

***“In facing common challenges, let’s do it together and in trust”***

*RWE4Decisions is a Payer led multi-stakeholder initiative applying a learning by doing approach, enabling dialogues about challenging issues, to develop potential solutions. The objective is to increase awareness and create preparedness amongst different stakeholders with regard to the use of real-world data when assessing the value of treatments for patients and healthcare systems.*

The RWE4Decisions multi-stakeholder work in 2021 has concluded :

1. RWE is not a panacea or a stand-alone issue - however **RWE has a clear place within, and can be a vital part of, an integrated evidence generation plan for highly innovative technologies.**
2. **Ongoing and structured light touch iterative dialogues** among stakeholders **along the life-cycle of a product** should be developed further. These interactions are needed to identify the specific gaps and uncertainties with regard to access, availability and affordability of highly innovative technologies that could potentially be resolved by RWE generation.
3. Integrated evidence generation plans should address the needs of regulators, HTA and payers. There is a need to move from **«fragmented recommendations to comprehensive guidance» to improve the standards and the credibility of RWD studies.**
4. **To support outcomes-based managed entry agreements (OBMEAs)** that can inform optimal use of high-cost therapies, **there is a need for a clear RWE generation plan**, that takes account of regulatory post marketing data collection requirements. This requires **financial investment in data infrastructure and alignment of approaches across borders.** DARWIN EU and the European Health Data Space will have a crucial role to play in this regard.
5. **All stakeholders** must contribute to the OBMEA to **deliver high quality real-life clinical data** that could reduce the decision-relevant uncertainties identified at the point of pricing and reimbursement. The RWE collected in OBMEA also has an important role in treatment optimisation.
6. All these elements prove that there is a need to support decision-makers through the **sharing of practical learnings** on the use of RWE in HTA/Payer decisions. RWE4Decisions will continue to work collaboratively with stakeholders, the European Reference Networks and other initiatives to develop clearer processes and guidance that identifies how robust RWE can be developed for HTA/Payer decisions.

A Steering Group will be established to guide the work plan of RWE4Decisions 2022 and determine the sustainability of this agenda.