RWE4Decisions REAL WORLD EVIDENCE

EVENT REPORT

The Use of Real-World Evidence for Decision-Making: Next Steps to Develop HTA Guidance

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SPEAKERS

Moderated by Diane Kleinermans, President of the Commission of Drugs Reimbursement, INAMI-RIZIV and Karen Facey, Consultant to RWE4Decisions

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In October 2021, RWE4Decisions held a webinar to reflect on existing guidance about the use of real-world evidence (RWE) and its applicability to HTA/Payer decisions.

The key challenge identified with the use of RWE to determine treatment effectiveness in HTA/Payer decision-making was related to the data itself (e.g., quality, timeliness, access and governance).

Key takeaways

- It was proposed that the challenges associated with use of RWE to determine treatment effectiveness in HTA/Payer decision-making could be described in terms of issues associated with:
    - **Data** – poor quality of data (including incomplete and missing data), data standardisation, timeliness of data, lack of robust data, inadequate data infrastructures, access processes and governance.
    - **Methodology** – issues related to design and analysis (e.g., selection bias)
    - **Trust and Transparency** – lack of trust in the robustness of findings from RWE studies (e.g., lack of trust in data and strategy and between stakeholders)
    - **Policy and Partnerships** – Lack of harmonization of policies and of evidence requirements between potential partners and lack of coordination at the international level between HTA and Payers.

- Panellists agreed that these themes were important, with the **data issues** (such as discoverability, availability, timely accessibility, quality, interoperability) **being paramount**

- Other potential themes included the need for **HTA and payer management support** to commit resources to develop capacity and work in the field of RWE and **education to upskill HTA bodies** to critically review RWE studies

- There is already existing guidance produced by trusted sources with expertise in pharmacoepidemiology and economic modelling (e.g., on the use of registries, analysis of health system data etc) which could be used by HTA/Payers. The **guidance most relevant to key questions that arise in HTA needs to be identified** and **guidance needs to be developed for the issues that are specific to HTA/Payers.**

- Building on the RWE4Decisions principles of collaboration and transparency the following are needed:
    - Sharing of use cases of RWE in HTA/Payer decisions to sign-post best practice
    - Registration of RWE study designs and analysis plans via a public portal

- **HTA and payers need to lead developments in the field of RWE** and not wait to build on what others (such as regulators) are doing. For this **policy leadership** is needed to commit financial resources that supports collaboration not just across the EU, but internationally, particularly with North America. This should support development of guidance and HTA/Payer demonstration projects.

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RWE4Decisions is a multi-stakeholder group, which has developed stakeholder actions that will better enable the use of real-world evidence in HTA/payer decisions about highly innovative technologies. The work has been commissioned by the Belgian National Institute of Health and Disability Insurance (INAMI-RIZIV) and contributors include HTA bodies and payers, regulatory agencies, patient groups, clinicians, industry and academic experts/researchers.

For further information and to watch the recording of the webinar, visit our website at https://rwe4decisions.com/event/the-use-of-real-world-evidence-for-decision-making-next-steps-to-develop-hta-guidance/

Do also follow us on Twitter and on LinkedIn

We want to hear what you are doing to progress learnings on the use of RWE! Contact us at secretariat@rwe4decisions.com if you would like us to include any relevant updates to our next quarterly newsletter coming out in November.