Developing Real-World Evidence to Deliver Innovation in HTA

14 November 2024 | 09:00 – 14:00 CET

BIP Meeting Centre, Rue Royal 2-4, 1000 Brussels

Annual RWE4Decisions Symposium: Key Takeaways

RWE4Decisions and its multi-stakeholder Steering Group held its Annual Symposium on 14 November 2024 in Brussels, themed 'Developing Real-World Evidence to Deliver Innovation in HTA'. The policy context for use Real-World Evidence (RWE) by HTA/Payers in Europe was explored, and the revised set of Stakeholder Actions to Generate better RWE for HTA/Payer decisions was launched.

Policy context for RWE to support innovation in HTA and improve patient access to innovative medicines

In the spotlight was the yet to be implemented European Health Data Space (EHDS) and the upcoming HTA Regulation. While the technical details of the EHDS legislation were just finalised by the EU institutions, concerns were raised about the EHDS implementation timeline due to be completed in 2030. Rapid technological innovations could significantly transform the landscape of health data management, potentially challenging the relevance of the EHDS by the time its secure system for the secondary use of data (for e.g. HTA) will be in use.

RWE4Decisions stakeholders await to see how RWE will feature in the first Joint Clinical Assessments (JCA) as the HTA Regulation enters into force in on 12 January 2025 for Oncology and ATMPs. A clear call for the JCAs to go beyond traditional relative effectiveness and think about other aspects of value was made, particularly in rare diseases. The Spanish HTA Agency AETS representative emphasized the importance of a proactive approach towards RWE throughout the lifecycle of medicines to help HTA/Payers anticipate future needs and challenges.

RWE also plays a key role in the EU pharma package, set to modernise the bloc's pharmaceutical legislation. Discussions are currently stuck in the Council, where national ministers cannot agree on the period of time that pharma companies would be granted regulatory data protection and market exclusivity for new innovative drugs, before other entities could access their data for e.g. the generics market.

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Launch of the revised Stakeholder Actions to Generate better RWE for HTA/Payer decisions

The Symposium underscored the necessity of collaborative efforts to generate better real-world evidence (RWE) for HTA and Payer decision-making about highly innovative medicines. The discussions recognized the need for partnerships to build comprehensive RWE that addresses all aspects of value. RWE4Decisions has therefore launched a set of revised Stakeholder Actions to Generate Better RWE for HTA/Payer Decisions.

The Actions propose a series of recommendations for seven stakeholder groups: national HTA/Payers, HTA/Payer collaborations , the pharmaceutical industry, clinical teams, patient groups, disease registry holders, and Analytics groups. Finnish Medicines Agency representative Piia Rannanheimo presented some of the Actions, such as the importance of overcoming the lack of collaboration of national HTA and Payers for effectively requesting, producing, and utilizing RWE. At the same time, HTA/Payers should influence national developments on the secondary use of health data and communicate their data needs, as the EHDS is being implemented. The need to showcase how RWE is used in decision-making, for example through national reports was emphasized.

RWE4Decisions will focus on mobilising the Actions in the following years and engage with the different stakeholder groups to prioritise their implementation.

Post-Launch Evidence Generation

RWE4Decisions continues to foster dialogue about effective operationalization of Post-Launch Evidence Generation (PLEG), particularly for outcomes-based agreements linked to pricing and reimbursement. In 2024 RWE4Decisions focus was placed on the approaches being taken by HTA/Payers in France, Spain, England Italy and Germany to anticipate the need for PLEG and build robust, but feasible RWD collection systems. The need for collaboration across HTA bodies and other decision-makers (such as EMA), and engagement with industry to discuss RWD needs at various points in the life cycle of a medicine was stressed.

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As Jo de Cock, former CEO of INAMI concluded, the past 5 years has seen an evolution of the positioning of RWE and it is essential for Payers in many ways. But more work is needed to develop co-creation of robust RWE to both inform initial HTA/Payer decisions and to resolve uncertainties post launch. This requires transparency from industry about RWE methods and from HTA about assessment approaches. Then Payers need to get more involved in these developments to ensure we can enable faster access to patients of highly effective treatments.

RWE4Decisions is a payer-led multi-stakeholder learning network commissioned by the Belgian National Institute of Health and Disability Insurance (NIHDI) and led by a multi-stakeholder Steering Group The wider community of contributors includes HTA bodies and payers, regulatory agencies, patient groups, clinicians, industry, analytics experts and academic experts/researchers. The RWE4Decisions Secretariat is provided by FIPRA, with sponsorship by the European Confederation of Pharmaceutical Entrepreneurs (EUCOPE), AstraZeneca, Boehringer Ingelheim, Gilead, MSD, Novartis, Pfizer, Roche and Takeda.

For further information, visit https://rwe4decisions.com/ and follow @RWE4Decisions on LinkedIn.

Contact us at **secretariat@rwe4decisions.com** to join the RWE4Decisions Learning Network.