

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

Fields marked with \* are mandatory.

## Introduction

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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

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1 You are welcome to answer the questionnaire in any of the [24 official languages](#) of the EU. Please let us know in which language you are replying.

English

\*2 You are replying

- as an individual in your personal capacity
- in your professional capacity or on behalf of an organisation

\*10 Respondent's first name

Justine

\*11 Respondent's last name

Korwek

\*12 Respondent's professional email address

jkorwek@transatlanticbusiness.org

\*13 Name of the organisation

Trans-Atlantic Business Council

\*14 Postal address of the organisation

Ave de Cortenbergh 168, 1000 Brussels

\*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

\*18 Please specify the type of organisation.

- Chamber of commerce
- Business organisation
- Trade Union
- Representative of professions or crafts

Other

**\*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](#), although it is not compulsory to be registered to reply to this consultation. [Why a transparency register?](#)

- Yes  
 No  
 Not applicable

**\*25 If so, please indicate your Register ID number.**

89092554724-82

**\*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

\*28 Your contribution,

Note that, whatever option chosen, your answers may be subject to a request for public access to documents under [Regulation \(EC\) N° 1049/2001](#)

- can be published with your organisation's information** (I consent the publication of all information in my contribution in whole or in part including the name of my organisation, 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 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

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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 oss borders](#), in compliance with EU data protection legislation.

29 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

30 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*

Data portability is necessary to fully realize the benefits of eHealth and deliver innovative treatment, particular in the case of personal medical devices.

31 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

32 Comments on previous question:

1000 character(s) maximum

Quick exchange of health data can be integral to improving treatment and care. The delivery of healthcare happens in motion, virtually anywhere and at any time, whether during an emergency, a disaster, migration or tourism. Data portability allows patients to upload patient generated health data or view, download and transmit that information, or be able to securely communicate data to a medical professional or a non-medical healthcare provider. Remote patient monitoring technologies, telehealth, mobile health (mHealth), and health IT, play an increasingly vital role in the global healthcare system.

Although health IT alone cannot heal a patient, when incorporated into the healthcare delivery system and utilized by care providers, it can lead to better decisions, avoid patient errors, increase efficiency, and help better understand individual and population health.

33 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

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

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:

Interoperability - Any measures taken by the EU to overcome barriers to access of data should consider interoperability between medical devices, personal connected healthcare products, electronic health records and health IT systems that enable remote patient monitoring and telehealth. We urge that regulators reduce the tendency by government to reinvent and redefine standards and guidelines. Governments should not create variants but utilize what already exists.

Interoperability between medical devices, personal connected healthcare products, and health IT systems, is not new to the EU. For years, projects featuring the use of remote patient monitoring or telehealth have taken place throughout Europe including in regions such as Catalonia (Spain), Veneto (Italy), Bavaria (Germany), Ile-de-France (France) and in countries like Denmark, the United Kingdom, Hungary, and Poland.

In the U.S. the Office of the National Coordinator for Health IT (ONC) recently conducted a two-year project to develop a policy framework to identify best practices, gaps, and opportunities for progress in the collection and use of PGHD for research and care delivery through 2024. ONC also released (Interoperability Standards Advisory) on "interoperability needs" associated with communication between certain types of personal health device and other information technology systems and specifically calls out health informatics standards under IEEE 11073.

Cross-border Data Flows - The cross-border free flow of data is essential across all industries to enhance economic growth and innovation, especially in the context of eHealth services delivery. Restrictions on data flows and associated infrastructure creates risks for patients through delayed response and undermines real-time monitoring. To fully realize the benefits of eHealth discussed above, the free flow of data should be uninterrupted while still ensuring industry compliance with data protection and security for patient data.

Privacy and Security - We believe that robust data protection and security will be fundamental requirements for the success and the widespread deployment of an eHealth/Health IT ecosystem. Current HIPAA Security Rule and EU Member State sectoral security provisions will need to be adapted in line with initiatives such as the Cybersecurity National Action Plan (CNAP) in the US and the EU Public-Private Partnership on Cybersecurity launched in 2016. Moreover, we welcome EU initiatives to develop industry-led, EU-wide codes of conduct (such as the ongoing work to create a privacy code of conduct on mHealth apps and the successfully completed working group to develop guidelines for health apps data to be reliably linked to EHRs) and certification mechanisms that can enhance citizens' trust in eHealth services and applications and facilitate their effective uptake in clinical practice, including across borders.

## **Making use of personal data to advance health research, disease prevention, treatment and personalised medicine**

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The increasing amount of data on the health and lifestyle of individuals has the [potential](#) 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.

39 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

40 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

44 Should [high-performance computing](#), [big data analytics](#) and [cloud computing](#) for health research and personalised medicine be advanced?

- Yes
- No
- Do not know

45 What would be the most important application areas?

*500 character(s) maximum*

High performance computing, big data analytics, cloud computing are all critical tools for the advancement of personalized medicine. In the consumer /individual space ever more sensors are embedded or attached to devices including in things we wear, medical devices that may be implanted and remotely monitored by physicians. In the B2B space, the explosion of sensors and data has led to the Industrial Internet/integration of big data analytics, IoT Machine-to-Machine services and cloud computing.

46 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

47 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*

eHealth is a promising emerging technology that opens up new business opportunities in the ICT industry and innovation that will dramatically improve care. It is important that the regulatory environment develops a sustainable model across eHealth services that also meets patient demands on services while maintaining a high level of privacy and security. Government will be relevant not only as policy-maker and regulator but also as enabler and adopter. From ensuring compatible regulatory regimes on security and privacy to transparent and predictable market access regimes, public sector services must be leading adopters of emerging technologies. Failure to recognize the interconnected and interdependent nature of these technologies and related business models may result in policy and regulatory frameworks that needlessly impede innovation through unnecessary burdens or unintended consequences. Coordination, cooperation and collaboration needs to extend across stakeholders and government

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

- Yes
- No
- Do not know

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

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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.

50 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

52 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

53 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

54 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*

55 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

## Useful links

[Digital Single Market Mid-term review \(https://ec.europa.eu/digital-single-market/en/content/mid-term-review-digital-single-market-dsm-good-moment-take-stock\)](https://ec.europa.eu/digital-single-market/en/content/mid-term-review-digital-single-market-dsm-good-moment-take-stock)

[Special Eurobarometer 460. "Attitudes towards the impact of digitisation and automation on daily life" \(https://ec.europa.eu/digital-single-market/en/news/attitudes-towards-impact-digitisation-and-automation-daily-life\)](https://ec.europa.eu/digital-single-market/en/news/attitudes-towards-impact-digitisation-and-automation-daily-life)

[Health in the Digital Single Market \(https://ec.europa.eu/digital-single-market/en/policies/ehealth\)](https://ec.europa.eu/digital-single-market/en/policies/ehealth)

[eHealth policies \(http://ec.europa.eu/health/ehealth/policy\\_en\)](http://ec.europa.eu/health/ehealth/policy_en)

[Communication on effective, accessible and resilient health systems \(http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex:52014DC0215\)](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex:52014DC0215)

[Research and innovation in health \(https://ec.europa.eu/research/health/index.cfm\)](https://ec.europa.eu/research/health/index.cfm)

[Roadmap: Communication on Digital transformation of health and care in the context of the DSM \(https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-3647743\\_en\)](https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-3647743_en)

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## **Contact**

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