Contribution ID: 99ed625e-923c-42c3-987c-22786d854b51
Date: 10/10/2017 15:54:20

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
- [x] in your professional capacity or on behalf of an organisation

*10 Respondent's first name

Max

*11 Respondent's last name

Eklund

*12 Respondent's professional email address

max.eklund@embl.de

*13 Name of the organisation

European Molecular Biology Laboratory

*14 Postal address of the organisation

Meyerhofstraße 1
69117 Heidelberg
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)
- [x] International or national public authority
- [ ] Other

*23 Please specify the type of organisation.

- [x] 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, although it is not compulsory to be registered to reply to this consultation. Why a transparency register?

- Yes
- (•) No
- Not applicable

*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 across 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

A rational and pragmatic solution would be make the self-management of data access a default option for all citizens, coupled with the possibility to opt out from self-managing.

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

EMBL remains at the forefront for providing large-scale bioinformatics services to worldwide communities of researchers and industry. We see that sharing of health data could be beneficial to improve biomedical research efforts and that sharing of such data could directly impact both treatment, diagnosis as well as the prevention of disease. An increased enrollment of participants across countries, for example, could improve the effectiveness of clinical studies and the monitoring of drug effectiveness within a population. Similarly, for diagnosing, finding new early biomarkers is crucial for many illnesses; rapid and harmonized data sharing could improve the validation of these markers and could thus facilitate and accelerate their application in the clinics. Last, self-management of data could improve the citizen's understanding of symptoms and conditions, which, as an example, could be advantageous for their health-related behavior.

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

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

*34 Please specify:

EMBL would welcome further efforts in harmonizing the legal framework for accessing health data across borders in Europe. Concerning infrastructure for accessing health data, there is a significant lack of appropriate IT infrastructure with proper access control mechanisms.

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

- [x] Heterogeneity of electronic health records
- [x] Risks of privacy breaches
- [x] Legal restrictions in Member States
- [x] Lack of infrastructure
- [x] Cybersecurity risks
- [x] Lack of technical interoperability
- [x] 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
- [x] Propose health-related cybersecurity standards
- [x] Support interoperability with open exchange formats
- [x] Support health care professionals with common (EU-level) data aggregation
- [x] Support patient associations with common (EU-level) data aggregation
- [x] 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
- [x] Propose legislation setting the technical standards enabling citizen access and exchange of Electronic Health Records amongst EU Member States
- [x] Other

*38 Please specify:

EMBL is supportive of the Commission taking the appropriate steps Under Article 50 of the General Data Protection Regulation (GDPR), in advance of the regulation becoming applicable in May 2018, as well as initiating a dialogue with intergovernmental organisations, in order to specify the conditions for personal data exports to them.

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)

- [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
- [x] Informing public health programmes
- [x] Supporting public health policy making

- [x] Helping products development
- [x] Increasing efficiency of health and social care
- [x] 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)

- [x] 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

> The use of data across different diseases/disease entities to enable new discoveries by linking data for example across medical areas of expertise and countries. Enhancing health research and personalised medicine would also require openly usable IT infrastructure, for example cloud commons, hybrid cloud setups and the distribution and orchestration of complex bioinformatics workflows on the cloud. To facilitate collaborative data analyses, standards for sharing of data should also be developed.

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

The Commission could fund major forward-looking science demonstrator projects with high visibility and scientific excellence, to show-case and promote the utility of health-data sharing to European scientists and clinicians. In addition to this, funding could be provided to support the use of computational tools in translational research and clinics, in order to collect data and to foster a harmonized data management/patient stratification as well as a (clinical) follow-up on patients for long-term risk / drug effectiveness assessments.

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

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

EMBL sees that there are at least four additional and equally important factors. First, the promotion of excellent biomedical research making use of electronic health data by fostering collaborative studies, enabling secure data sharing and by making IT infrastructure including clouds-solutions available for broad utilization for all European researchers. Second, the use of statistics and other evidence collected by public authorities and insurers. Third, the development of tools and strategies for working with patient data in a secure manner, and providing patients access to their data, as well as suitable computational for data integration and analysis. Fourth, additional public health initiatives or peer-led initiatives.

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
- [x] 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-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)

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

eHealth policies (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)

Research and innovation in health (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.euro eu/info/law/better-regulation/initiatives/ares-2017-3647743_en)

Contact

EC-DIGICARE-TASKFORCE@ec.europa.eu