Collaborative Discussion 1 – Peer Response 2 – Austin Mundy

Thank you Austin for your well-structured post.

As a complement to the regulations of medical devices by the U.S. Food and Drug Administration (FDA), the European provisions are anchored in the Medical Device Regulation (MDR) with regard to hardware and software for medical devices, which came into force on 26.05.2021. A basic summary of the requirements can be articulated as follows:

- Identification, analysis and assessment of cyber risks as part of a risk management system.
- Eliminate or reduce these security risks through safe design.
- Take additional protective measures for risks that cannot be eliminated.
- Provision of user information so that safe operation is possible and any justifiable residual risks for patient safety are clarified.

(THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION, 2017)

The new regulations mean that not only must new medical devices meet the requirements, but those that are already in use must be upgraded with regard to safety aspects. Under certain circumstances, this means an enormous amount of effort, as most of the devices that have already been developed do not meet the requirements of the new regulations and it must be checked whether retrofitting in terms of cyber security is even possible. When developing new devices, it makes sense to include the security aspects and legal requirements with regard to cyber security from IoMT as an integral part of the planning right from the start. However, developers and companies of IoMT products sometimes have no experience with security aspects, vulnerabilities and cyber threats, so they have to add a new security department to their company or get help from third parties (Boutros-Saikali et al., 2018). Companies like Cyone Security are already offering such services.

Despite the cost of setting up a cyber security department in a company or a service from a third-party provider, this is a sensible investment in capital to prevent even more complex and expensive retrofitting or even penalties for violating the FDA or MDR regulations

References:

Boutros-Saikali, N., Saikali, K. & Naoum, R. (2018) An IoMT platform to simplify the development of healthcare monitoring applications. Third International Conference on Electrical and Biomedical Engineering, Clean Energy and Green Computing (EBECEGC). Available from: https://ieeexplore.ieee.org/abstract/document/8357124 [Accessed: 17.11.2021]

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION (2017) REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745 [Accessed: 17.11.2021]