Real World Evidence Policy: Is Harmonization between Regulatory and HTA a help or a Hindrance?

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PANEL

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Evolution of RWE policies across HTA and Regulatory organizations

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Disclaimer

Views are my own and not that of my employer, Johnson & Johnson Medtech, nor any of the funding partners of the Innovative Health Initiative, or any of its affiliated entities.

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Real World Data **challenges** – what we hear...

- Data quality
- Data interoperability
- Data access and sharing
- Ethics and privacy
- EU wide frameworks

Real-world data/RWD is information pertaining to health status and health care delivery that is collected routinely from sources other than traditional clinical trials
Real-world evidence/RWE is derived from analysis of RWD.
www.iderha.org

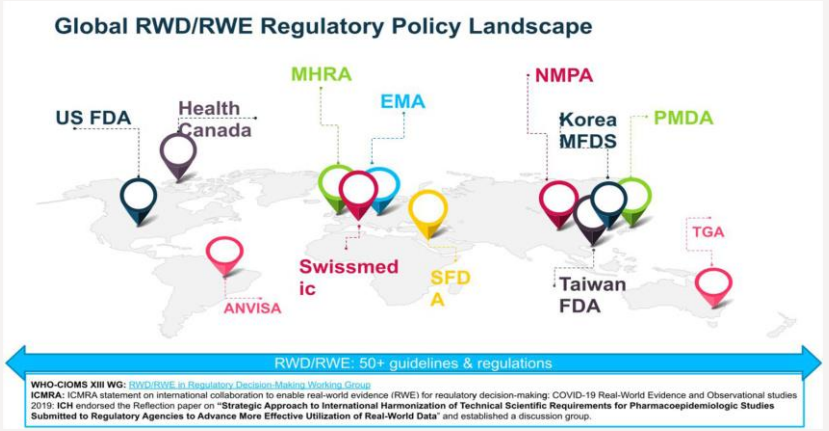
Real World Data **Study challenges** – what we hear...

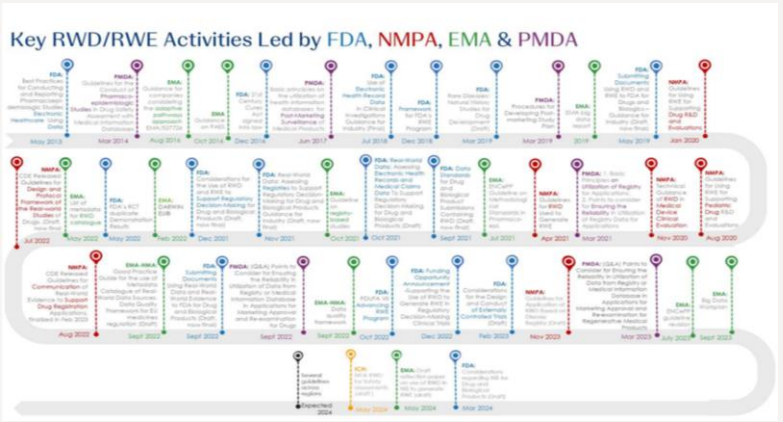
- Selection bias
- Confounding
- Lack of randomization
- Missing and Incomplete data
- Data protection

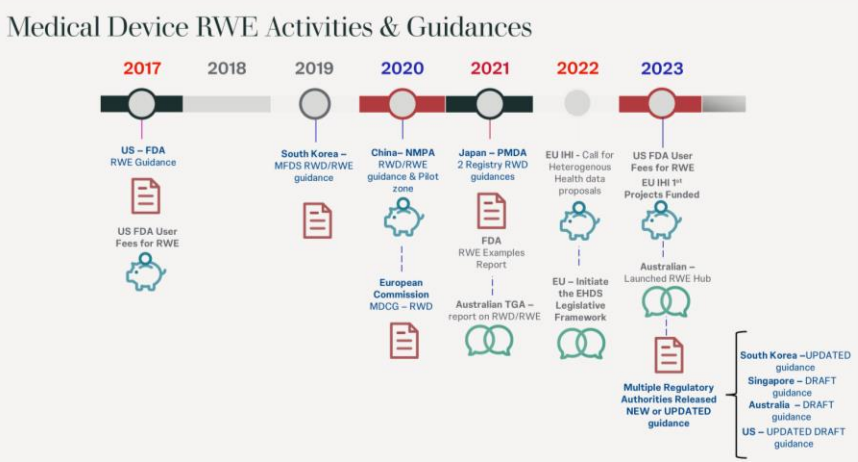
RWE for regulatory and HTA **acceptance** – what we hear...

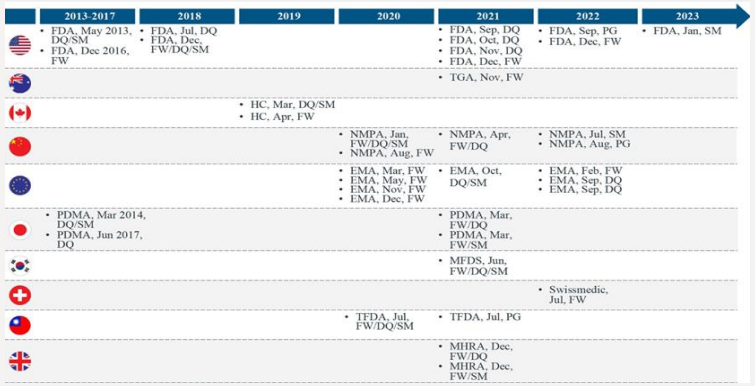
- Expectations in study design
- Preference for local data
- Acceptance requirements
- Multiple submissions
- Guidelines
- Adoption

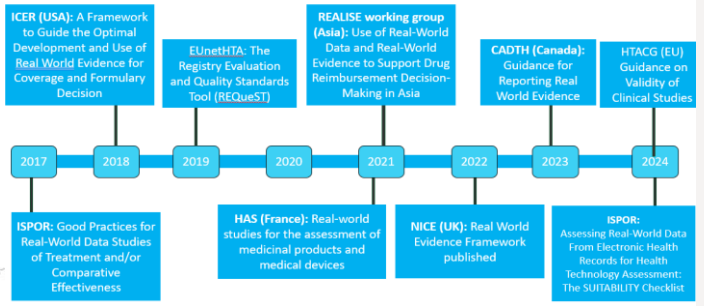
RWD/RWE **policies**– what we see…











https://globalforum.diaglobal.org/issue/may-2023/rwd-rwe-in-2023-regulatory-policy-world-tour/
IMDRF 2023 – Session 2 Real world Evidence. – adapted.
The maze of real-world evidence frameworks: from a desert to a jungle! An environmental scan and comparison across regulatory and health technology assessment agencies – PubMed
https://www.frontiersin.org/journals/medicine/articles/10.3389/fmed.2023.1236462/full

RWE for regulatory and HTA **acceptance** – what we are looking for...

- Similarities
- International data
- Collaboration
- Harmonization?

RWD/RWE what we want **to discuss…**

- Harmonization of RWE policy between regulatory and HTA?
- What has been harmonized? What hasn’t?
- What could be harmonized?
- Is it harmonization or convergence?