

White Paper

A joint response to the European Commission's Public Consultation on the European Health Data Space from HIMSS and PCHA




White Paper



HIMSS and PCHA warmly welcome the concept of the EHDS, which has the potential to become a core tool to allow all partners in healthcare, from healthcare providers, industry, research and citizen led organisations to collaborate to build more sustainable and resilient healthcare systems for all.

We stand ready to support this work through the Global Consortium for e-Health Interoperability, which we have founded in partnership with Integrating the Health Enterprise (IHE) International (IHE) International and Health Level Seven International (HL7).

Recognising the importance of standards in the operation of the EHDS, we welcome the intention of the Commission to assess the functioning, role and areas of competence of the current eHealth Network. We urge the Commission to consider the potential benefit of a body with a wider mandate, which could move current guidance on use of standards to a stronger legal base to better facilitate routine sharing of health data for care, care planning and research.



Background

HIMSS is a global advisor and thought leader supporting the transformation of the health ecosystem through information and technology. As a mission-driven non-profit, HIMSS offers a unique depth and breadth of expertise in health innovation, public policy, workforce development, research and analytics to advise global leaders, stakeholders and influencers on best practices in health information and technology. PCHA is membership-based HIMSS Innovation Company, working to accelerate the technical, business and social strategies necessary to advance personal connected health. PCHA is committed to improving health behaviors and chronic disease management via connected health technologies and is working to advance patient/consumer-centered health, wellness and disease prevention.

In Europe, HIMSS and PCHA bring together stakeholders from both the public and private sectors to exchange innovative ideas, discuss trends, challenges and solutions for health IT policy, regulation and implementation. We are proud members of the European Commission's eHealth Stakeholder Group, created to allow stakeholders to assist the European Commission in the preparation of legislative proposals and policy initiatives. HIMSS and PCHA have been involved in a wide range of EU level digital health projects.

Importance of Data

HIMSS and PCHA join with the European Union in embracing the necessity of developing a strategic vision for data collection, sharing, and access, including its potential to contribute to health system modernization. Digital health transformation is critical to organisational, community, national, and global goals of improving the health and well-being of every human everywhere. To that end, it is of strategic importance for the EU to promote systematic use of standards in the collection and labelling of data,

so that they may in turn be analysed and further used to provide actionable information that can be shared across communities.

Focus on Digital Health Interoperability

A core element of the work of HIMSS and PCHA is to facilitate interoperability in digital health throughout the healthcare ecosystem, as shown in the layers of the refined eHealth interoperability framework adopted by the European eHealth Network in 2015. The unique contribution of PCHA to address the challenges of interoperability is found in our [Continua Design Guidelines](#) which provide practical support for the use of recognised consensus standards to simplify the collection and sharing of health data generated by personal health monitoring devices and mobile apps to improve continuity of care.

In October 2019, HIMSS joined with IHE International to promote the use of the Continua Design Guidelines and cooperatively advance interoperability standards, profiling, and testing in the personal health space. PCHA co-sponsors the IHE Devices technical domain within IHE. The IHE Devices domain supports development of IHE Integration Profiles for Device Point of Care Interoperability (DPI), Patient Care Devices (PCD), and Personal Connected Health (PCH). PCHA also supports interoperability and conformance testing at the annual IHE North American and European Connectathons, which are highly structured industry interoperability testing events attended by major health IT market suppliers, public health agencies, medical device manufacturers, health app developers, and other key stakeholders.

More recently, in collaboration with IHE International and HL7 International, HIMSS established the Global Consortium for eHealth Interoperability to align the needs of national governmental agencies, health systems and their stakeholders with standards, profiling and implementation guidelines to help

health IT developers and end-users better leverage emerging interoperability standards such as HL7's Fast Healthcare Interoperability Resources (FHIR®) standard.

The Consortium's founding principles include providing the global healthcare community support in achieving better, lower-cost health outcomes by decreasing barriers and accelerating the rapid, coordinated, efficient deployment of next-generation, application programming interface (API)-based interoperable standards.

Drive for Digital Health

HIMSS and PCHA welcomed the publication of the European Commission's Communication on A European strategy for data and its White Paper on Artificial Intelligence of February 2020, and note their key importance in advancing European

adoption of digital health for the promotion of safe, accessible, equitable, and sustainable healthcare systems. We believe Digital Health connects and empowers people and populations to manage health and wellness, augmented by accessible and supportive provider teams working within flexible, integrated, interoperable and digitally-enabled care environments that strategically leverage digital tools, technologies and services to transform care delivery.

This paper supplements the response questionnaire HIMSS and PCHA have submitted jointly to the European Commission public consultations, focusing on the potential of a EHDS¹ as well as on the special demands of AI in high-risk healthcare solutions. HIMSS and PCHA seek to provide supportive input to the European institutions as they continue to drive the adoption of digital health tools in Europe.

Access of Personal Health Data

HIMSS and PCHA warmly welcome the creation of a common EHDS. Such a mechanism would provide a valuable tool to facilitate the appropriate re-use of health-related data to meet the needs of patients, healthcare providers, healthcare systems, as well as researchers and innovators. A EHDS would require that data are available, accessible, portable, and that the data space has a robust governance framework to build trust in the quality of the data and the appropriateness of their use.

Data availability

A workable EHDS demands that data are both available and accessible. The two concepts are closely linked and address the generation of data as well as the capacity to use it. One concept discussed in previous consultations to address the generation of data to be made accessible through the EHDS is a mechanism to support data altruism.

This demands both a system for allowing data controllers to provide access to data for secondary research, as well as educational tools to build trust and confidence of data subjects (patients) in such a system. While some systems for data altruism are already being developed at national level, notably in Finland with [FinData](#) and a social enterprise level, such as [Salus Co-op](#) in Spain, many challenges still exist to bring an EU level system of data altruism to fruition. These include issues of developing interoperable infrastructure to facilitate data sharing as well as a common legal basis under General Data Protection Regulation (GDPR) to allow data sharing. HIMSS and PCHA welcome the concept of greater data availability for research, and look forward to an EU-level system to support greater data availability for multi-country research.

¹ European Commission's Public Consultation on the European Health Data Space, May 2021 https://ec.europa.eu/commission/presscorner/detail/en/ip_21_2083

Data Accessibility

Currently, most patient data are stored across various healthcare providers (hospitals, health professionals, imaging clinics or labs) in disparate systems that are not interoperable. This is the case not only at national or regional level, but also locally, meaning that in many cases data cannot be shared easily even between departments of the same hospital or with associated physicians' offices. This results in difficulties for practitioners to exchange information and medical decisions not benefitting from longitudinal view of the patient. The COVID-19 pandemic has highlighted the need for interoperable data even more starkly than before, in particular as European healthcare systems seek to work together on contact tracing initiatives, research to find and develop vaccines as well as other medication to respond the virus, and in vaccine distribution. A further initiative could include developing an EU-wide project of synthetic health data sets, which could drive innovation by lowering the barriers to entry for startups and new health data projects.

The application of consensus standards and shared compatible formats and protocols for gathering and processing data from different sources across sectors, should be further encouraged through a rolling plan for information and communication technologies (ICT) for health standardization and (as regards public services) a strengthened European Interoperability Framework as proposed in the EU Data Strategy. Europe already benefits from a well-developed library of health system specific interoperability standards and protocols; it is time for Europe to engage more actively to promote the use of data standards. This can be done through more stringent requirements for compliance with interoperability guidelines, such as Continua Design Guidelines and IHE protocols in public procurement specifications.

The work underway in the United States to advance interoperability across the care continuum is an appropriate case study for the European

Commission to consider. The US has implemented new regulations that require more interoperability and data exchange across the entire healthcare ecosystem. The regulations build on standards-based information exchange that establish API requirements using the FHIR standard developed by HL7 International, including for patients to use APIs to be able to electronically access all of their electronic health information, structured and/or unstructured, at no cost.

Moreover, HIMSS and PCHA encourage the European Commission to leverage HIMSS's work on [Interoperability in the Healthcare Ecosystem and our Four Levels of Interoperability](#) in development of the Data Strategy. HIMSS defines interoperability as the following:



The ability of different information systems, devices and applications ('systems') to access, exchange, integrate and cooperatively use data in a coordinated manner, within and across organizational, regional and national boundaries, to provide timely and seamless portability of information and optimise the health of individuals and populations globally

Building on Foundational (Level 1), Structural (Level 2), and Semantic (Level 3), HIMSS added Organizational (Level 4) interoperability, that includes governance, policy, social, legal and organizational considerations to facilitate the secure, seamless and timely communication and use of data both within and between organizations, entities, and individuals. These components enable shared consent, trust, and integrated end-user processes and workflow.

Four Levels of Interoperability

Interoperability effectiveness is measured within these parameters:



1.

Foundational
Interoperability



2.

Structural
Interoperability



3.

Semantic
Interoperability



4.

Organizational
Interoperability

Data Portability

HIMSS and PCHA emphasise the importance of the Data Strategy's empowerment of individuals with respect to the use of their data. We also ask the EU to support initiatives to ensure that the right to portability of data, as provided for in Article 20 GDPR, is truly exercisable by patients. Only when patients can make their data fully accessible to healthcare providers of their choice can they actively be involved in directing their own healthcare. However, this demands that data are interoperable and that patients can truly benefit from access to healthcare within and across EU borders. In addition to making data portable, another critical issue is ensuring that an individual's contribution of data generated by personal devices or submitted directly by a patient can be more easily integrated with data in healthcare systems, such as electronic health records (EHRs). Future policy development also needs to capitalise on the importance of data coming from smart home appliances and wearables and ensuring that information is integrated into an individual's EHR.

Overall, we encourage the Commission to continue to support initiatives for individuals to better direct their own healthcare, but to also include more emphasis on actionable two-way information/data exchange between individuals and clinicians. Enabling broader two-way exchange processes is the next critical phase of work needed on behalf of individuals.

Robust Governance

The EHDS needs a clear and strong governance model, which builds upon the strengths of the GDPR. This will demand greater guidance at the EU level to address the current fragmentation in the implementation of the GDPR, which has arisen as a result of the variations in the application of the derogations the GDPR provides. Such fragmentation is particularly evident in the variation in legal bases used to legitimise the processing of health-related data as provided for in Article 9(2) (a-j) GDPR, which significantly impedes sharing data for cross-border care and research. However, any EU level governance tools, whether normative regulation, self-regulation or guidelines needs to be kept simple and clear so that they are easy to follow; and, be flexible enough to allow for the fast development pace of the digital health sector.

Digital Health Services and Products

New technologies offer digital health solutions to some of the current challenges of the national healthcare systems. With the increase of digital literacy and adoption of digital health solutions, more and more patients now have the ability to access digital services and manage their data, and some of their healthcare needs, digitally.

Digital health services and products include remote care delivery, monitoring, diagnosis and therapeutic services but also the management of patient health data. Digital devices contribute to both medical uses and general health uses. In a person's lifetime and in a device's lifetime (excluding very specific medical devices), much of the data generated will have no direct medical use for a clinician, but will add context to a patient's decision-space so that small changes in behavior will ultimately yield more health over the long term. Accordingly, it is important that digital health devices and service can be managed so that patients can retain the richness of data they may want, but that clinicians are not overloaded with data of very limited practical use.

One important aspect of digital health is telehealth, which is usually understood to cover remote consultation and remote monitoring. The challenges of providing routine care during COVID-19 has seen a significant rise in the use of such services. A key issue now is to allow the continued use of such systems, and their inclusion in the reimbursement codes for routine care.

In addition to telehealth as part of routine care, is the use of digital tools and services that are acquired and used by citizens as consumer devices. These devices and services generally have very low interoperability with formal healthcare records and the data they generate are often not useable by healthcare professionals. HIMSS and PCHA therefore suggest the European Commission support the use of data standards in consumer devices to allow for more effective data exchange with consumer devices.

Develop a robust health IT workforce

A well-trained workforce is necessary for the growth and proliferation of digital health, including new tools and services to be developed based on the use of new technologies. HIMSS and PCHA have long championed the nurturing of a stronger health IT workforce, and we would like to build on our efforts to reinforce the idea of building a stronger community of researchers, data scientists, and informaticists to help the entire field grow. The development of the health IT workforce, as well as the broader research infrastructure, must be prioritised for healthcare delivery improvements and efforts to promote better, more efficient care delivery. As the broader

shift to value-based care continues, the reliance on data analytics and the data sciences will continue to grow. However, the efforts of HIMSS and PCHA to support growth in the health IT workforce has faced challenges.

As technology becomes more routinely integrated into healthcare services, a knowledge base and understanding of technologies across the entire community is critical to push the field forward but also avoid clinician's overload. For example, a recent [European study](#) by HIMSS and Nuance highlights ways clinician's burnout can be alleviated with AI technology, particularly when addressing



routine-based and documentation-based tasks clinicians need to perform instead of spending more time with the patient.

HIMSS and PCHA recommend the EU consider providing greater training and career development opportunities to support a highly-trained health IT workforce that would include education in technology, with the option of deeper learning for those seeking careers in the developer or vendor space. We commit to working with the EU and individual governments to fulfill this need and continue our support of the work of the community in fostering the development of AI technology tools in addition to our specific health IT work—such as toward the push to value-based care delivery models.

As more biomedical data becomes digitised, through EHRs and other health IT applications, the ability to integrate clinical knowledge with biomedical and other digital data becomes critically important in support of broader care transformation. Any increase in support for the health IT workforce has to be accompanied by a concomitant increase in support for the AI-related workforce.

The European Union has a long history of investment in research and innovation, especially coming out of the COVID-19 pandemic, the need for significant EU investment in research and development should be strongly supported. Such investment should focus not only on basic science research, but also on training for healthcare professionals², and outreach programmes to build trust and confidence in the use of digital health tools and services.

As a long-time provider of both professional training and community outreach, HIMSS and PCHA would be delighted to support the European Commission in overcoming the existing training gap for digital health. A key tool for this could be the groups of experts HIMSS and PCHA bring together in their national and subject level ‘Communities’. These include a Community of chief technology officers of leading hospitals, a Community of nursing informatics professionals, a Community of women in health IT, and a ‘future 50’ community bringing together the top 50 Healthcare IT leaders in Europe. In addition, the dedicated team of companies working together in PCHA’s EU Policy Workgroup stand ready to support the work to be undertaken on the ambitious objective of the EHDS.

² See detailed calls to action from the HIMSS Europe Nursing Informatics Community regarding the acute need for investment in the technological and strategic skills of nurses in Community Position Paper: [“Beyond Recognition: An Unequivocal Demand for Greater Investment in Nursing Practice, Nurses’ Technological Skill and Inclusion in Healthcare Decision-Making”](#), May 2021

For further information on HIMSS/PCHA activities in Europe please contact

Petra Wilson
European Programme Director
pwilson@himss.org

For further information on HIMSS/PCHA activities globally please contact

Thomas M. Leary
Vice President, Government Relations
tleary@himss.org

Developed by HIMSS and PCHA in co-operation with its partners in industry and academia

