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 the approval 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	○	○		○	○	○
Continuity and access to safe and high quality healthcare	○	○		○	○	○
Development of methods for enabling the use of medical information for public health and research	○	○		○	○	○
Development of common identification and authentication measures to facilitate transferability of data	○	○		○	○	○

Access of patients to an electronic copy of the electronic health record	○	○		○	○	○
Cross-border provision of telemedicine	○	○	○	○	○	○

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	○	○	○	○		○
Facilitate delivering healthcare for citizens across borders	○	○	○	○		○
Promote citizens' control over their own health data, including access to health data and transmission of their health data in electronic format	○	○	○	○		○
Promote the use of digital health products and services by healthcare professionals and citizens	○	○	○	○	○	○
Support decisions by policy-makers and regulators in health	○	○	○	○	○	○
Support and accelerate research in health	○	○	○	○	○	○
Promote private initiatives (e.g. for innovation and commercial use) in digital health	○	○	○	○	○	○
Other	○	○	○	○	○	○

Please specify:

For questions 2.4, 2.5, 2.6 and 2.7.:
There is agreement with these objectives provided that:
a) robust personal data protection safeguards are in place.
b) digital health systems at national level are in place and provide the highest degree of protection of personal data.
For Q 2.7 specifically, EATG considers that a European framework on the access and exchange of personal health data should promote both private and public sector innovation (the question only refers to private initiatives.

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 MyH ealth@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 providecitizens 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 G D P R .

Furthermore, some conditions need to be in place to ensure easy, lawful and trusted exchange of health d a t a c r o s s b o r d e r s :

- 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)	○	○	○	○		○
The right to transmit my heath data in electronic format to another professional/entity of my choice	○	○	○	○		○
The right to request public healthcare providers to share electronically my health data with other healthcare providers/entities of my choice	○	○	○	○		○
The right to request healthcare providers to transmit my health data in my electronic health record	○	○	○	○		○
The right to request app providers to ensure the transmission of my health data in my electronic health record	○	○	○	○		○

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	○	○	○	○		○

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	○	○	○	○		○
Access my health data that is exchanged between health professionals or with other entities via a digital infrastructure	○	○		○	○	○
Access my health data that is exchanged between health professionals across borders via an EU electronic infrastructure	○	○		○	○	○
Access my health data on a mobile application and share it with healthcare professionals or other entities of my choice	○	○	○	○		○
The infrastructure or personal digital storage for accessing the data should be secure and prevent cyberattacks	○	○	○	○		○
Other	○	○	○	○		○

Please specify:

The control of access and sharing of one's data must be person-centred, therefore if 4.1 is a pre-condition for answers to Q 4.2 and 4.3.

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 An
- EU body
- Other

Please specify:

It is unclear to us who the digital health bodies are in each country.
EATG favours strong cooperation between national/regional bodies at EU level because there maybe too much national resistance to the setting up of an EU body

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)
- Other

Please specify:

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

Please specify:

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	○	○		○

Benefits for patients

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

Benefits on healthcare systems efficiencies

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

Other

Please specify:

If measures facilitating access to, control and transmission of health data for healthcare provide the highest degree of personal data protection and are effective, they will have a positive high impact in terms of improving the safety and quality of healthcare for patients.

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	○	○	○		○
Mandatory appointment of a national body that authorises access to health data by third parties	○		○	○	○
A public body collects the consent of individuals to share their health data for specified societal uses (“data altruism”) and manages their health data		○	○	○	○
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	○	○	○		○

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	☐	☐	☐	☐	☐		☐	☐
Administrative data in relation to reimbursement of healthcare	☐	☐	☐	☐	☐		☐	☐
Social care data	☐	☐	☐	☐	☐		☐	☐
Genetic and genomic data	☐	☐	☐	☐	☐		☐	☐

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)	☐	☐	☐	☐	☐		☐	☐
Pseudonymised format (without identifiers of individuals)	☐	☐	☐	☐	☐	☐		☐
Fully identifiable format	☐	☐	☐	☐	☐	☐		☐

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	☐	☐	☐	☐	☐		☐	☐
Safeguards for the access to health data for the purpose of re-use, in line with ethical and data protection requirements, are defined	☐	☐	☐	☐	☐		☐	☐

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

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	☐	☐	☐	☐	☐		☐	☐

Other

Please specify:

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

Please specify:

EATG answers no to Q12.2, due to the discriminatory nature of certain legislative frameworks and lack of respect for the fundamental rights of people living with and most affected by HIV (people using drugs, sex workers, gay and other men having sex with men, trans persons, people in detention, undocumented migrants) in some countries. We are concerned that national legislation in place certain countries would not offer the necessary fundamental rights safeguards. In that context, the sharing of personal health data could have harmful consequences for data subjects who are already discriminated against.

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	○	○	○	○	○	○
Other	○	○	○	○	○	○

Please specify:

This is an unclear question

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	○	○	○	○		○
Setting standards on interoperability together with national bodies dealing with secondary use of health data	○	○	○	○		○
Facilitating cross-border queries to locate relevant datasets in collaboration with national bodies dealing with secondary use of health data	○	○	○	○		○
Acting as technical intermediary for cross-border data sharing	○	○	○	○		○
Authorising access to cross-border health data (data processed in a cross- border or EU wide manner, such as European Reference Networks)	○	○	○	○		○

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		○	○	○	○	○
Stakeholders participating in the EHDS cross-border infrastructure are subject to the mandatory use of specific technical requirements and standards	○	○	○	○		○

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

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	○	○		○
Increased safety of health care and of medicinal products or medical devices	○	○		○
Faster innovation in health	○	○		○

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)	○	○		○
Reduced administrative burden in accessing health data	○	○		○

Technological progress	○	○		○

Other

Please specify:

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.

A primary benefit for the patient/health service user would be to be able to access the health service they need in any other member state.

The access and use of personal health data for the above mentioned purposes will only be possible with harmonisation of standards and technical requirements across EU member states. To ensure due process, respect for fundamental rights and trust between countries and trust of citizens, there will need to be improvements in standards and their implementation at national and EU level. Together with standards, improvement in technical requirements at national level across EU countries, will be necessary to make the EHDS operational. Without these upwards harmonisation of standards and practice, there will be no trust in the system, no data sharing and/or risk of breaches of fundamental rights, as well as practical barriers.

In that light, the European Health Data Space could be a tool for upward convergence across the EU, supporting a person-centred healthcare digital transformation at country and EU levels. It will be a tool for overcoming inequalities in health between and within member states. It will lay the ground for greater trust and collaboration between member states. It will respond to the demands of the large majority of citizens who demand greater EU engagement in the area of health to help improve health systems, public and individual health outcomes.

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 of health 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	○	○	○	○		○
Citizens have the possibility to transmit the data from m-health and tele-health into the EU health data exchange infrastructure	○	○	○	○		○

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.	○		○	○	○	○
Healthcare professionals can request transmission of the data from prescribed apps and other digital health services into the electronic health records of the patients	○		○	○	○	○

Other

Please specify:
This requires the patient to control which personal health data is shared and with whom.

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.

The observations below are drawn from a literature review and lessons learnt from the EmERGE project (EU co-funded project: https://www.emergeproject.eu/policy). A key

finding of the project is that “the implementation of the EmERGE app yielded benefits, such as ownership of one’s own health data; time and money savings associated with travel; less uncertainty about one’s health status; increased motivation around health behaviour; and the ability to preserve anonymity and avoid stigma”. (report from EmERGE closing meeting https://www.emergeproject.eu/meeting p. 4)

The use of the EmERGE and the way it was developed indicates some of the opportunities provided by digital health products and tools.

*1/ Digital care pathways present opportunities for health systems, including “**cost savings,** improved efficiencies, and better data management for clinical and research purposes (Cooper et al. 2017). Some challenges in implementing new mHealth interventions include the complexity and political nature of health systems decision-making; trust among various stakeholders; the nature of relationships between community and the clinic; and, whether or not the mHealth intervention is commercialised as a for-profit versus a non-profit enterprise”* (see EmERGE Deliverable 2.3; EmERGE Deliverable 2.4 and Deliverable 8.5: Policy Brief How EmERGE has addressed barriers in implementing mHealth in the EU https://www.emergeproject.eu/policy, p.7).

2/ By freeing up healthcare provider time for patients with complex health needs. *“By offering an alternative care pathway, those patients who choose to use the app will end up freeing up clinic time for those for whom the app is unsuitable or for those whose preference leans towards face-to-face interactions with healthcare professionals in their clinics”.* (https://www.emergeproject.eu/policy P.8). However, tele-health must be seen as an additional tool not a full replacement of face-to-face interactions between healthcare providers and patients.

3/ By addressing stigma associated with HIV positive status in the following ways: “fewer trips to facility and interactions with those who might stigmatise. Reduces burden of follow up .... Provides data source to share with partners to prove viral load undetectability” and therefore the virus is non-transmissible. (report from EmERGE closing meeting https://www.emergeproject.eu/meeting p. 4)

4/ By addressing ongoing challenges through a rigorous product and service co-design process, including *“stigma, the issue of disclosure, sometimes difficult relationships with clinicians and fears around confidentiality”* (report from EmERGE closing meeting *https://www.emergeproject.eu/meeting p.4)* .

5/ By increasing patient's ability to access their own health data. For now many clinical databases do not allow patients to access the medical record. mHealth-based technology developments could enable access. Policy Brief How EmERGE has addressed barriers in implementing mHealth in the EU https://www.emergeproject.eu/policy. Moreover patients were empowered to ask for access to other personal health data.

6/ By improving access to services, especially where patients have long distances to travel. Policy Brief How EmERGE has addressed barriers in implementing mHealth in the EU https://www.emergeproject.eu/policy

8/ By improving the quality and integration of care since it has potential for continuous clinical monitoring of different health issues (glucose, heart rhythm), support for other health applications (e.g. COVID-19). For now, *"mHealth initiatives are often closed systems, meaning that they refer to one health condition or aspect of health care only, forcing patients to use multiple apps for different* purposes *(Tomlinson et al. 2013)."* Policy Brief How EmERGE has addressed barriers in implementing mHealth in the EU https://www.emergeproject.eu/policy.

10/ There could be opportunities to integrate other functionalities

- social support functionalities.
- Information on medication that can be used in other members states.
- easy access to information on clinically relevant drug-drug interactions.
- COVID-19 vaccines and testing information.

10/ Anonymous Partner notification: For instance to receive anonymous and early notifications in case of a detected sexually transmitted infection in a recent partner; to facilitate access to a health care centre specialised in screening and treatment, to receive reminders for HIV pre-Exposure prophylaxis users. *https://www.weflash.fr/utilisez-lapp-flash/*

11/ Telehealth/mobile health solutions provide opportunities to reduce the carbon footprint of individuals by reducing some unnecessary travel of patients/other health service users.

12/ Telehealth services also present time and financial costs saving in reducing the need to travel to and back from the healthcare provider.

13/ By maintaining a certain level of care during COVID-19 lockdown and physical

distancing measures. Partners using the EmERGE app in Antwerp, Belgian found that "*for people enrolled in the EmERGE programme, it was fast and easy to send messages to advise people how to deal with their HIV care services during lockdown, including how to deal ART refills. A few people who were not enrolled in EmERGE missed their ART refill dates and ended up with extremely high viral loads. They would have benefitted from being part of the EmERGE programme*."
(report from EmERGE closing meeting *https://www.emergeproject.eu/meeting p.6)* .

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:

1/ There are risks related to breaches of personal health data, their misuse, involuntary forced health data disclosure. Data security around health status is a particular concern for conditions like HIV that are still highlighly stigmatised.This is a concern when national policies /legislation discriminate against certain population groups and/or when digital health products and service's development and implementation is driven by commercial interests.

According to research from the EmERGE project "where stigma and discrimination against people living with HIV is high, people feel that their data is safer when stored in a separate system https://www.emergeproject.eu/policy

2/ Digital health products and services development and deployment should be driven by service users and healthcare providers' needs and interests,not by healthcare cost-cutting or commercial logic. The latter risk being detrimental to adherence or quality of services and personal data security issues risk being secondary considerations.

3/ While digital technologies can serve to empower patients, not all of them have the ability to interpret this health data or engage with their data. Health and digital literacy is important in the context of telehealth and must be considered by policy makers, designers and implementers. Moreover, the fact that many people do not have access to smartphones or data plans or are afraid of lack of data security must be considered.

4/ In some places the EmERGE app did not solve other systemic logistical issues, such as needing to go to facilities for blood work or for picking up prescriptions"(report from EmERGE closing meeting https://www.emergeproject.eu/meeting p. 5)

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	○	○		○	○	○
Through minimum standards for tele-health equipments established at EU level	○	○	○	○		○
Through liability rules established at national level	○	○	○	○		○
Through liability rules established at EU level	○	○	○	○		○

Other

Please specify:

1/ Tele-health must be seen as an additional tool not a full replacement of face-to-face interactions between healthcare providers and patients.

2/ **"***mHealth solutions need to be accessible (including cost) for the most vulnerable people and be sure to leave no one behind. mHealth solutions need to be flexible and adaptable to different contexts in different countries and settings"* (report from EmERGE closing meeting https://www.emergeproject.eu/meeting p. 5 and https://www.emergeproject.eu/policy p.9)

*3/ "Country-level certification for mHealth solutions including clinical and nonclinical aspects. Ensure that applications from different providers can interact with country-level systems. Enforcing standards for eHealth and mHealth to provide for interoperability"(*report from EmERGE closing meeting https://www.emergeproject.eu/meeting p. 4)

4/ The European Health Data Space should have patient empowerment as core objective and work on the EU standardisation of data to facilitate cross-border exchange of Patient Summaries and ePrescriptions".(report from EmERGE closing meeting https://www.emergeproject.eu/meeting p. 4)

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)		○	○	○	○	○

A certification scheme granted by third parties (a mandatory independent assessment of the interoperability level)	○	○	○	○		○
An authorisation scheme managed by national bodies (a mandatory prior approval by a national authority)		○	○	○	○	○
Other	○	○	○	○	○	○

Please specify:

Having GDPR proof, publicly funded and publicly accountable digital health products and services infrastructure will foster trust and thereby greater willingness to take these up.

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	○	○	○	○		○
European guidelines on assessments for digital health products	○	○	○	○		○
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	○	○	○	○		○
Extend the possibilities at national level for reimbursing all tele-health services (including telemedicine, telemonitoring, remote care services)	○	○	○	○		○
Facilitate reimbursement of all tele-health services (including telemedicine, telemonitoring, remote care services) across the EU (i.e. mutual recognition)	○	○	○	○		○

National authorities make available lists of reimbursable digital health products and services	○	○	○	○		○
EU funds should support/top up cross-border digital health services that comply with interoperability standards	○	○	○			○
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 and use 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	○	○	○	○		○
Bodies established within the EHDS provide technical support (e.g. on control datasets, synthetic data, annotation/labelling) to data holders to promote suitability of their health data for Artificial Intelligence development.	○	○	○	○		○
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 for medical devices, and other competent bodies in their supervision of Artificial Intelligence products and services	○	○	○	○		○
Other	○	○	○	○	○	○

Please specify:

EATG supports the position of EPF regarding EU measures to facilitate sharing and use of data sets for the development and testing of Artificial Intelligence in healthcare.

"AI together with big data has the potential to transform several care delivery methods, and can provide great benefits at several levels of the healthcare value chain. However, as with any new technology, there may also be unrealistic expectations. Artificial intelligence has risks, limitations and concerns including ethical, technical, and legal issues, which are often closely connected.

AI depends on the availability of very large amounts of good/quality data. If the available data are not enough, not good quality, inconsistent, or biased, this limits the potential of AI to be useful. AI also has the potential to make wrong decisions; reliability and safety are particularly critical in healthcare, where errors can have serious consequences. The EHDS can surely play an important role in making sure that European AI solutions will be built on unbiased and good quality data. The EHDS framework can facilitate AI manufacturers' access to data in a secure and compliant framework in line with GDPR rules and to minimise potential risks in terms of data protection. The EHDS should also ensure that AI is built on good quality and unbiased data: through technical support, the EHDS can ensure that data will be 'by default' suitable for AI purposes.

Furthermore, the development of AI and machine learning also creates significant ethical risks, including in relation to the anonymisation and pseudonymisation of data, which poses risks to the privacy of individuals (e.g. through reverse engineering of data to identify individuals). A strong governance approach, that includes patient representation, should be embedded in the EHDS, ensuring that ethical risks are quickly identified and managed.

Finally, the EHDS should indeed also serve as a supporting framework to promote an harmonised approach to assess AI products and services for medicine agencies, notified bodies or other competent bodies.

Finally, the EHDS should carefully consider the type of data use and AI, between data used for public good versus commercial benefit. Collaboration within the EHDS for businesses and companies should be therefore guided by criteria of value and legitimacy (e.g. through participation in EU funded research, or return of results/data insights).

For an overview of EPF's broader view on AI in healthcare, it is possible to consult our response to the European Commission White Paper on AI."

In addition, EATG believes that the EU can establish a framework to deal with conflict of interests issues.

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:

Given the way in which Question 27 is formulated, we disagree. AI should not be a third subject in the relationship but a tool as any other tool. AI should remain a tool aiding decision- making, not replacing it or reducing human autonomy in decision-making or human interaction in healthcare.

The development of AI in healthcare should include a strong digital and AI literacy component,including on ethical issues for both healthcare providers, policy-makers and healthcare service users and patients.

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).		○	○	○	○	○
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?)		○	○	○	○	○

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

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

Bias in algorithm which may be detrimental to the patient, healthservice users and could be reflecting and strengthening structural or societal bias/discrimination.

AI should remain a tool aiding decision- making, not replacing it or reducing human autonomy in decision-making (both patient, service user or healthcare provider or human interaction in healthcare.

Furthermore, EATG supports EPF's position on addressing key ethical risks.

"Ethicists have identified a risk of limiting human autonomy if AI were to make a calculation on risk or restrict a patient's right to free, fully informed choice of (for example) treatment, if an AI system made certain decisions based on what it "thinks" is the best for the patient. Maintaining human oversight of AI based decisions and the decisions flowing from it is thus particularly important in healthcare. When discussing AI in healthcare, it will be fundamental to keep in mind the essential relation between the AI systems, healthcare professionals and patients.

As previously mentioned, AI must be seen as a support tool to improve care delivered by healthcare professionals (from diagnosis to treatment), but not as a replacement. Furthermore, AI, if used to replace real human contact, may actually increase social isolation and additional stress. This approach should clearly apply beyond clinical practice, when AI is used to inform broader delivery of services, public health interventions, and policy making in the field of healthcare.

Biases in data also introduce ethical issues in terms of the potential for AI-enabled decisions themselves to be biased or discriminatory. Biases in data collection can affect the type of patterns AI will identify. This is an issue since, for example, women and ethnic minorities are often underrepresented in clinical trials and large data sets used to train AI. Bias in the data will have an effect on the algorithm that is developed, replicating the bias found in society. Patients with multiple or rare diseases may also be affected by this. This issue should be tackled by making sure that AI is based on good quality and unbiased data.

Transparency is another key issue when it comes to Artificial Intelligence: as previously stated, explainable, ethical AI solutions should be preferred over "black box" methodologies, with rules for transparency and data governance. Clear rules, strategies, risk management and certification mechanisms will also have an impact on user confidence in AI-based products and services.

EPF calls for particular attention in ensuring that AI in healthcare enhances society, and is an enabler of – and not a threat to – patients' rights and wellbeing, guaranteeing that the value of real human contact is not minimised or entirely replaced by technological alternatives.

Finally, a crucial point related to AI in healthcare is linked to the crucial role of information for patients: patients have 'the right to be fully informed' about the functionality, consequences, and possible consequences of AI incorporation in e.g., health information, diagnosis and treatment procedures, health monitoring, transactions, and interaction. As matter of prudence, responsible parties (e.g., health professionals, authorities, industry) should follow the existing principles for informed consent and decision making."

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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?

The EU must ensure public ownership, transparency, accountability of AI players to ensure appropriate and trustable development, deployment and use of Artificial Intelligence in healthcare that would be aiding the best interest of the patients.

The EU can be a leading force in developing a person-centred AI framework by meaningfully engaging with patient organisations, health services users (in the case of diseases prevention) and organisations representing the interest of sub-population groups to co-design a regulatory framework and implementation measures to ensure that the use of AI in health care is safe, ethical and equitable.

We are in line with EPF's response to the EC **White Paper on AI, https://www.eu-patient.eu/globalassets/documents/1.-ai-white-paper_consultation-response_epf_statement-final.pdf** that the upcoming framework should take into consideration the following elements:

- "Addressing the key challenges of AI in health regarding human autonomy, human oversight, risks of social isolation, transparency and potential misuse of AI leading to issues such as overdiagnosis or unwanted exposure of patients'personal profiles.

- Focus on the dependency of AI on large amounts of good quality, unbiased, standardised, and interoperable data. Such data should also be treated keeping in mind the highest possible levels of data protection for patients

- Ensure involvement of citizens, patients and other relevant stakeholders – healthcare professionals, in particular – as a key action to achieve a European ecosystem of excellence for AI in healthcare

- Transparent, effective, and sustainable AI research and innovation. This should be built on principles such as accessibility and affordability of AI research and innovation results and products and on innovation priority-setting based on the patients' unmet health needs.

- Boost healthcare professionals skills and digital health literacy as a precondition to exploit AI at European level."

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:

Other remarks:

- Access to and control over one's own health data must be the cornerstone of EHDS, including the right to revoke and withdrawing consent.
- There should be clear and easily accessible and understandable information on the EHDS to generate engagement and trust of stakeholders, patients and service users in particular.
- Patients /service users must be able to experience positive change brought by EHDS.
- There should be different levels of entrance and different layers for use by
- citizens.

Further pre-conditions to answers to Q1, Q3, Q10, Q14 and Q19 (questions with no comment box options):

Q1: Changes in health data sharing across border

There may have been changes, but none that were reported/noticed by EATG members

Q3: Access to and exchange of health data for healthcare

a) the right to control one's own data should be paramount.

b) there should be simple and clear pathways to access one's own data, in order to ensure real opportunity to engage with one's own heath data.

Q10: Mechanism to facilitate access to health data for research, innovation, policy-making and regulatory decision.

EATG underlines the obligation to ensure anonymity and providing information in clear language that the patient/service user can understand.

Q14 : Role of the EU body in facilitating access to health data for research, innovation, policy making and regulatory decision.

All of the EU body's functions must be underpinned by robust privacy and personal

data protection, including the right not to be discriminated against, and data control over one's own data.

Q19. Actions to ensure access and sharing of health data nationally and across borders through digital health services and devices

- **citizen level**

EATG agrees provided that the people are able to engage with their own data. Information should be delivered in understandable language. There should be an easy pathway to one's one data and the ability to control one's own data.

- **Healthcare provider level**

EATG agrees provided the patients/service user gives their informed consent and can engage with their own health data.