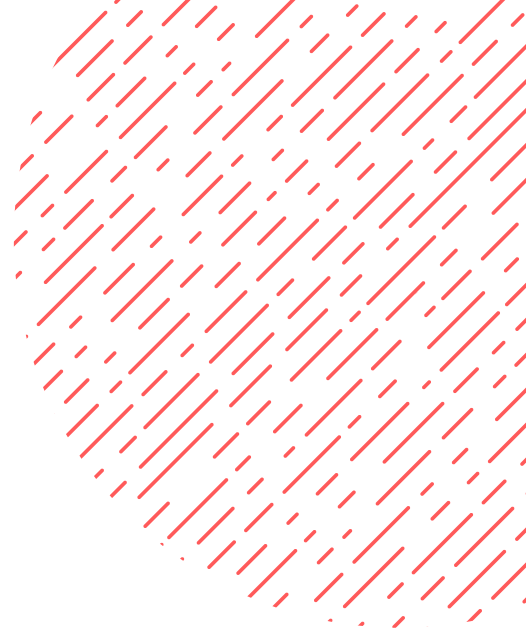# White Paper

A joint response to the European Commission's Data Strategy and White Paper on Artificial Intelligence from the Healthcare Information and Management Systems Society (HIMSS) and the Personal Connected Health Alliance (PCHA).

HIMSS

Personal Connected Health Alliance
A HIMSS Innovation Company

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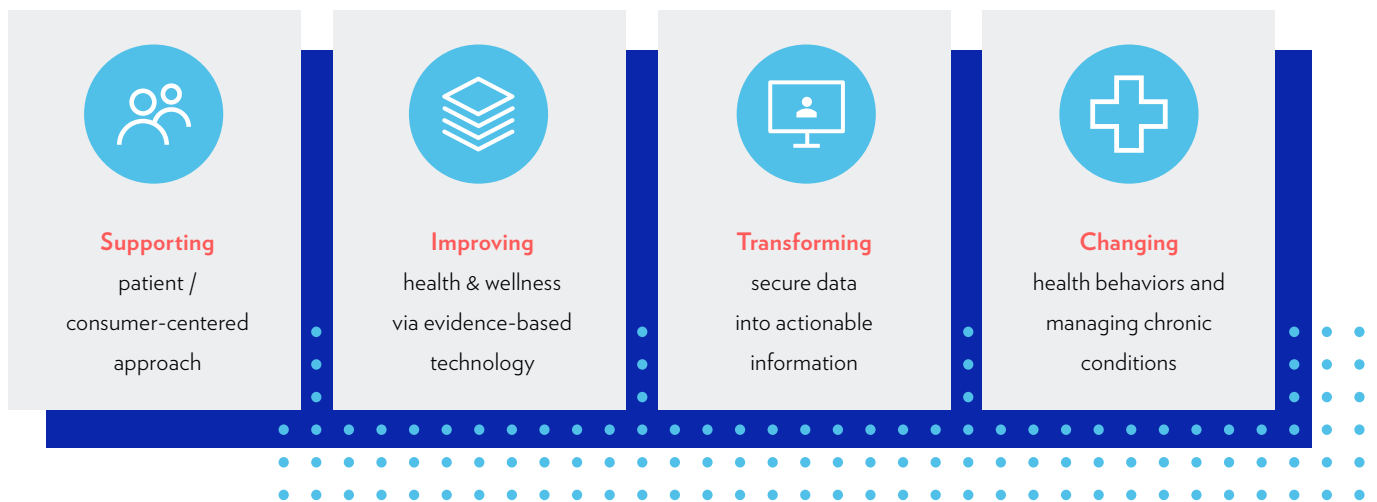
HIMSS and PCHA warmly welcome the Data Strategy and the White Paper on Artificial intelligence, but call for greater focus on data availability, access and governance in the Data Strategy and look for appropriate consideration for risk management, fostering of trust and attention to training in the adoption of EU policy on Artificial Intelligence

Background

Healthcare Information and Management Systems Society (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. Personal Connected Health Alliance (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, PCHA and HIMSS 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, and continue to engage in a number of Horizon2020 projects.

Supporting	**Improving**	**Transforming**	**Changing**
patient / consumer-centered approach	health & wellness via evidence-based technology	secure data into actionable information	health behaviors and managing chronic conditions

Strategic 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 visualization throughout society, including health system modernization. Digital health transformation is critical to organizational, community, national, and global goals of improving the health and well-being of every human everywhere. To that end, it is strategic important for the EU to achieve the development of high quality standardized data that can be analyzed and shared across communities.

In order to inform health system strategy to advance digital health transformation, we have developed a measurement tool — the HIMSS Digital Health Indicator (DHI). The DHI measures progress toward a digital health ecosystem. An ecosystem that connects clinicians and provider teams with people, enabling them to manage their health and wellness using digital tools in a secure and private environment whenever and wherever care is needed. Operational and care delivery processes are outcomes-driven, informed by data and real-world evidence to achieve exceptional quality, safety and performance that is sustainable. DHI guides health system leaders by measuring progress towards digital health systems, as well as transformation of digital care delivery that is focused on outcomes, and informed by data as well as real-world evidence.

A relentless focus on digital health interoperability

A core element of the work of HIMSS/PCHA is to facilitate interoperability in digital health throughout the layers of the refined eHealth interoperability framework adopted by the European eHealth Network in 2015, which embraces technical, semantic, operational, and legal challenges of interoperability. A key contribution of HIMSS/PCHA to address the interoperability challenges are the Continua Design Guidelines which provide practical support for the use of recognized 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/PCHA joined forces with Integrating the Health Enterprise (IHE) 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 Health Level Seven International (HL7), we 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 guide development efforts to help implementers of health IT better leverage emerging interoperability standards such as HL7 Fast Healthcare Interoperability Resources (FHIR®).

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.

Embracing Europe's drive for Digital Health
HIMSS and PCHA welcome 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 taking Europe to the next level in the adoption of digital health for the promotion of safe, accessible, equitable, and sustainable healthcare systems. We believe that Digital Health connects and empowers people and populations to manage health and wellness. Flexible, integrated, interoperable and care environments that strategically leverage digital tools, technologies and services can transform almost every aspect of care delivery.

This present paper supplements the response HIMSS and PCHA have submitted jointly to the recent European Commission public consultations, focusing on the potential of a European Health Data Space 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.

The European Health Data Space

HIMSS and PCHA warmly welcome the creation of a common "European Health Data Space" as outlined in the Communication. 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, and healthcare systems. A European Health Data Space (EHDS) would require that data are available, accessible, portable, and that the data space has a robust governance framework.

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 raised in the consultation 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 interoperable infrastructure to facilitate data sharing as well as a common legal basis under GDPR to allow data sharing. Here the recently adopted Guideline 5/2020 of the European Data Protection Board on Consent indicates a useful approach to a more stepwise provision of consent to sharing data for research. 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.

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 current COVID-19 crisis 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 as well as on basic research to find a vaccine and medication to respond the virus. A further initiative could include developing EU-wide synthetic health data sets, which could drive innovation by lowering the barriers to entry for startups and innovative 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 ICT 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 in encouraging the use of 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 is implementing new regulations that require more interoperability and data exchange across the entire healthcare ecosystem. The regulations build on standards-based data exchange that establishes application programming interface (API) requirements using the Fast Healthcare Interoperability Resources (FHIR®) standard, 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 optimize 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.

Data Portability

HIMSS and PCHA emphasize 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 by healthcare providers of their choice can they be actively involved in directing their own healthcare. This demands however 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 their own data is valued and incorporated moving forward, so patient-generated health data and patient-reported outcomes can be added to an individual's record and contribute to the development of their unique care plan. Future policy development needs to capitalize on the importance of data coming from smart home appliances and wearables and ensuring that information is integrated into an individual's electronic health record (EHR).

Overall, we encourage the Data Strategy to continue to drive 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 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 which the GDPR provides. Such fragmentation is particularly evident in the variation in legal bases used to legitimate 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. HIMSS and PCHA welcome the suggestion of the Data Strategy to explore the potential of a health sector specific Code of Conduct as provided for in Article 40 GDPR to address this issue. 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 flexible enough to allow for the fast development pace of the digital health sector.

HIMSS and PCHA note also that the right to data portability as enshrined in the GDPR is difficult to execute by patients with respect to health-related data, often impeding a patient's capacity to share data between healthcare providers when seeking a second opinion or accessing care across EU borders. An individual's right to data portability must be enhanced through technical enablers to remove cross-border barriers and sharing between health provider systems. PCHA and HIMSS call on the European Commission to work closely with the European Data Protection Board and advisory groups such as the eHealth Network to ensure that patients have better access to and portability of data which concerns them. An emphasis on decentralized data interoperability is also important to prevent the growth of data silos. This demands not only policy guidelines, but also greater emphasis on the use of standards to ensure that it is technically possible for data to be easily shared from one healthcare provider system to another.

Artificial Intelligence – A European Approach

Artificial Intelligence (AI) has huge power to create patient-centric and outcome oriented medical technologies and solutions. Moreover, patient expectations of more effective and personalized and convenient services are growing, as well as the ability to apply AI to ever-growing volumes of research and patient data to understand people at an individual level and deliver personalized products and services to them that provide increased medical value and quality of life. However, as an emerging technology AI demands that risks are managed, that trust in its proper use is fostered, that the needs of industry in developing AI tools are considered, and that a robust Health IT Workforce is developed to support AI adoption and advances.

A significant challenge in meeting these demands lies in the fact that application of AI especially in medicine and healthcare is still an emerging science and the concept itself lacks a harmonized definition and guidance. However, if legislative responses such as those set out in the White Paper are to be developed, a common definition of AI and its key components will need to be used across the EU to ensure that EU level legislation can be applied in a harmonized manner. Such a definition should be wide ranging covering machine learning and deep learning as well as other AI concepts, and should be regularly reviewed to ensure they remain fit for purpose.

Risk management

The White Paper on AI identifies many uses of AI in healthcare as 'high risk' because they will have a significant impact on an individual, and as such likely to be the subject of EU level regulation, including new models of liability and risk assurance. HIMSS and PCHA advocate for regulatory clarity, we urge the Commission to ensure that such legislation builds on the existing body of law which defines the use of technology in healthcare, notably the Medical Devices and In Vitro Medical Diagnostics Regulations which will be applicable from 2021 and 2022 respectively, the Clinical Trials Regulation and the GDPR. Only newly emerging/identified risks not covered by the existing rules could be considered for any potential regulation, if demonstrated that it is really needed.

HIMSS and PCHA urge the European Commission to take note of the proposed model for AI classification of the US Food and Drug Administration (FDA), which categorises AI into two groups: one, in which AI that is trained once is labeled as low (or lower) risk as long as the training set or the algorithms themselves were accessible and testable; the second category is AI that is self-learning. These systems are presumed to have higher risk associated with them because they are constantly changing.

Fostering Trust

It is also paramount that trust in AI is developed. As noted in the White Paper this is achieved through good levels of explainability of AI processes to ensure that users, such as physicians, and those directly affected by the use of AI in decision making, such as patients, are able to understand how AI is used. The White Paper focusses particularly on transparency of AI algorithms and calls for full transparency on training data sets for regulators of high risk applications. Without trust even highly trained data scientist would gather little input for their analysis. While

HIMSS and PCHA fully endorse the importance of building trust and note that transparency will be a core to doing so, we call upon the Commission to be measured in its requirements for transparency, noting that the development of AI necessarily contains some operations which cannot be made fully transparent; that due to its nature, some AI concepts contain operations which cannot be made fully transparent. The EU could step up efforts to earn citizen/patient trust, educate and make them aware of the benefits that AI can bring to their lives and health. Furthermore, HIMSS and PCHA urge the European Commission to take note of the need for a large body of highly trained data scientists who are accessible to work closely with Notified Bodies to ensure that they have the capacity to evaluate complex AI based solutions.

Meeting industry needs

As noted with respect to the EHDS, innovation in health technology needs good availability and appropriate access to high quality data. The integrity and availability of AI training and testing datasets is crucial to ensuring scientifically reliable results. While providing Industry with high quality training and test data sets is a key objective, it would be beneficial to also develop guidance/good practices for the industry to create high quality training and test datasets.

To meet the needs of a diverse continuum of AI interests and applications, there needs to be a wide variety of high quality datasets that are accessible to developers. Furthermore, research is needed to develop high-quality datasets and environments for a wide variety of AI applications, and to enable responsible access to good datasets, testing and training resources. As a result, the availability of high-quality datasets is truly relevant when discussing minimizing bias in AI processes and needs to be prioritized in all efforts moving forward. Algorithms can reproduce and magnify social biases and discrimination from using training data that mirror existing bias in society or that have a skewed representation. The capacity of industry to develop AI based tools therefore critically depends on access to data, which in turn demands that datasets are interoperable and standardized. HIMSS and PCHA therefore urge the Commission to continue in its work to drive up the use of interoperability standards.

As a membership organization, we count many smaller enterprises amongst members and accordingly welcome the focus on SMEs in both the Digital Strategy and the While Paper on AI. There is no doubt that start-ups and small businesses are of huge potential in digital health, to thrive and deliver they need the tools and infrastructure for Digital Health as well as standards and policies. We therefore strongly suggest that the Commission includes investment in tools such as international test data sets and API endpoints amongst its initiatives.

Develop a robust health IT workforce
Finally, a well- trained workforce is necessary for the widescale adoption and mainstream use of AI technologies. HIMSS and PCHA and 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 promoting strong collaboration within the community of AI

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 prioritized for the impact each can bring to AI technologies, as well as 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.

A knowledge base and understanding of AI technologies across the entire community is critical to push the field forward.   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 on AI technologies, with the option of deeper learning on AI 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 digitized, through EHRs and other health IT applications, the ability to integrate clinical knowledge with biomedical, lifestyle and other digital data becomes critically important in driving 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.
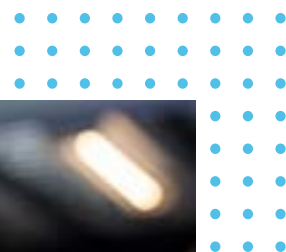
Conclusion

The European Union has a long history of investment in research and innovation; as the new budget of the EU is finalized in the coming months, 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 professionals, and outreach programmes to build trust and confidence in the use of AI in patient communities and wider citizen groups.

Our many tools, maturity models, and Digital Health Indicator can be of great use to the EU as the Digital Strategy takes shape. We look forward to the opportunity to demonstrating the strategic capabilities of these tools.

In addition, 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 training and awareness gap in AI, using not only its training experience but also mobilizing its well-developed communities. In Europe HIMSS and PCHA bring together a number of groups known as 'communities' from both the public and private sectors from across Europe to exchange innovative ideas, discuss best practices, trends, challenges and solutions. These communities gather not only on a regional level, but also in interest clusters. These include a community of chief technology officers of leading hospitals, a community of women in health IT, a nursing informatics community 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 stands ready to support the work to be undertaken on the ambitious objective of the European Data Strategy and the White Paper on Artificial Intelligence.

We look forward to the full development of the EU4Health Programme and the continued focus on digital health technology as a driver of efficient, effective and resilient healthcare in Europe.

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