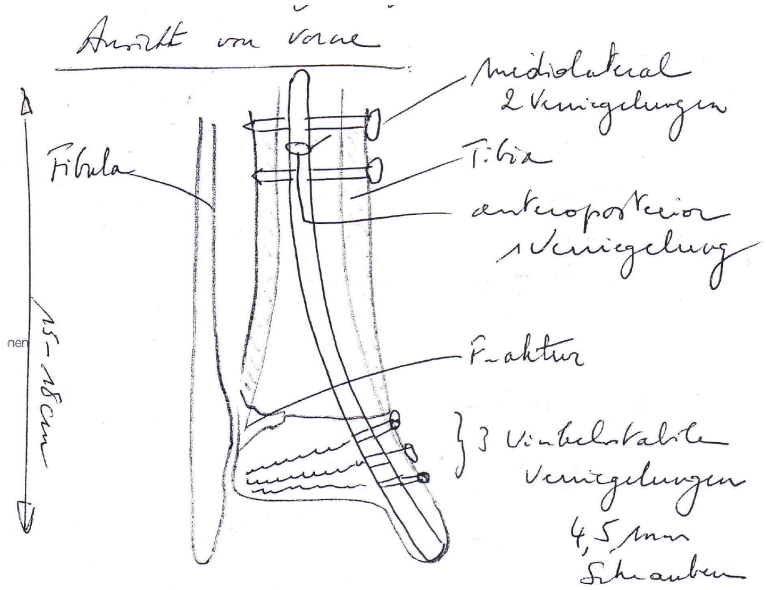
Early Clinical Investigations for Digital Health Technologies

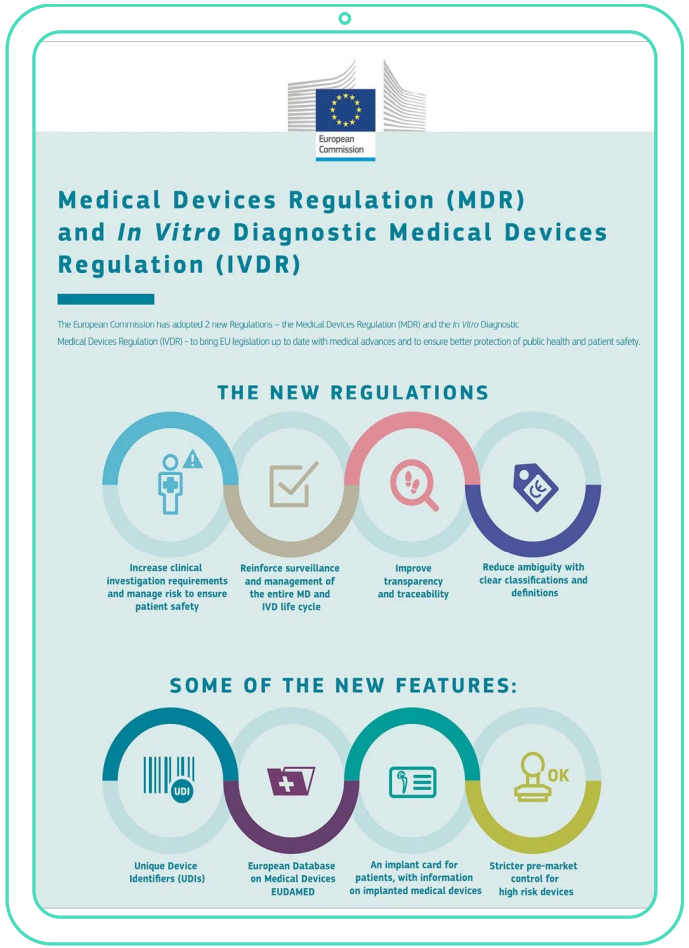
Univ. - Prof. Dr. med. Sebastian Kuhn, MME
Director of the Institut for Digital Medicine
Philipps - University & University Hospital Marburg
Sebastian.kuhn@uni - marburg.de

MEDICAL DEVICES & SaMD & AIeMDs



Images: Drawing (Prof. Pol M. Rommens), Mizuho Medical, own image

MDR & DHTs



- MDR introduced new requirements for DHTs
- MDR introduction often resulted in higher risk classification for DHTs (≥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 iterpretation within the EU/within individual countries
- EU AI Act as an additional challenge

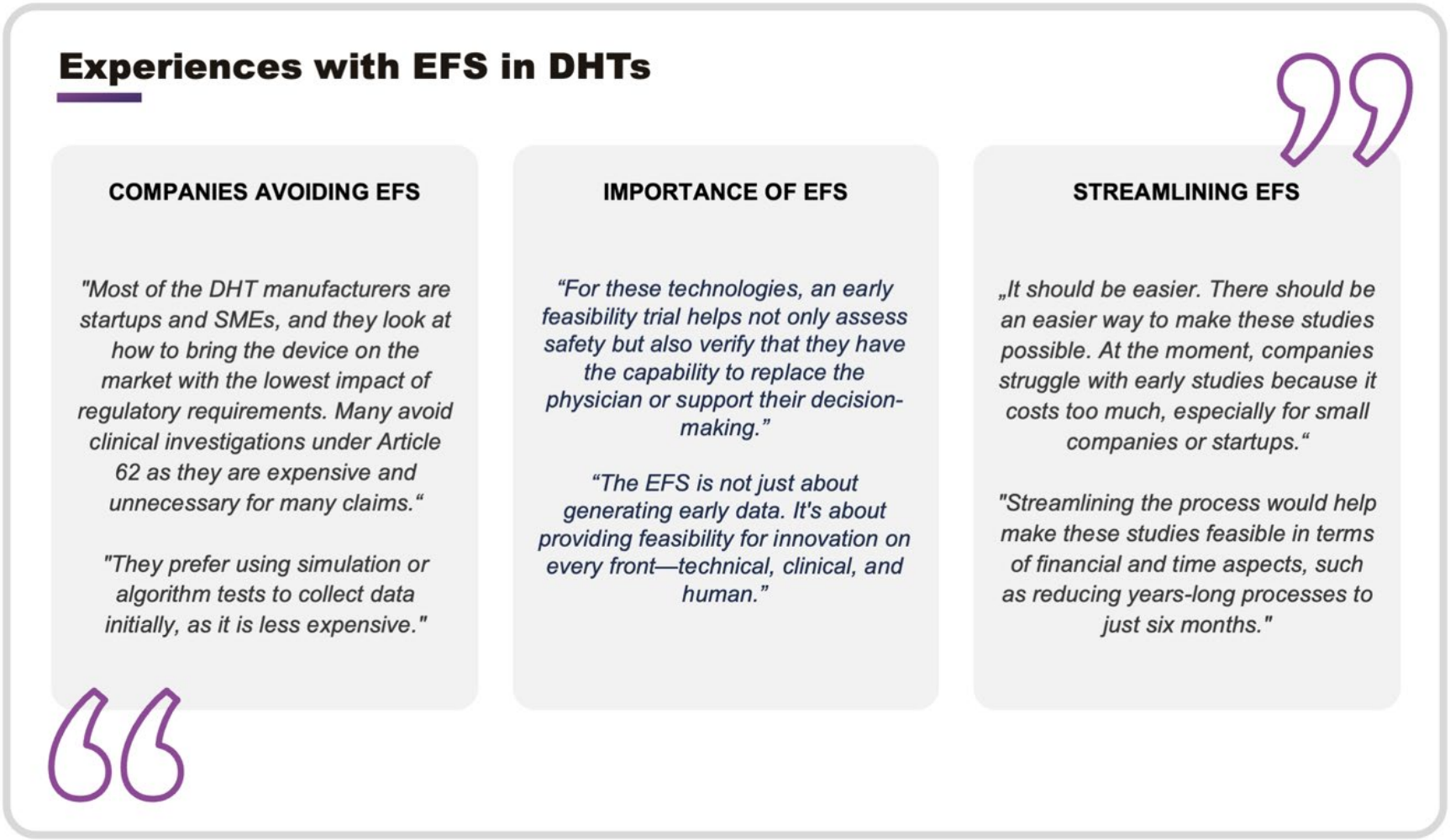
Image: EU MDR & IVDR

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.

Source; https:// heuefs.eu

STAKEHOLDER INTERVIEWS



Source; own image

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

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Need for EU EFS Program also reflecting DHTs

- **Call for a harmonized EU program** with :
  - Early and continous **dialogue**
  - **DHT-specific guidance** documents & templates
  - Provisions for **iterative software updates**

- **International inspiration** :
  - **FDAs 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

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Image: HEU - EFS Logo, QR - code to HEU - EFS Website