

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.

About you

* Language of my contribution

- Bulgarian
- Croatian
- Czech
- Danish
- Dutch
- English
- Estonian
- Finnish
- French
- German
- Greek
- Hungarian
- Irish
- Italian
- Latvian
- Lithuanian
- Maltese
- Polish
- Portuguese
- Romanian
- Slovak
- Slovenian
- Spanish
- Swedish

* I am giving my contribution as

- Academic/research institution
- Business association
- Company/business organisation
- Consumer organisation
- EU citizen
- Environmental organisation

- Non-EU citizen
- Non-governmental organisation (NGO)
- Public authority
- Trade union
- Other

* First name

Kristin

* Surname

Little

* Email (this won't be published)

k.little@ieee.org

* Organisation name

255 character(s) maximum

The Institute of Electrical and Electronics Engineers, Incorporated

* Organisation size

- Micro (1 to 9 employees)
- Small (10 to 49 employees)
- Medium (50 to 249 employees)
- Large (250 or more)

Transparency register number

255 character(s) maximum

Check if your organisation is on the [transparency register](#). It's a voluntary database for organisations seeking to influence EU decision-making.

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* Country of origin

Please add your country of origin, or that of your organisation.

- Afghanistan
- Djibouti
- Libya
- Saint Martin
- Åland Islands
- Dominica
- Liechtenstein
- Saint Pierre and Miquelon

- Albania
- Algeria
- American Samoa
- Andorra
- Angola
- Anguilla
- Antarctica
- Antigua and Barbuda
- Argentina
- Armenia
- Aruba
- Australia
- Austria
- Azerbaijan
- Bahamas
- Bahrain
- Bangladesh
- Barbados
- Belarus
- Belgium
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- Bolivia
- Dominican Republic
- Ecuador
- Egypt
- El Salvador
- Equatorial Guinea
- Eritrea
- Estonia
- Eswatini
- Ethiopia
- Falkland Islands
- Faroe Islands
- Fiji
- Finland
- France
- French Guiana
- French Polynesia
- French Southern and Antarctic Lands
- Gabon
- Georgia
- Germany
- Ghana
- Gibraltar
- Greece
- Greenland
- Grenada
- Lithuania
- Luxembourg
- Macau
- Madagascar
- Malawi
- Malaysia
- Maldives
- Mali
- Malta
- Marshall Islands
- Martinique
- Mauritania
- Mauritius
- Mayotte
- Mexico
- Micronesia
- Moldova
- Monaco
- Mongolia
- Montenegro
- Montserrat
- Morocco
- Mozambique
- Myanmar/Burma
- Namibia
- Saint Vincent and the Grenadines
- Samoa
- San Marino
- São Tomé and Príncipe
- Saudi Arabia
- Senegal
- Serbia
- Seychelles
- Sierra Leone
- Singapore
- Sint Maarten
- Slovakia
- Slovenia
- Solomon Islands
- Somalia
- South Africa
- South Georgia and the South Sandwich Islands
- South Korea
- South Sudan
- Spain
- Sri Lanka
- Sudan
- Suriname
- Svalbard and Jan Mayen
- Sweden

- Bonaire Saint Eustatius and Saba
- Bosnia and Herzegovina
- Botswana
- Bouvet Island
- Brazil
- British Indian Ocean Territory
- British Virgin Islands
- Brunei
- Bulgaria
- Burkina Faso
- Burundi
- Cambodia
- Cameroon
- Canada
- Cape Verde
- Cayman Islands
- Central African Republic
- Chad
- Chile
- China
- Christmas Island
- Clipperton
- Guadeloupe
- Guam
- Guatemala
- Guernsey
- Guinea
- Guinea-Bissau
- Guyana
- Haiti
- Heard Island and McDonald Islands
- Honduras
- Hong Kong
- Hungary
- Iceland
- India
- Indonesia
- Iran
- Iraq
- Ireland
- Isle of Man
- Israel
- Italy
- Jamaica
- Nauru
- Nepal
- Netherlands
- New Caledonia
- New Zealand
- Nicaragua
- Niger
- Nigeria
- Niue
- Norfolk Island
- Northern Mariana Islands
- North Korea
- North Macedonia
- Norway
- Oman
- Pakistan
- Palau
- Palestine
- Panama
- Papua New Guinea
- Paraguay
- Peru
- Switzerland
- Syria
- Taiwan
- Tajikistan
- Tanzania
- Thailand
- The Gambia
- Timor-Leste
- Togo
- Tokelau
- Tonga
- Trinidad and Tobago
- Tunisia
- Turkey
- Turkmenistan
- Turks and Caicos Islands
- Tuvalu
- Uganda
- Ukraine
- United Arab Emirates
- United Kingdom
- United States

- Cocos (Keeling) Islands
- Colombia
- Comoros
- Congo
- Cook Islands
- Costa Rica
- Côte d'Ivoire
- Croatia
- Cuba
- Curaçao
- Cyprus
- Czechia
- Democratic Republic of the Congo
- Denmark
- Japan
- Jersey
- Jordan
- Kazakhstan
- Kenya
- Kiribati
- Kosovo
- Kuwait
- Kyrgyzstan
- Laos
- Latvia
- Lebanon
- Lesotho
- Liberia
- Philippines
- Pitcairn Islands
- Poland
- Portugal
- Puerto Rico
- Qatar
- Réunion
- Romania
- Russia
- Rwanda
- Saint Barthélemy
- Saint Helena
Ascension and
Tristan da Cunha
- Saint Kitts and
Nevis
- Saint Lucia
- United States
Minor Outlying
Islands
- Uruguay
- US Virgin Islands
- Uzbekistan
- Vanuatu
- Vatican City
- Venezuela
- Vietnam
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Futuna
- Western Sahara
- Yemen
- Zambia
- Zimbabwe

The Commission will publish all contributions to this public consultation. You can choose whether you would prefer to have your details published or to remain anonymous when your contribution is published. **For the purpose of transparency, the type of respondent (for example, 'business association', 'consumer association', 'EU citizen') country of origin, organisation name and size, and its transparency register number, are always published. Your e-mail address will never be published.** Opt in to select the privacy option that best suits you. Privacy options default based on the type of respondent selected

* Contribution publication privacy settings

The Commission will publish the responses to this public consultation. You can choose whether you would like your details to be made public or to remain anonymous.

Anonymous

Only organisation details are published: The type of respondent that you responded to this consultation as, the name of the organisation on whose behalf you reply as well as its transparency number, its size, its country of origin and your contribution will be published as received. Your name will not be published. Please do not include any personal data in the contribution itself if you want to remain anonymous.

Public

Organisation details and respondent details are published: The type of respondent that you responded to this consultation as, the name of the organisation on whose behalf you reply as well as its transparency number, its size, its country of origin and your contribution will be published. Your name will also be published.

I agree with the [personal data protection provisions](#)

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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Continuity and access to safe and high quality healthcare	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Development of methods for enabling the use of medical information for public health and research	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Development of common identification and authentication measures to facilitate transferability of data	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Access of patients to an electronic copy of the electronic health record	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cross-border provision of telemedicine	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Facilitate delivering healthcare for citizens across borders	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Promote citizens' control over their own health data, including access to health data and transmission of their health data in electronic format	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Promote the use of digital health products and services by healthcare professionals and citizens	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Support decisions by policy-makers and regulators in health	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Support and accelerate research in health	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Promote private initiatives (e.g. for innovation and commercial use) in digital health	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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 **cross borders**:

- 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)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The right to transmit my health data in electronic format to another professional/entity of my choice	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The right to request public healthcare providers to share electronically my health data with other healthcare providers/entities of my choice	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The right to request healthcare providers to transmit my health data in my electronic health record	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The right to request app providers to ensure the transmission of my health data in my electronic health record	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Access my health data that is exchanged between health professionals or with other entities via a digital infrastructure	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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

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:

The IEEE Standards Association recommends looking at the broader standardization system addressing European needs that involves the ESOs, ISO/IEC/ITU, the Global SDOs such as IEEE, and the direct participation model provided by ETSI. This set of SDOs has for many years been developing standards that address European policy areas. This is particularly the case in the area of ICT standardisation, such as internet standards and new technologies including artificial intelligence and blockchain. The IEEE Standards Association believes it is in Europe's strategic interest to cooperate with this broader set of SDOs to develop standards and technical requirements at the EU level to support the exchange of data in healthcare.

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:

With the establishment of consensus-driven standards, an independent organization will audit the process to see if it meets the performance requirements of recognized technical standards and any applicable regulatory guidance. Depending on the design of the certification program, an assessment of the company's systems to ensure that processes are designed and implemented meet the standard's requirements would be needed. When these conditions are met, the independent third party, such as IEEE, could grant the entity the use of a certification mark for recognition of compliance.

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:

In the case of sharing personal/health data, an independent body functioning as a "quality control" on the interoperability of the data would offer third party objectivity in ensuring appropriate data governance models are followed. It would also deliver ongoing guidance and ensure that all entities involved in the transaction are following common processes to promote interoperability. Third party certification processes provide unbiased audits and certifications that can be used to confirm that appropriate processes were followed.

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
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Implementation costs for national healthcare providers (setting up infrastructure, complying with defined standards, etc.).	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Costs for healthcare professionals and providers (human resources, finances, etc.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Information and monitoring	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

Benefits for patients

	No impact	Moderate impact	High impact	I don't know / No opinion
Transparency on the processing of their health data	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Reduced costs stemming from not duplicating efforts and tests	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Reduced administrative burden	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

Benefits on healthcare systems efficiencies

	No impact	Moderate impact	High impact	I don't know / No opinion
Better healthcare provision (including risks and errors)	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Reduced costs and reduced duplication of efforts	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Reduced administrative burden	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Technological progress	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

Other

Please specify:



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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Mandatory appointment of a national body that authorises access to health data by third parties	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A public body collects the consent of individuals to share their health data for specified societal uses (“data altruism”) and manages their health data	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Administrative data in relation to reimbursement of healthcare	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Social care data	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Genetic and genomic data	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pseudonymised format (without identifiers of individuals)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Fully identifiable format	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Safeguards for the access to health data for the purpose of re-use, in line with ethical and data protection requirements, are defined	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Limit the transfer of non-personal health data outside the EU/EEA	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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)	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Access to health data is granted by a national body, in accordance with national law	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Access to health data is granted by a national body, subject to agreement of data subjects	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please specify:

The appropriate holder of patient data needs to be defined to help inform decisions regarding who can access the data and what can be accessed. This most often requires some level of regulatory guidance in defining those terms.

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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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

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	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Stakeholders participating in the EHDS cross-border infrastructure are subject to the mandatory use of specific technical requirements and standards	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Stakeholders need an audit, certification or authorisation before participating in EHDS cross-border infrastructure	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

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.).	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Operational costs such as human resources, finances, etc.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Information and monitoring	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Increased safety of health care and of medicinal products or medical devices	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Faster innovation in health	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

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)	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Reduced administrative burden in accessing health data	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Technological progress	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>

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.

The ability for responsible access, portability and use of patient health data would address a long standing disconnect between clinical research and medical practice. The use of real-world data (data derived from healthcare delivery/practice) into the research and development and clinical development of therapies would drive innovation in accelerating more precision therapies, encouraging more business start-ups and partnerships. Further patient access to data would inherently give patients the ability to better help their own outcomes and the right to understand how their data is used.

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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Citizens have the possibility to transmit the data from m-health and tele-health into the EU health data exchange infrastructure	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Healthcare professionals can request transmission of the data from prescribed apps and other digital health services into the electronic health records of the patients	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Other

Please specify:

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.

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:

The telehealth experience has risks in the form of security (vulnerability), lack of interoperability and threat to personal privacy. These are risks that could be addressed in the development of global standards developed in an open consensus process.

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	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Through minimum standards for tele-health equipments established at EU level	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Through liability rules established at national level	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Through liability rules established at EU level	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Other

Please specify:

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)	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

A certification scheme granted by third parties (a mandatory independent assessment of the interoperability level)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
An authorisation scheme managed by national bodies (a mandatory prior approval by a national authority)	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please specify:

Global standards developed in an open consensus process would be beneficial in establishing and validating credibility of the use of digital health tools and services. Inclusion of entities (digital health tool software and hardware manufacturers) help enable acceptance and adoption of the schemes needed to embrace these tools.

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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
European guidelines on assessments for digital health products	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Extend the possibilities at national level for reimbursing all tele-health services (including telemedicine, telemonitoring, remote care services)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Facilitate reimbursement of all tele-health services (including telemedicine, telemonitoring, remote care services) across the EU (i.e. mutual recognition)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
National authorities make available lists of reimbursable digital health products and services	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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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	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Bodies established within the EHDS provide technical support (e.g. on control datasets, synthetic data,	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

Please specify:

Testing of artificial intelligence in healthcare should have a set of guidelines similar to how medical devices have testing protocols. Therefore the derivative and access to the data sets should be defined when AI healthcare results are generated and should undergo similar type of review as other medical devices including any accredited standards that are followed and appropriate regulatory guidelines.

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

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)	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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?)	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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:

AI applications in healthcare are still quite young and hold great potential. To validate the algorithms and outcomes, AI requires access to significant amounts of diverse and validated data, which can be a major ethical concern. An important ethical consideration is ensuring diverse patient population data are included and accessible. Most often these are the groups without access to healthcare and therefore their data is not included.

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?

A combination of global technical data standards and policy guidance, as well as education and awareness programs for patients, would be critical in gaining trust by patients when it comes to AI applications with their health outcomes. Patients may have a higher degree of comfort when they understand how the technologies are used and verified.

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

0dbb746b-a16c-4fb8-8081-1daa0024bb70/IEEECommentsECHealthDataSpace_Addendum.pdf

Final comments:

Contact

Sante-consult-b3@ec.europa.eu