Unlocking the full benefits of health data

Recommendations from MedTech Europe

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MedTech Europe
from diagnosis to cure

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Executive Summary

Digital health makes healthcare better, safer, and more efficient, and advances the delivery of high-quality care. For digital health to reach its full potential, we need to unlock the benefits of health data.

Health data enables new ways of personal management of one's health and lifestyle. It can be integrated across a variety of platforms to enable better clinical care practice and decision making. Combining health data from different sources in an appropriate manner can empower people with information and deliver more robust evidence for the efficacy of treatments. Intelligent automation and artificial intelligence can improve access to care and assist healthcare professionals with routine or repetitive tasks. Data-driven research and innovation can deliver benefits across the care spectrum, from diagnosis to cure. In short, health data brings enormous benefits for people, healthcare professionals, and healthcare systems.

Medical technology companies need to process health data, both when developing new technologies and as part of their roll-out to healthcare systems. However, regulatory and legal challenges continue to limit access to health data by medical technology companies to develop new solutions for treating patients and advance personalised medicine and treatments. There is a need for clear rules under which the medical technology industry can collect, process, and share health data. The varied implementation and interpretation of the General Data Protection Regulation (GDPR) by national and local authorities create considerable legal uncertainties for industry, resulting in barriers to health data use.

MedTech Europe calls on European and national policymakers to make rules regarding health data use more consistent, with a specific focus on:

- rules for processing health data by medical technology companies for healthcare delivery and research and innovation;
- the legal basis for processing health data under the GDPR, and the interplay between the GDPR and the Medical Devices and In-Vitro Diagnostics Regulations;
- harmonised guidelines on anonymisation and pseudonymisation;
- exceptions for public interest and preventive medicine, in particular with regards to research conducted by medical technology companies;
- transfers of health data within and outside the European Economic Area.

The EU should take on a coordinating role to realise the full potential of health data. Aligning inconsistent national strategies through an EU-wide governance framework will enable the harnessing of health data in a resource- and cost-effective way.

The European Health Data Space has the potential to provide such a framework and be a major driver towards better access to, sharing, and use of health data. It should address the legal and regulatory barriers discussed in this paper, establish a robust and stable data governance framework based on European values, and appropriately balance the need for protection of personal data with innovation. In doing so, it will boost the competitiveness of the European medical technology industry and establish Europe as the premier location for healthcare research and development for the benefit of European citizens.

1. Introduction

Health data enables new ways of personal health and lifestyle management. It can be integrated across various platforms to allow for better clinical care practice and decision making. Intelligent automation and artificial intelligence powered by health data can improve access to care and assist healthcare professionals (HCPs) with routine or repetitive tasks, thus helping to relieve the burden on our healthcare systems. Data-driven research and innovation (R&I) can improve diagnostics and treatments, help with detection and understanding of diseases, and develop new treatments. In short, health data brings enormous benefits for people, HCPs, and health systems.[1]

The medical technology industry is at the heart of the health data ecosystem**,** providing data that meet the highest standards of validity, accuracy, and veracity, all by complying with strict regulatory requirements. This trust in the quality and accuracy of health data is a critical enabler for the digital transformation of healthcare.

The pace of the digital transformation and innovation in the development of new treatments is highly dependent on the medical technology industry's ability to successfully access, aggregate and appropriately use health data. To fully unlock health data's potential, regulatory and legal challenges need to be addressed. The European Health Data Space (EHDS), a European Commission initiative to harness the potential of health data to promote health care delivery and support research, should address these challenges and advance investment, infrastructures, interoperability and the building of trust and skills. MedTech Europe supports the EHDS and the building of a European health data ecosystem.

By processing and managing health data, the medical technology industry delivers benefits for people, HCPs, and healthcare systems, as the examples in section 2 show. Section 3 discusses the barriers that prevent data access and sharing for the medical technology industry and presents key recommendations for a governance framework that can unlock the benefits of health data. The conclusion considers the potential of the EHDS to address these barriers. MedTech Europe encourages the consideration of these points as we build the foundations of a European health data ecosystem.

2. The medical technology industry and health data

Health data allows access to meaningful insights. Physiological or diagnostic information can be made available to HCPs, patients, and their carers. Data can be collected, aggregated, and analysed for public health purposes or to power advanced analytics, as the following examples show.

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[1] For this paper we follow the provisions of the General Data Protection Regulation (GDPR), Art. 4 (15): 'data concerning health' means personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status".

Patient self-management and empowerment

Connected medical devices are increasingly used in the treatment of a variety of chronic diseases such as sleep apnoea, asthma, and chronic obstructive pulmonary disease. Access to accurate and timely health data allows individuals to manage chronic conditions like congestive heart failure or diabetes and enables them to connect factors such as weather, food intake, or physical activity to effects on their health. This empowers people to become agents of their own health, for example, by monitoring and benchmarking their outcomes or adapting their habits and lifestyle. Connected medical devices can also improve patients' adherence, reduce deteriorations, and decrease the overall burden on healthcare systems as doctors and hospitals only need to intervene in times of crisis. Access to data thus improves healthcare and adds to patients' knowledge, independence, control, and quality of life.

Remote patient monitoring

Data from medical devices, if shared with designated family members, carers, or healthcare providers through appropriate Information Technology Systems (with safeguards for

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Enhanced self-management of diabetes

Advancements in medical technologies have simplified the way in which we monitor and control the condition for people with Type 1 and Type 2 Diabetes, replacing routine blood sampling with an electronic sensor. Inserted under the skin, either on the abdomen or arm, the **sensor continuously monitors the patient's glucose level.**

With the help of medical technologies such as Continuous Glucose Monitoring (CGM) systems, people with diabetes can monitor their data, discover patterns and trends, and understand better the relation between their behaviour and their condition. Continuous data access is critical to management of the condition, promoting positive behaviour changes and improving outcomes.

People with diabetes who depend on insulin to regulate their blood glucose levels must constantly make calculations when to inject insulin and how much. Smart pens can assist with these calculations, while completely automated insulin delivery systems connect a CGM/glucose monitor with an insulin pump via an advanced algorithm to deliver appropriate insulin doses at the appropriate time, reducing the potential for error and improving quality of life.

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cybersecurity and data protection), can also be used to enable remote patient monitoring (sometimes also called telemonitoring), which facilitate monitoring and treatment delivery to patients outside the hospital settings. They rely on connected devices that collect data on physiological parameters, treatment delivery and patient use. Employed for example for monitoring chronic conditions such as diabetes, rheumatic, respiratory and autoimmune diseases, as post-surgery care or in remote settings, they transmit data to a digital platform where it is aggregated, processed, and synthesised.

Using remote patient monitoring, clinicians and providers can monitor and modify the therapy without the need for in-person consultations. Healthcare teams can quickly identify those individuals who are experiencing problems and require further intervention. Follow-up is then focused on patients in need while reducing unnecessary out-patient appointments. This frees up room for new patient set-ups.[2] Additionally,

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[2] PwC report 'Effects of telemonitoring on treatment of sleep-disordered breathing': Wrightington, Wigan and Leigh NHS Foundation Trust Hospital, p 30-31; October 2015, access here.

remote monitoring helps patients understand how a treatment protocol works and supports customisation and personalisation. It has shown to increase patient satisfaction while boosting the quality of care, allowing patients to feel constantly supported. Studies have shown that remote monitoring also improves adherence to treatment protocols.[3]

Monitoring device performance

Performance monitoring of medical and in-vitro diagnostic devices by near real-time transfers of data is required under the new Medical Device Regulation (MDR)[4] and the In-Vitro Diagnostic Medical Device Regulation (IVDR)[5]. During their entire life cycle, devices need to be checked whether they remain safe and effective. They can also signal when they require maintenance or replacement. Thus, risks are evaluated and contained in an efficient and timely manner.

> ### Cardiac Implantable Devices
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> Cardiac Implantable Electronic Devices (CIEDs) are used to monitor and manage cardiac arrhythmias. These devices are surgically implanted into patients and only require replacement after a few years. They improve patients' health and quality of life.
>
> The CIED delivers a patient's cardiac signals wirelessly; data can be downloaded to smart devices such as the patient's smartphone. Novel algorithms applied to the data allow to **identify a patient's conditions that previously went undetected** or could only be identified by specific tests. Data also helps **analyse the stability of the patient's condition, identify potential issues and to support customisation of care pathways**. This has greatly expanded diagnostic capabilities and reduced the costs of diagnosis, thanks to data analytics.

Aggregated data produced during the monitoring of a device's performance can also be used to evaluate outcomes, detect means to improve the medical device, identify new opportunities for innovation stemming from its use in non-clinical conditions, as well as assess its efficacy and cost-effectiveness to assess its real value. The ability to provide unambiguous evidence of value is essential for governments to determine the real value of devices to make efficient budget decisions. An improved and simplified access process for data sharing is required to enable the use of datasets for the abovementioned purposes.

Data analytics

Digital health technologies not only allow for the monitoring of vital parameters and diseases but can also be integrated with broader datasets to deliver more insights into how environments, behaviours and diseases are connected. Patient generated data outside of the clinical setting or data from trusted sources such as public environmental agencies can be combined with health data to alert patients of circumstances which

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[3] Sohn A, Speier W, Lan E, Aoki K, Fonarow GC, Ong MK, et al. (2020) "Integrating remote monitoring into heart failure patients' care regimen: A pilot study". PLoS ONE 15(11): e0242210, access here.

[4] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, access here.

[5] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, access here.

may negatively affect their well-being.[6] This could include, for example, activity levels, nutrition, or weather conditions. The integration of individual health data points with contextual information also enables better insights into a patient's health history and predicts future issues or co-morbidities.

Applying data analytics or artificial intelligence/machine learning (AI/ML) technologies can identify clusters of patients with similar characteristics, which can lead to new insights, changes in treatment or adapted patient behaviours. Comparable opportunities are available at a population level: the COVID-19 pandemic has illustrated how large-scale datasets enable HCPs to recognise patterns within populations and determine better treatment much faster.

Data analytics, computing modelling & simulation, and AI/ML will play a pivotal role to realise better outcomes and healthcare systems.[7] To grasp the diversity of physiology, genetics, biochemistry, etc. within populations, access to large scale datasets are a critical requirement. Fusing relevant datasets together and analysing them with state-of-the-art Information and Communications Technology solutions will help increase HCPs' understanding of patients' conditions and likely trajectory. It helps to paint a fuller picture of the persons' overall health status, and to potentially identify other factors that influence their condition.

Medical technology and prediction/prevention

Modern hospital beds feature embedded technologies that continuously **monitor patients' vital signs**. While monitoring improves care of the patient, combining the data with other data sources and AI-enabled technology within the hospital environment enables **new predictive care capabilities**, **such as identifying patients at risk of developing life-threatening conditions** or warn anaesthesiologists during surgery if a **drop in blood pressure is imminent.** They can then trigger timely intervention by hospital staff to **prevent progression or deterioration**. Access to data is key to improving these technologies.

For patients with advanced chronic respiratory conditions, data can even be analysed to **detect early deterioration of the patient condition**, enabling HCPs to drive appropriate intervention that could **prevent more severe progression**. Data can also **help patients understand how their condition is changing** and recognise how their behaviours are influencing their condition.

Medical alert systems with integrated activity monitors help elderly people stay independent while ensuring fast attention in case of need. Recording and analysing patterns of movement allows AI/ML systems to detect and predict falls or other deteriorations with high levels of accuracy, and thus help to prevent them, maintain quality of life, and avoid cost for emergency interventions and treatments.

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[6] The EU introduced the concept of high value datasets from public agencies and their easier availability in the proposed Open Data Directive (2019), access here.

[7] The substantial benefits of AI in healthcare, in terms of saved lives and efficiencies gained were detailed in the Deloitte/MedTech Europe report *The socio-economic impact of AI in healthcare* (October 2020), available at the MedTech Europe website.

Towards data-driven healthcare

Digitalisation is critical to realising compelling and actionable insights from health data. It helps to standardise procedures, improve consistency, and reduce error. It also enables the monitoring and comparing of performance and makes the practice of healthcare more evidence-based and transparent. It helps reduce operational costs by optimising clinical pathways. In the future, diagnosis timelines will be improved through faster data analysis and improved data access.

Device connectivity and real-time data access contribute to accelerated medical interventions. This can be particularly important for certain situations, such as cardiac monitoring or post-operative care scenarios where a time-critical response from HCPs may be necessary. Data fusion also has more routine applications, such as in managing respiratory conditions when prevailing environmental factors such as particulate levels in the air may negatively influence a patient's condition[8].

Digital surgery

Digital surgery represents the convergence of surgical procedures with information and communications technologies, robotics, intelligence, and data to **improve surgical precision, performance, and patient outcomes**.

Digitalising procedures enables the generation of data at each step of the surgical procedure. The physician still executes the procedure, but there is a digital overlay which provides input to the physician during the process. The data can be used to document how surgeons make decisions, to benchmark team performance in hospitals, to flag procedural innovations, and to develop best practices that can train other surgeons.

Data-driven insights and learnings provide an **objective and quantifiable approach** that replaces a more subjective, opinion-driven interpretation of performance. Ultimately, by reducing variability in the operating room, patients will benefit from consistent care.

Summary

In sum, digitalisation and the generation and processing of health data combined with other data sources (e.g., data from the patient journey, including nutrition, environment, or genomics) offer substantial opportunities to advance healthcare and make it better, safer, more efficient and, thus, more sustainable. Every day, data from medical devices enables better care for patients by supporting effective treatments, enhancing diagnostics, facilitating remote patient monitoring, and enabling personalised care, which in turn leads to a better quality of life. It also makes healthcare greener, by avoiding routine doctor visits, by preventing hospitalisations, and by moving data instead of people. The secondary use of health data for Research & Innovation (R&I) may lead to yet unthinkable insights and solutions in medical science and benefits for humankind.

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[8] Anderson, J.O., Thundiyil, J.G. & Stolbach, A. Clearing the Air: A Review of the Effects of Particulate Matter Air Pollution on Human Health. J. Med. Toxicol. 8, 166–175 (2012), access here.

3. Addressing legal barriers to effective data-driven healthcare

Many opportunities that can be derived from sharing and using health data are constrained by legal barriers. Aggregating health data from different sources and across regional or national borders is often difficult in practice. Making the digital health transformation a European reality requires addressing these barriers.

There is a need for legal certainty regarding the rules under which the medical technology industry can collect, process, and share health data. The GDPR plays a critical role in protecting the interests of individuals over their data and establishing rules for the processing of personal data (including health data).[9] However, the implementation and interpretation of the Regulation, including its inconsistent application across the EU Member States, create considerable uncertainties which result in barriers to health data use and additional compliance costs.[10]

Medical technology companies face difficulties in accessing and sharing data for secondary use purposes. For example, when they provide services to HCPs or hospitals, they may act as processors of personal data. In this scenario, the companies may not be able to use the personal data for R&I purposes, as it is unclear to what extent the GDPR allows access for such use. Similarly, medical technology companies are required to engage in pre- and post-market clinical investigations and studies, which require the collection and processing of sensitive data, access to which is not ensured.

Additionally, medical technology companies have specific obligations regarding vigilance and safety reporting. The MDR and the IVDR impose post-market surveillance obligations on medical technology companies. Both regulations demand better data collection and more use of data analytics (i.e., descriptive, diagnostics, predictive and prescriptive analytics) and data science (e.g., AI/ML with data processing capabilities). GDPR requirements are not always in tune with these MDR and IVDR expectations, and it is unclear to what extent MDR and IVDR can serve as a stand-alone legal basis under art. 9, 2, i) and j) of GDPR, for the processing of health data by medical technology manufacturers.[11] There is a need for consistency and further clarification of, on the one hand, the interplay of the GDPR with the MDR and IVDR, and on the other, how medical technology companies can use the regulations as a legal basis to process personal data under the GDPR, to the advantage of citizens, patients, and the healthcare system.

Due to this, MedTech Europe is calling on European and national policymakers to act. Clarification and more consistent application of the GDPR across Europe is urgently needed, especially on the following issues:

- The **rules on processing health data** for healthcare delivery (primary use) and for research and innovation purposes (secondary use) for the medical technology industry; not only with a focus on

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[9] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), access here.

[10] The February 2021 report *Assessment of the EU Member States' rules on health data in the light of GDPR* showed how unevenly Member States apply the GDPR, access here.

[11] The GDPR prohibits processing of personal data unless certain conditions apply, for example "processing is necessary for reasons of public interest in the area of public health" (GDPR article 9,2,i) or "processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes" (GDPR article 9,2,j).

existing medical technologies but also for the development of new ones based on existing data that currently cannot be used.

- The **legal basis for processing health data** under the GDPR, both regarding the extent the MDR and IVDR can serve as a stand-alone legal basis (see art. 9 (2) (j)) potentially complemented by appropriate harmonised guidelines, and regarding the misapprehension of many stakeholders of the difference between informed consent to participate in a clinical study and consent as one of (multiple) legal bases available under the GDPR.
- **Anonymisation and pseudonymisation,** where clear guidance in the form of harmonised guidelines, standards, or technical specifications is needed, for example, regarding the requirements for the appropriate level of data minimisation or obfuscation that preserves privacy while also retaining the usefulness of the data for analytic purposes.
- The **exceptions for public interest and preventive medicine,** in particular, with regards to research conducted by medical technology companies;
- **Transfers of health data**, in particular for research purposes within and outside the European Economic Area.[12]

The European Health Data Space presents an opportunity to build a clear legal framework for medical technology industry data use. Data access for industry should be carefully aligned to a clearly defined description of permissible and non-permissible data uses. Clear rules and guidelines would define the responsibilities and obligations of all stakeholders. There should be a common understanding of the interplay between the MDR and IVDR and the GDPR, as well as a common approach on how the medical technology industry is allowed to access and use health data for specific purposes (e.g. R&I) for the joint benefit of patients, HCPs and healthcare systems. In paving the way for data sharing, the legal framework should respect intellectual property and competition law: companies accessing health data should not be required to disclose the purposes of their research project in a way that would reveal business-sensitive or IP-protected information to their competitors.

Ideally, this legal framework would involve a collaboration of the medical technology industry, national and European authorities, and all relevant stakeholders, including healthcare providers, with the objective of a fair and consistent application of laws and regulations, including business suitable and secure cross-border data access flows and sharing. With appropriate mechanisms for compliance and data security, this legal framework should inspire public confidence and trust by reassuring citizens, patients, and HCPs that personal health data is only used for appropriate and legitimate purposes.

MedTech Europe calls on the EU to take on a coordinating role to realise the full potential of health data. Aligning inconsistent national strategies through an EU-wide governance framework will enable the harnessing of health data in a resource- and cost-effective way.

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[12] Consider *Innovation Without Borders: The Importance of Transatlantic Data Flows to Healthcare Innovation and Delivery,* Discussion paper by MedTech Europe, IPMPC, EFPIA and Advamed, December 2020), access here.

4. Conclusion

The European Health Data Space (EHDS), has the potential to be a major driver towards better access to, sharing and use of health data.[13] It has generated renewed interest in the potential of health data and there is a growing consensus that health data requires special consideration. While personal health data requires strict protection and security and should be subject to individual control, aggregated and anonymised health data is a powerful resource with enormous potential, and should in fact be considered a public social good. Recent European multistakeholder initiatives have resulted in calls for appropriate data governance that strikes a new balance between the needs of the individual and the benefits of health data use for society. There is a significant cost of not sharing health data.[14]

The EHDS offers a considerable opportunity to build a health data ecosystem. The EU is pursuing a comprehensive strategy that addresses several issues, including investment in infrastructure and security, momentum towards standards and interoperability, and initiatives towards building digital literacy, trust, and skills. At the heart of this strategy is legislation that will need to build a robust and consistent legal basis for the exchange of health data among the EU Member States and compliant Third Countries, including better alignment of the Member States' implementation of the GDPR.

The EHDS will give new impetus to health data use and could be a gamechanger for Europe's healthcare systems. If it addresses the barriers discussed in this paper and establishes a stable data governance framework based on European values that appropriately balance data protection with innovation, it will boost the competitiveness of the European medical technology industry and establish Europe as the premier location for healthcare research and development.

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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[13] MedTech Europe Response to the Inception Impact Assessment on the European Health Data Space (3 February 2021), access here.

[14] See for example the *Calls to Action On Health Data Ecosystems – Recommendations From Multi-Stakeholder Round Tables (February 2021) from the Digital Health Society and the European Institute for Innovation Through Health Data (I~HD)*, available online, or the forthcoming recommendations from the Digital Health Europe project (https://digitalhealtheurope.eu/). More information about Data Saves Lives is available at https://datasaveslives.eu/.

List of acronyms

AI	Artificial Intelligence
CIED	Cardiac Implantable Electronic Device
CGM	Continuous Glucose Monitoring
EHDS	European Health Data Space
GDPR	General Data Protection Regulation
HCPs	Healthcare Professionals
IP	Intellectual Property
IVDR	In-vitro Diagnostic Device Regulation
MDR	Medical Device Regulation
ML	Machine Learning
R&I	Research and Innovation