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Health data sharing governance - the voice of European experts interviewed

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Abstract. This article presents a summary of the main conclusions from 14 interviews with European experts, towards the creation of European guidelines on data sharing governance models and best practices, within the work carried out in the DigitalHealthEurope (DHE) H2020 project on Citizen-controlled data governance and data sharing. The overall work was broad and collected different stakeholders' opinions and visions on the theme by a large online survey, desk research and through public events, as well as a set of personal interviews, which are the specific outcome under analysis in the present article. The answers were gathered, clustered and analysed to understand the main trends, difficulties and best practices around Europe, the governance models currently in use and, in particular, how they guarantee the security and the privacy around citizens' data in order to build and maintain trust. Also, the incentive models used to engage with citizens, considering public and private initiatives' latest offers for consumers available on the market were studied. The key research questions underlying the process of information collection and the design of the inquiries concerned the policy and societal framework that leads to the need for citizen-centred governance models; the ways through which citizen-led data governance models, such as health cooperatives, can respond to current control challenges; lessons to be learned from data sharing initiatives that can be capitalised for health data campaigns; and finally the best practices and initiatives that may be used as reference for benchmarking, adaptation and adoption. The interviews and preliminary reports took place in 2020, accompanying the overall discussion and developments around the European Data Strategy and European Health Data Space.

Keywords. health data, data sharing governance, citizen-centric, governance models.

1. Introduction

DigitalHealthEurope (DHE) is a H2020 Coordination and Support Action that aims to provide comprehensive support to the Digital Health and Care Innovation initiative in the context of the Digital Single Market Strategy. The project's approach involves a number of actions that will

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boost innovation and advance the Digital Single Market priorities for the digital transformation of health and care.

One of the project tasks devotes to citizen-controlled data governance and data sharing, aiming to provide comprehensive guidelines on these topics upon three major accomplishments:

- To bring to publication an extensive review on the relevant initiatives and relevant models on data governance and data donation, with particular focus on European initiatives where citizens are directly in control of their personal data, such as health data cooperatives.
- To provide recommendations including a set of guidelines to implement a successful data sharing campaign.
- To gather a set of recommendations and key messages that may be guiding data governance future policies and implementation initiatives.

The theme of health data sharing governance is quite recent and evolving rapidly; the available literature is scattered and most opinions and findings are still being written or waiting to be published. Therefore, in the selection of the methods for the present work the authors acknowledged that a high involvement of stakeholders would be of extreme importance to the richness and depth of the work developed.

Within this context, between January and May 2020 a set of 14 online interviews were performed, with a selection of experts based on the desk search previously developed, and aiming for different geographical coverage and representativeness of a variety of organisations and interests in the field of health data sharing.

2. Interviews' analysis

2.1. Methods and stakeholders

The interviewees were invited to participate as experts in the Forum of Stakeholders on Data Governance and Data Sharing of the DigitalHealthEurope Project. With the request for a personal interview as the main objective, it was possible to engage 14 relevant stakeholders from different nationalities and representing relevant (private and public) organisations that have developed research and/or initiatives on citizen-controlled data governance and that contributed with their input to the final recommendations.

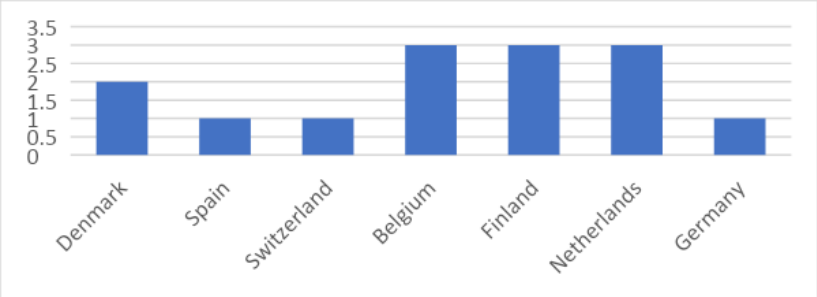

Figure 1 - Country representation of the interviewees

In this first contact by email, besides the generic explanation, a full interview pack was provided, containing the template with the interview questions, the consent form and a factsheet.

Regarding the methods to analyse the results, and since the interview only had open text answers, there was the need to understand how to utilise a structured method that would ensure sufficient objectivity.

The two main approaches to qualitative analysis - inductive and deductive - were defined and discussed between the team members that developed the interview analysis.

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For the purpose of this analysis, a deductive method was applied and the results were mapped in connection to the 17 main themes identified in section 2.2.

Thus, the qualitative analysis of interviews was developed based on a structure of guidelines that started with reading through the summaries and taking notes of the first impressions to identify common themes. Afterwards, a second careful reading brought to evidence the main themes and the most important insights. Annotation was further used to label the most important sentences, expressions or words attributing qualitative data types and patterns. The main opinions, differences and agreements and relevant concepts were also identified at this stage.

Then, the qualitative data was aligned to the most critical themes by creating categories and subcategories connected to the main areas and themes created during the annotation. In the interview analysis, the categories were created based on the interview questions and aligned if necessary. To segment the data, an excel sheet was created and shared amongst the researchers analysing the results, to develop the first data subdivisions.

The hierarchy between the different conclusions was established, towards the summary of the results, namely by going from the more general to the more specific themes, thus enabling the answer to key questions and the main objectives of the interviews, in a neutral and objective voice.

The result of this analysis was the main input for the following results

2.2. Methods and stakeholders

The interviewees were invited to The main conclusions extracted from the interviews are presented below, divided by the five sections of the interview form and following the categories used for the analysis of the results.

2.2.1. SECTION 1 – Big data and business models

a) Challenges to overcome related to the collection, storage and use of big data.

In general, the interviewees agreed that the technological issues are not the biggest challenge when it comes to the collection, storage and use of big data. The majority opinion is that the technological solutions currently available combined with the will, partnership and suitable privacy framework would allow the safe and secure data collection and sharing. It was highlighted that the most pressing issues to be solved are most likely the business models, legal questions and societal issues.

As mentioned before, the technology itself is not a problem. Rather data anonymisation, integration, interoperability of the data, people's control over the data, quality and interpretation of the data collaboration need to be improved and increased. Additionally, the data sharing should be incentivised. However, most people do not expect money for their data, rather better research, treatment, prevention, advice, feedback or/and services. This last statement was confirmed by the survey to citizens conducted within the project with nearly 1000 participants [1].

It was also mentioned that the mindset of professionals needs to change towards an acknowledgment of the value from "untraditional, not register-based and health-related" data sources, since there are many additional sources of data (e.g. real-world data) that may be of great help to research and health prevention and promotion.

An additional challenge is governance. Currently, the access to data sets is considered time-consuming and full of obstacles. And privacy and security should be strengthened. As citizens are increasingly aware of the value of their data, they also want to know how and what it is used for. Thus, regulation needs to be very clear regarding what it means in terms of pulling the other data into the category of "health data" with its special protections.

There were suggestions that such data potentially revealing health information indirectly should be regulated through a definition of the purpose for which it is used, rather than the content of the data point. Also, the data integration and standardisation are possibly in need of further developments.

b. Business models connected to big data

In general, there is little knowledge about the business models connected to big data, e.g. financial transaction models for data acquisition, which could be considered in the field of health and they are still often looked at as unsatisfactory or untrustworthy. One model referred to is that of the "data broker". This is the model where an intermediary takes the data from the health records, curates it and sells it to the pharma companies and research institutes. The Dawex platform [2] was mentioned by the interviewees. Also, MyData [3] was mentioned as a human-centric approach for data management, having as key element of their proposition to provide value for the companies in ethical use of data and to guarantee people the benefits from data sharing.

On a different perspective, the business models of the GAFA (Google, Amazon, Facebook, Apple) companies are widely known but referred to by the interviewees as potentially untrustworthy due to the numerous scandals with health data misuse or the lack of transparency on how the data is being used, by whom and for which purpose. A sentiment was referred to: that the concept of ownership of data needs to be abolished – data needs to be free, and the digital models should consider the digital functions and value. However, people should be in control over their data and they should be rewarded for sharing it.

The main question however persists: What is a business model that is transparent, ethical, provides incentives for data sharing and protects privacy? The health sector lacks a satisfactory model – the banking sector or car industry could serve as a benchmark for that.

c. Business models that could be recommended and those that raise concern

It was overall agreed by the interviewees that at this moment there is no specific business model in regard to health data governance that could be absolutely recommended or is fully proven. The following issues were identified as the most worrying ones:

- The possibility of health data on identifiable individuals being sold to an entity that then discriminates amongst individuals based on that private data. This could be an insurance provider or a government, for example.
- When the patients or citizens are not aware that their data is being used and how.
- The lack of awareness amongst citizens regarding their data control, which is also a hindrance factor for empowering models to be implemented.

2.2.2. SECTION 2 – Trust and consent

a. Trust as a big challenge to overcome concerning big data

Trust is a challenge? Yes and no and this depends on the perspective, according to the interviewees.

The annual Phillips study on health data [4] reveals that people feel rather comfortable about sharing their data, for example, with their doctor (general practitioner). But this does not mean that people want to share everything. Patients tend to share specific data to support finding cures, for themselves and others.

However, when the discussion is on sharing the complete health record, trust tends to be a big challenge to overcome, because people do not know who will have access to their data and how it is going to be used.

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In principle, giving users of online services control over their data is a positive thing. But a considerable amount of education is required to do so. The fatigue of scrolling and clicking "consent" to terms that have not been read or understood is well-known to all. Because of the numerous scandals with the GAFA companies, citizens should not depend solely on them, as often they have not been transparent in the use of data, which affects people's behaviour in the use of their technological platforms. Security and transparency on the "business model" are thus the major issues to ensure.

b. Actions to improve citizens' trust

The interviewees agreed that people share their data more easily when they know what 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 better services. It seems that understanding causes and good practices to benchmark would be helpful.

The following actions are thus recommended in order to improve the citizens' trust in data sharing:

On the general level:

- Ensure that individuals are aware which party uses their data and for what purpose, being especially clear on the difference between research only purposes and companies trading data for profit
- Enable citizens to control the utilisation of their data and take advantage of their rights, which requires promoting more digital education
- Create a new European digital social contract, with a broad agreement. This recommendation comes in line with the development of the European Health Data Space.

On the practical level:

- Set up a regulatory and monitoring independent European entity, representing national authorities, research, patient organisations and private sector
- Allow various levels of consent to data sharing in a gradual manner (e.g. from research only to commercial use)
- Establish an incentive scheme for individuals to share their data
- Adapt consent documents to be easily understandable
- Create a set of conditions to protect the data sharer
- Promote schemes which are respectful to privacy, safety and security.

c. Consent mechanisms to enhance citizens' trust

The interviewees in general agreed that some kind of dynamic consent is useful and should include ways of opting in and opting out. There are, however, some concerns about the solutions of this kind:

If not enough people opt-in, the data is fragmented and does not have value, especially as people tend to skip opting-in, but they almost never opt out. This means that the solution that is supposed to be empowering to people might be harmful for data sharing. It is of course possible to have a very unethical consent, that is fully legal, which shows that the basic principles in relation to data sharing must be established (e.g. by the new digital social contract mentioned before) to ensure an ethical use and purpose.

The consent must be designed very carefully so that people understand what is being shared with whom and why. As people do not usually read the consent, it must be clear, quick and

simple. More education towards citizens on the benefits of data sharing is needed and it should be transparent and ethical if the ultimate purpose is to promote that people opt in.

2.2.3. SECTION 3 – Governance models

a. Ethics and regulations

Main conclusions derived from the interviewees' replies indicate that it is necessary to consider the difference between security and safety. Whereas security is related to keeping the data safe (e.g. preventing data leaks), safety means that the data stays with its owner and there is no harm related to its use. It was mentioned by one of the interviewees that the current trend is to focus 95% on security, while the shift should be towards safety, i.e. how to produce safe data and how to make it secure.

Even though current privacy policies already explain what data is collected and for which purpose, they are often extremely technical and hard to understand, being thus necessary to make privacy policies more readable. Data sharing needs to be regulated, in a short timeframe, especially in the context of COVID-19, where there is an urgent need for quick access to high quality and secure data.

It was proposed that the system of ethical committees could be used for regulating the data sharing as well, or that a similar framework might be put in place. There is the example of Data Sharing Committees, which many organisations have already established [5] , but this is not uniform across Europe and sometimes overlaps with Ethics Committees. A European regulation that includes the framework for Data Sharing Committees and its collaboration with Ethics Committees to prevent potential increase of bureaucracy and multiple parallel requests is considered as a necessity.

Similarly, the sustainable and responsible data use should be implemented into existing frameworks for Corporate Sustainability and/or Environmental, Social, and Corporate Governance (ESG) and thus guide companies towards greater self-regulation. In summary, it is necessary to be more agile and innovative in regulatory mechanisms. In a liquid world, regulation needs to be much more flexible and quickly respond to citizens' rights.

b. Data governance models based on government decisions

When it comes to data governance models based on government decisions, some of the interviewees mentioned that those that depend on the state (e.g. in France, where the Ministry of Health is the one to decide about the use of data [6]), were considered somehow problematic, and not sustainable, as these are fragmented models on the state level.

In many countries, there are scientific institutes which are somehow related to the government, even though they are independent. They have access to the data, which they provide to the government for decision-making. The Findata model [7] in Finland is a detailed and advanced one, but very country-specific.

The experts further considered that, with the free movement of people and data in the EU, the fragmented models on the state level are neither workable nor desirable and thus models based on citizen empowerment should be prioritised, placing the health data not in the hands of companies or governments, however providing governments the information to allow evidence-based decision making.

c. Data governance models based on citizen empowerment

The experts highlighted it is necessary to further experiment in the field in order to achieve a good governance model that is agile and transparent, while also respecting human rights and individual's control over their data. Some existing models were mentioned by the interviewees,

including HDC examples, such as MIDATA [8], Data For Good [9], MyData, Health Data Bank [10], Open Humans Foundation [11], among others.

2.2.4. SECTION 4 – Health data cooperatives

a. HDC models and good practices

There were no consensual answers on this topic, but several scattered statements and examples.

One of the interviewees considers that HDC are part of the new digital social contract that was previously referred, and that there are many initiatives still developing, based on promising ideas, but need to grow. Also, that there are many HDCs (perhaps too many, as each of them works within their area of interest) and although they are generally considered as a good practice, their work is limited to a small area and they are thus often seen as increasing data fragmentation.

The following examples were referred to and commented:

- MyData governance model, that is now being developed and hopefully will be pushed by the governments. In this model, the individual is the point of integration
- Health Data Bank, similar to Health Data Collectives but with the difference that they assume the private ownership. However, it is the management of the HDB who decides about the data model, which means that individuals are not in control over their data.
- US-based Open Humans Foundation, where people can consent to the use of data by third parties. It is citizen-run but they still do not have a strong business model.
- The Holland Health Data Cooperative (HHDC), a citizen-driven, financed partly by the Ministry of Health and other institutions. The difficulty with many of those citizen-driven initiatives is that they have to cover the different areas, from data governance models to application areas to organisational development to legal issues. It is hard to gain traction and speed.
- Databanks by NTT (Japan), Health.Data.gov, HealthTrain, Data Collaborative, HealthBank Coop, and Salus Coop.
- MIData was referred as one of the best developed HDC in Europe but has its limitations. It combines the role of consent broker with the role of a data storer. This could mean that MIData is building another data silo. It is thus quite relevant to explore the concept of the data consent broker. HDC in the Netherlands mainly present themselves in this role. It shows how data can be used for the common good, while at the same time ensuring citizen control over their personal data.
- Savvy.coop, a collectively owned platform which connects healthcare companies and practitioners with patients who can directly inform their work–and get compensated for doing so.

b. Main potentials/ strengths and challenges/ weaknesses of HDC

It was referred that HDC may develop into a similar situation to blockchain and ledger systems: claiming interoperability, but with processes that work only within their own system, which is even a greater challenge in health and genomic data – working across the different layers of ecosystems and rendering them mutually inclusive is essential.

One highlighted challenge is to ensure that many different kinds of data can be processed within the Cooperative, while keeping up cybersecurity and general quality of the HDC. Another aim is to integrate existing data, instead of only collecting it. Even if they are seen as an inadequate approach by one of the interviewees, it is also acknowledged that HDC may be

useful wherever there is the need for a lot of data to deal with a concrete problem, such as COVID-19.

Like in any citizen-driven initiative there is often a lack of funding, reach, impact and professionalism and therefore there is the need to introduce and facilitate professional approaches on these organisations, especially when they concern health data, to ensure safety, security and protection of privacy. But even in case of well-funded and professional organisations it was referred that they might be too narrow, too siloed, covering only one disease area, e.g. oncology and too slow in demonstrating potential benefits for individuals about improved health.

Another mentioned weakness was that HDCs are yet another silo in the European data landscape in the regulatory perspective. Since private companies, the public sector, and governments all have their own rules and regulations to use and share data, HDCs are adding more complexity to this scene.

c. Strengths of the Health Data Cooperatives

The main strength pointed out to HDC is their role in setting up the agenda, making sure the citizens' voice is considered through the life of the data repository. From a patient perspective, the main aim is that research is done and provides direct gains on their disease. However, in this perspective, governance is usually forgotten and HDC can bring the discussion also to governance, which is essential.

In the same direction, one of the interviewees informed about the existence of the Data Commons Cooperative [12], which is a movement-building organisation, owned and controlled by cooperative development centres, federations, solidarity economy groups, and others, who want to maintain robust, accurate, useful platforms for sharing information. The cooperative gathers information and creates tools that make it easy for members to access each other's data, and broadcast information to the public.

d. Conditions to implement and upscale HDC initiatives around Europe

The key aspect to consider in the HDC model is that all needs are based on the individual. The individual becomes his own data repository, biobank and digital hub, given certain conditions: they should be professionally led, have a proper and safe infrastructure, and the organisation responsible for it does not have access to the data.

Europe is different from the Chinese or the American's system and this there is the need for a EU model and one of the interviewees refers that the cooperative model could be such a way forward, instead of one based only on research priorities, while it is more important to define a governance model that gives citizens real control. Citizens/patients will most likely recognise the need to prioritise the development of a good collective, citizen-driven health data governance model over quick wins in health through accelerated research. However, to better understand and frame this, it is recommended that funding and leadership are needed and that the EU should lead a larger experimentation.

There are however different opinions within the interviewees, in favour of sharing data for a wider research use, even not knowing at first what the final specific purpose of the use of that data may be. Some experts demand for less restrictions on a technical perspective, although they consider it important to know if it is for commercial or non-commercial use. The idea that the data can only be used for one specific purpose is seen as not ideal, being the most essential fact to know by whom and for what it is used.

There is thus a need to define a European code of conduct to upscale HDC initiatives and have the business models tested and demonstrated. It is also deemed necessary for the European

Union to take this type of decentralised governance models of technological platforms into account, otherwise, imagining the success of cooperative models becomes increasingly difficult.

2.2.5. SECTION 5 – Data sharing

a. Framing data sharing under the GDPR

Regarding the General Data Protection Regulation (GDPR) [13], some see it as a driver, while some as the barrier.

It is mentioned that there is the need to find the balance between the protection of the citizen and the demand of the different institutions for the data, as the GDPR should be the safeguard for the individual but it should also be an enabling frame for data sharing. It was further considered by one of the experts that data protection currently is being used as an impediment for data sharing, while it should be implemented as the ideal framework to allow safe and protected data sharing.

And at this moment, it is not fully understood as such, on one side because it is limited to Europe and, in terms of implementation, its interpretation is depending on the country, which hinders a uniform flow of data. It was further proposed that if, presumably, people would prefer to share de-identified data, there would need to be a clear standard as to what that means, since full anonymisation, by the GDPR definition, would likely render it valueless for research purposes. It could be a voluntary data transfer by the data subject, de-identified in accordance with defined procedures, including rules around who holds the key and allowable (re)-combination. This would have to be carefully designed but it could be an enabler for increasing health data sharing in Europe.

The GDPR can thus be seen as an enabler to provide data sharing value in a human-centric way, given the adequate tools to empower people are provided, including key components, such as an ethical consent form for data sharing (simple and easy to understand) and a clear governance model (with potential reward for the patient). However, both of these general tools are missing at this moment.

It was said by one of the interviewees that data sharing can be framed under the GDPR easily, since the purpose for the data processing has to be in place. The GDPR is also framing human centricity in data sharing and requesting service providers to give access to individual's data and enforce the portability of the data in the digital form, for example, by enabling data self-management and (effective) anonymisation (and combined: self-management of de-identification). A first step has been to recognise the portability of data between platforms in the new GDPR, but the mechanisms for this to be executed and controlled are not yet clear.

It was also mentioned that the GDPR is the umbrella legislation e.g. with the notion of consent. and thus data sharing is based on the GDPR but its roots, tools and governance will be further dependent on the Data Services Act [14] that was published in 2021.

The Data Act and the broader European Strategy for Data is seen as an adequate framework that should be supported by the Member States to build consent-based data sharing markets where data portability is ensured by setting requirements for standard Application Programming Interfaces (APIs) (minimum set of data).

b. The concept

From the interviews, the two concepts of data sharing and data donation were not seen as consensual and different opinions were provided. It was explained that data exchange happens when the individual is able to share their data with someone else for them to use it, thanks to technological solutions, allowing for the new spectrum of data sharing. In this sense, data

sharing was considered as a good term, since it means that the donor and receiver are equally getting benefits from the data shared.

In a separate note, it was considered that data sharing or donation should not be discussed in isolation, given the need for reciprocity, not necessarily on financial terms but understanding what the person gets back from sharing the data. It is thus proposed the concept of feedback sharing, making benefits tangible.

c. Models for the design and implementation of data sharing initiatives

When debating the model to consider for the design and implementation of data sharing initiatives, it was referred that the organisations asking for data should firstly understand what will be the societal reciprocity and provide the individuals with the instant feedback that would help them live a healthier life.

This could be accomplished with the support of communication campaigns, showing how data sharing can save lives, improve lives and that insists on the angle of trust. Also, people should be informed about data sharing and asked if they want to share their data when they seek a healthcare provider. The GPs should be well prepared and should have all the answers to the questions that patients might ask.

IHAN rulebook work [15] by Sitra Fund and its collaborators provided one attempt to model data sharing networks and their common rules and incentives. It also defined roles like service provider – data provider in data sharing networks. In addition, IHAN Blueprint [16] aims to explain basic building blocks needed to build data sharing initiatives.

It was proposed that the data governance initiatives around Europe should have a round of meetings with politicians and policy makers, with concrete use cases to demonstrate the best practices. This could be done via a proof of concept experiment, with well-defined data management models and analytics models, by engaging a multi-disciplinary and multi-stakeholder consortium, where robust, distributed technology is required, as well as digital education for citizens.

d. Involving and engaging citizens

As a key message from the experts, it was said that “people will be engaged if they get the benefit from using data”, understood as receiving data that will help people to make healthier decisions, that is, to understand the value for people (e.g. having better insights and improving the health of the citizens in the future) and give them something in return (e.g. annual analysis of the health status, feedback).

Citizens’ involvement could also occur through patient or other organisations that people have trust in, e.g. doctors and nurses organisations and in this kind of communication, the testimonies of the real partners should be included.

A Board steering the data sharing network, as well as an “Ombudsman”-like body representing citizens or patient-organisations was also mentioned as a suggestion in this field.

Key aspects to include in this awareness campaign include providing easy technological tools to manage personal data and empower citizens; increasing the understanding of the data sharing benefits and consequences; explaining and proposing new business models with data operators.

Acutely ill patients are considered to be easily involved, and the trickier aspect being to involve healthy citizens, In this aspect, the proposal to use similar initiatives to blood campaigns was mentioned.

Dissemination campaigns were considered to be helpful to clarify information on risks and benefits, so that citizens are more actively involved, namely workshops, fablabs and

consultation of consumer/patient associations, including here data literacy and in some cases the discussion on economic compensation mechanisms.

One additional recommendation was to further develop citizen science: not discussing data governance or data sharing itself in a more passive or active way, but aiming to discuss science by involving citizens in a constructive way of discussion, turning the debate livelier and more dynamic, and mainly making it concrete. Citizen science in health enables a direct engagement of citizens in health research and allows for different combinations of patient-driven research with different models of data collection, analysis and infrastructure. Thus, advancing communities of self-researching citizens in an action-research mode, was proposed with the aim to bring the public debate on a higher level, and generate the arguments and insights to tackle both technical, ethical and governance solutions.

e. Benchmarking for a health data sharing model

When it comes to the benchmark, services like Google maps, where the person provides data for the better service, is referred to as a potential inspiration but with the improved transparency and traceability and the organ donation schemes with their very good communication campaigns, showing the value of donation for saving lives, could be benchmarked in this area. When it comes to the non-health data sharing, one example mentioned was the one of BMW Car Data [17].

3. Discussion

Data governance can be modelled based on the level of the individual agency over the data and the benefits the individuals get from the data sharing:

- People as the owners of the data: this model assumes the independent agency, the individual ownership over the data and commercialisation of the personal data. People have a full agency over their data and benefit financially from the data used (based on the Jaron Lanier's individual ownership and micropayment model, 2013)
- People as a point of integration of the data: in this concept people 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 Paper, 2014)
- People as the donors of the data for public good: this model presumes that data becomes a part of the public infrastructure with the personal data becoming a public good. It could be assessed by anyone (in anonymised form) and sustainable (based on the Evgeny Morozov data as a public good, 2015)
- Trusted third party: data donors allow fiduciary to keep or use the property 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 R. Winickoff, 2003) [18]
- Collective: data as a common resource managed by the community institutions with the self-organised system (based on data as commons by Elinor Ostrom, 1990 e.g. HDC)

All of these models have pros and cons and they can complement each other.

The business models for the data acquisition and use were heavily discussed during the experts' interviews, who highlighted the need for sustainable business models to be developed in the health data sharing domain as a crucial element for the sustainability of the data sharing schemes.

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As for governance, the comments derived from the interviews showed concern for the differentiation between security and safety and the difficulty in understanding privacy policy documents, mentioning also the tension between the need for regulation and the need to gain insights in a fast and agile way, as demonstrated by COVID-19 crisis.

The interviewees broadly agreed that people are more eager to share their data when they know what 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 receiving better services in return.

The results of an annual Philips study [19] were given as an example, by showing that people feel rather comfortable about e.g. sharing their data with the GPs but not the whole medical record with different or varied stakeholders. This brings the issue of data privacy, data security and safety, as well as the citizen control over their data to the spotlight again.

In regard to the citizens' agreement to share the data, the interviewees in general agreed that the dynamic consent with the mechanism to opt in and opt out must be in place to allow people deciding where and for which purpose the data is being shared, although concerns were mentioned about the solutions of this kind, especially regarding representativeness of data and ethical issues.

4. Conclusions

Despite the fact that the business model is seen as a very important element, there is little evidence on the business models connected to big data in the health industry.

It is a shared opinion that more large-scale experiments are needed to understand and achieve a good governance model. HDCs are seen as a complex field, with many advantages and disadvantages, but this model could provide important inspirations, namely in what concerns the respect for human rights and the individual's control over their data.

There is a pledge for the development of a European model, not solely based on research priorities, but instead one that provides citizens with real control over their data. The European Health Data Space is seen as a first step but many developments are still to be taken, being funding and leadership, namely for a larger experimentation at the European level, some of the required actions proposed in this consultation.

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