MedTech Europe
from diagnosis to cure

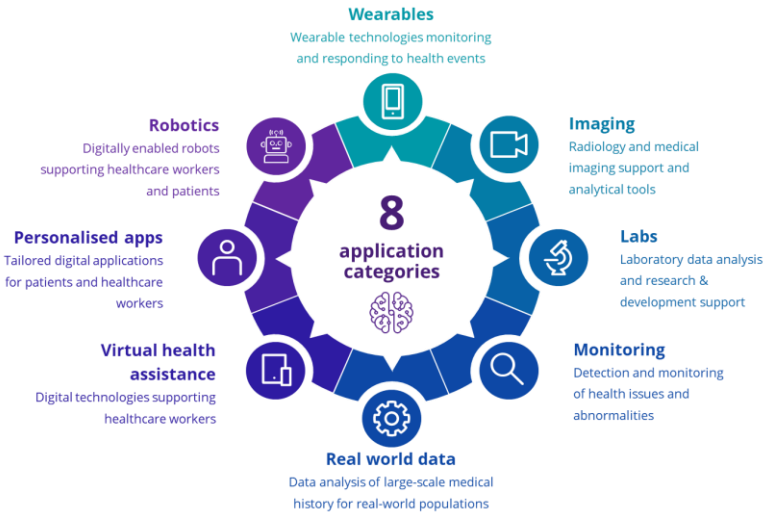
AI in medical technologies

Improving healthcare systems and patient outcomes

On 10 October 2022, MedTech Europe organised the in person event "AI in medical technologies: Improving healthcare systems and patient outcomes" in Brussels. During the event, participants discussed the benefits of Artificial Intelligence (AI) throughout the healthcare systems and presented an outlook on an AI regulatory system which works for patients and fosters health innovation. Speakers joined from the European institutions, the medical technology industry, patient and healthcare professional representatives, and healthcare insurance.

Participants agreed that AI has great potential to improve patient outcomes and improve healthcare systems. It may save up to 400,000 lives and free up to 1.8 billion hours yearly, equivalent to having half a million additional full-time healthcare professionals. Healthcare providers have embedded the technology into their workflows and decision-making processes, improving patient outcomes and access, supporting healthcare professionals and bringing benefits to society. At the same time, the patient uptake of AI medical technologies largely depends on their trust in AI and willingness to embrace it in healthcare.

However, reaching the full potential of AI will require an enabling environment where safe, high-quality, and trustworthy AI medical technologies can improve healthcare and patient outcomes. This encompasses the need for a regulatory landscape that supports the accessibility of AI in medical technology through a transparent and innovation-friendly legal framework aligned with sectoral legislation. MedTech Europe has already observed many instances where AI-enabled medical devices are able to support patients, healthcare professionals, and the overall healthcare system. A recent report commissioned by MedTech Europe identified eight application categories for such devices:



The medical technology sector is highly innovative and already well-regulated through the European Medical Devices Regulation (MDR) and the *In Vitro* Diagnostic Medical Devices Regulation (IVDR). Maintaining this environment to achieve the best possible outcomes for patients is crucial. To this end, MedTech Europe is closely following the discussion on the proposed AI Act in the European Parliament and the European Council to ensure that the safety of citizens is secured and that manufacturers can remain competitive on the international markets while fostering health innovation. In addition, the following key takeaways from the "AI in medical technologies: Improving healthcare systems and patient outcomes" event provide an overview from different perspectives on how to ensure that the AI Act does not disrupt the current regulatory environment for medical technologies.

The benefits of AI throughout the healthcare system

Healthcare systems have many players and stakeholders throughout the healthcare chain, from patients or healthcare professionals to health insurance and medical technology providers, that can benefit from digitalisation. One aspect of healthcare is the vast amount of health data that is currently not used to its full potential. When dealing with data and health data in particular, the FAIR principles have to be applied, namely the data meet principles of findability, accessibility, interoperability, and reusability. Secondly, it needs to become more visible how AI can benefit healthcare systems and its various applications such as by providing healthcare professionals with a real-time interpretation of brain scans and assist them in their workflows.

Views of the healthcare professionals

AI in the healthcare sector can help to manage the high number of processes and workloads within the healthcare setting and the health workforce. It can make repetitive tasks for healthcare professionals more manageable such as dictating medical reports and can also speed up more specific tasks. The application of AI in research and clinical trials is another excellent example which usually involves handling and processing a vast amount of data. AI can aid researchers in identifying criteria for randomised control trials to ensure the most efficient use of medicines for patients. It can also shorten the time for the discovery of new medicines.

However, when comparing the uptake of AI in healthcare to other sectors, its implementation is generally slower. Technologies must be designed as intuitively as possible to incorporate into the healthcare professionals' existing workflow. Hence, the healthcare professional should need **as few additional skills as possible**. When looking at the doctor-patient relationship, one has to consider the healthcare professionals' essential role as gatekeepers for patients. It will be necessary to ensure that patients can also fully benefit from AI. If healthcare professionals do not trust or see the need or benefits of AI, then it will not be used. It is therefore essential to create a secure and privacy-preserving system that delivers for people, patients, healthcare professionals, researchers, and innovators, while ensuring the meaningful involvement of patients. By legislating AI on a horizontal level as it is currently proposed, one should not forget the impact that the final regulation will have on the health sector, research and ultimately, patients.

Views of the healthcare mutuals

The goal should always be to ensure **healthcare access to all.** Most AI applications can be categorised by cost-efficiency, speeding up medicine approvals, and fraud detection through machine learning algorithms. Working with AI in health usually means dealing with a high amount of health data, which must follow the General Data Protection Regulation (GDPR). Therefore, when processing data, there needs to be explicit consent and a legal basis, which can create hurdles. Primarily working on high-risk technologies requires a data protection impact assessment (DPIA)

There are also other hurdles, such as the data quality because AI is only as good as the data it uses, the considerable early development costs of AI technologies, the fear of patients towards machine-automated decision-making, and digital literacy. It is vital for delivering on the potential of AI in healthcare to invest in increasing digital literacy to ensure uptake and successful diffusion of digital health data systems without widening existing inequalities in health, and with a view of building up public trust in secondary use of health data.

Views of the medical technology industry

AI's full-scale potential and benefits in healthcare are yet to be discovered. **There is currently insufficient access to and use of good data for research and AI can provide results that humans alone cannot**. There is a need for a robust policy framework and actionable steps to create an enabling environment for innovation. In addition, much work is left on the building blocks for funding, learning, and training while remaining ready for future challenges.

The **primary trend is that EU Member States want to digitalise healthcare**. To achieve this, it is crucial for healthcare services to be prepared. The tools exist, but there is a need for action from all stakeholders, not just the industries. It remains challenging to predict how successful the AI Act will be. There are still various aspects to work on, such as trust, skills, and training, especially as there is still scepticism from the healthcare professional community, which is the closest to the patient and thus can have the most significant impact on patient trust.

An AI regulatory system that works for patients and health innovation

While Member States have the sole competence over their healthcare system, sectoral legislations, such as the MDR and IVDR, provide a consistent level of protection for patients and healthcare professionals from risks related to these medical technologies. In addition, these legislations have provisions for AI-enabled medical technologies, which since then have been safely put on the market and used by patients and healthcare professionals.

The introduction of the AI Act sets specific requirements for AI that create legal uncertainty for the well-regulated medical technology sector. Policymakers must address these concerns to provide a consistent

legal framework that ensures the continued availability of innovative AI-enabled medical technology for patients, healthcare professionals and healthcare systems.

Views of the European Commission

The goal of the horizontal approach to AI was to create a system ensuring that everyone can rely on safe AI solutions. In general, such horizontal frameworks aim to create a fundamental common vocabulary, provide legal certainty, and avoid diverging national initiatives. A sound framework should have proportionate measures based on the levels of risk. **The European Commission relied on the New Legislative Framework (NLF) mechanism** as a successful regulatory model, which is also based on harmonised standards while conducting a careful assessment of the integration of such horizontal Acts.

The responsibility of the European Commission with horizontal legislation is to find a good integration which can be complicated when operating in a highly regulated environment. The European Commission is open to improving the current text to ensure good integration.

It is vital to rely as much as possible on sectoral legislation and ensure that the existing systems are not disrupted. For example, there should only be one conformity assessment.

The AI Act can provide legal certainty on AI by avoiding the introduction of new national or local initiatives. In addition, the AI Act promotes a higher level of involvement by stakeholders to achieve good regulation.

Views of a regulatory expert

For patients, there is a need for reliable and quick access to technologies which are safe and reliable. In Europe, the process of bringing new technologies onto the market is slow compared to the US. The policy objectives behind the AI Act are very promising, and **it deserves to be supported if it aspires to set the same standards as the GDPR**, especially as AI has enormous potential for good in healthcare. However, if the AI Act is to be successful, there remains a lot of calibrating to do. The regulation is primarily built on the NLF, which was meant for products and might not be as effective when the aim is to regulate technology.

It is essential to rely on sectoral legislation. For example, if AI is a safety component in a product, new requirements should align well with the sectoral legislation in a way that it should still work. With horizontal legislation, it is crucial to determine if the existing sectoral legislation does not already manage specific risks. Notified bodies for medical devices and *in vitro* diagnostic medical devices containing AI established in the AI Act proposal are yet to be determined. Similarly, the health institution exemption in the MDR and IVDR is essential to innovation but inexistent in the AI Act, which could create issues by removing the exemption.

Overlapping between horizontal and sectoral legislation cannot work if the underlying concepts differ. Various bodies stemming from different Acts will need to cooperate, both on a regulatory level and in practice. Therefore, it is crucial not to overcomplicate the implementation of the regulation.

Views of the medical technology industry

It is beneficial to have horizontal regulation, but the sectoral laws must not be neglected as there are still many sectors waiting. The current situation is an obstacle to innovation, especially for smaller companies, as medical technologies need a lot of data for development. A concern is that many companies already have their MDR certification for their products, and it is unclear what they will need to do with the new AI Act. While there is a need to handle the risk, it is also important to consider the reliability of the Act for planning security.

The Federal Ministry of Health is working on a digitalisation strategy in Germany. While there are eHealth records in Germany, the digitalisation of health is still at its beginning. Unfortunately, the Ministry driving for digitalisation change mainly focuses on transport and is unaware of medical technology manufacturers who also need access to data. However, in Germany, the only stakeholder excluded from access to available data is the industries.

The principle behind the AI Act is positive, but it needs to account for the reasonable regulations already in place and remain simple. Its success relies on collaboration between stakeholders.

Key takeaways from the discussion:

- It will be crucial to develop quality criteria for data, mainly when using external data. There must be transparency about who and why the data is used for secondary purposes.
- Implementing an interoperable system with one common language at the source is an illusion. There needs to be a system which processes what comes from the national level. Whichever format, it will be vital to remain widely accessible so that it does not create additional barriers. The diversity and quality of the data are equally important, as medical devices must be as inclusive as possible.
- AI can potentially advance clinical practices and alleviate the burden of conducting routine tasks.
- The core issues for manufacturers are that access to data remains challenging and that it is difficult for manufacturers to navigate the regulation as its goal focuses on creating a safety net for patients. In addition, with the cost of development, the need and access to reimbursement can be a big hurdle.
- It is important to remember that AI should only remove tasks and not add new ones, while over or under reliance on AI can be dangerous.

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

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