



RWE4Decisions: a multistakeholder approach

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RWE4Decisions: A payer-led initiative multi-stakeholder learning network about use of RWE for highly innovative



What?

Pragmatic and agile Learning Network about use of RWE to inform HTA/Payer Decisions



Why?

Encourage development of robust RWE to help optimize use of highly innovative technologies



How?

Payer-led, Multi-stakeholder
Built on principles of Collaboration and Transparency



Added Value?

'Learning by doing' approach

- share experience, pool resources
- sandbox approach - real problems, light-touch solutions
- build trust

Public outputs and events
Policy engagement – CAPR, Nordic Alliance, BENELUXAI, EU and beyond



THOUGHT LEADERSHIP (INAMI-RIZIV)

MULTI-STAKEHOLDER COMMUNITY

HTAs
 AOTMIT (PL), G-BA (DE),
 AIFA (IT), AIHTA (AT),
 INFARMED (PT), FIMEA
 (FI), ZIN (NL), KCE (BE),
 MoH (ES), NoMA (NO),
 NCPE (IE), TLV (SE),
 CADTH (Canada)

**Insurers/CAPR/
Institutes**
 AOK (DE), HIS (SI, AT)
 Procurement (Denmark)

**Clinicians/
Researchers**
 EORTC, relevant ERNs

Academia
 Università Cattolica del
 Sacro Cuore
 University of Edinburgh

Patients
 EURORDIS, ECPC
 AfM-Téléthon, SMAUK

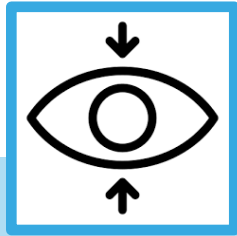
Regulators
 European Medicines
 Agency (EMA)

Industry
 EUCOPE & member
 companies*

The RWE4Decisions Secretariat (provided by FIPRA) facilitates the multi-stakeholder discussions with sponsorship by EUCOPE, *AstraZeneca, Gilead, Novartis, Roche and Takeda.



RWE4Decisions: case study workshops



Objectives

- Review recent experiences of use of OBMEA for Coverage with Evidence Development (CED) aimed to resolve HTA/Payer decision-relevant uncertainties for re-appraisal in future
 - GetReal
 - EUnetHTA PLEG
 - IMPACT HTA WP10
- Agree a RWE evidence generation framework for CED of 2 fictitious cases



Scope of June webinars

- Case 1:** therapy given to children on an ongoing basis at point of diagnosis of a rare neuromuscular disease
- Case 2:** a one-off cell therapy given to adults in a late-stage cancer



Multi-stakeholder discussions

- Agreement on Uncertainties
- ? Data sources for CED
 - ? Pros and cons of different data sources
 - ? Challenges in accessing data
 - ? Good practices
 - ? How to develop data collection protocol
 - ? Alignment of data collection requirements



Outputs

RWE4Decisions recommended actions for stakeholders to support payer/HTA decisions about highly innovative technologies



RWE4Decisions: main outcomes workshops

1. Need for national or collaborative horizon scanning processes to identify eligible technologies for OBMEA
2. HTA/Payers need to clarify the decision relevant uncertainties and identify key clinical questions and the data to be collected
3. OBMEA should only be initiated when sufficient data can be collected to resolve decision relevant uncertainties
4. For rare diseases collaboration across countries is needed to align data requirements and access to datasets
5. Processes need to be developed to interact with regulators to avoid duplication and to make use of DARWIN in the future



RWE4Decisions: main outcomes workshops

6. A proactive approach to data collection must involve all relevant stakeholders
7. All aspects of data collection plans should be documented and publicly reported
8. Financial investment in data infrastructure, collection and analysis is necessary
9. RWE4Decisions should support development of relevant guidance relating to generation of RWE in HTA/Payer decision making
10. Connection with collaborative initiatives as Beneluxa, Finose,... could lead to additional outcomes



RWE4Decisions: general learnings

1. RWE is not a panacea or a stand alone issue. Nevertheless it can be a vital part of integrated evidence generation plans.
2. Ongoing and structured iterative dialogues among stakeholders along the life cycle of a product should be developed further.
3. It is necessary to move from “fragmented recommendations to comprehensive guidance” and improvement of the standards of RWD studies
4. OBMEA should contain a clear RWE generation plan.
5. There is a need to support decisions makers through the sharing of practical learnings. A call to set up a learning network was repeatedly formulated

A word cloud featuring the phrase "thank you" in multiple languages and colors. The central and largest text is "thank you" in red. Other prominent words include "gracias" in green, "danke" in blue, and "merci" in orange. Smaller words in various colors include "спасибо", "dziękuje", "obrigado", "sukriya", "terima kasih", "감사합니다", "ngiyabonga", "teşekkür ederim", "dank je", "tapadh leat", "mochchakkeram", "go raibh maith agat", "arigatō", "dakujem", "merci", "sagolun", "hvala", "mauruuru", "kop khun krap", "grazie", "ευχαριστώ", "takk", and "merci".