IMDRF International Medical Device Regulators Forum

Medicines & Healthcare products Regulatory Agency

An Introduction to RWE and UK initiatives

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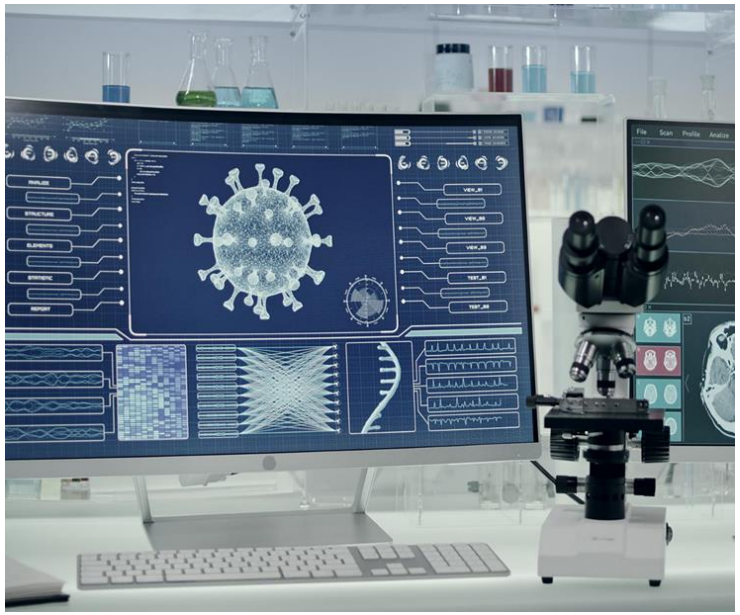
Agenda

- Understanding Real-World Evidence for Medical Devices
- Types and Sources of Real-World Data
- Challenges in Regulatory Use of RWE
- MHRA Initiatives and Guidance on Real-World Evidence

Real-Word Data (RWD) and Real-World Evidence (RWE)

- Real-World Data (RWD): Data on patient health status and/or healthcare delivery captured outside traditional trials
- Real-World Evidence (RWE): Evidence about the benefits and risks of a medical product, derived from analysis of RWD
- RWE reflects actual practice and can provide important insights into safety and effectiveness of devices in everyday clinical use
- RWE can capture device performance and patient outcomes in routine, real-world healthcare settings
- RWE complements evidence produced by a study by representing broader patient populations and providing longer-term outcomes



Real-world Evidence Across the Devices Lifecycle

- Traditionally used to monitor the performance of devices after regulatory approval
- Used less frequently when it comes to demonstrating the safety and efficacy of an intervention
- Use of such data has the potential to increase the speed and reduce the cost of development programmes and to be more representative of the true effects of a device in the community
- Running a study using RWD does not negate the importance of general principles relating to the strength of evidence produced by a study

Overview of Real-World Data Types

Disease, Device and Procedure Registries

Registries collect detailed clinical information, supporting treatment evaluation, particularly useful when Unique Device Identifier (UDI)-enabled.

Electronic Health Records (EHRs)

EHRs document clinical visits and patient care, providing comprehensive medical histories used for health analytics, particularly useful when linked to other health-relevant data sources, such as pathology and imaging.

Insurance Claims Data

Claims databases contain billing information from healthcare services, offering insights into care patterns and resource use.

Patient Generated Data

Patient-Reported Outcome/Experience Measures (PROMs/PREMs), information from wearables...

Challenges in Regulatory Use of RWE

Data Quality Challenges - The quality of the source data should be understood including its accuracy, validity, variability, reliability and provenance

Data Standardization Issues - Lack of standardized data formats hinders the consistent use of real-world evidence and integration of data

Assessing fitness-for-use - Using the appropriate data to answer the study question

Regulatory Uncertainty - Unclear regulatory guidelines create hesitation in adopting real-world evidence for decision-making.

Limited RWE Expertise – mindset and adoption - Few professionals possess in-depth knowledge of real-world evidence methodologies, limiting adoption.

Current MHRA Support for use of RWE

- The MHRA data strategy
- Medical devices post-market surveillance legislation
- Medical devices pre-market legislation
- MHRA guidance on the use of real-world data
- Scientific advice meetings

Key MHRA Programs and Pilot Projects to Encourage RWE Use

New legislation and pathways

Future enhancements of UK regs and innovative pathways

Guidance and Dialogue

RWE Scientific Dialogue Program pilot

Outcomes and Registries Programme

Collaboration between NHS England and MHRA aiming to build a single platform capturing procedure details, patient outcomes and long-term device performance for implantable devices.

Optimizing RWE Use

These combined efforts aim to enhance the integration and utility of RWE in decision-making and regulatory processes.

Conclusion

Importance of Real-World Evidence

RWE can play a crucial role in advancing medical device regulation and ensuring safety and effectiveness

Understanding Data Types

Knowing various data types is essential for accurate interpretation and regulatory compliance

Regulatory Guidance and Practice

Clear regulatory guidance around practical considerations strengthens regulator and stakeholder confidence in RWE use

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Thank you!

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