Paper PP27 – PHUSE US CONNECT 2024

Fidelity assessment of Real-World Data as an external control arm

Umayal Annamalai, Algorics, Bangalore, India

Karthik Venkataraman, Algorics, Bangalore, India

ABSTRACT

Real-world data is being extensively used across different areas of clinical research, including past personalized medicine, patient recruitment, treatment effectiveness, and post-approval safety evaluation. Furthermore, the FDA's commitment to considering real-world evidence in regulatory decision-making emphasizes the emerging role of real-world data in clinical research.

An important though niche use of real-world data is to serve as a control arm (CA) in clinical trials, which can be a reliable alternative to randomized control trials. However, real-world data presents a unique set of challenges in its use as an external control arm due to the 3 V's – Volume, Velocity, and Veracity. Hence, despite a multitude of advantages, it is evident significant planning and efforts are needed to leverage the power of real-world data as a control arm.

The objective of this presentation is to examine a scientific framework for conducting a fidelity assessment of real-world data implementation as a control arm, encompassing planning, execution, and reporting.

INTRODUCTION

In clinical research, real-world data (RWD) has become an invaluable tool, providing insights into real-world patient outcomes and treatment efficacy. Using RWD as a fidelity arm in clinical trial as a comparison to conventional randomized control arm is one creative way to apply the technology.

Using fidelity arms in RWD is a viable way to overcome the logistical, ethical, and financial issues associated with clinical trial design. Although fidelity arms have intrinsic complexity, addressing these obstacles could transform clinical research by establishing a link between controlled trial environments and actual clinical practice.

The poster explores the examination of the goals, challenges, and potential benefits of using fidelity arms obtained from RWD in clinical trial designs.

CHALLENGES IN RWD

Although real-world data is abundant and diverse, it is also disorganized, lacking and uneven.

The top 3Vs for RWD are:

VELOCITY:

Velocity in real-world data relates to the speed at which information must be processed, gathered, and generated. Data from real-world sources, including social media, sensors, and transactional systems, is being produced at a rate never seen before.

KEY ELEMENTS OF THE VELOCITY CHALLENGE'S:

Necessities for Real-Time Analysis:

To make prompt judgments, several businesses, such as banking or healthcare, need data analysis done in real-time or very close to it.

The speed at which data is generated may make traditional batch processing systems unsuitable for handling it. It might be challenging to analyze and draw conclusions from quickly streaming data in real-time.

Latency in Data:

Outdated insights could lead to delays in data processing and analysis. The relevancy of the information may be impacted by high data velocity due to increasing data latency. The faster data is analyzed, the more useful insights can be found.

Scalability and Infrastructure:

It might be difficult for conventional databases and processing systems to grow to meet the needs of high velocity data. Resolving this continuous data flow calls for a strong efficient technologies like distributed computing and stream processing must be implemented.

Intensivity of Resources:

An Overwhelming amount of data can strain the capacity of computers It might be resource-intensive to maintain the necessary processing and storage capacity to keep up with the velocity of data. This could result in higher expenses and make it harder to keep a responsive system up to date.

Real-Time Data Quality:

It is difficult to ensure data quality in real-time. Data that flows quickly may contain duplicates, errors and inconsistencies. It becomes quite difficult to verify and sanitize the data on the fly without slowing down the analytical process.

VOLUME:

The amount of information in real-world data is enormous and can be debilitating. Efficient processing methods and scalable infrastructure are necessary to manage, store, and derive valuable insights from this massive volume of data.

KEY ELEMENTS OF THE VOLUME CHALLENGE'S:

Multiple Sources of Data:

A wide range of sources, including social media, financial transactions, sensor data, medical records, and more, are frequently the source of RWD. It could be challenging when integrating and managing data from several sources because different sources may have different formats, structures, and standards, which makes it difficult to compile a dataset that is cohesive and consistent.

Requirements for Storage:

Large volumes of data demand a large quantity of storage space. To handle the enormous volume of data, Scalable storage solutions are necessary.

Collecting and Sorting Data:

Data filtering is necessary because not all data are relevant for analysis. Sorting through the massive amount of data to find the relevant subsets is difficult. However, it's necessary to consider what to retain and what to discard to avoid losing important information.

VERACITY:

The concept of veracity is based on the fact that data may contain mistakes, noise, and uncertainity.

KEY ELEMENTS OF THE VERACITY CHALLENGE'S:

Anomalies and Inconsistencies:

It's difficult to identify and deal with abnormalities, outliers, and inconsistencies. Analysis's insights could be misleading and may lead to incorrect conclusions in the absence of clear and reliable data.

Challenges with Data Integration:

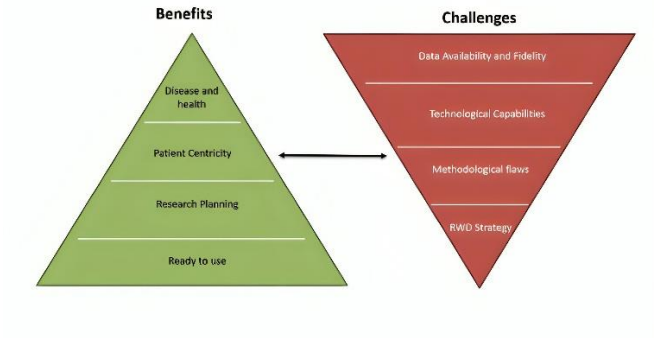
Discrepancies may arise when integrating data from different sources. Maintaining consistency in terms of definitions, units and standards becomes difficult when working with data from many systems or sources.

Data Ethics and Governance:

Governance and ethical issues affect the accuracy of data. To address ethical issues and guarantee transparency in data processing, robust data governance needs to be established.

RISK-BENEFIT-BALANCE

The use of Real-World data as an alternative to traditional randomized clinical trials in clinical research has both benefits and challenges,



BENEFITS:

- Real-world data provides a more comprehensive understanding of diseases and health outcomes.
- Through the inclusion of many patient populations, Real-world data promotes a patient-centric approach.
- Planning and executing research can be done more effectively with the help of RWD.
- It is easily accessible and doesn't need special settings or additional interventions.

CHALLENGES:

- Ensuring the integrity and availability of high-quality data is a significant issue.
- A Sufficient technological infrastructure is required to manage and analyze large volumes of diverse data.
- RWD studies are observational and may be susceptible to methodological flaws and biases.
- Fomulating an effective RWD strategy requires careful planning and coordination.

FIDELITY ASSESSMENT

Real-World Evidence data can be prepared for use as an external control arm by evaluating the elements within the three described stages and making knowledgeable decisions.

Let's delve into each stage and its essential components:

1. Planning Stage

- Early involvement of stakeholders in the process is to align with study goals and data needs.
- Ensuring the selected population is representative of the target patient population.
- Choosing the appropriate data source is essential to obtain high-quality and timely data.
- Defining the precise data points ensures that the study collects the necessary information to address the research question and meet regulatory standards.
- Developing a robust study which helps to control biases, ensures statistical validity, and supports the generation of reliable evidence.
- Ensuring compliance with regulatory standards and guidelines enhances the validity and acceptance of study results.

2. Execution Stage

- Data linkage enriches the dataset, providing a more holistic view of patient outcomes.
- High-quality data transformation ensures that the dataset is reliable, consistent, accurate, and appropriate for advanced analytics.
- Study results are reliable and credible when strict adherence to data quality standards is maintained.

3. Reporting Stage

- Clinically relevant outcomes enhance the applicability of study results to real-world healthcare decision-making.
- Adhering to the standards of regulatory-grade evidence creation in this study improves the credibility and acceptance of RWE in the context of regulatory decision-making.
- The Primary goal is to contribute meaningful evidence that informs healthcare decisions, treatment guidelines, drug development, or policy decisions.

By following these meticulously planned stages and considering the key elements within each, RWE can be effectively prepared for use as an external control arm, contributing valuable insights to the broader landscape of evidence-based medicine.

CONCLUSION

Using real-world data as a control arm in clinical trials presents challenges regarding data quality standards. Engaging stakeholders early in the process, carefully assessing risks and benefits, and meticulously planning and executing its usage can create value for both patients and sponsors. Furthermore, as regulators continue to recognize the significance of real-world data (RWD) in uncovering previously unrecognized insights, RWD can be instrumental in understanding the patient journey and facilitating data driven decision-making.

ACKNOWLEDGMENTS

We thank Gayathri Ravikumar and Rajesh Kumar Karthikeyan at Algorics for their continuous support towards this paper.

We thank Niveda Ramkumar at Algorics for the continuous support in reviewing this manuscript.

CONTACT INFORMATION

Your comments and questions are valued and encouraged. Please contact the author at:

Author Name: Umayal Annamalai

Company: Algorics

Email: umyal.annamalai@algorics.com

Website: www.algorics.com

Author Name: Karthik Venkataraman

Company: Algorics

Email: karthik@algorics.com

Website: www.algorics.com