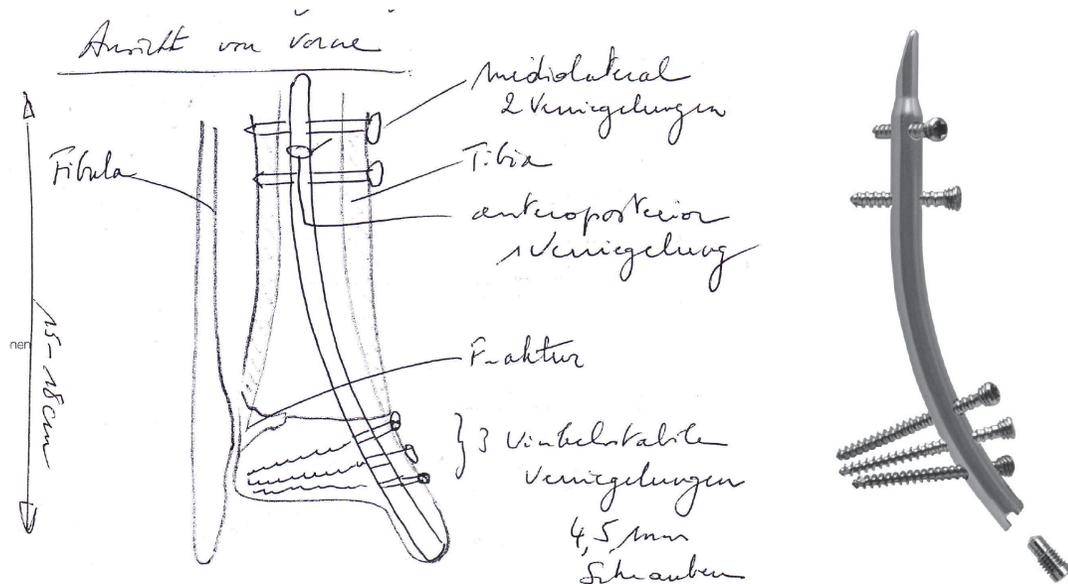


# Early Clinical Investigations for Digital Health Technologies

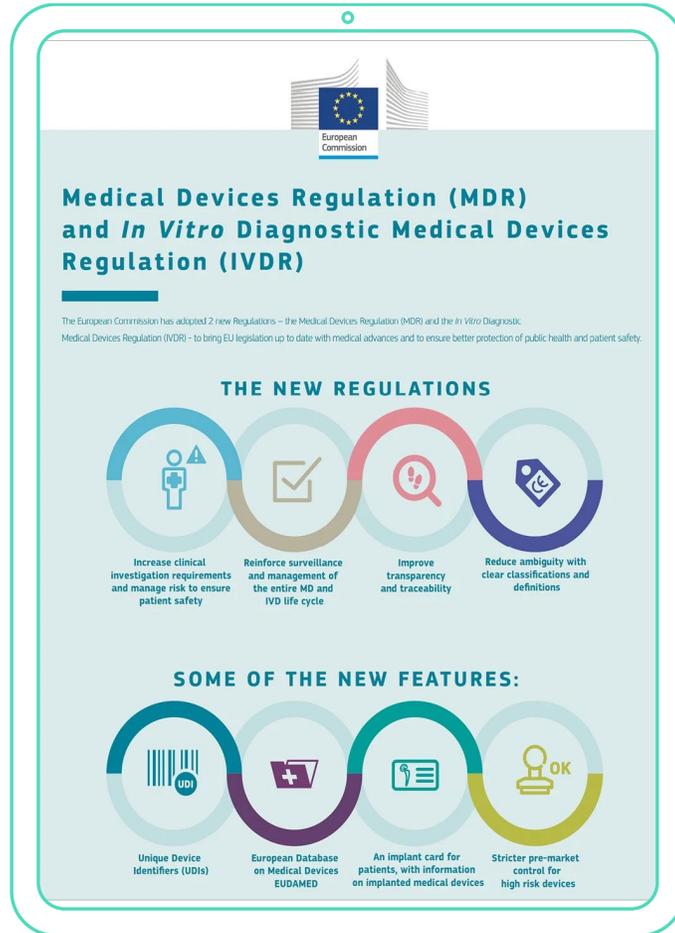
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# MEDICAL DEVICES & SaMD & AIeMDs



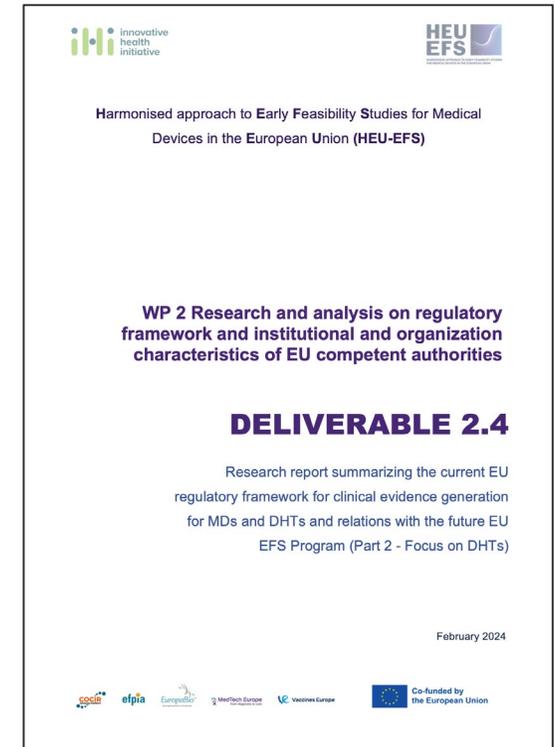
# MDR & DHTs



- MDR introduced new requirements for DHTs
- MDR introduction often resulted in higher risk classification for DHTs ( $\geq$ IIa)
- Higher risk classification raised pre-market clinical investigations expectations
- Currently, no concise guide for (early) clinical evaluations under the MDR
- Insufficient specifications for SaMD/ AI/ ML-MD (LLMS)
- Fragmentation & variation in interpretation within the EU/ within individual countries
- EU AI Act as an additional challenge

# HEU - EFS – DIGITAL HEATH TECHNOLOGIES

- 1. Regulatory Analysis:** Systematic analysis of MDR, guidance and ISO standards.
- 2. Scoping Literature Reviews:** Analysis of regulatory challenges for DHTs.
- 3. Focused Review on EU AI Act – MDR interplay:** Examination of the relationship between the AI Act and MDR.
- 4. Stakeholder Interviews:** Insights from DHT companies and Contract Research Organizations (CROs) on regulatory frameworks, clinical evidence needs, and EFS.



# STAKEHOLDER INTERVIEWS

## Experiences with EFS in DHTs

### COMPANIES AVOIDING EFS

*"Most of the DHT manufacturers are startups and SMEs, and they look at how to bring the device on the market with the lowest impact of regulatory requirements. Many avoid clinical investigations under Article 62 as they are expensive and unnecessary for many claims."*

*"They prefer using simulation or algorithm tests to collect data initially, as it is less expensive."*

### IMPORTANCE OF EFS

*"For these technologies, an early feasibility trial helps not only assess safety but also verify that they have the capability to replace the physician or support their decision-making."*

*"The EFS is not just about generating early data. It's about providing feasibility for innovation on every front—technical, clinical, and human."*

### STREAMLINING EFS

*„It should be easier. There should be an easier way to make these studies possible. At the moment, companies struggle with early studies because it costs too much, especially for small companies or startups."*

*"Streamlining the process would help make these studies feasible in terms of financial and time aspects, such as reducing years-long processes to just six months."*



# Underutilization of EFS in DHTs

- EFS are rarely used in DHT development despite clear benefits .
- Most developers avoid EFS whenever possible in favor of simulation /in silico studies and informal pilots .
- Main reasons :
  - Regulatory uncertainty
  - Lack of harmonized guidance
  - Lack of dialogue
- Missed opportunity to :
  - Refine user interfaces
  - Initial testing of safety and usability
  - Improve real - world performance early in development

# Regulatory Complexity & Fragmentation

- **MDR: hardware -based device logic vs. software - driven realities**
- **DHT - specific guidance largely missing**
- **Lack of dialogue with regulatory bodies leads to uncertainty and delays , with assessors often lacking DHT/AIeMD expertise .**
- **Fragmented interpretation across EU Member States:**
  - Software classification (Rule 11)
  - Documentation requirements
  - Ethics committee , CAs & NBs experience with DHTs
- **Dual burden of MDR + EU AI Act with overlapping / contradicting obligations**

# Need for EU EFS Program also reflecting DHTs

- Call for a harmonized EU program with :
  - Early and continuous **dialogue**
  - **DHT-specific guidance** documents & templates
  - Provisions for **iterative software updates**
- International inspiration :
  - **FDA's Digital Health Center of Excellence** provides expertise for DHTs
  - **Predetermined Change Control Plan (PCCP)** allows for rapid updates
  - **Germany's DiGA** digital health framework provides clarity in DHT regulations

# Implications for Policy & Practice

- **Develop EFS framework** which also reflects DHT - specific needs
- **Foster a transparent and collaborative regulatory culture**
- **Promote harmonization** across EU member states to ensure regulatory consistency
- **Align MDR and AI Act** to avoid duplication, clarify AI risk management & clinical evaluation
- **Address cost barriers** and incentivize early - stage clinical research (esp . SMEs)
- **Leverage synergies** with EU HTA projects (ASSESS - DHT, EDiHTA )

# THANK YOU



**HARMONISED APPROACH  
TO EARLY FEASIBILITY  
STUDIES FOR MEDICAL  
DEVICES IN THE  
EUROPEAN UNION**

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