Artificial Intelligence in Medical Technology: Delivering on the Promise of Better Healthcare in Europe

MedTech Europe
from diagnosis to cure

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Executive summary

The medical technology industry welcomes the new European Commission's priority focus on Artificial Intelligence (AI). Our industry sees enormous potential of AI to make healthcare better and safer, improve access and outcomes, empower patients and citizens with information, and make healthcare delivery more efficient.

There are several challenges that impede the deployment of AI in healthcare. These include a fragmented data landscape that makes access to or sharing of data difficult, a lack of interoperability, and a shortage of incentives for data sharing. Legal, technical and social challenges present additional obstacles for the sharing and aggregation of data.

To overcome these challenges, MedTech Europe recommends specific policy actions, also in reference to those drafted by the High-Level Expert Group on AI (HLEG), including:

- **Building data and infrastructure for AI –** aligning infrastructure with the goal of providing a solid flow of consistent data with standardised formats and the necessary cybersecurity provisions. In addition, MedTech Europe calls on all parties interested in aggregating health data across Europe to develop data governance models and work collaboratively with national governments, interoperability initiatives and stakeholders to make the European Health Data Space a reality.

- **Establishing a strong governance framework** – building on a careful sector-specific assessment for the needs of regulation, as well as on existing EU legislation and existing institutional structures to reap the benefits of AI, regulated on the basis of risk calculation and ethical standards.

- **Equipping the workforce with the necessary skills** – maximising the positive impact of AI.

- **Funding of AI** – investing in research and innovation, but also in resources for implementation and deployment. In addition, the medical technology industry calls for a new approach to the incentives; funding; and reimbursement of digital health technologies, including AI in healthcare.

MedTech Europe and its members are committed to being trusted and collaborative partners in policy discussions on the responsible application of AI in healthcare.

Introduction & purpose

Artificial Intelligence (AI – please refer to Annex I for our definition) holds the promise to support humans in their daily lives, to take care of routine tasks, and to advance human knowledge. These promises apply also to healthcare. In this paper, we will outline the potential of AI in healthcare and provide examples of promising implementations that are already in place or are ready to be deployed. However, as this paper lays out, there are challenges to unlocking the potential of AI that are specific to healthcare. From a specific healthcare and medical technology perspective, the paper reflects on the policy measures that will be critical to embracing AI in Europe, as well as on the *Ethical Guidelines* and *Policy and Investment Recommendations* published in 2019 by the European Commission's High-Level Expert Group on AI (HLEG AI).

MedTech Europe is committed to being a trusted and collaborative partner to the European Commission in its efforts to lay the foundation for building a comprehensive EU framework for AI. A common EU AI policy should be forward-looking, dynamic and sustainable. It should also encourage all stakeholders involved in the development of AI to work together towards the deployment of trustworthy AI in Europe.

I. The promise AI in the medical technology sector holds for society

AI could not come at a more opportune time. Healthcare systems in Europe are under pressure: rising costs, increasing prevalence of chronic conditions, ageing populations, growing demand and stagnating or shrinking healthcare workforces threaten their sustainability. At the same time, structural inefficiencies in the healthcare sector abound.[i]

Over the past decade, there has been an exponential growth in computational power and in the number of devices that generate data, while the cost of data storage has dropped dramatically[ii]. The amount and granularity of stored digital medical and healthcare data has never been greater[iii]. Almost a third of all data generated today is health data, and it is projected to grow dramatically[iv]. However, there is a growing concern that only a small portion of this data is being used to improve the quality and efficiency of care. The expansion in healthcare data has far outpaced our ability to analyse it.

Against this background, the healthcare sector is ripe for digitisation to make it more effective and efficient. The move to value-based healthcare will strengthen demand for better patient outcomes at a more sustainable cost.

Incorporating AI into innovative medical technologies can address pressing healthcare issues. Many AI applications in healthcare are already in operation or awaiting deployment that contribute to earlier disease detection, more accurate diagnosis, identification of new observations or patterns on human physiology, and development of personalised diagnostics and therapeutics. One of the greatest benefits of AI software resides in its ability to learn from real-world use and experience, and its capability to improve its performance. Annex II provides examples.

II. Challenges to AI in healthcare

The deployment of AI comes with potential limitations and risks if not implemented appropriately. In healthcare the challenges are often related to the specific nature of health data:

1. **Type of data**: The growing number of digital health devices is generating vast amounts of data, but it often remains trapped in silos. Data is often unstructured and does not follow standardised formats but follows proprietary protocols. As a result, even if silos were opened, data from systems from different vendors or providers could often not be compared or pooled.
2. **Quality of data**: Any medical practice depends on good information. AI requires access to good quality, representative, curated health data. Much of the existing data does not meet the required standards for clinical evidence and therefore does not translate into knowledge or clinical practice. Data is often statistically insufficient, it may not have proper translating mechanisms in place, or it may face additional constraints.[v]
3. **Sensitivity of data**: Healthcare data is different from a number of other kinds of data. It is deeply personal, sensitive and complex, and therefore subject to strict privacy and data protection rules. Those EU Member States that have set up electronic health record systems have won user trust by establishing strong protections, which limit data availability for research.

These challenges, along with potential solutions, are described further below:

Legal challenges

The legal frameworks which regulate AI systems in healthcare include the following:

- In Vitro Diagnostic Regulation[vi] & Medical Device Regulation[vii] (IVDR/MDR)
- General Data Protection Regulation[viii] (GDPR)
- National advertising and promotion laws
- Product Liability Directive[ix]
- Existing industry codes[x], in particular referencing ethical objectives and the principle of transparency

Which of these legal frameworks apply depends on the specific AI technology, context and application. The term AI is sometimes loosely applied to many technologies, designed to be used in diverse settings with widely varying consequences. The key challenge will be to determine how AI technologies fit into regulatory frameworks sometimes designed for an analogue world. These challenges must be addressed with the speed and scale necessary to serve the public interest, ensuring at the same time that legal frameworks do not slow or block the beneficial uses of AI.

Possible solution:

Legislation should consider the entire lifecycle of the AI solution so that patients, caregivers, healthcare professionals, and other users sufficient assurance of the safety, effectiveness and quality of those solutions.

Technical challenges

Data fragmentation

Health data is fragmented and often stored in silos by various actors and for different purposes, including provider IT systems, the clouds of device manufacturers, scientific databases, device and other registries, general IT and internet services, and the devices of individual patients and citizens.

In addition, health data is often kept in proprietary formats and systems that inhibit meaningful sharing of data. Several interoperability initiatives have sought to provide open, international formats and standards for health data. However, the healthcare sector has been slow to adopt a shared approach and the market has so far failed to solve the interoperability challenge.

Possible solution:

Governments, health authorities and procurers could help by identifying appropriate industry standards, including the aspects of traceability of how a AI solution came to a specific recommendation/decision, and by either mandating their compliance or by setting positive financial incentives, or both[xi]. European Member States have expressed their commitment to interoperability[xii], and the new Commission's plan to develop the European Health Data Space promises new momentum towards more alignment across Europe.

Cybersecurity

The goals of breaking up data silos and exchanging data present challenges to those in charge of cybersecurity. Health IT systems and medical technologies, like other computer systems, can be vulnerable to security breaches, potentially impacting the safety and effectiveness of the technology.

Possible solution

The healthcare environment is complex. Authorities, manufacturers, providers and users must work together to manage cybersecurity risks and build a clear framework across the healthcare ecosystem.

Social challenges

Finally, there are social and cultural challenges affecting various stakeholders: citizens, patients, healthcare professionals, healthcare providers, hospitals etc. Digital health can empower citizens and patients with information, but it requires users to have a certain level of proficiency and skill (also sometimes called "digital literacy").

Sometimes users lack trust that their data is being handled safely and withhold their consent to setting up electronic records. The European aspiration should aim towards European citizens being able to also receive medical care in other Member States without unnecessary restrictions in terms of access to or flow of their medical care data.

Digitisation also places demands on healthcare professionals who are required to adapt their clinical pathways, which brings along the necessary but not always straight-forward understanding of how AI solutions can fit and can enhance their medical practice. Often it is healthcare professionals who bear the

brunt of the conversion of paper information to digital information. In practice, digitisation causes more work initially before delivering efficiencies.

Possible solution:
Promoting professional education and training towards digital literacy should be an integral part of the policy agenda, considering both university education and lifelong learning programmes. Additionally, developing AI systems and algorithms requires specific skillsets which are also in short supply. Therefore, investment in education and training of such professionals (e.g. data scientists), in parallel to awareness and education of "traditional" healthcare stakeholders, is important. In addition, in order to find solutions to social challenges of AI, it will be important for authorities, businesses, academia and other organisations to join forces.

III. The commitment of the medical technology industry to ethical AI

The medical technology industry is committed to supporting the building of ethical and trustworthy AI systems and considers that the Ethical AI principles, defined by the HLEG AI, deliver a solid framework. Taking into consideration the specifics of AI as applied in healthcare, there are a few principles which stand out for the medical technology industry. MedTech Europe developed these in more detail in our response to the pilot process of the assessment list of the Ethical Guidelines for Trustworthy AI, here.

In summary, when considering regulating ethical AI in healthcare, policymakers should implement a patient-centric risk-based approach for AI and consider a governance framework that would address intended oversight, proportionality and risk management mechanisms.

IV. Call to action: Incentivising the realisation of AI in healthcare

The medical technology sector is a key player for the realisation of trustworthy AI in healthcare and supports the creation of a European Single Market for AI, as proposed by the High-Level Expert Group on AI (HLEG AI) and mandated by the European Commission.

There are certain policy measures proposed by the HLEG AI that we consider important for the deployment of AI in the healthcare sector, and hence, for enhancing European competitiveness in the global AI context.

Enablers of Trustworthy AI

Making AI trustworthy, and thereby securing the public's support, will be essential for its adoption and sustainability. Among the recommendations of the HLEG on AI, there are some that the medical technology industry views as priorities of special relevance for healthcare:

- Building Data and Infrastructure for AI

The importance of a data governance model where it is critical to have access to curated and consistent data has been laid out in greater detail in section II of this paper. Therefore, the proposals to "**Develop legally compliant and ethical data management and sharing initiatives in Europe" (policy measure 18)**, will be pivotal for the advancement of AI in Healthcare.

In conjunction, **policy measure 20 (Develop and support AI-specific cybersecurity infrastructures)** will be essential in responding to the need for a harmonised cybersecurity approach throughout healthcare supply chains.

- An enabling governance framework

The medical technology sector welcomes the effort of the HLEG AI to establish an appropriate governance and regulatory framework for trustworthy AI, by mapping, evaluating and taking into consideration existing EU law, as per **policy measure 27.1 (Conduct a systematic mapping and evaluation of all existing EU laws that are particularly relevant to AI systems.)**. Our sector has long-standing experience of operating in a highly regulated environment with both sectoral (e.g. Medical Devices Regulation 93/42/EEC, *In-Vitro* Diagnostic Medical Devices Regulation 98/79/EC) and horizontal regulations (e.g. General Data Protection Regulation 2016/679), which have specific provisions for the safety and performance of software as a medical device. Thus, we can provide sectoral expertise on future EU horizontal policy-making processes.

In order to maximise the value of AI in the healthcare sector, policies need to remain flexible and follow the evolution of technological development, and allow space for technology to thrive both within big and smaller companies. The medical technology sector welcomes the approach of the AI HLEG towards a risk-based, principle-based approach to AI regulation **(policy measures 26.1 & 26.4)**. This will allow technology to take an ethical course of development, supported by effective enforcement of existing legislation and self-regulation with the necessary enforcement mechanisms.

Desired positive impact in Europe

The HLEG AI has identified the "what" and the "how" for the desired positive impact which could be achieved in Europe with AI. For the medical technology industry, the following policy measures in several broader areas will be of significant importance:

- Digital skills and literacy for Healthcare Professionals, Citizens and Data Scientists

Equipping the EU workforce with the reskilling and continuing learning opportunities required to embrace ongoing technological developments are vital to maximising the positive impact of AI in the EU. As per the HLEG AI **policy measures 24 (Upskill and reskill the current workforce)** and **25 (Create stakeholder awareness and decision support for skilling policies)**, in the context of the healthcare sector, it will be essential to invest in enhancing the digital skills of healthcare professionals (HCPs). This could be done

through pre-certification of medical societies and advancement of the AI curricula for HCPs and hospital managers.

- Funding of Artificial Intelligence

Europe has both the excellent fundamental science and a vibrant, innovative medical technology industry but it needs support if it is to shape the digitisation wave with European solutions and standards.[xiii] For medical technologies to support the transformation of healthcare systems in Europe, it will be essential both to invest in research and innovation of AI **(policy measure 13: Develop a European strategic AI research roadmap)** but also to invest in its implementation and deployment **(policy measures 6: Boost the uptake of AI technology and services across sectors in Europe** and **11: Make strategic use of public procurement to fund innovation and ensure trustworthy AI).**

Furthermore, digital health technologies, including AI in healthcare, require a new approach to their funding and reimbursement. A subgroup of the European Commission's eHealth stakeholder group has published **"Proposed Guiding Principles for Reimbursement of Digital Health Products and Solutions"**[xiv] which make recommendations in the areas of criteria for reimbursement, funding sources, evidence generation and digital health assessment specifics.

V. Conclusion

MedTech Europe and its members commit to being trusted and collaborative partners in policy discussions on the responsible application of AI in health. A multi-stakeholder approach will be the foundation of a forward-looking and sustainable AI regulatory landscape. This ensures that policy remains dynamic and flexible, adapting to the evolution of technology.

By addressing the challenges set out in this paper, Europe can be a world leader in the design, development and deployment of AI healthcare solutions that are supported by the people. Not only can this deliver the changes needed to steer European health systems onto a sustainable path, it can also create a thriving global industry and achieve our shared goal of improving outcomes for patients everywhere.

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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Annex I

Regarding a **definition**, MedTech Europe is aligned with the definition of AI agreed by the High-Level Expert Group on Artificial intelligence (HLEG AI):

> *"Artificial intelligence (AI) refers to systems designed by humans that, given a complex goal, act in the physical or digital world by perceiving their environment, interpreting the collected structured or unstructured data, reasoning on the knowledge derived from this data and deciding the best action(s) to take (according to pre-defined parameters) to achieve the given goal. AI systems can also be designed to learn to adapt their behaviour by analysing how the environment is affected by their previous actions.*
>
> *As a scientific discipline, AI includes several approaches and techniques, such as machine learning (of which deep learning and reinforcement learning are specific examples), machine reasoning (which includes planning, scheduling, knowledge representation and reasoning, search, and optimisation), and robotics (which includes control, perception, sensors and actuators, as well as the integration of all other techniques into cyber-physical systems)."*[xv]

However, the term AI is sometimes used in a broader sense to denote software or algorithms, which is not always helpful.

Annex II

Medical technology solutions which can help address pressing healthcare issues in Europe:

- **Access to health services and shortage of healthcare professionals can be overcome by using algorithms to perform time-consuming tasks.**[xvi]
  - AI processes and interprets the physician's speech to generate data and information entered into an Electronic Medical Record (EMR), replacing typing as the most widespread and time-consuming method of data entry into an EMR (and helping to overcome their apprehension against EMRs).[xvii]
  - Computer-aided detection (CAD) systems help doctors to interpret medical images. CAD systems process digital images, highlighting possible diseases. By supporting decision-making, this technology can limit observational oversights and reduce error.[xviii] This improves the accuracy and speed of diagnoses, offering opportunities for earlier intervention which can save lives and costs.

- **Overuse of resources can be overcome through greater efficiency and optimisation in healthcare delivery.**
  - Predictive AI techniques improve the efficiency of patient operational flow – helping to prioritise hospital activity, improve hospitals' ability to admit patients and accelerating patient discharges. This delivers a more positive patient experience.
  - Data mining of longitudinal monitoring of activity tracker/fall alarms of elderly people enabled a medical technology company to discover patterns and predict future falls, allowing for preventative measures to avoid hospitalisation and loss of quality of life.

- **Diagnosis timelines can be improved through faster data analysis.**
  - Autonomous diagnostic decision-making systems help detect signs of diabetic eye disease (retinopathy). Images can be automatically screened and analysed, and results can be made available in less than a minute.
  - Machine learning algorithms can learn to see patterns based on thousands of digitised images and datasets, to help assess the risk of sudden cardiac death or other heart diseases based on electrocardiograms and cardiac MRI images.

- **Burden of lifestyle & noncommunicable diseases can be decreased through prevention, patient empowerment, coaching, remote monitoring and support for self-management.**
  - Telehealth platforms reduce the cost of chronic obstructive pulmonary disease (COPD) and asthma care. Data from sensors, connected to mobile apps, help to identify causes of symptoms, improve medication adherence, enhance disease management and improve quality of life. This approach offers patients the opportunity to share information with family members and their care team. By combining sensor data with patient self-reported data, patient and physician awareness of asthma symptoms can be improved and potential

triggers identified. This approach could lead to better health outcomes and reductions in healthcare utilisation by avoiding emergency room visits and hospitalisations.

- Personalised nutrition and health coaching through AI. Data from mobile app tracking of eating and physical habits, in combination with genetics and blood markers, can be used to help a person manage his or her diet, heart, weight and inflammation, and provide personalised nutrition coaching to optimise their diet and metabolism.[xix]

- **Selection of the right therapies is facilitated through personalised and precision medicine by improving accuracy and reducing unwanted variations.**
  - Clinical decision support systems integrate long-term patient data and co-create insights from imaging, pathology, laboratories and genetics. Key performance indicators are analysed and the systems are designed to personalise patient management and improve processes.
  - Cross-platform collaborations combine genomic profiling, next-generation sequencing and electronic records, using AI to identify which treatments show most promise for patients.

- **Disease outbreaks could be predicted and prevented through real-time predictive analytics.**
  - Predictive modelling. Customisable analytics platforms make sense of users' public health data, incorporating data on historic mapping, social media reports, weather conditions and housing to provide users with information on the severity, location and date of a next disease outbreak, months in advance.

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