Co-Creation of Real-World Evidence for Decision-Making
2022 Symposium on 'Policies & Partnerships'

Brussels, 24 November 2022: RWE4Decisions welcomes the new momentum to support the development and use of Real-World Evidence. This is particularly relevant in light of the implementation of the EU Regulation on Health Technology Assessment. Oncology and ATMP products will be assessed through Joint Clinical Assessments in 2025 and the importance of RWE is increasingly apparent. These highly innovative technologies are potentially life changing for patients suffering from debilitating or life-threatening diseases but there are significant uncertainties at the time of launch.

The proposed EU Regulation for a European Health Data Space will provide the much needed infrastructure for the sharing of primary and secondary data, and should address the fragmented and differing interpretations of EU data protection rules (GDPR) across Member States. Moreover, the EMA's Data Analytics and Real World Interrogation Network (DARWIN EU) is also a great step in the right direction and should enable collaboration between regulators and HTA bodies/Payers on the collection of data across the lifecycle of products.

The RWE4Decisions community identified four themes considered key to shaping the generation of robust RWE for HTA bodies and Payers which were discussed at the RWE4Decisions Symposium:
(1) Data availability, governance and quality; (2) Methodology - design and analytics; (3) Trust, transparency and reproducibility; and (4) Policies and partnerships.[1]

Following the feedback from today's Symposium, RWE4Decisions will continue driving multi-stakeholder dialogues to share learnings and identify solutions to challenges faced by healthcare decision-makers. Based on the principles of Collaboration and Transparency, which are underpinning the RWE4Decisions network, priorities for 2023 will be:

- Identification of case studies to explore development and evaluation of RWE for HTA/Payer purposes.
- Encouraging HTA bodies/Payers to share protocols and reports in a publicly accessible portal. This would help document Payers' specific needs for RWD and help align real-world data collection requirements across borders.
- Sharing experiences and examples, of use of real-world data in outcomes-based managed entry agreements (conditional reimbursement processes).

Jo De Cock, Senior Adviser to INAMI-RIZIV, who has been the thought leader behind the initiative, stated that: "*The landscape is evolving as RWE has gained traction in recent years. How will these joint clinical assessments take on board RWE? As Payers, we have to assess these innovations, how can real-world data be effectively collected to contribute to outcomes based managed entry agreements. RWE4Decisions is an important forum for collaboration between stakeholders and decision-makers to share learnings on current guidance, experience in practice and discuss new collaborative endeavours.*"

[1] The findings were published in: Capkun, G., Corry, S., Dowling, O., Asad Zadeh Vosta Kolaei, F., Takyar, S., Furtado, C., . . . Facey, K. (2022). Can we use existing guidance to support the development of robust real-world evidence for health technology assessment/payer decision-making? International Journal of Technology Assessment in Health Care, 38(1), E79. doi:10.1017/S0266462322000605

For further information about RWE4Decisions, visit https://rwe4decisions.com and follow the initiative on Twitter and LinkedIn

About RWE4Decisions:
In 2020, RWE4Decisions called for a **multi-stakeholder Learning Network on Real-World Evidence**. Led by a Steering Group, the initiative collaborates with around 80 HTA bodies and payers, regulators, health policy decision-makers, patient representatives, clinicians, data analysts, industry and academics. The objective is to develop practical learnings on the potential use of RWE when assessing the value of treatments for patients and healthcare systems.
FIPRA has facilitated the multi-stakeholder discussions with sponsorship by the European Confederation of Pharmaceutical Entrepreneurs (EUCOPE), AstraZeneca, Bayer, Boehringer Ingelheim, Novartis, Roche and Takeda.

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