Contribution ID: bb36aa8a-22bf-486e-82a4-a1af2e1f1aee
Date: 12/10/2017 17:25:38

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.

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

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*13 Name of the organisation

Biobanking and BioMolecular resources Research Infrastructure - European Research Infrastructure Consortium - BBMRI-ERIC

*14 Postal address of the organisation

Neue Stiftingtalstrasse 2/B/6, 8010 Graz, AUSTRIA

*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

*20 Please specify the type of organisation.

- ○ Think tank
- ◉ Research institution
- ○ Academic institution

*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&reference=WHY_TRANSPARENCY_REGISTER)?

- (•) Yes
- ( ) No
- ( ) Not applicable

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

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*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 (http://www.europarl.europa.eu/RegData/PDF/r1049_en.pdf)

- **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 across borders (http://ec.europa.eu/health/cross_border_care/policy_en), 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):

1,000 character(s) maximum

Patients' right to access to their health data is key for their autonomy. It allows choice of care: without their data, patients cannot ask for qualified external second opinion. However, we do not suggest mandatory self-management of health data. Individuals can ask for self-management of personal health data only after receiving information on risks of misuses or abusive requests for access (from employers or insurances etc.). In research, delegated data management by hospitals, biobanks, universities or other research institutions seems more protective. Legal, ethical and technical studies should be promoted to understand how informed individuals can access their health data (raw data and some derived data) in a portable form: it could allow new uses of the data, based on pro-active individuals. Furthermore, personal health data management strategies should have regard for the integrity of data in registries, furthering health research in the public interest.

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:

1,000 character(s) maximum

Provided that common standards at EU level allow appropriate personal data protection and interoperability of both data and processing systems. This is critical to fully benefit from data exchanges in terms of health care/scientific knowledge. Transnational access to health data is key for providing cross-border health care. This however has to consider the patient's rights to decide on his/her health data sharing and transportability.

33 What are the major barriers to electronic ***access*** to health data?

- [x] Risks of privacy breaches
- [ ] Legal restrictions in Member States
- [ ] Lack of infrastructure
- [x] Cybersecurity risks
- [ ] Lack of awareness
- [ ] Lack of interest
- [x] Others

***** 34 Please specify:

The risks related to the intentional or unintentional access, use, loss or destruction of these special categories of personal data creates challenges to the digitalization of health. Awareness and technical literacy are two additional challenges in regards to ageing population. Digitalization will require education efforts and the provision of new kind of support services (technical, legal and health counselling for ex.). The risk of data loss is also particularly important in particular if Europe engages towards massive digitalization. Therefore resilient systems and data safeguards or other recovery solutions are important.

Another important barrier is the lack of interoperability standards, accepted Europe-wide. For example, important differences exist in the use of medical classification lists: many EU countries use ICD-10, while many others use SNOMED CT or others. Nonetheless, there are few positive examples tio be used as models, such as DICOM/PACS in radiology, which is widely accepted globally.

Finally, the public awareness on the importance of sharing data needs to be strengthened.

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

- [x] 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
- [x] Others

*36 Please specify:

Heterogeneity of health records formats often results in heterogeneity of the data themselves, to the detriment of data quality, technical interoperability and of actual usefulness of such data. Furthermore, most disease phenotypes are described in plain text in national language, which creates a language barrier for data exchange and interoperability across borders.

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
- [x] 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
- [x] Other

*38 Please specify:

Several items could be ticked here but it seems that a step by step should be adopted. Developing standards for data quality and reliability including aspects related to interoperability with open exchange formats would mount a good and achievable step towards facilitating better data sharing (including with researchers), on which deeper forms of integration could build. Ultimately, harmonizing e-health records at EU level in a democratic process could be considered as the best way to achieve interoperable, accessible, secured, health records and ease data aggregation methods based on experiences from the previous steps.

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&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.

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)

- [x] Improving health care organisation
- [x] Improving clinical practice
- [x] Improving social care organisation
- [x] For your own treatment
- [x] 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
- [x] Other

41 Please specify

Progressing research and innovation is BBMRI-ERIC key objective. This can happen only in an European Research Area where data protection principles, data subjects' rights and ethical rules are respected throughout the data processing activities regardless of the data location: e.g. in terms of transparency (in terms of research processing purposes, research results, research institution governance arrangements and policy etc.).

Share data to improve health care organization, clinical practice, social care organization and, ultimately, someone's treatment options are equally relevant. Without data sharing across all the fields mentioned, the implementation of health innovations would be hampered, and clinical and applied research would not be neither feasible nor successful.

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)

- [x] My data is secure and only accessible to authorised parties
- [x] 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
- [x] Other

43 Please specify:

It should also be possible to alter or withdraw consent to (or, as is the case in some forms of processing, opt out of) such a processing in an easy way with the initial data controller. Choices should be channeled thereafter to any other processor.

We strongly support the encryption of data. However backward traceability should be allowed if the patient/citizens wishes to receive information back. Backward traceability is crucial to ensure reciprocity, to patients/citizens.

44 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

45 What would be the most important application areas?

500 character(s) maximum

Research/care of common chronic diseases (cancer, diabetes, CVDs) and rare diseases

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?

1,000 character(s) maximum

- Provide funding and policy guidance to further enlarge existing infrastructures;
- Support the creation of larger transnational collaborations via pan-EU tools and instruments, like the European Open Science Cloud;
- Promote interoperability as a key policy objective for the completion of the single market in health

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:

1,000 character(s) maximum

There are several issues relate to the use of big data analytics for personalised medicine that pose major challenges for data processors:

- Availability of data;
- Lack of harmonized data quality and structure;
- Lack of infrastructural capacity;
- Ethical and legal barriers to the use of the data;
- Data privacy and security;
- technical implementation.

Concerns also rise from saving and transferring data in cloud-based systems (e.g. social media).

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

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…).

1,000 character(s) maximum

Citizens' feedback processing will be costly and time-consuming for physicians. Such interactions regarding treatments' quality could go to the national pharmacovigilance services.
Improve e-health services such as emergency services access and teleconsulting could greatly play a role. A better access to medico-administrative data for health research and statistics too.

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

1,000 character(s) maximum

If knowledge transfers should be supported in order to spread successful initiatives in the domain, digitalization of health will require coordinated efforts in so many areas that research is still needed to cope the technical, legal, ethical, social and practical aspects of digitalization and inform decision makers at national and EU levels.

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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