Value Assessment of Medical Devices - RWE

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Disclosure

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What is Real World Evidence (RWE)?

- Real World Evidence is generated by analyzing data gathered from outside of controlled clinical trials. The intent is to provide evidence of performance and outcomes of products in real world settings.

- RWE helps clinical and non-clinical stakeholders understand how products and procedures will perform in their hospital

Why is Real World Evidence important?

-The healthcare landscape is changing, and non-clinical stakeholders, including health technology assessment (HTA) bodies, have more influence in how the value of a medical device is assessed.

-In addition to randomized controlled trials, HTA bodies rely on observational studies, consensus statements (expert opinion), and patient-reported evidence for their value assessment.

Emerging global concepts in HTAs for Medical Devices

- Need for HTAs to be fit for purpose, recognizing differences between devices and drugs
  - Regulatory pathways differ by evidence requirements
  - Significant challenges for RCTs to be conducted in surgical procedures
  - Lack of evidence protection for devices
  - Strong effect of surgeon and hospital on outcomes
  - Rapid life cycles and lack of standard comparator group

- RWE provides a new source of evidence beyond RCTs and requires time and usage for evaluation
  - Science and capabilities emerging across industry and healthcare

RWE Capability a Significant Investment to Ensure High Quality and Robust Data

People & capabilities	Process & governance	Data	Technology
Leadership	Ideation & prioritization	Data strategy	Tech distributors & vendor strategy
Organization design	Agility & scalability	Data quality & management	Reference architecture
Talent	Process re-engineering & automation	Data analytics & modeling	Application development
Change journey & process	Governance	Ethics & sharing	Cloud vs. on premise
Knowledge management	Value realization	Regulation & compliance	Security, reliability, & continuity

Source: Deloitte Analysis

Medical Devices: Application of RWE

- HTA evaluations after launch allow for the evaluation of evidence after period of adoption
  - Registries, Observational Studies, Large Database Analyses
- Hospital procurement process and Value Assessment Committees evaluate “Total Value” including service model, inventory management, sterilization, professional education in addition to technology evidence AND may consider coverage with evidence or alternative contracting models to capture proof of value
- Industry can play a pivotal role with emerging investment capabilities in RWE to provide up to date analyses leveraging large databases and reports from registries to hospitals, payers, and surgeons

Examples

- UK – Total Hip Replacement
- Canada – Drug Eluting Stents
- US – Bariatric Surgery
- US - FDA

Source: https://www.nice.org.uk/guidance/ta304