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Biosimilars Real World Evidence: Proving the point

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Abstracts

Biosimilars Real World Evidence: Proving the point

Biosimilar manufacturers face an uphill struggle to fully mobilise their product portfolio. Against a background of aggressive defence strategies by originator companies, often sceptical prescribers must be brought on board, the anxieties of patients reduced, and payer demands for lower prices addressed. Real World Data (RWD) and Real World Evidence (RWE) play a key role in building stakeholder confidence and establishing market presence.

In Biosimilars Real World Evidence: Proving the point, FirstWord analyses the strategies that lead to meaningful and trusted RWD and the critical role it plays for biosimilars in educating payers, physicians and patients on safety, efficacy and cost effectiveness.

Discover on this page

- The executive summary below, taken directly from the report, presents key findings from the research
- The rigorous research objectives and methodologies employed to produce the report
- Detailed report contents
- Why this report is important to you

Executive Summary

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Understanding how drugs work in the real world marks a significant value proposition for stakeholders, including patients, prescribers and payers, largely because patients have characteristics and treatment experiences that can differ significantly from those observed in the hyper-controlled environment of a clinical trial.

The interest level for real-world data (RWD) in the pharmaceutical industry is high across the board, but has perhaps reached fever pitch for biosimilars, mainly because their abbreviated regulatory pathway can foster distrust about the safety and efficacy of these lower-cost therapies compared to their more rigorously reviewed reference products. However, collecting and analysing these data presents unique challenges for biosimilar manufacturers.

This report analyses the current RWD needs of various stakeholders and how biosimilar developers can put the right pieces together to form a comprehensive body of evidence that demonstrates the value of their products. Throughout this report, answers to the following questions are provided and discussed:

What types of RWD are most requested?

Biosimilars are promoted as a cheaper alternative to costly biologicals, but taking this tack has led some experts to believe that ‘cheaper’ is synonymous with ‘not equivalent to’ the more costly originator therapies. Therefore, many stakeholders still very much crave additional data about the safety and efficacy of biosimilars, particularly in instances where indication extrapolation has been used to grant approval.

When and under what conditions should RWD be provided?

Currently, RWD are provided as part of a post-market approval agreement in the European Union (EU) or requested by payers in the US following market launch. However, the experts argue that it would be far more useful if these types of studies were performed in tandem with traditional clinical trials. This holds particularly true for any biosimilar approved via indication extrapolation, as often RWD represent the first data on the therapy’s use in a particular patient population, and thus would go a long way to assuage any prescriber and patient trepidation regarding the use of an ‘untested’ treatment.

How influential are RWD for biosimilars?

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The reach of RWD and real-world evidence (RWE) is somewhat stifled by the general lack of knowledge about biosimilars and what they entail. However, physicians still reference the data to help prove the 'sameness' of the therapies, payers are leveraging the data to help inform where in the treatment algorithm the biosimilar should be positioned, and the manufacturers themselves are using the information to better connect with patients and patient advocacy groups.

How are biosimilar manufacturers creating RWD?

Biosimilar developers are leveraging a variety of tools and modalities to gather and analyse RWD. Further, this work is taking place both within companies themselves and through partnerships with other companies or even regulatory bodies and other interested parties.

What are the challenges to providing RWD?

Current challenges to generating RWD include a lack of experience – particularly in the US – as well as the fact that not enough time has passed for long-term RWD to be collected. These challenges are certainly unique to biosimilars due to the area's relative lack of maturity, but this is expected to change as familiarity with the products increases.

How can RWD for biosimilars be enhanced and continually improved?

To improve the quality and applicability of RWD, the experts suggest that biosimilar manufacturers consider working more collaboratively with other stakeholders – particularly regulatory agencies – to help collect and disseminate information.

What is the future for RWD in biosimilars?

Provided some of the significant hurdles associated with generating RWD in this specialty are addressed, the experts suggest that these data could eventually become a cornerstone of regulatory applications and generally play a greater role in supporting the decision-making processes of all stakeholders.

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Research Methodology and Objectives

Payers, health technology assessment agencies and other stakeholders are increasingly interested in knowing whether a medicine works in the real world, and not just in the trial setting. Real-world data (RWD) and real-world evidence (RWE) are key to answering their questions about the value of medicines in the real world.

The research methodology for this report included primary research through in-depth interviews with experts working within, and responsible for, RWD and RWE in pharmaceutical companies. These key insights are supported and contextualised by extensive desk research.

Key questions explored in this report include

- What are RWD and RWE?
- What is enabling RWD and what are the barriers for RWD?
- Why is there so much interest in RWD and RWE?
- How important are RWD and RWE for market access?
- How are RWD and RWE being used in market access?
- Which companies are leading on RWD and RWE?
- What can companies benchmark themselves against for RWD and RWE in market access?
- What is the future for RWD and RWE?

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Why this report is important to you

Interest in real-world data has reached fever pitch in recent years, particularly for biosimilars, where data to illustrate safety and efficacy outside of the controlled confines of the clinical trial environment is frequently requested by stakeholders. This report analyses the current RWD needs of various stakeholders and how biosimilar developers can put the right pieces together to form a comprehensive and persuasive body of evidence that demonstrates the value of their therapies.

This report will enable you to

Understand what RWD and RWE are and who is driving demand

Identify the barriers developers must overcome in collecting RWD that is meaningful and trusted by stakeholders

Learn why there is so much stakeholder interest in RWD and RWE and how it must be nuanced to meet different needs

Appreciate how demand for RWD/RWE differs in the US and EU

Assess the critical importance of RWD and RWE for biosimilar market access

Evaluate the RWD and RWE strategies that are being successfully used today

Anticipate the future biosimilar RWD and RWE climate

Pharma RWD/RWE Expert Contributors

The report is informed by the practical knowledge and insights of 13 RWD/RWE experts, and includes contributions from people who work for leading companies such as Pfizer, Amgen and Celltrion.

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