Innovative approach in development of harmonized methodologies for ethical risk assessment in AI enabled medical devices

Key Questions*:*

1. *What are potential blind spots (ethical risks) in wide adoption of AI in medical devices?*
2. *How can such risks be classified or contextualized? Who/what stakeholders are relevant across the value chain of mitigating such risks?*
3. *What aspects of existing AI frameworks (AI Act, HLEG AI Trustworthy AI, FDA guidance) are relevant to create a harmonized assessment of AI in medical device/connected healthcare ecosystem*

Background/Challenge:

In the last decade, significant advancements have been made in incorporating Artificial intelligence (AI), and technology in healthcare ecosystem. For instance, medical device manufacturer Siemens Healthineers leads the charge in creating connected ecosystems for medical infrastructure to optimize performance in hospital as well as improve patient experience. Recently the company created a partnership with the Medical University of South Carolina (MUSC) to develop a digital twin (an AI based solution) to improve workflows in the hospital, with the overall aim of cost reduction and "ensuring specific interventions or processes are performed together and not separately to ensure efficiency"[1]

Most connected healthcare environment require vast array of data – usually patient data, infrastructure data as well as network data. Such interconnectedness means multiple layers of risks can arise. Today's conformity assessment for medical devices mostly considers various unrelated regulations without a cohesive approach or focus on ethical risks.

This poses potential risks to both medical device manufacturers, as well as end users (doctors, technicians, or even patients).

Given growing concern to ensure strict compliance to data privacy, the challenge can be encapsulated in these challenges:

1. For policy makers such as EU, how can guidance be created/**expanded** to regulate use of AI in connected healthcare (hardware & software)
2. Uncertainty for manufacturers regarding strict compliance with existing regulations while ensuring patient privacy and safety
3. Lack of clarity on ethical frameworks applicable to AI enabled medical devices
4. Unharmonized certification standards for AI

[1] https://web.musc.edu/about/news-center/2019/08/23/a-year-later-musc-siemens-healthineers-partnership-shows-progress

Proposed research method:

To understand the especially VUCA (volatile, uncertain, complex, and ambiguous) [2] context of MedTech industry, it is important to examine the developments in MedTech overtime. For project strategy, the following research methods will be utilized.

1. Document analysis – comprehensive examination of available document/database that cover AI enabled medical devices with respect to their risk class
2. A qualitative interview with experts on both sides, i.e., manufactures and regulators to then develop a survey.
3. Consequently, a survey of developers of AI technologies to understand the challenges in covering the ethical dimensions.

NOTE: The student may choose to select a qualitative or quantitative approach depending on the scope and time.

Expected Outcome include but not limited to:

- Improved guidance for medical industry regarding AI usage with respect to safety and security in the FDA's "Software as a medical device, SaMD"[3]
- Potential strategies to bridge the ethical blind-spots, specifically, expanding the current spectrum of the MDR to specifically consider impact of AI in medical devices.
- Process overview of data collection phases, data training phases applicability of AI and recommended ethical framework.
- Setting coherent rules and consistency across applicable EU laws is essential to overcome the risk of fragmentation, duplication, or even conflicting requirements[4].
- Regulatory guidance on applicable laws to minimize ethical risks – creating national and international guidance[5] Recommendations on the creation of ethical review board.
- Outline of legal guidelines and laws applicable for AI development in medical devices

Relevant research:

- *Cybersecurity and AI Standardization*
- *Ethical Issues of Digital Twins for Personalized Health Care Service: Preliminary Mapping Study*
- *TUM*
- *Benchmarking saliency methods for chest X-ray interpretation*

If interested, please contact:

- Dr. Ibrahim Halfaoui: ibrahim.halfaoui@tuvsud.com
- Edmund Balogun, edmund.balogun@tuvsud.com

[2] https://hbr.org/2014/01/what-vuca-really-means-for-you
[3] https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device
[4] https://www.euractiv.com/section/digital/opinion/how-the-ai-act-could-unintentionally-impact-access-to-healthcare/
[5] https://podcasts.apple.com/us/podcast/patient-twinning-the-future-of-healthcare/id1618029606?i=1000580133743&sf170676150=1