Can Real-World Data Explain Patient Benefit?

Report of Roundtable – 3 June 2026

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Introduction

On 3 June 2026, the RWE4Decisions multi-stakeholder learning network organised a virtual roundtable meeting entitled "**Can Real World Data Explain Patient Benefit?**". It brought together 65 participants from across the healthcare landscape in Europe and North America, including staff from health technology assessment (HTA) bodies, public payers, national health ministries, regulatory agencies, EU institutions the pharmaceutical industry and patient groups; data analysts, registry holders and academics. The meeting enabled rich, cross-sector discussion about how patient relevant outcomes could be captured in the real-world setting.

Co-moderated by Eric Sutherland (Organisation for Economic Cooperation and Development (OECD)) and Karen Facey (RWE4Decisions Senior HTA Advisor), the meeting opened with a scene-setting intervention, followed by a topic introduction and three case study presentations that grounded the discussion in practical experience about development of patient relevant outcomes for use in the real-world setting. These inputs shaped dynamic exchanges during the multistakeholder breakout discussions that fed into the plenary reflections. Notably, this Roundtable marked the first edition to feature dedicated perspectives from HTA/Payers, adding valuable decision-maker insights and strengthening the overall depth of the discussion.

People-centred digital health systems: Eric Sutherland and Isaura Guttiérez Vargas (OECD)

Eric Sutherland (OECD) opened the discussion by underscoring the central role of patient involvement in shaping more responsive and effective health systems. Drawing on the OECD's Patient Reported Indicator Survey (PaRIS), which captures the perspective of over 100,000 patients on health systems and digitalisation, he highlighted the growing importance of integrating patients' voices in the digital transformation of healthcare. These insights are reflected in the OECD report on "Building people-centred digital health systems: lessons from PaRIS", published on 25 March 2026 (see here). Eric then invited his colleague Isaura Guttiérez Vargas (OECD) to present key findings from the report and implications for designing more people-centred digital health systems.

Drawing on the findings from the PaRIS survey, Isaura highlighted several important lessons on the current state of patient-centred digital health systems. First, she pointed to a significant awareness gap: while 93% of primary care practices across OECD countries actively use electronic medical records, only 80% of patients are aware that they can access these. This gap underscores that the mere availability of digital tools does not guarantee their effective use; patient engagement therefore remains essential. Second, Isaura underlined that patients who are required to repeatedly provide the same information when moving between healthcare providers report notably poorer experiences. The survey demonstrates that they experience a 15-point reduction in perceived quality of care, a 15-point drop in trust in the healthcare system, and a 20-point decline in person-centred care in comparison to those who do not face this burden.

Building on these findings, Isaura highlighted four key enablers for effective patient-centred digital health systems:

- patients must be aware of their rights and the data they can access;
- patients must be supported to develop digital literacy;
- digital tools need to be intuitive and easy to use;
- governments must establish policy frameworks that place patients in control of their own data.

Following Isaura's presentation, Eric highlighted the increasing influence of digital technologies in shaping patient behaviour. Patients are increasingly turning to digital tools and artificial intelligence (AI) for health-related information: it is estimated that over 232 million patients use ChatGPT for such purposes within a single week, and in the United Kingdom (UK), around one in three patients consults AI-driven tools before seeking advice from a healthcare professional. These trends underline both the widespread adoption of digital solutions and the pressing need to ensure that they are used in a reliable, safe, and meaningful way. In this context, Eric stressed the responsibility of health systems to build trust, support informed use, and ensure that digital innovation translates into tangible patient benefit, and this is where real-world data (RWD) can prove valuable.

The challenge of using RWE to demonstrate patient benefit? Meni Styliadou (Takeda)

Meni Styliadou shared insights based on Takeda's experience in an IQWiG assessment of a treatment for ALK-positive metastatic non-small cell lung cancer (NSCLC). During its evaluation, IQWiG differentiated between patients with brain metastases and those without. For patients with brain metastases, the available data demonstrated a clear additional benefit, leading to a positive recommendation. For patients without brain metastases, although there was insufficient evidence to demonstrate a significant overall survival benefit, robust data on quality-of-life improvements were considered sufficient to justify a modest additional benefit, ultimately supporting a positive recommendation.

This case illustrates that even some of the most stringent HTA bodies recognise the value of patient-reported outcomes (PROs) in their assessments. It underscores the importance for pharmaceutical companies to systematically capture PROs within clinical trials. However, such data are typically derived from pivotal clinical trials, as they remain largely unavailable in real-world settings. This is primarily because PROs are not routinely captured in electronic health records, due to the complexity involved and the significant investment in digital infrastructure required; an investment that many healthcare systems are not able to make. While registries may offer relevant data, these are often characterised by inconsistent data collection methods, limited interoperability, fragmentation, and restricted access, particularly for industry stakeholders. A potential solution to these challenges could be the development of a trusted and scalable European registry framework. Such a framework could strengthen the use of real-world evidence (RWE) by establishing a shared infrastructure that leverages digital technologies, reduces burden, and optimises care delivery.

The importance of high-quality, user-friendly technology to capture PROs was also emphasised. Enabling patients to effectively share data with healthcare systems requires state-of-the-art digital tools that are accessible to both patients and healthcare professionals. Ideally, such tools should strengthen interactions between patients and healthcare professionals, thereby facilitating high-quality data as a natural by-product.

This approach has the potential to enhance primary care and support shared decision-making, while simultaneously generating more standardised and higher-quality data across Europe. In turn, this would improve evidence generation and enable continuous assessment of innovative treatments entering the market. Overall, this model represents a potential “win-win” solution, underpinned by trust between patients, healthcare providers, and other stakeholders.

Case study presentations

Patient-led real-world data collection integrating with disease registry – Mark Skinner (Institute for Policy Advancement Ltd)

Mark Skinner shared his extensive experience as part of the haemophilia community to illustrate how RWD platforms can be designed to better capture patient benefit, particularly through the integration of PROs within registries specific to those living with inherited bleeding disorders.

There has been significant progress in haemophilia care, transforming from a condition with no available treatment in the 1960s to one where patients today can achieve near-normal life expectancy. In this context, registries can play an important role, not merely as tools for data collection, but as critical instruments to support, monitor, and continuously improve the quality of haemophilia care. Importantly, their value extends beyond clinicians and policymakers to patients themselves and the wider health system.

As a result, it is imperative to incorporate multiple perspectives into development of disease registries, including clinical, patient, regulatory, and HTA bodies. Each group brings different perceptions of value, evidence expectations, and data needs when assessing therapy benefits alongside associated costs, burdens, and risks of treatment and disease impact. This implies that the value of a treatment should not be limited to efficacy endpoints alone, but should be based on a stepwise approach grounded in what patients deem relevant, with a focus on functional cure and health equity. This requires systematic collection of relevant and well-defined outcomes across the entire life cycle of a treatment, from clinical trials to real-world use, to avoid research waste arising from inconsistent measurement.

These considerations led to the PROBE global study, designed by patients, for patients, to collect information on outcomes that matter most to them. Running for over 14 years across more than 100 countries, and in over 45 languages, PROBE has contributed to the development of patient-centred core outcomes sets that have informed registries and clinical trial work by establishing

a common understanding of what should be measured. These outputs have helped establish transformative haemophilia clinical trials and post-launch evidence generation.

Drawing on experience from three ICER HTA reviews conducted over a five-year period [1] [2] [3], Mark highlighted an evolution in the understanding and recognition of key outcomes in HTA, which has marked a positive step for progress in haemophilia treatment. Today, PROBE is integrated within t, an international registry collecting standardised clinical data on people with haemophilia and has most recently been included as part of the national registries in Austria, Canada, Japan, and Mexico. World Bleeding Disorder Registry (WBDR), an international registry collecting standardised clinical data on people with haemophilia and has most recently been included as part of the national registries in Austria, Canada, Japan, and Mexico.

Real-World Evidence that is driven by what patients consider to be important is essential to advance care. Stronger real-world evidence enables patient advocates to deliver more effective advocacy that goes beyond emotion and anecdotal arguments and provides the evidence to support the introduction and evolution of care using outcomes that matter to patients.

Pan-European Health Outcomes Observatory's work towards advancing the routine use of patient-reported outcomes in real-world evidence across Europe – Jørgen Schøler Kristensen (Pan-European Observatory)

Jørgen's presentation offered insights from the Health Outcome Observatory (H20), a 2020-2026 IMI project that became the Pan European Observatory (PEO), a non-profit organisation aiming to transform patient experiences into evidence that supports better healthcare decisions.

Referring to the OECD's 'Health at a Glance' 2025 report (see here), Jørgen highlighted that patients increasingly expect high-quality, accessible, and trusted care supported by more information, improved disease control, and greater satisfaction. However, healthcare systems remain under considerable pressure, reinforcing the need for cost-efficient solutions that support the delivery of high-quality care. Regarding the secondary use of data, Jørgen emphasised that HTA and outcome-based reimbursement are likely to become increasingly important in healthcare systems. At the same time, continued innovation remains essential, requiring a strong life sciences sector and research to ensure that new treatments continue to patients.

Jørgen then presented the work undertaken during the 2020-2026 IMI-funded Health Outcomes Observatory (H2O) project. The project aimed to establish patient-trusted approaches to data collection and standardisation at the European level. Initially implemented through national observatories across several disease areas, H2O focused on collecting PROs, combining them with electronic health record data (EHR), and making these available in a federated manner. This model enabled the PEO to address research and policy questions, including those posed by industry stakeholders, while aligning with the European Health Data Space (EHDS). Following completion of the project, the PEO now aims to strengthen patients' voice in healthcare by transforming patient experiences into evidence that support better decision-making. By enabling

[1] ICER. Valoctocogene Roxaparvovec and Emicizumab for Hemophilia A: Effectiveness and Value; Final Report. Institute for Clinical and Economic Review, November 20, 2020. https://icerreview.org/material/hemophilia-a-update-final-evidence-report/

[2] ICER. Gene Therapy for Hemophilia B and An Update on Gene Therapy for _Hemophilia A: Effectiveness and Value. Available from: https://icer.org/wp-content/uploads/2022/05/ICER_Hemophilia_Final_Report_12222022.pdf

[3] ICER. Gene Therapy for Hemophilia B and An Update on Gene Therapy for _Hemophilia A: Effectiveness and Value. Available from: https://icer.org/wp-content/uploads/2022/05/ICER_Hemophilia_Final_Report_12222022.pdf

patients to measure and share outcomes in a standardised and trusted way, the PEO connects patients, clinicians, researchers, policymakers, and industry within a shared ecosystem.

Jørgen underlined that HTA agencies and healthcare systems across Europe face similar challenges. First, routinely collected EHR data often fail to capture information on side effects, quality of life, and patient outcomes. Second, routinely collected data is often incomplete and of variable quality. Finally, EHR data alone remain of limited value for HTA authorities, payers, regulators and other decision-makers, highlighting need for more robust evidence.

Returning to the central question of whether RWD can explain patient benefit, Jørgen argued that the combination of PROs and healthcare data represents a particularly valuable source of evidence and is increasingly being used in regulatory and HTA processes. However, methodological challenges remain, including the need to accelerate data collection and data quality, ensuring that evidence is of sufficiently robust for decision-making. Scaling these approaches will require further development and could be supported by the implementation of the EHDS. Finally, trust among both patients and healthcare professionals was emphasised as a critical enabler. Without trust, data sharing remains limited, and data quality suffers. Building and maintaining this trust is therefore essential for the success of RWD initiatives.

Honing patient-relevant outcomes for real-world use – Steven Harjes (Hematon)

Steven presented the patient perspective, informed by Hematon's work across multiple projects to better capture patient outcomes.

Steven highlighted the key challenges associated with capturing patient data. Importantly, while PROs are increasingly well captured in clinical trials, their integration into routine clinical practice remains limited. As a result, many patients do not consistently report outcomes, leading to gaps in data coverage. In addition, the lack of integration across existing data sources further constrains their usefulness. Steven therefore emphasised the real value of moving towards global, disease-specific registries capable of consolidating currently fragmented initiatives, both within and across countries, into a single, coherent system.

From a patient advocacy perspective, Steven outlined several key objectives. First, data should be aggregated into a robust evidence base that reflects patients' experiences in day-to-day care. Second, generating evidence suitable for HTA requires the use of standardised datasets and questionnaires to ensure outputs are coherent, comparable, and actionable. Third, sustained patient engagement throughout the care journey is essential to encourage and maintain data sharing. Many patients may not be motivated enough or lack the necessary support to share their data, often due to limited familiarity with digital tools or because they are simply not asked. Finally, PRO data should be linked with clinical data, as this integration is critical to generate meaningful insights into patient outcomes that can support decision-making.

Building on Mark Skinner's presentation and the importance of considering multiple perspectives, a clear divergence emerges between healthcare professionals and patients in their approaches to capturing PROs. Healthcare professionals prioritise consistent data collection at fixed intervals, relying on a broad set of standardised measure to generate scientifically robust evidence. In contrast, patients often perceive PROs questionnaires as burdensome, particularly when questions appear to be irrelevant to their condition or when they are being required to report at fixed intervals even when no changes occur, while lacking the opportunities to report meaningful changes when they do arise. This misalignment represents a significant barrier to participation and can lead to low engagement or dropout. Additional barriers include limited patient energy levels due to their condition, and complex and legalistic consent forms, which tend to discourage rather than support participation in data collection.

To address these barriers, Steven identified several practical solutions. First, consent processes should be simplified by replacing lengthy consent documents with clear, concise formats, such as infographics, on the purpose and benefits of data sharing. This would help patients better understand the value of their contribution and increase their willingness to participate. Second, while maintaining standardisation, questionnaires should focus on collecting information that is meaningful and relevant to patients. Inputs from surveys and disease-specific PROs could be used to filter and prioritise the most meaningful data points, ensuring that only essential information is collected to generate robust evidence. Third, greater flexibility in reporting frequency should also be introduced, with reporting triggered by changes in medication or health status and less frequent reporting during periods of stability. Finally, maintaining patient engagement requires regular feedback demonstrating how patients' data is being used and the impact they generate.

Steven further noted that a key challenge lies in transforming captured data into evidence that is acceptable and actionable for HTA bodies and payers. Decision-making in this context is often strongly influenced by economic considerations, requiring a clear demonstration of value. This includes the need to better capture and translate quality of life improvements into economic terms that can inform decision-making.

Looking ahead, Steven outlined several goals, including first, increasing patient participation in data sharing, with the ambition of enabling more than 90% of patients to share relevant data through flexible mechanisms. Second, aligning data collection approaches with HTA requirements to ensure that the resulting evidence can effectively support decision-making. Third, integrating clinical data and PRO within international disease-specific registries, allowing outcomes to be directly linked to treatments. Finally, exploring the use of RWD collected in routine care settings outside clinical trials as a control arm for innovative treatments, particularly given the diversity of existing standards of care.

Q&A

The presentations section finished with a Q&A, which highlighted several important considerations for the use of RWD and PROs in generating evidence on patient outcomes and inform decision-making:

- The discussion highlighted that focusing solely on "patient benefit" may be too narrow, and that a broader concept of "patient impact" may be more appropriate. Participants noted that evidence generation should capture both positive and negative aspects of care, including treatment burden and unintended consequences. This reflects a shift towards a more holistic understanding of outcomes, aligned with real-world patient experience.
- A central theme of the debate was the importance of clearly defining the research question underpinning PRO collection. Participants noted that different stakeholders (patients, clinicians, HTA bodies, policymakers) require different types of evidence. The intended purpose of data collection (clinical decision-making, HTA, policy evaluation) should determine the type of PROs collected, how frequently they are measured, and which methodological approaches are used. Without a clearly defined research question, there is a risk of collecting data without clear relevance or use, undermining both credibility and patient engagement.
- The discussion also highlighted a critical gap between data collection practices and the value perceived by patients. Examples were shared of patients completing PRO questionnaires without understanding their purpose or seeing any impact on care. This can lead to reduced trust and engagement, and questions around the meaningfulness of

the data collected. This highlighted the need to ensure that data collection is transparent, purposeful, and visibly linked to outcomes or decisions.

- Participants also acknowledged that different decision-making contexts require different types of evidence. Information that is valuable in supporting conversations between patients and healthcare professionals may differ from the evidence required by HTA bodies assessing new technologies or by policy makers evaluating broader population outcomes. This complexity may become even more pronounced in international or multi-country settings, where diverging HTA requirements and decision-making frameworks could make it challenging to adopt a "one-size-fits-all" approach to evidence generation.
- A strong consensus emerged that PROs should be rooted primarily in the clinical encounter, rather than driven by secondary uses: PROs should support meaningful dialogue between patients and healthcare professionals. A more flexible, tailored approach was suggested, whereby patients and clinicians identify the outcomes most relevant to the individual context. High-quality data generated through these interactions could subsequently support broader evidence needs, including those of HTA bodies and policymakers.

Breakout group discussions

Following the presentations, participants were divided into multi-stakeholder breakout rooms facilitated by Martine Elias (Myeloma Canada), Tove Holm-Larsen (DataFair), and Prof. Dalia Dawoud (Cytel Inc.), with the support of scribes Melinda Hanisch (MSD), Gabriela Ochoa Gracia (Rotterdam University), and Maddie Shipley (ISPOR).

Discussions focused on how patient-generated data should be collected, used and valued in practice, including questions around patient empowerment, feedback mechanisms, feasibility of data collection (including digital tools), data quality, and the role of stakeholders such as clinicians and caregivers.

- **Patient ownership, empowerment, and feedback**
  - Patients should be empowered by ownership of their data and should experience tangible benefits from sharing it. A key concern was that patients are often asked to provide data without receiving feedback on how those data are used or what impact they have had. This was seen as problematic and potentially detrimental to continued engagement.
  - Ensuring that patients receive meaningful feedback and understand the benefit generated from their data was highlighted as an important priority for sustaining participation and trust.

- **Patient and caregiver relevance**
  - Participants discussed different approaches to collecting patient-generated data, including the use of apps and wearables. However, concerns were raised that increasing data collection requirements could place additional burden on clinicians and healthcare systems, which may struggle to monitor and respond to growing volumes of information.
  - Technology was nevertheless seen as a potential enabler, provided it supports standardised data collection and remains flexible to patients' individual situations and levels of digital literacy.
  - The importance of caregivers was also highlighted, including the need to better understand caregiver experiences and the wider impacts of illness on productivity and daily life. Participants noted that this area warrants further exploration.

- **Data quality, trust, and transparency**

- Data quality was identified as a key concern across groups, particularly due to differences between clinical trial data and data collected in routine care settings.
- Participants noted that trust in decisions informed by RWD depends on confidence in the quality and transparency of the data and methods used. Building trust was therefore seen as a critical priority, requiring openness about how data are collected, used and interpreted, as well as greater involvement of patients throughout the process.
- Transparency regarding the different interests and perspectives of stakeholders was also considered important to support constructive collaboration.

- **Use of patient data in decision-making**
  - Participants recognised that patient-reported data is increasingly being considered in decision-making processes, including HTA, even though there are still differences in how qualitative and quantitative evidence are considered.
  - Interest was expressed in gaining a better understanding of how patient-reported data has influenced decisions in practice, including through concrete examples, demonstrating their contribution to HTA recommendations and reimbursement decisions.
  - Discussions also highlighted that the intended purpose of data collection should guide decisions regarding what information is collected, how it is collected, and how it is used.

- **Scaling, collaboration, and broader considerations**
  - Participants emphasised the importance of collaboration across countries and stakeholders to strengthen the collection and use of patient-generated data, particularly in areas such as rare diseases where international cooperation may be essential. At the same time, challenges related to legal frameworks, differences in infrastructure and varying levels of digital maturity across jurisdictions were acknowledged.
  - Discussions also highlighted the challenge of scaling successful initiatives from small examples to broader systems. Participants reflected on the need to identify appropriate methodologies, and implementation approaches that can support wider adoption while maintaining data quality and stakeholder trust.
  - A shared commitment to improving patient outcomes emerged across stakeholder groups, alongside recognition of the need for continued dialogue to advance this agenda.
  - Participants also reflected on the need to accelerate progress while ensuring that approaches to data collection remain sustainable and capable of supporting the long-term use of data.
  - Despite the challenges identified, discussions reflected a shared commitment across stakeholder groups to improving patient outcomes and highlighted the importance of continuing dialogue to advance this agenda.

Exclusive insights from HTA representatives

As a new element introduced by RWE4Decisions, the Roundtable concluded with reflections from two HTA representatives, who responded to the breakout discussions and shared perspectives, drawing on both a European perspective (Denmark) and a non-European perspective (Canada). Their contributions helped anchor the discussion in real-world HTA practice and highlighted that, despite differences between systems, many of the challenges surrounding patient-generated data, RWE, and decision-making are shared internationally. It

also gave participants a much clearer sense of how the issues raised throughout the Roundtable translate into actual HTA processes, which strengthened the overall discussion.

Christian Dehlendorff from the Danish Medicines Council framed his reflections around the idea that data collection should create a "win–win–win" situation, benefiting patients, clinicians, and HTA bodies alike. Ensuring that patients benefit from sharing their data is not only important in its own right but also supports better data collection through improved engagement and adherence. He also highlighted the importance of clearly defining which outcomes should be collected, stressing that these need to be relevant simultaneously for HTA decision-making, for clinicians following disease progression, and for patients themselves. This is particularly important given that HTA bodies rely on approaches such as cost-utility analysis, which require appropriate ways of measuring patient-relevant aspects like quality-of-life data that is not always well captured in current sources. This becomes even more critical in the context of outcome-based agreements and earlier access pathways, where there is a growing need to understand how treatments perform in real life, beyond survival, including from the patient perspective.

Building on this, **Colette Raymond** provided a Canadian HTA perspective, complementing and reinforcing several of these points, while also bringing a strong emphasis on methodological rigour and evidence standards. She noted that HTA agencies are inherently interested in outcomes that matter to patients but emphasised that this interest must be matched with high-quality, robust data. In particular, patient-reported outcomes should be valid, appropriate for the population, and capable of capturing meaningful concepts for patients. At the same time, the well-known challenges associated with real-world evidence, including bias and variability, require careful critical appraisal. Colette also noted that generating robust patient-reported evidence was recognised as a resource-intensive and time-consuming process, underscoring the importance of transparent and consistent reporting and to ensure that evidence generation aligns with HTA expectations.

The **reactions from participants** further deepened and, in some cases, challenged these HTA perspectives by illustrating how these issues play out in practice across different stakeholders. Several interventions emphasised that the timelines required to generate meaningful patient data are often incompatible with HTA processes, with patient organisations noting that it can take years to develop appropriate instruments, collect and curate data, and be ready for submission. This led to a strong call for much earlier involvement of patients and partners, including at the earliest stages of development. Others highlighted that different stakeholders approach real-world evidence from fundamentally different perspectives: HTA bodies may focus on validating decisions around efficacy and cost-effectiveness, while clinicians are more concerned with managing treatment and side effects in practice, and patients focus on concrete impacts on daily life, such as the ability to carry out everyday activities which are often not systematically captured.

Participants also questioned more fundamentally what real-world evidence is being collected for, and how it should be used over time, noting that its purpose may differ depending on the context, whether for HTA, clinical care, or broader understanding of patient experience. This was reinforced by exchanges pointing out that real-world evidence can serve multiple functions and does not need to be limited to a single use case, but that clarity on its intended purpose is essential. At the same time, there was recognition that patient evidence can play a decisive role in HTA, particularly in situations of uncertainty, where it can highlight benefits that are not captured in traditional clinical outcomes and can ultimately influence decisions.

Overall, the exchange between HTA representatives and participants created a particularly rich and grounded discussion, showing both the openness of HTA bodies to patient-relevant data and

the practical challenges of generating, aligning, and using such evidence across different stakeholders and timelines.

Conclusion

The Roundtable discussions highlighted both the growing importance of real-world data in capturing patient benefit, and the practical challenges associated with generating evidence that is fit for decision-making. While patient-reported outcomes are increasingly recognised as essential to capturing outcomes that matter to patients, their integration into routine care remains limited, raising questions about feasibility, data quality, and alignment with stakeholder needs.

The inclusion of reflections from HTA representatives brought an important, practice-based perspective to these discussions. Across both European and Canadian experiences, there was a clear openness to the use of patient-relevant data, but also a strong emphasis on the conditions required for its use: outcomes need to be clearly defined and relevant across stakeholders, data must be robust and methodologically sound, and evidence generation must be planned early. These reflections reinforced that patient-generated evidence can play a meaningful role in addressing uncertainty and informing decisions, provided that it meets the standards required within HTA processes.

A recurring theme throughout the Roundtable was the need for greater clarity regarding the purpose of data collection. Different stakeholders rely on real-world evidence for different objectives, whether to support clinical care, inform HTA, evaluate broader policy questions, or better understand patient experiences. This purpose should guide decisions about which outcomes are collected, how they are measured, and how the resulting evidence is ultimately used. Without this clarity, there is a risk of generating data that is neither meaningful for patients nor actionable for decision-makers.

The discussions also highlighted the importance of ensuring that patients derive value from sharing their data, including through feedback and opportunities to inform care and decision making. Sustained patient engagement was recognised as critical not only for improving participation, but also for strengthening the quality and relevance of the evidence generated.

Overall, the Roundtable pointed to the need for stronger collaboration and earlier coordination across stakeholders to align expectations, strengthen methodologies, and develop data collection approaches that are both feasible in practice and fit for decision-making. Unlocking the full value of real-world data will depend on ensuring that evidence generation ultimately translates into meaningful benefits for patients and health systems alike.

RWE4Decisions is an HTA/Payer-led multi-stakeholder Learning Network, which, in 2024, developed of a set of new Stakeholder Actions to generate better real-world evidence for HTA/payer decisions about highly innovative technologies.

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