world evidence studies can inform product development, regulatory interactions, and patient outcomes. These studies are beneficial for establishing the value proposition of a product. Here are the six major areas to consider when conducting a real-world evidence study. Unlike clinical trials, real-world evidence studies (RWEs) are nonrandomized studies of healthcare data. They often require non-specialist reviewers to assess the validity of the results, as they do not typically involve randomization. This steer provides theoretical guidance on reviewing the validity of RWE studies and focuses on those that make causal inferences. In other words, it evaluates whether a treatment option is more effective or safer in the real world than a placebo (Robinson, S., et al. 2020). A significant benefit of RWE is its ability to provide insights faster and at lower costs. However, it also has limitations and questions about its validity and reliability. In this regard, real-world evidence studies complement clinical trials. In cancer, for example, real-world overall survival (OS) data are accepted by oncologists due to their objectivity and comparable to OS data from RCTs. Nevertheless, how does RWE work, and so It can be challenging to determine which of these studies will ultimately be the best (Burcu, M., et al. 2020).

Main Text

The Design of Real World Evidence Studies

The design of real-world evidence studies is crucial to developing new health technologies. In addition to enhancing the clinical research process, real-world evidence studies can provide insight into specific patient subgroups (Dagenais, S., et al. 2022). For example, researchers can use real-world data to explore the efficacy of specific therapies for patients with a certain age, socio-demographic, and co-morbid conditions. Additionally, real-world evidence studies can supplement traditional outcome measurements by analyzing biometric data collected during physician visits (Jahanzeb, M., et al. 2020). One of the most critical aspects of the design of Real-World Evidence studies is real-world data collection. Real-World Data is the information obtained through the ongoing care of patients. Its purpose is to provide a complete picture of the actual effectiveness of treatment and the adverse effects of the treatment. In this way, Real-World Evidence studies can inform the recruitment of participants for a clinical trial. These studies also contribute to the overall value demonstration of a treatment. The EMA recently launched framework contracts with research and academic institutions to fund real-world evidence studies. These studies can also include efficacy and safety research (Velcheti, V., et al. 2022). Real-World Evidence is becoming increasingly common as regulatory bodies and payers look for ways to validate their products. This type of evidence can help improve health care quality, reduce costs and accelerate understanding of new therapies and their effects. Further, real-world studies can help the development of new treatments by filling the gap between research and real-world practice (Musat, M. G., et al. 2022).

Planning of Real-World Evidence Studies

Real-world evidence studies are essential components of value demonstration for pharmaceuticals, diagnostic agents, and medical devices. Planning for real-world evidence studies allows for seamless integration of health economics and outcomes research. These studies provide essential data for a product's value proposition and market access (Hooper, P., et al. 2021). This article will discuss some key considerations in planning real-world evidence studies. Nevertheless, how do you plan for these studies? Read on to learn more. Organizers of clinical trials strive to incorporate a diverse patient population, including underrepresented groups (Dagenais, S., et al. 2022). Such diversity enhances the applicability of research findings. For example, researchers leveraging digital technologies to collect real-world data during the COVID-19 pandemic have leveraged digitization and digitized data to support their real-world evidence strategy. Ultimately, real-world evidence helps drive product development decisions. For regulators, RWE is a critical step in developing new health technologies (Xia, A. D., et al. 2019). In December, FDA issued the Framework for the Real-World Evidence Program. Similar guidance was issued in 2017 for medical devices. RWE is used for multiple purposes, including generating hypotheses for prospective studies, acting as a historical or concurrent control group, and demonstrating biomarker validity. However, it is essential to note that the FDA does not require RWE to be used in approval decisions (Hiramatsu, K., et al. 2021).

Challenges in Real World Evidence Studies

With the rapid rise of digital data, the life science industry is exploring integrating Real World Data, also known as RWE, into its experimental pipeline (Helanterä, I., et al. 2022). Because the development and approval of new drugs are expensive and risky, Real World Data provides an

alternative source of clinical evidence. It can also improve drug development by identifying unmet medical needs. This article will look at the critical challenges in RWE studies. Traditional clinical trials are still vital to medical innovation (Schofield, G., et al. 2021). New drugs and medical devices are studied extensively and tracked before distribution and sale. These studies are essential in determining the safety and efficacy of new products, but they can be limited in their participation and may not reflect the reality of many patients. Further, the lack of generalizability of clinical trial results across patient populations poses a challenge for their use in drug development. In addition to data quality, real world data is often subject to bias (Grimberg, F., et al. 2021). The FDA states that the key to preventing bias is randomization. Ideally, study groups should be balanced by risk factors. The use of wearable devices can help researchers collect RWD. A real-time monitoring system could also reduce the cost of RWE studies. However, these advantages come with various challenges, so real-world data is still not a perfect substitute for controlled clinical trials (Fadini, G. P., et al. 2022).

Conduct of Real World Evidence Studies

Unlike traditional RCTs conducted in a controlled environment, real-world evidence studies look at treatments in standard settings. They are based on data gleaned from administrative claims databases, electronic health records, and patient registries. Real-world evidence studies have great potential to complement research findings and fill knowledge gaps in practice (Hayes, T., et al. 2020). They can also provide valuable information on the effectiveness of specific therapies, how patients use them, and their outcomes. To conduct a meaningful RWE study, gathering data from a real-world setting is essential. Physicians are a crucial component of data-gathering (Schneeweiss, S., et al. 2021). They routinely enter structured clinical data into EHR systems and submit claims to payers, providing invaluable real-world evidence. These data are de-identified, which makes them an excellent source for RWE studies. They also help researchers identify unmet medical needs in the community. RWE studies may also encourage funders to include a drug on a drug formulary or provide better access to the market. Funders may assess the cost-effectiveness of a particular drug based on RWE (Musat, M. G., et al. 2022). The RWE studies may compare products in a hospital setting. In oncology, for example, patients receive multiple treatment lines and varying devices. Quality of life is essential in orthopedics, and RWE studies can prove that a treatment is worth the money (Ladouce, S., et al. 2017).

The Difference between RWE and Clinical Trials

RWE is derived from pragmatic clinical trials and a spectrum of real-world data. It may be gathered during routine practice or for research purposes. Observational studies using routinely collected data are the most common RWE (Dagenais, S., et al. 2022). However, these studies can have biases due to several factors. For example, the study's results may not represent actual patients. This is where the real-world data comes in handy. In addition to the limitations, RWE can also be biased and unreliable (Seeger, J. D., et al. 2020). Quality real-world evidence studies are increasingly important in decision-making in health care. Real-world studies can complement clinical trials by providing additional insights on medication use. They may also help answer the question of whether a treatment is safe, effective, and cost-effective in patients. RWE is becoming increasingly crucial to biopharmaceutical companies and life science researchers as an essential source of information on the effectiveness of different treatments. Therefore, it is crucial to understand the differences between these two types of evidence (Cramer-van der Welle, et al. 2021). Quality real-world studies may be less reliable than clinical trials because of confounding factors such as age, obesity, and sedentary lifestyle. They may also have more significant side effects and are difficult to generalize to a larger group of patients. RWE is more reliable than clinical trials in many cases but may not be entirely comparable to clinical studies. Despite its limitations, RWE studies are highly useful in evaluating the effectiveness of different interventions in the real-world (Tashkin, D. P., et al. 2020).

Advantages of Real World Evidence Studies

Real-world evidence is a type of clinical research based on patients' daily observations. The data is obtained retrospectively or prospectively and relates to the patient's health status and care. T real-world data represents ninety-five percent of all patient data compared to clinical trials. The data collected in real-world studies include all patients, regardless of criteria. In this way, real-world data has the potential to answer questions that can never be answered in a clinical trial (Hager, A., et al. 2021).

RWE studies can overcome some of the limitations associated with clinical trials, including lack of generalizability, short-term efficacy, and patient safety. Real-world data can be collected from a diverse cross-section of society and be more helpful in determining whether a new treatment will work in the real world. Further, real-world data can better identify rare adverse effects than RCTs (Seibert, K., et al. 2021). In addition, real-world data can provide more reliable findings than randomized controlled trials (RTC) for various reasons, including disease severity and adherence (Yin, X., Han, et al. 2020).

The advantages of real-world evidence are often less apparent. For example, clinical trials are not representative of the real-world environment and lack the information needed to make the proper decision for each patient. In addition, real-world data may not be as well-confirmed as clinical trial data, which can be incomplete or unreliable. Regardless of their advantages, real-world studies are not a replacement for clinical trials. They are increasingly becoming the norm for research as a more comprehensive understanding of therapeutic options becomes available (Csoke, E., et al. 2022).

The Scope of Real World Evidence Studies

The definition of a real-world study is a broad category encompassing data routinely collected rather than gathered

during a study. Such data include interventions and randomized controlled trials (RTC) but not those collected in conventional RCTs, usually done during the Phase 3 study (Laurent, T., et al 2022). In addition, real world data can be used to select the most appropriate sites and cohorts for clinical trials. Whether a study uses real-world data for its outcome depends on the methodology. The scope of real-world evidence studies is broad and varies by product and industry. It may include clinical studies, observational research, and post-market surveillance (Helanterä, I., et al. 2022). It should be recognized that these studies are not perfect and require further validation. The goal is to identify the most relevant data for specific products and to improve clinical trial designs and site selection. Regardless of its specific focus, real-world evidence studies have the potential to influence regulatory decisions in many different settings (Gómez-Ulloa, D., et al. 2020).

Another essential function of RWE studies is evaluating new treatments' effectiveness. These studies are valuable for assessing the effect of new interventions on real patients and their outcomes over time. Real-world studies can also help researchers and industry partners better understand the impact of new products on people's lives. Real-world evidence studies are also helpful in supplementing traditional outcome measures with patient-generated data, such as self-reported outcomes and biometric data collected between physician visits (Liu, S., et al. 2022).

The Myth about Real World Evidence Studies

The Myth About Real World Evidence Studies - Are They Necessary? This myth is not new; it has been around for decades. Researchers are increasingly using real-world data to study the effects of drugs on millions of patients (Hill, N. R., et al. 2020). The FDA has approved 34 drugs based on real-world data in the last 70 years. Initially, these studies focused on rare diseases, but that has changed in recent years. However, if you are interested in understanding the benefits of RWE, it is essential to understand the difference between the two types of studies. In clinical trials, real-world data is collected from various sources (Eichler, H. G., et al. 2021). Traditionally, collecting data from older individuals has been challenging, as they prefer technologies from previous generations. Therefore, mandating smartphones might negatively affect the study population. This myth may have merits, but it is still based on false assumptions. The key is to ensure the study is valid. Using real-world data, clinical trials can improve patient care (Purpura, C. A., et al. 2022).

The Real-World Evidence Transparency Initiative aims to address these concerns and establish a culture of transparency among RWE studies. Transparency is vital for the credibility of clinical trials, and RWE studies are no different. The Center for Open Science developed and hosted the Real-World Evidence Registry. This registry is a tool for researchers and practitioners to exchange data. The Open Science Framework facilitates collaboration and transparency. So, it is a good idea to consider using RWE studies (Facile, R., et al. 2022).

CONCLUSION

Real-world evidence can be invaluable in many ways, not the least of which is helping researchers develop new medicines. These data come from studies of existing drugs in the real world, not controlled trials. Although real-world evidence may be noisier, it can also inform future trials. Real-world evidence is precious for diseases and conditions where clinical trials do not cover the entire population. Moreover, RWE can study the effects of a drug over a more extended period than a standard clinical trial.

For this reason, it is essential to consider real-world evidence's value when conducting studies. The FDA acknowledges the value of RWE and has established criteria for assessing its quality. High-quality, real-world data must be transparent, unbiased, and codified to industry standards. It is a need for time to explore the real-world data and use it to find a new treatment.

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