MedTech Europe
from diagnosis to cure

# Inception Impact Assessment
## The European Health Data Space and the view from MedTech Europe

3 February 2021

## 1. Introduction

MedTech Europe welcomes the opportunity to provide the comments of the medical technology industry to the European Health Data Space Combined Evaluation Roadmap/Inception Impact Assessment.[1]

As indicated in its statement on the European data strategy of May 2020, MedTech Europe **supports the project of the European Health Data Space (EHDS)** and its corresponding initiatives.[2]

Improved and expanded sharing of, and access to, health data will improve healthcare access, quality, and outcomes, advance scientific research, and, through data analytics and AI, bring tangible benefits to European citizens, to society and the economy. The medical technology ("medtech") industry is, alongside Europe's public and private universities and research institutions, at the forefront of research and innovation, and needs to be part of the conversation when access to health data for research is discussed.

The **medtech industry is at the heart of the health data ecosystem**. Medical devices and in-vitro diagnostic devices deliver clinical grade data, as a result of compliance to strict regulatory requirements; moreover, trust in the veracity of health data is a critical enabler for the digital transformation of healthcare. The medtech industry's digital health solutions annotate and enrich data (by adding various identifiers, stamps, and other metadata, contouring lesions, labelling and combining data) to turn raw data, which are mere strings of digits, into datasets of high value that can become precious research tools that improve the lives and health of people.

This role of the medtech industry to the data economy should be considered when discussing matters such as data access and exchange. Access to data for the medtech industry is, therefore, not a reward but an enabler to deliver improvements and innovations to the delivery of healthcare. Innovation in the development of new treatments and protocols is highly dependent on the medtech industry's ability to successfully access and appropriately utilise health data."

**In the medtech industry's view, the EHDS initiative can accelerate the digital transformation of Europe's healthcare systems and create the conditions for better use of health data by:**

- Building a **trustworthy health data ecosystem** supported by transparent governance principles, streamlined infrastructures and mechanisms facilitating data access and sharing while protecting individuals' rights.
- Improving **the quality of health data** by requiring robust data integrity checks and interoperable data formats that conform to internationally accepted standards, and setting models to ensure adoption and compliance by all stakeholders.

[1] The document is available here for download: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12663-A-European-Health-Data-Space-

[2] The statement is available at https://www.medtecheurope.org/news-and-events/news/medtech-europe-statement-on-the-european-strategy-for-data/

- Advancing **the conditions for research that lead to the development of innovative solutions** by accelerating capabilities for the re-use of health data within and across European Member States (as well as countries outside the EU that offer an adequate level of data protection), including by the medtech industry.
- Creating **an institutional infrastructure** for easy access to health data of European citizens and patients that offers consistent, easy-to-understand rules and fair conditions for access.
- Supporting the **development of skills in the healthcare workforce and the optimal integration of AI systems** in healthcare.

The EHDS can thus reinforce the competitiveness of European industry and new business opportunities by improving data access while offering a model that respects individual rights, including the right of privacy and data protection, and ensures safety and security for all actors.

## 2. Barriers

MedTech Europe agrees with the problem description ("*Problems the EHDS initiative aims to tackle*") in the Inception Impact Assessment, and would like to add:

- **Insufficient health data exchange for healthcare service provision**: The industry would add that the lack of data exchange and interoperability reflects years of underinvestment in digital health infrastructures, and insufficient political leadership in making it a priority and providing guidance and direction. The EHDS initiative can play a critical role in filling this gap, while the COVID-19 pandemic has put a light on it.
- **Exercising access and control over own health data**: Citizens should be empowered to access and manage their own health data. Electronic health record ("EHR") systems and digital health tools should be improved to fully deliver on the right to portability of health data for citizens and to provide the essential clinical information in a patient-friendly language across the EU. We welcome that this is being addressed, with a growing number of healthcare systems requiring developers of medical technology solutions to deliver data along certain specifications.
- **Fragmentation of digital standards and limited digital interoperability between healthcare systems**: The industry supports the voluntary European EHR Exchange Format as a critical means to overcome Europe's digital health fragmentation, and calls on national and regional health systems and providers to adopt it.
- **Access to health data for primary and secondary use of health data**. The industry shares the view that the fragmentation in GDPR implementation by the Member States and inconsistent interpretation across the EU pose critical obstacles for health data use, both for the care delivery (primary use) and to foster research and innovation (secondary use), and welcomes steps to overcome this fragmentation. We also recommend further clarification when a data set can be considered sufficiently anonymised so it can be used and shared for research purposes (including commercial scientific research by medtech companies). The definition of "secondary use" should be clarified to enable the use of anonymised research data, for example medical images without patient information, to allow data processing for additional engineering purposes (e.g. computer modelling and simulation) that are not linked to the original study.

- **Movement and provision of digital services and products:** The industry shares the view that the divergence in regulations and administrative practice at the national level often hinder the cross-border provision of health services. However, we welcome reimbursement initiatives for digital health technologies in a growing number of Member States, and call on all Member States to cooperate with a view to aligning the assessment procedures and criteria that digital products or services need to meet to be eligible for reimbursement, to overcome fragmentation.
- **Digital health tools integrate artificial intelligence**: AI in healthcare has considerable potential to help save lives, save resources and reduce the burden on the healthcare workforce.[3] AI in healthcare is already regulated via the Medical Devices Regulation (EU Regulation 2017/745) and the In-vitro Diagnostics Regulation (EU Regulation 2017/746). MedTech Europe would advise caution when considering introducing new generally applicable AI-specific legislation, in particular in view of the risk of creating conflicts between the various AI-relevant regulations, and of the need to avoid creating additional barriers for the development of AI-supported medical technologies. In the highly regulated medtech sector, guidance that provides interpretation and describes novel approaches to (existing) requirements fulfilment may promote more development efforts and enable developers to navigate the EU regulatory environment for the medtech industry more easily and efficiently. Equally, more support is needed to upskill the healthcare workforce and to develop models for optimal integration of AI technologies into healthcare organisations.

The medtech industry misses in the problem description that the European Health Data Space initiative should address the gaps in trust and skills. We address this below.

## 3. The legal basis of the European Health Data Space

- **To what extent are the provisions of the cross-border healthcare Directive sufficient for exchange of health data and free movement of digital health services and products? Do these provisions allow re-use of health data for future research, innovation and development, policy-making and regulatory activities?**

  The medtech industry is of the opinion that conceptually, the EHDS should not be limited to the promotion of cross border services or data transfers. It should also address the broader issue of data access for permissible data use subject to appropriate safeguards, e.g. for research and innovation purposes, and not solely for the provision of care. Some of the issues medtech companies have faced, in particular with regards to access to data in care delivery as well as research, both relating to clinical research (research on humans) and non-clinical research (on data, e.g. computer modelling and simulation), re-use of health data, have their origin in different European legal frameworks. The legal basis chosen for the EHDS should allow for embedding this broader concept of data transfer.

  More specifically, some of the issues encountered on these issues relate to the GDPR's implementation and interplay with MDR/IVDR and health legislation in the Member States.

[3] See Deloitte/MedTech Europe, *The socio-economic impact of AI in healthcare,* October 2020 (https://bit.ly/3is08WR).

Clarification or more consistent application of the GDPR across Europe is urgently needed, especially around (1) the rules on processing health data for research purposes by medical technology product manufacturers (including commercial scientific research by medtech companies); (2) the extent to which MDR/IVDR can serve as a stand-alone legal/regulatory basis for the processing of health data (see Art. 9, par. 2, i, GDPR), in order for medtech companies, for example, to access data to support regulatory obligations; (3) guidelines or clarification on the concept of 'personal data' and 'non-personal data (e.g. through guidelines by European Data Protection Board (EDPB); (4) harmonised guidelines/standards or technical specifications on anonymisation (through updated EDPB guidelines on anonymisation techniques) and pseudonymisation of health data, including medical images[4], and (4) the exceptions for public interest and preventive/occupational medicine.

- **Is the cross-border healthcare Directive consistent and complementary with existing data protection legislation and with the Data Governance Act? To what extent is new EU legislation necessary to enable free movement of digital health services and products?**

  As pointed out in previous consultations, MedTech Europe supports the idea that, while assessing the need for new legislation, the application of existing legislation (in particular sector-specific rules) should be taken into account to understand whether any gaps exist, to avoid overlapping and conflicting regulations. In addition, as a matter of principle, the medtech industry favours an EU-wide alignment as opposed to Member State legislation. It is also important to point out that regulations and administrative practice at the national level may sometimes contradict the policy options made at the EU level. Industry concern is however that even where the EU would decide to act via a legal instrument (vs. guidance) to avoid fragmentation, and assuming the favoured instrument is a regulation (vs. a directive), this does not necessarily avoid fragmentation. For instance, provisions in the GDPR allow Member States to adopt additional rules in matters of health, genetic and biometric data, and this has led to fragmentation. A more consistent implementation with regards to health data across Member States is urgently needed.

## 4. Recommendations

The European Health Data Space project will advance and accelerate the digital transformation of healthcare, in good part by ensuring data is compatible and easily transferred. The inevitable changes in current practices (e.g. IT systems upgrades, new clinical pathways etc.) will help make healthcare better, safer and more effective. The European Health Data Space offers a vision, process and means to accelerate this transition, before digital health technologies deliver their efficiencies, new knowledge and intelligence, and a shift from care to prevention by improving disease prevention and early detection.

[4] For example, the Health Insurance Portability and Accountability Act of 1996 (HIPPA) of the U.S. is providing a list of fields that needs to be removed to get anonymised data. This can be a solution the European legislator may want to consider as well.

**MedTech Europe calls on the EU to take on a coordinating role to realise the full potential of health data for improved outcomes and innovation.** Aligning incongruent national strategies through an EU-wide governance framework will enable Europe to harness the power of health data in a resource- and cost-effective way. Such a framework should include:

- **Benefits for citizens.** The European Health Data Space needs the trust and acceptance of Europe's citizens, and needs to correspond to national and regional initiatives to create a trusted personal space for citizens to safely store and manage their health data. Citizens need to be equipped with digital health literacy, and skills to manage their data. This will also enable healthcare providers to store, administer, assess and exchange data on behalf of citizens. The personal health data space needs to meet citizens' expectations for safety, security, stability and usability, and it must adapt to the changing circumstances, growth in data, technical innovation and new use cases. It must become a living health data resource.
- **Advancing trust.** If the benefits are real, and the regional and national initiatives for personal data space meet citizens' needs, trust will follow. The health data governance framework must foster trust among citizens, patients, and healthcare professionals that their data benefits research and innovation, and it is used appropriately. Data access for the medtech industry should be carefully aligned to a clearly defined description of permissible and non-permissible data uses and appropriate safeguards. Thereby, the privacy roles and responsibilities of the parties involved need to be clarified, in particular as regards to the identification of controllers and joint controllers, and the appropriate safeguards that may need to be implemented. This is key to inspire public trust and confidence in the European Health Data Space.
- **GDPR.** MedTech Europe calls for more harmonisation of GDPR interpretation and application across the Member States, especially also as regards national divergence in the field of health, genetic and biometric data, secondary use and anonymisation of health data**.** Instruments such as Codes of Conduct could help advance in a common understanding and application of data protection rules in specific data use scenarios.
- **Intellectual property (IP) and competition law safeguards**. It is important that companies accessing data not be required to disclose the purposes of their research or innovation project in a way that would reveal business sensitive or IP-protected information to their competitors.
- **Interoperability.** Achieving technical and semantic interoperability and seamless exchange of data and information is critical to the success of the European Health Data Space and improvements in clinical operations, patient outcomes and cost of healthcare. The interoperability of electronic health records, in line with the European Electronic Health Record Exchange Format, as well as semantic and technical interoperability should be strengthened. The governance framework should prioritise standardisation needs and improve data interoperability. MedTech Europe calls on governments and healthcare authorities to develop guidance, recommendations and mandates (in the form of digital health strategies, action plans, or other indicative statements) that advance interoperable data ecosystems consistent with, and based on, international consensus standards, to avoid national and regional fragmentation.
- **Cybersecurity.** Trust in the safety and security of digital health tools and services is critical, and cybersecurity needs to be a cornerstone of the European Health Data Space. Healthcare organisations and business associates (e.g. vendors, manufacturers in the procurement and

supply chain) must implement robust security measures to protect patient data from an increasing number and variety of threats. Vulnerabilities in wireless networks, for instance, may offer an easy entry point for hackers who may have the ability to exploit such vulnerabilities, yet these networks are of critical importance to healthcare organisations, as they make it easier to access patient information and optimise the delivery of care. Best practices for healthcare cybersecurity need to keep pace with the evolving threat landscape, addressing threats to privacy and data protection on endpoints and in the cloud, and safeguard health data while in transit, in use or at storage/rest. Achieving security of private and health data requires a harmonised and sophisticated security approach.

- **Liability**. Industry believes that applicable liability regimes regulating medical technologies, including digital health technologies, continue to be fit for purpose. As technology continues to evolve at high speed, we see, at this stage at least, value in developing guidance – rather than introducing legislative changes – to clarify certain issues. As mentioned above, the medtech industry suggests avoiding new rules that may conflict or overlap with existing rules and as such, we would suggest building on regulations already existing, such as the Product Liability Directive (PLD) and sector specific regulations (for us, MDR/IVDR) to be built on through guidance and completed if, and only if, actual gaps are clearly identified for AI technologies.
- **Datasets for training robust, accurate and safe AI solutions.** The European Health Data Space should make it a priority to harness datasets for training and testing AI solutions in healthcare. It should work with and through Digital Innovation Hubs that can play an important role in the uptake of AI technologies in healthcare, by building models of integration in healthcare organisations, addressing their services, organisational arrangements and workflows as well as contributing best practices regarding accessing testing and reference facilities, AI standards, development of AI expertise, and partnership support; which could then be consolidated and refined at EU level to develop a set of guardrails for AI innovation.
- **Skills.** Digitisation places demands on healthcare professionals (HCPs) 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. Promoting professional education and training towards digital literacy for healthcare professionals should be an integral part of the policy agenda, considering both university education and lifelong learning programmes. 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. This investment in enhancing the digital skills of HCPs, could be done through pre-certification of medical societies and advancement of the AI curricula for HCPs and hospital managers.

## 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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