Consideration & Future Opportunities Identified Through Utilization of RWE

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Outline

Assessment of RWE Guidances Globally

Recent Updates and Feedback

EU Successful RWE Examples

Conclusions

Global Guidance on RWE
Analysis by RAPID Global Regulatory Acceptance WG

Current Landscape for Global Regulatory Acceptance of Real-World Evidence for Medical Devices

Perspectives from the RAPID Global Regulatory Acceptance Group.

By Kenneth Cavanaugh, PhD; Aaron Lottes, PhD; Melanie Raska; Alexia Bwensa; Megan Estes, PhD; Misti Malone, PhD; Rajesh Shah, MD; and Marti Velezis

- IMDRF
- US
- Japan
- China
- Korea
- Australia
- UK
- EMA

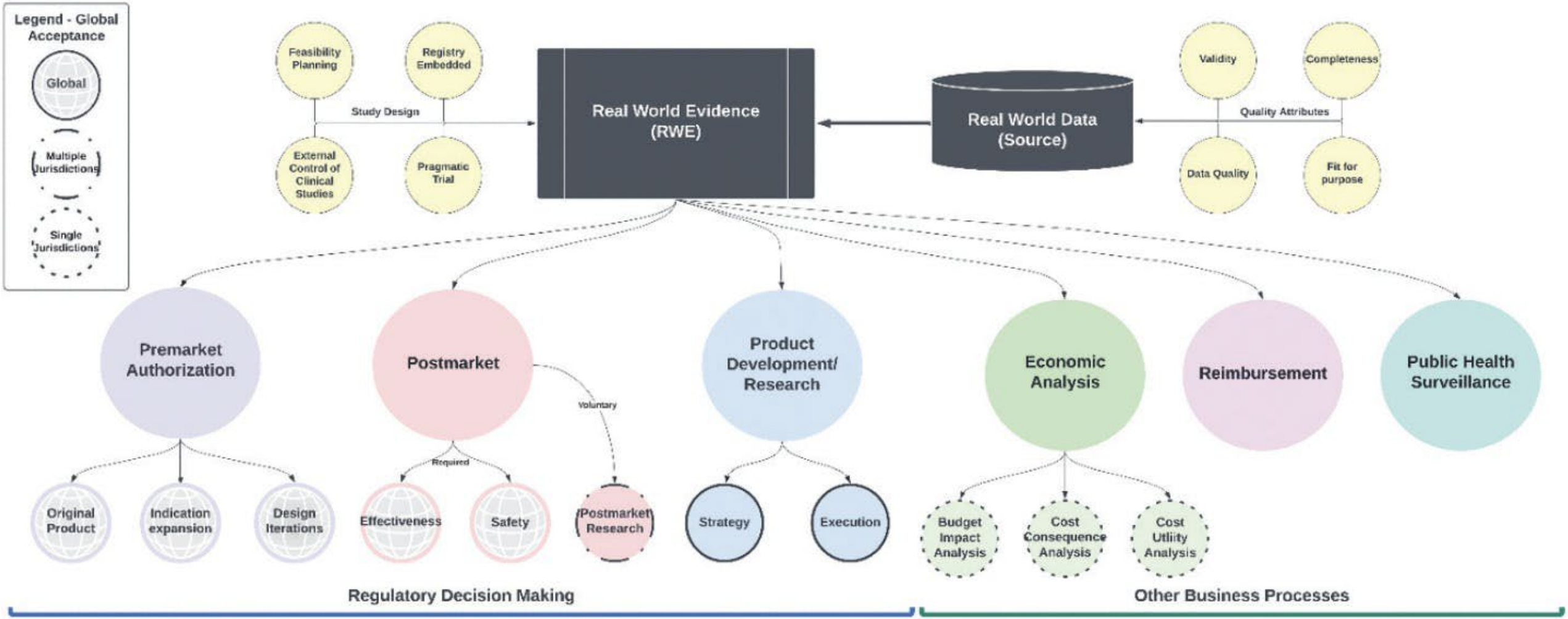
Analysis Findings

Many similarities across jurisdictions, no surprises:

- US FDA RWE Guidance is a core document
- Data Quality is critical
- RWE can be accepted for various uses
- Post-Market Surveillance is a common potential use

General concepts discussed, but often lacking specifics

Study design considerations sometimes mentioned


Legend - Global Acceptance
Global
Multiple Jurisdictions
Single Jurisdictions
Feasibility Planning
Registry Embedded
Study Design
External Control of Clinical Studies
Pragmatic Trial
Real World Evidence (RWE)
Real World Data (Source)
Validity
Completeness
Quality Attributes
Data Quality
Fit for purpose
Premarket Authorization
Postmarket
Product Development/ Research
Economic Analysis
Reimbursement
Public Health Surveillance
Voluntary
Required
Original Product
Indication expansion
Design Iterations
Effectiveness
Safety
Postmarket Research
Strategy
Execution
Budget Impact Analysis
Cost Consequence Analysis
Cost Utility Analysis
Regulatory Decision Making
Other Business Processes

FDA RWE Examples

90 examples of RWE used to successfully support regulatory decision making

Valuable to help industry consider RWE opportunities across product types and classes, and different RWE sources

Limitation – successes only

https://www.fda.gov/media/146258/download

Recent Updates (MHRA, TGA, ANVISA)

Consideration of RWE for SaMD (TGA)

Global Harmonization for RWE (ANVISA; drug focus)

Continued focus on data quality (all)

Continued emphasis on discussing RWE proposal with regulator in advance of submission (all)

MHRA Pilot RWE Scientific Dialogue Programme

Key points:

- Help refine evidence generation strategies
- Provide clear guidance on regulatory expectations

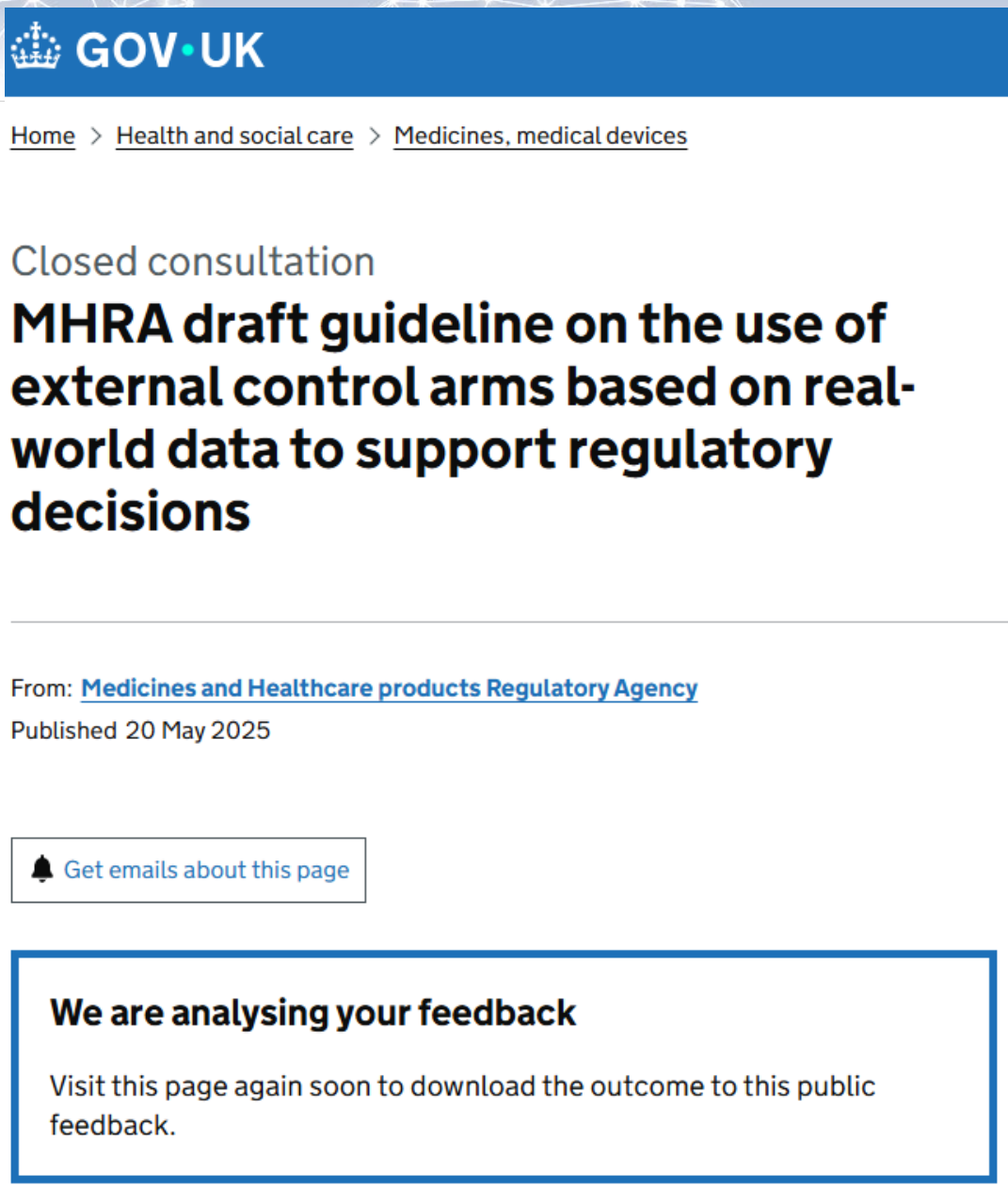
BUT…only for medicinal products, **medical devices excluded from pilot**

https://www.gov.uk/government/publications/mhra-real-world-evidence-scientific-dialogue-programme

MHRA Guideline on RWD Control Arm

General Content

- Key Principles to consider
  - Specific methods not discussed
- Scenarios when RWD external control arm may be appropriate
  - Must address concerns of bias
- **Examples** of scenarios, endpoints and designs are provided
- Meet with regulator to discuss



GOV·UK

Home > Health and social care > Medicines, medical devices

Closed consultation

MHRA draft guideline on the use of external control arms based on real-world data to support regulatory decisions

From: Medicines and Healthcare products Regulatory Agency

Published 20 May 2025

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Visit this page again soon to download the outcome to this public feedback.

Industry Feedback on FDA Updated RWE Guidance (Draft)

Contains Nonbinding Recommendations

Draft – Not for Implementation

Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices

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Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

Document issued on December 19, 2023.

Industry Feedback on FDA Updated RWE Guidance (Draft) Comments or Suggested Improvements:

Industry Feedback on FDA Updated RWE Guidance (Draft) Areas that Need Further Clarification:

Data:

- Sources (and associated details)
- Quality
- Verification
- Transparency
- Cleanliness
- Ownership
- Availability

Industry Feedback on FDA Updated RWE Guidance (Draft)
Most helpful change:

Examples
Details
Expectations

Other Recent RWE Efforts: IDERHA

Integration of Heterogeneous Data and Evidence towards Regulatory and HTA Acceptance

- European public-private partnership launched in April 2023
- Published global landscape analysis of current policies for using RWD and RWE in HTA and regulatory decision-making
  - Responsible data sharing
  - Patient-centric decision-making
  - Challenges and opportunities with RWD and RWE
  - Current landscape of RWE policies
  - Policy gaps, emerging best practices, priorities for action

https://www.iderha.org/landscape-analysis

Recent Published Examples (July 2025) – EU focus

https://media.raps.org/m/5650f39b479a427e/original/25-7_Fink_RWE.pdf

Recent Published Examples (July 2025) – EU focus

Four case studies:

1. Total Knee Replacement (class III)

- **RWE to confirm safety and performance through 10-year life**
- Data collection through a registry at 10 sites
- Identify new risks and evaluate benefit:risk ratio
- Track off-label use
- Limitation: pain and function outcomes often missing at 10 years

Recent Published Examples (July 2025) – EU focus

Four case studies:

2. Implantable Surgical Suture (class III)

- **RWE to collect 12-month outcomes across multiple applications**
  – Support MDR CE Marking
- Retrospective chart review survey
- Understand usage, identify risks, confirm state of the art performance
- Limitation: potential missing data and device size details
- Completed within 15-month timeframe

Recent Published Examples (July 2025) – EU focus

Four case studies:

3. Medical Imagery Processing and Analyzing Software (class IIa)

- **RWE to support safety and performance for rare indications**
- Anonymized datasets from disease-specific databases or health centers – Images processed and compared to practitioners' report
- Limitation: limited dataset sizes for rare conditions
- Supported device use in underrepresented patient populations

Recent Published Examples (July 2025) – EU focus

Four case studies:

4. Surgical Instruments (class IIb)

- **RWE to demonstrate conformity with EU MDR requirements**
  - Gather clinical data from real-world usage
  - Legacy device, but with limited clinical data
- Questionnaire provided to a representative sample of surgeons
- Limitation: additional follow-up necessary to gather specific device details
- Data collected in < 12 months and supported CE Marking

Recent Published Examples (July 2025) – EU focus

Conclusions:

- Variety of RWE collection methods supported different needs for different product types and classes
  - Prospective, retrospective
  - Custom registry, retrospective data collection, questionnaire
  - Initial approval, fulfill post-market requirement
- Different notified bodies may have different requirements

Would the same RWE cases be acceptable in US or Japan?

- Continuing need for more examples, clarity, and harmonization

Conclusions and Future Work

Examples and case studies are extremely helpful to industry

Better understanding PMDA registry consultation process may help encourage more RWE in Japan

- RAPID WG is drafting a paper comparing US and Japan processes

How can HBD help?

- Encourage POCs that include RWE
- Share learnings and examples – both successes **and** failures

Thank you/Questions