



Better citizens' access to & sharing of health data

White Paper



This paper was developed for the
European Commission by



Lead Authors

Nuno Silva
Samuel Jacinto
Luis Caturno
Diogo Martins
Vanessa Mendes (SPMS)

Editors

Diane Whitehouse (EHTEL)
Anett Ruszanov (empirica)
Strahil Birov (empirica)

Acknowledgements

DigitalHealthEurope has received
funding from the European Union's
Horizon 2020 Research and Innovation
programme under the Grant Agreement
No. 826353.

DISCLAIMER

The information and views set out in this
publication are those of the authors and do not
necessarily reflect the official opinion of the
European Commission. The Commission does not
guarantee the accuracy of the data included in
this study. Neither the Commission nor any
person acting on the Commission's behalf may be
held responsible for the use which may be made
of the information contained therein.

Introducing the challenge

DigitalHealthEurope, a project taking place with the support of the European Commission, has three main priorities for the digital transformation of health and care (DTHC). One of them is **citizens' secure access to and sharing of health data across borders**.

By 2020, citizens' secure access to and sharing of data across borders was under considerable pressure. Throughout the past year, the global COVID-19 pandemic had a significant and unparalleled impact on the health, social and economic condition of every country in Europe. In healthcare, the imposition of lockdowns and social distancing has **modified traditional face-to-face healthcare delivery models**. This new situation has led to a rapid acceleration in the adoption of digital solutions, especially the use of telehealth – including virtual consultations and remote patient monitoring. The ongoing implications of pandemics – and their direct and indirect effects – now need to be borne in mind. Of considerable importance is **citizens' engagement and involvement in access to and control of their own health data**.

One of the DigitalHealthEurope **White Papers** outlines potential future directions on health data, and citizens' secure access to it. The paper's ultimate purpose is to offer potential **key messages for national and regional policy makers and authorities**, while bearing in mind the background context of COVID-19.

The paper outlines conclusions around three themes:

- ▶ **Digital health literacy**, its importance and how it can be advanced.
- ▶ **Access to and sharing of data:**
 - The way patients/citizens **access their health data** and how the access can be promoted.
 - How **sharing data** can be easier to do, yet secure, including the role played by infrastructure.
- ▶ **Engagement and involvement** on the part of citizens and patients.



To reach these conclusions, DigitalHealthEurope undertook **an analysis** of the work of numerous European projects, initiatives, and proposals for strategic solutions. DigitalHealthEurope's work also encompassed **interviews, surveys, meetings, and stakeholder engagement**.

This **summary report** outlines the major themes of the whole White Paper. For more detail, read DigitalHealthEurope's full deliverable D4.1: *White paper on better citizen access & control of data*. Take a look too at other complementary DigitalHealthEurope White Papers.¹ See especially DigitalHealthEurope's "recommendations on the European Health Data Space" report.²



¹ <https://digitalhealtheuropa.eu/results-and-publications/>

² https://digitalhealtheuropa.eu/wp-content/uploads/DHE_recommendations_on_EHDS_July_2021.pdf

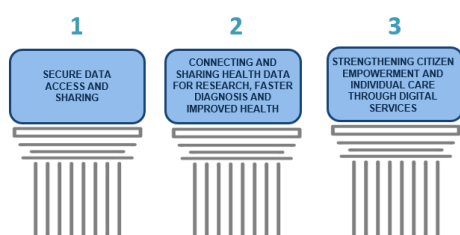
Considering underpinning policies and issues

The **Digital Single Market**³ was launched by the European Commission in 2015. It aims to open up digital opportunities to people and businesses, and enable the European Union (EU)'s single market to shape digital society across Europe. Health is one of the important sectors on its agenda.

Digitalisation is key to health. It can support continuity of care at national level and across borders: this is an important provision for people who spend time abroad, whether for business or leisure purposes. It can assist in the reform of health systems and their transition to new care models that are centred on people's needs. It can also enable a shift away from hospital-centred systems to more community-based and integrated care structures.⁴

A relevant **Communication** was published by the European Commission in April 2018.⁵ Its focus was on "enabling the digital transformation of health and care (DTHC) in the Digital Single Market, empowering citizens and building a healthier society" It was produced in response to the Council Conclusions that invited Member States and the Commission to work together to seize the potential offered by digital technologies in health and care.

The Communication lays out European Union actions in **three priority areas**. The first of these three areas is the focus of this White Paper.



Priority areas of digital transformation of health and care.

Health data and data management are crucial when it comes to empowering citizens and building a healthier society. Thus, the DTHC's first priority is to make it possible for **citizens to exercise their right to access their health data across the European Union**,

including through the interoperability of Electronic Health Record (EHR)⁶ systems.

"Citizens should have secure access, anywhere in the EU, to a comprehensive electronic record of their health data. Citizens should remain in control of and be able to share their health data securely with authorised parties (for medical treatment, preventive services, research or for any other purpose they deem appropriate). This should be irrespective of where the data is located and in line with data protection legislation. Unauthorised access should be prevented."

Introducing citizens' health data access

Citizens' **right to have access to their own health data** is a core principle of the European Union data protection *acquis*. Flexible systems and tools are needed that enable citizens to access their own data and information on the use of their data, as well as to manage their consent to processing and sharing their health data, including for secondary use. These systems and tools will help to give people insight into/better control over the use of their health data, thus promoting trust and transparency. Account is also taken of the different attitudes and preferences of individuals or groups when it comes to accessing and managing their data online.⁷

DigitalHealthEurope started its work on better citizens' health data access by drawing on some **key principles and initiatives made public by the European Union**. Among them were statements made by the eHealth Stakeholder Group in 2013⁸ and a 2017 Open Public Consultation.⁹

"EHRs have the potential to empower consumers and patients by providing them with easier access to their health information, allowing them to exert more control over their health records, thereby becoming more responsible and more active in their own care while facilitating communication with their health professionals."

The 2017 Open Public Consultation showed that more than 90% of the almost 1,500 respondents from 35 countries agreed that **citizens should be able to**

³ <https://ec.europa.eu/digital-single-market/en/policies/shaping-digital-single-market>

⁴ <http://www.oecd.org/health/ministerial/ministerial-statement-2017.pdf>

⁵ http://ec.europa.eu/newsroom/dae/document.cfm?doc_id=51628

⁶ https://www.eu-patient.eu/globalassets/policy/ehr-survey-2020_summary_final.pdf

⁷ <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2017:440:0003:0009:EN:PDF>

⁸ <https://blogs.bmj.com/ejhp/2014/04/15/four-reports-of-ehealth-stakeholder-group-published/>

⁹ https://ec.europa.eu/health/sites/default/files/ehealth/docs/2018_consultation_dsm_en.pdf

manage their own health data. More than 80% agreed that sharing of health data can improve treatment and prevent diseases.¹⁰

A 2020 DigitalHealthEurope's large-scale citizen survey of more than 900 Europeans¹¹, however, showed that more than half of all the respondents did not know who has access to and control of their health information.

Today, some European citizens can access part of their electronic health records at national level or across borders, while many others have limited digital access or no access at all.¹² Data is often not traceable or are scattered about in different locations. Currently, there are limitations to the extent to which citizens' health data exchange takes place in Europe.

In the Spanish autonomous region of Andalucía, there are different ways to access digital health data. A web-based citizen folder (Clicsalud+) and a mobile-based one, Salud Andalucía, are open to all citizens belonging to the Andalusian public healthcare system (SSPA), a collective of 8.5 million Andalusian inhabitants. Salud Andalucía includes information of interest and news about current healthcare, as well as two specific tools on COVID-19 (a self-test and a virtual assistant). It offers access to a catalogue of health-related apps approved by the Andalusian Public Health System.

Some European initiatives are, however, seeking to expand a move towards greater health data exchange: examples include X-eHealth.¹³

Many regulatory and legislative developments are underway. Major enablers of citizens' access to and management of their personal health data, through their implicit provision of a European legal framework for the cross-border sharing of data, are the General Data Protection Regulation (GDPR)¹⁴ and eIDAS Regulation.¹⁵

The ability of citizens and healthcare providers to securely access and share electronic health records can result in a number of benefits:

- ▶ Improvement in the quality of care for citizens.
- ▶ Reduction in the cost of healthcare to households.
- ▶ Support for the modernisation of health systems in the Union.

These approaches save time for all the parties involved and improve the quality of care. It is for this reason that, in 2019, agreement was reached about a standardised exchange format for electronic health records in Europe.¹⁶

Focusing in Europe on better access to data

From 2018 onwards, there has been a growing consensus in Europe that digital healthcare data sharing could go further than only improving a patient's individual care through early diagnosis.¹⁷ Health data sharing could enhance global healthcare innovation, provide a better understanding of disease, and advance development of new treatments.

Better access to health data has to include and find an improved complementarity among a wide range of concerns, such as functionality, security, usability and accessibility, performance, privacy, and trust.¹⁸ These are among the main factors to encourage citizens to manage their own

health data information in a safe, confidential, transparent, and secure way.

The European Union needs to develop a robust sustainable alternative for the use of personal health data that stand in contrast with the approach of American (USA-based) technology companies that seek to profit from people's social or personal data. There is a clear need for a business model that benefits both the actual providers and owners of the data.

As health data becomes more available to doctors, patients, and healthcare professionals, each member of the healthcare ecosystem can improve their own effectiveness.¹⁹

¹⁰ <https://ec.europa.eu/digital-single-market/en/european-policy-ehealth>

¹¹ <https://digitalhealtheuropa.eu/wp-content/uploads/2020/11/Consultation-Paper-Citizen-controlled-health-data-sharing-governance.pdf>

¹² https://ec.europa.eu/commission/presscorner/detail/en/IP_19_842

¹³ <http://www.x-ehealth.eu/>

¹⁴ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=EN>

¹⁵ <https://www.eidas/home/>

¹⁶ <https://digital-strategy.ec.europa.eu/en/library/recommendation-european-electronic-health-record-exchange-format>

¹⁷ <https://connections.eithealth.eu/documents/1955789/0/Need+report+Personal+Health+Data+for+Citizens/bf28978b-3a0a-e655-93b1-84a17e3a9a29?version=1.0>

¹⁸ <https://www.med.uio.no/helsam/english/research/projects/capable/>

¹⁹ <https://www.jmir.org/2013/3/e65/>

Capturing the evidence

The **evidence** used to build the content of the full White Paper was gathered from a number of sources. Some sources were desk research-based. Others involved discussions with people.

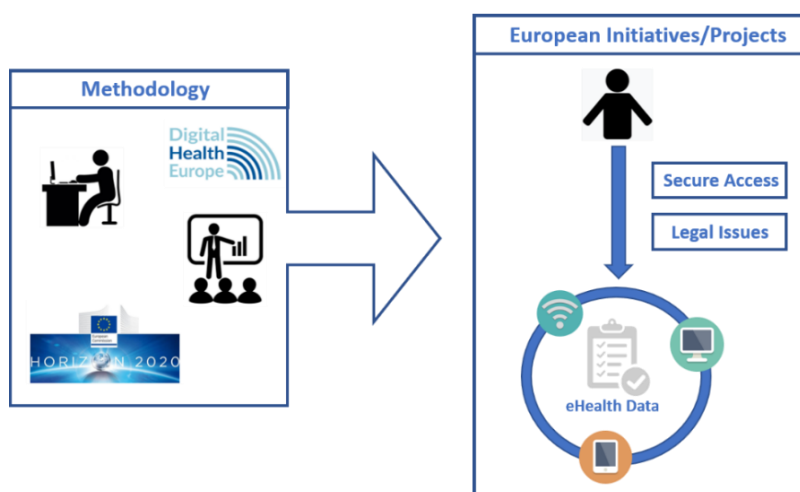
First, a study was undertaken. It produced a **systematic collection of initiatives** which address the issues and solutions to a citizens' secure access and sharing of health data. Its scope was to analyse and summarise the most relevant projects and national/regional initiatives used today in Europe related to citizens' access and the management of the health data, by taking into account interoperability standards, data privacy, and security issues.

Second, a **small set of seven interviews** were conducted that focused on two issues: citizen access to and sharing of data relevant to their health, and identification and communication.

Third, follow-up took place through a **larger survey**. It gathered together 13 responses from a range of European Member States. The survey concentrated on enabling factors and building blocks to access to health data. It built the foundation for concepts and findings used in later stages of the work done by DigitalHealthEurope. It helped in developing a sense of engagement and commitment on the part of the Member States: they identified their own initiatives around citizens' secure access to health data and made an overall assessment of them.

Fourth, throughout 2019, 2020, and 2021, DigitalHealthEurope organised several **interactions with experts, institutions and stakeholders** on citizens' secure access to data, including interviews, workshops, and events.^{20, 21, 22}

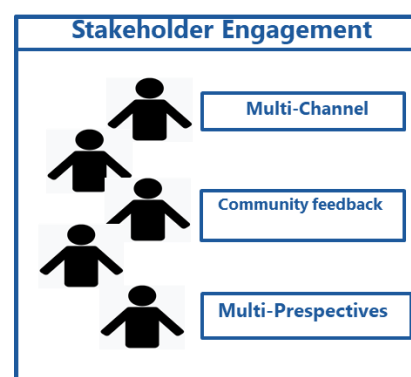
With all these initiatives and events, DigitalHealthEurope had the opportunity to gather important **stakeholder views**.



Representation of different types of stakeholder engagement

A good definition of **stakeholder engagement** is:²³

“the process by which an organisation involves people who may be affected by the decisions it makes or can influence the implementation of its decisions. They may support or oppose the decisions, be influential in the organisation or within the community in which it operates, hold relevant official positions or be affected in the long term”.



Methods used to capture evidence on citizens' secure access to health data

²⁰ <https://ehealthsummit.pt/news/portugal-ehealth-summit-2019/>

²¹ <https://www.healthdataforum.eu/>

²² <https://www.aging2.com/about/>

²³ https://en.wikipedia.org/wiki/Stakeholder_engagement

Outlining barriers and enablers

According to the General Data Protection Regulation²⁴ which entered into application on 25 May, 2018, all European Union citizens have the **right to access and share their own data**. This right should put citizens in control of the use of their personal data, including health data.

By sharing their health data for better prognosis, diagnosis and treatment, citizens should become more empowered and therefore better able to steer their own health. Developments in big data processing and artificial intelligence (AI) promise that far more personalised lifestyle advice will become available to citizens, based on these data.

Many **challenges** still have to be overcome, however, before such a vision becomes reality.

DigitalHealthEurope launched its work into investigating the challenge of citizens' use of health data by deep-diving into **four main areas of concern**:

- ▶ Citizens' access and control of data.
- ▶ Digital health literacy.
- ▶ Citizens' engagement strategies, including data cooperatives and social media.
- ▶ Access to health data tools.

Starting from a stakeholder workshop held on 21 March 2019,²⁵ DigitalHealthEurope used findings from many European Member States and regions, experts, and stakeholders to build a concrete picture of the **barriers** and **enablers** in this whole field. This summary offers an overview of those obstacles and facilitating mechanisms as seen largely during the early stages of work of DigitalHealthEurope.

Citizens' access and control of data

Two sets of findings on **barriers** and **enablers** emerged in relation to citizens' access and control of data. One set related to what acted as an obstacle or a facilitator to the initiatives themselves; the second set referred to citizens' own access to/control of data.

Barriers and enablers to the initiatives themselves:

Key information provided to DigitalHealthEurope enabled the analysis of 24 initiatives/projects from 11 different countries in Europe. Eleven projects took place at national level, nine at regional level, and four at European level. Most projects were undertaken at national level. There was, however, a high degree of

regionalisation of health services in certain countries such as Italy, Spain, and the United Kingdom.

Most initiatives/projects referred to a **citizen portal** through which citizens can access their health data. Most of the portals allowed the scheduling of medical appointments, digital prescriptions, and repeat prescriptions (e.g., in Estonia and Portugal). Particular patients were sometimes targeted (such as older people, people with chronic diseases, and people needing home care or specific prescriptions). Examples of **different kinds of data** in such portals included diagnostic images, laboratory results, medical records, prescriptions, and information about vaccinations.

There were five **barriers** identified to the implementation of the initiatives.

List of barriers to the implementation of initiatives analysed

- ✓ A lack of digital literacy, mainly on the part of older people.
- ✓ Data is often not understandable by patients.
- ✓ Resistance to change, on the part of either or both patients and doctors.
- ✓ Interoperability challenges.
- ✓ A lack of dissemination of information about the initiatives.

All the initiatives were also analysed in relation to the security and protection of health data. A priority that was highlighted was the need for **access to the portal to be strictly controlled through personal credentials**. Examples of such credentials include the use of an identity (ID) card, mobile ID, a personal identification number (PIN), or usernames and passwords.

There were seven most relevant factors mentioned that acted as **enablers** to the portal initiatives' **success**.

List of enablers to the success of the portal initiatives analysed

- ✓ User-friendliness.
- ✓ High digital literacy.
- ✓ Widespread interest in digital services.
- ✓ Availability of mobile technology.
- ✓ Data security.
- ✓ Provision of services, such as digital prescriptions and digital health data.
- ✓ Financial incentives.

A **broad consensus** arose in DigitalHealthEurope that digital healthcare data sharing will not only improve a patient's individual care through early diagnosis, but could enhance global healthcare innovation, provide

²⁴ <https://gdpr-info.eu/>

²⁵ <https://digitalhealtheurope.eu/events/digitalhealtheurope-collaboration-platform-on-citizens-secure-access-to-and-sharing-of-health-data-workshop/>

a better understanding of disease, and advance development of new treatments. Much DigitalHealthEurope work focused, nevertheless, on citizens' own access to and control of health data.

Barriers and enablers to citizens' own access to and control of data: Some reactions and thoughts from DigitalHealthEurope interviewees show the practicality and pragmatism of citizens' needs in terms of access to and control of their own data.



Key questions that built on these citizens' reactions and thoughts are: How can citizens co-manage their data with organisations so as to allow meaningful action for different parties? What are the challenges to such an approach? What are the barriers?

Three key challenges arose. First, they related mostly to the concept of **trust** (see e.g., difficulties expressed relating to health and care professionals lack of trust of patient data entry or data coming from home-based or personal devices. Second, another main barrier lay around the lack of **choice of interface** and the limited **re-usability of the data**. Third, in some cases, the most important challenge was the **need for strong authentication mechanisms** to enable access to sensitive data stored in an electronic health record. On the one hand, this third challenge can be seen as technological but, on the other hand, it also represents access difficulties for certain sectors of the population (e.g., older or elderly adults) The main resulting challenge would therefore be **the degree of digital literacy** needed to understand and make effective use of health data.

There are 12 main barriers that citizens face in terms of accessing their own data.

Main barriers to citizens' access to their own health data

- ✓ Fragmentation of citizens' health data on different platforms and coming from different sources.
- ✓ Citizens are not aware of how they can access their data from their homes.
- ✓ Lack of clear policies, education and guidelines for patients.
- ✓ Low digital skills and literacy of some social groups of patients and health professionals.
- ✓ Lack of financial incentives to use digital health tools.
- ✓ Lack of interoperability of systems.
- ✓ Lack of unique, secure identification mechanism for enabling access.

- ✓ Low awareness from the citizens' side of the importance of data.
- ✓ Few efforts on the part of government agencies to promote existing platforms.
- ✓ Insufficient change management efforts to make use of digital tools into a "new normal".
- ✓ The predominance of digitisation over digitalisation of services.
- ✓ The unwillingness of key change actors (doctors, nurses, administrators) to adopt the new (digital) tools.

Regarding the **enabling** factors, both **education** and **trust** play a key role. According to the results which emerged from the interviews, citizens will be 'open' to sharing their data if they understand and trust that the data will be used for the public good and for research. Additional enabling factors can also be considered.

Main enablers to citizens' access to own health data

- ✓ Health and digital literacy.
- ✓ Simple intuitive tools to pool in all citizens' data in one space.
- ✓ Increased awareness of the public about the importance and value of having access to their data.
- ✓ Broadband and education.
- ✓ Good IT infrastructure, connectivity, and devices.
- ✓ Financial incentives to use digital health tools.
- ✓ User-friendly digital health solutions.
- ✓ Unique point of access of all health data.
- ✓ A unified identity for each citizen.
- ✓ Open statutory data exchange platforms
- ✓ Personal data exchange and storage options complementary to patient portals.
- ✓ Regulated means of creating 'trusted' data brokers.
- ✓ Quality tools that solve real problems.
- ✓ A clear and operational legal and administrative framework for the development of such tools.
- ✓ Effective change management strategies.
- ✓ The actual needs that people have for accessing health data.



Driven by pragmatism, patients need to access their records and that access should be facilitated. People do not only want to access their data, they also want **more functionalities** to be added. Alternative approaches to the use of products and tools could be applied, based more around **co-design**. Products or services co-designed with end users could enable people to be connected with **data brokers** who could handle in a trusted way any complexity that people experience.

In Póvoa de Varzim-Vila do Conde Hospital Center, citizen spaces were created in each centre that had the mission of helping users to join the hospital and national health service digital platforms. Adherence to a digital mobile key was provided as well as support in creating emails and access to teleconsultations. One of the most successful initiatives in Portugal was the "The Hospital goes to the beach" initiative, which was awarded with "An action INCoDe.2030" seal and, with governmental approval, integrated into the "National Initiative in Digital Skills".

Digital health literacy

The use of **information and communication technologies** (ICT) in health is increasingly common, and is fast becoming mainstream. According to the World Health Organization, 58% of its Member States have an eHealth strategy, 55% of the countries have legislation to protect electronic patient data, and 87% of countries report having one or more national initiatives.²⁶

Digital technologies can help citizens and professionals address preventable risk factors associated with chronic diseases. They can support active and healthy ageing, and facilitate early detection of symptoms and timely treatment, thus reducing the need for more demanding, later treatments. Digital solutions that empower citizens with access to their personal health data are central to supporting a shift in health and care provision; they enable citizens to be actively engaged in the prevention of chronic conditions (i.e., in active and healthy ageing), adherence to treatments, and provide feedback on the quality of health and care.²⁷

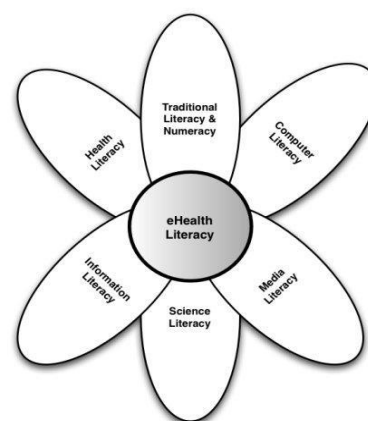
For better access to digital health for all people regardless of their age, **digital literacy** plays a crucial role. Digital literacy is more than technological know-how: it includes a wide variety of ethical, social and reflective practices that are embedded in work, learning, leisure and daily life.

With regard to citizens' control over their personal data, the example of MIDATA, from Switzerland, shows how data can be used to strengthen the engagement of citizens with healthcare systems, as well as with their own health.

Governments that are interested in equipping citizens with **21st century skills** have to commit themselves to putting digital literacy and the promotion of the associated competences into focus in their **strategic plans**. Digital literacy is associated with the **skills that enable the use of information** available to citizens: so that they can access, analyse, organise, produce, and

disseminate the relevant data using the available technologies.

Digital health literacy is the ability to seek, find, understand, and appraise health information from electronic sources and apply the knowledge gained to addressing or solving a health problem.²⁸ (Digital health literacy is also referred to as eHealth literacy.) The World Health Organization refers to a "lily model"²⁹ where it is shown that digital health literacy has an influence on/can support **other types of literacy** (e.g., digital literacy or what is also called 'computer literacy').



World Health Organization's "lily model" of digital health literacy

Digital health literacy and education: One of the main aspects mentioned to DigitalHealthEurope during its investigations, upstream of all others, was **education**. Agencies and governments should make strong investments into the education of citizens and professionals with respect to digital literacy. For patient organisations and health bodies, public investment in education should be the top priority. It is also crucial to involve professionals very early on in their careers in digital health-related themes, even before graduation. They should be involved in the design of functionalities and other technical/usability aspects, in order to become familiar with these tools from a very early stage of their career.

Investment in time and money in digital health literacy is restricted by the fact that a general assumption is often made that people, including those who use technology every day, are absolutely comfortable with using it. People must be involved in the development of new technologies and newer digital tools, regardless of their perceived general

²⁶ <https://www.who.int/ehealth/en/>

²⁷ https://ec.europa.eu/newsroom/dae/document.cfm?doc_id=51628

²⁸ https://www.who.int/global-coordination-mechanism/working-groups/digital_hl.pdf

²⁹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1550701/>

proficiency in using technological tools and solutions. There are many positive effects that can emerge from a better use of ICT solutions, when information is shared between clinicians and patients. With particular regard to patients, patients would be able to understand their own health much better and make better decisions. There will be fewer negative concerns for people experiencing illnesses to think about, and more time for them to engage in more activities that increase their life quality. Patients' satisfaction will surely increase, and the **savings in terms of energy and time** will be meaningful.

The European Strategy for Data³⁰ (19.2.2020) calls for a **common European Union (EU) skills data space**. In order to improve the competitiveness of people in the Union, the document identifies the need to have a data strategy that permits people to gain high-quality qualifications, learning opportunities, jobs, and skills sets. This aspiration demands a Europe-wide acceleration in digital literacy, including digital health literacy.

From the information gathered in DigitalHealthEurope, a simple summary can be made of the main **barriers** found in relation to digital health literacy.

Barriers to digital health literacy

- ✓ Assumptions that people who have the knowledge to use technology also have knowledge about the health digital tools available.
- ✓ Lack of financial support.
- ✓ Lack of training support.
- ✓ Difficulties in developing initiatives that reach everyone.

As for the factors that permit digital health literacy to be addressed, the main **enablers** gathered in DigitalHealthEurope follow.

Enablers to digital health literacy

- ✓ Citizens and professionals see the potential for prevention when they are able to use the digital tools available.
- ✓ People already have good knowledge on how technology works.
- ✓ Initiatives exist inside hospital centres to promote and inform people about access to digital portals and services.
- ✓ Strong agency and government investment on education of citizens and professionals works well.

- ✓ Inclusion of professionals and even patients/citizens in the development process of digital solutions is a positive move.

In essence, there is an important role to be played by **health professionals in reaching out to citizens** and incentivising them to learn about, use, and adopt new solutions to access and control their data. This health professionals' role has an underpinning, very important, foundation in **education and training**: it needs to be provided by organisations that have the responsibility to provide proper **training and opportunities for professionals and citizens**.

Citizens' engagement strategies

DigitalHealthEurope uncovered a number of **citizens' engagement strategies** that exist with regard to citizens' access to and control of their own health data. They are located in a range of reports, health movements, projects, and platforms. Associated with these examples are ways of modelling health data and means of using social media. For more detail, read DigitalHealthEurope's full deliverable D4.1: *White paper on better citizen access & control of*

data.

The intention behind these findings and examples is to create the conditions that enable **changes in citizens mindsets' and behaviour**, helping them to move towards a higher involvement and awareness of the importance of **citizen engagement in their own care**.

With regard to initiatives that increase the adherence of citizens to digital tools to access their health data, many of the stakeholders interviewed in DigitalHealthEurope identified important practical components of citizen engagement strategies to manage their health data. The report entitled "**How Personal Health Data could contribute to citizens managing their health outcomes**", which emerged from the Citizen Hackathon Stockholm³¹, performed by EIT Health³², was referenced several times. This report states that EIT Health should focus its efforts on demonstrating the feasibility of collecting and storing data in such a way that citizens will be the stewards of the use of their own data.

Patient empowerment is one of the key elements of patient-centred healthcare. It can be seen as both a pre-requisite for and an outcome of patient-centred

³⁰ https://ec.europa.eu/info/sites/info/files/communication-european-strategy-data-19feb2020_en.pdf

³¹ <https://connections.eithealth.eu/documents/1955789/0/Need+report+Personal+Health+Data+for+Citizens/bf28978b-3a0a-e655-93b1-84a17e3a9a29?version=1.0>

³² <https://eithealth.eu>

healthcare – a goal as well as a process.³³ There has been some work done in the field of patient safety to investigate strategies for empowering psychiatric patients.³⁴ The results suggest that healthcare providers consider patients as crucial partners in risk management and expect them to play a key role in actively enhancing safety. Policy makers should be aware that risk management in **mental health** settings particularly relies on the therapeutic relationship between health professionals and patients.

For citizens to be able to access and share their health data in a conscientious and fully informed way, their empowerment in terms of skills and competences is an important approach. The **World Health Organization** defines citizen empowerment³⁵ as “a process through which people gain greater control over decisions and actions affecting their health”. Most citizen engagement projects focusing on personal health data should take note in the design of the data platform of the intensely diverse backgrounds of participating citizens. Target groups should be actively supported by means of training and a very user-friendly design (of both the appearance and functionality of any tool).

One You was a campaign launched by Public Health England which aims to help adults avoid developing future diseases caused by modern lifestyles. Based around an app, it encourages people to reappraise and reprioritise their lifestyle choices. It reminds people that it is never too late to improve their health – making small lifestyle changes such as eating well, drinking less alcohol, quitting smoking or being more active can double a person's chances of being healthy at 70 years and beyond. The campaign encourages adults to take part in a free online health quiz, called 'How Are You', to identify where they can make small changes in their lifestyles.

The key message on **user design** coming from the DigitalHealthEurope expert interviews was that citizens / patients are all different and cannot be treated as a whole, when talking about empowerment and data. An essential aspect is to educate the user in the value and risk of storing and sharing their personal health data. Conscious citizens make for more engaged citizens. This is essential since “Citizens should be seen as the main hub of information in healthcare”. Successful approaches for stimulating engagement include full transparency, and the use of “microlearnings” to educate people and keep users informed on what happens to their data.³⁶

Citizen engagement requires an active, intentional dialogue between citizens and healthcare providers. The idea behind citizen engagement is that citizens should have some power over the decisions that affect their health. A strengthening of this engagement can be seen in the **Smart4Health**³⁷ initiative.

There is potential to build up citizens' engagement through the **Health Data Cooperative**³⁸ (HDC) model. In this model, citizens and their data take up a central position in the healthcare system, and society

benefits from the health-related and financial advantages that aggregation of the data brings.

Empowering citizens by providing them with a platform to safely store, manage, and share their health-related data is a necessary element in the **transformation process** towards a more effective and efficient precision treatment. Such health data platforms should be organised as **cooperatives** that are solely owned and controlled by their members, and not by shareholders. **Members** determine which data they want to share, for example with doctors, or to contribute to research for the benefit of their own health and that of society. Members decide on how the **revenues generated by granting third parties access** to the anonymised data that they have agreed to share should be **invested in research, information or education**.

The **core principles of the HDC model** are integrated into the HDC platform, which is a transparent interaction platform (see figure below). This platform is composed of three different components and provides its users with the possibility to perform a variety of functions.



The components of the health data cooperative (HDC) platform and the core principles of the HDC model

³³ <https://www.eu-patient.eu/policy/Policy/patient-empowerment/>

³⁴ https://www.euro.who.int/_data/assets/pdf_file/0020/113834/E93430.pdf

³⁵ <https://connections.eithealth.eu/documents/1955789/0/Need+report+Personal+Health+Data+for+Citizens/bf28978b-3a0a-e655-93b1-84a17e3a9a29?version=1.0>

³⁶ <https://connections.eithealth.eu/documents/1955789/0/Need+report+Personal+Health+Data+for+Citizens/bf28978b-3a0a-e655-93b1-84a17e3a9a29?version=1.0>

³⁷ <http://www.smart4health.com/home>

³⁸ <https://www.karger.com/Article/FullText/489994>

Social media: Communication with citizens and patients is becoming vital. Social media is playing an ever-important role in this responsibility.

Healthcare organisations are realising that social media can be used to stimulate campaigns and initiatives, improve the public's trust in the healthcare system, and to both understand and improve their presence in health promotion. Healthcare providers can use social media to provide opportunities to serve the **public** and their **employees**, and recruit **talent/personnel**. Since there are no geographical boundaries involved in social media, providers can reach a **larger audience** within seconds.

Member States in the **World Health Organization European Region** report that their healthcare organisations are using social media to promote health messages as part of health campaigns (81%; 35 countries.)³⁹ Several Member States report additional uses of social media, including:

- ▶ By the ministry of health for **promotion campaigns**, sharing information with the public, and sharing multimedia about the activities of the ministry.
- ▶ By health organisations to **connect generators of and subscribers to health content**.
- ▶ By health organisations to **listen and respond to the public**.
- ▶ Introducing **social networks for health workers and consumers of health services**.

Through '**social media listening**' (or '**social listening**'), responsible health ministries are able to form and shape initiatives based on the volume and topics of health conversations in social media. Through a social media response, they can also contribute to online conversations or questions.

Social media is **changing the way** in which patients, professionals, healthcare providers, and other relevant stakeholders, engage with each other as well as how health-related information is given and received. **Data analytics** that use social media will continue to be developed and offer meaningful insights into citizens' engagement and health trends.

Access to health data tools

Access to health data is important for citizens. According to the interviews undertaken in the context of DigitalHealthEurope, there have been several developments in the use of tools that enable citizens to make use of their clinical and personal health data across Europe.

Access tools can be seen from two different perspectives: their benefits and their remaining challenges.

On the one hand, according to the experts interviewed in DigitalHealthEurope, it is important that **health data should be easily accessible**, independent of the specific platform used. The health data should not be 'separated' from the patient. It should be data which a patient can choose to share or not for various purposes, but which can certainly be accessed in an emergency. Like government or administrative data, it should form a part of a patient's ID.

The means of control of access is not the main issue; access can be undertaken in any way. Regarding the means of data storage, they could be associated with a device, encrypted and stored in the cloud, to be accessible. On the other hand, from a technical perspective, **sharing information is not the biggest challenge**. The key issue is to assure **the quality of the data** from the patient and to prevent **input overload** on the part of the care organisation: this can be done through high-quality "filter" algorithms. Once the quality of data is assured, much of the care can be decentralised and move away from doctors/hospitals to self-care provided by patients themselves or through nurse-led care. This less centralised approach would increase access and quality of data at the same time as it would reduce costs.

From all the information on "access tools" that has been explored and gathered in DigitalHealthEurope, the benefits that access tools contribute in their role in providing better citizen access and control of data are clear. A few challenges are still associated with access tools, however.

Key benefits that access tools play in citizens' access and control of health data

- ✓ Integration and transfer of health information.
- ✓ Accessibility for all (universal design).
- ✓ Personalisation of data from official sources with personal data and notes).
- ✓ Health literacy.
- ✓ Information security.
- ✓ Help to coordinate and administer health information (privacy and ethical considerations).

Remaining challenges with access tools

- ✓ Newer methods such as wearables are yet to be integrated into health systems.
- ✓ Quality of the data in the systems.

³⁹ https://www.euro.who.int/_data/assets/pdf_file/0012/302331/From-Innovation-to-Implementation-eHealth-Report-EU.pdf

Moving towards a set of strategic solutions

DigitalHealthEurope worked towards identifying the most relevant solutions on better citizens' health data access. Based on different interactions – interviews and events held with specialists and stakeholders – the goal was to show recent main trends in healthcare innovations and to outline some possible “lines of action”.

Examples of the strategic solutions offered cover how to advance **digital health literacy**, how to promote **patient access to data**, how to enable **data sharing** and engage with and involve **citizens and stakeholders**, and what kinds of **infrastructure** are needed in support.

Health Movement EIT Health project was a dynamic ecosystem of community actors which acted to prevent chronic diseases. The impact of the initiative came from lowering the risk of developing lifestyle-related chronic diseases and decreasing costs with preventive interventions. The Health Movement contributed to educating individuals on health, lifestyle and their individual diseases by using their personal health data to empower the individual to make the right decisions for a better life, as well as to reinforce their engagement.

design stages of digital tools; the creation of patient empowerment programmes; the use of different incentive structures by private insurance companies to empower their patients; benefits demonstration(s)

by clinicians to patients of their use of digital health tools and the highlighting of better patient outcomes when patients are empowered by

their data.

Advancing digital health literacy

Digital health literacy is of key importance. Work is underway to focus on a **common agenda** for it.⁴⁰

Citizens and healthcare professionals represent the most important stakeholder groups in the discussion on digital health literacy. **Institutions/groups** also need to be included: examples are healthcare facilities, hospitals, healthcare providers, regulators, and even medical schools.

How to tackle barriers and enablers to digital health literacy are key areas of discussion.

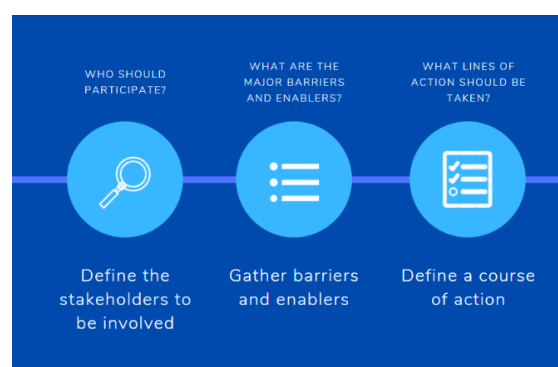
Among the priorities raised for agencies and funding programmes:

First, have the **funds** and to define a **budget** for digital health literacy promotion.

Sheffield University Hospitals in the United Kingdom started to discharge older patients from hospital to their homes, and afterwards assessed their support needs in the environment where they live rather than inside the hospital itself. The programme grew to serve 10,000 patients in a single year, who got home three to four days faster, thereby saving 30,000 to 40,000 acute-care bed days. Data, and a unique patient engagement strategy, generated dramatic improvements in cost, process, and patient experience.

Second, with regard to digital and data, **data should be clearly transparent** and there has to be full trust from both sides. There is a need for citizens to trust the health systems to be able to actually use them. **Understanding of the patterns of using daily technology for health** is needed for all ages and social groups of people. Include a **respectfully cultural and structured approach** towards citizens in order to transmit trust and quality of information. Third, the healthcare sector should look “outside” healthcare systems and promote digital health literacy in **collaboration with other institutions**.

Fourth, be aware of **good practices**. Examples include: consultation of patient groups in the early



Approach to develop a common agenda to advance digital health literacy

Fifth, consider training and education. In the Andalusian region in Spain, there are some **training centres for digital competences** that help elderly people to handle digital technologies. The centres assist the older adults to obtain a digital certificate for using health apps.

Indeed, there are **multiple lines of action** that can help to make progress on better digital health literacy in terms of tackling barriers and facilitating enablers.

Lines of action to advance digital health literacy

- ✓ Simplicity is needed, both of hardware and software, together with an interface standardisation.
- ✓ Design and implement educational campaigns for all citizens concerning digital health literacy.
- ✓ Include digital health modules in university programmes / courses for medical doctors, nurses, and all other healthcare workers.
- ✓ Couple any digital transformation with policies to tackle the digital divide / literacy.
- ✓ Keep the conventional way of accessing services alongside the digital means.
- ✓ Pay special attention to developing fully accessible technologies, with a clear focus on user usability.

⁴⁰ https://www.collectiveimpactforum.org/sites/default/files/Collaborating%20to%20Create%20a%20Common%20Agenda%20handout_0.pdf

- ✓ User-centred design is a cornerstone of a good digital health tool especially dealing with the current diverse range of digital and health literacy across generations.
- ✓ Allow and promote co-creation of digital solutions with health professionals and citizens/patients.
- ✓ European Union-wide digital literacy acceleration is needed, including digital health literacy.

Access to and sharing of data

There are several important ways of examining access and sharing of data. DigitalHealthEurope looked at promoting patient access, enabling data sharing, and focusing on infrastructure.

Promoting patient access

Enabling of **mobile-based access** facilitates enormously access to health data for people who are not so experienced with computers or other technologies. People can be encouraged to manage their own health in electronic / personal health records with data automatically retrieved by **an app from wearable devices** like a smart wristband or a smartwatch. Meaningful options include centralised intuitive tools to manage one's own health, linked to a universal interoperable electronic health record, and easily and user-friendly access, independent of whatever platform.

The cross-border Interreg Senior Friendly Communities (SFC) approach focuses on older people's public health in the EU Meuse-Rhine region, a border region between Belgium, Germany and the Netherlands. The approach supports communities to promote healthy ageing, especially for people with dementia, people with late-life depression, and informal caregivers. It makes use of the World Health Organization's framework of Active and Healthy Ageing, with its three pillars of health, participation, and security.

Five examples of experiences and reports act as an introduction to the promotion of patient access.

The 2021 **Health Data Forum**⁴¹ indicated that one of the effective ways to promote patient access and sharing of data and creating more confidence in its use by citizens, involves showing explicitly what the data is used for. More specifically, in July 2020, the "**Time to Patient Access**" initiative report called **Every Day Counts**⁴² helped stakeholders across Europe establish a common understanding of causes of delays in patient access to new cancer treatments.

The promotion of patient access to data is related to the relationship between a healthcare professional and a patient: this relationship is multi-faceted, and goes far beyond medical expertise about the specific disease involved – it is crucial in providing patients

with a better healthcare experience. **Continuity of care, integration of care, and shared decision-making** are three key aspects of this relationship.⁴³

The empowerment of patients in daily practice relies on **technology** and the way it is used. Practical approaches to empower patients vary in scope, aim, and technology. In the medium-term, if the relevant obstacles and gaps are successfully addressed, technology will encourage the emergence of "**a new patient**" fully equipped for the challenging healthcare scenarios of the 21st century.

Examples of experimentation are occurring both outside Europe and inside Europe. Outside of Europe, there are relatively successful **health data repositories**, such as 23andme⁴⁴ and PatientsLikeMe.⁴⁵ Across Europe, several **solutions have promoted patient access to health data**. Eleven regions from across the European Union participated in the EU-funded **SUSTAINS** project, which ended in 2014: this joint learning initiative gave patients access to their personal health records and other online services.^{46,47} A 2018-2021

Norwegian Research Council-sponsored project is called **CAPABLE**.⁴⁸ It has the aim of creating a tool that enables citizens to use their clinical and personal health information actively to manage medication, improve nutrition, and facilitate health services coordination.

Enabling data sharing

Data sharing is made possible in a wide variety of different ways. Among the range of **important topics** raised inside DigitalHealthEurope are: the cultural and educational aspects of data sharing; the initiatives that can help with awareness-raising on data sharing; the impetus towards data sharing created by COVID-19, both worldwide and in Europe;^{49,50} the challenges to data sharing taking place in hospitals; the benefits offered by AI; and the importance of Europe's plans for a European Health Data Space.

Digital health is much more than a technological transformation. It is a **cultural evolution of health and**

⁴¹ <https://www.healthdataforum.eu/>

⁴² <https://efpia.eu/publications/downloads/efpia/every-day-counts-improving-time-to-patient-access-to-innovative-oncology-therapies-in-europe/>

⁴³ <https://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-019-4215-x#Fig1>

⁴⁴ <https://mediacenter.23andme.com/>

⁴⁵ <https://www.patientslikeme.com/>

⁴⁶ <http://www.sustainsproject.eu/>

⁴⁷ <https://ec.europa.eu/digital-single-market/en/news/giving-patients-access-their-health-data-pilot-results>

⁴⁸ <https://www.med.uio.no/helsam/english/research/projects/capable/>

^{49,49} <https://www.who.int/news-room/events/detail/2020/10/25/default-calendar/world-health-summit-2020>

⁵⁰ <https://www.mobihealthnews.com/news/cross-border-collaborations-lead-data-sharing-efforts-during-covid-19>

care delivery. In order to develop solutions which enable citizens to share data, society needs to trust data in fields such as security, privacy, and the right to use data.

Europe needs a **health data coalition** to build public understanding of the value of health data, and enhance confidence in how data is collected and used.⁵¹ An example **initiative** is Data Saves Lives⁵², led by the European Patients' Forum (EPF) and the European Institute for Innovation through Health Data (i~HD).

According to Dr. Stella Kyriakides, Commissioner for Health and Food Safety at the European Commission, the COVID-19 pandemic has come to show the **positive impact of digital solutions in public health terms** because of their enormous potential to save lives. They also show how to support care systems, thus making them better, stronger and more egalitarian. Since the beginning of the pandemic, Europe has seen a huge growth in the use of digital tools in the area of health and care, in order to safely **connect patients to health professionals**. These tools are a key facilitator to enable care and consultations to continue when face-to-face visits are not possible or safe. **A new European Union interoperability gateway system** will connect, contact tracking and alert applications from participating European Union countries. COVID-19 has accelerated **the drive to share health data even across borders**.^{53,54}

Allowing health data to flow more freely between countries in Europe could aid in fighting the coronavirus, while helping regions to be better prepared for future pandemics. The European Centre for Disease Prevention and Control (ECDC) has organised an initiative called "Unlocking the potential of data in light of early lessons from COVID-19".⁵⁵

Lessons learnt from people's experiences around the pandemic are key.⁵⁶ A report entitled "A shared vision for the future of health in Europe: lessons learnt from the COVID-19 pandemic"⁵⁷ provides a synthesis of the lessons learnt.

Key points of lessons learnt

- ✓ Support the measurement and collection of standardised health data, including results relevant to people and patients, in all European healthcare systems.
- ✓ Create a forum for better access to healthcare innovation.
- ✓ Facilitate multi-stakeholder partnerships with regions and cities.
- ✓ Ensure effective health coordination and leadership in the European Union.
- ✓ Invest in Europe as a real research and innovation pole.
- ✓ Coordinate research efforts across Europe to address complex emerging health challenges together.
- ✓ Ensure greater flexibility to support trans-national research.
- ✓ Establish an ethical framework for AI that is flexible and specific to the healthcare sector.

Data sharing is clearly of importance, especially when facing major pandemics and epidemics. In many European countries, however, **clinical data is held by individual hospitals and clinics** despite the existence

of centralised public health systems. These institutions decide for themselves what types of data to collect and in what format to store it, and there is no clear framework for how it should be anonymised and shared.

AI could be helpful here in helping with data collection. Currently, in leveraging AI to improve and tailor treatments,

technology companies struggle with obtaining training data for their algorithms. Drawing from the experience of **three start-ups**, a practical, operational article entitled "Building Healthcare AI in Europe's Strict Regulatory Environment"⁵⁸ describes a five-step process for consolidating the data. AI has the potential to fundamentally change healthcare practices, provided one can **integrate the distributed data in the world's health ecosystems**. What companies such as Owkin⁵⁹, ExactCare,⁶⁰ and Nabta⁶¹ are achieving in Europe could serve as a useful template for similar initiatives in other markets – most notably in Asia and Latin America – that are facing the same challenges.

The Portuguese Institute of Oncology (IPO) in the city of Lisbon has launched a mobile application – MyIPO Lisboa – for its patients, who can have access to data on their appointment schedule, treatments, medical examinations, and medications. In parallel, agreements were signed with institutions in the local community (such as city councils, third age universities, social institutions, churches or monasteries) in order to provide a place with a computer with internet access and a professional person trained in the use of digital health platforms. These institutions are closer geographically to their citizens. In these spaces, it is possible to carry out a series of requests and teleconsultations, thereby avoiding unnecessary trips to the hospital being made on the part of the patient.

⁵¹ <https://www.efpia.eu/about-medicines/development-of-medicines/digital-health/>

⁵² <https://datasaveslives.eu/aboutds/>

⁵³ <https://horizon-magazine.eu/article/coronavirus-accelerates-drive-share-health-data-across-borders.html>

⁵⁴ <https://www.euhealthcoalition.eu/recommendations/>

⁵⁵ <https://www.ehfg.org/conference/programme/sessions/innovative-digital-solutions-for-comparable-data-strong-health-systems-and-good-decision-making>

⁵⁶ <https://www.euhealthcoalition.eu/eu-health-summit/>

⁵⁷ <https://echalliance.com/wp-content/uploads/2020/10/Recommendations-EU-Health-Summit-2020.pdf>

⁵⁸ <https://hbr.org/2020/10/building-health-care-ai-in-europes-strict-regulatory-environment>

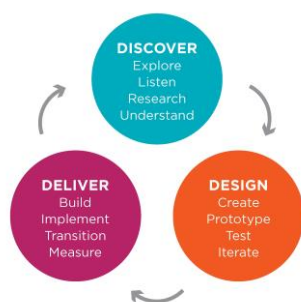
⁵⁹ <https://owkin.com/>

⁶⁰ <https://www.exactcarepharmacy.com/>

⁶¹ <https://startup.orange.com/en/candidature/nabta-health-2/>

Europe is moving ahead with **policy advances** at both European Union and national levels. Examples include the proposed European Health Data Space, the recommendation for a European Electronic Health Record exchange, and Germany's new Digital Supply Act.⁶² Business is urging Europe to create common regulations in order to create a level European playing field and boost competitiveness on world markets. Policymakers need to **craft a European model** that balances the life-saving benefits of digitalisation with public concerns and fears over privacy, healthcare de-humanisation, and the possibility that highly personal data could become yet another monetised commodity.⁶³

For this, **engaging and involving citizens and stakeholders** will be key. **Human-centred design** is a way to involve patients or end users in developing and improving products, and consequently promote their access to health data. The approach is alternatively called **co-creation** or **participatory design**: it is a multidisciplinary methodology that draws from cognitive psychology, ethnography, and interaction design.⁶⁴



A human-centred design process

Focusing on infrastructure

Patients' access, management and exchange of health data among healthcare organisations are a significant challenge, due to the sensitive information and the privacy issues involved. Health record maintenance

and sharing are among the essential tasks in the healthcare system. The **security of identity** is a prime example. It is also of essential importance to have a **secure infrastructure for electronic health records and health data** in general.

eIdentity: The European regulation⁶⁵ on **electronic identification and trust services for electronic transactions in the internal market** (eIDAS Regulation) was adopted by co-legislators on 23 July 2014. It is a milestone that provides a predictable regulatory environment to enable secure and seamless electronic interactions between businesses, citizens and public authorities, bringing Europe one step closer to having a secure underpinning infrastructure. Thanks to the eIDAS regulation, from November 2019 onwards, citizens of the

In 2018, Estonia started the Central Health Information System which provides "a Personal Digital History as internet service". The central system is a patient-oriented system based on the individual's personal identity (ID) code. In the central system, data were collected about visits, diagnoses, treatment, examinations and recommendations, which are visible to all the clinicians who treat specific patients. For security reasons, the doctors' access to the central database is allowed only via the use of a professional ID-card. Access is allowed only to licensed healthcare providers. All the information collected is linked to the Estonian Medical Images Bank, the Prescription Centre, and healthcare providers systems via the X-Road. X-Road's software-based solution, called X-tee, is the backbone of e-Estonia. To ensure secure transfers, all outgoing data are digitally signed and encrypted, and all incoming data are authenticated and logged. The Estonian electronic health record has a specific service portal for patients – the Patient Portal. Every person has access to the portal via their ID card and can look at their own health data.

European Union can now use the national identity schemes in six countries (Croatia, Estonia, Germany, Italy, Luxembourg, and Spain) cross-border to access **European online public services**. Businesses can also benefit from this cross-border recognition of electronic identification because the use of eID under eIDAS is open and available to the private sector.⁶⁶ Electronic Identification (eID) and Trust Services, as key enablers for secure cross-border electronic data transactions and central building blocks of the Digital Single Market, can influence national and regional approaches to **empowering citizen access and management of their own health data**.

Security and protection of health data: Access to e.g., **health platforms** needs to be strictly controlled through the use of personal credentials, such as identity (ID) cards, mobile ID, personal identification numbers (PINs) or usernames and passwords. There are several examples of **Citizen Portals** where citizens can access their health data, such as laboratory results, vaccination information, and prescriptions. Most of these portals allow scheduling of medical appointments and digital prescriptions.

*In Croatia, identity verification for access to e-services is done by the **national identification and authentication system (NIAS)**. NIAS is a comprehensive IT solution for identifying and authenticating users on a national level, which enables the inclusion of several types of credentials with different levels of security, from level 2 (the lowest) to level 4.*

⁶² <https://www.healthcareitnews.com/news/emea/germany-introduces-digital-supply-act-digitalise-healthcare>

⁶³ <https://www.friendsofeurope.org/events/a-digital-health-revolution-the-european-health-data-space/>

⁶⁴ https://www.healthit.gov/sites/default/files/onc_records-request-research-report_2017-06-01.pdf

⁶⁵ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0910&from=EN>

⁶⁶ <https://ec.europa.eu/digital-single-market/en/news/national-eids-six-countries-available-eu-citizens-use-cross-border>

Other initiatives are still under development. Several include research and development projects operating under the Horizon 2020 programme^{67,68,69} (therefore their access methodologies or issues related to data storage security and legality are not yet defined). One potential direction is the need to design a **system using the cloud** that helps to ensure authentication and provides integrity to health records.

European Structural and Investment Funds: Last but not least, of course, financing also counts. Innovation and improvement play a role in supporting strategic infrastructural solutions. The **European Structural and Investment Funds**⁷⁰ (ESIF) address this by focusing on the objectives of “enhancing access to use, quality of information and communication technologies”.

Improvements in infrastructure that can have other positive impacts and outcomes

- ✓ Availability and accessibility of all services, thus reducing inequalities in terms of health status.
- ✓ Concentration on specialised (health and care) services.
- ✓ Conversion of infrastructure for prioritised purposes within a strategy for cost-effective and sustainable health systems.
- ✓ Better opportunities for implementing clinicians' decision-making support systems.
- ✓ Better monitoring and proactive strategies based on health risk identification and prediction.
- ✓ Better coordination and integration of different elements of care.
- ✓ Better support of self-management for patients.



⁶⁷ <https://konfido-project.eu/>

⁶⁸ https://konfido-project.eu/system/files/private/konfido/konfido_conceptpaper.pdf

⁶⁹ <https://www.shield-h2020.eu/>

⁷⁰ https://ec.europa.eu/health/sites/health/files/health_structural_funds/docs/esif_guide_en.pdf

Developing recommendations

Whilst analysing national, regional initiatives and relevant projects and showcasing the value of investing in citizen and patient empowerment through data, the DigitalHealthEurope focus activity on **better citizens' access to health data** identified a number of key ideas and principles. They can help DigitalHealthEurope in developing a common strategic agenda on **better citizens' access and control of data and EHR exchange formats**.

These ideas are clustered around **three areas** which are illustrated in the three boxes below. Each area is based on a set of observations: the largest collection of insights is on **access to and sharing of health data**.

At project level, DigitalHealthEurope integrated these ideas and principles (see below) into "recommendations on the European Health Data Space"⁷¹ report published in July 2021. That report outlines three areas of proposals for **regulatory action**; common **policy** and strategy; and **actions for further support**.

Digital health literacy

- ▶ Include digital health literacy in **governments' strategic plans**.
- ▶ Help digital health literacy to **improve health data sharing and impact health outcomes positively**.
- ▶ Appreciate that better citizens' digital health literacy improves a **sentiment of trust and the achievement of better (health and care) outcomes**.
- ▶ **Do not see age as the main indicator** of a person's level of digital health literacy.
- ▶ **Ensure that there is no increase in inequality** when digital transformation takes place.

Access to and sharing of health data

- ▶ Strengthen the **privacy and security** of health data.
- ▶ Show explicitly **what health data is used for** so as to give confidence for citizens to share data.
- ▶ Take into consideration, as barriers to data access, **other factors than just technology**.
- ▶ Use **person-centred solutions**.
- ▶ **Talk about "control"** instead of "ownership" of data, so as to enable citizens to be at the centre of the discussion.
- ▶ Create **practical cooperation between organisations**, for example, among health data cooperatives.
- ▶ Ensure that **citizens should have the maximum decision power about their data**.
- ▶ Encourage the eHealth Network and eHealth Stakeholders Group to **monitor findings from clusters of European projects** that work on citizens' access to health data.
- ▶ Develop a **sustainable model for the use of personal health data in the European Union**.

Engagement and involvement of citizens and stakeholders

- ▶ Develop digital solutions by using involvement, **co-design, co-creation and cooperation with all stakeholders**.
- ▶ Involve all stakeholders (e.g., professionals, information technology ethical experts, patients, and informal carers) in **building solutions so as to increase trust from citizens**.
- ▶ Do more work/research to **assess why cooperation and co-creation are still not used more widely** in society and communities.
- ▶ Ensure that **consent is informed**.
- ▶ Define **citizen-centredness** in more detail.



⁷¹ https://digitalhealtheurope.eu/wp-content/uploads/DHE_recommendations_on_EHDS_July_2021.pdf