Digital Health Europe

DHE Consultation with citizens/patients on the European Health Data Space

2021

This paper was developed for the European Commission by

Dipak Kalra, Zoi Kolitsi, EUROREC
Carola Schulz, empirica
With:
The invited contributors / patient representatives (see Annex 1)
and the DigitalHealthEurope project team

DISCLAIMER

The information and views set out in this publication are those of the authors and do not necessarily reflect the official opinion of the European Commission. The Commission does not guarantee the accuracy of the data included in this study. Neither the Commission nor any person acting on the Commission's behalf may be held responsible for the use which may be made of the information contained therein.

DHE Consultation with citizens/patients on the European Health Data Space

This document reports on the European Health Data Space (EHDS) consultation of DHE with citizens, as healthy individuals and as patients, in order to explore their expectations of, and possible interactions with, the EHDS.

DigitalHealthEurope (DHE) is a co-ordination and Support Action (CSA) that provides support to advancing the initiatives outlined in the European Commission's Communication on the Digital Transformation of Health Care in the Digital Single Market COM(2018)233.

This short report introduces the scope of the DigitalHealthEurope (DHE) consultation with citizens/patients on the European Health Data Space; it describes the attendees, with further detail given in Annex 1; it outlines the context and future ambitions for a European Health Data Space and; it provides the feedback given by participating citizens/patients on their willingness to contribute data to the European Health Data Space, their perception of the benefits of using health data on a European scale, and their considerations of important principles and values underpinning the European Health Data Space. The basis for these questions is laid out in Annex 2.

Introduction and scope

This section outlines the character of the consultation, the contributors to the discussion and the approach employed.

About the consultation

This consultation was one of a series of DHE workshops/webinars and surveys that took place during spring, summer and fall 2020, in support of the second priority of the Communication: Better data to advance research, disease prevention and personalised health and care. These topics it raises are relevant to shaping the success of the proposed **European Health Data Space**. The DHE consultation exercise is intended to lead to a common understanding of what actions are needed by the European Commission (EC) and other key stakeholders in order to support the implementation of a number of use cases in different contexts. These contexts include: health data use for the provision of care and self-care, for regulatory purposes and health systems research; disease outbreaks and priority research and innovation areas, including drug and medical device development; artificial intelligence (AI) and predictive modelling; personalised medicine.

As part of this consultation work of DHE, a "White Paper on Better Utilisation of Data Infrastructures to Support Secondary Uses of Health Data" was published in February 2020. Its aim was to support a dialogue focusing on the needs of the health industry innovation and research sectors that would complement the scope of the EHDS COM(2020)66 "A European strategy for data" presented by the EC in the same month.

The White Paper was followed by a report on the DHE Consultation with Industry on the European Health Data Space

The purpose of this focus group report is to present to the EC the identified citizen and patient perspectives on the EHDS. This feedback is intended to be complementary to any direct input that individual citizens/patients or related organisations may have provided to the EC.

Participation

The virtual focus group brought together 35 experts (and 5 organisers). The core group consisted of 17 patients from many regions of Europe. They are people who are living with at least ten conditions including diabetes, Parkinson's disease, cancer, multiple sclerosis, obesity, rheumatic arthritis sometimes in multi-morbid combinations. In addition, some 10 further representatives from the DHE consortium, patient organisations, and the EC joined the meeting. In general, the meeting was typified by wide-ranging discussions among patients and other interested stakeholders.

It should be however noted that the workshop participants were primarily digitally literate and involved in discussions on the topics of data sharing. As such, they do not reflect the average European population and therefore a much broader consultation would be needed to reflect the current prevailing opinions amongst European citizens.
The list of participants is included in Annex 1.

Approach

The focus group was run virtually. The consultation took place through several sessions, consisting of structured moderated discussions via a combination of voice and use of a chat box (text). The discussions were captured as responses to a set of 'guiding questions' (see Annex 2).

These questions were circulated in advance of the focus group, and some initial responses from individual patients/citizens were presented orally to the group to stimulate discussion. To compensate for the limitations of a remote meeting, written inputs to the questions were invited for a time interval after the meeting. This report also takes these written responses into account.

Opening plenary

The online meeting was opened by Dipak Kalra, the President of EuroRec, alongside Zoi Kolitsi, Digital Health Strategist of EuroRec, Belgium. They introduced the agenda of the meeting and invited the participants to present themselves.

Following the introduction, Veli Stroetmann, the director of empirica Gesellschaft für Kommunikations- und Technologieforschung mbH Germany, introduced the DHE project.

Birgit Morlion, Programme and Policy Officer, DG CNECT, talked about the EC's vision for digital health, focusing mainly on the attitudes of people towards sharing and accessing their health data. Ms Morlion mentioned the current boom in digital health tools, driven by the need to respond to the effects of COVID-19, and the efforts needed to increase the quality and trustworthiness of such tools after the corona pandemic spread slows or ends. Then Ceri Thompson, the Deputy Head of the eHealth, Wellbeing and Ageing unit, DG CNECT, elaborated on the European Health Data Space, the digital transformation of health and care at European level, and the three objectives that this vision includes, namely:

- Give citizens better access to their health data, everywhere in the European Union (EU),
- Use digital services for citizen empowerment and person-centred care,
- Connect and share health data for research, faster diagnosis, and better health outcomes.

Ms Thompson also devoted attention to the challenges that the EC faces, such as how to increase the data available for reuse, as well as the strategy that is being deployed to fulfil the visions of digital transformation in health and care. In this context, health data is a part of the Common European Data Spaces.

Ioana-Maria Gligor, Head of Unit for European Reference Networks and Digital Health, DG SANTE, continued this presentation. She presented a matrix outline of the EHDS, aiming at better healthcare, better policy making, and better research and innovation on one axis and the governance, quality of data and infrastructure on the other. One topic of special importance referred to was artificial intelligence in healthcare. Enabling testing and experimentation facilities that enable AI developers to work with real world data is seen a crucial step in the improvement of healthcare: this gives one strong reason to substantiate the importance of the EHDS.
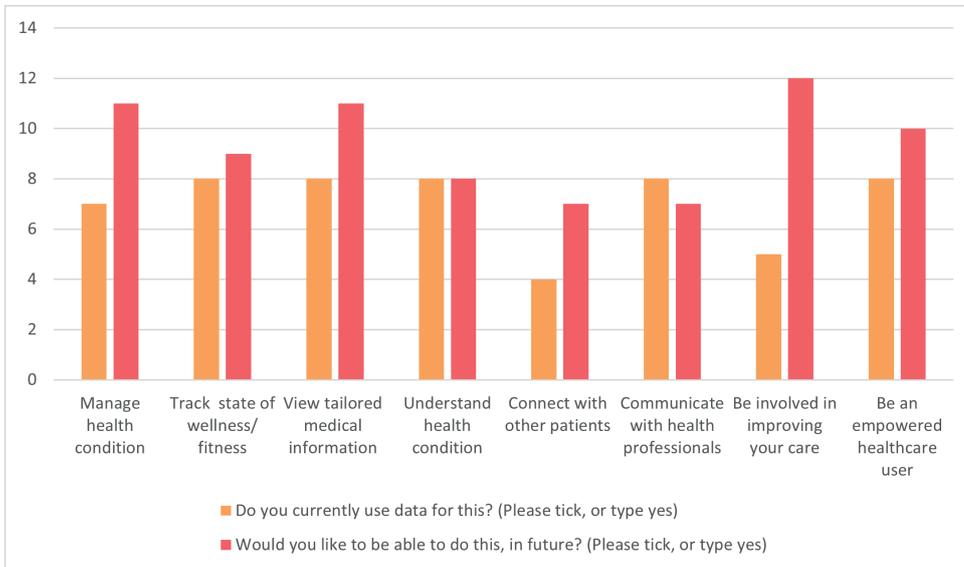
Current data use context and future ambitions

> Participants were asked about the type of health data to which they currently have access the purposes they use it for and the purposes they would like to use it for in the future. They were asked about the format in which they access the data.

The citizen/patient respondents typically use health data to stay up-to-date about their own wellbeing, communicate better with their healthcare providers, and be empowered users of health and social care. Conducting their own research on their specific condition(s) is equally a major driver for them to access data. Patient organisations use available aggregated health data for identifying areas that need improvements, suggesting and implementing initiatives to improve the wellbeing of their constituencies.

However, there is a big gap between the respondent's current use of data for these purposes and their needs. There are three main areas in which participants declared having less access to data than they would like. The three greatest gaps are in areas that relate to being actively involved in improving the quality of their care, accessing personally tailored medical or lifestyle information, and managing a health condition.

**Figure 1. Current data use context
and future ambitions**

The participants gave feedback about health data formats and health data types. They also emphasised the need for training programmes and on digital literacy.

Regarding the **data formats** in which they view their records, citizens/patients shared a concern about disjointed data stored across multiple locations that does not represent the whole picture of their health record and is stored in a variety of formats. Typically, data is only partially available digitally as an electronic health record (EHR) and is not always downloadable or user-friendly to read and understand. Paper printouts are reported to be the conventional format in which many citizens/patients gain access to health records.

Data types to which citizens do not have access, but would like to access, include those items that currently help manage their personal care and lifestyle decisions but would also help them to understand the impact of the treatments they have received.

These data could include comparisons with aggregated data on their condition (derived anonymously from similar patients); epidemiological data; and data/outcomes from studies in which they have participated. All these data should be available in a form that is easily understandable by citizens/patients and using lay language.

In the reverse direction, patients and citizens can now collect a lot of personal health data, such as lifestyle and symptom tracking and self-management of conditions, that is not shared with their health professionals and not taken into account in care decisions and planning.

Citizen/patient contribution to the EHDS

Participants were asked whether and under what conditions they would be willing to contribute their data to the EHDS.

Focus group participants were presented with a spectrum of data uses. These spanned insights that might directly influence and improve the care to individuals, populations or health systems, through to many kinds of research use.

The summary of these discussions supported the 3-tier concept for health data use adopted by DHE: usage for provision of individual care; population level data supporting learning health systems; and big health data supporting innovation and research. There was a generally positive view on the part of participants on these three different kinds of use, including the possibility that these uses would be supported in the future through the EHDS.

Digital
Health
Europe

DHE Consultation with
citizens/patients on the European
Health Data Space

Use of Data in the EHDS

Individual level health data	Population level health data	Big health data
EHR systems, apps, sensors, genomics, Clinical Decision Support, AI guidance	EHR systems, regional & national eHealth infrastructure	National & international research infrastructures Federated query research platforms + cross-sectoral services
Used for: • Health status monitoring • Continuity of care (including the patient and caregivers) • Care pathway tracking, clinical workflow management • Real-time feedback and guidance to patients and clinicans • Personal medicine • Disease interception, prevention and wellness • Healthcare provider reimbursement	**Reused for:** • Healthcare provider performance and planning • Quality and safety, care pathway optimisation • Medical device and algorithm refinement • Pharmacovigilance • Public health surveillance • Public services and resource planning	**Reused for:** • Epidemiology • Digital innovation: devices, sensors, apps • AI development • Personalised medicine and biomarker research • Diagnostics development • Disease understanding and stratification

Figure 2. Uses of Data in the common European health Data Space

There was therefore a strong positive response on the part of the participants to contributing data to the EHDS, but with some limitations: i.e., only provided that certain conditions would be fulfilled. When asked what assurances would make them feel most confident about the secondary use of their data, most participants declared the need to be certain that the data would not be misused, including knowing what sanctions may be applied. This statement was linked to their feared loss of control over the data.

Participants felt that assurances are needed for several aspects of data use and reuse in the EHDS: transparency, engagement, privacy, data quality, and data governance and ethics.

Transparency over how the confidentiality and protection of personal data is assured, whether that is regulated and checked at a Member State level; what value is extracted out of this data use and by whom and how its use leads to benefits for patients/citizens.

It was considered of a lesser importance to know the purpose of health data reuse on a case-by-case basis. Participants expressed a wish to either provide general approval based on guidelines made known to the public beforehand and/or to be informed about the use of their data after it has been used. Participants agreed that the plurality of health systems and regulations in Europe is a challenge to accessing and reusing data across different countries.

Engagement through collaboration to ensure that explanations describing each type of data are written in a form that is under-standable to citizens/patients; there is value in individuals being able to see and check their own data to verify that is both complete and accurate and that processes are in place to enable any omissions and errors to be rectified. This approach improves the usefulness of the data for immediate care (which is important to both patients and clinicians) and re-use.

Privacy i.e. sharing anonymous health data, in which the identity of the individual cannot be discovered, makes that sharing more

acceptable to some patients. However, to gain this trust there needs to be robust anonymisation, not simply the removal of demographic identifiers.

Data quality, especially for self-collected data, is an important potential element of contribution. Sharing diverse kinds of data may distribute data of variable and unknown quality, unless each data source is clearly labelled, and its quality can be assessed. Improving citizen and patient awareness of the importance of data quality, and engaging them in that educational process, is an important pre-requisite to data-sharing. It is also important for professionals to better understand the quality influences on personally collected data.

Data governance and ethics around access to data and analysis of databases that hold personal information is an imperative. The ethical uses of data must be observed. There needs to be a transparent approval process around access and the purpose of that access. Data access should be regularly monitored, and the outcomes from using the data published in a form that is accessible and understandable to citizens/patients.

For patients to correctly interpret their health data, appropriate **patient training programmes and methods** are very important. They indicated that there is no use of looking at data unless they understand what they are looking at. This training needs to include understanding professionally generated and personally generated health data.

Digital literacy was considered crucial by the participants. A digitally literate patient will be able to have more meaningful conversations with their health professionals, by more effective in interpreting the results of a health examination and answering questions such as "What treatment are you recommending? Why are you recommending it? Are there other options? Why should I decide to receive this treatment at this hospital?" Being able to ask such questions knowledgeably, in an informed way, will in turn change the traditional culture/model of the patient-doctor relation-ship. Focus group participants felt this to be an important development.

Benefits from using health data at a European scale

Participants were asked whether, and how, they already make their data available outside of their primary healthcare context and whether they support this kind of data sharing for secondary use.

Most participants stated that they do not routinely share their data for secondary use. Those who do either do so as a by-product of using some health apps, providing data for patient registries, or as part of some 'data donation' options.

A clear majority of participants supported the idea of the public contributing their data to the EHDS for research and public health monitoring purposes. However, there was sometimes reluctance expressed on an individual level to actually contribute data. Hence, a suggestion was made that an EHDS opt-out model should be offered, but 'opt-in' was not necessary. The participants identified the need for a more in-depth discussion on the topic of public contributions of data, through what methods.

When asked whether they should be personally rewarded for sharing their data, most participants declared that they had no need for a tangible reward, neither financial nor non-financial, but referred to the goal of the common good. Benefits from being part of a shared health data network might be that an individual can see all of their health data through one access point. They should be able to gain new insights from that data. However, some suggested either 'in-kind' recognition or offered creative solutions, like badges to be displayed on social media. Others suggested that rewards might be appconly for purely commercial uses of their data.

Protecting European value

Participants were asked whether, and how, they already make their data available outside of their primary healthcare context and whether they support this kind of data sharing for secondary use.

Principles that focus group participants deemed as crucial were compliance with the EU General Data Protection Regulation (GDPR), anonymisation of data, ethical use and respect for citizens'/patients' preferences. They stated that respecting the need for citizens/patients to know how their data is used and receive feedback on research results must be safeguarded. The trustworthiness of the governance rules should be sought at a societal level, as it is almost impossible to establish trust through choice at the individual level. This makes it important to define how individuals and society will influence health data governance.

The question of data ownership vs. data stewardship is an element that needs to be clearly addressed. There is a difference between holding one's own data, controlling the uses of the data, and owning the data. Individuals feel that they have rights over their data. Giving different choices/options is very important, as different people have different attitudes and hold different views. Regular information on the use of data in the EHDS was considered essential by all focus group participants, which they saw as a crucial measure in order to build public trust. This trust was seen as a basis to enable acceptance of the EHDS in the first place.

WORKSHOP CONCLUSIONS

Patients and citizens often have limited access to their professionally generated health record data in a form that they can make use of. They would like to combine that data electronically with their own self-management and lifestyle data, in order to make better informed decisions for themselves and to collaborate in joint decision-making with their healthcare professionals.

The health data that they access needs to be presented to them in format and in language that they can understand. There was a strong emphasis on the importance of greater investments in digital and data health literacy so that patients and citizens can be empowered users of their health data. This education should include the importance of data quality and how to ensure it.

Combining professionally generated data and personally generated data into a single health data resource will also mean that professionals have access to their patients' personally-generated data and could take it into account for decision-making and planning.
Patients and citizens are generally supportive of their health data being used to improve the quality of health services, for public health and for research, whether publicly funded or industry research. Their main concerns can be expressed as two complementary conditions:

- The protection of their identity, meaning that an important condition on the use of the data is robust anonymisation.
- That the purposes for which the data are used must be targeting benefits for health and healthcare, must be approved by trustworthy bodies who have transparent decision-making rules and who publish the decisions they have made and the benefits that have arisen from the uses of data that they have approved.

Provided these conditions are met, there was a majority view that contributing data to the European Health Data Space (and other similar data ecosystems) would largely be supported, but an opt-out option should be provided for those individuals who have more personal reservations. There was a general feeling that an opt-in model was not necessary.

Annex 1: List of participants and contributors

	LAST NAME	FIRST NAME	DELEGATION
1	Aligiannis	Konstantinos	Rare Diseases Europe - EURORDIS
2	Andriciuc	Cristian	Romanian Federation of Diabetes Associations
3	Avedano	Luisa	The European Federation of Crohn's & Ulcerative Colitis Associat ions - EFCCA
4	Bakonyi	Zsofia	European Federation of Pharmaceutical Industries and Associations - EFPIA
5	Bauer	Birgit	Manufaktur für Antworten/individual
6	Bonfiglio	Silvio	Age Platform
7	Bowman	Jacqueline	Third-i
8	Calabro	Michele	Europeans Patients' Forum - EPF
9	Carrasco	Laura	Parkinson Madrid
10	Christodoulou	Andreas	Cyprus Association of Cancer Patients and Friends – PASYKAF
11	Cordero	Estefania	Europeans Patients' Forum - EPF
12	Dantas	Carina	ECHAlliance
13	Eyers	Ingrid	Individual
14	Fanos	Margherita	Programme Officer at DG Communications Networks, Content and Technology - DG CNECT
15	Gligor	Ioana-Maria	Head of Unit for European Reference Networks and Digital Health - DG SANTE
16	Hajdu	Maria	DG CNECT
17	Jacinto	Samuel	Servicos Partilhados do Ministerio de Saude Portugal – SPMS
18	Jakab	Ivett	Europeans Patients' Forum Youth Group – EPF YG
19	Kalra	Dipak	EuroRec
20	Kolitsi	Zoi	EuroRec
21	Marsella	Marco	Head of Unit eHealth, Well-being, and Ageing - DG CNECT
22	Marti	Tino	European Health Telematics Association – EHTEL
23	Morlion	Birgit	Programme and Policy Officer, Mobile Health - DG CNECT
24	Nangle	Raymond Thomas	Individual
25	Popa	Veronica	Rare Diseases Europe - EURORDIS
26	Popova	Jana	Europeans Patients' Forum - EPF
27	Riggare	Sara	Individual
28	Ruszanov	Anett	European Regions Research and Innovation Network – ERRIN
29	Schmidtmann	Daniel	empirica Gesellschaft für Kommunikations- und Technologieforschung mbH
30	Schulz	Carola	empirica Gesellschaft für Kommunikations- und Technologieforschung mbH
31	Simonyan	Merri	empirica Gesellschaft für Kommunikations- und Technologieforschung mbH
32	Stroetmann	Veli	Director empirica Gesellschaft für Kommunikat ions- und Technologieforschung mbH
33	Susuzlu	Gözde	Europeans Patients' Forum - EPF
34	Svensson	Hanna	Individual
35	Thompson	Ceri	Deputy Head of eHealth, Wellbeing and Ageing Unit (DG CNECT)
36	Tram	Nhu	Age Platform Europe - AGE
37	Wheatstone	Pete	useMYdata, UK
38	Whitehouse	Diane	European Health Telematics Association – EHTEL

TOPIC A: Your context and ambitions for using health data

1. What is your major drive for accessing and using health data, either your own health data or population level data? (Please tick all that apply to you.)

Purpose for using health data	Do you currently use data for this? (Please tick, or type yes)	Would you like to be able to do this, in future? (Please tick, or type yes)
Manage a health condition that you have		
Track your state of wellness or fitness		
View medical or lifestyle information that has been tailored to your health situation		
Understand your health condition better, and take decisions about your own health		
Connect with other people with the same conditions or health concerns as you		
Communicate and collaborate with your health professionals		
Be actively involved in improving the quality and safety of your care		
Be an empowered user of health and social care services		
Other (please specify)		

2. In what forms is most of your health data accessible to you? For example, on paper, viewed on a web page, downloaded as electronic documents, in spreadsheets, in a database, or in another form?

_____

_____

_____

3. What kinds of health data would you like to use, but do not have access to?

_____

_____

_____

4. If you had access to all of your health information, from your different healthcare providers, combined with data you yourself collect, how would you most want this to benefit you?

_____

_____

_____

TOPIC B: Your possible contribution to the European Health Data Space (EHDS)

1. Are you in favour of your health data being part of the EHDS[1], if this was done in a secure way? (Please choose only one option)

☐ Yes, fully in favour   ☐ It depends   ☐ Not at all in favour

2. If you feel "It depends", what assurances would make you more in favour? If you feel "Not in favour" what are your major concerns that inhibit the inclusion of your health data in the EHDS?

_____

_____

_____

3. How important is it to you that any of your health data in the EHDS is used for the following purposes?

a. Improving your own health and care e.g. when you are travelling abroad?

☐ Very important to me   ☐ Not very important to me

b. Improving quality, safety and efficiency of health systems, monitoring the population and public health

☐ Very important to me   ☐ Not very important to me

c. Developing new knowledge though clinical and epidemiological research, new drugs and medical devices and innovative data driven services?

☐ Very important to me   ☐ Not very important to me

4. If you feel that your health data could be re-used for any of the purposes above, beyond the care of your own health, what would make you more trusting about your health data being used for further analysis? Please select the ones that you feel most strongly about.

a. Knowing more about how it will be used
b. Having sufficient guarantees that it will not be misused
c. Having confidence that your identity will be hidden
d. Being informed about who has accessed the data and how it has been used,
e. Other (please specify)

_____

_____

_____

5. Is it important that you could choose the purposes for which your health data may be analysed? If so, how would you like to make your preferences known?

_____

_____

_____

6. Do you think you should be personally rewarded for making your data available for others to analyse? If so, what kind of reward would you like? If not, is there another way you think the public should benefit from their health data being analysed by others?

_____

_____

_____

[1] While this space is not fully specified yet, for the purposes of this discussion, it is sufficient to consider the general thrust and direction of the European Data Strategy for the creation of a European Health Data Space (EHDS). This is one of the priorities set out in a Commission mandate with the aim to foster the exchange and sharing of different kinds of health data (electronic health records, genomics, registries, etc.) in Europe.

TOPIC C: The benefits from using health data at a European scale

7. Do you already make your health data available to anyone or to any network apart from your normal healthcare providers? (For example, do you use a health or wellness app that shares your data with others?) If so, can you briefly say with whom your data is shared, and why?

_____

_____

_____

8. Do you support the principle of the public making their health data available through the EHDS for research and for public health monitoring?

_____

_____

_____

TOPIC D: Protecting European values

9. Are there any principles about the uses of health data that are important to you, and about how the EHDS protects data and regulates how the data is used?

_____

_____

_____

10. How important is it to you that the EHDS publishes regular information about who has made use of the health data it governs, and for what purposes?

_____

_____

_____

11. Are there any other points about the use of health data and the EHDS you would like to be discussed during the meeting?

_____

_____

_____

**Digital
Health
Europe**

emp!r!ca