

Real-world Evidence for Economic Evaluation of Medical Devices

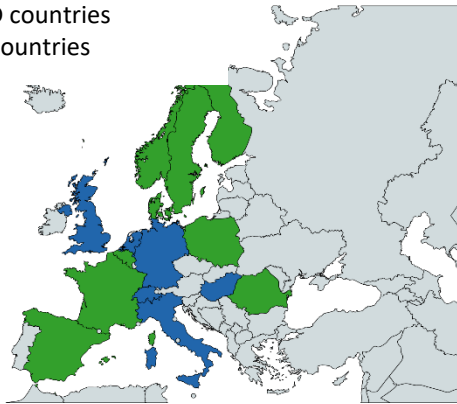
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RWE & HTA so far

- Increasing attention on the use of Real World Evidence (RWE) to support decision-making for medical devices;
- Real-world data (RWD) necessary but not sufficient for generating RWE;
- No common understanding on how to define RWD and RWE.

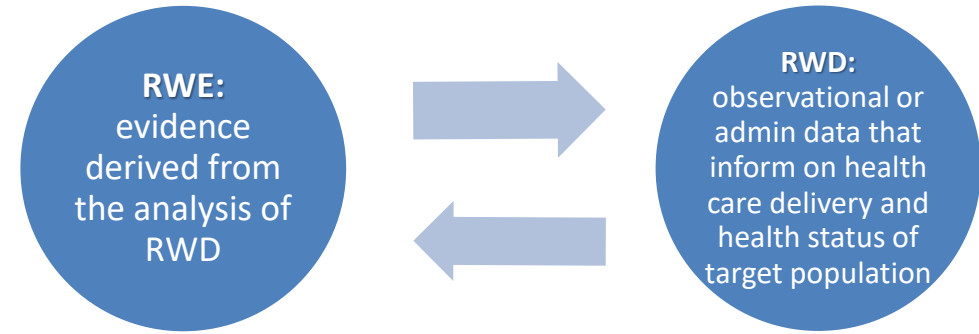
1. What is the current availability of RWD in Europe?
2. Are existing sources of RWD suitable to produce RWE for HTA of MD?

■ COMED countries
■ Other countries



Research strategy

- Assessment of RWE by mapping existing sources of RWD in **15 European countries** and at **pan-European** level.
- **3 case studies** to assess existing differences across countries in terms of availability of RWD sources and their suitability to do economic evaluations.



	Arthroplasty	TAVI and TMVR	da Vinci robotic surgery
Technology	Mature case	Recent case and new generation devices	Recent case
Main RWD source	National registry	International observational studies and registries key source	Single or multi centre observational studies
Economic outcomes	Length of stay, type of procedure most commonly available	Length of stay, type of procedure and operative time most commonly available	Operative time very important
Health outcomes	Mortality, revision, readmission most common	Health outcomes available based on shared standard	Heterogeneous outcomes, given diagnosis was not considered

Key challenges & future directions in the use of RWD for HTA

- Facilitate data accessibility;
- Increase standardization/harmonization of health and economic outcomes across countries and regions;
- Promote joint collaborations and cross-country coordination to collect standardized RWD.