MarketScan



The life sciences industry is evolving, here's what you need to know

How real-world data and evidence is informing regulatory decisions, reducing health equity barriers, maximizing value and painting the full patient picture with data linking.

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Introduction

It's no secret that life sciences companies are facing new challenges due to the volume and complexity of technology and real-world data surrounding them. These challenges have sparked innovation and evolution across the healthcare continuum, especially when it comes to real-world data (RWD) and evidence.

We have had the honor to have a seat at the table, helping the industry rally behind RWD and break down silos with new ways of thinking. Most recently, we've seen real-world evidence help:

- Inform regulatory requirements and accelerate development lifecycles
- Reduce health equity barriers with accessible and inclusive clinical trials
- Link across multiple payers and data sets, painting the full patient picture

Every day, RWD continues to add more value to the healthcare ecosystem and product development processes. But the work is far from done. To truly transform human health, we need to continue simplifying complexities and let real-world data shine a light on meaningful, real-world evidence (RWE). Here's a summary of what life sciences companies need to know.





Effective and informed treatments

How real-world data and evidence informs regulatory requirements and gets treatments into the hands of patients faster



Getting a treatment approved is a long, resource-intensive process. We're seeing the FDA leverage RWE in review processes, serving as a complement to traditional trials. This newfound push for real-world evidence is modernizing the regulatory framework and accelerating the development of safe treatments. In the United States, the FDA is looking at new ways of incorporating RWD into applications and shows no signs of stopping, with the Europe market following close behind.

With the FDA and other regulators encouraging regulatory submissions including RWD and synthetic control arms (SCAs), we are seeing improvements in drug development processes. For example, clinical drug trials typically exclude pregnant women out of an abundance of caution. Now, thanks to advances in technology, those same trial sponsors can study and protect pregnant women through an abundance of data.

How RWD is helping protect pregnant women ↗

Leveraging RWD in post-marketing surveillance helps monitor the safety and efficacy of treatments post-approval, such as identifying safety signals and monitoring long-term outcomes.

Inclusive and accessible studies

How real-world data and evidence is reducing health equity barriers with inclusive and accessible clinical trials

A complete dataset is an inclusive dataset. An analysis of clinical trials between 2008 and 2018 found that:

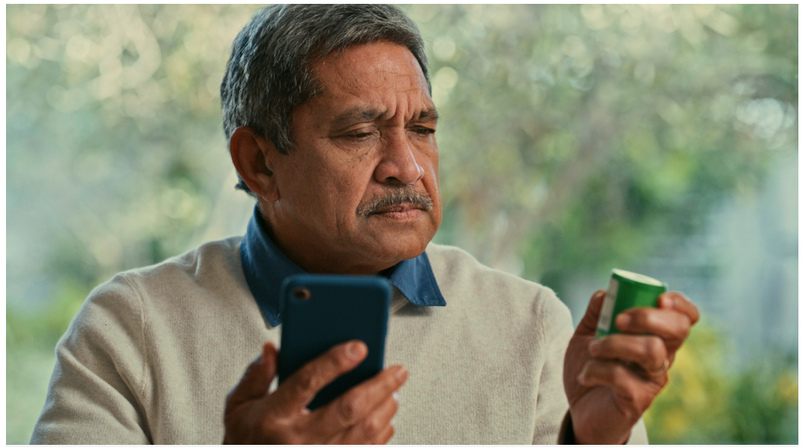
- **78%** of participants were white, and 22% were racial or ethnic minority groups
- **55%** of participants were male, and 45% were female[1]

The under-representation of women and minority groups in clinical trials has been a concern for years because it could limit the generalizability of study findings. Specific populations may be at higher risk of certain diseases and excluding them from clinical trials limits the development of effective treatments for those groups. Thankfully, progress has been made to increase diversity in clinical trial participants and design more inclusive studies, but there is still a long way to go in achieving full representation.

As the world raced to find a COVID-19 treatment, companies and patients began to trust and rely on technology more. Over time, the level of comfort has increased, and more people are trading personal data for convenient experiences. This presents a big opportunity to improve clinical trial access through convenient, inclusive innovations.

With most of the population now owning a smartphone, studies and treatments have become increasingly accessible to disadvantaged populations, helping break down century-long barriers.[2] For example, studies are now leveraging patient-generated data, such as wearable devices, to help reduce disparities by increasing access to disadvantaged populations.

Designing clinical trials with inclusivity and accessibility in mind gets us one step closer to health equity. We anticipate future regulations to not only require collecting diverse variables, but also standardizations to help keep the data clean.



Holistic and personalized care

How real-world data and evidence is helping paint the full patient picture with data linking



Access to healthcare data has played a crucial role in the advancement of medical discoveries and providing patients with quality care. However, patients may switch employers, providers or insurance plans, leading to their health data being trapped in silos – locking up precious insights with them.

That's where our secret weapon comes in. Multi-payer sourced data helps organizations protect and enhance their RWE through continuity. Helping break down silos and increase access to regulatory-grade patient data.

Managing large volumes of fragmented data can be complicated and lead to data gaps. But when done effectively, linking real-world data from various sources can provide a 360-degree view of the patient. Providing a more complete understanding of the factors that impact health across the continuum of care. In turn, informing healthcare decisions and improving patient outcomes.

Enabling the right linkages and prioritizing completeness of datasets will help accelerate the industry into the next era. Personalized, accessible healthcare.

Looking ahead

How MarketScan data, services and applications help strengthen, accelerate and simplify RWE studies.

Hear how we can help →

Learn more about MarketScan ↗

It's clear that the next evolution of life sciences is full of promising innovation with the increased use of RWD and RWE. As comfort with technology continues to bloom and regulations and safeguards are put in place, the opportunities become even more inspiring.

As we continue to combine controlled research with, real-world data, more complex research questions can be answered. This in turn will inform regulatory decisions, reduce health equity barriers, maximize value and improve the patient experience.

This new era of integrated data is full of promise. A world where treatments become more inclusive, more accessible and more personalized. That world is what drives our passion to combine forces with medical trailblazers and work together to answer complex questions.

MarketScan® is an industry leading partner to strengthen, accelerate and simplify your RWE studies. Bridging treatment expectations and concrete healthcare outcomes, we deliver a strong foundation for both research and regulatory-grade studies.

For decades, we have created a best-in-class portfolio that is scalable to your organizational needs, helping answer some of the most complex medical questions. Unlock insights with our real-world datasets built on precision. Expedite your real-world evidence studies with our team of research experts and simplify your analysis with intuitive applications.



About Merative

Merative is a data, analytics and technology partner for the health industry, including providers, health plans, employers, life sciences companies and governments. With trusted technology and human expertise, Merative works with clients to drive real progress. Merative helps clients orient information and insights around the people they serve to improve decision-making and performance. Merative, formerly IBM Watson Health, became a new standalone company as part of Francisco Partners in 2022.
Learn more at www.merative.com

Resources:

1. Clark, L.T. et al. (2019) “Increasing diversity in clinical trials: Overcoming critical barriers,” Current Problems in Cardiology, 44(5), pp. 148–172. Available at: https://doi.org/10.1016/j.cpcardiol.2018.11.002.
2. Riley, Wayne J. “Health disparities: gaps in access, quality and affordability of medical care.” Transactions of the American Clinical and Climatological Association vol. 123 (2012): 167-72; discussion 172-4.

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