

07 Feb 2022 | Opinion

Medical Affairs – Realizing The Potential Of Real-World Evidence To Transform Patient Care

by

As a growing strategic priority across the health care industry, real-world evidence is increasingly being recognized for its potential to transform patient care.

More companies are realizing the value real-world evidence (RWE) – the clinical evidence regarding the potential benefits or risks of a therapy generated from data relating to patient health or the delivery of health care – can add at every stage of a therapy’s lifecycle. RWE can not only help companies better understand a product’s safe and appropriate use in a post-approval setting, but the data can also inform innovation, trial design, personalized medicine, regulatory filings and optimize decision-making for better patient outcomes.

But, as the demand for use of RWE increases, we must ask ourselves “*Are we doing all that we can to unlock its full potential to transform patient value?*” As stewards of real-world knowledge within our organizations, Medical Affairs has an increasingly strategic role, not only in defining the best way to generate evidence, but also the smartest ways to access and utilize it.

A Powerful Window Into The Patient Experience

The concept of RWE is not new. However, an increased focus on outcomes is fueling an enhanced understanding of the value it can deliver, while the ever-expanding size and availability of wider and deeper datasets, and innovative analytical methods, continue to build its potential. The industry has seen rapid growth in the scale and type of patient data available, sourced directly through telehealth, mobile and wearable devices, and electronic health records.

The improved availability of data adds a nuanced level of insight that can look beyond the efficacy and safety results of traditional clinical trials. It provides a *holistic window* into the patient’s disease, outcomes and experiences, helping to enrich



CHARLOTTE KREMER Source: *Astellas Pharma*

our understanding of what matters most to patients and what they would value in a therapy. For example, *Astellas Pharma, Inc.* are exploring the use of wearables to understand the impact of sleep disturbance on patient outcomes. In another study, we used machine learning to further estimate the size of a target patient population in a reimbursement database for a disease that is not well characterized. The results indicated that patients may be under-treated, because their conditions are not well recognized, which leads to suboptimal care and highlighted the need for enhanced disease awareness.

The Right Capabilities To Translate RWE Into Value

Medical Affairs is uniquely positioned to unify this growing wealth of RWE, to fill existing knowledge gaps and support the development of an integrated RWE generation plan by looking at the totality of evidence.



JUDITH NELISSEN *Astellas Pharma*

Indeed, as a function, Medical Affairs intrinsically represents the broad perspective, interests and needs of multiple stakeholders. Its role is centered on a deep understanding of the burden of disease, what health care professionals need to better diagnose and treat patients, what payers want to see to assess cost and value, and ultimately, what information patients need to inform their treatment decisions. By effectively leveraging RWE, Medical Affairs can translate insights into strategies for our organizations, to clearly differentiate patient needs and patient outcomes and help best prioritize the innovations that deliver the value that matters most.

It is from this holistic viewpoint that Medical Affairs can release the strategic potential of RWE, to enhance the value of therapies for the doctors who prescribe them, the health systems who ensure access to them and the patients who depend on them.

Elevating The Patient's Voice Early

As the role of Medical Affairs in delivering RWE capabilities evolves, so too does our

understanding of where we can enhance our work and how we can increase transparency.

A significant amount of RWE tends to be published and shared through scientific communications into the public domain, but we also have a responsibility to articulate the patient voice. RWE insights need to be accessible, particularly when we start looking at the real-world experience from the patient perspective.

This conversation needs to happen early within our organizations, clearly and effectively communicating the value RWE insights can deliver. Medical Affairs can play a key role here, not only as stewards of the insights, but helping to translate that RWE back to patients in a way that resonates and has meaning to them. This is a growing area of expertise for those working within the field and one where a concerted effort must be made to upskill and enhance our efforts.

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Comparative Effectiveness

We have ambitious goals to transform patient care and RWE provides an opportunity to look more closely at the performance of our medicines in the real world. Comparative real-world effectiveness is an area where we know we can do better, and Medical Affairs can help to drive positive change.

For example, Astellas Pharma conducted a comparative analysis to further understand outcomes for men with metastatic castration-resistant prostate cancer who had not previously received chemotherapy. Using the US Veterans Health Administration Database, the results showed that, on average, men treated with enzalutamide were able to stay on therapy longer, had significantly lower health care costs and experienced improved survival compared to the comparator. To our knowledge, this was the first real-world study to evaluate the comparative effectiveness of enzalutamide in this setting.

We must now take a leadership position and be at the forefront – utilizing RWE to enhance comparative effectiveness analysis and a willingness to take the necessary intelligent risks to address questions raised in the real world on how treatment options compare in certain patient populations. Even if the answers may challenge us to think differently, we must be ready as organizations to act with agility and flexibility, ensuring we have the right capabilities and cross-functional collaboration in place to adapt quickly to what the data are telling us. This is the right thing to do for patients and will ultimately enhance our overall understanding of how to improve

outcomes.

Championing Standards

Our industry is evolving and building capabilities to be smarter in the way we access and analyze data to really answer the questions that our stakeholders are asking, and to give perspective on points of differentiation to further refine and define value. RWE is making an important contribution to that, broadening our collective view of creating value, to insights and possibilities to benefit entire healthcare systems.

Medical Affairs is uniquely positioned to play a pivotal role in unlocking the power of this “integrated evidence vision” of the future, generating the right information to help decision makers make the right decisions, at the right time. Moving us toward a more interconnected ecosystem, where patients and other stakeholders are both the source and the recipients of information.