

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](#) 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

Julia

*11 Respondent's last name

Hagen

*12 Respondent's professional email address

j.hagen@bitkom.org

*13 Name of the organisation

Bitkom e.V.

*14 Postal address of the organisation

Albrechtstrasse 10, 10117 Berlin, Germany

*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.**

5351830264-31

***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

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 [cross 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

Citizens have the right to manage their own health data and they should be able to decide what their health data is used for, who accesses them, etc. Transparency about management and use of health data will lead to more trust and acceptance.

One example that illustrates why it is important for patients to manage their own health data are initiatives presented under the hashtag #wearenotwaiting (e.g. on Twitter). Patients who in many cases suffer from chronic diseases, such as diabetes type I, share how they use technology to improve their quality of life and their health. Many approaches follow a DIY mode and patients try out new technical solutions that become available to them because they do not want to wait for such innovations to have passed the numerous legal thresholds in the healthcare system. This illustrates that patients are waiting for digital solutions. Therefore, we they need to have the power over their data so that they can get things rolling.

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

Sharing of health data is beneficial for many reasons. One example is that coordinated action between health professionals and care takers becomes much easier. With regard to the risk of cross-medication, sharing data will contribute to saving lives. Experts estimate that up to 20,000 people die every year in Germany because of dangerous cross-medication cases, allergies etc. Secondly, sharing health data will be beneficial in case of emergencies where information on intolerances, pre-conditions, etc. can be crucial to the right treatment. Without shared health data this is difficult to achieve.

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

*34 Please specify:

There are also subjective concerns such as risks of privacy breaches but they are not objective barriers.

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:

In addition to legal restriction in Member States, there are legal restrictions in state laws (Länder) in Germany. These (data protection or hospital) laws are not harmonised and require e.g. in some cases that health data may not leave the premise of the hospital (data localisation). Due to this lack of harmonisation, ICT companies have to meet different requirements in each state, which leads to considerable effort and costs and hampers the uptake of digital innovation in the healthcare system. Furthermore, with the harmonisation of data protection and information security, it is questionable whether such regional approaches are necessary. Such barriers should be examined in light of EU law (e.g. GDPR, Free Flow of Data, etc.) and be removed. Otherwise, it will be difficult to understand how Europe can improve access to health data if even within a country like Germany frameworks are disperse. In addition, we observe a lack of trust by doctors in data from other sources.

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:

The EU should support the uptake of pilot programmes in a country/ a region in order for digital innovations to gain more acceptance and to prove their added value for health care.

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

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

42 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

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

Health research and disease prevention and personalised medicine are three important fields. An equally important field with a different application are decision support systems for health care professionals.

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

We are convinced that technological trends like cloud computing, high-performance computing and big data will fundamentally transform healthcare. The EU should for example encourage the application and the piloting of IoT, cognitive computing and block chain technologies in healthcare. For instance, block chain technologies can represent a technological solution to the need of building trust and creating transparency about data use. In order for the transformation of healthcare to happen, the right infrastructure needs to be in place. For example, German hospitals are lacking behind in terms of IT-investments. They need however, a solid infrastructure for digital innovations like personalised medicine to be possible.

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

- Yes
- No
- Do not know

49 Please explain what prevents the use of big data analytics:

1000 character(s) maximum

In Germany, there are specific barriers in certain states (Länder) as managed above. Another aspect is the difficulty of defining the purpose of big data applications. A definition of the purpose of processing personal data is a key principle data protection but not fully compatible with how big data research in medicine is working.

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.

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

51 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

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

Healthcare providers also need objective data (in addition to feedback that might be subjective), insurers can provide meta data on the status of healthcare. In addition to feedback from citizens, objective data from other players (insurances, healthcare provides, public authorities, etc.) is required to create a holistic picture.

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

56 Please specify

1000 character(s) maximum

The EU should focus on getting innovation on the ground, to citizens and patients, in order to enable a better understanding of new therapies, diagnostic tools, etc. and to improve acceptance. Other aspects are important too, however, a practical approach is needed at this stage to get things rolling.

Useful links

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