Public Consultation: Transformation Health and Care in the Digital Single Market

Fields marked with \* are mandatory.

Introduction

The purpose of this consultation is to define the need and scope of policy measures that will promote digital innovation in improving people’s health, and address systemic challenges to health and care systems. Those measures must be aligned with legislation on the protection of personal data, patient rights and electronic identification. The consultation collects views on:

Cross-border access to and management of personal health data;

A joint European exploitation of resources (digital infrastructure, data capacity), to accelerate research and to advance prevention, treatment and personalised medicine;

Measures for widespread uptake of digital innovation, supporting citizen feedback and interaction between patients and health care providers.

The European Commission reserves the right to publish all contributions to the consultation unless non- publication is specifically requested in the general information section of the questionnaire.

The public online consultation will close on the 12th of October 2017.

In case your response includes confidential data please provide a non-confidential version.

About you

1 You are welcome to answer the questionnaire in any of the [24 official languages](http://ec.europa.eu/education/official-languages-eu-0_en) of the EU. Please let us know in which language you are replying.

* 2 You are replying

 as an individual in your personal capacity

 in your professional capacity or on behalf of an organisation

3 Please specify your profile  Citizen

 Health and care professional (e.g. doctors, nurses, social care professionals)  Other

* 4 First name
* 5 Last name
* 6 Email address

If you do not have an email address, please write "Not available".

* 7 Country of residence  Austria

 Belgium Bulgaria Croatia Cyprus

 Czech Republic  Denmark

 Estonia Finland France Germany Greece Hungary Ireland Italy

 Latvia

 Lithuania

 Luxembourg Malta

 Netherlands Poland

 Portugal Romania

 Slovak Republic  Slovenia

 Spain Sweden

 United Kingdom  Other

* 8 If "other", please specify:
* 9 Your contribution,

Note that, whatever option chosen, your answers may be subject to a request for public access to documents under [Regulation (EC)](http://www.europarl.europa.eu/RegData/PDF/r1049_en.pdf)

[N°1049/2001](http://www.europarl.europa.eu/RegData/PDF/r1049_en.pdf)

 **can be published with your personal information** (I consent the publication of all information in my contribution in whole or in part including my name or my organisation's name, and I declare that nothing within my response is unlawful or would infringe the rights of any third party in a manner that would prevent publication)

 **can be published provided that you remain anonymous** (I consent to the publication of any information in my contribution in whole or in part (which may include quotes or opinions I express) provided that it is done anonymously. I declare that nothing within my response is unlawful or would infringe the rights of any third party in a manner that would prevent the publication.

* 10 Respondent's first name
* 11 Respondent's last name
* 12 Respondent's professional email address
* 13 Name of the organisation
* 14 Postal address of the organisation
* 15 Type of organisation

Please select the answer option that fits best.

 Health and care organisation (e.g. hospitals, clinics, social and community care)

 Service provider (e.g. digital health services, data and technology services, insurance providers)  Private enterprise (other)

 Professional consultancy, law firm, self-employed consultant  Trade, business or professional association

 Non-governmental organisation, platform or network  Research and academia

 Churches and religious communities

 Regional or local authority (public or mixed)  International or national public authority

 Other

* 16 If "other", please specify:
* 17 How many employees does the company have?  More than 250 employees (Large enterprise)

 Between 50 and 250 employees (Medium-sized enterprise)  Between 10 and 49 employees (Small enterprise)

 Less than 10 employees (Micro enterprise)  Self-employed (Micro enterprise)

* 18 Please specify the type of organisation.  Chamber of commerce

 Business organisation  Trade Union

 Represenative of professions or crafts  Other

* 19 If "other", please specify:
* 20 Please specify the type of organisation.  Think tank

 Research institution  Academic institution

* 21 Please specify the type of organisation.  Regional public authority

 Local public authority

 Public-private sub-national organisation  Network of public sub-national authorities  Other

* 22 If "other", please specify:
* 23 Please specify the type of organisation.  Intergovernmental organisation

 EU institution, body or agency  National parliament

 National government

 National public authority or agency

* 24 Is your organisation included in the Transparency Register?

In the interests of transparency, organisations, networks, platforms or self-employed individuals engaged in activities aimed at influencing the EU decision making process are invited to provide the public with relevant information about themselves, by registering in Transparency Register and subscribing to its Code of Conduct.

Please note: If the organisation is not registered, the submission is published separately from the registered organisations (unless the contributors are recognised as representative stakeholders through Treaty provisions, European Social Dialogue, Art. 154-1)

If your organisation is not registered, we invite you to register [here](https://ec.europa.eu/transparencyregister/public/ri/registering.do?locale=en), although it is not compulsory to be registered to reply to this consultation. [Why a transparency register](http://ec.europa.eu/transparencyregister/public/staticPage/displayStaticPage.do?locale=en&amp;reference=WHY_TRANSPARENCY_REGISTER)?

 Yes No

 Not applicable

* 25 If so, please indicate your Register ID number.
* 26 Country of organisation's headquarters  Austria

 Belgium Bulgaria Croatia Cyprus

 Czech Republic  Denmark

 Estonia Finland France Germany Greece Hungary Ireland Italy

 Latvia

 Lithuania

 Luxembourg Malta

 Netherlands Poland

 Portugal Romania

 Slovak Republic  Slovenia

 Spain Sweden

 United Kingdom  Other

* 27 If "other", please specify:
* 28 Your contribution,

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[N°1049/2001](http://www.europarl.europa.eu/RegData/PDF/r1049_en.pdf)

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 **can be published provided that your organisation remains anonymous** (I consent to the publication of any information in my contribution in whole or in part (which may include quotes or opinions I express) provided that it is done anonymously. I declare that nothing within my response is unlawful or would infringe the rights of any third party in a manner that would prevent the publication.)

Respondents should not include personal data in documents submitted in the context of consultation if they opt for anonymous publication.

# Access to and use of personal data concerning health

A major change in the way we receive and provide health and care services is giving citizens the possibility to effectively manage their health data i.e. to grant access to this data to persons or entities of their choice (e.g. doctors, pharmacists, other service providers, family members, insurances) including [acr](http://ec.europa.eu/health/cross_border_care/policy_en) [oss borders](http://ec.europa.eu/health/cross_border_care/policy_en), in compliance with EU data protection legislation.

1. Regarding the statement "Citizens should be able to manage their own health data", do you...  Strongly agree

 Agree

 Neither agree nor disagree  Disagree

 Strongly disagree

1. Comments on previous question (e.g. what kind of information, obligatory self-management of data access vs optional, delegated management only to certain persons or organisations – e.g. doctors, pharmacists, other service providers, family members, others):

*1000 character(s) maximum*

Citizens and patients should have the choice to access and comprehensively manage their health data – without having the obligation to do so. Ideally, the extent to which a patient or citizen wants to manage their data should also be adjustable to the individual’s needs and wants. Delegated management is very important, but the extent to which data is accessible should be adjustable to the different persons (doctors, pharmacists and family members or carers do not necessarily need the same information).

1. Regarding the statement "Sharing of health data could be beneficial to improve treatment, diagnosis and prevention of diseases across the EU", do you…

 Strongly agree  Agree

 Neither agree nor disagree  Disagree

 Strongly disagree

1. Comments on previous question:

*1000 character(s) maximum*

The majority of patients favour their sharing of data, keeping in mind that this is done with an eye on improving treatments, diagnoses and prevention both for themselves and for others. At the same time, safeguards should be put in place so that the data is secure, as well as anonymous and cannot be traced back to the person, when it comes to data used for research. Sharing of health data should remain an individual choice; opting out should not limit access to services or participation in clinical trials. Individuals deciding to share their data should be aware of all the consequences that this might have in terms of who might be using their data for what purposes and whether their data can be reused, or sold. A comprehensive discussion of these issues should always be part of the informed consent process for any research project, so that the person is able to make a meaningful choice regarding whether or not to share their data.

1. What are the major barriers to electronic ***access*** to health data?  Risks of privacy breaches

 Legal restrictions in Member States  Lack of infrastructure

 Cybersecurity risks  Lack of awareness  Lack of interest

 Others

* 34 Please specify:

Unless the data is collected by the patients themselves (eHealth applications, mHealth, etc.), it is usually gathered by healthcare institutions or professionals with very limited access by patients. There is a lack of awareness when it comes to the rights of patients to access their data, and practical issues such as lack of infrastructure are also encountered when it comes to access of data. Often, patients are not told they can have access to their data, which may also be held by different healthcare providers (e.g. hospital, GP) without one overall electronic medical file. Even though there may be legislation in place, patients still face difficulties in terms of waiting times and/or fees to be paid to access their records.

35 What are the major barriers to electronic ***sharing*** of health data?  Heterogeneity of electronic health records

 Risks of privacy breaches

 Legal restrictions in Member States  Lack of infrastructure

 Cybersecurity risks

 Lack of technical interoperability  Data quality and reliability

 Lack of awareness  Lack of interest

 Others

* 36 Please specify:

Sharing of data either between different parts of the healthcare system (hospital, GP, specialists, care facilities) is still far from a reality in the EU. This is the case for various of the above reasons, while there is a rapidly increasing demand and expectation from patients for this to be the case. When it comes to sharing data with research institutions or other instances that need the data for the development of healthcare, the main concerns focus (from a patients’ perspective) mostly on security and privacy issues as well as on the unintended consequences that this may have. Risk of privacy breaches may be a key factor for some patients, but more often for the general public. Legal restrictions in member states are a key factor for conduct of cross-country clinical trials.

37 What should the EU do to overcome barriers to access and sharing of data?

The EU should:

 Standardise electronic health records

 Propose health-related cybersecurity standards

 Support interoperability with open exchange formats

 Support health care professionals with common (EU-level) data aggregation  Support patient associations with common (EU-level) data aggregation

 Provide the necessary infrastructure for Europe-wide access to health data  Develop standards for data quality and reliability

 Increase awareness of rights on data access under European law  Focus on access in cross-border areas

 Propose legislation setting the technical standards enabling citizen access and exchange of Electronic Health Records amongst EU Member States

 Other

* 38 Please specify:

Although all of the above reasons can help in overcoming this problem, priority and focus should be put on standardised electronic health records and cybersecurity standards. The European Commission should undertake an comparative analysis of patients’ access to their own health data in Member States as well as the barriers patients face, which would support Member States in implementing best practice and the advocacy efforts of patient organisations.

# Making use of personal data to advance health research, disease prevention, treatment and [personalised medicine](https://ec.europa.eu/research/health/index.cfm?pg=policy&amp;policyname=personalised)

The increasing amount of data on the health and lifestyle of individuals has the [potential](https://ec.europa.eu/futurium/en/content/future-health-care-deep-data-smart-sensors-virtual-patients-and-internet-humans) to advance research, improve disease management and support health policy, notably if exploited in a coordinated way across Europe and in compliance with EU data protection legislation.

1. Would you agree with the principle that personal health data should be made available for further research, on a case-by-case basis, in a secure way, and in compliance with data protection legislation?

 Strongly agree  Agree

 Neither agree nor disagree  Disagree

 Strongly disagree

1. For which purpose would you agree to make your health data available provided this is in compliance with data protection legislation? (Choose as many as you wish)

 Improving health care organisation  Improving clinical practice

 Improving social care organisation  For your own treatment

 Progressing research and innovation  Developing health insurance schemes  Informing public health programmes  Supporting public health policy making  Helping products development

 Increasing efficiency of health and social care

 Helping developing countries' health care systems  None of the above

 Other

1. Please specify
2. If you share your health and/or lifestyle data for research, the following preconditions have to be ensured. (Choose as many as you wish)

 My data is secure and only accessible to authorised parties  My data is encrypted and cannot be traced back to me

 My data is only used in 'not for profit' activities

 My data is only shared between societies and institutes researching my disease area  Other

1. Please specify:

As there is a big difference between patients and citizens regarding the extent of willingness to share their data (especially disease and lifestyle data), as well as on the nature and purpose of the research, it is important that the individual is fully informed (in an easy and understandable way) and be given the choice of sharing or not sharing their data. Some patients may wish to decide based on the purpose or type of research for which the data is being used; others may wish to decide on type of user (e.g., only not-for-profit). Some may give fully open access whilst others may wish to decide again with regard to each new application. Individuals’ preferences can also change over time. Options should be provided for making these choices.

1. Should [high-performance computing](https://ec.europa.eu/programmes/horizon2020/en/h2020-section/high-performance-computing-hpc), [big data analytics](https://ec.europa.eu/digital-single-market/en/policies/big-data) and [cloud computing](https://ec.europa.eu/digital-single-market/en/policies/cloud-computing) for health research and personalised medicine be advanced?

 Yes No

 Do not know

1. What would be the most important application areas?

*500 character(s) maximum*

There is a great potential in those new technologies which should certainly be fully explored, and if positive promoted and advanced. As with every type of research in the area of healthcare, taking into account the patient perspective (needs, wants and expectations of patients) should be central in those developments.

1. Would it be useful to further develop digital infrastructure to pool health data and resources securely across the EU (linking and/or adding to existing infrastructure capacity)?

 Strongly agree  Agree

 Neither agree nor disagree  Disagree

 Strongly disagree

1. What, if anything, should the European Commission do to stimulate the use of data and digital tools to advance research, disease prevention and personalised medicine?

*1000 character(s) maximum*

patient feedback is essential; patients, particularly people living with one or more chronic diseases, have a different perspective and experience of health and care than other people (citizens). In addition, health literacy initiatives to enable people to use digital tools, critically appraise and apply digital/other sources of health information; indicators that are co-developed with patients to measure patients’ priorities for clinical and quality of life outcomes; indicators that accurately capture gaps in access and the extent to which care is well integrated, particularly for patients with (multiple) chronic conditions.

1. Do you / Does your organisation encounter barriers to using big data analytics for personalised medicine?

 Yes No

 Do not know

1. Please explain what prevents the use of big data analytics:

*1000 character(s) maximum*

*Not applicable*

# Promoting uptake of digital innovation to support interaction between citizens and health care providers

This section looks at the current status of digital services in health and care. It also addresses the role that individual citizens, health and care providers, industry, public policy authorities and the EU can play in the improvement of disease prevention and treatment in Europe.

1. Do you currently have access to digital health services (e.g. remote monitoring, consultation with doctors or any other kind of service provided through digital means)?

 Yes No

 Do not know

1. Would you like to have access to digital health services (e.g. remote monitoring, consultation with doctors or any other kind of service provided through digital means)?

 Yes No

 Do not know

1. As a citizen, are you able to provide feedback to your health care provider on your treatment through electronic communication channels?

 Yes No

 Do not know

1. Please indicate to what extent you agree with the following statement: Citizen / patient feedback to health care providers and professionals on the quality of treatment is essential to improve health and care services.

 Strongly agree  Agree

 Neither agree nor disagree  Disagree

 Strongly disagree

1. Please describe other factors you consider essential or more important than citizen feedback in order to improve health and care services (e.g. statistics and other evidence collected by public authorities and insurers, research, public health initiatives, education, cost-efficiency, the sharing of best practices…).

*1000 character(s) maximum*

Citizens and patients feedback in improving health and care is a central component. Next to that, a coherent, integrated approach to health care is needed as well as the promotion of a good collaboration between the different actors in the healthcare ecosystem. Next to that, increasing citizen’s health literary and investing in public health and educative initiatives is of importance. At European level, and given the diversity of European healthcare systems, the sharing of good practices should be promoted as well as the enabling of necessary support for Member States to be able to implement those practices, is needed.

1. What should the EU do to support the goals of disease prevention, better treatment and giving citizens the means to take informed decisions on health issues (by means of digital innovation)?

 Provide support for knowledge transfer between member states and regions  Support regions and municipalities in rolling out new services

 Support EU associations of patients and clinicians to improve clinical practices  Support further research

 Promote common approaches for feedback mechanisms about quality of treatment  Other

1. Please specify

*1000 character(s) maximum*

(1) Promotion of access to accurate, objective, unbiased, user-friendly and scientifically up-to-date information relevant to patients’ needs, on all aspects of health from promotion and prevention to disease (self-)management and therapeutic options, based on patients’ identified needs and analysis of gaps. (2) Overview of existing resources and their implementation across the EU, as well as gaps and policy options for further action. (3) Patients’ access to their own health records. (4) Health literacy should be a part of all policies, including education, food, urban planning, social protection, and employment. (5) Support of research to inform policy.