MedTech Europe
from diagnosis to cure

MedTech Monthly

March 2025

Dear readers,

This week marks a turning point for digital health in Europe. With the publication of the European Health Data Space (EHDS) in the official journal of the EU, we are taking a big step toward a future where health data works for people, empowering patients, supporting innovation, and improving care across borders.

But what does this mean for patients? Imagine a person living with a chronic condition who, thanks to EHDS, can securely access and share their medical records across borders, receiving timely and personalised treatment wherever they are in Europe. Or a researcher leveraging electronic health data to drive breakthroughs in rare disease treatments. The impact of EHDS will be felt in real lives, in meaningful ways.

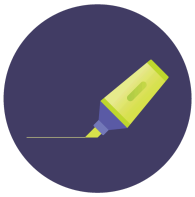
For EHDS to truly deliver on its promise, we must get the implementation right. That means harmonised rules, clear governance, and strong collaboration between all health stakeholders. Trust and efficiency are key to making this work for everyone.

At MedTech Europe, we are committed to making this vision a reality. We have joined forces with partners across the health sector to share recommendations on EHDS governance, ensuring it is built to last. Supporting knowledge exchange, investing in digital skills, and securing sustainable funding will also be crucial for success.

Bringing EHDS to life will take a collective effort, from policymakers to patients, healthcare professionals to industry. Collaboration across the health community will be crucial to building a seamless, trusted, and innovative digital health ecosystem that benefits all of Europe.

Best regards,

- Miriam D'Ambrosio, Senior Manager Communications



Highlights of the month

Health stakeholders advocate for enhanced collaboration in European Health Data Space implementation

Verena Thaler
Manager Data Governance

READ THE FULL RECOMMENDATIONS HERE

On 5 March 2025, a coalition of 39 European health leaders has published a joint statement welcoming the publication of the European Health Data Space (EHDS) regulation in the EU's Official Journal, underscoring the need to promptly establish an inclusive, well-resourced Stakeholder Forum to ensure the effective implementation of the EHDS.

The Stakeholder Forum is envisioned as the cornerstone of the effort to successfully implement the EHDS, providing a platform for diverse voices to engage in meaningful dialogue. An inclusive, collaborative approach involving citizens, healthcare professionals, researchers, providers, payers, industry, and patient representatives will build trust and support the EHDS adoption. The coalition is calling for early and sustained investment in the Forum's operations, including measures to promote inclusivity, transparency, and actionable contributions.

Key recommendations include setting up the Stakeholder Forum, investing in capacity building and funding, and promoting transparency in the EHDS Board.

Clean Industrial Deal – what's in it for the medical technology sector?

Sigrid Linher
Director Sustainability & Environment

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On 26 February 2025, the European Commission presented its first 100-days initiative, the Clean Industrial Deal together with an Action Plan Affordable Energy and the first Simplification Omnibuses on Sustainability and Investment.

Key aspects of the deal tie in well with MedTech Europe's recommendations, i.e., on accelerating and scaling access to affordable, clean energy as key decarbonisation lever also in the medical technology sector or the potentials of the circular economy, a reinforced Single Market and the role of thinking beyond price in public procurement. More is needed to tap into the potential of a competitive, clean-tech European medical technology industry as a driver of future prosperity and sustainable growth.

Blogs & podcasts

A rare disease diagnosis and a new baby

Can Europe unlock the power of data while protecting privacy?

At 40 weeks pregnant, Lisa Godden was told that her baby bump was significantly smaller than it should be. Nobody imagined that this could be due to a rare and potentially life-threatening heart condition called peripartum cardiomyopathy (PPCM).

READ LISA'S STORY

Renate van Kempen, Data Anonymization Expert & Data Scientist, shares her views on key points such as, data-driven insights, striking a balance, and implementing a robust framework.

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In short

Joint reflection paper on EU full participation in Medical Device Single Audit Program

Dario Belluomini, Manager International Affairs

On 17 February 2025, MedTech Europe and COCIR published a joint reflection paper calling for the European Union's full participation in the Medical Device Single Audit Program (MDSAP) and enabling the recognition of MDSAP certificates for the purpose of CE marking medical devices and in vitro diagnostic medical devices.

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Urgent call for clarity on clinical strategy discussions

Jana Russo, Manager Medical Devices

MedTech Europe, European Self-Care Industry Association (AESGP), MedTech & Pharma Platform and COCIR express their concerns that the recently updated MDCG 2019-6 Requirements relating to notified bodies revision 5, while providing further framework for structured dialogue, has not addressed the ongoing absence of clinical strategy discussion in the pre-submission space.

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Empowering a Healthier Tomorrow: Discover this year's theme for The MedTech Forum 2025

Claudia Peters, Events Manager

In a world where healthcare is rapidly evolving, medical technology plays a critical role in shaping a healthier future. This year, The MedTech Forum embraces the theme "Empowering a Healthier Tomorrow", conveying the commitment to driving meaningful change through medical technologies.

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MedTech Europe's response to the European Commission's call for evidence on a Critical Medicines Act

Georgiy Bogdanov, Manager Market Data

On 30 January 2025, the European Commission launched a call for evidence on a Critical Medicines Act. Responding to the consultation, MedTech Europe insists that medical devices, diagnostics, and digital health solutions remain excluded, as solutions to address shortages in the pharmaceutical sector will not be effective for the medical technologies sector.

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MedTech Europe participates in European Data Protection Board consultation on pseudonymisation

Mirella Kavadaki, Junior Legal Counsel

Pseudonymisation plays a key role in protecting privacy while enabling the responsible use of health data. To support a clear and balanced regulatory approach, MedTech Europe has contributed to the European Data Protection Board's (EDPB) public consultation on the draft Guidelines 01/2025 on Pseudonymisation.

READ OUR FULL CONTRIBUTION HERE

Conference Vetting System: Webinar recording and training deck now available on EthicalMedTech website

Dhana Ong, CVS Compliance Officer

We are pleased to announce that the recording of our recent webinar is now available in the resources section of EthicalMedTech website, under the "Video Trainings" section.

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The Innovative Health Initiative's calls for proposal 9 and 10 are now open

Patrick Boisseau, Director General Industry Strategic Initiatives

The Innovative Health Initiative's (IHI) latest calls for proposals are now open. Call 9, is an applicant driven approach aligned with the IHI's key objectives; Call 10 covers diverse topics, including digital labelling for medical technologies.

Find the full details, deadlines, and supporting resources here.

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MedTech Europe's revamped website is now live

Gabriel West, Officer Communications

On 24 February 2025, MedTech Europe launched its revamped website, making it easier to explore our priorities and activities. Our single hub, MedTech Views, now centralises all digital content and communication materials. Come and discover our revamped website, and stay connected with the medical technology community.

EXPLORE THE REVAMPED WEBSITE

CONTACT US

MedTech Europe
from diagnosis to cure

MedTech Europe is the European trade association representing the medical technology industries, from diagnosis to cure.

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