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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

Samira

*11 Respondent's last name

Essiaf

*12 Respondent's professional email address

office@siope.eu

*13 Name of the organisation

SIOPE – European Society for Paediatric Oncology

*14 Postal address of the organisation

Avenue E. Mounier 83
B-1200 Brussels
Belgium

*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

*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.

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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

- (●) **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

Successful approaches are about multi-stakeholder dialogue and collaboration, balancing data privacy and the need for research progress. This is particularly true for childhood cancers as a collection of rare diseases - together, they are the leading cause of children's death by disease in Europe and an important contributor to morbidity in survivors. Cross-border data exchange is vital to foster research for more and better cure. A "broad one-time consent" is a basic requirement in childhood cancer research, underpinned by right of withdrawal, privacy safeguards, and involvement of trusted third parties. Depending on the child's age, parents' consent may be applicable. Survivors may wish to take over responsibility of their data when reaching adulthood and give a second broad consent at this point, as well. The Survivorship Passport is an innovative tool that empowers survivors to have control of their data while allowing access to medical/ research professionals if they wish.

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

Whereas individual types of cancers in children and adolescents may be rare, taken together paediatric cancers represent a leading public health issue in Europe. As a result of these two characteristics – rarity combined with important shared burden – paediatric cancer patients and survivors stand to benefit significantly from health data sharing in research, provided that it involves trusted third parties based on a broad consent with safeguards in place. Secure data transfer is highly important when undertaking research on paediatric malignancies as a collection of rare diseases as well as to ensure long-term follow up of survivors as they transition to adult care settings and /or move cross-border. Another important consideration for paediatric cancers is making sure that costs involved in accessing data for research, quality improvement, and provision of better information should not be excessive as most of such activities are funded by voluntary sector donations or patient efforts.

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:

Regarding Risks of privacy breaches, this barrier is mostly perceived risk – to keep personal data safe in research, it is masked, or “pseudonymised”, via state-of-the-art technologies. Unmasking only occurs when absolutely needed and according to strict rules. Individuals behind the pseudonyms given are not directly identifiable for the researchers involved in a specific research task.

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
- [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
- [x] 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:

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Funding is instrumental to secure sustainability of existing eHealth networks
and platforms.
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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
- [x] Other

41 Please specify

As an organisation that represents the professionals delivering cancer care for children and adolescents in Europe, conducting research and improvement projects and with close links to parent and patient associations, SIOPE would be positive about all of the list with one possible exception – 'Developing health insurance schemes'. We would replace that notion with the need to understand the 'value' of a whole pathway of treatment and care in terms of clinical benefits and outcomes that matter to patients divided by the costs to deliver it.

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
- [x] Other

43 Please specify:

Not applicable as responding as an organisation

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

Outcome data collection and long-term health surveillance: To adequately monitor the optimal use of therapies in both paediatric and adult cancers, it is critical to invest in and develop outcome research, real life data collection on utilised therapies and big data in health such as by linking long-term observational studies (registries).

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

Fostering interconnection is the only way in Europe to arrive at a sustainable base for future joint data analysis and research including clinical trials and biobanks in rare diseases. Also, given the mobility of the European population throughout their lives, it is important to pay attention to developing the concept of a EUPID – European unique patient identifier (EUPID). Furthermore, EU funding for implementing pilot studies on data analysis, such as in relation to MAPPYACTS, INFORM and other precision medicine studies, is of substantial importance.

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

The first barrier is the current lack of access to data that contains sufficient clinical and demographic detail on each patient to answer relevant questions about specific interventions. These data exist in a variety of settings (hospitals, community health care records) but are not joined up at an individual person level nor available to researchers. In rare diseases, digestion of Big Data based on international collaboration to overcome small volume sample sizes is required in order to investigate disease mechanisms but also to promote functional studies. Many areas of health ICT innovation require greater capacity – both trained workforce and analytical platforms.

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…).

1000 character(s) maximum

Continuous monitoring of the cancer burden and survival is essential through national population based cancer registries. Enhancing data collection with more details of tumour and patient demographics and outcomes that matter to patients, with feedback to regions, countries, healthcare professionals and public are key improvement drivers.
Poor diagnosis and treatment of childhood cancer is still a reality in certain cancer types and countries. There are still large disparities in Europe in access to standards of care including highly specialised interventions. There is an urgent need to implement mechanisms enhancing diagnosis and treatment of patients and sharing knowledge across Europe.
The Cross-border healthcare paediatric network ERN PaedCan will aim to implement cross-border virtual advice, treatment and care through virtual advisory board functions. Further functionality is possible with eHealth tools, incl. linking to research platforms.

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)?

- [x] Provide support for knowledge transfer between member states and regions
- [ ] Support regions and municipalities in rolling out new services
- [x] Support EU associations of patients and clinicians to improve clinical practices
- [x] Support further research
- [x] 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

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