# CURRENT AND FUTURE USE OF RWE IN HTA DECISION-MAKING: PAYERS VIEW GLOBALLY

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November 2024

# There are more and more useful data available in addition to RCTs …

(+) *Most robust*

- **Secondary care databases,** e.g. Hospital Episode Statistics (HES)
- **Primary care databases**, e.g. general practitioners and family doctors
- **Surveillance and monitoring data**, e.g. drug safety monitoring data
- **Public health and Social care data**
- **Audits data** (clinical practice, registries of the use of medicines, devices, etc.)
- **Syndicated data** captured by market research
- **Patient-Reported data**
- **Patient organisation data**
- **Real-time data** (digital health technologies, including apps and wearables)
- **Social Media data**

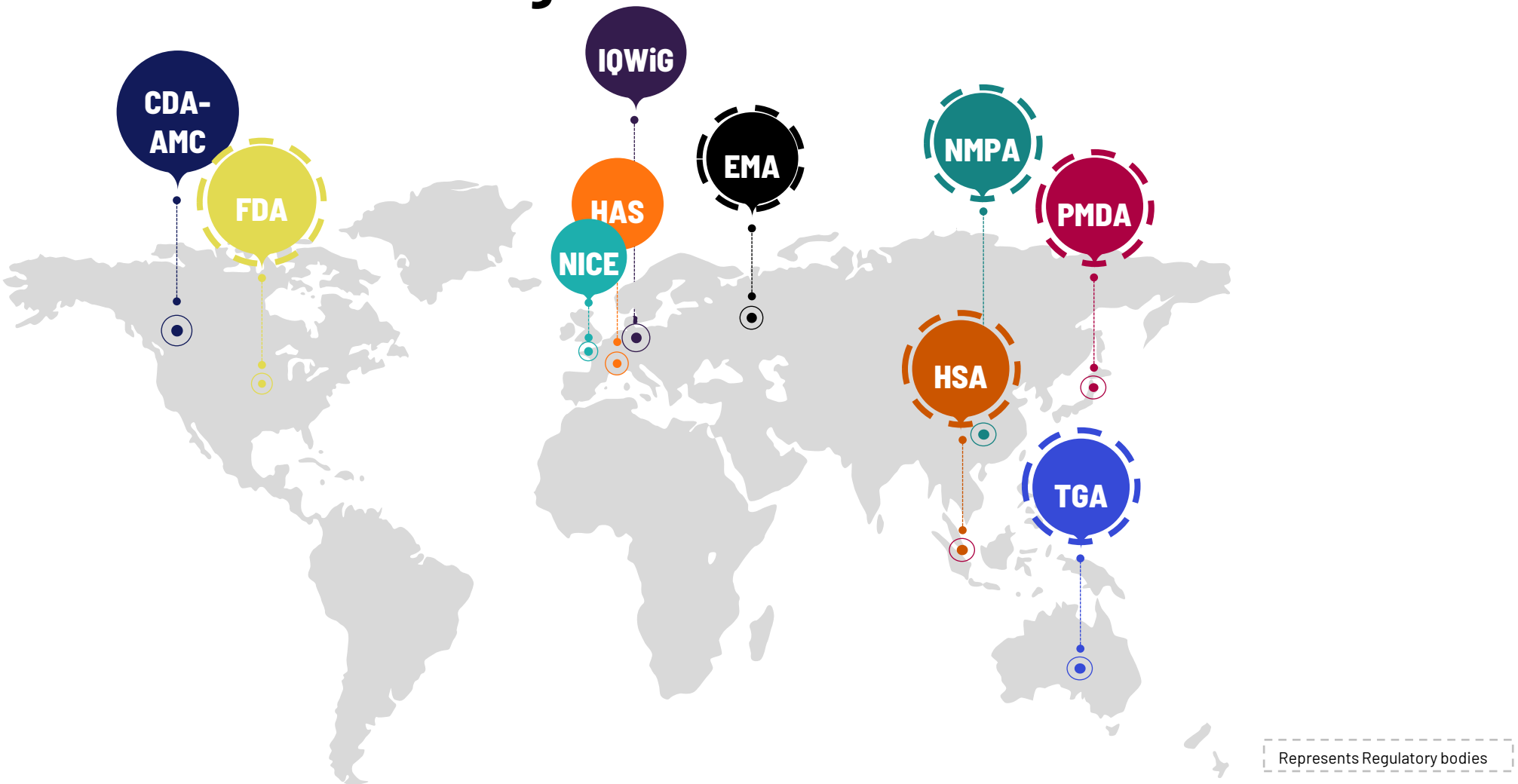
(-) *Least robust*

## 3 key conditions must generally be met for Real world evidence (RWE) use by HTA bodies:

**The data must be:**

- ✓ **Available**
- ✓ **Acceptable**
- ✓ **Accessible**

# ...and in the recent years, HTA bodies have become increasingly receptive to RWE and their integration into their evaluations




HTA bodies: CDA-AMC: Canada's Drug Agency; HAS: Haute Autorité de Santé; IQWiG: Institute for Quality and Efficiency in HealthCare; NICE: National Institute for Health and Care Excellence; EU Health Technology Assessment Regulation
Regulatory bodies: MDA: Pharmaceuticals and Medical Devices Agency; TGA:Therapeutic Goods Administration; HSA: Health Sciences Authority; NMPA: National Medical Products Administration;

# We fielded an online survey with payers from the Ipsos payer panel across EU and non-EU member states

## Objective

To explore the **payer perspective regarding the challenges and opportunities associated with integrating Real-World Evidence (RWE)** into evidence submissions for reimbursement decision-making by HTA bodies, both in the present and future contexts.

## Methodology

Ipsos carried out an **online survey targeting payers**, utilizing a brief questionnaire

## Topics

- RWE **Guidelines**
- **Barriers** to Adoption and concerns
- **Importance** in reimbursement decisions
    - **Applications** in Decision-Making
    - Benefiting **Treatments**
    - Preferred **Data Sources**

## Sample

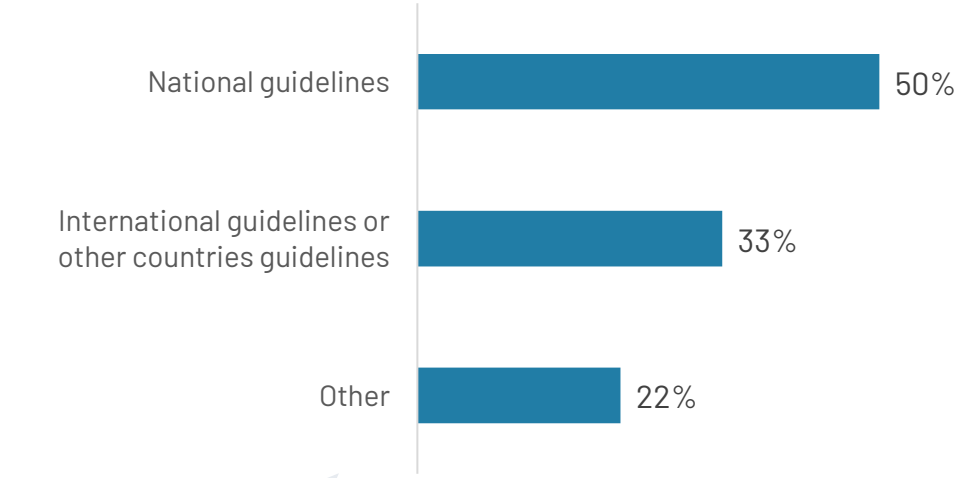
N= **18 payers** from both national and regional agencies

## Scope countries

**Canada, France, Germany, Italy, UK, Spain, Belgium, Denmark, Portugal**

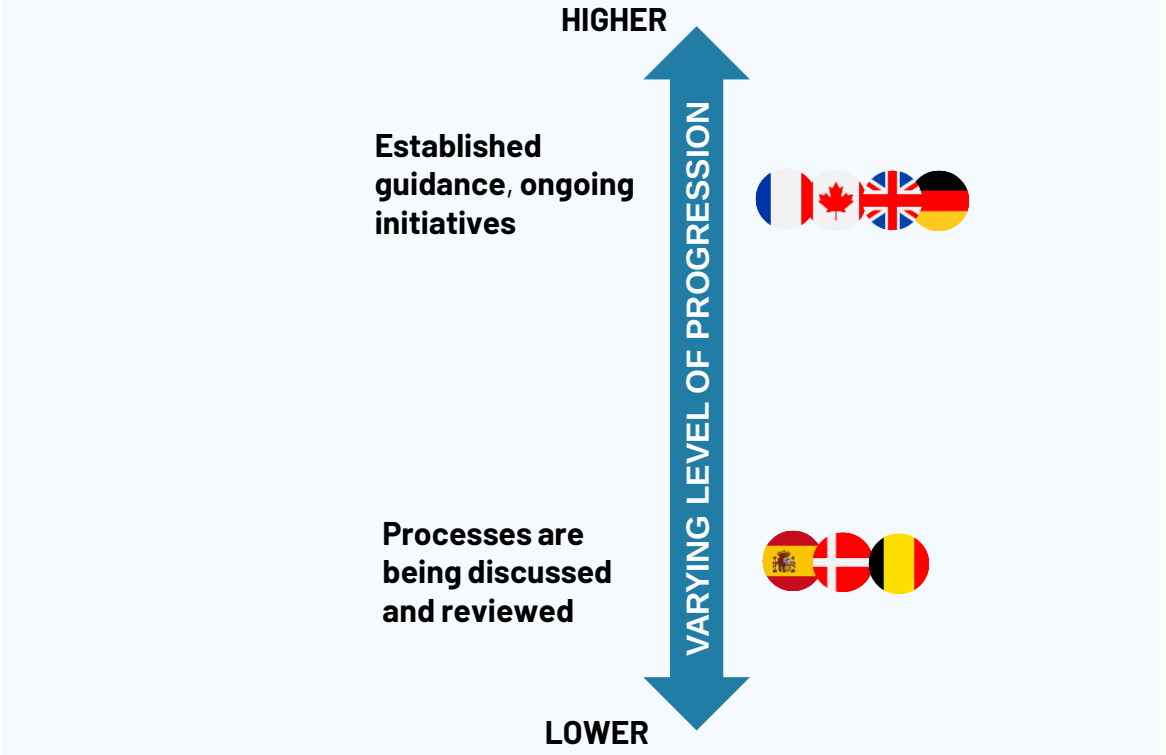
# EU countries with less developed RWE guidelines or frameworks often rely on international ones while developing their own national guidelines

## RWE guidelines used to guide the development and use of real-world data in HTA evaluations




Incl. EMA, FDA, peer-reviewed journal articles

## Countries are at varying stages of integrating RWE into HTA

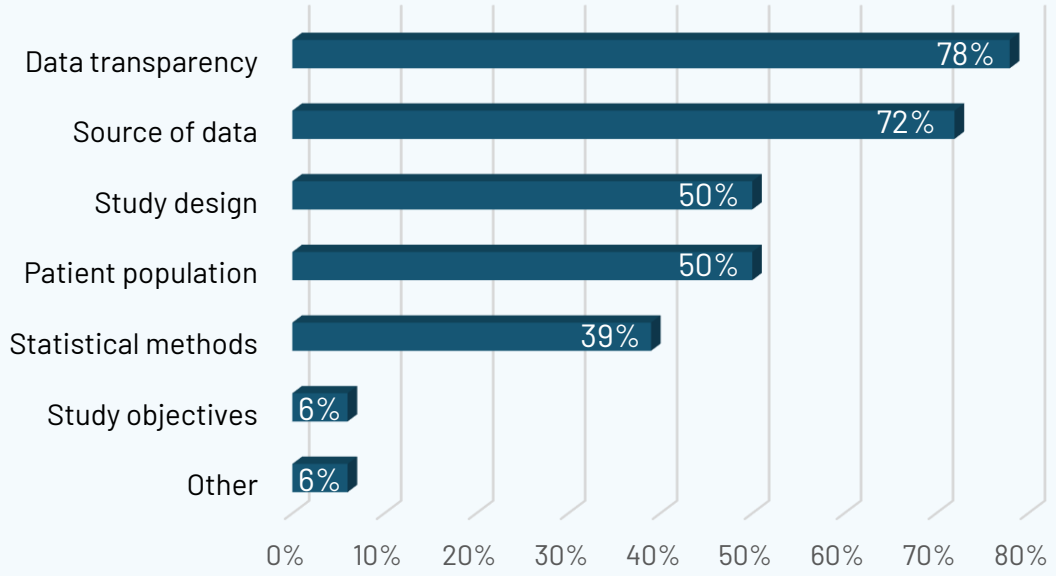



*There is an increased emphasis on future data generation and AI usage, alongside efforts to digitalize data through national platforms in FR & IT*

# Data quality, transparency, and source are identified as primary barriers, with study methodology and data handling expertise also posing issues

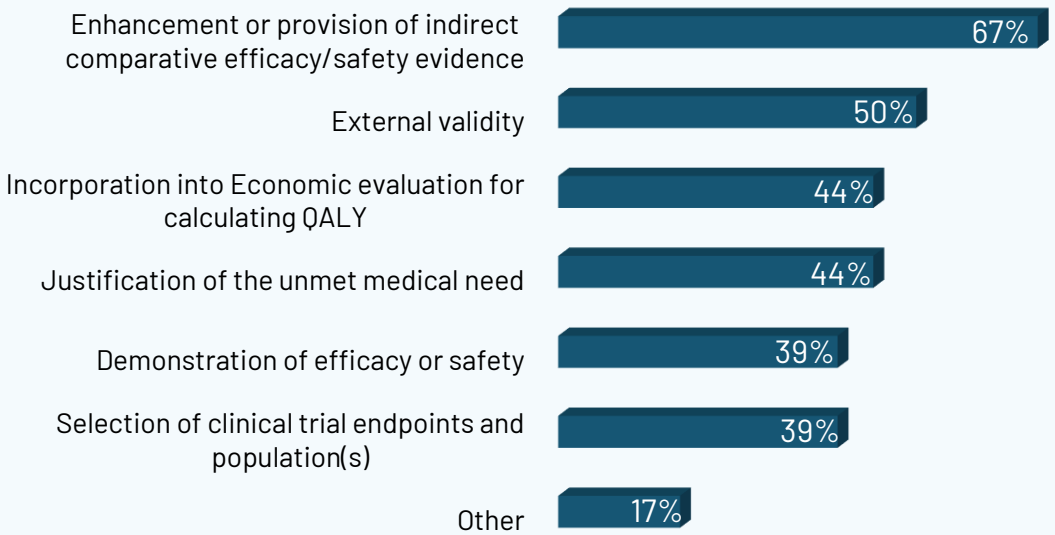
## Barriers to the adoption and use of RWE data in HTA decision-making


## Critical Concerns in RWE Acceptance for HTA



# Payers value RWE mostly for ITC, mainly in chronic or rare diseases, and prefer data from pragmatic trials, registries, and observational studies

## Applications where RWE studies enhance decision-making




*Other EU markets don't see its value in ITC and in ES don't see it in selection of clinical trials end-points and population; FR & DE don't see its value into economic evaluation for QALY calculation*

## Treatments benefiting the most from RWE

**78%**
**Treatments requiring monitoring or long-term/chronic management (e.g. diabetes, MS)**

**67%**
**Treatments for populations with very low prevalence (e.g. orphan diseases)**

## Preferred sources and type of real-world data to be prioritized in HTAs†

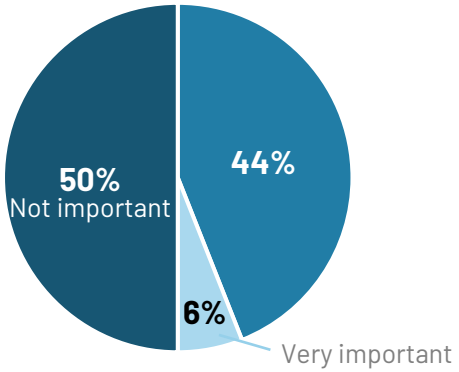
**78%** **Pragmatic clinical trials**

**61%** **Product and disease registries**

*Additional sources suggested, ordered by preference, include Observational studies (50%) Electronic Health Records (44%), Administrative Claims (39%), Health Surveys (11%), Patient-Generated Health Data (11%), and Interviews & Focus Group Discussions (6%).*

# Payers are divided on RWE importance, which is believed to potentially influence reimbursement, though reliance solely on RWE is likely limited

## Importance of RWE in HTAs

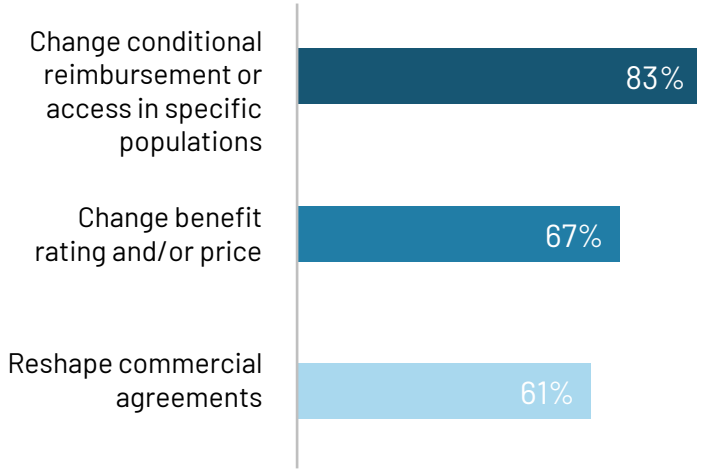



Payers in France, Germany, Belgium, and Portugal considered the incorporation of RWE in HTA submissions as unimportant

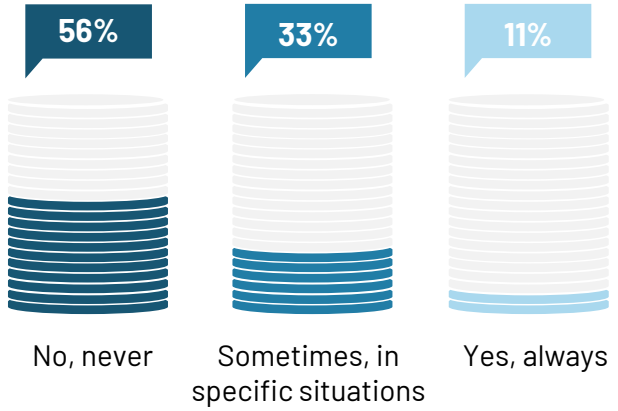
Whilst it was perceived important by payers in Canada, UK and Denmark

Opinions were split in Spain and Italy

## Potential impact of RWE on HTA outcome




## Reimbursement Feasibility Based Solely on RWE



# To enhance the integration of RWE into HTAs, establishing trust, clear standards, and utilizing relevant data tailored to specific questions is key

## Enhanced Data Integration

Payers' concerns about RWE can be overcome by **building trust in the quality, transparency, and source of RWD**. By addressing potential biases in observational data, using appropriate statistical techniques may ensure some level of transparency in the analysis process.

## Addressing Key Questions

Pragmatic trials and registries are often preferred for RWE because of their higher acceptance rates. Payers have concerns about data quality, study design, and potential bias in RWE studies**. Clear guidelines and standards for using RWE are still needed, and education on evaluating and interpreting RWE** is crucial for payers. Although guidelines can be helpful, they are still under development in many regions, highlighting the need for **continued discussion and collaboration.**

## RWE's Evolving Role

While RWE primarily complements RCTs, it offers a cost-effective approach to address uncertainties and provide supplemental data**. Payers are increasingly recognizing the value of RWE, but its use as the sole evidence for reimbursement decisions remains limited**.

# THANK YOU

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