IMDRF International Medical Device Regulators Forum

EU2023 EUROPEAN UNION Chair

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Real World Evidence

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Monday, March 27, 2023

Session Topics

Status of Global Regulatory Acceptance of RWD/RWE & Lessons Learned

IVD Perspective and Examples of RWD/RWE

Incorporating RWD Sources into Regulatory Decision-Making Processes

Uses of Real-World Evidence from US FDA, TÜV SÜD and China NMPA

Panel Discussion

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Status of Global Acceptance of RWD/RWE in Regulatory Activities and Lessons Learned

Heather M Colvin, MPP

Director, Evidence & Outcomes, Global Regulatory Policy

Johnson & Johnson MedTech

Timeline of Medical Device RWE Activities & Guidances

2010

US Institute of Medicine

Called for a Learning Health Care System

2016

US FDA awarded funding for NESTcc to MDIC

2017

US – FDA Guidance RWE

US FDA User Fees for RWE

2018

2019

South Korea – MFDS RWD/RWE guidance

2020

China– NMPA RWD/RWE guidance & Pilot zone

European Commission MDCG – RWD

2021

Japan – PMDA 2 Registry RWD guidances

FDA RWE Examples Report

Australian TGA – report on RWD/RWE

2022

EU IHI - Call for Heterogenous Health data proposals

EU – Initiate the EHDS Legislative Framework

2023

US FDA User Fees for RWE

Australian TGA – Launched RWE Hub

Investment in Real-World Data and Evidence Capabilities

FDA

User Fee and Congressional Commitments

- Updated Guidance(s)
- Training for reviewers
- Reporting and Public Engagement
- Investment in infrastructure, processes and policies to improve the access to RWD and the generation of RWE

EU-MDR

RWD/RWE for EU MDR

- Guidance on sufficient clinical evidence for legacy devices (MDCG 2020-6)
- Post-market clinical follow-up (PMCF) Plan Template (MDCG 2020-7)

innovative health initiative

- 2022 Call for Proposals for Access and integration of “heterogeneous health data” for improved healthcare (2023 launch)

CHINA NMPA

Real-World Evidence Activities

- 2019 Real-World Evidence Guidance(s) release
- Annual RWE conferences
- Creation of RWE Pilot Zones

BoAo Lecheng Pilot Zone

Great Bay Area (GBA)

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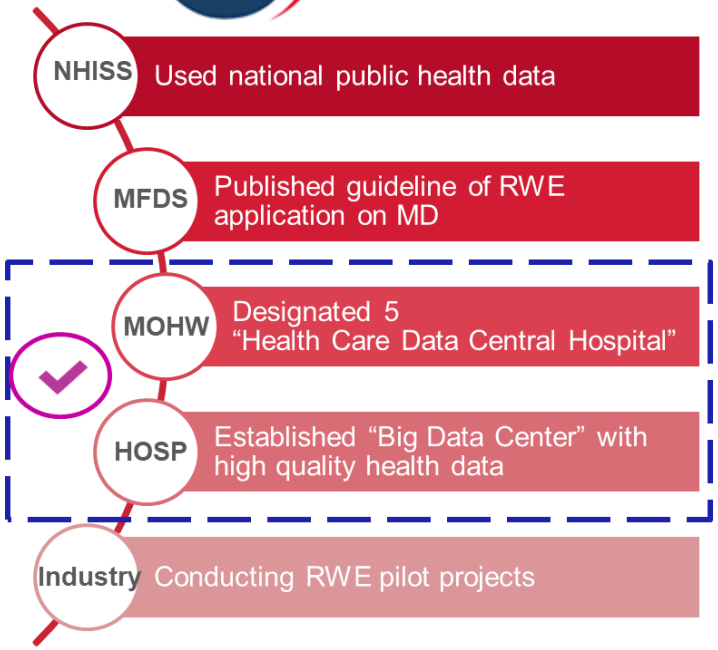
Investment in Real-World Data and Evidence Capabilities

KOREA MFDS



- Guidance for Utility of Health Care Data
- RWE guidance revision

Pmda JAPAN

Real-World Evidence Guidances

- Basic Principles on Registry Utilization for Applications
- Points to be Considered to Ensure Reliability in Utilization of Registry Data for Applications
- Data infrastructure and access (e.g., Mid-Net, National Database of Health Insurance Claims, and private companies' medical databases)
- Engagement with external stakeholders

TGA Health Safety Regulation

2021 Report Findings

- Ambiguity (internally and externally) limits adoption
- Need for improved communication

2022 Action Plan Created

2023 RWE Hub

- Adopted definition
- Launched online RWE Hub

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Lessons Learned

Relevance of Study Question

- Various Uses of RWE
- Access to relevant RWD
- Determining the feasibility
- Limitation of different data sources

Data Characterization Fit for Purpose Assessment

- Pooling & linking data
- Differences in health care systems
- Understanding the RWD and the Standard of Care

Rigor of the Study Design and Analytical Methods

- Protocol development
- Benefit of different methodological approaches

Totality of Evidence and Strength of the Findings

- Different roles RWE can play in submission
- Complementary to traditional clinical evidence approaches

Establish ongoing transparency/communication through the study (pre-, during, post)

Challenges and Opportunities

Technical

Data "Quality"

- Terminology
- Standard of care and existing codes
- Common data models
- Characterization of data sources and outcomes

Methodology

- Alignment on appropriate analytic methods
- Data extraction and curation
- Data linkage capability

Policy & Process

Data Access & Sharing

- Data access/sharing policies
- Multi-stakeholder data sharing agreements
- Oversight/auditing for decision-making

Transparency

- Patient protections and informed consent
- Ethical concerns among professionals and public
- Transparency and reporting requirements

Adapted from The Network For Excellence in Health Innovation. Real World Evidence: A New Era for Health Care Innovation. (2015) Issue Brief.

Growing Need for Evidence

Evolution of Medical Products

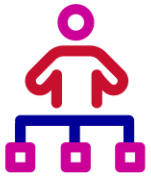
Expanding Sources of Clinical Data & Evidence

Emerging Needs of Decision Makers

Possible Next Steps

Build on the foundation laid by the early Guidance documents and experiences

Enable appropriate access to health data for quality research



Advance multi-stakeholder partnerships to develop consensus

- RWD Characterization and Fit-for-Purpose Assessment requirements
- Analytical methods
- Appropriate transparency expectations

Focus on International Harmonization

THANK YOU / QUESTIONS

Heather Colvin

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