Trustworthy Artificial Intelligence (AI) in healthcare

MedTech Europe's response to the
Pilot on the Trustworthy AI Assessment List 2.0

28 November 2019

Rationale & Introduction

On 8 April 2019, the European Commission High-Level Expert Group on AI (HLEG AI) presented the Ethics Guidelines for Trustworthy Artificial Intelligence (AI). With this paper, to be read as an addition to the response to the Pilot on the Assessment List of the Ethics Guidelines for Trustworthy AI, MedTech Europe aims at providing the medtech industry's contribution on this question of ethical AI and form the basis for any future discussion on the topic.

MedTech Europe believes that AI has the potential to greatly improve the delivery of healthcare and other services that advance well-being, if it is validated by the authorities, accepted and supported by the Healthcare Professionals and Healthcare Organizations and trusted by patients. Embedding AI in an ethical framework that respects fundamental rights, is legal and meets regulatory requirement, is critical to building support and trust.

Legislation in this area of ethical scaffolding needs to respond in a balanced manner to the polarisation of two objectives. On one side the necessity of innovation, which is not geographically limited to Europe (or any other region), and on the other side taking into account the effects that this has already had and will continue to have in the development of society, respecting and safeguarding the universally recognised core values.

Therefore, we would recommend to policymakers and regulators to implement a patient-centric risk-based approach for the research, validation and approval of AI on the context of clinical decision support or digital health solutions or systems.

In addition, to avoid overregulation and the related legal uncertainty consequences, it is necessary to underline the importance of global consistency between AI regulatory frameworks, to provide AI developers and users with legal certainty and assurance that such frameworks can operate efficiently and effectively in the global context.

Background

The medtech industry has a long-standing experience with operating in a highly regulated environment, including stringent self-regulation, in a field dealing with highly sensitive and/or safety-critical application domains. As such, we are committed to be a collaborative and constructive partner in the AI policy dialogues, able to bring in valuable insight on the matter at hand.

Artificial Intelligence (AI) in MedTech, will generally fall into the characterisation of "software" as per the definition of the Medical Device Regulation[1] (MDR) and IVD Regulation[2] (IVDR). As such, AI in MedTech is already subject to a well-developed safety and performance regulatory regime for their development and use. The regulatory framework not only defines the roles and responsibilities for the different players but also ensures that the benefits outweigh the risks and that technologies are safe and reliable. Any assessment of medical AI systems will need to reflect these existing regulatory requirements, which are primarily the following:

- General Data Protection Regulation[3] (GDPR)
- IVDR/MDR and related standards
- Advertising and promotion laws
- Product Liability directive[4]
- Existing industry codes[5], in particular referencing ethical objectives and the principle of transparency

Ethical considerations for MedTech

The medtech industry is committed to the building of ethical and trustworthy AI systems. Industry acknowledges that ethical practices can and do have a role in shaping technological development. The Ethical AI requirements, defined by the HLEG AI, capture in its entirety a solid framework for trustworthy AI.

In this paper, MedTech Europe focuses its comments on specific requirements which have greater relevance for the medtech sector. However, there are multiple concepts and ideas which overlap and therefore it is important to consider these as being interrelated but they will not be discussed separately through the paper. In brief:

- The HLEG AI requirement on "**Privacy and data governance**". There are numerous regulations, frameworks, and standards that have been put into place or are currently under development regarding data privacy and security, such as GDPR, the NIST (US National Institute of Standards

[1] Medical Device Regulation (EU) 2017/745
[2] In-Vitro Diagnostic Medical Devices Regulation (EU) 2017/746
[3] General Data Protection Regulation (EU) 2016/679
[4] Directive 85/374/EEC on liability for defective products
[5] MedTech Europe Code of Ethical Business Practice (Dec. 2015); EFPIA Code of Practice (Jun. 2019); COCIR Code of Conduct (Mar. 2018)

and Technology) Cybersecurity Framework, ISO 27001 [6] (specifying an Information Security Management System, a suite of activities concerning the management of information risks), HITRUST[7] (US Health Information Trust Alliance), HIPAA [8](US Health Insurance Portability and Accountability Act), and others and therefore prior to creating AI-specific privacy and governance models.

- The core goal of AI technology in MedTech is to save and improve people's lives. Therefore, the HLEG AI requirements for **Diversity, non-discrimination and fairness**, and for **Societal and Environmental Well-being** are essential and are addressed throughout the development and integration of AI in medtech solutions, but their implications will not be discussed in depth.

  For instance, avoiding bias is a general challenge in healthcare and is addressed via medical ethics. Specifically to AI, the real challenge of discrimination and fairness is above all the availability of adequate data sets, whereas historical data may contain bias which would perpetuate discrimination and unfair treatment. This challenge is not exclusive to healthcare, but it is extremely important to be addressed, including policies on data access and sharing, to avoid unintended consequences in the delivery of care.

Taking into consideration the specifics of AI as applied in medical technologies, the current paper reflects on the requirements, which are more distinctive for the medtech industry:

1) Accountability
2) Human agency & oversight
3) Transparency
4) Technical robustness & safety

1) Accountability

Accountability in medtech AI is implemented via the applicable regulatory frameworks referred to above. Prospectively, in order to comply with MDR/IVDR, medtech companies are formally required to demonstrate to the authorities that they are fulfilling their responsibilities of safety and performance of the products that they place on the market[9] and in doing so, prevent untoward events from happening in the future. Accountability is critical for use approval, quality and

[6] ISO/IEC 27001:2013 — Information technology — Security techniques — Information security management systems — Requirements, https://www.iso27001security.com/html/27001.html
[7] US Health Information Trust Alliance, https://hitrustalliance.net/
[8] US Health Insurance Portability and Accountability Act, https://searchhealthit.techtarget.com/definition/HIPAA
[9] MDR and IVDR include both audit rights by authorities as well as post-market surveillance obligations on manufacturers which ensures reporting of any negative impacts as well as minimization of any of such impacts.

compliance, inspection readiness, and ultimately patient safety. As such accountability is a major component within a Quality Management System (QMS) companies need to implement. Retrospectively, product liability, whose principles focused on risk management and uncertainty may be broadly extended to AI in MedTech[10].

Medtech solutions are part of the healthcare ecosystem, where each player is responsible for their part. Hence, it would be useful to invest in broader awareness and education programs on AI not only for end-users but also for the authorities and regulators, which evaluate the risk of such new technologies before approving technologies and guarantee appropriate redress.

With reference to the specific point on auditability of AI, as evolutive systems, it may be worth mentioning that today there is no standard and in the MedTech industry a range of solutions are applied, ranging from high level of governance and risk assessment to specific AI audit programmes.

Medtech companies are at the forefront of innovation in digital health, very often coming from Small and Medium Enterprises (SMEs). It is necessary to recognise the distinct challenges facing different sized companies and acknowledge that often there is proportionally a greater resource commitment from smaller companies, when they need to comply with broad and all-encompassing European policy frameworks.

2) Human Agency and Oversight

AI in healthcare can serve as an essential tool for Healthcare Professionals (HCPs) to help them improve patient outcomes and quality of care. MedTech Europe supports AI which is conceptualised to inform HCPs and at the same time keep them connected to the humans who design and deploy it, and hence avoid a deflection of human responsibility. Data sets, however refined they may become, should always require human oversight for any resulting decisions to be fully informed and accurate. To ensure this, the MedTech industry would like to outline that it operates in a healthcare ecosystem, where a broad dialogue between, but also training and education of, Healthcare

[10] Referencing the European Commission's most recent report on Product Liability Directive (PLD), which determined that the PLD continues to be fit for purpose, it also highlighted that technology has and continues to develop at break neck speed. As a result, legal and regulatory frameworks can at times struggle to keep up. Therefore, the medtech industry does support developing non-binding to clarify certain issues under the PLD issues, which are directly or indirectly linked to AI/ML in medtech. This may include: (1) the circumstances in which software constitutes a product and is therefore covered by the Product Liability Directive; (2) referring to or incorporating sector specific legislation definitions where appropriate (e.g. the MDR/IVDR for definitions of software relating to medical devices and in-vitro diagnostics); (3) that damages covered by other legislation should be sought under those frameworks (e.g. GDPR); (4) the scope of the Development Risk Defence and its applicability to cybersecurity; (5) that the PLD's current expiry periods are sufficient.

Professionals and Organisations, patients, payers, industry, policymakers and other relevant stakeholders is needed to ensure that this requirement is met.

3) Transparency

As already recognised by the Council of Europe[11], in the AI context, transparency can have several different meanings. It may consist in a disclosure on the AI applications used, a description of their logic or, where possible, access to the structure of the AI algorithms[12] and – where applicable – to representative datasets used to train the algorithms. It could also be considered as transparency when the end-user is aware that the device is empowered by an AI. Moreover, transparency can be both an ex-ante or an ex-post requirement for data-centred decision-making.

As a fundamental principle, the medtech industry re-confirms its commitment to transparency, in particular with regards to our interactions with different stakeholders[13]. Such transparency takes different forms. Member companies support training and communication to both the users of their AI solutions (i.e. mostly HCPs) as well as enabling those users to communicate appropriately with those affected by an AI system (i.e. the patients), including the understanding of the outcome.

From a medtech company perspective, these issues require the right governance and representation, including control mechanisms, based on a risk-based approach to ensure that in a proper setting a medtech solution delivers the right outcome.

4) Technical robustness and safety

In the healthcare sector, where data is particularly sensitive, building this trust between technology and patient is a priority for the medtech companies.

The efficacy of AI applications relies heavily on access to datasets on which the system has been trained. The higher the quality of data that goes into the system, the better the outcome of the AI-specific task. Without access to data the potential of AI will not be realised in healthcare. However, there are practical issues surrounding the implementation of AI healthcare, including data sharing and privacy, transparency of algorithms, data standardisation, and interoperability across multiple platforms, and concern for patient safety.

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[11] COE Report on Artificial Intelligence, Consultative Committee of the Convention for the Protection of individuals with regards to automatic processing of personal data (Convention 108), Artificial Intelligence and Data Protection: Challenges and Possible Remedies (Jan. 2019)
[12] Where third-party algorithms are incorporated in a medtech solution, the traceability will be limited to the disclosure of the AI applications used.
[13] MedTech Europe Code of Ethical Business Practice (Dec. 2015)

Today, to ensure technical robustness and safety for medical technologies, including AI, there are existing harmonised standards, such as IEC 62304 (*Medical device software - Software life cycle processes*) and ISO 14971 (*Medical devices - Application of risk management to medical devices*), which could be leveraged. At international level, there is also guidance such as IMDRF SaMD guidance documents (such as N12 - *"Software as a Medical Device:" Possible Framework for Risk Categorization and Corresponding Considerations* and N41 - *Software as a Medical Device (SaMD): Clinical Evaluation*) which should be relied upon, where possible, when considering the risk categorization and clinical evidence requirements of AI medtech products.

Beyond these standards, to ensure technical robustness and safety in product development and commercialization, MedTech Europe would support developing international guidance, not sector-specific, relating to elements such as:

- Data curation,
- Bias in data acquisition,
- Data management,
- Algorithm robustness and fairness, and
- Monitoring and feedback mechanisms.

Conclusion

MedTech Europe welcomes the objective to frame concerns and expectations around AI. Medical technologies are enabling more precise prevention, diagnosis, treatment and monitoring of illnesses and innovation in this field continue to be developed through breakthroughs in science and the digital revolution, which includes Artificial Intelligence (AI).

While AI in MedTech today can rely on existing regulatory frameworks, there may be highly iterative, autonomous AI models and technologies which may require the development of additional (technology-neutral) guidance and/or an international regulatory approach[14] which would facilitate regulatory approval of a rapid cycle of product improvement and allow these devices to continually improve while providing effective safeguards[15]. Principle-based guidance is favoured by MedTech Europe as it can be broader in scope and interpreted specifically to meet the challenges of a changing world, whereas detailed legislative provisions do not appear to be able to react quickly enough to socio-economic and technological change.

MedTech Europe is committed to be a trusted and collaborative partner to the new European Commission in its effort to lay the ground for building an all-encompassing EU framework for AI. A common EU AI policy should be forward-looking, dynamic and sustainable, encouraging all stakeholders involved in the development of AI to work together towards the deployment of trustworthy AI in Europe and beyond.

For the general position of MedTech Europe on AI, please refer to the MedTech Europe's position paper on "Artificial Intelligence in MedTech: Delivering on the Promise of Better Healthcare in Europe".

[14] Where a medtech AI system changes its performance and safety characteristics during its use and without explicit manufacturer involvement, MDR/IVDR would not apply but provides a good model for inspiration, as distribution of role and responsibilities can inform an evolution of the understanding of the responsibilities in the healthcare ecosystem, providing a balance which enables innovation while maintaining standards for safety and effectiveness.

[15] For reference, please see: FDA, Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning, April 2019.