

REALITY MEDICINE: HOW PAYERS, REGULATORS AND PHARMA ARE WORKING WITH REAL-WORLD DATA

A tsunami of data from the real world, rather than the confines of a controlled clinical trial, is transforming the way medicine is practised. This is principally because it enables money to follow patient outcomes rather than simply the provision of services and treatments. Pharma companies, like every other stakeholder, are on a steep learning curve to make sense of this data and need to know what payers, regulators, healthcare systems and their competitors are also doing in this respect. More than anything, they need perspective to understand what can realistically be achieved with real-world data (RWD) now and in the future. And, given the broad-ranging effects of RWD on healthcare systems, they need to start building bridges between the R&D and commercial sides of their companies, so the RWD effort can be informed by as many people within pharma as possible.



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EXECUTIVE SUMMARY

Real-world data may be over-hyped right now in terms of what it can realistically achieve, but nobody doubts it is the principal means by which healthcare systems will be revolutionised over the next 20 years or so. This is because the real-world picture enables an outcomescentred approach to take root so healthcare money can deliver value rather than merely provide services and treatments.

But it is not easy to work with RWD, embracing as it does all the human aspects of medicine that are so rigorously deleted from randomised clinical trials. These include patient co-morbidities, lifestyle choices and the fact that patients seldom follow the instructions on the prescription label. Moreover, the datasets that have built up over the years from insurance claims and electronic health records are not always accurate and don't readily interconnect, being based on different coding systems and relating to the often disparate medical protocols that are practised in the countries or healthcare systems in which they were created. These, and many other challenges, are currently being addressed worldwide as all stakeholders want to work with RWD for their own reasons.

This report focuses on how RWD is currently being used by payers, regulators and pharma companies. It does so from the perspective of pharma people who are not necessarily trained in health economics and outcomes research to enable them to enter the conversation and shape how RWD is used. In that sense it provides a guide to the basics of RWD, such as the rapidly changing market for data, how this data is currently being translated into insights, and the difficulties of striking an appropriate balance between methodologies and cost.

This report provides an overview of why RWD is important to pharma, how the landscape is evolving, and the critical importance of first, talking to payers to find out what they want and, second, building bridges between the commercial and R&D sides of the organisation so RWD can inform every aspect of the business. This includes not only everything from early-stage R&D to market access but also all the opportunities that are evolving for collaborative working.

Pharma companies have never had so many opportunities to enter into partnerships with healthcare organisations, charities, patient communities, physician communities, payers and more. It is for this reason that all departments in pharma companies need to have a feel for the rapidly changing healthcare economies they work in, the shifting mind sets among regulators and payers, and a considered view of how RWD can help them achieve their departmental aims.

These are exciting times and the main message from everyone who contributed to this report is that it is early days. RWD has enormous potential. This is not just in securing market access for drugs, the traction point for most companies to get involved. Nor is it just about improving the efficiency of the R&D process. It is also about what the wealth of RWD coursing round healthcare systems can reveal about patient care. If pharma companies want to be part of that bigger picture they have to at least start thinking about how every one of their departments can access and effectively use the insights revealed by RWD.



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