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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

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Caroline
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*11 Respondent's last name

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COSTONGS
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*12 Respondent's professional email address

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c.costongs@eurohealthnet.eu
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*13 Name of the organisation

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EuroHealthNet
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*14 Postal address of the organisation

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Rue de la Loi, 67
1040 Brussels
Belgium
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*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

*16 If "other", please specify:

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Not-for-profit organisation, health organisation
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*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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48562122691-12
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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

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Self-management of data access can improve the empowerment of citizens; this is
important to reinforce specific health behaviours. Necessary considerations
before looking into how citizens could manage their own health data:

▶Motivation: it is important to talk about citizen empowerment as opposed to
obligation. Only intrinsic motivation will lead to genuine change. Obligation
may demotivate citizens and risk decreases attention and interest
▶Opportunity: this refers to the physical and financial constraints that may
occur for some groups. Here it is important to consider vulnerable groups.
These groups may not have documented status, a social security number or might
not own a smart device. The wrong approach may exclude these groups even more
by limiting the accessibility to health
▶Capacity: Citizens need to be able to understand and apply the opportunity
found; this includes having the necessary technical skills, health literacy and
understanding their rights and obligations
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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

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Better identification, flows and use of data can potentially facilitate better
prevention and promotion as well as diagnoses and effectiveness of current
treatment methods; these are examples of how sharing health data could be
beneficial.

Both from past and future data sets from research projects, also sensors in
smart devices collect datasets, which are more objective, cost-effective and
potentially larger than traditional questionnaire exercises. Anonymization and
consent are key in the use and application of health data.
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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:

> ▸ Financial, social and environmental barriers: barriers which are not listed relate to the financial, social and environmental limitations which vulnerable and deprived groups face. Health and care benefits in the digital single market precondition ownership of digital device, while technical skill gaps exist between generation and social standing; furthermore accessibility differs depending on area, where internet accessibility is limited in more rural areas.
>
> ▸ Lack of infrastructure: Interoperability is necessary both between and within Member States to ensure availability of health data for an EU-citizen in another EU country, also the different social services and data ought to be integrated with health data, while respecting privacy rules and acquiring consent by the citizens.
>
> ▸ Lack of awareness: awareness and trust are closely interconnected. Therefore, to encourage uptake of digital solutions, it is necessary to make citizens aware of the opportunities as well as risks and to gain their trust through extensive European privacy measures. It is also important to ensure the inclusion health and social care professionals in order to encourage citizen participation as well as to ensure that the integrated opportunities potential for health in the digital single market are exploited.
>
> ▸ Lack of interest: Interest might with time become a decreasing problem. Yet, it is important to recognise that today is the age of inequality in digital and technical literacy and skill. Some people among the older generations do not have the preconditions for good skills in technology and digital solutions. The access to health of this group should not be dependent on their predisposition   to this new technology. For other age groups, it could be good to acquire training in order to benefit from this technological development. The health inequalities inherit in generational divide in terms of technological exposure should be addressed and tackled. Lastly, the vulnerable groups which are mentioned previously, among others homeless and irregular migrants, would also risk further social exclusion in such mainstreaming of data production and use.
>
> ▸ Legal restrictions in Member States: legal settings at the Member State level reflect national difference and should therefore be respected according to the principle of subsidiarity and proportionality. On the other hand, the EU could have an apt role in encouraging mutual learning among "like-minded" Member States.

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:

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▶ Legal restrictions in Member States: legal settings at the Member State level
should be respected according to the principle of subsidiarity and
proportionality.

▶ Lack of awareness AND EDUCATION: It is necessary to sufficiently involve
citizens and support for citizen empowerment in order to increase awareness,
this means that the citizens properly understands the implications – benefits
and risks – of sharing data. It is important to consider that very little
knowledge of citizens about technique and digitalisation is self-learned, which
causes citizens to have very different understanding of data. Thus, education
/training in literacy and technical skills, including digital and health
literacy, are vital for citizens (as well as providers and professionals) to
avoid widening health inequalities within and between states.

▶ Lack of apt funding structure: The reimbursable models that health and social
care professionals manage within reflect a less digital age. Funding structures
should not discourage health and social care professionals from using digital
and data-based solutions. This change necessitates public drivers at national
level. Public procurement as well as authorisation and certification processes
connected to involvement of third parties are necessary. Both should be
alleviated through mutual learning between Member States and accompanied by
comprehensive data protection regulation at EU level. Furthermore, the EU has
an important role in encouraging this process through EU projects revolving
around such strategies.

▶ Other: It is important that any regulation and non-regulation taking place
respects certain fundamental principle, e.g. 1) The health of the European
citizen's comes before any other objective; 2)  Respect the principle of
proportionality and subsidiarity. 3) Access to health for all.
In addition it is important to recall that digital health technologies are a
means to a goal, where health and wellbeing are set out in the TEU objectives.
The proximate relationship to the health professional or caregiver should not
be substituted for only digital solutions; patient choice is fundamental.
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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:

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All ticked elements are necessary to overcome the barriers to access and
sharing health data. In addition several measures ought to be taken into
account based on the barriers elaborated in the two previous questions.

1.       Base health and care in the Digital Single Market on overarching
principles: 1) Improve the health of citizens. 2) Access for all. 3) Respect
the proportionality and subsidiarity principle.
2.       Address the determinants influencing health inequalities inherit in
the three headlines mentioned in question 30: Motivation, Opportunity and
Capacity.
3.       Ensure awareness, trust and understanding of citizens.
4.       Ensure high involvement of health and social care professionals.
5.       Encourage adaption through mutual learning between Member States.
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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
☑ Other

41 Please specify

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▸ Values: The all-embracing values that matter for me to share my health data
are that my health data is used for the good of my health and general public
health, as opposed to economically-vested interests, that no citizen is
excluded from the benefits of accessing and sharing health data and that
citizen empowerment is actively applied, which means that citizens are supplied
with the knowledge, awareness and understanding of what health data sharing
means for them in the Digital Single Market. These values are elaborated in
question 38 outlining 5 actions necessary to overcome barriers to health and
care in the Digital Single Market.

▸ Developing health insurance schemes: This purpose is not desirable. Changing
health insurance schemes according to health data can improve the situation for
some while deterring it for others thereby leading to health inequalities.

▸ Other: This consultation addresses the benefits health data can have for
research. Health data should not be limited to the research perspective
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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

43 Please specify:

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▶ My data is anonymous: is pertinent for citizens; this should also be taken
into account where a particular rare disease could risk exposing the patient in
that the identity could be figured out.

▶ My data – and the use of my data – can be traced by me: It is important to
maintain trust by allowing the citizens to check what their health data is used
for, this can both encourage citizens who are considering sharing their data as
well as retain those citizens who may be considering opting out again. This
would also make the system more resilient in cases of smear campaigns against
the Digital Single Market.

▶ Everyone has the option to share their health data: It is necessary that the
data used in research reflects the wider population(s), including different
social standings in order to understand health inequalities better, as opposed
to only having data from people who own smart device. This aim also
necessitates that all groups in a population are equally aware of what it means
to share and access their health data through the Digital Single Market.
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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?

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Health data has the game-changing opportunity to be linked to big data which
allows for integrating health with other sectors. This can end silo-thinking.
This link allows integrated approaches where health, social, economic and
environmental factors can be understood together. Policy making & evaluations
can become well-balanced. Linking health data & big data can bring the EU one
step closer to a holistic, effective and sustainable health sector. This,
however, opens a serious privacy issue.
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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

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▶Go beyond this aim: the EC should not limit itself to only advance research,
disease prevention and personalised medicine. It should also encourage the game-
changing opportunity to end silo-thinking and supporting integrated and
holistic approaching in policy making and evaluation in Member States.

▶Include professionals: It is necessary to ensure a high level of inclusion of
health and social care professionals in order to encourage uptake and use of
digital tools. Health authorities continue to be highly trusted and respected,
for which reason their acceptance will make great impact. Yet health systems
suffer austerity measures. Increasing the digital uptake and trust of health
and social care professionals could in turn be stimulated by the European
Commission through mutual learning projects.

▶Training & education: Comprehensive training and educational campaigns will be
important in improving the digital literacy of health + social care
professionals + informal carers.
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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

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▶The transformative role: Digital health tools and processes can play a
transformative role in the shift towards health promotion and disease
prevention in Europe. Health data has the potential to prioritise integrated
health promotion, disease prevention, provision of care and monitoring for
people from vulnerable groups; thereby reducing health and social inequalities.
Emerging technologies can further empower patients and carers by giving them
more control over and understanding of their health

▶Inclusiveness of citizens and health care and social care professionals: It is
key for citizens, health care professionals and social care professionals to
take part of the Digital Single Market by sharing and using health data

▶Sharing of best practices across European countries: the EU should encourage
mutual learning between Member States in order for the leading Member States to
show their methods and achievements and to respect and understand the
differences between Member States
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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

> ▶Health literacy & health education: For the citizens to take informed
> decisions it is a necessity to be backed with health literacy and health
> education, both for the citizens as well as the health care and social care
> professionals. It is important that any citizen is aware of what he or she
> gives consent to when sharing their health data. Rights and obligations should
> not be fitted in the conventional terms and conditions agreement, which is not
> read or understandable to many citizens. The EU will do clever in providing
> communication materials of different sort that can in an easily-understandable
> way explain what it means to share health data in the Digital Single Market.
> Offering this can avoid groups who feel at uneasy to share their data, and this
> can reduce health inequalities between this group and those groups who does
> manage to find and understand this information by themselves.

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