Digital health data and services – the European health data space

Fields marked with * are mandatory.

Introduction

The European Health Data Space (EHDS) is a Commission priority that aims at making the most of the potential of digital health to provide high-quality healthcare, reduce inequalities and promote access to health data for research and innovation on new preventive strategies, diagnosis and treatment. At the same time, it should ensure that individuals have control over their own personal data.

Innovative solutions that make use of health data and digital technologies, among others digital health solutions based on data analytics and artificial intelligence (AI), can contribute to the transformation and sustainability of healthcare systems, while improving people's health and enabling personalised medicine. The development of these technologies requires access by researchers and innovators to substantial amounts of (health) data.

The Commission announced in the Communication on the European Strategy for Data its intention to deliver concrete results in the area of health data and to tap into the potential created by developments in digital technologies. The collection, access, storage, use and re-use of data in healthcare poses specific challenges that need to be addressed within a regulatory framework that best serves individuals' interests and rights, in particular as regards the processing of sensitive personal data relating to their health. As a follow up, the Commission adopted its Data Governance Act proposal (2020) laying down conditions around access to certain categories of data, and containing provisions to foster trust in voluntary data sharing.

This public consultation will help shape the initiative on the EHDS. It is structured in three sections focusing on:

1. the use of health data for healthcare provision, research and innovation as well as policy-making and regulatory decision;
2. the development and use of digital health services and products;
3. the development and use of Artificial Intelligence systems in healthcare.

The Commission has launched a separate public consultation on the Evaluation of patient rights in cross-border healthcare. You can follow the relevant link if you wish to reply.

Depending on your answers, the questionnaire may take approximately 40 minutes.

Section 1: Access and use of personal health data for healthcare, research and innovation, policy-making and regulatory decision-making

Personal health data include a wide range of data on individual's physical or mental health and information on healthcare received. Health data, including genetic and sometimes biometric data, may reveal information about the health status of a person. Individuals need to have the right tools at hand for managing their health data. These should allow them to consult and share their health data with health professionals or other entities of their choice. This should facilitate receiving adequate healthcare including abroad (doctors, hospitals, pharmacies, etc.).

In addition, sharing personal health data with researchers and innovators could improve health research and innovation in prevention, diagnosis and treatments. Sharing personal health data with policy-makers and regulators such as European and national medicine agencies could facilitate and speed up theapproval of new medicines and pass laws that are based on real world data. For this, a mechanism would need to be established that facilitates access to personal health data for further use while protecting the individuals' interests and rights on their health data in compliance with the General Data Protection Regulation (GDPR).

Q1. The cross-border healthcare Directive has established the eHealth Network and an infrastructure to facilitate health data sharing across the EU (Article 14) and includes other aspects with relevance for digital health. In the last 5 years are you aware of any changes in the following aspects of health data sharing across border?

	Greatly reduced	Slightly reduced	No changes	Slightly increased	Greatly increased	I don't know / No opinion
Exchange of health data such as patients' summaries and ePrescriptions	○	○	○	This one	○	○
Continuity and access to safe and high quality healthcare	○	○	This one	○	○	○

Development of methods for enabling the use of medical information for public health and research				This one		
Development of common identification and authentication measures to facilitate transferability of data						This one
Access of patients to an electronic copy of the electronic health record				This one		
Cross-border provision of telemedicine						This one

Q2. Should a European framework on the access and exchange of personal health data aim at achieving the following objectives?

	Not at all	To a limited extent	To some extent	To a great extent	Completely	I don't know / No opinion
Facilitate delivering healthcare for citizens at national level					This one	
Facilitate delivering healthcare for citizens across borders					This one	
Promote citizens' control over their own health data, including access to health data and transmission of their health data in electronic format					This one	
Promote the use of digital health products and services by healthcare professionals and citizens			This one			
Support decisions by policy-makers and regulators in health				This one		
Support and accelerate research in health					This one	
Promote private initiatives (e.g. for innovation and commercial use) in digital health			This one			
Other					This one	

Please specify (no limit):

The European Federation of Allergy and Airways Diseases Patients' Associations (EFA) is a full member of the European Patients Forum (EPF), is a member of the EPF Digital Health Working Group and has therefore helped develop EPF's contribution and endorses it overall.

Like EPF, EFA mostly stresses that a European framework on the access and exchange of personal data should have the goal in improving healthcare delivery for all Europeans, both within and across borders, while ensuring the highest level possible of interoperability, safety, data protection and avoiding potential misuse of data. Moreover, we consider this legislation should aim first and foremost at facilitating patients' access to healthcare at national and at EU level, including access to their data.

To better inform institutions about the digital health expectations and needs, EFA is at the latest stages of conducting a survey on the digital asthma and COPD patient in Europe. We will gather the views of n=1,000 patients in 5 European countries and publish a survey report early 2022. EFA will request a meeting with the European Commission to present you with the findings in detail. In the meantime, the preliminary results of the survey (n=756) show that:

- Digital health should not replace in person healthcare, more than 60% of patients surveyed prefer personal contact for their care.
- The number one concern for asthma and COPD patients is data privacy (94% of respondents).
- More than 50% of patients do have concerns about sharing their health data digitally, even if anonymized, and around one third simply do not want their data to be shared digitally.
- Some aspects that would justify patients sharing their data digitally are improving their condition, developing new drugs, helping researchers understand the disease and its causes, and getting early warnings on disease deterioration. These choices apply for more than 70% of the current surveyed sample.

These scientifically validated preliminary survey results, and many more, have guided our response to this consultation on the European Health Data Space.

EFA thanks our members for their contribution during two workshops we have organized to put together our response to this consultation.

1.1. Access to and exchange of health data for healthcare

Currently, several Member States exchange health data across borders within the framework of the cross-border healthcare Directive to support patients in obtaining care when travelling abroad. Health data such as electronic prescriptions and patients' summaries are exchanged through an EU infrastructure called MyHealth@EU. Patient summaries provide information on important health related aspects such as allergies, current medication, previous illness, surgeries, etc. Work is being carried out to support the exchange of additional health data, such as medical images and image reports, laboratory results and hospital discharge letters and to provide citizens with access to their own health data.

Moreover, access and control of citizens' over their own health data should be improved. The COVID-19 crisis also showed the importance of citizens being able to access and share in electronic format some of their health data (e.g. test results, vaccination certificates) with healthcare professionals or other entities of their choice. Facilitating such access and sharing by individuals of their health data in electronic format may require extending the rights of individuals with respect to their health data beyond those guaranteed in the GDPR.

Furthermore, some conditions need to be in place to ensure easy, lawful and trusted exchange of health data crossborders:

- Healthcare providers need to have digital systems in place to exchange data securely with other health professionals and digital health devices.

- Healthcare providers need to comply with the applicable provisions of the GDPR, in particular the requirement to rely on a legal basis in order to be able to lawfully exchange health data cross borders.
- Data need to be in the same format and correspond to a common data quality, cybersecurity and other interoperability standards on which healthcare professionals can rely.
- Relevant mechanisms may also be implemented to support the uptake of these standards (such as labelling, certification, authorisation schemes and codes of conduct).
- Cooperation of national digital health bodies in the development of interoperable standards and specifications.

The questions below seek to gather stakeholders' views on the rights and tools that would support access by citizens to their own health data (beyond the rights guaranteed in the GDPR).

Q3. How important is it for you to be granted the following rights?

	Not at all	To a limited extent	To some extent	To a great extent	Completely	I don't know / No opinion
The right to access my health data in electronic format, including those stored by healthcare providers (public or private)	○	○	○	○	This one	○
The right to transmit my heath data in electronic format to another professional/entity of my choice	○	○	○	○	This one	○
The right to request public healthcare providers to share electronically my health data with other healthcare providers/entities of my choice	○	○	○	○	This one	○
The right to request healthcare providers to transmit my health data in my electronic health record	○	○	○	○	This one	○
The right to request app providers to ensure the transmission of my health data in my electronic health record	○	○	○	○	This one	○
Healthcare providers that fail to provide me access to my health data in an electronic format and to transmit it to a healthcare provider/entity of my choice are sanctioned or receive a specific fine	○	○	This one	○		○

Q4. Which of the following elements do you consider the most appropriate for controlling access and sharing your health data with healthcare professionals?

	Not at all	To a limited extent	To some extent	To a great extent	Completely	I don't know / No opinion
Access my health data through a personal digital storage and share it with health professionals of my choice					This one	
Access my health data that is exchanged between health professionals or with other entities via a digital infrastructure					This one	
Access my health data that is exchanged between health professionals across borders via an EU electronic infrastructure					This one	
Access my health data on a mobile application and share it with healthcare professionals or other entities of my choice					This one	
The infrastructure or personal digital storage for accessing the data should be secure and prevent cyberattacks					This one	
Other					This one	

Please specify:

We fully support EPF's proposal that all the options listed in the questionnaire above should be part of a comprehensive framework that allows patients to fully access and control their health data, deciding how to access it, share it and for which purposes. This is an essential precondition that should be met even before diving into questions regarding tools, platforms, and different means.

Regarding access, EFA argues that people living with chronic diseases prefer using current digital channels such as laptop, smartphone, and smartwatch, which are likely to remain stable overtime.

One of the concerns raised in our community is data security. Given the sensitivity of health data, all data access points should be secured, especially personal portable ones. We recommend and envisage digital interfaces that do not encourage storage (download) of health data into mobile applications, as those are a higher risk of being stolen, hacked and overwritten. We therefore encourage developing a one-stop-shop architecture for health data to ensure interoperability, encryption, literacy, and security.

The questions below seek to gather stakeholders' views on the measures needed to enhance the sharing of health data between healthcare professionals including across borders. Some common standards and technical requirements agreed at EU level could be applicable to healthcare providers in this view.

Q5. In your view, who is best suited to develop these standards and technical requirements at EU level to support exchange of data in healthcare?

- National digital health bodies cooperating at EU level
-
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An EU body

Other (this one)

Please specify:

At EFA we consider the EU has important competencies and knowledge to help build an ambitious and functional European Health Data Space, while EU Member States, as the healthcare authorities providing services, have the responsibility to grant and protect people's health. We therefore encourage that health standards and technical requirements are coordinated by an EU body in close collaboration with Member States. An EU coordination will help reduce health data access inequalities among patients living in Europe, as well as disseminate know-how on technical advancement.

Q6. In your views, how should these standards and technical requirements be made applicable at national level and across the EU?

- Through a labelling scheme (a voluntary label indicating the interoperability level)
- By a certification scheme granted by third parties (a mandatory independent assessment of the interoperability level)
- By an authorisation scheme managed by national bodies (a mandatory prior approval by a national authority) (this one)
- Other

In addition to the requirements laid down in the proposed Data Governance Act, providers of personal data spaces/data sharing services could be subject to sectoral requirements to ensure interoperability of health data exchanges. The question below seeks to gather stakeholders' views on any additional measures needed.

Q7. Which of the following measures would be the most appropriate:

- By a labelling scheme (a voluntary label indicating the interoperability level)
- By a certification scheme granted by third parties (a mandatory independent assessment of the interoperability level)
- By an authorisation scheme managed by national bodies (a mandatory prior approval by a national authority)
- Other (this one)

Please specify:

At EFA we believe that health data use, exploitation and transfer should be governed by the highest quality criteria and that standards and technical requirements should be evaluated by national authorities. We encourage this process for both primary and secondary use of data. This approach also applies for question 6.

The question below seeks to identify and assess the impacts (benefits and costs) that would arise from

measures facilitating the access to, control and transmission of health data for healthcare including across borders.

Q8. (For healthcare professionals only) **In your views, what would be the costs on healthcare professionals/providers of measures facilitating access to, control and transmission of health data for healthcare?**

	No impact	Moderate impact	High impact	I don't know / No opinion
Implementation costs for national healthcare providers (setting up infrastructure, complying with defined standards, etc.).	○	○	○	○
Costs for healthcare professionals and providers (human resources, finances, etc.)	○	○	○	○
Information and monitoring	○	○	○	○
Other	○	○	○	○

Please specify:

Q9. In your views, what would be the benefits for stakeholders of measures facilitating access to,control and transmission of health data for healthcare?

Access to efficient and safe care

	No impact	Moderate impact	High impact	I don't know / No opinion
Facilitated access to healthcare across borders in the EU	○	○	This one	○

Benefits for patients

	No impact	Moderate impact	High impact	I don't know / No opinion
Transparency on the processing of their health data	○	○	This one	○
Reduced costs stemming from not duplicating efforts and tests	○	○	This one	○
Reduced administrative burden	○	This one	○	○

Benefits on healthcare systems efficiencies

	No impact	Moderate impact	High impact	I don't know / No opinion
Better healthcare provision (including risks and errors)	○	○	This one	○
Reduced costs and reduced duplication of efforts	○		This one	○
Reduced administrative burden	○		This one	○
Technological progress	○	○	This one	○

Other

Please specify:

EFA welcomes the digitalization of health data as a tool for patient empowerment complementary to in person healthcare. We expect patients to have access to medical records in home countries and alleviate the language burden. They will be empowered by truly multidisciplinary care by the providers of their choice. Patients with chronic conditions also envisage better linkages between health records and family history.

But not all will be immediate benefits. EFA considers that it is difficult to assess how much the burden will be reduced for patients thanks to the introduction of digital health data. The administrative and economic duties linked to digital health can still be rather high to coordinate in the setting up of the European Health Data Space, as there are different family members and many healthcare professionals to coordinate for people with chronic conditions and co-morbidities.

Another aspect that should not be neglected is that digital health should remain complementary, and not obligatory. Patients should not be forced, by law nor de facto, to switch to digital data.

EFA's preliminary survey DIG-IT survey results show that around half of asthma and COPD patients in Europe would like to be trained by healthcare professionals and staff on the use of digital health, which would entail an extra investment on healthcare budgets.

1.2. Access and use of personal health data for research and innovation, policy-making and regulatory decision

Access to health data for research, innovation, policy-making and regulatory decisions within the EU is currently quite complex and subject to national laws. In the proposed Data Governance Act the EU Commission proposes rules

- on access and sharing of data across sectors
- on access to data held by public bodies
- on data intermediary services (sharing of data between businesses and sharing of data between citizens and businesses)
- on sharing of data by individuals and companies through a trusted third party for wider good purposes (e.g. research) and based on their consent (so called "data altruism").

Health data are considered to be particularly sensitive and their processing is subject to stricter requirements under the General Data Protection Regulation. The proposed Data Governance Act allows for the possibility for additional sectoral legislation to set up and further specify the role of national bodies taking decisions on access to data by third parties; also in the area of health, such sectoral legislation must ensure full compliance with EU data protection rules. The Data Act currently in preparation will also assess how non-personal data held by businesses could be shared with the public sector for better policy making.

The questions below seek to gather stakeholders' views on the measures needed to facilitate the access to health data by researchers, innovators, policy-makers and regulators, in a trustworthy manner and in line with EU data protection rules.

Q10. What mechanism do you consider more appropriate to facilitate the access to health data for research, innovation, policy-making and regulatory decision? Please rank from the most (1) to the least (4) preferred option

	1	2	3	4	I don't know / No opinion
Voluntary appointment of a national body that authorises access to health data by third parties	○	○	This one	○	○
Mandatory appointment of a national body that authorises access to health data by third parties	○	This one	○	○	○
A public body collects the consent of individuals to share their health data for specified societal uses ("data altruism") and manages their health data	This one	○	○	○	○
A private not-for-profit entity collects the consent of individuals to share their health data for specified societal uses ("data altruism") and manages their health data – as designed in the proposed Data Governance Act	○	○	○	This one	○

Q11. In your opinion, would additional rules on conditions for access to health data for research, innovation, policy-making and regulatory decision be needed at EU level?

Health data categories

	Yes, for policy and regulatory purposes	Yes, for research purposes	Yes, for innovation purposes and commercial use	Yes, for treating other patients	Yes, for education purposes	Yes in all cases	Not in all cases	I don't know / No opinion
Health data from medical records	☐	☐	☐	☐	☐	This one	☐	☐
Administrative data in relation to reimbursement of healthcare	☐	☐	☐	☐	☐	This one	☐	☐
Social care data	☐	☐	☐	☐	☐	This one	☐	☐
Genetic and genomic data	☐	☐	☐	☐	☐	This one	☐	☐

Format (for any of the above data categories)

	Yes, for policy and regulatory purposes	Yes, for research purposes	Yes, for innovation purposes and commercial use	Yes, for treating other patients	Yes, for education purposes	Yes in all cases	Not in all cases	I don't know / No opinion
Anonymised aggregated format (e.g. statistics)	☐	☐	☐	☐	☐	This one	☐	☐
Pseudonymised format (without identifiers of individuals)	☐	☐	☐	☐	☐	This one	☐	☐
Fully identifiable format	☐	☐	☐		☐	This one	☐	☐

Eligibility

	Yes, for policy and regulatory purposes	Yes, for research purposes	Yes, for innovation purposes and commercial use	Yes, for treating other patients	Yes, for education purposes	Yes in all cases	Not in all cases	I don't know / No opinion
Criteria and conditions for providing / accessing data in the EHDS are defined	☐	☐	☐	☐	☐	This one	☐	☐
Safeguards for the access to health data for the purpose **of re-use, in line with ethical and data protection** requirements, are defined	☐	☐	☐	☐	☐	This one	☐	☐

Limit the transfer of non-personal health data outside the EU/EEA	☐	☐	☐	☐	☐	☐	This one	☐

Security

	Yes, for policy and regulatory purposes	Yes, for research purposes	Yes, for innovation purposes and commercial use	Yes, for treating other patients	Yes, for education purposes	Yes in all cases	Not in all cases	I don't know / No opinion
Conditions for the secure access to health data are defined	☐	☐	☐	☐	☐	This one	☐	☐

Other

Please specify:

At EFA, we understand the need for improvement of the current framework. However, we would like the Commission to conduct an evaluation on the application of current EU rules for health data to understand if they have created already a stable environment on data sharing and how to advance them.

Any new rules around health data need to be patient-centric, understand the importance of handling sensitive personal data and create safeguards with identity protection/anonymization or pseudonymization certifications (as noted by GDPR Preamble 28). EU and national policy makers should ensure that any existing or newly rising policy and regulatory gaps and inefficiencies from the previous frameworks are addressed by a watchdog or independent monitoring agency such as the European Data Protection Supervisor.

Like within EPF's response, we have mostly chosen yes, in all cases, not to overwhelm and complexify legislation, but rather to take the opportunity to define health data criteria, format, use and European liabilities due to its exploitation. On the use of data across EU borders, we would like to enable research that responds to patients' needs: diseases do not have frontiers, therefore data that could help reduce them should not be forces to have them either.

Importantly, under the format, EFA considers that under no circumstances fully identifiable health data should be used and shared for secondary use. From our patient perspective, there are no reasons validating patient identification outside primary use of health data to provide health services. Some diseases come with stigma so consent should be given in very specific terms. There is today much research conducted claiming to ensure total anonymity but our federation reports that participants and respondents can be traced back. Data therefore should not identify the person.

Finally, when patients are sharing their health data there should be a clear ethical framework accompanying it. Patients should have the right to receive different opt-ins, like the basic uses that appear in this question. Moreover, EFA considers that health data for commercial use should be subject to additional consent.

Q12. How appropriate do you consider the below elements in facilitating access to health data held by private stakeholders (hospitals, businesses) for research, innovation, policy-making and regulatory decision:

	Not at all	To a limited extent	To some extent	To a great extent	Completely	I don't know / No opinion
Access to health data is granted by the data holder, on its own decision (current situation)	○	○	This one	○	○	○

Access to health data is granted by a national body, in accordance with national law				This one		
Access to health data is granted by a national body, subject to agreement of data subjects					This one	
Other					This one	

Please specify:

From our perspective, access to any data should always be based on consent. Consent should be always given by the patient, via an affirmative declaration except in strictly defined cases (life of patients being endangered, or an anonymised data usage for preventive medical policy making measures) to ensure transparency, patient right awareness and safeguards by the current legislation.

Q13. Which incentives would facilitate sharing of health data held by private stakeholders?

	Not at all	To a limited extent	To some extent	To a great extent	Completely	I don't know / No opinion
A fee						This one
Other						This one

Please specify:

Patients in our network call for a strong governance framework developed for health data held by private stakeholders, especially if that data will then be subject to commercial use. The debate is a difficult one as the fact of establishing fees implies that patients' data have a value despite they are not "selling it" (rather, they are paying to get the care they need). Would fees impact the price and accessibility of the services they need? If the patient has given consent, should not that be enough to enable the right for those data to be shared, even at a large scale?

Q14. Do you agree that an EU body could facilitate access to health data for research, innovation, policy making and regulatory decision with the following functions?

	Not at all	To a limited extent	To some extent	To a great extent	Completely	I don't know / No opinion
Bring together the national bodies dealing with secondary use of health data, for decisions in this area	○	○	○	This one		○
Setting standards on interoperability together with national bodies dealing with secondary use of health data	○	○	○	This one		○
Facilitating cross-border queries to locate relevant datasets in collaboration with national bodies dealing with secondary use of health data	○	○	○	This one		○
Acting as technical intermediary for cross-border data sharing	○	○	○	This one		○
Authorising access to cross-border health data (data processed in a cross-border or EU wide manner, such as European Reference Networks)	○	○	○	This one		○

Q15. How useful would EU level action in the following areas be to address interoperability and data quality issues for facilitating cross-border access to health data for research, innovation, policy-making and regulatory decision?

	Not at all	To a limited extent	To some extent	To a great extent	Completely	I don't know / No opinion
Stakeholders participating in the EHDS cross-border infrastructure are subject to a voluntary labelling scheme on the use of data quality and interoperability technical requirements and standards		This one	○	○	○	○
Stakeholders participating in the EHDS cross-border infrastructure are subject to the mandatory use of specific technical requirements and standards	○	○	○	○	This one	○

Stakeholders need an audit, certification or authorisation before participating in EHDS cross-border infrastructure	○	○	○		This one	○

The question below seeks to identify and assess the impacts (benefits and costs) that would arise from measures facilitating cross-border access to health data for research, innovation, policy-making and regulatory decision.

Q16. (For healthcare professionals only) **In your views, what would be the costs on healthcare professionals/providers of measures facilitating such access?**

	No impact	Moderate impact	High impact	I don't know / No opinion
Implementation costs (setting up infrastructure, complying with defined standards, etc.).	○	○	○	○
Operational costs such as human resources, finances, etc.	○	○	○	○
Information and monitoring	○	○	○	○
Other	○	○	○	○

Please specify:

Q17. In your views, what would be the benefits for stakeholders of measures facilitating such access?

Access to cutting-edge, efficient and safe care

	No impact	Moderate impact	High impact	I don't know / No opinion
Availability of new treatments and medicines	○	This one	○	○
Increased safety of health care and of medicinal products or medical devices	○	This one		○
Faster innovation in health	○	This one		○

Benefits on healthcare systems efficiencies

	No impact	Moderate impact	High impact	I don't know / No opinion

Better informed decision-making (including risks and errors)	○	This one		○
Reduced administrative burden in accessing health data	○	This one	○	○
Technological progress	○	This one		○

Other

Please specify:

The current system governing public health has created certain social and health inequalities where patients as part of vulnerable groups must face the consequences. EFA strongly advocates for the adoption of digital health policies enabling patient empowerment, education and increase of health literacy.

In practice health literacy might entail financial cost for patients, lack of IT tools such as laptops, mobile phones to use available digital applications, and access to fast and reliable internet connection. Any implementation of digital solutions should consider health and social inequalities and take up actions to tackle them (examples of this can be the offer of financial aid to develop health literacy among the population, reducing pricing on IT devices for health related issues, create public infrastructure open to the public with internet and computer access, regular training on how to use digital health platforms and services, available contact department assisting and navigating access to the digital health services).

Tackling healthcare inequalities and empowering patients can be assisted using the data owned by healthcare facilities. Hospitals have available, large scale data covering various diseases affecting different populations groups. Those data are filtered and classified by age/gender/location or other categories and can identify patient patterns, creation or prioritization of high-risk groups making them a valuable, direct pool of information.

Q18. Please indicate any other impacts on relevant economic, environmental, social or fundamental rights of a future European Health Data Space allowing for the access and use of personal health data for research, innovation, policy making and regulatory decision-making.

The creation of a European Health Data Space facilitating access and use of personal health data for research, innovation, policy making and regulatory decision-making has a potential positive impact for all levels in our health systems. The increased availability of data can help policy makers and regulators to make better and more effective evidence-based decisions while facilitating research and innovation based on outcomes that really matter to people.

Facilitate access and use of data, however, it must go hand in hand with providing patients with assurance on how the data is used and that it is used in line with the purposes for which the personal data were initially collected. Patients should also be made aware of possible consequences of the intended further processing for data subjects and adequate safeguards must be ensured (such as encryption and pseudonymisation).

The creation of a future EHDS may also help identify and ultimately tackle differences and inequalities between Member States (and potentially between sectors) in terms of health data digitisation, access and sharing mechanisms. Said differences and inequalities will have to be carefully considered in the deployment of the EHDS to avoid increasing disparity across Europe in

the digitalisation of health and care systems.

Section 2: Digital health services and products

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

Digital health services and products include remote care delivery, monitoring, diagnosis and therapeutic services but also the management of patient health data. Telemedicine can for example facilitate remote diagnosis or monitoring when patients and doctors/hospital are in different EU countries. Digital health services can be delivered via medical devices, such as remote monitoring of blood pressure, or specific software and algorithms are applied in analysing medical images or processing health data collected from wearable devices to process personalised medical suggestions.

National health authorities could pro-actively analyse the data from multiple sources to improve their healthcare system. Citizens could benefit from these services and products if they can be offered without barriers across the EU while ensuring data privacy and liability. To ensure this, solutions need to be found for adhering to minimum quality standards for example through certification and labelling, for interoperability and for reimbursement.

General principles for providing cross-border telemedicine services are set out in the cross-border healthcare Directive. According to this legislation the rules of the country where the patient is treated apply. The place of treatment is the country where the health care provider is established. EU countries need to ensure the following:

- Patients should receive a written or electronic record of the treatment
- Patients have the right to receive, upon request, the relevant information on the applicable standards and guidelines on quality and safety
- Transparent complaints procedures have to be in place.

Q19. How useful do you consider action in the following areas to ensure access and sharing ofhealth data nationally and across borders through digital health services and devices?

Citizens

	Not at all	To a limited extent	To some extent	To a great extent	Completely	I don't know / No opinion
Citizens **have the possibility** to transmit the data from m-health and tele-health into their electronic health records	○	○	○	This one		○
Citizens have the possibility to transmit the data from m-health and tele-health into the EU health data exchange infrastructure	○	○	○	This one		○

Healthcare professionals

	Not at all	To a limited extent	To some extent	To a great extent	Completely	I don't know / No opinion
Healthcare professionals have the right to access to patients' digital health records and to data pertaining to the patient's use of digital health products or services.	○	○	This one	○	○	○
Healthcare professionals can request transmission of the data from prescribed apps and other digital health services into the electronic health records of the patients	○	○	○	This one		○

Other

Please specify:

The most important precondition before access and sharing of health data digitally is patient consent. Once this is enforced, guaranteed, and protected, the European Health Data Space can function.

The possibilities to transmit health data into electronic health records and the health Data Space should exist and be encouraged as the most effective way towards Real World Evidence. Patients today are constantly generating data, and that data could enable a more productive conversation with healthcare professionals, a better understanding of the patient's condition.

Q20. Please indicate the most important impacts of the deployment and use of digital health products and services. Please consider relevant economic, environmental, social or fundamental rights impacts.

Broader deployment and use of digital health products and services can surely benefit patients at different levels. Better communication with healthcare professionals, improving self-management and monitoring of their own condition, easier access to their health records and sharing of their health data within and across-borders, improved access to healthcare for patients in remote areas are only few examples of the main positive impacts of digital health.

However, the deployment and use of digital health products and services must take into consideration a series of current challenges, including cultural and linked to potential reticence to use digital health.

- ***Financial impact:***

Due to the operational costs on public health and services, additional funding will be needed by countries to install large scale systems (either from building the IT infrastructure from scratch or optimize the current operational systems). In the case of public healthcare facilities, such as hospitals, due to underinvestment, they might not be able to introduce platforms facilitating the access to digital services to patient (such as doctors' appointments availability). On the other hand, there is a risk that the financial burden itself will eventually be born by patients since there are societal groups lacking access to primary utilities such as laptops or home computers, or mobile phones supporting the related software.

- ***Social impact:***

Awareness is needed on the fact that not all social groups have access to internet and to IT basic equipment. These social inequalities result in potential exclusion of vulnerable groups from using and benefiting from digital products and services. Consequently, the inability to access those services risk to deteriorate their already fragile social situation. Moreover, we should be aware that the objectives of those policies should not lead or target to a loss of human dimension for healthcare. The physical contact and bond between patient and doctor should never become a secondary priority but remain the pillar of the provision of healthcare services.

Q21. Do you think that tele-health could entail additional risks for the patients and for the doctors?

- ○ Yes
- ○ No
- ○ I don't know / No opinion

Please explain:

While the correct application of tele-health solutions can improve the relationship between patients and healthcare professionals, and access to care, there are some essential elements to be taken into consideration:

- Tele-health should, in normal conditions, not be seen as a replacement for traditional care but rather as an additional tool;
- Increased trust issues from the patients' point of view;
- The correct use of tele-health needs adequate skills and access to digital health solutions, both for healthcare professionals and patients to avoid risks of data privacy breach on handing multiple files by doctors.

- Additional stress for both patients and doctors, from difficulties in accessing and using digital solutions to depersonalisation of care, and adopting additional tools in already overcrowded schedules;
- Potential risks of mis-diagnosis, errors and miscommunication exacerbated by the use of tele-health solutions;
- Tele-health also requires proper access to digital tools. The digital divide currently existing within and across EU countries should be therefore taken into consideration.
- Patients with hearing, vision or physical impairment, dementia and other conditions are potentially prevented from using technologies related to tele-health.

Q22. If you see such risks, how should they be addressed?

	Not at all	To a limited extent	To some extent	To a great extent	Completely	I don't know / No opinion
Through protocols/rules for tele-health established at EU level	○	○	This one	○		○
Through minimum standards for tele-health equipments established at EU level	○	○	This one	○		○
Through liability rules established at national level	○	○	This one	○		○
Through liability rules established at EU level	○	○	This one	○		○

Other

Please specify:

Allergy, asthma and chronic obstructive pulmonary disease (COPD) are chronic diseases with comorbidities influencing many Europeans, hence a promotion of **digital health services and products is needed**. The use of tailor-made eHealth services can help:

- **Reduce misdiagnosis**: According to an EFA led survey, 16% of asthma and COPD patients across Europe get a wrong first diagnosis.
- **Foster the benefit of patient-centricity** and diagnosis
- Assist in **enabling optimal care decisions** and improving **treatment adherence**.
- **However, digital health cannot replace the face-to-face encounter with your healthcare provider. AI should not be used to perform tasks of Emotional Intelligence.**
- **Empower the patient community** as end users by introducing, developing, and delivering platforms for self-disease management plans.
- **Foster digital literacy**, including through the development of training tutorials to relevant stakeholders on data privacy breaches
- Promote **digital health equity**, removing barriers to access digital services
- Enable the **modernization of IT critical infrastructure** funded by EU budget.
- **Combat misinformation** and encourage **myth busting campaigns** by EU organisations (EDPS, EC), national government in cooperation with National Data protection authorities,

NGOs, Watchdogs, independent authorities

Meanwhile, we should always keep in mind that machine learning algorithms are made by humans, and they are prone to commit human based mistakes. For example, an AI model, based on correlation and not causation criteria, designed for predicting the risk of death for a patient with pneumoniae, learned that patients who have asthma and pneumonia face lower mortality rate than patients suffering from asthma, because the first category receives more aggressive treatment and thus have lower mortality rates. This system potentially might not be able to correctly assess a case-by-case situation and identify additional risk factors.

Q23. How appropriate do you consider the following actions to foster the uptake of digital health products and services at national and EU level?

	Not at all	To a limited extent	To some extent	To a great extent	Completely	I don't know / No opinion
A labelling scheme (a voluntary label indicating the interoperability level)			This one			
A certification scheme granted by third parties (a mandatory independent assessment of the interoperability level)			This one			
An authorisation scheme managed by national bodies (a mandatory prior approval by a national authority)					This one	
Other					This one	

Please specify:

Patients are the end-users of health products and services and they require simple, accessible information on safety and quality that in our view, should be given through the validation of a national authority and a seal, like they exist already for the medical device sector, and the medicines sectors

Q24. How appropriate do you consider the following measures in supporting reimbursement decisions by national bodies?

	Not at all	To a limited extent	To some extent	To a great extent	Completely	I don't know / No opinion

European guidelines on reimbursement for digital health products				This one		
European guidelines on assessments for digital health products				This one		
An EU repository of digital health products and services assessed according to EU guidelines to aid national bodies (e.g. insurers, payers) make reimbursement decisions				This one		
Extend the possibilities at national level for reimbursing all tele-health services (including telemedicine, telemonitoring, remote care services)				This one		
Facilitate reimbursement of all tele-health services (including telemedicine, telemonitoring, remote care services) across the EU (i.e. mutual recognition)				This one		
National authorities make available lists of reimbursable digital health products and services				This one		
EU funds should support/top up cross-border digital health services that comply with interoperability standards					This one	
and ensure the access and control of patients over their health data						

Q25. In your view, should access to EU funds for digitalisation in healthcare by Member States be conditional to interoperability with electronic health records and national healthcare systems?

- Yes
- No
- I don’t know / No opinion

Section 3: Artificial Intelligence (AI) in healthcare

The objective of this section is to identify appropriate rules (e.g. on the deployment of Artificial Intelligence systems in daily clinical practice) that would allow EU citizens to reap the benefits of Artificial Intelligence in healthcare (e.g. improved diagnosis, prognosis, treatments and management of patients). Artificial Intelligence systems in healthcare are primarily used in providing medical information to healthcare professionals and/or directly to patients and this raises new challenges. The Commission will propose a horizontal Artificial Intelligence regulatory framework in 2021. This proposal will aim to safeguard fundamental

EU values and rights and user safety by obliging high-risk Artificial Intelligence systems to meet mandatory requirements related to their trustworthiness. For example, ensuring that there is human oversight, and clear information on the capabilities and limitations of Artificial Intelligence.

Q26. How useful do you consider the following measures to facilitate sharing anduse of data sets for the development and testing of Artificial Intelligence in healthcare?

	Not at all	To a limited extent	To some extent	To a great extent	Completely	I don't know /No opinion
Access to health data by Artificial Intelligence manufacturers for the development and testing of Artificial Intelligence systems could be securely, including compliance with GDPR rules, facilitated by bodies established within the EHDS	○	○	This one	○		○
Bodies established within the EHDS provide technical support (e.g. on control datasets, synthetic data, annotation/labelling) **to data holders** topromote suitability of their health data for Artificial Intelligence development.	○	○	○	This one		○
Bodies established within the EHDS, alone or with other bodies established under the Testing and Experimenting Facilities, provide technical support **to medicine agencies, notified bodies formedical devices,** and other competentbodies in their supervision of ArtificialIntelligence products and services	○	○	○	This one		○
Other	○	○	○	○	○	○

Please specify:

Q27. In your view, is the introduction of Artificial Intelligence in healthcare creating a new relationship between the Artificial Intelligence system, the healthcare professional and the patient?

- ○ Yes
- ○ No
- ○

I don't know/No opinion

Please specify:

AI should be complementary in the relationship of Patient and Healthcare Professional, but it should never substitute it nor erase in-person healthcare services.

The use of AI is beneficial in optimising day-to-day operations, contributing to large population-scale cure treatments strategy and boost multidisciplinary care. It removed technical and administrative costs, delays, and burdens (long processing of data and tracking relevant scientific information directly to HCP) since it is a system used in all stages of healthcare (prevention, diagnosis, treatment, assist in decision making, foster innovation and quality healthcare services), allowing to HCP more patient-focused space and time, increasing their availability, and providing additional insights to patient's medical situation. Patients can benefit from a Digital Health Space in many ways as end users, but they should be included actively in any discussions for the creation of an infrastructure that considers their needs. Allergy, asthma, and COPD are medical conditions with similar symptoms and interlinked triggers that can aggravate a patient's health, yet with different therapeutic demands. For example, allergens can trigger both allergies and asthma, asthma can in turn increase the symptoms of COPD and allergy and asthma combined can increase the risk of COPD development in certain vulnerable population groups.

More specifically in the case of asthma and COPD as both chronic diseases, accurate data are not available due to the lack of early diagnosis or frequent misdiagnosis. According to EFA's Access survey, in the case of asthma the first diagnosis through a non-specialist general practitioner or community doctor only occurred in 41% of the respondents while the average time to get an appointment with a specialist can be quite lengthy (up to 5 months). Regarding misdiagnosis, it is very frequent that asthma symptoms can be wrongly identified with COPD ones. In COPD cases, diagnosis is given by specialists rather than general practitioners, but it can be erroneous as well leading to great delay in receiving the correct one. These challenges could be tackled with digital services identifying the availability of specialists according to patient's location, connecting them with HCP of their choice, by using digital platforms and contributing to the development of a sustainable disease's self-management.

Coming to self-management of allergy, patients can benefit from real-time applications for tracking allergens and pollutants concentration in specific areas to avoid or getting more access to diagnostic tests. This can be achieved with a user-friendly use of the Copernicus data system linking the EU digital health initiatives with environmental protection tools. With the patient community engagement, patients can feel less lonely on their disease, as per real-time information from other people going through the same symptoms.

Q28. How useful do you consider the following measures to ensure collaboration and education between Artificial Intelligence developers and healthcare professionals?

	Strongly agree	Somewhat agree	Neutral	Somewhat disagree	Strongly disagree	I don't know / No opinion

Artificial Intelligence developers are obliged to train healthcare professionals on the use of Artificial Intelligence systems provided (e.g. how Artificial Intelligence predictions should be best understood, applied in daily clinical practice and used for the best interests of the patients).	This one	○	○	○	○	○
Health care professionals and/or providers should						
demonstrate understanding of the potentials and limitations in using Artificial Intelligence systems (e.g. adopt protocols indicating in which cases a third opinion should be obtained when the Artificial Intelligence system reached a different opinion from the physician?)	This one	○	○	○	○	○

Q29. In your view, are there specific ethical issues involved in the use of the Artificial Intelligence in healthcare?

- ○ Yes
- ○ No
- ○ I don't know / No opinion

AI algorithms and machine learning tools are created to perform human replicated tasks. The automatization of large IT infrastructure, mimicking the human behavior creates social ethical and legal concerns that need to be addressed from the first stages of concept and software development.

We should always keep in mind that AI patterns are not neutral and can result in biased irregularities by certain data ingestion. Examples of ethical challenges can be found in the process of collecting and aggregating data from various sources. Determinants of social inequalities need to be considered as well. Taking as an example the higher rates of asthma occurring in lower income groups, this steers the debate of providing healthcare equality in terms of access and service provision in all citizens and how AI can solve or deteriorate the current status quo. The output generated from AI algorithms and the decisions made based on it, can lead to discrimination by not including important social background factors such as people's income and ethnicity (as mentioned before considered in asthma prevalence determinants) in the data gathering and processing results.

These real-life indicators show how important is the inclusion of patient representatives in the AI utilisation debate of healthcare, to ensure that **patients interests are defended**, **their needs are taken into account** and offering substantial **medical input for the public authorities' decision**-making process and **feedback to corporate stakeholders** to developing a successful digital product.

Moreover, AI can mislead. They often focus strictly on specific tasks, which replicate human biases and overfit data to make predictions leading to repeatable errors for cases falling outside of the general system that they have been designed for. Examples of this type of mistakes have been the i**) IBM Watson cancer initiative**, where the model was trained on hypothetical data and then graduated to real clinical situations too quickly **ii) Apple's HealthKit,** an application designed to track the intake of selenium and copper, where the male-based software development team neglected to include a women's menstrual cycle tracker until iOS 9.

Please explain what these issues are and how do you believe they could be addressed:

- Digital health cannot replace the face-to-face encounter with the healthcare provider. It should be conceived as a part of the healthcare system and help address persisting issues such as follow-up, adherence, isolation, and lack of self-management plans.
- Asthma patients rely on healthcare professionals more than expected with an 81% rely on their general practitioners for the management of their asthma. They have expressed the need to have access to specialists treating their diseases (nurses could also be included as an option).

Specific attention should be given in the following areas:

- Process for consent granting to be in accordance with GDPR rules (ensuring that the individuals understand what they are consenting to) and any violation should be enforced by local data protection authorities.
- Choose the correct AI algorithm and analysis tool to avoid biases, misconception or errors in handling data and providing results

Any new regulatory initiative or reassessment of a current legal framework should focus on ensuring

- User's data and PII (Personal Identifiable Information) safety: defining and respecting the definition, rights for patients and compliance requirement by data processors (data storage, handling and transmission to third parties – if applicable)
- Identify the related accountability of AI infrastructure users

Q30. Are there general comments you would like to make about measures needed to support the appropriate and trustable development, deployment and use of Artificial Intelligence in healthcare that would be aiding the best interest of the patients?

For a successful European Digital Health Space development, launch and acceptance by patients as end users, the European Commission needs to combat the misconceptions around the use of AI in healthcare and address the ongoing ethical and technical concerns of the general public.

Artificial Intelligence is not harmful as an IT tool, but we need to remain wary of the way it is used. There are a lot of misconceptions in popular culture that do not reflect the reality and the options offered by this technological advancement. The Commission needs to build trust among patients on the use of AI. This trust can only be fostered by informing patients from the very beginning, and in all stages of the process (since AI is used in prevention, diagnosis and decision making on treatment by healthcare professional) about the involvement of AI in the decisions on their healthcare – and, finally, by empowering patients to hold the decision-making made by AI into account where necessary. By building trust on the institutions and procedures in place we avoid the rising of health scrutiny and mistrust such as the Antivax movement.

Patients have the right to transparency on how their data will be used and what procedure or system will be in place from the very first stages of their eHealth journey. With accurate and proper information, patient disengagement can be avoided, and a sustainable utilisation will be guaranteed.

Finally, the European Commission needs to create and ensure an environment of safe technology while imposing safeguarding practices in terms of compliance and surveillance in the sensitive areas of data gathering, processing, portability, and privacy.

Thank you for your contribution to this questionnaire. In case you want to share further ideas on these topics, you can upload a document below.

Please upload your file:

Only files of the type pdf,txt,doc,docx,odt,rtf are allowed

Final comments:

We welcome the European Commission's decision to consult civil society stakeholder's opinion and perspective on the upcoming European Health Data Space. Our general goal is to encourage the sharing of health data for the purposes of advancing diagnosis, disease management, cross-border healthcare, research, and the development of treatment; while ensuring the handling of patients' health data is fully in line with the GDPR framework and other relevant safeguards of the existing EU framework. In the text below you can find our comments and proposal on top of the previous responses.

EFA strongly advocates for protecting and exercising the fundamental right of consent of patients protected by EU legal framework and the institutions. Patients need to develop strong health literacy regarding the right of giving and revoking their consent for use of their sensitive health data, implications, and risk of not exercising this right. It is notable that younger generations and young patients due to their familiarity and use of digital tools (apps) they tend to give consent in platforms without always considering what those concessions entail for their digital footprint (cookies permission, navigation apps, geolocalisation add in, smartwatches etc). The request for consent is also significant not only in the case of using data by healthcare professionals or facilities but also when the data is addressed to commercial use. During the creation of the new European Health Data Space, the European Commission needs to use all the policy and legal tools at its

disposal, deriving from EU treaties and initiatives to protect any malicious use of patients' data. AI in EU level is subject to GDPR provisions, but also to other cross-sectoral legal frameworks such as administrative law (how decision-making is achieved in law enforcement operations), competition law (in terms of digital product authorisation), consumer law (protection of patients/ citizens being end users of a product), constitutional law of Member States and executive acts by data protection authorities in favor of the data subject. This cross-sectoral combination of protection mechanisms in place can ensure the liability, accountability of safe AI usage by implicated actors, protection of patients' data, risk prevention and development of a compliant and trustworthy digital health environment.

We have noticed that this consultation is not touching upon the different incentives and tradeoffs of the future European Health Data Space to the relevant stakeholders. EFA strongly advocates for the availability of incentives as a factor providing further motivation for this project resulting in a faster project implementation and allowing patients to benefit from it as soon as possible. To this regard we have identified the following proposals for hospitals and healthcare professionals:

- For **hospitals**, the incentive should be the **reception of credits and acknowledgement** for their contribution extended beyond patient treatment services, considering the access in large-scale databases and different types of disease information, creating rich information platforms, fruitful for AI processing and input/output result production beneficial for the medical community.
- For healthcare professionals, incentives should include **skillset development** on AI and IT health literacy that will lead in increased knowledge, adaptability, expansion of their scope of services, activities, and contribution to patient community.