IMDRF International Medical Device Regulators Forum

EU2023 EUROPEAN UNION Chair

European Commission

European Union

RWE: EU notified body's perspective

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OVERVIEW

- Notified bodies
- Current regulatory situation in EU
- Future

EU Notified Bodies

- EU medical device regulatory system is a ‘third party system’
- EU ‘third parties’ are called notified bodies
- Notified bodies are
  - Organisations
    - different format (e.g., semi-public, private)
  - Designated and monitored by EU authorities to perform regulator’s tasks
    - i.e. decisions on market access for medical devices in mid- and high risk classes
  - *De facto* ‘extended arm’ of the regulators

EU COM website factsheet

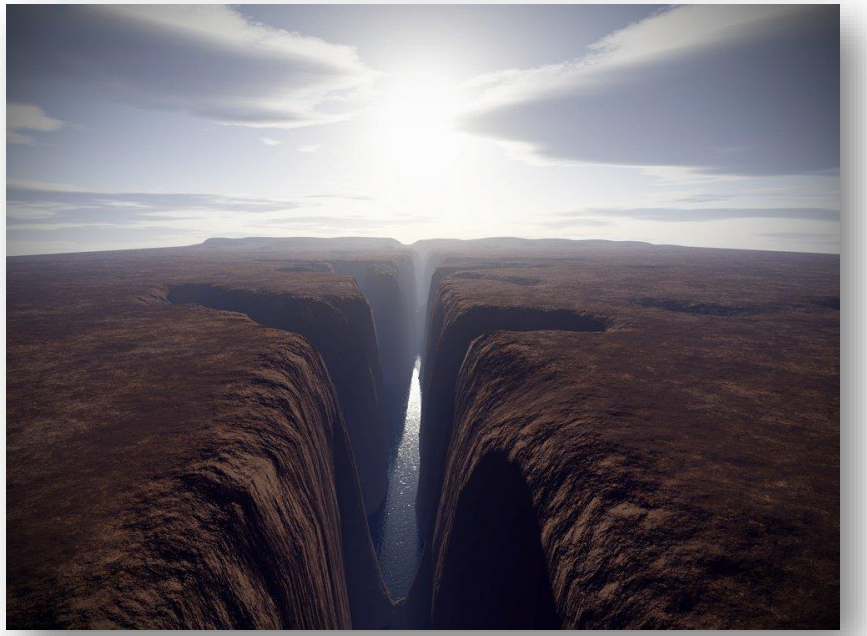
Building on Tom Melvin´s presentation:

Expectations can differ

Regulators

Overall compliance

- *with the current legal requirements*
- *for a specific device/IVD*



Clinicians

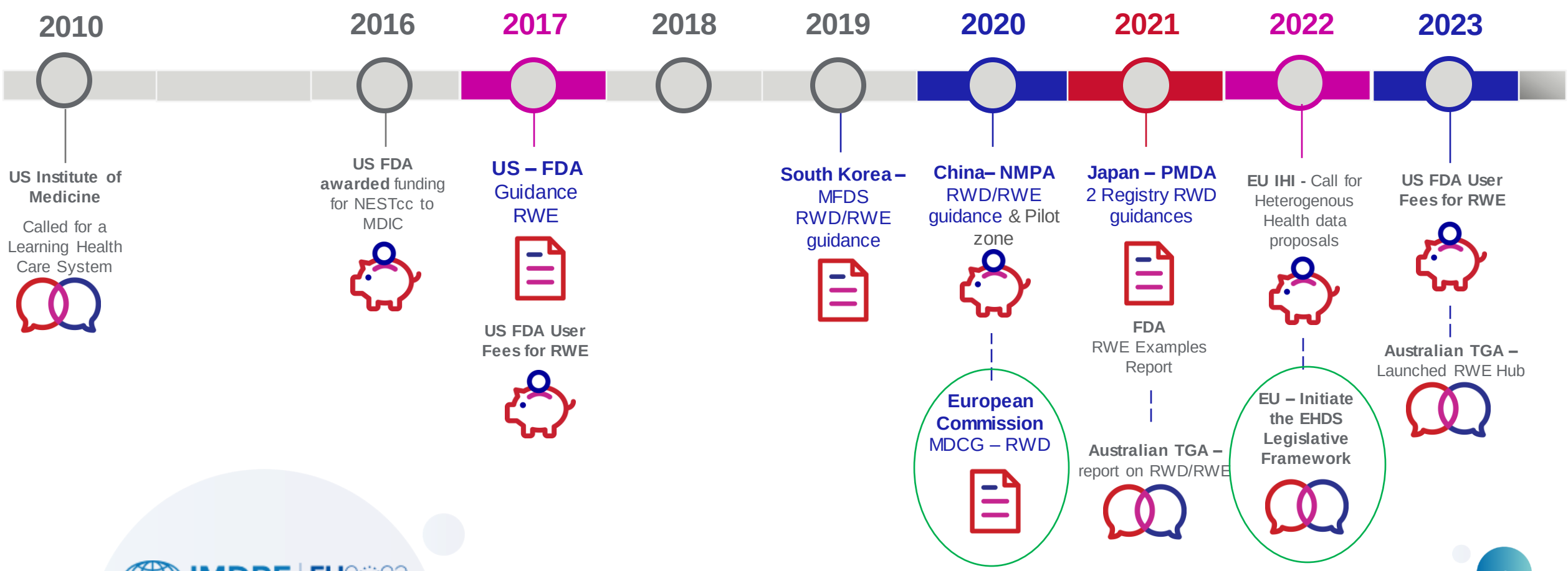
Evidence based practice

Clinical evaluation as key concept

- ‘clinical evaluation’ means a systematic and planned process to ***continuously*** generate, collect, analyse and assess the clinical data ***pertaining to a device*** in order to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer (*EU MDR art 2.44*)
- ***pertaining to a device***
- ***continuously***

Building on Heather Colvins´s presentation:

Timeline of Medical Device RWE Activities & Guidances



European Commission
MDCG – RWD

MDCG 2020-6 (April 2020)

Clinical evidence needed for legacy devices

- `legacy devices´ = medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC
- Table with ´hierarchy of clinical evidence for legacy devices' (in Appendix III)
  13 categories of clinical evidence sorted from 'strong' to 'weaker'
- Top 4:
  1. Results of high quality clinical investigations
  2. Results of high quality clinical investigations with some gaps
  3. Outcomes from high quality clinical data collection systems such as registries
  4. Outcomes from studies with potential methodological flaws but where data can still be quantified and acceptability justified
- Class III legacy devices and implantable legacy devices which are not well-established technologies should have sufficient clinical data as a minimum at level 4.

- Conclusion: Specific types of RWE (registries) accepted to substantiate market access of legacy devices

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MDCG – RWD

MDCG 2020-7 (April 2020)

Post-market clinical follow-up (PMCF) Plan Template
A guide for manufacturers and notified bodies

- In Section C. Activities related to PMCF: general and specific methods and procedures . some examples of different activities related to PMCF are listed, e.g.
  - A manufacturer device registry (specific for the type of device or the group of the medical devices the product belongs to) can be indicated together with a description and a summary of the plan. A pre-specification of what quality and quantity data – based on the risk of the device(s) and the associated accessories – to be collected and analysed shall be included. Any possible evaluation of suitable national public registries with clinical data on the manufacturer's own device and/or on similar devices could be specified in this section, identifying the expected quantity and quality of data to be gathered and the search protocols to be adopted
  - Planned Real-world evidence (RWE) analyses could be indicated in this section, together with a summary of the plan including the design, sample size, the endpoints, and analysis population. The real-world data (RWD) from which these analyses are based on should be of sufficientquality and come from reliable data sources.
  - Surveys planned to collect information about the use of the concerned medical device could be described.
- Conclusion: Collection of RWE/RWD is the context of PMCF is encouraged

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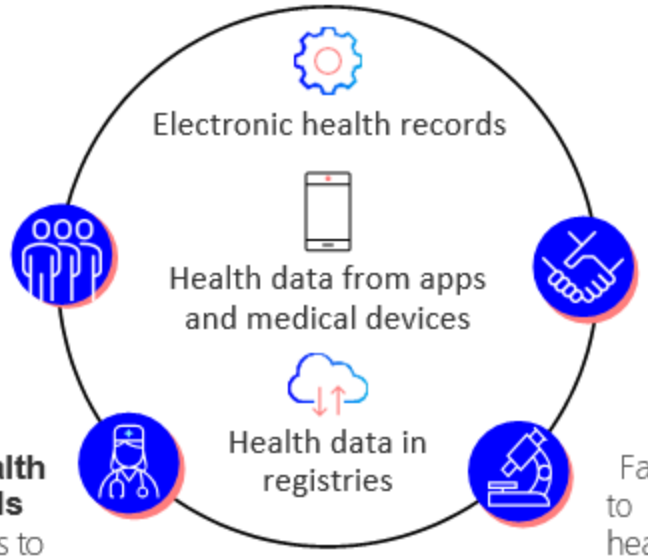
EU – Initiate the EHDS Legislative Framework

European Health Data Space

Better diagnosis and treatment, improved patient safety, continuity of care and improved healthcare efficiency

Empower **individuals** to have control over their health data

Enable **health professionals** to have access to relevant health data



Assist **policy makers and regulators** in accessing relevant non-identifiable health data

Facilitate access to non-identifiable health data for **researchers and innovators**

Better health policy, greater opportunities for research and innovation

EU – Initiate the EHDS Legislative Framework

European Health Data Space

- advantages specific for regulators & policy makers:
  easier, more transparent and less costly access to non-identifiable health data for the benefit of public health and the overall functioning of healthcare systems and to ensure patient safety
- Advantages for all EU citizens
  - control of your own health data
  - security and privacy ensured
- High expectations for the future!

THANK YOU / QUESTIONS

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