Recommendations on How to Reach the Full Potential of the Proposed European Health Data Space

HIMSS, the Healthcare Information and Management Systems Society, welcomes the European Commission's proposal for the European Health Data Space (EHDS).

HIMSS stands ready to support the creation of the European Health Data Space. We believe that our organisation can contribute significantly to the joint effort that is needed across the continuum of the health ecosystem to ensure that the EHDS will be developed as a well-used resource that responds to real needs.

What we recommend

In order to reach the full potential of EHDS to create a long lasting legacy for generations to come, HIMSS urges the European Parliament and the Council as co legislators, as well as the European Commission and the Member States to pay attention to the issues listed below, not only throughout the legislative process for adopting the Regulation on the EHDS, but also in the next phases when further implementing details will be developed and structures, processes will be put in place at EU, national and regional levels to execute the vision of the EHDS.

1. Clarity of definitions and coherence with other legislation

2. Improving interoperability

3. Engagement with third world coutries

4. Building trust and digital skills

5. Support to Member States

Three Groups who Share the HIMSS Vision to Better Health through Information & Technology

PROFESSIONAL ORGANISATIONS
Medical Associations, Industry Associations, Federations of Nurses/CNIOs, Patient Organizations, etc.

ORANIZATIONAL AFFILIATES
Healthcare Providers, Administrators, Municipalities and Regions

NON-PROFITS AND ACADEMIC INSTITUTIONS
EU Projects, Universities/Academic Programmes, eHealth agencies, PR & communication agencies, etc.

Building Blocks of a Digital Health Ecosystem

POPULATION HEALTH & WELLNESS

DIGITAL CAPACITY

Individuals are meaningfully connected to providers to manage health

ANALYTICS & TRACEABILITY
Outcomes

INTEROPERABILITY
Democratization of Data

GOVERNANCE & WORKFORCE

- Enables people to manage health, predicts risks
- Transforms data into konwledge, insights and outcomes
- Mobilize and enable data exchange across the journey of care
- Data stewardship, privacy, security, workforce integrity are foundational

Who We Are

Our vision is to realize the full health potential of every human, everywhere. A mission-driven nonprofit, HIMSS serves the global health ecosystem in our shared goal of leveraging information, data, and technology for health equity and quality healthcare.

A trusted society and advocate for digital health transformation, HIMSS spans more than sixty years of growth and collaboration with world leaders, governments, healthcare providers, members, and other stakeholders. Our work informs innovation, public policy, workforce development, and data analytics -- all geared toward digital healthcare delivery for every global citizen.
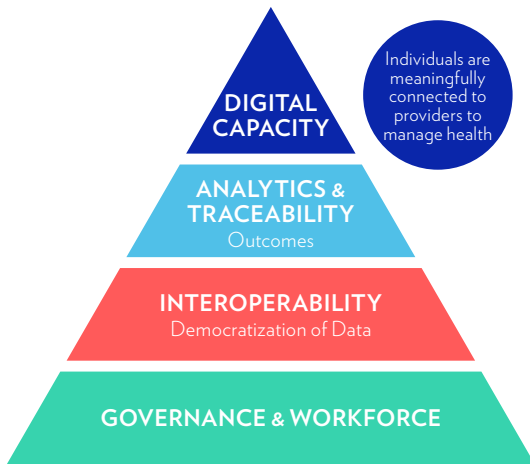
HIMSS delivers key insights, education, and engaging events to healthcare stakeholders to ensure they have the right information at the right time to make sound strategic, clinical, operational, and financial decisions.

HIMSS shares a common vision with its global membership of about 120,000 individuals, 430 provider organizations, 500 nonprofit partners, and 550 health services organizations. We address the various challenges of modern healthcare delivery, study the impact of social determinants on population health, and the increased consumer demand on healthcare systems constrained by lack of resources.

We address all this with a special focus on equity, cost efficiency, quality, workforce, and patient experience.

1. Clarity of definitions and coherence with other legislation

We believe that to provide regulatory certainty with existing and emerging legislation across the EU, the terms used to define key actors and processes, such as data holder, recipient and user set out in Article 2 of the proposed EHDS Regulation, require further careful assessment. Without the **clarity on foundational definitions in alignment with legislation that are relevant to drive the digital transformation of health and care,** such as General Data Protection Regulation (GDPR), Data Governance Act (DGA), Data Act, Medical Device Regulation (MDR), a significant risk of fragmented interpretation and implementation of the law exists.

As COVID-19 has demonstrated, **clearly defined access to and usage of data will facilitate research, innovation, preparedness, and response.** From the secondary data usage point of view, it is important to ensure that rules on aggregated data are consistent across the EU to foster cooperation between countries to underpin timely life-saving solutions.

HIMSS recommends testing definitions with a range of user groups and would be happy to engage the HIMSS Communities to help assess the understandability of key terms, concepts and their application on various healthcare domains.

2. Improving Interoperability

HIMSS welcomes the Commission's emphasis on improving interoperability in the healthcare sector through mandatory self-certification of EHR systems; however, it is only partly addressing the challenge of building sustainable and resilient healthcare systems.

The full health potential of all citizens can only be achieved if they play an active role in their wellbeing and care. While EHR interoperability is an important element, a fully **interconnected digital environment, including infrastructures and governing structures over the continuum of care is needed.** Accordingly, HIMSS urges the co-legislators to ensure that the EHDS Regulation **includes the mandatory interoperability certification of telemedicine and wellness applications.** We also urge the legislative partners to consider the potential of certification to ensure technology meets a scaled level of capabilities, including interoperability. We recommend the EC and Member States consider extending certification requirements to access. Quality, and safety. This is of particular importance as telemedicine solutions and wellness applications are used in the wider healthcare ecosystem that includes social care, home care, and care of the elderly.

Lessons learned regarding similar initiatives globally, for instance the Certified Electronic Health Records Technology (CEHRT) in the United States within the framework of the Meaningful Use program, demonstrate that **certification increases purchaser confidence in the foundational capabilities of the technology, but does not lead directly to operational interoperability without clearly defined expectations and attestation requirements.**

We encourage the European institutions and Member States to take certification as a minimum baseline requirement to enable interoperability and build trusted frameworks to ensure that certified **EHR systems can meet the needs of local health systems and can furthermore** create certainty in the internal market and **encourage innovation at all levels of healthcare delivery.**

HIMSS stands ready to support the European efforts to increase interoperability through its extensive engagement with standards development organisations, for instance the Global Consortium for eHealth Interoperability which is led by HIMSS, IHE International and HL7 International.

HIMSS has developed a Global Interoperability Indicator which can be used across the EU to measure progress toward interoperability at the national or jurisdictional level to shape strategies on organisational and structural dimensions.

3. Engagement with third world countries

The EHDS is European, but health and disease know no borders. Without undermining the efforts to create high quality EHDS infrastructures, we believe that health systems and life sciences **research from third countries should be encouraged and supported**. While the current proposal outlines how third country national data access bodies may engage with the EHDS, **the extent to which researchers from outside the EU may collaborate with EU colleagues and counterparts remains regulated under the terms of GDPR** Article 9(4) which risks that the research community will face a **fragmented legal landscape**.

HIMSS can offer its expertise to further the discussion on this topic with wide range of stakeholders by building on our experience collaborating with governments and international organisations across the globe to create forums that can complement traditional international negotiations by facilitating discussions on topics that are complex and challenging, for instance the Transatlantic Collaborative on Digital Health between WHO Europe and HIMSS, and the Digital Health Advisory Group for Europe

(DHAGE), the thought leadership platform for key decision-makers in Europe to identify synergies and nurture collaborations on digital health policies.

4. Building trust and digital skills

The **need to build trust in the EHDS among patients, healthcare professionals and researchers** is acknowledged in the proposal. HIMSS urges the legislative partners to re-assess the **reporting requirements** set out in Article 39 and the obligations set out in Article 38 to ensure that they are sufficient to build and maintain the trust of patients, healthcare providers, policy makers and researchers.

HIMSS welcomes the initiative to include quality labelling of wellness apps and urges the Commission to make good use of the recently started Label2Enable project which focuses on trust, use and adoption of a quality certification scheme for mobile health apps. The **mandatory registration of health data** required in Article 7 is welcomed, but it **must be supported by implementing legislation that draws on the experience of stakeholders and supports the development of data registration skills**. We see the need to help healthcare workers and allied professionals to develop and maintain trust in the benefits of digital transformation by providing accessible and user-friendly professional development throughout career different paths.

The recent **DHAGE reports published by the Finnish Ministry of Social Affairs and HIMSS** offers valuable insights on topics such as Digital Inclusion covering health equity and digitally enabled workforce for the future and Trust to bridge the digital health gap. We pledge to continue our initiative and use all our events

and media platforms to provide education and engagement in relation to EHDS.

HIMSS Professional Development initiatives are designed to anticipate the need for a qualified digital health workforce in the face of ever-evolving health policy and governance developments, business and patient care challenges, changing payment and care/wellness models, and disruptive innovations. We have a full suite of offerings from in-person and online education to internationally recognized certification programs to ensure health workers acquire, and refresh, appropriate levels of digital health knowledge competencies to ensure their professional growth.

5. Support to Member States

HIMSS welcomes the inclusion of **significant budgetary allocation as well as recognition of capacity building to support Member States** to implement necessary improvements. However, as health systems have different levels of maturity in EHR standardisation across the EU, and there might be significant differences in digitalisation even within national borders, we urge the Commission to ensure effective use of the available budgets.

We recommended that a **common and standardised bench-marking model is used to assess Member States' capacity** to implement the EHDS and to measure compliance, with the adoption of the priority tools for primary use of data.

HIMSS has significant experience helping Member States with such assessments and is ready to share the learnings. Our **Digital Health Transformation program** employs a series of globally relevant digital healthcare maturity assessment tools to measure outcomes of technology investment, system delivery and workforce capabilities between current and aspirational standards.

As an example, in 2021-22, the **DigitalRadar** consortium, which includes HIMSS and other research and advisory partners, **carried out the evaluation on behalf of Germany's Federal Ministry of Health**. The analysis of more than 1,600 German hospitals found that they achieved the highest marks on structures and systems while patient participation and telehealth had the most room for improvement. The insights delivered by the project will help hospitals identify the imminent next steps on their digital transformation journey and prioritise their resources accordingly.

To learn more about HIMSS and what we do to facilitate stakeholder engagement, please view:

HIMSS: New Perspective on Global Healthcare

HIMSS Policy Briefing on EHDS

HIMSS Webinar on EHDS: What you need to know