



## DigitalHealthEurope recommendations on the European Health Data Space

Supporting responsible health data sharing and use  
through governance, policy and practice



This report has been prepared by the DigitalHealthEurope (DHE) consortium in support to the European Commission's Communication on the Digital Transformation of Health and Care in the Digital Single Market and its initiative for a European Health Data Space.

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## List of acronyms and abbreviations

AI	Artificial Intelligence
CSA	Coordination and Support Action
DGA	Data Governance Act
DHE	DigitalHealthEurope
DTHC	Digital Transformation of Health and Care
EC	European Commission
EDS	European Data Spaces
EDPB	European Data Protection Board
EHDS	European Health Data Space
eHDSI	eHealth Digital Service Infrastructure
EHR	Electronic Health Record
EHRxF	European Electronic Health Record Exchange Format
EOSC	European Open Science Cloud
ERDRI	European Rare Disease Registry Infrastructure
ERN	European Reference Network
FAIR	Findable, Accessible, Interoperable, Reusable
GDPR	General Data Protection Regulation
HTA	Health Technology Assessment
ICT	Information and Communication Technology
ITU	International Telecommunication Union
MDR	Medical Device Regulation
MS	Member States
RWD	Real World Data
RWE	Real World Evidence
SDOs	Standards Developing Organisations
WHO	World Health Organization

# 1 Vision and foundation

## 1.1 Introduction

DigitalHealthEurope (DHE) is a Co-ordination and Support Action that provides support on advancing the initiatives outlined in the *European Commission's Communication on the Digital Transformation of Health and Care in the Digital Single Market* COM(2018)233 (DTHC).

There is a rapidly growing interest in making greater use of routinely collected health data, within and outside the healthcare system (Real World Data - RWD) with an increased acceptance of Real World Evidence (RWE) by Regulators. This interest is emphasised in Priority 2 of the DTHC Communication: “*Better Data to Promote Research, Disease Prevention and Personalised Health and Care*”. Corresponding investments in this field are being made across the whole of Europe. What is to be pursued is the use of real-world data by healthcare professionals, public authorities, regulators, industry and innovators to ensure that healthcare practice, health systems, products, innovative technologies and therapies meet a patient’s needs and lead to favourable health outcomes. Such outcomes include improvement of understanding of health and disease; better anticipation of disease outbreaks; faster diagnosis and development of more effective preventive measures and treatments. These non-exclusive aspirations are relevant to shaping the success of the common European Health Data Space (EHDS), that promotes a vision for seamless health data use continuum for care, research and innovation within an ethical, secure and transparent governance framework.

While the EHDS is broader than the scope of priority 2 of the Communication, this set of recommendations focuses in particular on those legislative, policy and implementation support enablers for better availability and use of data to promote disease prevention, personalised health and care and research. The recommendations are the result of several consultations with stakeholders that took place over 18 months from early 2020 to mid-2021, an extensive analysis of health-specific and cross-sectorial studies and initiatives on the common European Data Space (EDS) and the numerous inputs published by EU level professional and industry organisations and other digital health communities<sup>1</sup>. Over the last year, DHE also participated in and contributed to several events and consultations external to DHE, including to the consultation on the European Open Science Cloud (EOSC). These discussions, together with conclusions emerging from other areas of work across DHE, have also informed the recommendations.

Over 136 participants attended the consultations and an equivalent number of individual proposals and positions have been recorded during the consultations and roundtable discussions. A great number of them echo the most common concerns across the stakeholder landscape, and have reached the European Commission (EC), Member States (MS) and the relevant communities through different consultation channels or spontaneous contributions.

## 1.2 A vision of the common European Health Data Space

A vision of the still not fully defined common European Health Data space was developed and discussed across the consultations, leading to a good level of alignment, the latter being a prerequisite to drafting recommendations that resonate well with stakeholder perceptions.

At the onset of this EHDS exploration, there was already sufficient knowledge and methodologies for supporting the uses<sup>2</sup> of real-world data, collected for health care purposes,

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<sup>1</sup> Such ecosystems studied are the myHealth@EU, the Regulators and the Rare Disease communities and the life sciences research community served by the ELIXIR platform.

<sup>2</sup> This encompasses uses of data for the purposes it was collected for and reusing it for other purposes; the term is used to replace the traditional terms of “primary” and “secondary” which imply an artificial hierarchy of use.

in research and innovation and particularly the role and the functioning of federated interrogation networks. We also found that EU, regional and national approaches share many common aspects of architectures and governance, elements of infrastructure design, success factors and bottlenecks that need to be further addressed. This is also reflected in the increasing national legislative initiatives and associated infrastructures to support data uses and create digital capacities for research. Our current context creates the opportunity for building upon these experiences to accelerate progress, fuelled by a fast-developing health data economy, within a transparently governed, common European Health Data Space supporting EU innovators and researchers for the benefit of European citizens.

The vision and main characteristics of the common European data spaces have been also outlined in two EC Communications, both supported by the “Directive on open data and the uses of public sector information”<sup>3</sup>, the Artificial Intelligence (AI) Strategy<sup>4</sup>. Specifically, COM(2018)232 “Towards a common European data space”<sup>5</sup> introduced the vision of a common European Data Space across several sectors; the strategy for its implementation has been further defined in the recently released COM(2020) 66 “A European strategy for data”<sup>6</sup> which has laid the foundations for the Proposal for a Regulation on European data governance (Data Governance Act - DGA)<sup>7</sup>.

The Act aims to create a framework that encourages greater uses of data by trust in data intermediaries<sup>8</sup> and strengthening citizens’ agency and various data-sharing mechanisms across the EU. The proposal sets out rules relating to the following:

- ▶ Conditions for uses of public sector data (including personal data) that are subject to existing protection, such as commercial confidentiality, intellectual property and data protection.
- ▶ Obligations on providers of certain data-sharing services, defined as entities that provide various types of intermediation services.
- ▶ Introduction of the concept of data altruism and the possibility for organisations to register as “Data Altruism Organisation recognised in the Union.”
- ▶ Establishment of a European Data Innovation Board, a new formal expert group chaired by the European Commission.

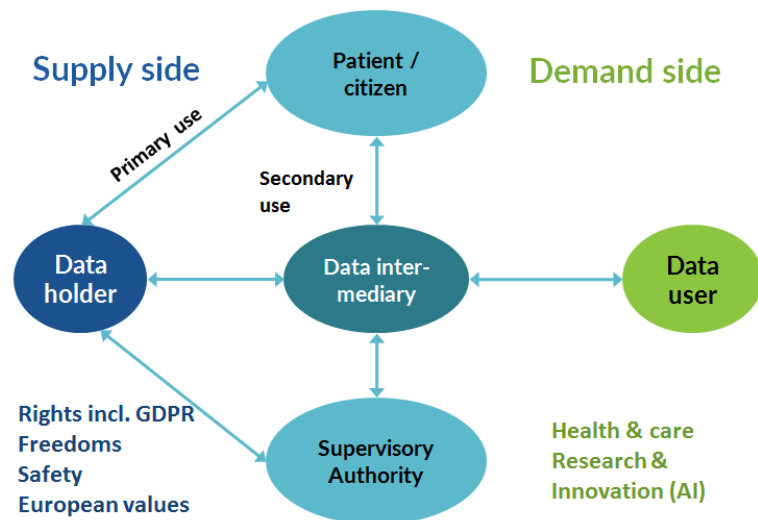


Figure 1: Role of data intermediaries in the EDS Governance

<sup>3</sup> Directive (EU) 2019/1024 on open data and the re-use of public sector information

<sup>4</sup> White Paper on Artificial Intelligence: a European approach to excellence and trust

<sup>5</sup> <https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:52018DC0232>

<sup>6</sup> [https://ec.europa.eu/info/sites/info/files/communication-european-strategy-data-19feb2020\\_en.pdf](https://ec.europa.eu/info/sites/info/files/communication-european-strategy-data-19feb2020_en.pdf)

<sup>7</sup> Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on European data governance (Data Governance Act) COM/2020/767 final <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020PC0767>

<sup>8</sup> Data intermediaries mean data sharing service providers as referred to in the DGA

The EC is in addition preparing a specific legal framework for the EHDS to address issues especially pertinent for or specific to the use of health data and is currently running a series of stakeholder consultations on the relevant Impact Assessment Framework.

Underpinning the DGA and the EHDS is a concept of using data for the public good, which has some alignment with the concept of data as a ‘public good’. However, as the traditional socio-economic definition of a public good demands that the use of the good does not diminish its value and that its use cannot be excluded, it is not perfectly suited to health data, since the potential to exclude, or control, the use of health data is a core expression of the rights of the data subject. The recommendations presented by the DHE project therefore seek to support the adoption of regulatory frameworks and business models in which data can be used multiple times, whilst respecting the rights of individuals, so that individuals and society as a whole might benefit from such use. As such, they promote a form of data as a public good, which we have termed ‘data for the public good’.

In line with this overarching governance principles running across all Data Spaces, our research and consultations have led us to an initial conceptualisation of this Health Data Space, incorporating existing and emerging research infrastructures, usually in the form of federated interrogation networks, where health data are not transferred and pooled but are made temporarily accessible for remote analysis by researchers. This “health data on demand” strategy allows health data to remain where they are, behind the firewall of the institution entrusted with protecting the privacy of the data subject. At the same time, the algorithms are sent to the data-holding entity and analytical results are sent back from the querying of the data.

The transition to federated health data infrastructures is accelerated by EU initiatives to exploit datasets in a Findable, Accessible, Interoperable and Reusable (FAIR) manner. While FAIR is an attribution of the data, rather than its use, the core of our DHE concept of data for the public good is also that its use should follow this principle.

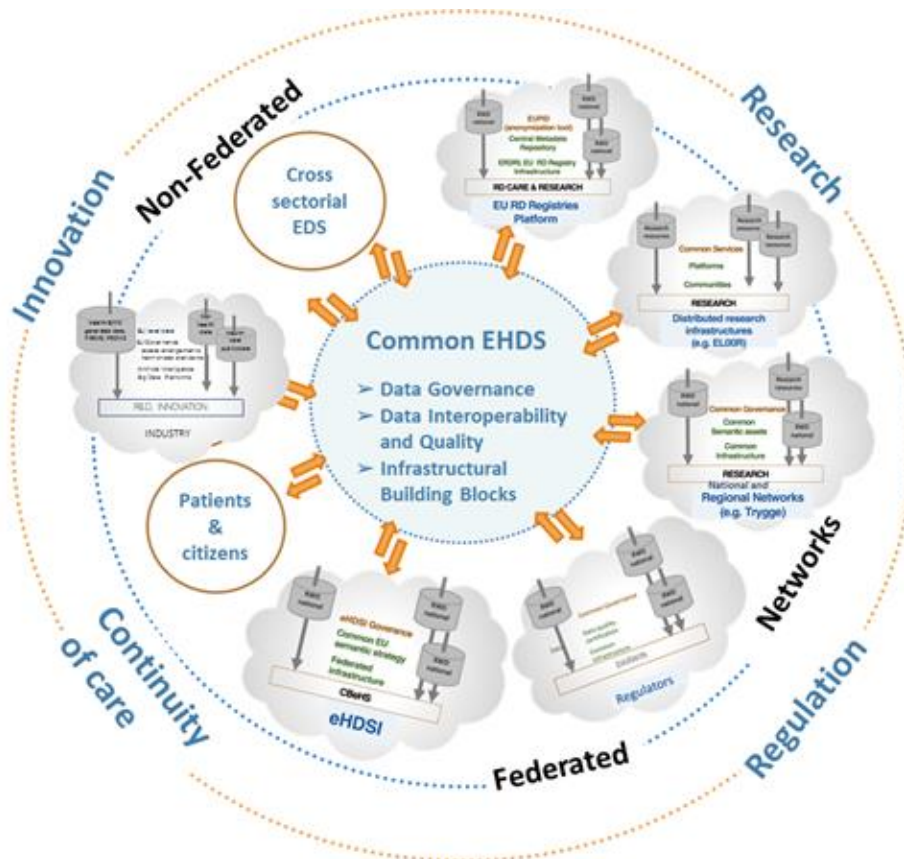


Figure 2: DHE working concept of the EHDS

Outside such networks, EU citizens contribute data through apps linked to wearable devices and fitness, nutrition and in general healthy lifestyle programs. This data has the potential to boost innovation, leveraging on big data and AI resources and computing power. Sets of public sector information, including through other sectors such as climate change, food and agriculture are also relevant to the EHDS.

### 1.3 Foundation layer of DHE recommendations

In DHE we have chosen to concentrate efforts around three major areas that represent significant transition challenges towards the common European Health Data Space:

- ▶ From privacy protection to citizen protection
- ▶ From “citizen as data subject” to “citizen as key change agent in the health data ecosystem”
- ▶ From policy and regulatory frameworks to engagement, adoption and implementation.

The direction of travel indicated by the concepts above addresses the core objectives of the Data Governance Act (DGA) (Figure 1).

- ▶ The *enabling agency<sup>9</sup> of the citizen* in determining which personal health data may be accessible for which use beyond the primary purpose of data collection (care provision for a given care episode).
- ▶ The key *enabling functions of data intermediaries*, connecting the data demand side to the data supply side, based on data sharing agreements, and their provisioned enabling capacity to operationalise and safeguard such citizen preferences on one hand, and cooperate with data providers and data users on the other hand. The objective is to generate high value, trusted Real World Data and data derivatives that can be used to answer specific research and policy questions or to power data enabled services.

Beyond DGA generic governance the DHE Recommendations have been also anchored on the following foundations:

#### 1.3.1 Citizens driving demand for FAIR data

Citizens and patients were seen as bringing a fresh potency to the demand for more interoperable and better data quality, beyond the use of the data and the strictly defined concerns of the DGA. We have also identified the great interest among citizens and patients to make better use of their own health data, which is partially data from Electronic Health Records (EHRs) and partially their own generated health data. This means that the fragmented landscape of patient facing applications and sensors must be driven strongly to be more interoperable with EHR data, so that these can be combined and used as a collective rich data resource by all.

#### 1.3.2 Data for the public good

As noted above, the traditional socio-economic concept of a public good is not fully applicable to health data. However, the potential of the use of health data to create good for the public is widely acknowledge and indeed underpins the EHDS. EU health-data-specific legislation should therefore support the concept of the use of health data as being inherently for the public good in which all stakeholders have a common interest, and where the value derivable from the data can be delivered widely across society. As well as allowing the use of health data to create public good, the concept should include the duty to make use of data where public benefit can

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<sup>9</sup> The word “agency” generally means action or intervention producing a particular effect; it is used here to indicate the importance of facilitating the capacity of the citizen to be a change agent.



be derived or be reasonably anticipated and should specify frameworks to facilitate such uses. This should be further supported by EU level guidance (see section 3.1.)

A core aspect of driving understanding and acceptance of this concept is that the emerging regulatory frameworks and business models should create conditions and transparency which allow those who make use of health data to demonstrate how value is returned to society.

In the following sections proposals for actions are presented and numbered as follows: proposals for regulatory action: R1 - R10, where R stands for regulatory, followed by proposals for common policy and strategy: P1 - P10 (P = Policy) as well as proposals for actions for further support: S1 - S11 (S = Support).

## 2 Proposals for regulatory action

### 2.1 Adapt the legal framework for trustworthy data collection, access and uses

Creating a common European Health Data Space for accessing and/or sharing data - mechanisms by which data can be made accessible to other entities, including the explicit transfer of data sets, remote access to data sets, distributed querying or other federated architectural mechanisms - for care purposes requires that:

- ▶ MS have in place national legislation, policy and infrastructures to facilitate access to and sharing of data within and across national borders.
- ▶ National infrastructures can be federated through common governance mechanisms (policies, guidelines, codes of conduct, agreements) and supported by EU-level infrastructures enforcing governance and further providing supporting tools and services.
- ▶ EU-level agreements on data sharing, data formats and agreed metadata as well as a common testing, assessment and audit framework are in place and have stimulated interoperability strategies at national levels.
- ▶ The EU agrees on an aligned long-term vision for sustainable scaling up; securing commitments of MS and the key stakeholders and providing an EU-level of co-ordination of policy and action for implementation.

In order to facilitate the adoption of mechanisms and policies above, it is important to recognise that networks of care providers and health professionals are instrumental in defining and adopting standards of the services to be commonly provided. Contributing to a high level of empowerment of key stakeholders would deliver fast and sound common agreements on clinical governance. Some useful lessons for the creation of such networks can be learned from experience of the European Reference Networks (ERNs), but it will be important to take note of the variation in health systems across the EU and to accommodate flexibility to foster uptake.

R1. Any new EU level legislation that is adopted in connection with the EHDS, and data uses more widely, should specify the elements of a trustworthy framework for health data collection, access and use that is employed when datasets are made available to diverse organisations for analysis. It should make provisions for secondary implementing legislation, where appropriate in conjunction with soft-law tools, to further specify:

- ▶ Guidelines on the types of the uses of health data that are acceptable/supported in the EU, and those that would not be supported, based on common European values; such a list should be reviewed regularly, should be based on public consultation and be readily accessible to citizens enabling them to understand the sort of uses to which data concerning them – whether personal or anonymised - may be put.

- ▶ A comprehensive set of guidelines and measures to ensure that transparency of, and accountability for, data use is preserved. The development of such guidelines and measures should include the capacity for citizens to be represented in the process of their development and access to transparent information about adherence to them by all entities who access and make use of health data.
- R2. The EU health-specific legal framework, through appropriate legal provisions and facilitators, should enable the adoption of privacy risk stratification approaches, connected to pseudonymisation levels. This would provide for organisations to proportionately balance the risk and level of protection with the intended public good from using the data to be achieved and further minimise this risk through proper diligence to avoid the identification of individuals.
- R3. The EU health-specific legal framework should encourage national and regional health data infrastructure providers and coordinators, the research community, public health agencies and European data infrastructure programmes to increase and coordinate investments that support the creation and management of data infrastructure.
- R4. The EU health-specific legal framework for data use should be adopted in plain language to facilitate the harmonised interpretation throughout all MS and a common understanding of all relevant stakeholders, including citizens, industry and other stakeholders.
- R5. Insofar as is necessary, once the EU level legislation for the EHDS has been implemented, MS and stakeholders should co-operate to develop a specific Code of Conduct as provided for under Article 40 of the GDPR to further support the uses of health data for research.
- R6. Use the capacity of the Professional Qualifications Directive<sup>10</sup> (or other relevant legislation) to promote Continuing Professional Education to develop data skills and an understanding of the GDPR across medical and legal communities.
- R7. The European Data Protection Board (EDPB) should be requested to develop detailed guidance on the relationship between the GDPR, the new EHDS legislative framework, the DGA and other relevant legislation in order to avoid potential fragmentation across the MS in the interpretation of the legislation.

All legal and ethical objectives require funded and supported systems to ensure that the voices of the stakeholders are heard in order that stakeholder voices may be fed into the policy and legislation development process at every level, and so more become readily and widely accepted (see section 4.1).

## 2.2 Accelerate interoperability across Europe and globally

- R8. The EU health specific legal framework for data use should:
- ▶ Ensure that compliance with interoperability standards at national level, in particular in digital health solutions procurement, is embedded in and supported by EU level legislation, and readily translated into national or regional level legislation and policy.
  - ▶ In line with the data safety imperative, consider the inclusion of harmonised interoperability and data quality standards into CE marking<sup>11</sup> of digital health solutions in the context of new implementing legislation to be adopted under the MDR and/ or apply the principles driving medical device safety to data safety through eHealth interoperability and data quality harmonised requirements.

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<sup>10</sup> Directive 2005/36/EC on the recognition of professional qualifications; <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32005L0036>

<sup>11</sup> CE marking: administrative marking affirming the manufacturer's conformity with European health, safety, and environmental protection standards for a product, [https://ec.europa.eu/growth/single-market/ce-marking\\_en](https://ec.europa.eu/growth/single-market/ce-marking_en)

- ▶ Include provisions for EC implementing and delegated acts for defining such standards in a stepwise, use case-based approach.
- ▶ Ensure that a regular review of level of interoperability achieved with a healthcare system is undertaken at national level and published at EU level, with assessments made public and addressed in public scrutiny.

R9. The EU health data specific legal framework should encourage the development of MS level legislation and/or other enablers to support realisation of the right of data portability as provided for in GDPR and facilitate consumer device data integration.

R10. The EC and the MS should:

- ▶ Look for opportunities to reinforce interoperability compliance as a requirement of EU level consumer protection legislation.
- ▶ Use the upcoming Medical Device Regulation (MDR) implementing legislation to support common approaches to data models and FAIR data labelling and tools.

### 3 Proposals for common policy and strategy

#### 3.1 Enable data for the public good

P1. Sharing health data for the public good demands policies, codes, guidelines and tools to balance the interests of both individuals and organisation (personal privacy, intellectual property) with public interest in resilient, efficient and effective health systems.

P2. As well as allowing the use of health data to create public good, the concept should include the duty to make use of data where public benefit can be derived or be reasonably anticipated and should specify frameworks to facilitate such use. This demands that EU, MS and stakeholders must act collaboratively to adopt policies that encourage all stakeholders to support and promote repositories of pooled anonymised health data as a key component of ensuring that data can be used for the public good:

- ▶ Define the public benefits that might be included in concepts of data use for the public good.
- ▶ Define criteria for data use and the assessment of the value generated.
- ▶ Facilitate the use of common tools to ensure a high level of accountability appropriate for data reuse.
- ▶ Develop the governance framework to assure trust in the use of data for public good.
- ▶ Ensure citizen engagement in the development of the tools and frameworks needed to use health data for the public good.
- ▶ Define standards for consent to secondary uses of health data, such as appropriately worded broad consent.

P3. The need to scale up learning from health data and to respond to urgent knowledge needs, requires a less fragmented and more pooled approach to the representation and storage of health data, so that data can be analysed rapidly, through appropriate approvals and governance, across multiple health and care providers, systems and countries.

P4. The EC and the MS should work towards EU level guidance on:

- ▶ Defining the public good that can be achieved through health data use in public policies and strategies.

- ▶ Making data sharing a requirement for public sector bodies, in accordance with Directive (EU) 2019/1024 (the “Open Data Directive”) as well as the DGA proposal (Art. 3).
- ▶ Publishing reports that demonstrate the public value generated by data uses in order to build citizen trust and reinforce data providers engagement.

### 3.2 Support citizen agency

P5. In line with the objective of promoting the use of health data for the public good, MS and EC should cooperate to:

- ▶ Engage in EU level dialogue with industry and added value service innovators on commonly acceptable policies on returning benefits to health systems and society in general.
- ▶ Consider policies for Return on Investment from European data infrastructures supporting responsible and safe data and other suitable policies that entail a visible financial or other tangible benefit.
- ▶ Explore and promote person-centric approaches and solutions for data sharing (incl. useful tools integrating meaningful self-generated data), by implementing, developing large-scale field testing and assessing results and impacts.
- ▶ Equip health data intermediaries with the necessary technical and operational tools, including national frameworks of data interoperability, to ensure data quality and portability.
- ▶ Design and implement EU level and national infrastructural building blocks to provide citizens – at a large scale - with the mechanisms to control the use of their data and exercise their rights, ensuring transparency, accountability and clarity.
- ▶ Develop a new European-wide or global digital contract to set the foundation for those digital behaviours and transactions, which are currently not clearly regulated.
- ▶ Encourage and support the use of patient generated health data and patient outcome data in the clinical setting and its use for public health and research.
- ▶ Raise awareness among citizens about their rights with respect to data use as well as data portability.
- ▶ Support and promote patient health data activism in patient associations and other civil society associations to help raise awareness of the importance of health data interoperability and reusability in building safer and better healthcare systems.

### 3.3 Facilitate public engagement, digital literacy and skills

P6. The EC and MS should scale up investments in public engagement and literacy programmes that begin in school and continue throughout the life course. This should include education about the available tools and platforms for illness prevention and self-management.

- ▶ Support and provide the governance and technical tools to enable the active engagement of the public in exploring and specifying their preferences regarding the uses of health data.
- ▶ Actively involve patients’ and citizens’ representatives in the development and monitoring of the governance frameworks for trustworthy data access and use.
- ▶ Adopt mainstream policies and strategies for digital literacy for the public, existing and future health professionals and managers, researchers, regulators, public health and

political decision makers to scale-up the knowledge and skills of all stakeholders who collect, use or make decisions about health data.

- ▶ Foster the development of continuing education programmes for health care professionals and legal professionals on data protection, data protection legislation and mechanisms to comply with it.
- ▶ Provide financial support to further develop digital literacy programs for both professionals and citizens.
- ▶ Encourage the development of platforms supporting public debates and engaging a broad spectrum of stakeholders.

### 3.4 Leverage the efforts of technology innovators

P7. The European Commission and the MS should:

- ▶ Explore models for incentivising data integration into EHRs and health systems from consumer devices. This should include supporting the development, profiling and adoption of interoperability standards and data quality rules applicable to patient and citizen generated data through apps, wearables, sensors and complementary non-health but health relevant data such as pollution and climate data.
- ▶ Establish a multi-stakeholder forum for co-creating and sharing valuable and proven business models for secondary use of diverse kinds of health data.
- ▶ Recognise the potential value, and leverage, the penetration of major digital health consumer ecosystems (such as iOS and AndroidOS) within mHealth solutions.
- ▶ Establish new models at a European level to certify, embed within health systems and share evidence of outcomes using soft law and cooperative agreements.

### 3.5 Ensure data quality and data interoperability

P8. The European Commission together with Member States should

- ▶ Ensure proper implementation of the right to data portability as set out in the GDPR on a large-scale and with the optimal utility to the data subject.
- ▶ Take measures to improve data quality at health care provider level and ensure that data from devices and/or reported by patients can migrate to a common health data space.
- ▶ Pursue EU-level agreements with the relevant Standards Development Organisations (SDOs).
- ▶ Complement the current digital health standardisation agenda with a 5-year strategy and roadmap that encompasses the development and maturation of standards and interoperability specifications for telehealth, particularly tele-monitoring as well as clear timed output for different profile-associated guidelines.
- ▶ Implement a “secure health data handling” label for federated health data platforms, networks and products to convey trust for consumers and facilitate adoption.
- ▶ Control the use and dissemination of interoperability standards centrally where legally possible.
- ▶ Collect and disseminate information about success stories (including financial and societal value from different business models) for secondary use of health data.
- ▶ Collect information about the impact of various incentives for data sharing and take appropriate action.

- ▶ Define a common approach towards encryption and anonymisation techniques.
  - ▶ Adopt a standard communication protocol which enables citizens to download their health data in line with the GDPR.
  - ▶ Enable a radical change in ICT products and procurement, to support a transformational approach to health data.
- P9. The EC and the MS should work with appropriate stakeholders towards EU level guidance to
- ▶ Develop a minimum digital health competency set.
  - ▶ Facilitate a more motivating culture among healthcare professionals including through requirements for more user-friendly EHR system user interfaces.
  - ▶ Define requirements for a balanced European approach to new initiatives to support informed consent, such as privacy dashboards and identity management services and tools. This would enable a more dynamic and citizen-centred approach to establishing trust.
  - ▶ Foster a common approach and share best practices towards data security measures building on the GDPR and the DGA.
  - ▶ Incentivise data sharing through financial support of curation activities where this is needed to make data more shareable, and public recognition of entities making substantial contributions of reusable data.
  - ▶ Incentivise, supporting and monitoring the quality of shared data, including through the adoption of common data quality criteria and labels that data controllers who provide data to the EHDS are required to use and display when sharing data.
- P10. The EC should more strongly encourage health data generated through its funded projects to be more widely reusable via the EHDS.

## 4 Proposals for actions for further support

### 4.1 Support large scale implementation pilots and health data infrastructures

- S1. The EC, through its funding instruments and policy support programmes should prioritise large scale and multi-stakeholder cross organisational/sectoral network pilots, involving health data use in domains that present the greatest opportunities for making quick advancements and drawing useful and transferable learnings to less mature domains. These should be supported by Co-ordination and Support Actions as appropriate (see 4.2).
- S2. Scale up investments in the development of use case driven data specifications in which multiple interoperability standards are profiled to fit well together, alongside data quality rules, to promote consistent and consistently usable data resources across Europe, for example to enable reliable AI development. These data specifications need to be additional and complementary to the EHRxF and should benefit from extensive large-scale piloting efforts both cross-border and between local, regional and national health organisations.
- S3. Opportunity areas may be prioritised according to the following non-exhaustive list of criteria:
- ▶ Where aggregated FAIR and good quality health data has been collected in national institutional registries,
  - ▶ Where there is significant potential of linking data to EHR systems and enrich it with patient reported outcomes and personal device data.

- ▶ With concurrent existence of cross-border collaborating networks of institutions, where the data is held.
- ▶ Where there is clear and direct anticipated impact in terms of improving patient care, healthcare and healthcare financing systems and patient experience.
- ▶ Where availability of linked, curated and harmonised data across EU MS can demonstrate significant potential for digital innovation and contribution to the FAIR data economy.

S4. Example opportunity areas include:

- ▶ Social insurance registries holding information of resource usage and health care costs. When combined with EHR data and patient reported outcomes, they can fuel a virtuous cycle of learning - including through HTA and other assessment frameworks – and improvement, as well as a plethora of patient-centred and health care system oriented digital services.
- ▶ Disease registries held in health care institutions and competent organisations, which can leverage lessons learned from the ERN experience and the EU infrastructure (ERDRI) linking rare disease registries. This experience should be augmented by creating a high level of connectivity with EHR systems and patient reported data including for improving the data collection methods in the registries themselves.
- ▶ Expanding existing and/or evolving cross-border infrastructures such as the eHDSI to support cross border, digital health services for chronic disease patients. These services should leverage the current and foreseen basic cross border services (exchange of patient summaries, e-prescriptions, lab and image data) to create integrated cross border services<sup>12</sup>. Taking this step would also require clinical and business models based on the voluntary harmonisation of mobile health practices, including App assessment and certification frameworks and integration of mHealth into health care and health financing systems.

S5. The implementation of support actions described above should entail:

- ▶ Attracting pump-priming investments for implementation and early operation.
- ▶ Developing medium and long-term business models for sustainability, including return on investment.
- ▶ Investing in the actual data, e.g., in data quality improvements and data provision resources.

## 4.2 Support large scale implementation through specific focus projects and co-ordination and support actions

S6. The above-mentioned large implementation pilots and projects will require to be further supported by projects in a number of areas to trigger concept development and to help multiple sites across different countries to scale up digital health adoption and health data ecosystems, including the wider use of homecare/telemonitoring solutions connected to health care professionals. A large, branded effort, like “One Million Connected Homes” initiative aggregating Ministries of Health and EC<sup>13</sup>, could be a way to communicate this effectively and put resources from industry and local councils, and to focus on a quantifiable target, exploring the potential of Internet of Things and AI.

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<sup>12</sup> VALUeHEALTH has explored in detail the preconditions for expanding the current cross border services into this priority area, identified the gaps that need be addressed and exemplified it through a real-life user story.

<sup>13</sup> In a model not too dissimilar from “One Million Genomes”.

S7. Areas needing additional co-ordination and support include:

- ▶ Addressing horizontal technical challenges, such as standardisation of administrative patient data, consent management tools and consent services including interoperability of consent, infrastructural building blocks and reference implementations to support harmonised practices across data intermediaries etc.
- ▶ Elaboration of EU level guidance, leveraging MS current and planned practice, providing target standards for population and professional digital, health and data literacy.
- ▶ Educational curriculum development for the public, and the medical and research community, for a 21st century in collaboration with professionals' associations, informal health data caregivers and other digital health relevant partners such as medical schools and universities, and Ministries of Education. It should focus on a digital health curriculum and minimum competency set and promote concepts and good practices of patient data custodianship.
- ▶ Design and implementation of communication strategies, campaigns and technical platforms to encourage patients and citizens to become strong advocates for joined up (interoperable) health data. Support of citizens in balancing illness and wellbeing (prevention) needs and championing their active engagement in all aspects of policy and strategy relating to the uses of health data for care and for the public good.

S8. Support regional and national early adopters to collaborate across borders to develop best practices and act on lessons learned to accelerate the use of data. This should leverage mature and high priority use cases which support:

- ▶ The design, creation and management of big data infrastructures.
- ▶ Consolidated efforts ensuring health data at source is of a good and known quality, appropriately harmonised.
- ▶ Efforts ensuring the development of well framed questions can generate trustworthy answers to support more accurate evidence-based decision-making.
- ▶ The promotion and uptake of federated data models to facilitate interoperability, connectivity and fair data access while upholding GDPR compliance.
- ▶ Consolidated efforts on one or a small number of common data models so that data harmonisation methods, tools and skills can be scaled up to become a readily available and affordable resource.
- ▶ The definition of a common approach towards data encryption and anonymisation techniques.
- ▶ The deposition of project outputs ensuring they are accessible and reusable for future projects, with an emphasis on interoperability and collaboration to avoid redundancy.

S9. Accelerate interoperability across Europe, through support to Member States to more proactively aligning with each other on common interoperability standards choices and promoting their adoption through procurement and products cross-border with the active engagement of patients and citizens whose data must also be interoperable.

S10. Enable running European projects to support the European Health Data Space by focusing supplementary funds on a common catalogue of project outputs.

### **4.3 Establish a European Digital Health Hub**

S11. Establish a European Digital Health Hub to act as a central, maintained and sustainable focal point, to bring together knowledge and resources to:



- ▶ Collect, assess, consolidate resources and expert guidance and facilitate access of clinical and research communities, and MS/regions to and use of the EHDS assets produced through the above actions and other projects and initiatives.
- ▶ Connect to it digital health hubs and encourage their development where they do not exist, such that they can be gateways to MS specific information and link to shareable trusted resources.
- ▶ Use synergies with WHO EU Observatory and WHO/ITU mHealth Hub.

#### 4.4 Scale up research and innovation to advance Europe's digital capacity for clinical research

S12. Invest in research and innovation areas that better enable fine-grained and highly personalised digital twins<sup>14</sup> and avatars<sup>15</sup> to be analysed at scale as just-in-time virtual cohorts<sup>16</sup>, addressing gaps in integrating multimodal data at EU level, to tackle holistically high-priority disease areas such as cancer and brain disease.

- ▶ Scale up the capture and integration within EHRs of genomic, biomarker and microbiome information from patients.
- ▶ Scale up the fusion of health data with agriculture and environmental data spaces to address challenges such as antimicrobial resistance and lifestyle influences on disease.
- ▶ Demonstrate data sharing collaborations with industry data spaces to improve the design, monitoring, post market surveillance and predictive maintenance of medical devices and equipment installed in health care provider organisations.
- ▶ Accelerate research into information security advances to enable the federated analysis of this rich multimodal data without diminishing its accuracy for advanced techniques like AI development, whilst ensuring robust data protection:
  - Errors and statistical corrections for low quality data, and the generation of synthetic data, e.g., for the training and validation of AI.
  - Risk-based anonymisation methods that incorporate a proportionate approach to the levels of risk according to a wide view of safeguards and the intended societal benefit from using the data.
  - The development of synthetic data sandboxes to enable research into novel security approaches and the training of AI algorithms.

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<sup>14</sup> Digital Twin: Digital assets that use data about genomics, proteomics and other omics, as well as EHR data and multiple wellness and behavioural (humanome) data to "represent" a certain individual. (Note: not to be seen as a fixed definition, but rather as a helpful descriptor for this context)

<sup>15</sup> Avatar: Digital representation/personification (may not fully capture all aspects of a person) of an individual (often only the face) or its personality, that acts and eventually reacts in similar ways as the individual would have reacted. (Note: not to be seen as a fixed definition, but rather as a helpful descriptor for this context)

<sup>16</sup> Virtual cohorts: Groups of digital twins that allow/serve the purposes of in silico testing/experimenting with simulations of usage of a drug/other intervention, to try to create in-silico trials. (Note: not to be seen as a fixed definition, but rather as a helpful descriptor for this context)

## ANNEX: DHE Consultations

DHE Event	Participation
Joining the Dots Conference November 2019	150 conference participants The recommendations were presented formally to the eHealth Network.
Consultation with Industry 26/05/2020	40 experts <ul style="list-style-type: none"> <li>• Competitive ICT and service innovation industry</li> <li>• Health IT,</li> <li>• Pharma,</li> <li>• Medical devices,</li> <li>• Publishing and research organisations</li> <li>• Networks and associations</li> <li>• Representatives from DG CNCET and DG SANTE</li> </ul>
Consultation with citizens, incl. patients 22/10/2020	17 citizens/patients <ul style="list-style-type: none"> <li>• All regions of Europe,</li> <li>• At least ten health conditions</li> <li>• Sometimes in multi-morbid combinations</li> </ul> 10 further representatives <ul style="list-style-type: none"> <li>• Patient organisations</li> <li>• Representatives from DG CNCET and DG SANTE</li> </ul>
Consultation on cloud technology in health data use 25/03/2021	19 participants <ul style="list-style-type: none"> <li>• Competitive ICT and service innovation industry</li> <li>• Publishing and research organisations</li> <li>• Networks and associations</li> <li>• Independent experts</li> <li>• Representatives from the European Commission</li> </ul>
eHealth Stakeholder Group Webinar: Recommendations for responsible health data sharing and use 28/05/2021	56 participants <ul style="list-style-type: none"> <li>• Representatives from 25 eHSG member organisations</li> <li>• Representatives from DG CNECT and DG SANTE</li> </ul>
<b>DHE Supported Events</b>	
Two industry Round Tables organised by DHS and I~HD: <ul style="list-style-type: none"> <li>• Acceptance criteria for societal trust in the use of health data, 03/09/2020</li> <li>• A recipe for trustworthy digital health: standards, architecture and value, 30/10/2020</li> </ul>	27 participants <ul style="list-style-type: none"> <li>• Patient organisations,</li> <li>• Healthcare providers,</li> <li>• Payers,</li> <li>• Ministries,</li> <li>• Data protection authorities,</li> <li>• Industry and industry associations</li> <li>• Representatives from the European Commission</li> </ul>