

MedTech Europe Statement on the European Strategy for Data

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MedTech Europe welcomes the European strategy for data with its compelling vision to improve and expand access to data and to drive innovation in advanced analysis and artificial intelligence for the benefit of the European citizens and the economy. In the health sector, the data strategy and the European Health Data Space initiative will add momentum and resources to the efforts to digitally transform Europe's health systems and enable secondary use of health data, building on:

- Public healthcare systems that aspire to deliver universal access for all and enjoy the trust and support of their citizens;
- Electronic health records delivered by these same health systems that ensure citizen access and control of their personal health data;
- The European eHealth Digital Service Infrastructure (eHDSI or MyHealth@EU initiative) connecting national and regional health services and their EHR systems;
- The cooperation of European Commission, Member States and relevant stakeholders to build the most suitable model and framework for the governance of the European Health Data Space; and
- A harmonised European legal framework for data protection, data sharing and health data processing for research purposes.

These elements serve as pillars of a health data framework that not only utilises citizens' and patients' data to make healthcare better, safer and more efficient, but also unleashes the power of health data to be used beyond the purpose for which it was originally collected: to enable advanced digital and remote healthcare services and monitoring of systems performance; to advance research and innovation; to further transparency on quality, outcomes and cost-effectiveness, and to power public health monitoring and tracking of epidemics, personalised medicine and task automation/artificial intelligence.

MedTech Europe **welcomes the actions** foreseen in the EU data strategy, especially:

- The alignment of Member States' treatment of health data through a Code of Conduct, and the work on health data governance mechanisms for data sharing and artificial intelligence;
- Investments under EU funding programmes and support for further deployment of national electronic health record systems, data infrastructures, computing capacity; and
- The promotion of interoperability of health data through the further development of the Electronic Health Record Exchange Format and other initiatives to advance the FAIRification of data.

MedTech Europe has participated in the consultation for the European Strategy for Data and has offered specific feedback on the questions posed. In addition, we would like to make the following **recommendations**:

- *Access to data:* In the healthcare sector, the right to access and control individual data needs to be balanced against the responsibility of healthcare professionals and manufacturers of medical devices to deliver safe and high-quality care.
- *Legal clarity:* 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, (2) access to data to support regulatory obligations of such companies (e.g. under the Medical Device Regulation and In Vitro Diagnostics Regulation), (3) harmonised guidelines/standards or technical specifications on anonymisation of health data, (4) the exceptions for public interest and preventive/occupational medicine.
- *Interoperability:* We are seeing increasingly national healthcare systems requiring developers of medical technology solutions to deliver data along certain specifications¹. There is a risk of fragmentation. The EU could take a coordinating role to avoid multiple and inconsistent national recommendations or strategies to fully accomplish the potential of data and AI. In this regard, we urge the European Commission to further develop the European EHR Exchange Format recommendation to cover specifications for data from medical/IVD devices and services.
- *Awareness and skills:* In the debate about health data, positive messages and resources about their benefits for healthcare delivery and research are often absent. The EC should support efforts to advance trust and educate patients and citizen about the benefits that data and AI can bring to their lives and health. In addition, citizens and patients need to be equipped with the necessary digital literacy and skills.

MedTech Europe looks forward to working with the European Commission and all stakeholders to advance the health data revolution in Europe's systems for health and care.

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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¹ Most recently such specifications were included in the German government's *Digitale-Gesundheitsanwendungen-Verordnung (DiGAV)* and the April 2020 *Leitfaden für Hersteller, Leistungserbringer und Anwender*, available at [www.bfarm.de/DE/Medizinprodukte/DVG/ node.html](http://www.bfarm.de/DE/Medizinprodukte/DVG/node.html).