

White Paper

# Making Real-World Evidence Meaningful and Actionable

*Embedding communications strategies in RWE initiatives*

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# Introduction

Real-world evidence (RWE) has become increasingly important in healthcare decision-making as it is used ever more frequently in published research, regulatory approvals, clinical guidelines, health technology assessments, and market access decisions.<sup>1-3</sup>

RWE complements clinical trial data to provide a 360-degree view of product performance, both pre- and post-launch. This validates the product value proposition and positively informs decision-making around its use.



To fulfil the potential of RWE, relevant, clear, and actionable insights must reach healthcare stakeholders and enable evidence-based decisions. Communications strategies must therefore be employed to ensure that data dissemination is both well planned and executed effectively for optimal impact.

In this white paper, we discuss best practice for integrating RWE generation with effective communications strategies to maximise the impact of RWE investment on everyday clinical practice and patient care.

# The importance of RWE

## RWE is increasingly important for healthcare decision-making

The value of RWE lies in deep insight-generation to inform decision-making. This is driven by the growing amount of electronic data available in everyday practice and is bolstered by the rising demand for information from healthcare stakeholders about drug utilisation, effectiveness, and safety post-launch. Furthermore, RWE presents an opportunity to expand on and complement the results from traditional clinical trials in the pre-launch phase, potentially leading to faster approval and delivery of medication to patients.<sup>4,5</sup> A launch performance analysis has identified RWE as a 'strategic differentiator for launch excellence'.<sup>6</sup>

*'The value of RWE lies in deep insight-generation to inform decision-making.'*

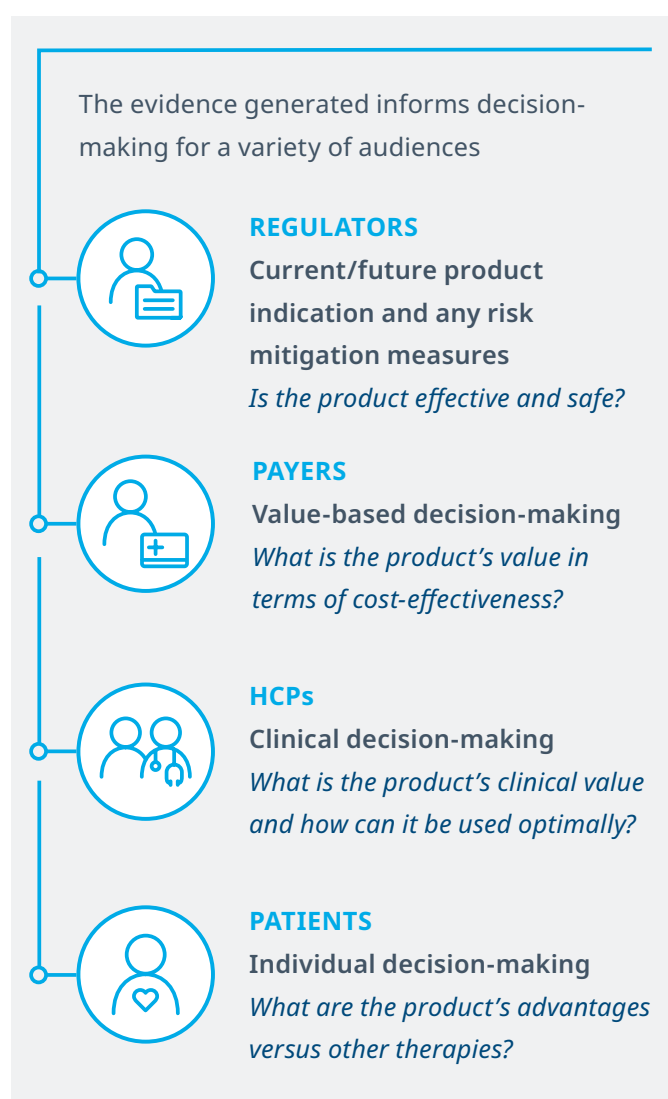
**Throughout the entire product life cycle, RWE has become an increasingly important source of insight to:**

- understand the clinical and commercial contexts in which products will be positioned
- optimise the design of clinical trials; for example, by informing patient selection or providing external comparators
- contribute to the evolving regulatory approval processes for novel therapies
- expand the product data bank to enable understanding of what works in routine clinical practice for optimal product use
- prove product value and contribute to competitive differentiation
- educate and support decision-making.

## RWE can inform decision-making for a variety of audiences

The final users of RWE comprise regulators, payers, healthcare professionals (HCPs), and patients. These stakeholders have different insight and evidential needs to inform their decision-making (Figure 1).

**Figure 1: RWE audiences and their different decision-making needs**





## Communications transform RWE from data to actionable evidence for its audiences

Medical communications experts are professionals who use effective communications strategies to inform, engage, and educate healthcare stakeholders. They therefore act as a bridge between the evidence generated and its final users.

### The role of effective communications in the design of products' overarching RWE programmes

Overarching RWE programmes comprise multiple types of real-world studies, such as epidemiological studies in the disease area of interest, drug use, safety and effectiveness, and health economics. These programmes are normally set up to comprehensively fulfil the needs of the final audience beyond clinical trials. Effective communications involve understanding the final audiences and delivering information that meets their needs via their preferred channels. Communications experts apply this focus in the design of RWE programmes to understand different stakeholders' requirements and areas of interest and enquiry. This helps the 'voice of the customers' find its way into evidence-generation planning and ensures that the RWE programme is designed to provide relevant answers to the important questions.

In addition, medical communications experts take a forward-looking approach, anticipating future trends, category dynamics, and changes in stakeholders' needs – and apply this expertise to feed into an evolving and future-proofed RWE strategy design.

#### **Integrating effective communications strategies into the design of overarching RWE programmes delivers the following benefits:**

- increases understanding of the overall real-world programme approach
- establishes where this fits with a product's clinical evidence in further demonstrating the product profile and value proposition

- contextualises individual study designs within the programme
- builds anticipation for the eventual results, and supports a consistent scientific narrative across all studies, ensuring that the RWE strategy's overall value is clear to all audiences.

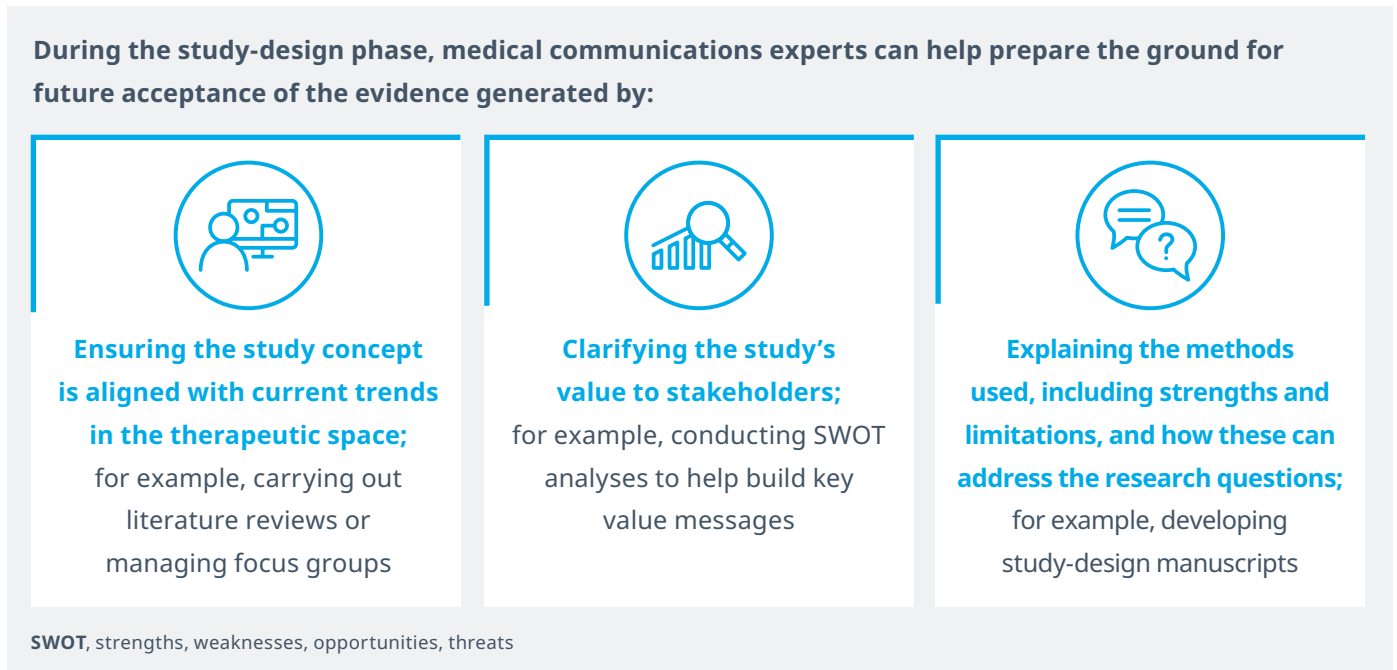
### Medical communications experts enrich individual studies from the start

The uptake by the final audience of the evidence generated is particularly challenging with real-world studies. This is due to the different levels of awareness, knowledge, and perception of: real-world data and their sources; non-interventional designs and methods; and the regulatory pathways involved, all of which are well-known barriers to RWE acceptance.<sup>7</sup> If involved from the start, medical communications experts help to overcome these barriers through the dissemination of relevant information at each step in a study's life cycle.

During the study design phase, communications experts start building the roadmap towards uptake and creating impact for the final results through dissemination of study-related information, such as the methodologies used, the strengths and limitations, and the clinical value (Figure 2). A detailed communications plan should be agreed at this early stage to identify initial target dissemination activities, including scientific congress presentations and peer-reviewed journal articles.

During the study execution and publication phases, the pre-agreed dissemination plan ensures that the evidence generated appropriately enters the published bank of scientific work as rapidly and effectively as possible. In addition, communications experts use educational activities – such as the creation of medical and patient information documents, or seminars, webinars, and workshops – to translate, contextualise, and interpret RWE so as to have an impact on decision-making.

Figure 2: Communications strategies from the start of RWE studies



## Engaging study stakeholders

Medical communications experts design and use effective engagement plans to unite stakeholders with different priorities into a cohesive team, working together towards a common goal. This should be the aim of all RWE studies, so that they can fulfil the business strategy and satisfy the needs of the different audiences, leading to more informed decision-making.

Depending on the type of RWE initiative, study stakeholders may vary from just a few individuals within operational teams to a broad range of:

- internal functions (e.g. those in medical affairs, commercial/marketing, health economics, legal, regulatory, and senior management)
- external experts (e.g. patient groups, key opinion leaders and HCPs, professional associations, payers, and regulatory experts).

*'Medical communications experts design and use effective engagement plans to unite stakeholders with different priorities into a cohesive team, working together towards a common goal.'*

## INTERNAL STUDY STAKEHOLDERS

The implementation of internal engagement plans is key to ensuring that internal communications are effective and impactful. This can unite internal stakeholders in accomplishing the study's goal, while also making sure that external communications are consistent and harmonised. For example, effective internal communications can motivate and inform those involved with internal study operations about the important role they are playing in the study and the impact that the eventual results will have; or they can provide clarity for country-level medical affairs managers on the strategic value of the RWE results and their role in supporting the product profile, thus enabling a timely and effective plan for local educational and dissemination activities.

To be effective, an internal engagement plan must be flexible enough to address the various company functions with different, sometimes even conflicting, business goals and needs (e.g. medical affairs versus commercial, operational team versus senior management, marketing versus legal and regulatory functions, global team versus local affiliates).

**Medical communications experts can get ahead of these conflicts by mapping stakeholders' needs to relevant engagement strategies in order to:**

- determine those stakeholders who need simply to be kept informed (e.g. more senior management) versus those who need to be coordinated more closely (e.g. country-level medical affairs)
- understand different internal stakeholders' needs and tailor:
  - message content (level of detail and angle)
  - cadence (how often and at what stage in the process)
  - channels (e.g. emails versus presentations versus virtual group meetings).

This systematic planning optimises engagement tactics to reach the relevant parties in an effective, consistent, and coordinated manner.

**EXTERNAL STUDY STAKEHOLDERS**

Engagement with external stakeholders, including external operational teams, can best be planned

through the involvement of Steering Committees, which can advise on the study design and execution (Table 1). An advisory Steering Committee can stay focused on anticipating and understanding the audiences' needs and how best to solve them. Medical communications experts can support Steering Committee activity by defining a meeting's cadence and timing, determining tactical agendas, and providing detailed reports.

Subgroups of the Steering Committee can function as Communications Advisory Groups for the development and continued update of dissemination plans and to ensure conference and other relevant event deadlines are met. These Communications Advisory Groups, working with medical communications experts, can also help to identify strategies for broader dissemination (e.g. promotional aspects, publications, or peer-to-peer education), including journals, digital platforms, and other channels that are more accessible to the wider healthcare and patient communities.

**Table 1: Strategies to engage study stakeholders**

INTERNAL ENGAGEMENT STRATEGIES	EXTERNAL ENGAGEMENT STRATEGIES
<p><b>Internal stakeholders</b></p> <ul style="list-style-type: none"> <li>• Study teams</li> <li>• Medical affairs</li> <li>• Other company functions, including commercial, legal, compliance, pharmacovigilance, health economics, corporate communications</li> <li>• Senior management</li> </ul> <p><b>Medical communications experts can support the development of engagement strategies aimed at improving collaboration among internal teams and functions by:</b></p> <ul style="list-style-type: none"> <li>• helping to understand the role and involvement of each stakeholder on the study</li> <li>• providing examples of engagement tactics that can be used for each stakeholder based on their interest in the study</li> <li>• providing the communications tools and templates that best apply to the different internal stakeholders' requirements</li> </ul>	<p><b>Advisory Steering Committees should comprise a variety of stakeholders in the disease area to cover all the decision-making needs, e.g.</b></p> <ul style="list-style-type: none"> <li>• patient groups</li> <li>• key opinion leaders and HCPs</li> <li>• professional associations</li> <li>• regulatory experts</li> </ul> <p><b>Professional medical communicators can support continued Steering Committee engagement to optimise the design and execution of RWE initiatives by:</b></p> <ul style="list-style-type: none"> <li>• defining the cadence and timing of meetings</li> <li>• determining tactical agendas</li> <li>• providing detailed reports</li> </ul> <p><b>The Communications Advisory Group, in collaboration with medical communications experts, can advise on:</b></p> <ul style="list-style-type: none"> <li>• the early and timely planning of key congresses and other strategic events to ensure submission deadlines are met</li> <li>• various aspects of engagement and dissemination (e.g. promotional aspects, publications, or peer-to-peer education)</li> </ul>

## Effective multichannel communications help ensure reach, impact, understanding, and use in decision-making

Peer-reviewed scientific publications play a critical role in the communication of research results. However, it would be a mistake to assume that the publication of results is the end of a communications plan. In fact, it is only the beginning.

### **An effective communications strategy recognises the range of additional channels and tools that can be used to reach audiences most impactfully.**

- Busy HCPs require additional engagement and tools to effectively summarise RWE findings and apply them to their own clinical practice.<sup>8</sup>
- Many patients want and need research findings translated into plain language summaries that are publicly available.
- Policy-makers need quick answers through focused communications with high clarity and broad applicability.
- Biopharma companies may already have in-field medical science liaisons (experts available to discuss RWE and its clinical implications directly with HCPs). Ensuring that medical science liaison teams are up to date with RWE studies and data and have the right training and tools is therefore essential.

## The accelerated opportunity of digital communications

Dissemination, education, and engagement tools must keep pace with constantly evolving technology and the consequent changes in the patterns of information consumption. This was clearly demonstrated during the COVID-19 pandemic, during which social distancing led to a boom in virtual conferences and the development of new, creative ways of remote engagement and education.

Healthcare stakeholders are now looking at different ways of consuming and accessing information.<sup>8</sup> Although published articles remain the key source of data, the digital enhancements that accompany evidence-based articles, such as visual abstracts or videos, have become an important reference format for clinical decisions. In addition, digital platforms, virtual conferences, and online education have become the preferred channels for knowledge-sharing.<sup>8</sup>

Several constantly evolving tools exist for effective communications within these channels. Digital communications experts can help identify and utilise the most appropriate tools for the different audiences to reach individual communications goals. For example, data visualisation techniques can facilitate the recognition of patterns and relationships in order to communicate a message in a more compelling and interesting way;<sup>9</sup> they are useful for communicating and making sense of complex and evolving data sets. Mapping, infographics, charts, and tables are all examples of data visualisation, each of which is suitable for communicating different quantitative relationships to different audiences. These visualisations can be even further enhanced by virtual or augmented reality tools or gamification.

In this digital revolution, companies need to adapt their internal processes to the new communications channels so as to ensure content management and compliance. The early involvement of medical communications experts can help companies to plan in advance in terms of the tools required, including selection of the most appropriate channels and better understanding of the implementation processes (Table 2).



**Table 2: Value of digital communications channels for RWE audiences**

	<b>CORE FEATURES</b>	<b>APPLICATION OF CORE FEATURES TO RWE COMMUNICATIONS</b>
<b>MAILINGS/ EMAIL PROGRAMMES</b>	<ul style="list-style-type: none"> <li>• Allow an inexpensive sequence of communications to key audiences to tell a story over time</li> <li>• Can be tailored according to the needs of specific audiences</li> <li>• Reach audiences quickly</li> </ul>	<ul style="list-style-type: none"> <li>• Design different audience journeys for different areas of interest for maximum relevance</li> <li>• Communicate an evolving data picture over time</li> </ul>
<b>WEBSITES/ DIGITAL TOOLS</b>	<ul style="list-style-type: none"> <li>• Allow the development of interactive elements</li> <li>• Easily updated with new/changing information</li> <li>• Can include complex data visualisations and graphics</li> </ul>	<ul style="list-style-type: none"> <li>• Data models enable users to select and compare different data sets, selecting and overlaying cohorts of interest</li> <li>• Enable building of data sets over time as new data become available</li> <li>• Easily customisable for different stakeholder groups and geographies</li> </ul>
<b>VIDEOS/ PODCASTS</b>	<ul style="list-style-type: none"> <li>• Dynamic visual storytelling</li> <li>• Enhance engagement</li> <li>• Allow audiences to digest content at their own pace</li> </ul>	<ul style="list-style-type: none"> <li>• Provide investigator and expert presentation, commentary, and contextualisation of data to enhance relevance and understanding</li> </ul>
<b>WEBINARS</b>	<ul style="list-style-type: none"> <li>• Real-time discussion of topics of interest by one or more presenters</li> <li>• Include live streams of the presenter talking, showing slides, and/or using a whiteboard, plus live chat and Q&amp;A sessions</li> </ul>	<ul style="list-style-type: none"> <li>• Possibility of discussing different viewpoints through the participation of different key opinion leaders and subject matter experts</li> <li>• Allow audiences to ask questions and receive clarification in real time</li> </ul>
<b>FACE-TO-FACE/ VIRTUAL CONFERENCES</b>	<ul style="list-style-type: none"> <li>• Allow large audiences from all over the world to attend</li> <li>• May be face-to-face, virtual, or hybrid</li> </ul>	<ul style="list-style-type: none"> <li>• Raise the profile of RWE by enabling scientific exchange through conference presentations, exhibition stand activities and materials, and satellite meetings</li> </ul>

Q&A, question and answer



## Conclusion

The value of RWE lies in the new, informed insights it generates, which, in turn, enable improved decision-making. To achieve this, the eventual communication of evidence is as important as its generation. Pairing robust study design with effective data dissemination ensures that the evidence generated is understood, meaningful, and actionable for its audiences. In order to be impactful, communications and study stakeholders' engagement plans must be developed from the start, thus becoming an integral part of both RWE programmes and individual studies. This

can be achieved by early involvement of medical communications experts, who ensure the RWE generation efforts are translated into meaningful dissemination strategies and educational initiatives. Publications are critical, but innovative tools based on new technologies should also be explored to align with modern ways of consuming information, thus reaching the final audiences in a more efficient and engaging way.

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# About the authors



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Rebecca is responsible for the Medical and Patient Communications group within IQVIA, a full-service medical communications agency that has specialist capability in the compliant and impactful communication of RWE through effective publication and presentation strategies enriched by multichannel communications outreach.

With more than 20 years' communications experience, Rebecca works with HCPs, patients, and caregivers to understand unmet needs and develop programmes that measurably improve patients' healthcare and that are executed at a regional, national, and global level.



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Markus has more than 20 years' experience of advising life science clients on a broad range of topics, including RWE strategy, launch readiness, go-to-market models, and brand and commercial strategies.

An area of particular interest is the value of RWE and its impact on pharmaceutical businesses, and this has been the focus of several white papers that he has published recently.

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