



# SALUS.COOP

Towards citizen governance and management of health data

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Ideas for change + Mobile World Capital Barcelona Foundation  
December, 2016



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Barcelona, December 2016

## Summary

Changes in the capacities and demands of citizens, data-driven innovations and technological developments in research invite us to reconsider the role of citizens in the healthcare sector, both at individual and collective levels. Mobile World Capital Barcelona Foundation and Ideas for Change have investigated how such roles can be reconfigured to accelerate research and innovation in healthcare, and thus deliver positive social impact.

The goal of the collaboration agreement was to explore the viability of a citizen-driven model of collaborative governance and management of health data, by proposing an approach that builds on three key frameworks:

- Governance and relational framework
- Technological framework
- Legal framework.

To meet these goals Ideas for Change conducted field and desk research. First, the state of the art of existing health data sharing initiatives was reviewed and interviews with experts and practitioners were performed. These included health sector professionals, patient associations, researchers and experts in the field of data intensive technologies, among others.

Second, the collected data was analyzed by using thematic analysis and key emergent themes were crafted. These themes were then further analyzed and discussed with a selected group of specialists in two validation sessions.

Third, the research outputs were synthesized by assembling higher-level findings that inform on a number of recommendations to frame and activate the vision for “Salus”. This report presents the outputs organized in three chapters:

**Chapter 1** describes the investigation. It discusses why this study is timely and relevant, presents the vision and objectives of the project, as well as the methodology applied.

**Chapter 2** presents the main findings and derives four key pillars to structure a citizen-led governance model for health data:

- Conditional donation;
- Collective benefits;
- Motivational incentives;
- Management of rights.

**Chapter 3** introduces the proposed model. It identifies the key agents and describes the different flows of exchange that sustain the system of relationships among them (economic, data and services). Furthermore, it also explores the legal feasibility of the approach and the existing technologies that could enable the model.

Finally, the report concludes with key findings derived from this research.

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CHAPTER 1

# THIS STUDY

## 1.1 Context

Advances in the field of Information and Communication Technologies are generating enormous amounts of data, which are laying the groundwork for fostering collective intelligence and encouraging advances in a range of different sectors.

Health is one of the sectors that produces the largest volume of data, related to citizens' health and lifestyle. Within this sector, data are generated from different sources, such as Electronic Health Records systems (EHR), Personal Health Records systems (PHR), Hospital Information Systems (HIS), Laboratory Information Systems (LIS) and Radiology Information Systems (RIS or PACS). New forms of data collection are being added to these sources on an individual level (devices, sensors, etc.), as well as on a social (social networks, blogs, etc.) and environmental level (geo-positioning sensors).

The future of medical research will be significantly reliant upon the potential for combining and integrating all of these data sources<sup>1</sup>. The benefits of using data in research and medical services provision are tangible and significant, as indicated by several studies<sup>2,3</sup>.

Currently, the large amount and variety of data

includes both structured data (e.g. analytical tests) and unstructured data (e.g. images, videos and free text). Unstructured data management has become one of the main challenges faced by health administrations today. It is estimated that 80% of health data are unstructured<sup>4</sup>. The lack of data structuring hinders the processes to integrate and share that information. As a result, most health data is currently stored in silos, which makes it difficult to reuse, compare, and share.

However, there are several processes that can transform unstructured data into accessible and reusable data (e.g. capture, interoperability, and analysis processes). One such example is the growing implementation of big data processing systems. Within public health systems, there are currently several projects aimed at the integration and interoperability of health information on a European level (e.g. Epsos<sup>5</sup>), national level (e.g. HCDSNS<sup>6</sup>) and regional level (e.g. HC3<sup>7</sup>). These projects have digital sites for citizens that allow them to check their personal health information (e.g. La Meva Salut<sup>8</sup>). Nevertheless, none of these options legitimizes data ownership for citizens, because, for instance, they do not provide citizens with the tools to use, transfer and share their

<sup>1</sup> Feldman, B., Martin, E. M., & Skotnes, T. (2012). Big Data in Healthcare Hype and Hope. October 2012. Dr. Bonnie, 360.

<sup>2</sup> Association of Medical Research Charities (2016) "A matter of life and death: how your health information can make a difference" AMCR 2016.

<sup>3</sup> The Benefits of Data Sharing. In Olson, S., & Downey, A. S. (Eds.). Sharing clinical research data: workshop summary. 2013 National Academies Press.

<sup>4</sup> Unstructured Data in Electronic Health Record (EHR) Systems: Challenges and Solutions. ©2013 DATAMARK, Inc.

<sup>5</sup> <http://www.epsos.eu>

<sup>6</sup> <https://www.msssi.gob.es/profesionales/hcdsns/home.htm>

<sup>7</sup> [http://ticsalut.gencat.cat/ca/projectes\\_estrategics/historia\\_clinica\\_compartida\\_a\\_catalunya/](http://ticsalut.gencat.cat/ca/projectes_estrategics/historia_clinica_compartida_a_catalunya/)

<sup>8</sup> <https://lamevasalut.gencat.cat>

The data heals  
**Improve diagnosis**

The Haematological Malignancy Research Network (HMRN) is a collaboration between epidemiologists, a centralized diagnostic service and 14 hospitals that are capturing detailed data on treatments, responses and outcomes of clinical trials of every patient with haematological cancer in Yorkshire and Humberside. Since 2004, data of more than 20.000 patients has been registered. These data have provided a very valuable insight into potential pathways to diagnosis, gaps and inaccuracies in physician guidelines about symptoms, variations in treatment responses and a socioeconomic survival effect.<sup>1</sup>

1 Haematological Malignancy Research Network

information.

The Spanish Article 18.1 of Law 41/2002 on patient autonomy, states that “The patient has the right to access [...] the documentation of his or her medical records, and the right to obtain a copy of the data contained therein.” Accordingly, it can be claimed that data ownership corresponds to citizens. However, currently, citizens’ access to data is limited, since they can only consult certain health information (e.g. La Meva Salut,

in Catalonia), which, is largely unstructured thus very difficult to reuse. Therefore, citizens’ ownership of the data becomes very difficult to implement in practice.

Nonetheless, transparent access to health information presents challenges in the governance of the same. New mechanisms need to be developed to protect citizen confidentiality and privacy, while ensuring free access to information for the benefit of the common good. Advances in the field of genomics show there is scope for developing new infrastructures, resources and policies that promote the exchange of data for the common good<sup>9</sup>. The Human Genome Project<sup>10</sup>, Encode Project<sup>11</sup>, Personal Genome Project<sup>12</sup>, Wellcome Trust Case Control Consortium<sup>13</sup>, and Spanish BioBancos Network<sup>14</sup> are some examples. Most of these initiatives, however, consider citizens as passive agents, since they are not involved in the process beyond the informed consent they sign when agreeing to donate their data<sup>15</sup>.

These are some of the questions that have driven the study described in this report:

9 Kaye, J., & Hawkins, N. (2014). Data sharingpolicydesign-forconsortia: challengesforsustainability. *Genome medicine*, 6(1), 1.

10 <https://www.genome.gov/>

11 <https://www.encodeproject.org/>

12 <http://personalgenomes.org/>

13 <https://www.wtccc.org.uk/>

14 <http://www.redbiobancos.es/>

15 Woolley, J. P., McGowan, M. L., Teare, H. J., Coathup, V., Fishman, J. R., Settersten, R. A., ... & Juengst, E. T. (2016). Citizenscienceorscientificcitizenship? Disentanglingthe uses of publicengagementrhetoric in nationalresearchinitiatives. *BMC medical ethics*, 17(1), 1.



The data heals  
**Improve prevention**

A team from the Houston Methodist Research Institute has developed software that extracts medical information from clinical reports, patient scan records, and mammography results. It builds risk estimation models to reduce unnecessary biopsies.<sup>1</sup>

1 Patel, T. A., et al.,(2016). Correlating mammographic and pathologic findings in clinical decision support using natural language processing and data mining methods. Cancer.

- Is it possible to involve citizens more actively in the decision-making process related to the use of their health data?
- What kind of governance models can be developed to give citizens ownership and control of their health data?
- How can we encourage data sharing that benefits citizens, health professionals, researchers, healthcare providers and companies willing to offer services/products?

“Today, the clinical and genetic information of cancer patients is held in a variety of places: academic medical centers, community hospitals, disease-specific foundations, pharmaceutical companies, and the government. There is very little sharing of data among these institutions”  
Hamermesh R. and Giusti K., One Obstacle to Curing Cancer: Patient Data Isn’t Shared. Harvard Business Review, 28 Nov. 2016

“Today the public invests heavily in cancer research through federal tax dollars, but the current academic publishing environment hampers innovation and discoveries. Research articles are hidden behind paywalls, and delayed from release by long embargoes. Research data remain unavailable, or are restricted from being machine-readable to allow deeper analysis. An alternative system, where all publicly-funded cancer research and data are required to be shared, would allow researchers to unlock their content and data for reuse with a global audience, and co-operate towards new discoveries, analysis, and cancer treatments.”  
Ryan Merkley CEO, Creative Commons, 2016 (Wiki Creative Commons)

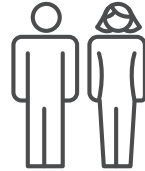
## 1.2 Vision and objectives

In accordance with the current context, it is believed there is a need to promote new forms of health data management that recognize the right and ability of citizens to decide when, how, what, why and with whom they want to share their health data. With the support of the Mobile World Capital Barcelona Foundation, a study has been developed, which aims:



To explore the potential for developing a citizen-driven model of collaborative governance and management of health data, which enables citizens to collectively share data and therefore accelerate research and innovation in healthcare.

In order to address this objective, a model (hereinafter, the Salus model) is envisioned (Fig. 1). It takes three main groups of actors into account:



**Citizens:** the legal owners of their health data, which are stored in several databases.



**Data keepers:** the owners of the databases where citizens' health data are stored. Some potential data keepers include private and public health centers, smart device companies (wearables, apps).



**Data users:** the parties interested in accessing the data for different purposes. Possible recipients include researchers, companies and public administrations.

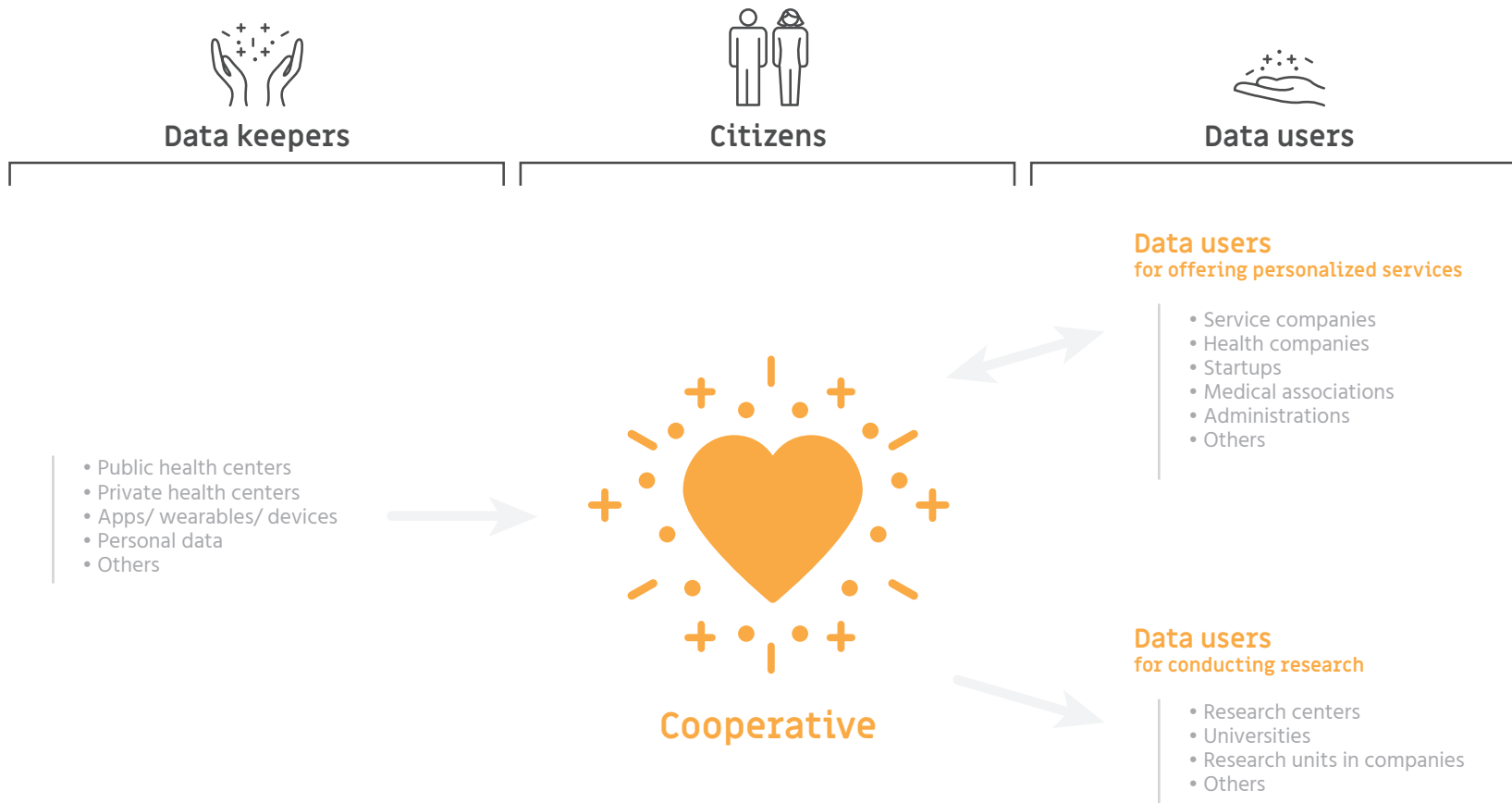


FIGURE 1. Salus model projection

This project is the first step towards understanding the viability of implementing a model such as Salus. The aim of this study is not to be exhaustive but rather to inspire new ways of thinking and framing the promising interplay between citizen's health data and participation.

The focus of this research is on understanding

how the model can be applied in a specific case: breast cancer. This disease has been chosen for several reasons: (i) in Catalonia there is an active and empowered patient association, (ii) there are several research centers that are renowned worldwide and (iii) there is a high social awareness about this disease.

## 1.3 Methods

The overall objective of this project has been achieved by:

1. Gathering opinions and suggestions from experts representing each identified group
2. Analyzing existing initiatives on health data sharing
3. Designing a possible governance model that recognizes citizen ownership of health data.

This study was developed by following a qualitative approach to data collection<sup>16</sup>. The following sections describe the research methods followed.

### Semi-structured interviews

Semi-structured interviews were conducted with representatives of each of the three groups: citizens, data keepers and data recipients. Interviews were aimed at understanding people's interests and perceptions of the envisioned Salus scenario. Before the interviews, a brief presentation describing the Salus model was sent to interviewees. Each interview began by explaining the Salus model, and then questions were asked about (i) the perceived benefits, risks and barriers, (ii) the possible conditions that could be established, and (iii) any other

relevant issue perceived by the interviewee.

To determine the sample group of interviewees a snowball sampling approach<sup>17</sup> was followed. Representatives with an involvement in breast cancer, were identified. The selected sample was made up of 24 people, including citizens', representatives of the data keepers and data recipient, and other experts in the fields of ethics and technology. For the citizen group, members of breast cancer associations and other associations, such as fibromyalgia and chronic fatigue patients, were also selected. In both the data keeper and data recipient groups, participants included professionals from several hospitals and institutions involved in cancer treatment and research, such as the Institut Català d'Oncologia (ICO), Instituto Oncológico Baselga (IOB), Hospital Sant Pau, Hospital Clínic and Hospital del Mar. From the group of experts, bioethics researchers from the University of Barcelona, bioinformatics researchers from Bioinformatics Barcelona, and open data experts from Barcelona Open Data Foundation were interviewed.

Interviews were conducted in person or by telephone. Notes were taken during each interview and transcribed for subsequent analysis. Data were analyzed by two coders through deductive thematic analysis<sup>18</sup>, which consisted of reading the notes, creating reference

<sup>17</sup> Goodman, L. A. (1961). Snowball sampling. *The annals of mathematical statistics*, 148-170.

<sup>18</sup> Braun, V. and Clarke, V. 2006. Using thematic analysis in psychology. *Qualitative research in psychology*, 3(2): 77-101. doi: 10.1191/1478088706qp0630a

<sup>16</sup> Gill, P., Stewart, K., Treasure, E., & Chadwick, B. (2008). Methods of data collection in qualitative research: interviews and focus groups. *British dental journal*, 204(6), 291-295.

codes (tags), identifying themes by grouping related codes together, and reviewing themes in an iterative model by checking the entire data set. Themes were discussed during group sessions with the research team in order to validate and refine them (Figure 2).

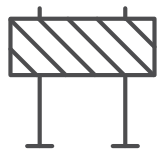
The core themes that emerged from our analysis, and that are used to present the results in section 2, are as follows:



**Universal benefits:** innovation (research, business), provision (prevention, service management).



**Terms for data donation:** control (over access, over use), transparency and communication, collective benefits, anonymity and security



**Barriers:** entry barriers for citizens (motivation, lack of understanding, access), barriers between the parties involved (doctor-patient, medical practices, distrust among parties), technological barriers (unstructured data, non-aggregated data, natural language).



FIGURE 2. Map with initial themes that emerged from the analysis of data interview. Used in the group session with the research team.

## Desk Research

In order to better understand the envisioned scenario in relation to the current health data ecosystem, information on existing initiatives led by governments, companies, research centers, citizens and others were collected. Information was gathered in scientific magazines (e.g. Nature, Nature Genetics), Journals (e.g. BMC Medical Ethics, Genetics in Medicine, Genome Medicine, Nature Biotechnology), conferences proceedings (e.g. Workshop on Sharing Clinical Research Data 2013) and the Internet (e.g. ProPublica, websites of the identified initiative).

## Validation sessions

The analysis of interview data, as well as the analysis of existing initiatives, was presented and confirmed in two validation sessions. 34 experts participated in these sessions, of which 12 were interviewed in advance. Each session started with a presentation made by the research team in which the results of the interview analysis and a preliminary analysis of existing initiatives were presented. In each session, participants were grouped

into three teams and asked to fill out a table (Fig. 3) with the benefits and risks they perceived in relation to different governance models (i.e. individual, public, private and cooperative). At the end of the activity, each team presented the resulting table to the other teams. The session concluded with an open group discussion aimed at summarizing the main conclusions. Subsequently, the tables filled out during the validation sessions were analyzed by the research team to highlight common topics and concerns.





	 <b>Individual</b> Maria's health data is stored in her personal hard disk	 <b>Private</b> Maria stores her health data on a platform owned by a private company (e.g. Apple health or other PHR apps)	 <b>Public</b> Maria's data is stored in public databases. Maria has credentials to access her data (e.g. La Meva Salut)	 <b>Cooperative</b> Maria's data is stored in different databases. Maria has access credentials and shares them with the cooperative under specific conditions that she established.
Benefits				
Risks				

FIGURE 3. Matrix used in the validation sessions.

CHAPTER 2  
**RESULTS**

This chapter presents the results of the research conducted as part of this project. Section 2.1 presents an analysis of existing data sharing initiatives that are related to the goal of this project. Sections 2.2 and 2.3 detail the results of the field study, namely the interviews and validation sessions. Section 2.4 summarizes the results by outlining the four aspects that have been identified as fundamental to creating a citizen-driven governance model for health data, and that have been used for designing the Salus model presented in chapter 3.

## 2.1. Mapping existing health data sharing initiatives

It is well-known that the healthcare sector needs data on a large number of people in order to make advances in medical research. This need has generated a demand for involving citizens in order to encourage them to make their data available<sup>1</sup>. There are numerous initiatives that have promoted data sharing for research, and they differ in terms of: mission statements, approaches to citizen involvement, data policies, funding schemes, governance model, and promoters, among other aspects. Within these initiatives, the focus has been on the elements that are considered most relevant to the project's objective: the citizen's role and governance

<sup>1</sup> Woolley, J. P., McGowan, M. L., Teare, H. J., Coathup, V., Fishman, J. R., Settersten, R. A., ... & Juengst, E. T. (2016). Citizen science or scientific citizenship? Disentangling the uses of public engagement rhetoric in national research initiatives. *BMC medical ethics*, 17(1), 1.

models.

Five different roles for citizens, which range from a more passive to a more active role, have been identified. By governance model, it is meant the control and management scheme related to the type of party running the initiative. For example, an initiative led by a government institution is likely to derive a governance model that resembles the provision of public services. On the other hand, an autonomous association of people will require a non-hierarchical and participatory arrangement, here referred to as collective direct democracy.

Table 1 shows a breakdown of the citizen's role. Table 2 details the type of participants who promote and govern the initiative, which is a key element to defining the governance model. Table 3 presents the correlation between the two.



Role of citizens	Characteristics	Examples
Informed and consenting patients	People are asked to give their consent to donate their data for public research.	Visc+ (Catalunya) Cara.data (UK) Genome Project (Estonia)
Contributors	People proactively decide to donate their health data by, for instance, uploading personal data into platforms.	DataDonors Open Humans
Consumers	People share data with companies who provide them with health devices, applications or services.	PHR apps (e.g. Microsoft HealthVault) Wellness Apps and other devices (Fitbit, Garmin, etc.) Personal service (e.g. 23andMe)
Prosumers	People are provided with tools that enable them to be involved in research. For instance, they can provide information about their disease through social networking tools (PatientsLikeMe).	Social networking services: e.g. Patientslikeme
Partners	People are informed about the use of their data and can participate in decision making processes.	HealthBank Midata.coop OHDC

TABLE 1. Breakdown of the role of citizens in health research initiatives based on data sharing.

Promoters	Governance agreement	Examples
Governmental institutions	Public	Visc+ (Catalunya) Cara.data (UK) Genome Project (Estonia)
For profit companies / Corporate	Private	PHR apps (Microsoft Health Vault) Wellness Apps and other devices (Fitbit, Garmin, etc.) 23andMe Patientslikeme
Not-for-profit organization: associations, foundations, NGOs	Collective - representative democracy	DataDonors Open Humans
Autonomous public associations (e.g. cooperatives)	Collective - direct democracy	Health Bank Midata.coop OHDC

TABLE 2. Breakdown of governance models in health research initiatives

Although all the initiatives analyzed share the same objective (engaging citizens in biomedical research) the way that citizen’s involvement is conceptualized and articulated varies hugely. Our analysis shows that privately held initiatives mainly focus on providing citizens with products or services, which results in new data being generated (e.g. genomic data (23andMe), social networking conversations (PatientsLikeMe), and sensor-generated data (FitBit)). These data are used in business-driven research projects that result in patents, products or new drugs from which (only) the company derives a financial profit. This is the case, for instance, of 23andMe, a company that provides customers with genetic information, which has then been used to obtain patents. This stirred up controversies about the extent to which “any (private or public) organization involved in research that relies on human participation, whether by providing information, physical material, or both, needs to be transparent, not only in terms of research goals but also in terms of the strategies and policies regarding commercialization”<sup>2</sup> (p.382). Other initiatives rely on a representative governance model (e.g. associations, foundations), wherein citizen participation is conceptualized in terms of proactive data donation to research projects decided on by boards of directors. Initiatives driven by public institutions tend to

<sup>2</sup> Sterckx, S., Cockbain, J., Howard, H., Huys, I., & Borry, P. (2012). Trust is not something you can reclaim easily: patenting in the field of direct-to-consumer genetic testing. *Genetics in Medicine*, 15(5), 382-387.

	Public	Private	Collective/ repre- sentative democracy	Collective/ direct democracy
Informed and consenting patients	Visc+ (Catalunya) Cara.data (UK) Genome Project (Estonia)			
Contributors			Datadonors Open Humans	
Consumers		PHR apps (Microsoft HealthVault) Wellness Apps and other devices (Fitbit, Garmin..) 23andMe	Open Humans Personal Genome Project	
Prosumers		Patientslikeme		
Partners				HealthBank Midata.coop OHDC

TABLE 3. Relationship between governance models and the role proposed to citizens

conceptualize participation in terms of passive patients/  
citizens who have the civic duty to participate in public

research<sup>3</sup>. Participation is conceived in terms of data donation, and no opportunities are given to citizens to set research priorities and agenda.

In summary, both the representative and public models leverage a rhetoric of altruism, while the private model uses the appeal of the benefits offered to individual users, for instance in terms of the service or product.

Contrary to the aforementioned models, a limited number of newly established initiatives are trying to adopt a more participative and citizen-driven governance model, which consider citizens as actual partners and owners of the initiative. This means that citizens can exercise the right to an economic reward for profits generated by data use, such as in HealthBank, and the right to participate in decision-making processes, such as in MiData.coop. This model of citizen direct governance is still in its infancy and, to the best of our knowledge, only a few such initiatives exist worldwide, and they have not yet been deployed in full.

There is a need then to understand further how a model of this type could be enacted, and what challenges it might face. The study presented in this report aims to contribute towards filling this gap.

<sup>3</sup> Woolley, J. P., McGowan, M. L., Teare, H. J., Coathup, V., Fishman, J. R., Settersten, R. A., ... & Juengst, E. T. (2016). Citizen science or scientific citizenship? Disentangling the uses of public engagement rhetoric in national research initiatives. *BMC medical ethics*, 17(1), 1

## 2.2. Results of the interviews



### 2.2.1. Universal benefits

All the groups interviewed perceive clear benefits in developing a system that facilitates access to health data and promotes data sharing. More specifically, they emphasized that access to data has great potential for supporting healthcare service provision and boosting innovation in this field.

#### PROVISION

In relation to the provision of services, data providers highlighted the potential shared health data holds for the provision of services in terms of disease prevention and the development of personalized treatments. The interviewees pointed out that these two aspects, both provision and personalization, could imply improved resource management and a reduction in costs for the public health system, as well as an improvement in the service provided to patients.

#### INNOVATION

In terms of innovation, all the interviewees highlighted the potential of shared health data, especially in terms of accelerating research into medicine. The parties interviewed pointed out people's altruistic instinct when

it comes to health problems, and their willingness to cooperate either to cure their disease or to help future generations.

**“Patients with breast cancer have an altruistic instinct that will lead them to provide data if they feel that this action may help advance research into the disease.” Patients Association**

Finally, it should be noted that another topic that emerged during the interviews was the potential for new businesses to be developed as the result of shared data, which could contribute to improving the current healthcare service model.

**“Data can create industry benefits in terms of creating new products and services for citizens.” Professional care and research.**



### 2.2.2. Terms for data donation

As described above, the willingness to share health data has generally been very positive among respondents. Nonetheless, our analysis also highlights that interviewees would not be willing to allow access to their data just for the sake of sharing. Rather our analysis outlines the desire to donate data under a series of conditions described next:

#### CONTROL

Regardless of the general willingness to donate data, there is a clear desire to control which data is shared, who has access to the data, what will the data be used for and who will benefit from such use. Some interviewees pointed out that prior to any use of the data, permission should be sought from the owner.

#### TRANSPARENCY AND COMMUNICATION

One of the conditions required to allow control over the data is guaranteed transparency for the whole process, from data requests to delivering the results. Transparency goes hand in hand with clean and clear communication, which is the basis for allowing conscious and informed decision-making by data owners. Patient associations emphasized the importance of being able to know what is happening to their data at all times, since one of their fundamental goals is to safeguard the wellness of their members. A lack of proper communication could put their trust at risk, and with it, the participation of members.

**“It is important to always provide clear information and full transparency about how data are being used, both at the start and end of the process.” Patients Association**

#### COLLECTIVE BENEFITS

Respondents believe that an economic compensation to individuals who decide to give their data

may have a negative effect. They pointed out blood and organ donation models as good examples, since in these cases altruism prevails over any individual benefit to the donor. Some interviewees outlined other non-economic forms of compensation, such as individual compensation in the form of services, or collective compensation in the form of charity donations.

**“There should not be an economic compensation for releasing data. But whoever receives the data could make an economic contribution to a social or a research project. The person who has provided the data should be able to choose the type of project.” Patients Association**

**“It would be interesting to explore the possibility of providing companies with data that could be used to offer personalized services to patients.” Health professional**

There is a clear perceived risk among most respondents regarding data being used for profit, which would not benefit citizens and could even be used against them. The most noteworthy case reported in several interviews relates to health insurance, as the improper use of health data by insurance companies may result in insurance contracts that do not benefit the individuals. Interviewees also highlighted that the sale of data for profit may have a negative impact.

In summary, all interviewees agree that the use of health data must fulfill the condition of generating a clear and unequivocal collective dividend, from which society as a whole can benefit. Scientific research is considered a key feature to achieve this goal. Moreover, interviewees highlighted three important aspects regarding promoting research for the common good:

- The importance of encouraging open access research publications.
- The importance of publishing all clinical trial results.
- Free and responsible research that addresses the real needs of society.

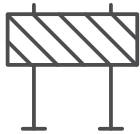
#### ANONYMITY AND SECURITY

According to all interviewees, in order to respect citizens' privacy it is very important to design a system that can ensure data anonymity. Therefore, they pointed out that the system designed must avoid other parties being able to re-identify citizens through data crossing.

As some interviewees pointed out, when working with health data it is not possible to state that data are totally anonymous, since some data are unique (e.g. genetic data) and as such it could be easily re-identifiable through data crossing. Several respondents suggested that different procedures should be applied depending on the likelihood of re-identification. Moreover, accurate information about the potential risk of re-identification should always be provided. The probability of

re-identification depends, among other factors, on: (i) the amount of data available with regard to each individual; (ii) the number of individuals in the database; and (iii) the number of people with the same pathology (rare diseases).

Another factor to consider is the security of data storage systems. It should be robust enough to withstand computer attacks, which are increasingly frequent in the healthcare sector. As some interviewees pointed out, a distributed system could ensure a higher level of security, since data would not be centralized in a single database.



### 2.2.3 Barriers

#### ENTRY BARRIERS FOR CITIZENS

The parties interviewed identified possible barriers that could have a negative impact on citizens when making their initial decision to join the cooperative, and which might mean the organization could end up having access to data which is insufficient and biased (e.g. if only very active and motivated citizens join the cooperative). The amount of data and quality of the sample are key factors to ensure anonymity and have a valuable sample that can be used for research.

#### Motivation

The fact that all of the interviewees were highly motivated to participate in the proposed model must not

be taken as reflection of reality. Interviewees highlighted the importance of motivating those citizens that are not implicitly motivated to participate. In this regard, the participants of the validation sessions remarked on the need to develop individual incentives and rewards for our system. For example, they proposed the possibility of offering services to citizens that could help them manage their health, such as Personal Health Records (PHR).

This might be a strategic aspect, taking into account that there are a growing number of PHR health apps. Citizens might be interested in uploading their data to these apps in exchange for services that can help them manage their health. However, none of the already existing PHR allow citizens to share their data in a collective way; furthermore, many do not clearly explain what happens to the uploaded data, which is not aligned with the aforementioned condition of a collective benefit.

#### Help to understand

Nowadays there is a widespread lack of knowledge about how the research system works, and what the data loops are. This means that the benefits of donating health data may not be evident to citizens, which in turn may have a negative impact on the participation of some citizens, who may not understand the value of the model proposed.

**“There is a risk of non-participation if there is not a clear evidence of the benefits related to donating. Information is essential in this case and can help mitigate any possible doubts and concerns.” Health professional**

#### Access

Interviewees believe there might be some difficulties in accessing certain groups. For example, a lack of technological knowledge among certain citizens may have an impact on their levels of participation, as some of the informational and decision processes will only take place in digital contexts. Also, it might be difficult to access people who are not very proactive and motivated. This might be the case, for example, for citizens who are affected by a specific illness but are not members of the existing patients association.

#### BARRIERS BETWEEN DIFFERENT PARTIES

Some other barriers are related to what might occur between the different parties involved in the system. These barriers might arise given that: i) the proposed model changes the current relationship between some parties (e.g. doctors - patients), ii) some medical practices might be affected, or iii) there might be some mistrust towards the implicit objectives of some of the parties.

Perceptions of the possible changes in the doctor – patient relationship

Health professionals consider that having access to a large amount of data related to their health could cause a certain level of anxiety among citizens. This poses the risk that some of the information could be misinterpreted, or that citizens might carry out erroneous self-diagnoses.

**“The result of an analysis, prior to a diagnosis, could be misinterpreted and generate a feeling of anxiety among patients. While understanding that patients have the right to this information, we need to be aware that this vulnerability should be managed.” Health professional**

This could affect the relationship between the health professional and the patient, given that there is currently asymmetric information between these two parties (e.g. the doctor has access to more information than the patient). If the proposed system is put in place, the asymmetry of the information will be reduced more quickly than at present (websites, mobile, devices, etc.).

On the other hand, interviewees highlight that health professionals might feel judged on the information provided to citizens. Patients could ask them for explanations of certain diagnoses and treatments recommended by other health professionals.

#### Perception of possible changes to medical practices

Interviewees highlighted that the new system for data sharing should not increase the workload of health professionals. They are concerned that the new system

might have a negative impact on their work (e.g. forcing them to introduce more data in the system or making them complete more application forms, forcing them to reduce the quality and quantity of the time they spend with patients). Thus, this model must make sure to include user-centred-designed technologies that do not have a negative impact on in-person healthcare services.

#### Distrust between actors

Interviews have shown that there is certain mistrust towards some of the parties involved in the system. In this sense, our results confirm what other studies have already shown<sup>4,5,6</sup>: citizens are less willing to share data with private companies because they fear that pharmaceutical companies or other private institutions might make non-ethical use of their data. On the other hand, interviewees also recognize that these parties play a critical role, as they provide medicine and offer services that improve people's health. The main challenge in this regard is to ensure that the results obtained thanks to citizens' data are used for the common good. The price of medicine, research agendas, and the transparency of results, are perceived as the key elements to ensure this objective. These results reaffirm the importance of putting access conditions

<sup>4</sup> KPMG Survey, 2015. UK adults trust GPs with digital health-care data but don't want data from their fridges to be shared

<sup>5</sup> Weitzman, Elissa R., et al. "Willingness to share personal health record data for care improvement and public health: a survey of experienced personal health record users." *BMC medical informatics and decision making* 12.1 (2012): 1.

<sup>6</sup> Personal Data for the Public Good – Health Data Exploration Project. 2014. Robert Wood Johnson Foundation

in place for the data to create a collective benefit, as described in the previous section.

#### TECHNOLOGICAL BARRIERS TO DATA

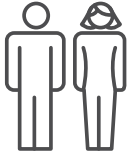
Some of the interviewees pointed out potential technological barriers that could hinder the development of the system. The biggest barrier is linked to the fact that most health data are currently saved on a non-structured format. Blood analytics, for example, are delivered in a PDF format. Furthermore, some non-structured data contain natural language (e.g. reports written by the doctor). These documents need to be interpreted clearly before they can be classified.

It is worth pointing out that some interviewees claimed that these barriers are likely to be overcome in the short term, thanks to rapid technological developments in the field.

## 2.3. Results of validation sessions

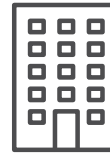
The analysis of existing initiatives (section 2.1) has revealed a wide variety of governance models in data management systems. Two validation sessions with 34 experts have been conducted in order to explore the perceived benefits and risks of four types of governance models: individual, private, public, and cooperative. A scenario was presented to help participants envision each of the models. The results can be summarized in the following diagrams:





## INDIVIDUAL

<p><b>Scenario:</b> Maria's health data are stored on her personal hard disk</p>
<p><b>Benefits:</b></p> <ul style="list-style-type: none"> <li>• <b>Autonomy:</b> individuals do not depend on others to decide what to do with their data.</li> <li>• <b>Control:</b> individuals have maximum control over their data, thus there is minimal fear about potential misuse of the same.</li> </ul>
<p><b>Risks:</b></p> <ul style="list-style-type: none"> <li>• <b>Limited contribution to research:</b> individual data are not very valuable for research, since the value of personal data lies in its aggregation.</li> <li>• <b>Data loss:</b> if data are lost, individuals cannot complain to third parties because data were held on personal storage.</li> <li>• <b>Isolation:</b> since there is not a trusted party acting as informant, individuals willing to donate data for research do not know how to do it. Moreover, individuals may receive requests from third-parties about accessing/using data, and might not know how to react as they do not have adequate information.</li> </ul>



## PRIVATE

<p><b>Scenario:</b> Maria stores her health data on a platform owned by a private company (e.g. Apple health or another PHR app)</p>
<p><b>Benefits:</b></p> <ul style="list-style-type: none"> <li>• <b>Direct incentive to individuals:</b> people are motivated to upload their health data on company platforms because they receive services and products in exchange that enable them to access and manage their data in an easy way.</li> <li>• <b>Technological capacity:</b> companies are perceived to have high level of technological capability. People feel they can rely on the technology used.</li> </ul>
<p><b>Risks:</b></p> <ul style="list-style-type: none"> <li>• <b>Ultimate purpose of data:</b> people have little or no knowledge about what companies do with their data. The terms of use that people sign up to use the product are often difficult to understand. One key point is that some users might not be aware about secondary use of their data.</li> <li>• <b>No interoperability:</b> generally speaking, companies do not have access to the medical records stored in the databases of different health centers.</li> <li>• <b>Risk of losing data:</b> despite the general trust in the technological capability of companies, there is still the risk of potential data loss.</li> </ul>



## PUBLIC

<p><b>Scenario:</b> Maria's data are stored on several databases owned by public institutions. Maria has a login to access her data (e.g. La Meva Salut).</p>
<p><b>Benefits:</b></p> <ul style="list-style-type: none"> <li>• <b>Large volume of data:</b> public institutions potentially have access to many medical records, and to all of the data stored on public health centers. This large volume of data would make it possible to conduct population-based research.</li> <li>• <b>Guarantor of data use:</b> public institutions are perceived to be good guarantors of data use, as their objectives are in the public interest.</li> </ul>
<p><b>Risks:</b></p> <ul style="list-style-type: none"> <li>• <b>Political changes:</b> public institutions are subject to political changes, which might slow down, or even stop, initiatives promoted by previous governments.</li> <li>• <b>Little capacity of investment:</b> little capacity for investment might lead to technological solutions being developed that are not sufficiently innovative, or there might be a lack of incentive for accelerating research in healthcare.</li> <li>• <b>Risk of losing data:</b> public institutions are often accused of being rigid, slow to adapt, and crippled by bureaucracy. The perceived risk is that this rigidity and slowness might affect the overall management of the data sharing system, and could eventually result in a missed opportunity to make the most of the data to accelerate research.</li> <li>• <b>No direct decision from the citizen:</b> citizens do not take part in the decisions made regarding the secondary use of health data.</li> </ul>



## COOPERATIVE

<p><b>Scenario:</b> Maria's data are stored on different databases. Maria has a login to access her data, and shares them with the cooperative under specific conditions that she has established.</p>
<p><b>Benefits:</b></p> <ul style="list-style-type: none"> <li>• <b>Integrative model:</b> the cooperative can integrate data from different sources, both public and private data keepers (hospital, private clinic, and wearables). This would allow different type of information to be integrated and correlated, including habits, sensors, and medical records.</li> <li>• <b>Guided decision:</b> people willing to donate their health data can be informed and assisted by the cooperative, which provides them with the information needed to take an informed decision about their data. People who trust the cooperative can delegate decisions to it.</li> <li>• <b>Independent from political changes:</b> unlike public institutions, the cooperative does not depend on political changes.</li> </ul>
<p><b>Risks:</b></p> <ul style="list-style-type: none"> <li>• <b>Lack of individual incentives:</b> there might be a lack of interest if people cannot clearly see how they personally benefit from participating in this model.</li> <li>• <b>Lack of critical mass:</b> motivating a large number of people to participate in the cooperative might be challenging. It might thus be difficult to reach a critical mass of participants, which is key to having a representative sample for research studies.</li> <li>• <b>Complexity of governance model:</b> the governance model is viewed as being complex, especially with respect to building trust, transparency, and ensuring public interests.</li> <li>• <b>Difficulty in accessing the data:</b> the infrastructure of data systems is complex, which means it might be challenging to access data from different sources. The data transfer process by public authorities might also be slow due to bureaucracy and legislations.</li> </ul>

In conclusion, the validation sessions highlighted the importance to carefully consider the following two aspects:

- **Individual incentives:** besides ensuring public interests, it is important to give concrete benefits to individuals in order to motivate them to participate. Individual incentives are the driving force that makes possible to reach a critical mass of participants and make worthwhile contributions to science.
- **Flexible and transparent collective governance:** groups of people have greater control over their data than individuals acting alone. The collective governance model should ensure transparency and participation in decision-making processes. This should be enabled by a flexible participation infrastructure that allows for informed decisions and a delegative democracy. Transparency fosters trust, which is key to encouraging people to participate in the model.

## 2.4. Conclusion: The pillars for citizen-driven governance of the health data

In summary, the results of our study have highlighted four fundamental principles that should be considered the pillars of any citizen-driven governance model for health data management.



### Conditional donation

Citizens have the right to decide under which conditions they want to donate their health data.

The transfer of data would be made in the form of a donation. This donation would be motivated by the altruistic spirit of citizens and would prioritize the common good over any individual economic benefit. In any case, certain conditions should be fulfilled by the data receivers in order to respect the altruistic spirit of donors. Citizens want to know who will be using their data and what for. With this information, they will be able to decide if they want to donate their health data or not. In this regard, clear and transparent communication throughout the process is a fundamental aspect of donation.



## Collective benefits

The use of data by any parties involved should provide a clear benefit to society.

The system needs to ensure that the use of data by any of the parties has a clear and unequivocal benefit for society as a whole. For instance, the outputs of the research conducted by using citizens' data could be made universally available under an open licence. Moreover, citizens should be given the possibility to identify research priorities and set research agendas. The specificities of any governance protocol that allows a given system to ensure, safeguard and produce a collective benefit must be further investigated.



## Motivational incentives

Incentives should be given to individuals to motivate them to donate their data. Incentives should not be monetary.

We need to find an incentives system that can motivate as many citizens as possible. This would enable access to a data sample that is diverse and representative enough to be valuable for researchers. Nevertheless, the incentives should not be monetary for the individual, so that they do not hinder the common good. Incentives could be provided, for example, in the form of services to members of the cooperative.



## Management of rights

A participatory governance model should be deployed to guarantee the collective benefits of data use and citizen control over the fate of their data.

A collective governance model that enables the access to and management of decentralized databases is required, while applying the conditions established by data owners. The governance model would manage: i) the conditions established by members of the cooperative, ii) the credentials required to access the data and iii) requests from data receivers, which must comply with the principles established by the cooperative.

CHAPTER 3

# SALUS: towards citizen governance and management of health data

**Following the results of our study, a model for citizen-management and governance of health data is proposed. The model responds to the following needs:**

- To empower individual citizens so that they can control what happens to their data (Pillar 1: conditional donation) and to incentivize them to donate their data (Pillar 3: motivational incentives).
- To aggregate health data from large groups of citizens, who govern the aggregated dataset as collective and according to the terms agreed by the group itself (Pillar 4: rights management).
- To foster research and innovation in healthcare through the use of the aggregated dataset, by allowing citizens to identify research priorities and set research agenda (Pillar 2: collective benefits).

In this section a model that aims to meet these goals is presented. It includes the following frameworks:

- Governance and relational framework
- Technological framework
- Legal framework

It is worth emphasizing that this study represents an initial exploration that outlines possible scenarios that could inspire new ways of thinking about and framing the interplay between citizen's health data and participation. For this reason, this report does not present a complete and exhaustive description of the proposed model. It outlines some of the aspects that should be taken into

account in successive phases of this study, and that might contribute towards achieving this project's overall objectives.

### **3.1 Governance and relational framework**

The proposed model is made up of a series of different actors (section 3.1.1) and the relationships between them (sections 3.1.2 to 3.1.5).

The relationships between them are enacted through i) the set of values exchanged between them and ii) a set of agreements that define these exchanges. In terms of the exchange of values, three types of value flows have been identified: i) data flows, ii) service flows and iii) economic flows. The data flow represents the main pillar of the system. The service flow acts as an incentive mechanism that motivates the different parties in the model to participate and get engaged. The economic flow allows the model to be economically sustainable. Overall, these three flows make up an ecosystem wherein assembled datasets are the main assets of a system based on data economics.

Five different types of agreements have been identified to regulate the relationships among parties: i) ethical agreements, ii) membership agreements, iii) data transfer agreements, iv) service agreements and v)

exploitation agreements. Each one is aimed at the different parties and flows in the model. Overall, these agreements make sure that activities arising from the aforementioned flows comply with the fundamental principles established by the cooperative.

It is important to note that all the decisions regarding the specific content of these flows and agreements will be made collectively, through the internal governance processes of the cooperative. The parties,

flows and agreements shown in the next section are intended as a preliminary proposal.

### 3.1.1. Ecosystem of actors

Our proposal requires an ecosystem formed by groups of different actors in order to be viable. Each party provides a different value to the model, and this value could either be in terms of data, infrastructure, services, or research.

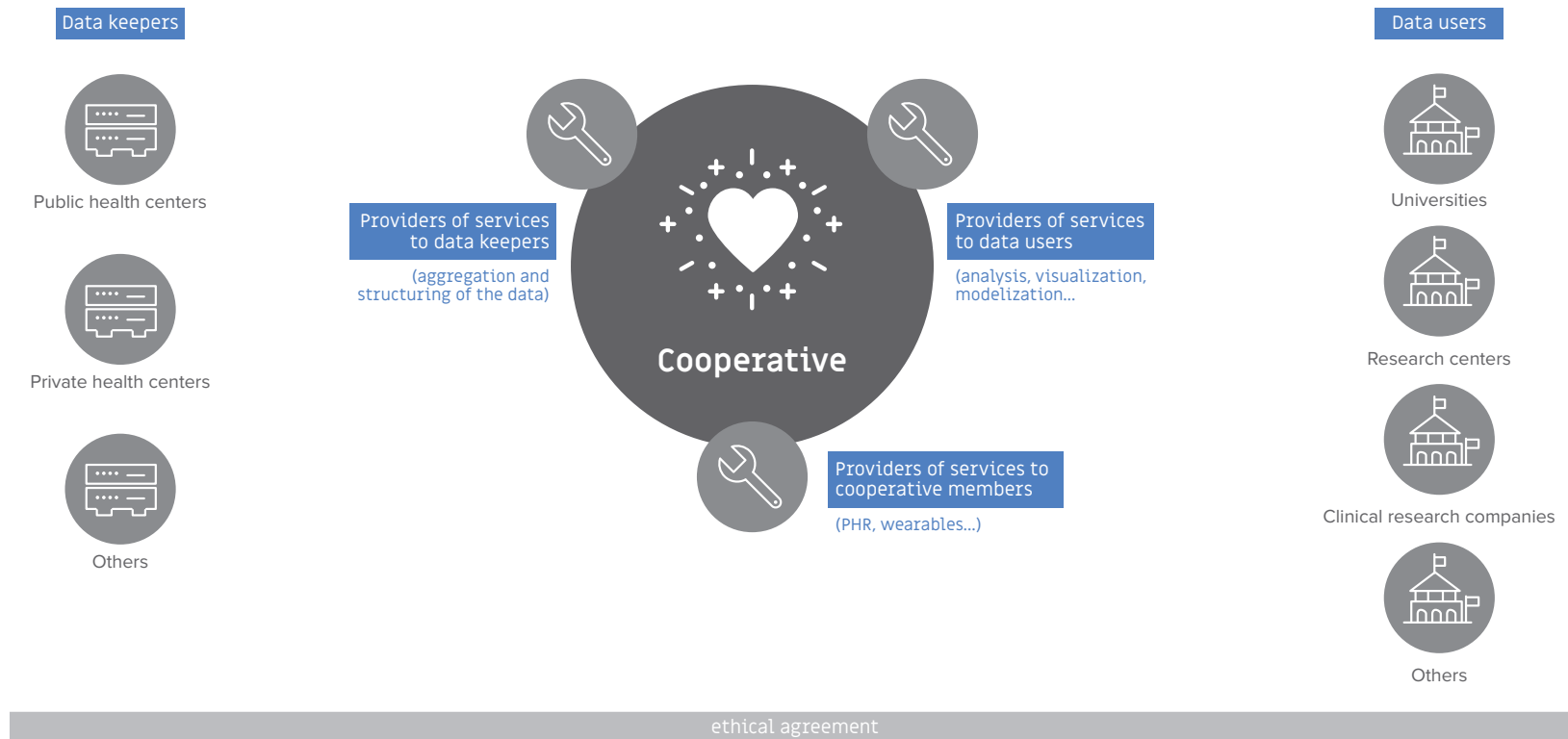


FIGURE 4. Ecosystem of actors



## THE COOPERATIVE

The results of our study pointed out the need to develop a collective structure that would ensure: (i) transparency in data processes and data usage; (ii) the participation of citizens in decision-making processes; (iii) shared ownership of any value generated. A cooperative model could and should allow us to meet these goals.

*Value provided:* The cooperative is the mediating agent between the different parties. The cooperative proposes and implements governance and management systems, which are used to articulate the relationships between parties. By building upon principles of liquid democracy enabled by new technologies (e.g. smart contracts<sup>1</sup>), the cooperative will have a governance structure that will ensure a dynamic, transparent and agile decision-making process.

## COOPERATIVE MEMBERS

This group includes citizens who join the cooperative.

*Value provided:* They give the cooperative the legal authority to access data on their behalf, under the terms set by the individual members, and only when fulfilling the objectives of the cooperative.

*Value received:*

- They can vote in the cooperative assembly,

which enables them to control the fate of their data.

- They can actively contribute to set research agendas by (i) donating their data to specific research projects and (ii) taking part in decision-making processes through which the cooperative chooses which research projects should the data be granted to.
- They can access services and products (PHR, apps, etc.) offered by service providers accredited by the cooperative.

## DATA USERS

This group includes all the parties who are interested in accessing the cooperative dataset for research and innovation purposes.

*Value provided:*

- They conduct research by making use of the cooperative dataset, thus providing valuable information to the cooperative itself and the society as a whole.
- They develop products and services by making use of the cooperative dataset, thus accelerating innovation in healthcare.

*Value received:* Access to an assembled set of health data from various sources under the economic conditions set by the cooperative.

<sup>1</sup> O'Day, C. Liquid Democracy and Emerging Governance Models. Consensus Media. 24 August 2016

## DATA KEEPERS

This group includes all the parties that own the databases storing citizen health data.

**Value provided:** Access to the health data of cooperative members.

**Value received:** The data are returned to data keepers in a structured and aggregated format. In this way data keepers can progressively improve the quality of their databases.

## SERVICE PROVIDERS

This group of parties are instrumental to put the service flow in place (described in section 3.1.3.), providing values -services- to all the parties involved in the model. In order to be a service provider, companies must be accredited by the cooperative. The accreditation is aimed at ensuring the quality and transparency of the services provided, as well as the work processes. Three main groups of service providers were identified, depending on the parties they provide the service to.

**Value provided:**

- **To cooperative members:** They provide health related services or products to cooperative members, giving them a material incentive to join the cooperative.
- **To data keepers:** They provide data from cooperative members to data keepers in an aggregated and structured form. This helps obtaining an important set of correlated

information that ensures patients and other parties in the health system are offered more effective services and treatments.

- **To data users:** Upon request by data users, they can provide users with data processing services, such as visualization, modeling, features extraction, analysis, and more.

**Value received:** The cooperative offers service providers with a strategic option to enter a new market and gain access to a range of potential customers, e.g. patients, health centers, research centers.

Being a Salus accredited company could have a positive impact on a company's image.

### 3.1.2. Data flow

The data flow links up all the parties in the model and serves as the basis for their relationships. The process envisioned is laid out in six steps. Some of these steps could be automated or accelerated, while remaining transparent in the process. Further research is needed to determine how to balance transparency and automation through the right technological solutions and governance processes.

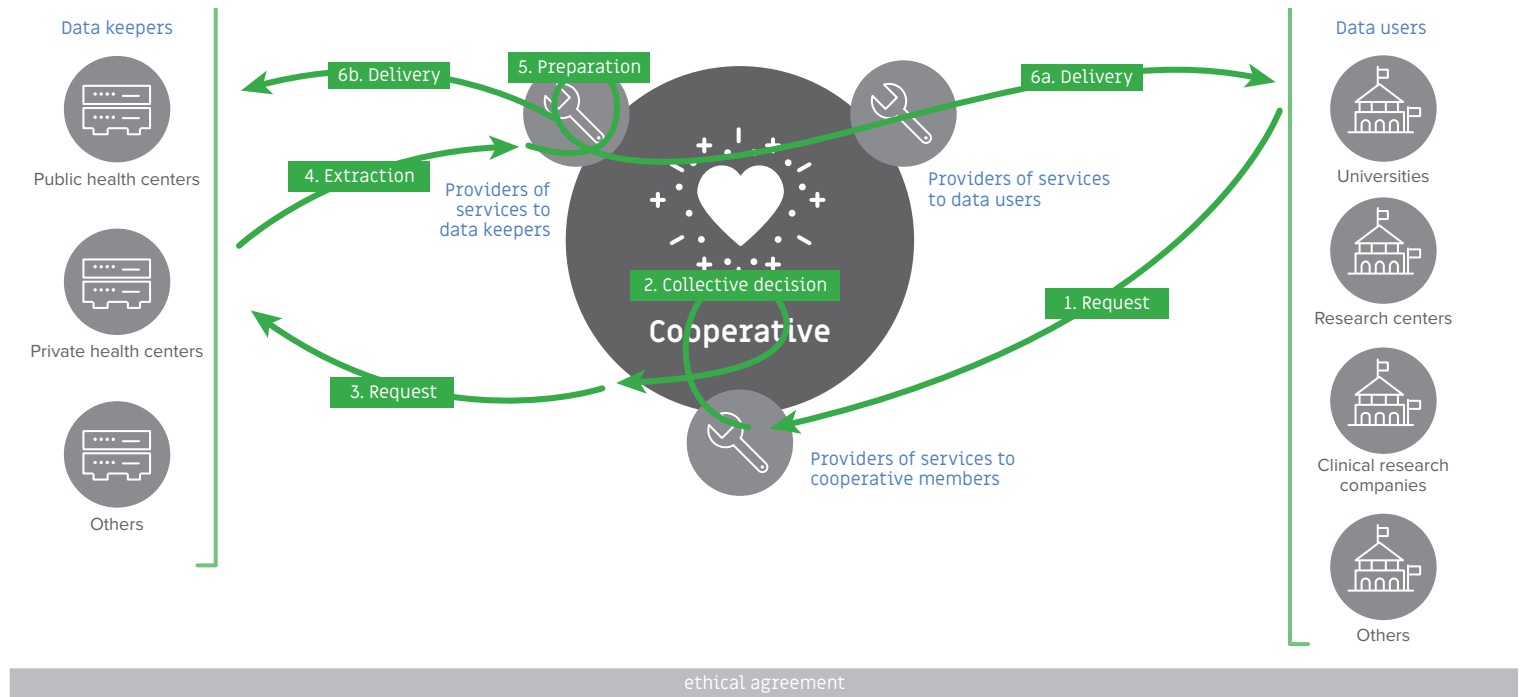


FIGURE 5. Data flow.

#### 1. Request

A group of researchers submit an application to request a certain set of data. The application contains detailed information about the research study: data usage, access and storage, funding, expected outcomes, licensing, etc. If approved, researchers sign a contract wherein they declare their liability in case of negligent data usage.

#### 2. Collective decisions

Internal bodies in the cooperative review the grant application and decide whether it complies with the cooperative's statute. If it does, a price is automatically established for data access, according to the criteria of the cooperative assembly. Internal governance processes allow individual members to decide whether to donate data to each particular grant application.

#### 3. Request

The cooperative requests the data from health centers, in accordance with the agreements entered into place between the two parties.

#### 4. Extraction

Technological providers accredited by the cooperative extract data from health center databases, in accordance with the agreements between the parties. Initially the data is neither structured nor aggregated.

#### 5. Preparation

Data undergo a process of anonymization, aggregation and structuring, carried out by the technological providers associated with the cooperative.

#### 6a. Delivery

Raw anonymized data are delivered to researchers. Additional services, such as data visualization, modeling and analysis, can be provided by accredited technological partners.

#### 6b. Delivery

Aggregated and structured data are returned to the data keeper - health center.

### 3.1.3. Service flow

One of the key findings of our study is that incentive mechanisms should be established in order to motivate parties to participate in the model. The service flow in the Salus model is aimed at reaching this goal. Accredited companies are in charge of developing the services to be provided to different parties.

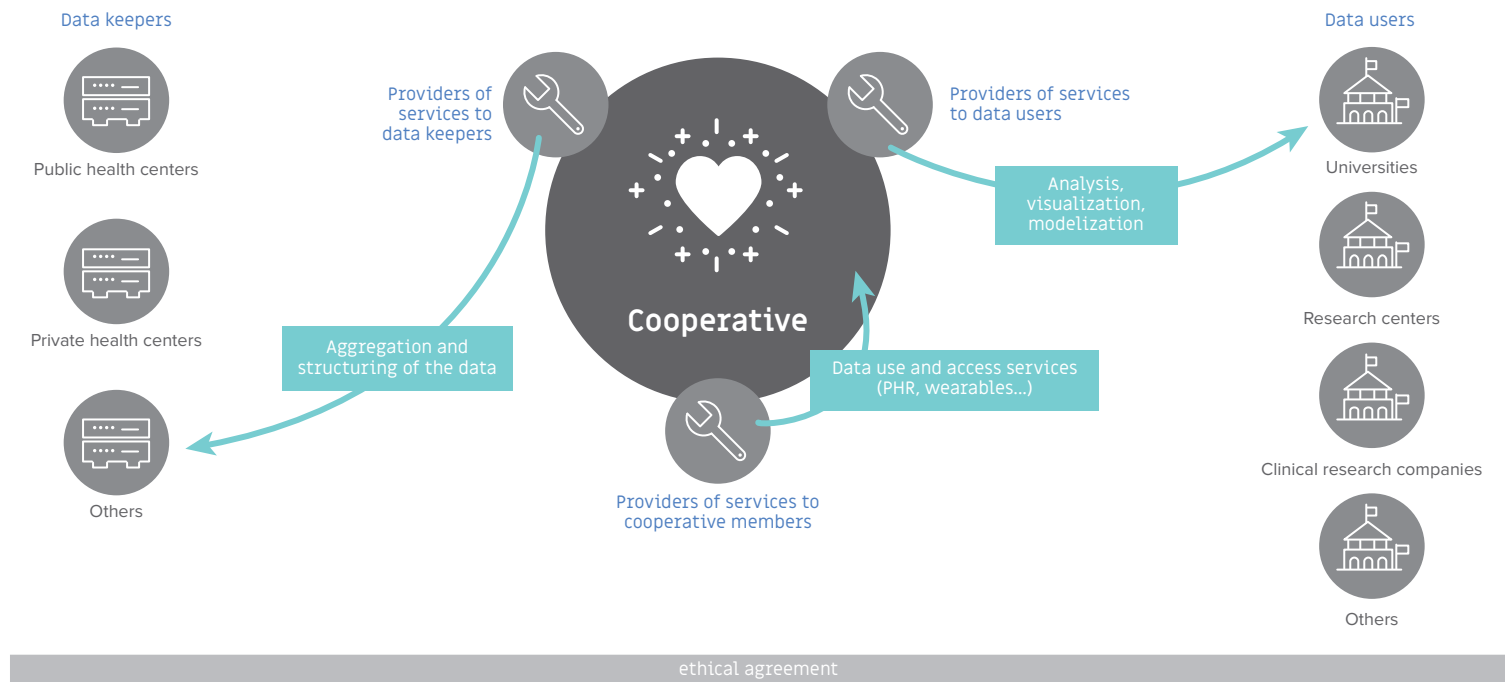


FIGURE 6. Service flow.

#### Services for members:

Our findings highlight that citizens might be willing to participate if they perceive personal benefits. Services provided to cooperative members could be aimed at helping them access and manage their integrated health records by providing them with the right tools (e.g. Personal Health Record apps). Other potential services could facilitate self-management of diseases. Purchasing these services as a group would imply a reduction in price.

#### Services for data keepers:

Our findings pointed out that accessing data from different data keeper systems might be challenging, due to both technological and bureaucracy barriers. It is also well-known that data keepers, such as public health centers, often face challenges in keeping data structured and aggregated. The proposed model aims to address these challenges by rewarding data keepers with structured data from the cooperative members. In this way, as the Salus model progressively takes shape, data stored in data keepers' databases will be gradually structured. Data keepers should be motivated to proactively participate in the model and speed up their administrative processes.

#### Services for data users:

Data (pre-) processing services could be offered to data users on request. Some examples of these services include cleaning, features extraction, modeling and visualization. These services are aimed at increasing the quality of the data offered.

### 3.1.4. Economic flow

The system of relationships also requires an economic flow that will maintain the structure of the cooperative, and payment for the services provided by the associated service providers.

The economic flows identified in this model are structured around two key elements (i) an internal currency, named SalusCoin, and (ii) a variable price for access to data according to a set of key variables.

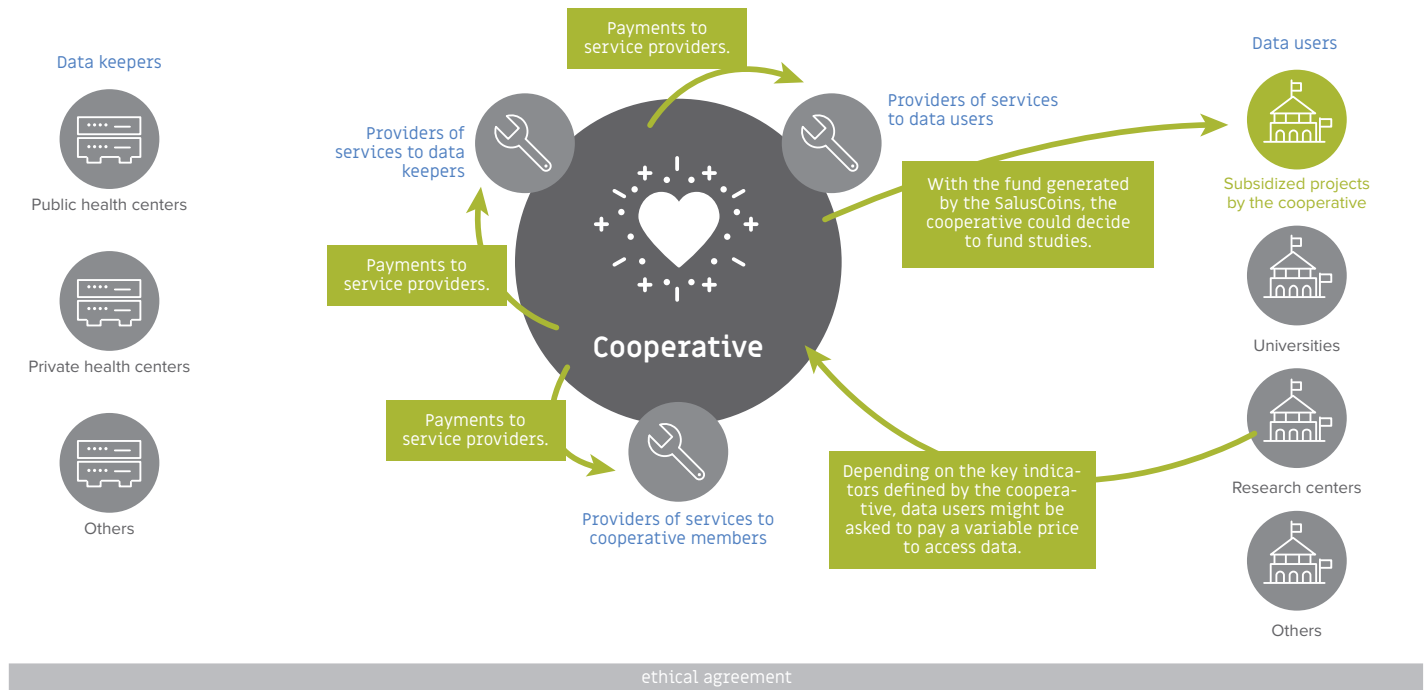


FIGURE 7. Economic flow

#### INTERNAL CURRENCY: SalusCoin

SalusCoin is the internal currency developed by the cooperative, which gives value to data and the participation of cooperative members. Our research showed that the organization should be a non-profit entity and that members of the cooperative should not receive personal monetary incentives. For this reason, the creation of an internal currency was proposed to allow the cooperative to reward the contribution of all the parties involved in making the model possible.

#### VARIABLE PRICE

In order to achieve our goal of having an impact on medical research agenda, the cooperative could promote certain data uses over others. To this end, the cooperative might decide to offer different economic conditions to different data users, for instance, to academic or commercial users. The variable price that the cooperative applies to data users is aimed at having impact on the research agenda. For instance, better conditions can be provided to research projects that are more aligned with the values of the cooperative, and charge a higher price for projects that are considered less relevant by members

of the cooperative (e.g. research on rare diseases vs. research on wrinkles).

In order for the cooperative to determine the price to be applied, data users would be asked to specify relevant information in their grant application. In general terms, the price would be positive, negative or zero.

**Positive price:** When applying a positive price, data receivers will have to contribute economically to the cooperative in order to gain access to the data. This amount would respond to the costs incurred by the service providers to make the data accessible, or would be higher if the data requested is not aligned with the values of the cooperative.

**Zero:** If the price applied is zero, the cooperative would share the data at zero cost to the data receiver.

**Negative price:** There might be certain cases in which the cooperative wants to contribute to research in a specific field, not only with data, but also financially. In these cases the cooperative would invest SalusCoin in supporting a specific research project (e.g. breast cancer).

### REVENUE STREAMS

Taking into account the two key elements that affect the monetary exchanges of the cooperative, diverse revenue streams are envisioned.

## Factors that affect the pricing decision

The cooperative defines the price to apply to data, according to a set of variables. Possible variables are:

- Type of party requesting the data (e.g. academic user, commercial user)
- Aim of the research project for which the data will be used
- Partners involved in the research project
- The research project's funding scheme
- Expected output
- Applicable licenses and publications policies
- Previous transactions with the cooperative
- Additional services (e.g. visualization, modeling, etc.)

**Payments made by data users:** Depending on the price range determined by the cooperative, data users might be asked to contribute financially to the cooperative.

**Fees paid by service providers for receiving accreditation:** In order to ensure the reliability of the services provided and the security of the data processes, the cooperative would accredit companies that want to act as service providers. Being accredited by Salus would provide a market opportunity for service providers, so Salus will charge a fee to obtain the official accreditation.

**Membership fee:** Citizens who want to join the cooperative will be asked to pay a membership fee.

A portion of this contribution will be placed in the cooperative fund, and the rest will be provided to the individual in the form of SalusCoin in their personal wallet.

### INCOME DISTRIBUTION

The income received from the revenue streams described above will be distributed in the following ways: it will be used to cover the infrastructure and running costs of the cooperative, and to create a fund to influence the research agenda.

**Infrastructure and running costs of the cooperative:** To cover the cost of the cooperative's technological infrastructure and running costs.

**Fund owned by the cooperative:** A fund owned by the cooperative will be created to grant funding from the cooperative to specific research projects. Thanks to this mechanism, the cooperative will be able to actively influence the research agenda and promote research in areas that are not currently being explored. Therefore, thanks to this fund, the cooperative is able to contribute to the research fields that the cooperative considers to be the most important, not only with data, but also with financial resources.

**Cooperative member wallets:** Each cooperative member will have a personal SalusCoin wallet. Members receive SalusCoin when: i) they contribute with their data to the

cooperative (more data equals more SalusCoin); ii) they actively participate in the governance processes of the cooperative. Citizens can use SalusCoin to acquire services from accredited service providers, or to fund research projects promoted by the cooperative.

### 3.1.5. Relational agreements

The relationships between the parties are bound by a set of contractual agreements that outline the ethical behavior, value exchange, technological standards, terms of data use, etc., to which the parties must agree. Various types of agreements have been identified. Some of them apply univocally to all the parties, while others are specific to certain groups. These agreements require the management of the divergent interests of the parties, by addressing issues such as licensing, intellectual property and data protection. In order to meet the cooperative's commitment to transparency, an important future project would be to explore ways to make these agreements easily understandable to everyone, in order to allow cooperative members to make an informed decision.

An important role of the cooperative is to ensure that these agreements are respected. Legal contracts should include a clause that states that the cooperative is not responsible in cases of non-compliance by third parties.

The specific content of these agreements would be determined by the collective decision of group members. Some important aspects to take into account are

highlighted below.

**ETHICAL AGREEMENT.** This agreement is addressed to all the parties involved in the model. It defines the cooperative's aims and the ethical principles that all the parties agree to abide by. It also states the permitted purposes of the activities related to data sharing and use. Two important dimensions of the ethical code are transparency and participation. All the parties involved must agree to be open in terms of the processes that involve data transfer and use. The cooperative is committed to facilitated participation in all decision-making processes and offering democratization tools that allow members to easily participate.

The ethical agreement works as a declaration of intent and is not therefore legally binding. Parties involved in the Salus model can however be held to account for breach of an ethical agreement by cooperative members. Moreover, some ethical dimensions are included in the other legally binding contracts signed by Salus participants.

**MEMBERSHIP AGREEMENT.** This regulates the rights and duties of cooperative members and it establishes that only individuals can become members of the cooperative. Some of the members' rights are: the right to vote in decision-making processes, the right to set (and update) the terms of use and access to data, the right to be informed about data usage, and the right to withdraw

at any time. A person who wants to become member of the cooperative must agree to give permission for the cooperative to access his/her data, under the conditions stipulated by the individual, as established by his/her rights.

**DATA TRANSFER AGREEMENT.** This regulates the contractual relationship between data keepers and the cooperative. The agreement establishes the right of data keepers to be 'rewarded' with data that are better-structured than the initial data provided. In other words, data will be returned to them after having been structured and aggregated. The agreement also establishes that data will be processed in an anonymous and safe way, according to existing laws.

**SERVICES AGREEMENT.** This regulates the contractual relationship between the service provider companies and the cooperative, as well as service provider companies and the third parties (data users, cooperative members, data keepers) that receive the services. Service provider companies are not part of the cooperative, and they do not therefore have voting rights. However, to participate in the model, companies must receive accreditation issued by the cooperative. The service agreement could also concern IP ownership and the licensing of the services developed by using the cooperative dataset.



**EXPLOITATION AGREEMENT.** This agreement is for data users who make requests for accessing member data. The core of this agreement regulates the allowed data usage, the conditions under which data are donated, and the obligations to which data users must adhere. It also covers the criteria that govern the economical flow between the parties. By establishing the kind of data usage that is allowed, this agreement plays a critical role in safeguarding the cooperative's principle of collective benefits, ensuring that data are actually used to accelerate research and generate collective benefits.

This agreement also concerns IP ownership, licensing and publication conditions, in order to address divergent interests. In this regard, an important objective of this agreement is promoting licensing that ensures the lowest possible drug price (e.g. royalty free, non-exclusive), limited confidentiality and the open sharing of knowledge (e.g. creative commons, open-access publications).

## 3.2 Technological framework

Four core components define the technological framework of Salus:



### Identity and Security Management System

This component is made up of different levels:

- The first would allow members of the cooperative to be identified with a unique ID, which would be related to IDs from other sources (CIP, Health insurer services card, etc.). This would make it possible to access information about a particular member on all the databases on which his/her information is stored.
- The second would make it possible to identify data keepers who have data from members of the cooperative.
- The third would identify data users who wish to make use of data under the established conditions.

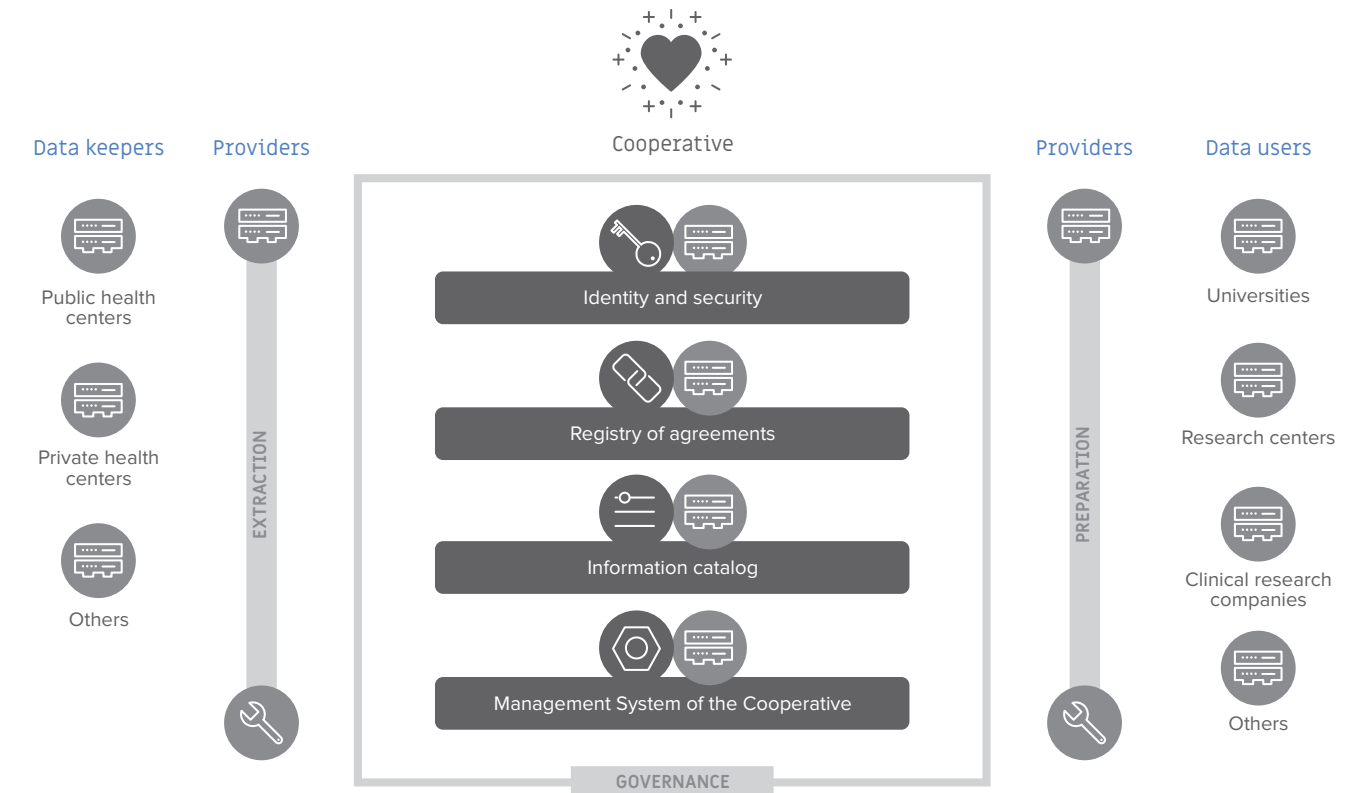


FIGURE 8. Technological framework.

- The final level would identify different service providers, which would contribute to new services for the other parties participating in the model.

With regard to the last three points, the type of identification used to guarantee a person's identity would require the implementation of digital certificates.

Security model would affect: (i) the four components mentioned above, where it is necessary

to highlight the need for exhaustive controls over the traceability of information flows, and (ii) the parties that can intervene in the Salus model, describing their commitments in the different smart contracts. A member of the cooperative would always be able to exercise their rights, as established in the Data Protection Act (Ley Orgánica 15/1999, de 13 de diciembre, de Protección de Datos de carácter personal), with respect to the Access, Rectification, Cancellation and Opposition (ARCO) of the information.

In the future access model to be developed, it would be essential to maintain trust in terms of security and confidentiality. This is key to ensure an univocal citizen identification system. The system would include security requirements and would guarantee the traceability of any access to the information, which would then be available for consultation by members of the cooperative whenever required.



### Registry of Agreements

This technological component would guarantee that all of the agreements between the different parties in the model (section 3.1.5) would be fulfilled under the established conditions. To this end, a notary function could be implemented through Blockchain technology (see next section).



### Information Catalog

The information catalog consists of an index with statistical information on cooperative members. This repository should make queries to different data keepers in order to keep the index up-to-date, for example via 24/7 web services technology. This index would make it possible to identify the availability of the type of information required by data receivers, as well as the location of the information with the different data keepers, which would allow queries to respond to different information requests. This model does not foresee a centralized information repository, but rather a distributed repository in which information is stored in the different data keepers' servers. A decentralized model would avoid the risk of a cyber-attack and would establish a basis of universal trust.



### Management System of the Cooperative

The management system would allow the different operations of the cooperative to be carried out. It would make it possible, for example, to manage the different mechanisms of remuneration for all the parties of the model (section 3.1.4) as well as the other economic flows for the cooperative. The system could also include functionalities that support both the management and

governance decisions of the cooperative, as well as other transversal decisions affecting members.

## The potential for applying Blockchain technology in Salus model

The disruptive nature of Blockchain technology can be seen in the field of finance, but a trend towards new forms of use is emerging<sup>2</sup>. Bitcoin is perhaps the most widely known use of Blockchain. Health industry giants like Merck or Phillips have already started venturing into this technology in search of more efficient solutions for the sector.

An emerging technology like Blockchain could solve some of the challenges associated to the Salus model, especially those related to the transparency and flexibility of the internal governance processes in the cooperative, as well as the distributed model of data.

One such future application of this technology could be in the **Registry of Agreements** component, wherein a “notary function” could be implemented. Through the use of smart contracts, this function would verify and validate the different types of agreements that are established between the parties in the cooperative<sup>3</sup>. The technical development of smart contracts is very new. However, there are already several protocols (e.g. Ethereum) and

platforms, under different levels of development, that are working towards such contracts becoming an everyday occurrence.

**Identity and Security** is another component in which Blockchain could be used. It is currently difficult to verify whether a user is who he claims to be, and this technology shows promise in resolving this kind of issue. Blockchain technology will allow users to create their own tamper-proof digital identity, a kind of Blockchain ID that will soon replace the usernames and passwords that are used today<sup>4</sup>. The public key infrastructure (PKI) works like a safe deposit box with two keys, one to encode and one to decode. The cooperative should be safe as long as its members do not share their PKI with someone else.

Blockchain also offers technological advantages in terms of **distributed architecture**, like the one that is envisioned in the Salus model. Blockchain would allow data to stay where it has been originated, thus avoiding the need for a centralized repository.

**“For the first time ever, we have a platform that ensures trust in transactions and much recorded information no matter how the other party acts.” Don Tapscott (Donnelly J., Healthcare: Can the Blockchain Optimize and Secure It? BitCoin Magazine 12 Jan. 2016)**

<sup>2</sup> Donnelly, J., Healthcare: Can the Blockchain optimize and secure it? BitCoin Magazine, 12 Jan.2016

<sup>3</sup> Barbiero A. ¿Podría la tecnología Blockchain ser una alternativa para las apps de salud? Co-Salut 13 Aug. 2015 <https://goo.gl/vAQvyE>

<sup>4</sup> Tapscott, D., & Tapscott, A. (2016). Blockchain Revolution: How the Technology Behind Bitcoin is Changing Money, Business, and the World. Penguin.

## Seven Principles of Blockchain

The seven principles of a Blockchain economy, as proposed by Don and Alex Tapscott<sup>1</sup>, are well-aligned with the principles defined in the Salus model.

### Principle 1: Networked Integrity

Due to the fact that the Blockchain is spread out over thousands of computers, it is “networked” and participants in a Blockchain economy are incentivized to maintain “integrity”, as every interaction is indelibly recorded. Through networked integrity that relies on a consensus to clear transactions (through so-called “Proof of Work” or “Proof of Stake”), the use of intermediaries is no longer required.

### Principle 2: Distributed Power

The system distributes power across a peer-to-peer network with no single point of control. No one person or organization has a disproportionate control over the whole, or access to an overly large amount of data.

### Principle 3: Value as Incentive

All stakeholders have aligned incentives. It is possible to work for your own interests, while also benefitting society as a whole. Reputation matters. This is true in the real world as well, but in the virtual, Blockchain economy, it would likely be less concentrated on certain established powers.

<sup>1</sup> Tapscott, D., & Tapscott, A. (2016). *Blockchain Revolution: How the Technology Behind Bitcoin is Changing Money, Business, and the World*. Penguin.

### Principle 4: Security

Given the distributed nature of Blockchain technology, there is no central point of failure, and if one person behaves recklessly their capacity to cause damage is limited.

### Principle 5: Privacy

People get to be in complete control of their data. The Blockchain protocols make it possible to choose the level of privacy users are comfortable with in any given transaction or environment. It helps better manage identities and interaction with the world.

### Principle 6: Rights are preserved

Rights and freedoms are clear and enforceable, as they become part of the Blockchain. Smart contracts are put in place, which basically allow transactions to proceed only when predefined benchmarks have been reached and agreed upon by all parties.

### Principle 7: Inclusion

Everyone in the world should have the ability to participate in the global Blockchain economy. The aim is to reduce the barriers to participation, and to enable the greatest number of people and parties to have technologies and services at their disposal, under the premise that the economy works best when it works for all of us.

**“We will develop a common fabric for the entire industry. A blockchain to run the entire healthcare continuum: the free and instant transfer of healthcare data.” Micah Winkelspecht, Gem Health (Prisco, G. The Blockchain for Healthcare: Gem Launches Gem Health Network With Philips Blockchain Lab, BitCoin Magazine 26 April 2016)**

### Principal success factors and challenges for the model

Instrumental factors for the success of the Salus model and the challenges for the same, in terms of the technological definition, will be focused on committing to the information catalogs for the different members of the cooperative. Moreover, they will guarantee the application of international standards (technological, semantics, etc.) that allow the availability of structured information. To share among the range of different parties and information sources, it is essential to have univocal identities, not only for the cooperative members, but also for the information content (index) in order to avoid misleading interpretations.

Organizational factors for success and overcoming challenges will be focused on ensuring transparency and information security. Advances on these lines are the basis for promoting trust, and therefore the participation of citizens in the model.

## 3.3. Legal framework

To set out the legal guidelines for the project, the laws that constitute the applicable normative framework for the cooperative have been identified to ensure the integrity of the health data and that of the members of the cooperative.

According to our analysis there does not seem to be any legal impediment for the deployment of the proposed model.

Three main categories of regulations have been identified:

- **Laws related to data protection:** Law 15/1999, the Data Protection Act; new regulation of the European Parliament, EU 2016/679
- **Laws related to patients information:** Law 41/2002 on Patient Autonomy; Law 21/2000, on the Rights to Information Concerning Patient Health and Autonomy and Clinical Documentation
- **Laws related to cooperatives:** Catalan Law 12/2015 on Cooperatives

### REGULATIONS RELATED TO DATA PROTECTION



#### Law 15/1999, the Data Protection Act, and recent European Reform

As a general law, article 7.3 of Law 15/1999 states the following “personal data that refers to racial origin, health and sexual relations may only be collected, processed and transferred when, in the general interest, a law or the

affected person expressly provides consent”. This article determines the fundamental right to the protection of personal data, and expresses the ability of the citizen to cede information to an interested party.

This Law also regulates the protection of health data, and includes recognition of the rights of access, rectification, cancellation and opposition that make up the system of guarantees, and form an essential aspect of the right to personal data protection.

### **The new European Data Protection Regulation (EU 2016/679)**

The new European Data Protection Regulation also applies on similar lines. This reform aims to give citizens back the control of their personal data, and to ensure high protection standards in the digital environment throughout the EU. Among other provisions, the new law also includes:

- The right to **“forgetfulness”**, through the correction or suppression of personal data,
- The need for a **“clear and affirmative consent”** to the processing of their personal data by the person concerned,
- **“Portability”**, or the right to transfer data to another service provider

The different member states of the EU will have a period of two years to apply the changes in the directive to national legislation.

## REGULATIONS RELATED TO PATIENT DATA



### **Law 21/2000, on the Rights to Information Concerning Patient Health and Autonomy and Clinical Documentation.**

Article 3.1 of this Law establishes that “The holder of the right to information is the patient. Persons linked to him or her must be informed to the extent that is expressly or tacitly permitted.”

With regard to the right to access medical records (documents accrediting a healthcare relationship), Article 13.3 states: “The right of the patient to access medical records may also be exercised by a representative, provided that it is duly accredited.”

Both provisions ensure legal representation by the cooperative, with express authorization by the citizen, for access to clinical information. This complies with the conditional donation of data by citizens in accordance with the ethical principles of the cooperative.



### **Law 41/2002, on Patient Autonomy**

Article 5.1 of this law tacitly establishes that “The patient holds the right of information. Those related to the patient, through family or by law, will also be informed to the extent that the patient expressly or tacitly allows it.”

Regarding the right of access to clinical information, this law establishes the following in article 18.1 “The patient has the right of access [...] clinical history documentation and to obtain a copy of the data contained therein”, as

well as, “The right of the patient to access medical records can also be exercised by a duly accredited representative”.

### REGULATIONS RELATED TO COOPERATIVES



#### Law 12/2005 of Catalan Cooperatives

The Law is based on the historical general principles of the International Co-operative Alliance (ICA) and, on an international consensus that a cooperative is, “A co-operative is an autonomous association of persons united voluntarily to meet their common economic, social, and cultural needs and aspirations through a jointly-owned and democratically-controlled enterprise.” Likewise, it covers the principles that should govern the activity of cooperatives in Catalonia, which are included in the present law, and are those defined by the ICA. The principles are the following:

- Voluntary and open membership;
- Democratic member control;
- Member economic participation;
- Autonomy and independence;
- Education, training and information;
- Co-operation among co-operatives,
- Concern for community.

The cooperative principles covered in this law will shape the management and principles of the cooperative in the Salus model.

### Other regulation related to the Salus model



#### Ley 16/2003, de 28 de mayo, de cohesión y calidad del Sistema Nacional de Salud

(Law 16/2003, of 28 May, on the cohesion and quality of the National Health System):  
Citizens receiving the benefits of the National Health System will have the right to healthcare, health information and documentation, in accordance with Law 41/2002, of 14 November (Article 7.2).



#### Ley 44/2003, de 21 de noviembre, de ordenación de las profesiones sanitarias

(Law 44/2003, of 21 November, on the organization of health professions):  
Patients have the right to receive information according to what is established in Law 41/2002 (article 5.1.f)



#### Ley 55/2003, de 16 de diciembre, del Estatuto Marco del personal estatutario de los servicios de salud

(Law 55/2003, of 16 December, on the Statutory Framework of the Statutory Staff in Health Services):  
The duties of statutory staff include the duty to duly inform users and patients about their care process, as well as the services available (article 19.h.), in accordance with the rules and procedures applicable to each case and within the scope of their responsibilities.



CHAPTER 4

# CONCLUSION

## Conclusion

Access to large sets of health data is key to advancing medical research. However, today, health data are fragmented and guarded in silos, thus hindering their access and sharing by researchers.

Diverse initiatives around the world, ranging from public to private organizations, have attempted to overcome these hindrances by proposing new ways to share and generate health data. However, only a few of them legitimize data ownership for citizens and enable them to exercise control over the fate of their data.

The investigation and proposed frameworks presented in this report aimed to explore how a citizen-driven model of collaborative governance and management of health data, which enables citizens to collectively share data, can accelerate research and innovation in healthcare. Towards this end, Ideas for Change conducted field and desk research aimed to gather opinions and suggestions from key agents in the healthcare sector, and analyze the current health data ecosystem along with a sample of existing initiatives.

The findings of this research highlighted four fundamental principles that should be considered the pillars of any citizen-driven governance model for health data management:

- (i)** citizens should be given the right to decide under which conditions they want to donate their health data;
- (ii)** the use of data by any parties involved should provide a clear benefit to society (e.g. the resulting research outputs

are made universally available under an open license);

**(iii)** incentives (non-monetary) should be offered to individuals to motivate them to donate their data;

**(iv)** a participatory governance model should be deployed to guarantee the collective benefits of data use and citizen control over the fate of their data.

Drawing upon the results of this research, a cooperative governance model that enacts these four principles has been designed. The proposed model considers the creation of an ecosystem of actors that provide different types of value to the model: data, services, and economic. The relationships among the agents are regulated by a set of contractual agreements that ensure compliance with the principles established by the cooperative members. Openness and transparency are fundamental to the model, which enables data contributors to participate in decision making. The investigation and resulting approach presented in this report offer a new vision to reshape the health data sharing ecosystem. We trust that, if fully applied, this vision has the potential to deliver systemic change.

**Data:** scarcity → abundance

**Management:** individual → collective

**Channels:** intermediaries → direct

**Knowledge:** asymmetry → symmetry of information

**Publications:** selective → integral

**Actors:** a certain number → multiplicity

**Innovation:** on products → on processes

# IDEAS FOR CHANGE



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Barcelona, December 2016



# SALUS.COOP

Towards citizen governance and management of health data

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