



Citizen-controlled health data sharing governance Consultation paper



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This paper was developed for
the European Commission by



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Acknowledgments



DigitalHealthEurope has received funding from the European Union's Horizon 2020 Research and Innovation programme under the Grant Agreement No. 826353.

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Introduction

Discussions on data sharing reflect **multiple perspectives, interests, and even biases**. These tensions need to be acknowledged while policy-makers and citizens search for **potential compromise solutions** that can be implemented in the short- and medium-term.

At the cornerstone of discussions on citizen-controlled data sharing, there is an urgent need to improve the testing of new data sharing governance models, the amount of data being shared, and citizens' awareness – and ultimately their trust – in data sharing.

The four **key questions on citizen-controlled data sharing** covered in this paper are:



- What is the **policy and societal framework** that leads to the need for citizen-centred data sharing governance models?
- How can **citizen-led data sharing governance models**, such as health cooperatives, respond to current 'control challenges'?
- What can be learned from **data sharing initiatives and health donation related-areas** that can be taken advantage of in health data campaigns?
- Which **good practices and initiatives** may be used as **references** for benchmarking, adaptation, and adoption?

To investigate citizen-controlled data sharing, DigitalHealthEurope approached its work using a range of methods. It undertook an extensive desk review and international benchmarking, performed a set of interviews with experts, and launched a large-scale consultation with citizens. The resulting findings have been discussed in numerous events, workshops and webinars and are summarised in this consultation paper.

The DigitalHealthEurope project has been made aware of several core challenges to citizen-controlled data sharing governance raised by stakeholders. These include obstacles for researchers in accessing data sets; need for strengthening privacy and security; need for citizens to know by whom, how, and what valuable data is used for; need for Regulations to be made very clear regarding what other types data can be considered in the category of "health data" with its special protections.

Overall, it appears that **technology itself is not perceived as the main barrier** to data sharing. Other aspects to be tackled and improved are **governance**, the practical implementation of **data anonymisation, informed consent, digital literacy, interoperability, citizens' control over data**, and **the quality of data**.

The **three most important domains** that need to be tackled in the area of data sharing governance are:

- Legal questions
- Societal issues
- Business models.



This report presents the **key success factors and approaches identified**.

There is a need to **develop more person-centred solutions for data sharing and mechanisms for data-control for citizens**.

To implement **a successful data sharing campaign**, important aspects to be considered include core concepts (such as transparency, information, and awareness) and their correlation with governance and technology.

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Key messages from European experts and citizens and findings from desk research

This section brings together **DigitalHealthEurope's emergent findings** from its desk research, set of interviews and its consultation of 900+ Europeans.

In general, the 14 interviewees agreed that the **technological state-of-the-art is not a key barrier** to data sharing.

In the opinion of many interviewees, **the technological solutions currently available – combined with the appropriate will, a partnership, and suitable privacy framework – would enable safe and secure data collection and sharing.**

Interviewees highlighted that the **most important challenges to be tackled are those connected to business models, legal questions, and societal issues**, including communication plans and strategies.

Data anonymisation, informed consent, digital literacy, interoperability, citizens' lack of control over data, the quality and interpretation of the data collaboration were cited by interviewees as being the challenges most in need of attention and action.

The interviewees agreed that **citizens share their data more easily when they know what the data is actually being used for** and feel that it can benefit them in some way, e.g. by contributing to better research, treatment or by receiving better services in return. The findings of a large survey (900 + respondents across Europe) undertaken by DigitalHealthEurope reinforced this observation.

The 2019 results of an annual Philips study¹ also showed that citizens feel rather comfortable about sharing their data with e.g., general practitioners, but not their whole medical record with different or varied stakeholders.

With regard to **citizens' agreement to share data**, in general the interviewees held the view that **a dynamic consent must be in place with the mechanism to opt in and opt-out** so as to allow citizens to decide where, and for which purpose, their data is being shared. There were, however, some concerns expressed about solutions of this kind, especially regarding data and ethical issues.

As for **governance**, the interviewees showed concern about the **need to differentiate between security and safety** and the difficulties posed in **understanding privacy policy documents**.

Last but not least, there was **tension expressed between the need for regulation and the need to gain insights into data in a fast and agile way** – as has been clearly demonstrated by the initial spread of the COVID 19 pandemic.

Data sharing governance models

Data sharing governance can be presented in the form of a model. It is crucial to present these models in ways that are **easy for citizens to understand**.

Models can be based on the level of **individual agency**² over the data and the benefits the individual gets from the data sharing. All of these models have **advantages and disadvantages** that can be compared and contrasted.

There are at least two options for presenting data sharing governance models.

Here, individual agency is represented by a set of statements about **citizens** and other entities like **trusted third parties** and **collectives**:

- **Citizens as the owners of the data:** this model assumes 'independent agency', i.e., individual ownership over the data and commercialisation of the personal data. Citizens have full agency over their own data and benefit financially from the data used (based on Jaron Lanier's individual ownership and micropayment model³)
- **Citizens as a point of integration of the data:** in this model, citizens have control over their data and they receive the benefits for the use of the data in the form of better research, better services and better information (based on MyData White Paper⁴)
- **Citizens as the donors of data for public good:** this model assumes that data becomes a part of the public infrastructure and personal data becomes a public good. The data could be assessed by anyone in anonymised format, and be sustainably (based on Evgeny Morozov's view of data as a public good⁵)
- **Trusted third parties:** data donors allow a fiduciary⁶ for the benefit of a specified party, the beneficiary; an institutional review board supervises and monitors the database, ensures accountability, sanctions. (based on the model by D. and R. Winickoff⁷)
- **A collective:** data is considered as a common resource managed by community institutions within a self-organised system (based on data as commons by Elinor Ostrom⁸ e.g. Health Data Cooperatives).

1. www.philips.com/futurehealthindex-2019

2. Individual agency: an individual's independent capability or ability to act on one's will

3. <https://www.simonandschuster.com/books/Who-Owns-the-Future/Jaron-Lanier/9781451654974>

4. <https://julkaisut.valtioneuvosto.fi/bitstream/handle/10024/78439/MyData-nordic-model.pdf?sequence=1&isAllowed=y>

5. <https://newleftreview.org/issues/II91/articles/evgeny-morozov-socialize-the-data-centres>

6. Fiduciary: a trusted third party to keep or use the property (here: the data)

7. <https://www.nejm.org/doi/pdf/10.1056/NEJMsb030036>

8. https://wtf.tw/ref/ostrom_1990.pdf

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A simpler, alternative way to present these models is outlined here.

Data sharing governance models can be modelled based on the kind of **agency** that each model offers to the person.

- **Economic:** citizens become economic parties in the data sector (the example is that of the model of the United States of America)
- **Public/Government service:** driven by the Government which provides services to the citizens who can then either share their data or not (the model of Finland)
- **Trusted third party:** An individual is in charge of their own data through a trusted party (The MyData model, in connection with a number of other models)
- **A collective:** underlines a collective (such as Health Data Cooperatives) rather than an individually driven approach to data.

Business models for the data acquisition and use are of considerable importance.

More broadly, interviewees made several observations about the importance of **data sharing governance models**.



When it comes to **models based on government decisions**, interviewees mentioned that those models that depend on the state, government, or public service alone were considered problematic and unsustainable. With the free movement of citizens and data in the European Union, fragmented models operating on the level of the individual state were considered to be neither workable nor desirable.

In regard to **models based on citizens' empowerment**, some existing initiatives were mentioned by the interviewees. Attention was especially paid to **Health Data Cooperatives**.

To develop a good governance model, a certain degree of **experimentation 'in the field'** is needed. There should be some agility. As soon as a governance model is transparent, it will be well accepted, as any good governance model should respect human rights and an individual's control over their data.

Interviewees highlighted the need for **sustainable business models** to be developed in the health data sharing domain as a crucial element for the continuity of data sharing schemes. Despite the fact that business models for data governance were seen as a very important element, there was little knowledge among the experts consulted about the business models connected to big data in the health industry.

Health data cooperatives are a complex field of activity, with many **advantages and disadvantages**. However, this cooperative model could provide important inspirations.

The following three models were mentioned during the interviews:

- **Data broker:** a model where the **intermediary** obtains the data from health records, curates the data, and sells the data to pharmaceutical companies and research institutes
- **The Dawex platform:** a global data marketplace and data exchange platform⁹
- **Business models of 'platform companies':** these 'platform companies' are often referred to as the 'GAFA'-companies: Google, Amazon, Facebook and Apple).

There is a need for a **European model for health data sharing**.

The **cooperative** model could be a step for this way forward.

It is important to **define a data sharing governance model that gives citizens real control**. Hence, it should not be a quickly chosen model based uniquely on research priorities.

The model should emerge **at a European level**, and be based on **larger experimentation**.

Funding and leadership are needed.

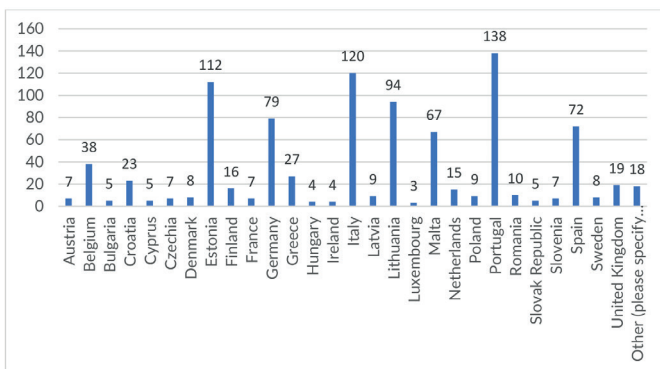
9. <https://www.dawex.com/en/>

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Data sharing - findings from a large-scale citizen survey

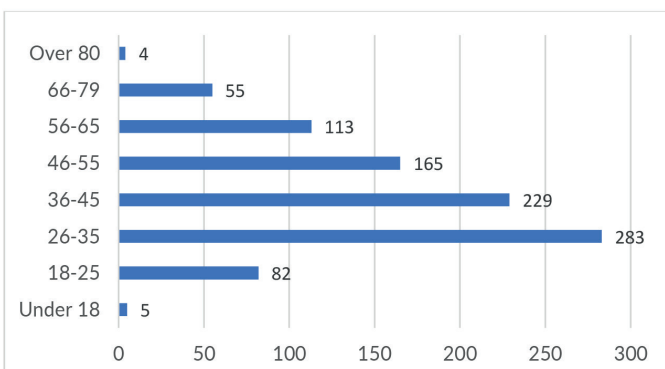
A large survey was developed with the aim to understand personal knowledge, attitudes and opinions related to the following questions: who can access my data, with whom would I share it, for which purpose. The survey was made available in EUSurvey in all EU languages. It was widely disseminated through the project partners' professional and family networks, using also social media such as Facebook, Twitter, LinkedIn.

The survey reached 936 responses, almost the double of the initial goal set, with participants from all EU countries, and from United Kingdom, the United States and Switzerland. The countries with most responses were Portugal (138), followed by Italy (120) and Estonia (112). All countries were represented; however, the participation was not controlled and is thus not well balanced, possibly connected to the dissemination networks of the project partners.



Number of answers per country

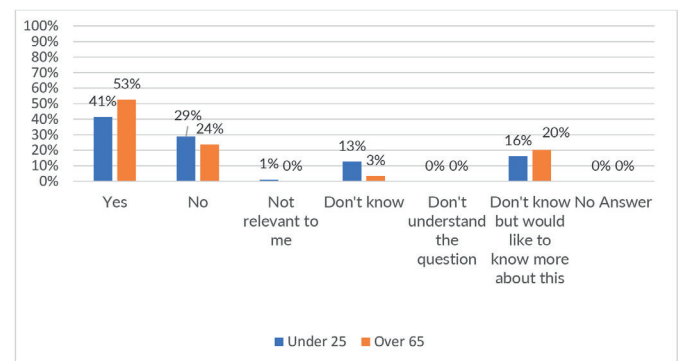
The most represented age ranges were [26-35], followed by [36-55] and the participants were approximately 65% women and 35% men.



Number of answers by age

From the large-scale survey findings, it was clear that a considerable percentage of citizens reveal a significant **lack of information on data sharing in the health and care sector**.

A total of 57% of the 936 respondents did not know **who has access and control of their health information**. No gender distinctions were relevant in the survey findings; however, results by age show that older adults (53%) are better informed about data sharing than younger ones (41%) and more eager to understand the topic if they are not aware yet of the issues at stake.



Answers by age to question about access to personal health data

Older adults seem to be much more favourable to share their data as a principle (67% vs. 37%), while younger citizens appear to prefer to analyse the situations case-by case (46% vs. 30%). On the other hand, no youngster answered with a firm "no" to the possibility of data sharing, while 10% of the older participants stated that under no context would they agree to share their data.

It can be assumed that older adults may possibly be **easily incentivised to share** their health data, and the main awareness-raising and communication efforts should be on **educating the younger generations**.

It seems that there is a **high awareness of the value of data for the common good**.

Eighty per cent of the survey participants were fully aware that their health data may be of interest for research on diseases, medicines, and other issues related to health. The use of concrete, positive results achieved through the **use of big data**, for example, may be an interesting way of initiating **information campaigns**.

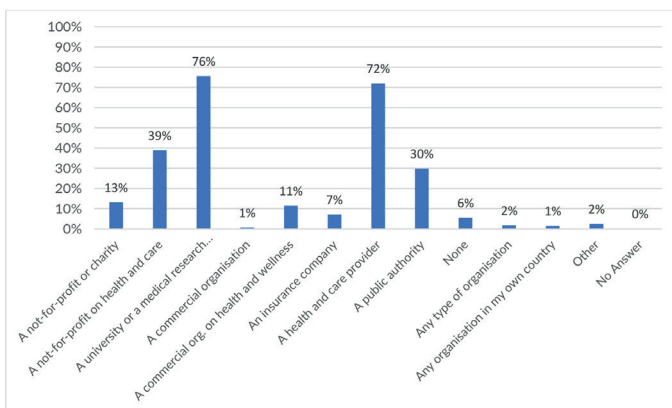
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This idea of **incentivising data sharing by connecting the aims of both research and health** seems to be in line with the type of organisation participants are most willing to share their data with, which are mainly healthcare and research-related:

- **76%** of survey respondents were willing to share data with a university or a medical research organisation
- **72%** of survey respondents were willing to share data with a health and care provider.

There was **less willingness to share data with commercial organisations** (< 1%). The rate was a bit higher if the commercial organisation is one developing and delivering health and wellness products and services (11.4%).



Answers to "with which organisations would you be willing to share your data"

In principle, more willingness can be observed if there are sharing governance models that can provide specific information on how the health data is used and for which purpose. Fifty-eight per cent



of the participants in the survey would agree to give other citizens access to their health data if it were to be used for the good of others, but only if they can **analyse each situation on a case-by-case basis**. Only 35% of respondents agreed to share data whatever the reason or context.

Regarding **potential rewards** for the sharing of data, the answers were classified as follows:

- **63%** of survey respondents wish to be notified of any research results helpful for society
- **60%** of survey respondents wish to be notified of research results helpful for their own disease or condition
- **21%** of survey respondents do not wish any reward, but
- **10%** highlighted the monetary factor.

The **concerns about barriers to data sharing** from the 14 interview results and from the large-scale survey are very similar.

Distinct strategies on data sharing governance models for different age groups may be a strategy to achieve more willingness to share.

They highlight:

- A lack of incentives and/or benefits for the citizens concerned
- A lack of transparency about how the data is collected, for which purpose and how is it shared
- A lack of awareness on the part of citizens about their rights to control their data
- A lack of business models that ensure trust and privacy by design
- Complicated and technical consent mechanisms
- Privacy policies that are difficult to understand.

Positively, there are some **enablers**. **More education is needed** for citizens on their rights to control their data and the benefits of data sharing. Trust can be increased through means such as:

- Consent should be **ethical by default**
- Data sharing and its benefits should be **easy to understand and easy to manage**
- Citizens should have **control over their own data**.

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Moving towards a framework for citizen-controlled data sharing

Key to operating successful data sharing are the formulation of a **framework** of explanation, the organisation of a **dissemination campaign**, and an overall focus on trust.

A **framework** is needed to incentivise and provide the conditions for citizens to be able to share their own data. In policy terms, it highlights **transparency, information, awareness** and the **building of trust**. In technical terms, it focuses on **data sets, tools, and interoperability**. All the activities are planned around a **citizen-centred model**:

And although these actions are being strongly incentivised and discussed, there is still lack of maturity on stable data sharing governance models. Thus, silos still remain and the tools, either digital or legal and ethics-related need to be further developed and made coherent between Member States.

Facilitating actions should include:

- Bring key stakeholders including researchers and citizens/ patients together to **discuss** concepts such as **the “common**

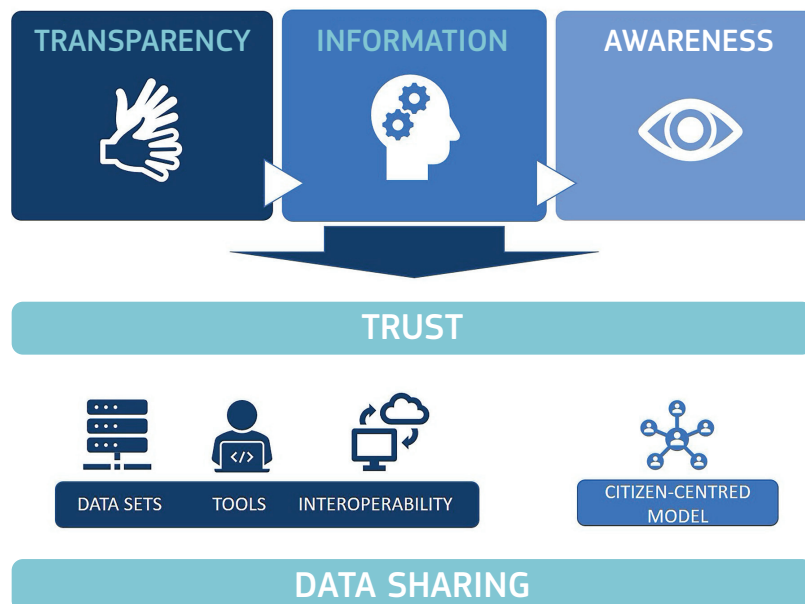


Figure 1 – The framework for citizens' data sharing

Improving awareness on the topic of data sharing and the concepts, tools and business models around it is the first step to laying the grounds for innovation in the area of data sharing. This includes providing reliable and accessible information in a very transparent way. It includes three main steps:

- Preparation of **easy to read, high-quality and accessible communication materials**
- Dissemination through social media of **personal stories, videos, and easily memorable statements** connected to the need for data and its interest for research, including health-related research
- Organisation of short communications at public events, aimed at lay audiences/readerships and by using famous presenters from non-scientific areas (e.g. actors, singers, leading athletes, etc.)

All of these are strategies that have been used in previous donation campaigns or awareness-raising campaigns which can be benchmarked as they had proven good results in the past.

A strong communications campaign on data sharing will only be effective when it is possible to provide a **quick and agile message** for citizens, so that they feel moved to share their data, and they understand the model, the tool and the consequences of their action.

good” or the **balance** between care for society as a whole and individual protection.

- Create **funding and operational conditions** to experiment with different data sharing models so as to understand which mechanisms can help to better assess difficulties, results and impacts for more informed decisions for the future.
- Take advantage of the **differences of opinions and expectations between different age groups** – target different communication messages; test different models that are tailored for various groups.
- Create **transnational frameworks** to address ethical challenges, refine consent mechanisms, and provide clear and easily understandable models for citizen-centred information connected to data sharing.

Trust is the key word in this process. To gain trust:

- Information must be clear
- Rules need to be transparent
- Implementation must be easy.

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Recommendations for further discussion

On a general level:

- Make sure citizens know who uses their data and for what purpose. (Transparency and accountability need to be made clear so that citizens to understand the differences between the commercial and non-commercial use of data.)
- Provide citizens with the mechanisms to control the use of their data and exercise their rights.
- Introduce digital education – to ensure the dual role of both citizens and healthcare professionals as drivers for change.
- Explore and promote person-centric approaches and solutions for data sharing, by implementing, developing large-scale field testing, and assessing results and impacts.

On a practical level:

- Learn about citizen-controlled data sharing through trial and error, by developing and implementing, large-scale field testing and assessing its results and impacts.
- Elaborate European Guidelines on regulating data sharing at national level.
- Develop and introduce a system of incentives for citizens who share their data.
- Introduce a set of conditions to protect data sharers.
- Promote digital solutions which respect privacy, safety and security.

These suggestions will be further discussed with experts in the upcoming DigitalHealthEurope roundtable discussions and the resulting recommendations will be validated by key stakeholders prior to their submission to the European Commission.



DigitalHealthEurope.eu has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 826353.



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