MedTech Europe's call to action for an interoperable data ecosystem for digital health

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Executive Summary: This paper reflects the medical technology ("medtech") industry's view on one of the most persistent barriers to the deployment of digital health technologies services: their lack of interoperability. The paper places the need for interoperability in a wider context of digital health fragmentation, notes the opportunity in European publicly funded healthcare systems to address the issue, and calls major stakeholders to take action to advance an interoperable ecosystem for digital health in Europe. The proposed actions include:

- **Leadership:** Governments and healthcare authorities to develop guidance, recommendations and mandates (in the form of digital health strategies, action plans, or other indicative statements) that raise awareness about the benefits of interoperable data ecosystems, and advance these ecosystems on the regional, national and European level.
- **Procurement**: In accordance with these digital health strategies and their technical specifications, payers and providers to adopt common standards and mandate adherence to these in their procurements to ensure digital health interoperability. The demands from payers and procurers will ultimately affect the supply side of the digital health market.
- **Investment**: The European Commission (EC) and Member States to further promote the building of digital health infrastructures and solutions, and make financial support contingent on adherence to the specifications outlined in the EHR exchange format, and on collaboration with standards organisations like DICOM (Digital Imaging and Communications in Medicine), HL7 (Health Level 7), IHE (Integrating the Healthcare Enterprise), and others.
- **Other industries**: Other industries adjacent to the healthcare sector, including the consumer devices industry for lifestyle and fitness products, the large IT companies, and the social media giants, to embrace an interoperable data ecosystem and open, international standards, and make data available to the healthcare sector.

MedTech Europe is committed to supporting the digital transformation of health and care, and to making a positive contribution to a more interoperable digital health ecosystem where data flows, systems communicate, and information empowers citizens, patients and carers, and healthcare professionals.

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Our vision

An **open and interoperable digital health ecosystem** where health data and information flow freely and securely between and across platforms and systems from different vendors and across borders; an ecosystem to inform and empower citizens and patients, healthcare professionals and providers, payers and authorities, science and research; an ecosystem, in full compliance with applicable privacy and data protection principles, with the ultimate goal to transform the provision of health services towards better access, safer services, and integrated, patient-centred, care.

The promise of digital health and the role of medtech

There is widespread agreement that digital health technologies and services have the potential to make our health and care systems safer, better and more efficient. Readily available data and information can reduce medical errors, support care coordination and workflow, and assist healthcare professionals in diagnostic and treatment decisions. Connected devices and sensors can empower citizens and patients with information and enable remote monitoring and self-management of chronic conditions or prevent them in the first place. Sharing of health information among patients, carers, and health professionals enables integrated, patient-centred care. Finally, the aggregation and analysis of health data, in combination with real world data (environment, transport, welfare etc.), paired with artificial intelligence, can advance personalised care, precision medicine, public health, and science. In short, digital health may transform our health systems, and make them more sustainable.

The medtech industry is a critical enabler of digital health. It makes the advanced connected medical and in vitro diagnostic devices and technologies that deliver health data with clinical accuracy and veracity, as well as state of the art safety and security, on which patients, providers and researchers rely.

Yet, despite the rapidly evolving and expanding field of digital health innovations and a growing body of evidence that data and digital solutions can transform healthcare, digital health models are not being widely adopted. There is an emerging consensus that lack of interoperability is a major factor holding back investment in, and deployment of, digital health.[1]

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[1] MedTech Europe accepts the MDR's definition of interoperability: "'interoperability' is the ability of two or more devices, including software, from the same manufacturer or from different manufacturers, to:
(a) exchange information and use the information that has been exchanged for the correct execution of a specified function without changing the content of the data, and/or
(b) communicate with each other, and/or
(c) work together as intended."

In its December 2017 conclusions the European Council - the body of the governments of the 28 EU Member States - noted:

> "Barriers to scaling up the potential in digital health and connected care, such as dominance of data silos, lack of interoperability and of common standards for measuring clinical and patient reported outcomes, limited access and use of large databases for research and innovation purposes, lack of funding and financial incentives, fragmented markets across the EU and across the spectrum of services, still exist and progress in implementing the data-driven digital solutions in the health sector remains limited."[2]

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Overcoming fragmentation towards integrated, patient-centred care

The vision of digital health, of patient data and information being made available at the point of care, is compelling. The reality, on the other hand, is often marked by fragmentation and "data silos". The European Commission and a group of stakeholders in the European Innovation Partnership for Active and Healthy Ageing (EIP AHA) noted in their *Blueprint - Digital Transformation of Health and Care for the Ageing Society* in 2016:

> "Lack of interoperability is both a reason for and a result of market fragmentation. It perpetuates market fragmentation and creates significant barriers to entry, especially for innovators and SMEs. Better coordination of care requires open platforms and widely adopted standards on which each player can contribute and innovations can thrive."[3]

In Europe, where healthcare is often considered a public good and individual right, and where public healthcare systems funded through taxes or social charges deliver at least basic and often advanced services, this fragmentation has been addressed in recent years:

- The General Data Protection Regulation of May 2016 has enshrined harmonised principles of individual control over personal data and the importance of patient consent;
- Through countless EU projects and processes like the EIP AHA, policymakers in the European Commission and relevant stakeholders have routinely affirmed their commitment to a vision of integrated, patient-centred care (including in the aforementioned *Blueprint*);

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[2] *Council conclusions on Health in the Digital Society — making progress in data-driven innovation in the field of health,* (2017/C 440/05).

[3] *Blueprint - Digital Transformation of Health and Care for the Ageing Society. Strategic Vision Developed by EIP AHA Stakeholders*, December 2016, http://ec.europa.eu/newsroom/document.cfm?doc_id=40787 (accessed on 28 February 2019)

- Patients and citizens, who are funding healthcare systems with their taxes and contributions, are demanding better access to their own health data and the option to share their own data with healthcare professionals;[4]
- Regional and national health authorities are building electronic health record (EHR) systems, patient platforms, and other technical infrastructures to receive and hold patient health data (at divergent speeds);
- the European Commission has facilitated the cross-border exchange of health data, and in February 2019 issued, in collaboration with the eHealth Network, the *EHR Exchange Format* with recommended technical specifications based on open, international standards.[5]

Patients, stakeholders and policymakers share a commitment to patient-centred care and to treating patients' health data in full compliance with applicable data protection laws. This commitment, together with the strong role of healthcare authorities and the public sector in healthcare delivery, offers an opportunity for overcoming the digital health fragmentation in Europe.

MedTech Europe's commitment and call to action

MedTech Europe shares the commitment to integrated, patient-centred care, and supports the vision of an interoperable data ecosystem. MedTech Europe welcomes the European Commission's EHR Exchange Format and its technical recommendations. This approach – along with the build-up of the eHealth Digital Services Infrastructure (eHDSI) – will guide the formulation and implementation of national and regional digital health strategies. The format will also guide the technical frameworks for data architectures, and eventually (with mandates for adherence to standards) purchasing and procurement decisions from healthcare authorities and providers. MedTech Europe is committed to advancing digital health interoperability and to helping accelerate the change.

The field needs a concerted effort. To enable the digital transformation of health care, we invite policymakers and all stakeholders to engage and contribute to an interoperable data ecosystem through:

- **Leadership:** Governments and healthcare authorities to develop guidance, recommendations and mandates (in the form of digital health strategies, action plans, or other indicative statements) that raise awareness about the benefits of interoperable data ecosystems, and advance these ecosystems on the regional, national and European level.

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[4] This observations is born out by presentations and conversations with patient advocates, and amplified in relevant stakeholder documents, for example (1) European Health Parliament, *The Recommendations by the Next Generation* 2 April 2019, see https://www.healthparliament.eu/ehp4-policy-recommendations/; or (2) EU Health Summit *Shared vision for health,* 29 November 2018, see https://www.euhealthsummit.eu.

[5] See http://europa.eu/rapid/press-release_IP-19-842_en.htm. Referenced standards in the EHR Exchange Format include:
Health Level Seven International (HL7) CDA release 2,
Digital Imaging and Communications in Medicine (DICOM)
profiles and methods of Integrating the Healthcare Enterprise (IHE).
For future work the EC references HL7 FHIR and distributed ledger technologies (ie, blockchain).
See https://ec.europa.eu/newsroom/dae/document.cfm?doc_id=57254

- **Procurement**: In accordance with these digital health strategies and their technical specifications, payers and providers to adopt common standards and mandate adherence to these in their procurements to ensure digital health interoperability. The demands from payers and procurers will ultimately affect the supply side of the digital health market.
- **Investment**: The European Commission (EC) and Member States to further promote the building of digital health infrastructures and solutions, and make financial support contingent on adherence to the specifications outlined in the EHR exchange format, and on collaboration with standards organisations like DICOM (Digital Imaging and Communications in Medicine), HL7 (Health Level 7), IHE (Integrating the Healthcare Enterprise), and others.
- **Other industries**: Other industries adjacent to the healthcare sector, including the consumer devices industry for lifestyle and fitness products, the large IT companies, and the social media giants, to embrace an interoperable data ecosystem and open, international standards, and make data available to the healthcare sector.

On a wider note, the shared commitment to an interoperable data ecosystem will unlock considerable public investment in the digital health infrastructure that is often underdeveloped. Digital health offers an opportunity for more procurers to adopt a value-based healthcare approach that sees the industry not as the deliverer of equipment, but as a trusted partner to co-develop and co-create advanced products and services for the benefit of patients.

This interoperable health data ecosystem will create a level playing field that offers considerable opportunities especially for small and medium size enterprises to offer specialised products and services on the basis of common platforms. It will contribute to the competitiveness of European industry, and advance the Digital Single Market.

Benefits for all

It will be healthcare authorities and payers that will be among the biggest beneficiaries of an interoperable digital health ecosystem. As trustees of patients' and citizens' data, they will be regulating access according to patients' preferences and striking the balance between individual and societal needs. Healthcare systems will be able to collect and aggregate data from a wide variety of sources and process it with the help of advanced IT analytics, AI and machine learning to spot trends and patterns to inform critical policy decisions.

Finally, the ultimate beneficiary of the digital health ecosystem will be citizens and patients who will interact with healthcare professionals through timely communication channels, including advanced telehealth services and remote monitoring; who gain quality of life by spending more time outside hospitals and doctors' offices; who will benefit from advanced data and genome analytics to obtain insight into individual risk factors and have a chance to adapt their lifestyle; and who will continue to enjoy advanced healthcare services at sustainable costs. In the end, the benefits go to society as a whole.

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.

For more information, visit www.medtecheurope.org.