Milestone M8.4

Presentation of a first set of data altruism definitions, use cases and findings

30 September 2021

0   DOCUMENT INFO

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0.2   KEYWORDS

Keywords	TEHDAS, Joint Action, Health Data, Health Data Space, Data Space, HP-JA-2020-1

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1   Executive summary

"The Joint Action Towards the European Health Data Space (TEHDAS) helps the Members States and the Commission in developing and promoting concepts necessary for sharing of data in secondary use for purposes of citizens' health, public health, as well as health research & innovation in Europe."

Work package 8 (WP8) will provide evidence for decision-makers and healthcare professionals in the European Union so that they can more effectively promote the secondary use of health data and the acceptance thereof by citizens. To do so, deliverable D8.2 will produce the "Report on lessons learned to be applied and recommendations for data altruism practices in the implementation of construction of national and European health data spaces".

The first milestone in this work is M8.4 "Presentation of a first set (catalogue) of data altruism definitions, use cases and findings about consent and accessibility issues (means of verification: catalogue approved by stakeholders'). The deliverable of the milestone is this document based on a literature review including scientific publications, reports, and policy papers, as well as on results of other Work Packages, mainly WP5. This document makes no recommendations on data altruism practices in the implementation of construction of national and European health data spaces or takes no positions on the current political discussion regarding exact definition of data altruism and data governance or EU competency on health policy. Additionally, this document does not cover certain topics that will be addressed in other TEHDAS outputs.

It is worth noting that the available literature on this topic, as well as the number of use cases and examples are relatively limited. Terms are quoted in this document as they appear in the given publications e.g. "data altruism" or "data donation", although "data altruism" is in line with the terminology of TEHDAS. For the definition of data altruism, an important conclusion is that the purpose of sharing data, the type of data, and the range of data subjects[1] need to be clearly specified.

The set of classified use cases contains twelve groups, from the health data types being used through the organisations being in charge of the data altruism system to the tools of citizen involvement in the system. M8.4 identified a few projects (examples) that has already seen some success at the national, European, and international levels offering good practices for altruism structures and functions for the future European Health Data Space (EHDS). Consent is discussed as a key topic. It is concluded that in cross-border and cross-organisational data exchange, parties may face challenges due to different forms of consent.

Final conclusions will be drawn in the further work to carry out by M8.5 and M8.6. It is clear that further analyses are needed on the concept and definition of data altruism, and its role in citizens' participation and empowerment in the health sector.

The Appendix lists the literature reviewed. Publications are referred to in the document according their number in the Appendix.

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[1] GDPR, Art 4 para (1) defines "data subject" as an identified or identifiable natural person; an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

2   Context

The overarching aim of TEHDAS is to develop the future policy, legal and technical framework for the sharing and secondary use of health data in the EU.
The current document is the first deliverable of Task 8.2 within Work Package 8 of TEHDAS.
The aim of Task 8.4 and Task 8.5 is to provide options on how data altruism can:

- increase effectiveness of data governance structures and functions of primary and secondary use of citizens' health and health-related data across Europe,
- help health data access points or other health data governance structures involving citizens.

Three documents (Milestones 8.4, 8.5 and 8.6) will be produced to prepare D8.2 report on lessons learned to be applied and recommendations for data altruism practices in the implementation of construction of national and European health data spaces (M24).
This document contains basic findings to help understanding obstacles and enablers to achieve O8.4objective of WP8, to improve policymaking and facilitate decisions on which data generated and held by citizens can be used, how and by whom for the public good and interest (scientific research, public health, sustainable healthcare systems) purposes in a manner compliant with GDPR.
The document contributes to improving citizen capacity to engage with data and improve citizen trust in data sharing through providing an overview on definitions, use cases and consent related questions of data altruism.

This document (8.4) seeks to respond to the following questions:

- What are the specificities of data altruism in health compared to many other fields, and what are the obstacles and enablers to achieve specific objectives of WP8?
- Why governing data altruism in the context of European data spaces requires dedicated legislation in a specific European Health Data Space?

These specificities will then point to how the governance of the European Health Data Space needs to be designed. This will be the topic of the subsequent document M8.5 that will seek to respond to the following questions:

- How the governance of European Health Data Space needs to be designed and who are the actors involved? How can obstacles and enablers be addressed to achieve specific objectives of WP8?
- Can all health data exchange in secondary use be governed by one piece of legislation?

Current document (M8.4) builds on documents M5.2 and M5.7, as TEHDAS Joint Action prepares for various aspects of data governance in a dedicated work package (WP5).
It also builds on preliminary documents of M8.1 "Literature review of citizen's perception of and engagement with health data in Europe".
Data altruism needs to be seen in a wider context of citizens' empowerment. The document makes no recommendations on data altruism practices in the implementation of construction of national and European health data spaces or takes no positions on the current political discussion regarding exact definition of data altruism and data governance or EU competency on health policy.
Additionally, this document does not cover the following topics that will be addressed in other TEHDAS outputs:

- Obstacles to cross-border data sharing (Task 5.1)
- National GDPR interpretations and derogations (Task 5.2)
- Elements and mechanism of governance (Task 5.4)
- Citizens' perceptions: this topic will be covered during two other Tasks of WP8:
  A literature review of citizens' perceptions of and involvement with their health data (Task 8.1) and an e-consultation that will be conducted at the end of 2021-beginning 2022 to question citizens on their perceptions and preferences towards health data secondary use and sharing. (Task 8.2)

This document takes as a starting point the Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on European data governance and amending Regulation (EU) No 2018/1724 (Data Governance Act - DGA). [9]

DGA, according to the EU Data Strategy, will be an enabling legislative framework for the governance of common European data spaces addressing issues such as making it easier for individuals to allow the use of the data they generate for the public good, if they wish to do so ("data altruism"), in compliance with the GDPR. [2]

3   Introduction and Methodology

The literature review was completed with the aim to map options, use cases and good practices on how data altruism can increase effectiveness of data governance structures and functions of (primary and) secondary use of citizens' health and health-related data across Europe. Its scope covered a wide range of documents including policy papers, reports, or scientific publications.

The literature review provides an initial set of:

- Overview for definitions of data altruism for the future EHDS.
- How data altruism / data altruism bodies need to be considered in EHDS governance (link to WP5).
- Identification of good practices and risks for implementing data altruism practices and how data altruism helps health data access points or other health data governance structures involving citizens as well as what value data-altruism brings to society, business and citizens.
- Findings how requirements for consent and accessibility are dealt with by different types of data altruism practices (incl. identification of potential barriers and opportunities).

3.1   Methodology

As a first step, key topics, issues, questions, and keywords describing health data altruism were identified by the task contributors. Result of the brainstorming is illustrated in figure 1.

Figure 1 – Keywords for data altruism

According to the scope of literature review, Task 8.4 team started finding and selection of resources relevant to the following questions and keywords:

- **Do features of health and health related data require any specific approach for addressing regulation and facilitation of data altruism?** With a special regard to:
  - recognised data altruism organisations
  - voluntary sharing of data
  - collecting data
  - data for purposes of general interest (common good)
  - allowing data sharing

- data gathering for public interest
- consent from data subjects or permissions to process data

- **Other questions and keywords:**
    - Is consent required if researchers do not access the data? - Trusted Secured Environment (TSE) / Privacy Preserving Techniques (PPT).
    - Are there specificities of health data altruism (services)?
    - Is it possible to provide "standardised" data altruism services?
    - Code(s) of Conduct for altruism services?
    - Digital Democracy and altruism?
    - Data altruism versus or/and other means of sharing/donating data? - One can ask if all voluntary data donations are altruistic.
    - To what extent cyber security requirements can discourage citizens?
    - Data mediators versus data altruism organisations versus TSE/PHT (federated and visualised datasets)? - Train Track project.
    - How to make sure that data altruism is "fair" for all? – Transparent, bringing value to all parties involved etc.
    - Relation to the recitals of Data Governance Act.
    - Value proposition for citizens (how to bring back value to citizens / MyHealthMyData) - Emphasis on value for citizen: value proposition to citizens is important, considering that data produce value for the individuals.
    - FAIR/MyData - In addition to data altruism, other means of fair data economy and person-made data to be added.
    - Emerging business models - Promoting the emergence of business models.

All these keywords were considered in the context of health/healthcare, while inspiration from other sectors were also useful. (For a special instance, social care data came into consideration in the context of certain country examples [1].)

3.2   Health sector specificities

Specificities in health

The Commission proposal on the Data Governance Act (DGA), Art. 2 (10) defines data altruism as "the consent by data subjects to process personal data pertaining to them, or permissions of other data holders to allow the use of their non-personal data without seeking a reward, for purposes of general interest, such as scientific research purposes or improving public services". [73] In "EXPLANATORY MEMORANDUM" of the DGA it is also stated "data altruism" refers to data voluntarily made available by individuals or companies for the common good. The importance of volunteering was stressed in the context of data donation as a model for citizen science health research as well. [15] It is important to emphasis that under GDPR, data subjects are allowed to change or revoke their consent and have a right to object against processing their data and those provisions will have to be complied with by any future system where the data of individuals will be made available.

At the time of finalising[2] the current deliverable, negotiations on the Commission Proposal of the DGA are underway in the EU institutions, and it can be expected that the original text will be developed further. National data altruism policies of the Member States are a key issue, as well as compliance with codes of conduct related to data altruism by the relevant organisations and stakeholders. Discussions also include the definitions of the DGA like "data altruism". The idea of data altruism

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[2] There is a Note from Presidency to Delegations including a compromise text available, published on the Council website, 7th September 2021, 11599/21, Interinstitutional File: 2020/0340(COD).

might have come from industry, i.e., data of institutions possibly earlier or in larger extent than data of individuals. Data Governance Act would also like to promote the concept of "data altruism" in order to encourage businesses and public sector organisations to promote data sharing for the "common good". Based on discussions with advisory group members, it also worth analysing if there were the opportunities (and strengths, weaknesses and threats) of data sharing through data intermediary and/or data altruism organisations.

In healthcare, however, data of individuals are definitely of high interest for public good purposes, while data of legal persons (institutions, companies) remains of interest too, both by researchers and authorities.

In many cases, when health or health-related data are requested to be shared, not only the ownership cannot be (legally) identified, but also the data subjects themselves, or at least it is difficult to separate them. Several examples can be mentioned, e.g., data about payment for a treatment can relate to a specific patient or the healthcare provider or both.

Therefore, (use) cases of single-subject and multi-subject data seem to need the same attention as use cases by the purposes of requesting access to the data or use cases by the resources where data can be accessed (discussed in section 4). While the introduction of these use cases can be found in section 5, definitions of data altruism are introduced and assessed in this one.

Reasons of specificities in health
It can be stated based on the literature that the concept of data altruism becomes relevant, in addition to the existing mechanisms for further use of patient data for research based on notions of public health and solidarity. [1]

Specific characteristics of different sectors may require the design of sectoral data-based systems, as it is stated in recital 3 of DGA that sector-specific EU legislation on technical, administrative or organisational requirements shall also apply to services or entities providing data altruism services.

We have to emphasise that, while databases need to be integrated, health datasets require stronger safeguards as they can be subject to obligations of professional secrecy/medical confidentiality regulated at national level too. Furthermore, health data can also include other information e.g., related to behaviour or lifestyle of a person and his/her family members or other persons in their environment. Such data need to be treated as special category of data (sensitive data) in order to protect additional data subjects, in particular if related to vulnerable groups (e.g. children, employees, etc.).

Ownership
The term "ownership" of data is used in some of the publications reviewed but this term is debated. The Nivel Study points out the one cannot give away fundamental rights on his or her personal data. It also adds that healthcare records may contain data concerning other individuals like the families of patients or healthcare professionals. Therefore, we can stress that the possibility (right) to access data cannot be considered as obtaining ownership but a "licence to use", as the rights of individuals over their data is a fundamental right.

Problems with different interpretations of the "ownership" of clinical data are discussed [27], adding that ownership language can also be applied to non-property relationship between patients and data. As it is pointed out, several actors have interests or claims on clinical data but no one actually owns such data, consequently, the term "ownership" should not be understood as private property in a legal meaning. However, while citizens have fundamental rights to data containing information about them, there can be intellectual property rights of those who create collections and analyses of data, which include a creative (value adding) component. An important conclusion is that the link between citizens and health data is that data are about the citizens and protected, but do not belong to them [27]. It is line with the concept of GDPR where data subjects' rights over data are protected but not as a property right.

Motivations

Besides volunteering, the emphasis is on serving the public good or public interest without expectation of any reward. However, because of the individual's relationship with the community, this cannot be achieved in a pure way. The word altruism in itself means something a little different. Altruism refers to the fact of caring about the needs and happiness of other people and being willing to do things to help them, even if it brings no advantage to yourself. The origin of the term goes back to therein: mid-19th century, coming from French altruisme, and from Italian altrui "somebody else", originally from Latin alteri huic "to this other".) In this way, altruism is not about the relationship with the public (public good or general interest), which includes the individual, but with others, and it is not only about giving up reward, but also about giving up what one already has, or facing risks that would not otherwise arise (e.g., security issues or unexpected costs of meeting technical requirements). Therefore, citizen engagement shall address all these determinants.

The basic meaning of "altruism" in the context of unselfishness can only partially be seen as a motivating factor influencing the economic sense of the term irrational decision. [64]
For this reason, most authors, in defining data altruism (or a closely related subject area), also examine the motivational factors influencing "donation of data" or "consent to data sharing and use". Authors have found that the main motivation is to contribute to and share in the value resulting from the use/re-use of data. It is also added at some points that it is without reference to a particular research project. There are distinct reasons to share personal data for obtaining a share in the value created by data reuse. [90]
According to broader explanations of altruism, individuals voluntarily share their health data for specified societal uses, with or without specific reference to research. (People can also consent to the sharing of data generated for other purposes if they are sensitised to contribute to public benefit/social purpose, scientific or translational research, scientific or business innovation.) In addition, some authors pay special attention to the ethical challenges and opportunities as well. [15]

It was also emphasised that, while altruism itself (willingness or intention to have benefit for others without delivering immediate individual benefit for the altruist) is a significant predictor, little is known about how it contributes to the specific belief that could people have an ethical obligation to allow their health information to be used for research.

Research results show that general altruism as well as trust in the health system and in care providers are associated with a significantly higher likelihood of believing there is an ethical obligation. [83] Relationships between altruism and self-interest were also analysed and sorted in two groups: independent (altruism and/or self-interest) and contingent on something (e.g., altruism contingent on avoiding harm). [75]

Further introduction of citizens' motivations for data sharing prepared by TEHDAS WP8 contributors will be available at M8.1 – Citizens' perception of and engagement with health data secondary use and sharing in Europe – a literature review.

4 First set (catalogue) of data altruism definitions

4.1 Description

The aim if this section is to present an overview of definitions found as a result of the literature review. Most of the publications reviewed do not define data altruism, however, explanations can be found, and such explanations often contain important elements that could be used to formulate a definition.

According to the draft DGA "data altruism" means the consent by data subjects to process personal data pertaining to them, or permissions of other data holders to allow the use of their non-personal data without seeking a reward, for purposes of general interest, such as scientific research purposes or improving public services. In addition, to the definition in article 2, some inspiration to general considerations about data altruism can be found in DGA in article16 General Requirements for registration of data altruism organisations.

In case of data altruism in healthcare, significant gap can be detected as to what is the message for citizens and even institutions, i.e. what they are expected to do if it comes to the question "data altruism in healthcare". In many documents that have been made available in EU from 2018 until now (May 2021) there is very little to this question. Moreover, there are similar concepts that deal with sharing data called data altruism (e.g., data donation, data solidarity).

Further descriptions of data altruism can be found in EU documents giving orientation or certain elements for a definition. The Communication from the Commission – A European strategy for data (COM/2020/66 final) refers to data altruism as an issue to be addressed by the legislation foreseen on data spaces: „to make it easier for individuals to allow the use of the data they generate for the public good, if they wish to do so ("data altruism"), in compliance with the GDPR."

4.2 Key findings and results of literature assessment

The Nivel Study refers to data altruism through which individuals can make data concerning themselves available to researchers for public good purposes. [1] Data altruism is also defined as „A system to allow patients to make data available for research without reference to a particular research project (also known as data altruism)". It makes a distinction between data altruism and the re-use of data from sources such as Electronic Health Records (EHRs), hospital information systems and disease registries (while this distinction has not appeared in the definition and the use in the DGA).
It is important to note that different terms are often used in a similar meaning like data altruism. Data donation for research [15] is defined as the action in which people voluntarily contribute their own personal data that was generated for a different purpose to a collective dataset at certain forms of public participation (which can be contributory, collaborative or co-created). The Nivel Study concludes that both the terms data altruism or data solidarity are used in preference to the term data donation as the latter implies ownership transfer.

Digital health knowledge production can promote expressions of altruism and acts as a source of new responsibilities for individual and collective health. Performances of this altruism range from individual instances of sharing personal health data to being actively involved in the production of digital technologies. Over time these individual encounters with digital technology generate feelings of belonging to a community of peers. [84]

The concept of a new social contract was discussed in the frames of the Nordic Health 2030 Movement. It was emphasised that individuals must be encouraged to become their own point of care, and data altruism is the driving element of the new data model, along with other elements including data sources, datasets, data identity, data standards and data outcomes. [94]

The idea of a social contract was also raised [19], highlighting three key elements of a social contract: reciprocity, solidarity, and altruism, found that altruism includes an expectation of the subject to receive own benefits but this benefit is not immediate and/or comes parallel with a benefit to others.

MedTech Europe, commenting on the DGA [08] highlighted their arguments on data altruism:
- The definition should include research and development in the health care industry as it benefits citizens and healthcare systems, as well as the economy.
- The definition should include non-digital data, too
  - mixed datasets (i.e., personal and non-personal data) should be taken into consideration
  - definitions should be aligned with the GDPR.

The European Data Protection Board (EDPB) [35] finds that the DGA entails several significant inconsistencies with the GDPR, notwithstanding the statement in the recital that it is "without prejudice" to the GDPR. The EDPB urges the co-legislators of DGA to address the important criticalities, thus avoiding that the DGA creates a parallel set of rules, not consistent with the GDPR, as well as with other Union law. DGA should contain the definitions of "personal data", "data subject", "consent" and "processing" referring to the definitions in the GDPR; on the other hand, the DGA"s definitions of "metadata", "data holder", "data user", "data sharing", "data altruism" should be amended to avoid inconsistencies and legal uncertainty, and to be in line with the protection of personal data.
To address inconsistences, EDPB urges the co-legislators to carefully consider the interplay between the DGA and the GDPR, the definitions/terminology use in the DGA, and to make sure that the fundamental requirements of GDPR like the appropriate legal base and derogations for special categories of personal data. [35]
EIT Health Consultative Group "Contribution to the discussion on the European Commission's Data Strategy and AI White Paper - Report by the EIT Health Consultative Group, 31st May 2020" emphasised the need to make it easier for individuals to allow the use of the data they generate for the public good, if they wish to do so (known variably as, "data altruism" and "data donation"). In this context, data altruism is a tool to drive greater solidarity. However, the issue of over-reliance on donated data or data altruism is also noted. Legal guidance and codes of conduct as set out in Article 40 GDPR are proposed to support systems to develop data altruism to ensure that the perspective of all stakeholders can be addressed. [07]

In addition, the term "data altruism" is also used in the meaning of sharing and management of personal data for specified societal uses. [92]

4.3   Examples

Based on country correspondents' responses, the Nivel Study shared country examples of data altruism as well. A few key features can be highlighted from the country examples in relation to the description of data altruism:
- The purpose of data sharing is primarily research, but data can be made available for clinical or planning purposes, too.
- Data subjects are in most cases patients or insured persons.
- Data users include authorities, university and hospital researchers, clinicians, medical colleges and pharmaceutical companies researching new treatments.
- Data subjects have an option to make their data available which implies an explicit consent, while in certain cases an opt-out form is also applied (more information on the types of consent and its analysis could be useful).

The Nivel Study highlighted the following key features of specific country examples for data altruism/solidarity system in place (UK) or in process (DK and DE):
- Denmark: The system is focused on research. Researchers can apply for access to data locally with data custodians, or for the whole country. Health data can be combined with other data types.

- Germany: The Patient Data Protection Act, 2020, provides insured persons as of 2023 the option of making data stored in the electronic patient record available for research. Data subjects are insured persons and the system is based on their informed consent to share data. Data can be shared via the Research Data Centre or for specific areas or projects.
- UK: The National data opt-out is an NHS England/NHS Digital policy initiative enabling patients to opt out from the use of their data for research or planning purposes. The Scottish Health Research Register (SHARE) is a NHS Research Scotland initiative created to establish a register of people willing to share their data for research projects.

Further country examples are listed in the Nivel Study, considered relevant because there are data governance or data access bodies which can be important players in the data altruism mechanism:

- Ireland: Access to data in the National Cancer Registry may be provided by the data controller to some researchers. This system demands notification of patients, a high level of transparency and the right to refuse or withdraw.
- Findata: The Finnish Health and Social Data Permit Authority, acting as "one-stop shop" for health and social data access, in operation since 2020, providing services to grant data permits, and to collect and deliver data for use based on requests.
- French Health Data Hub: HDH is a platform where pseudonymised health data from different sources is duplicated and made available. It is both an infrastructure and a health database catalogue, and offers related services, allowing project coordinators to access data and/or link different databases.
- Statistics Netherlands (CBS): The independent national statistics agency, providing statistical information on social issues, including health. Researchers can obtain health and other data for research purposes.
- Spain: BIGAN Health Research Infrastructure, Aragón, integrates a technological infrastructure and a data lake gathering individual population and patient data from the regional health service and health related information systems from Aragón.

4.4   Potential learnings for successful governance

In connection with the risks related to data altruism it was emphasised that a data governance framework should ensure that individual rights, confidential business information, trade secrets, or intellectual property rights are not undermined without introducing administrative burdens through additional legal regulatory layers.

EPF shared its opinion that a public body should collect the consent of individuals to share their health data for specified societal uses ("data altruism") and manages their health data. [92] Development of protocols or procedures for the practical exercise of voluntary transfer of data, as well as patients' control over their data was also proposed.

In addition to the DGA, it is also important to mention the Data Act [100], announced by the European Strategy for Data (2020) as a horizontal legislative initiative, which would complement the DGA proposal. The aim would be to create fairness in the data economy by addressing the difficulties of access to and use of data. It may be complemented by the sectoral data spaces. The initiative would include both personal and non-personal data. Its scope would cover:

- Use of privately-held data by the public sector (business-to-government),
- Data access and use in business-to-business situations,
- Establishing more competitive markets for cloud computing services,
- Safeguards for non-personal data in international contexts.

Although the focus is on the B2B/B2G context, it may be relevant from the perspective of data altruism that, according to the impact assessment, the usability of data generated by individuals would provide data subjects with a broader range of choice and augmented authority and control over the use of such data.

4.5   Conclusions drawn from the literature review as regards a definition of data altruism

Based on the results of the literature review, a few important aspects of data altruism can be highlighted as elements to be considered or debated when defining data altruism.

- Alternative terms like "data solidarity" and "data donation" are used in similar meaning or context as data altruism. Data solidarity can be understood as a more general term, while data donation implies property rights. That is why "data altruism" seems the most suitable.
- Subjects of data altruism can be individuals, citizens or patients, and public and private entities could be too.
- Research is in most cases defined as the purpose of sharing data but other purposes like clinical care or political decision-making are also mentioned.
- The type of data is usually health data, but they can also be combined with other types such as social data.

5   First set (catalogue) of data altruism use cases

5.1   Description

What may be considered when it comes to data altruism if one wants to keep completeness of view and consider various aspects associated with this topic? Following classifications from diverse viewpoints, (especially on managing data) may help to understand complexity of use cases in data altruism in health and healthcare, and serve as bases for further considerations.

1. Data Originator (data subjects):
   a) Patients/Citizens
   b) Family members
   c) Contacts
   d) Professionals
   e) Organisations (non-private data)

2. Possible sources of health data:
   a) Health and health related personal health records[3] captured by wearables, mobile health devices, or direct to consumer genetics/DNA tests, etc.)
   b) Health data from electronic medical records / electronic health records[4]
   c) Administrative data in relation to reimbursement of healthcare
   d) Social care data
   e) Genetic and genomic or other data repositories
   f) Well-being data and additional information captured and stored by citizens

3. Methods of releasing (granting) the access to the data
   a) Data subject to give consent with sharing data that are collected by a collector typically for primary purpose
   b) Providing direct access to database of the data subject, otherwise protected for access, or shared only for primary purpose
   c) Bringing/transferring data to a third party from own repository of the data subject, in cases when the directs access is not suitable, possible, safe, or convenient
   d) Access to a health database where individual data would be aggregated and de-identified

4. Data recording time period
   a) Disclosure only of a given data set (sets) of the data subject, created in a defined period of time
   b) Disclosure only historical data
   c) Disclosure of future data only
   d) Disclosure without time limitation, even for future (e.g., „all data in a specified repository")
   e) Posthumous medical data donation

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[3] A Personal Health Record (PHR) contains the same types of information as EHRs (diagnoses, medications, immunisations, family medical histories, and provider contact information) but is designed to be set up, accessed and managed by patients. (Source: DigitalHealthEurope, Glossary) Therefore, PHRs are typically used by patients and their families to access and manage their health information and organize their health care.

[4] According to the definitions of DigitalHealthEurope the Electronic Health Record (EHR) is a comprehensive medical and cross-institutional record or similar documentation of the past and present physical and mental state of health of an individual in electronic form. Electronic Medical Records (EMRs) are digital versions of the paper charts in clinician offices, clinics, and hospitals. EMRs contain notes and information collected by and for the clinicians in that office, clinic, or hospital and are mostly used by health care providers for diagnosis and treatment. Therefore, EHRs and EMRs are provider-centric records that are used by healthcare professionals to store and manage patient health information and data and include functionalities that directly support the care delivery process.

5. Scope of the consent related to future users
   a) Onetime consent for single user to share data of the data subject
   b) Multipurpose consents for certain restricted range (geographical, research discipline, kind of research, kind of users) to use data by respectively defined users
   c) Universal consent for the use of the data subject's data by any user
   d) Subsequent sharing of data collected by a user with further user not participating in the original consent
   e) Modification or withdrawal of consent (granular, full)

6. Scope of the consent in terms of purpose of the use by a user
   a) Only for specified activities (given project only, medical research in general, policy)
   b) For group of similar activities (several research projects, e.g., consecutive, or disease specific ones)
   c) Combined (for delivery of healthcare for citizens at national level and/or cross-border and for research and innovation)
   d) Policy-making and regulatory decision-making, governance (system level),
   e) Management (organisational level)
   f) Unlimited

7. Scope in terms of types of data records associated with the data subject
   a) Only selected specified records (e.g., CT images only, but no other modalities or records)
   b) All records related to one disease or condition of the data subject but not related to other ones
   c) All records available in given database(s) e.g., of a telemedicine/wellness service provider
   d) All data in all records kept about the data subject

8. Scope in terms of GDPR
   a) Only duly anonymized data
   b) Data with some personal/commercial information (e.g., age, location, in case of companies amount of goods purchased)
   c) Disclosure of data as is, incl. personal (commercial) information
   d) Granting right to publish certain personal data (e.g., in case of unique medical procedures)

9. Value for data subject for data sharing
   a) For free
   b) Reward for costs associated with sharing, incl. e.g., transport, media used and data quality assurance
   c) Additional reward, e.g., to motivate data subjects to provide data, e.g., in given time
   d) Mixed scenario, e.g. some data for free and some (more complex) with covering costs
   e) Information or communication to data subject about the impact for her/his data altruism.
   f) Obtaining/providing a share in the value resulting from the use/re-use of data (in a broader context)

10. Contributory forms of public participation
   a) Contributory (where members of the public primarily contribute data) [15]
   b) Collaborative (where members of the public may assist with research design, analysis, or dissemination) [15]
   c) Co-created (where members of the public and scientists work together on a more equal footing) [15]
   d) Direct involvement
   e) Involvement through patients' representatives

11. Content and form of the data donated or let assessable
   a) Donation of organs and body parts and data to biobank (providing access to the use of data from the biobank

b) Donation of EHR/PHR (or other form of) data managed by the (health or social) care provider of the data subject
c) Donation of health and wellbeing data captured and shared by the data subject

12. Bodies and organisations or platforms receiving and or providing access to health data
   a) Public data/biobanks
   b) Non-profit data/biobanks
   c) Business/commercial data/biobanks
   d) Higher education institutions (HEI) and Research, Development, and Innovation (RDI) organisations/data/biobanks
   e) Transaction, technology, and connectivity platforms

5.2   Key findings and results of literature assessment

In this section some important questions, issues and/or ideas that are relevant to a given group of data altruism use cases, are introduced through:

● Identification of good practices and risks for implementing data altruism practices and how data altruism helps health data access points or other health data governance structures involving citizens.
● Findings how requirements for consent and accessibility are dealt with by different types of use cases (incl. identification of potential barriers and opportunities).

One of the first categories of risks identified during the literature review can be associated with posthumous medical data donation (PMDD), one resulting from the non-individual nature of medical data and one resulting from source of the data being a deceased individual without any control over future uses of the data. [13] The second source of risks concerns the provenance of the donated medical data and the potential use to which the donated data can be put. The first risk, however, applies not only for PMDD, but also for providing access to data in general. The first source concerns the nature of the donated medical data, specifically that medical data is seldom just about one individual but also often relates to others, who may be harmed as a result. Therefore, data altruism organisations, as well as governance structures, must pay special attention mitigating or avoiding it.

Second risk, concerning the provenance and use of the donated medical data, is, according to the literature reviewed, a crucial threat to developing a framework that respects the values and preferences of the data subjects, and that reassures potential citizens that their expressed wishes will be respected after death. [13] This risk also applies in general (not only for PMDD): If data subject learns about any change in the purpose of the use of health data, consent could be withdrawn or modified.

A third risk identified during the review is related to the methods of granting access to data can have spill-over effects on economy and on the achievement of policy goals. For example, trade secrets rules may affect individuals' ability to have a say on the reuse of health data or how the governance of personal data may affect national security. In recent years, some countries have enacted laws restricting foreign investment in data-rich firms or they mandated that such investments must undergo a special review process, because policymakers in several countries have come to recognize that personal data sets can be stolen from both public and private sources and cross-referenced to reveal individual as well as national security secrets. [90] This raises the question if data altruism organisations could be considered "data-rich firms", so topic should also be further studied.

A fourth risk identified is related to the Donation of data [sharing data] that can happen both linked or not linked to the donation of biological materials. However, concerns around dignity and commodification are present in data donation too, as well as injustice and unfairness are also major moral concerns. Donors [data subjects], in addition to financial gain, need information on useful product development, as it is suggested by the literature review. It is also crucial if there are the same

quality controls and ethical evaluations as the traditional academically run research projects have. Privacy issues and keeping data de-identified or anonymous is also an essential requirement for data (and material) donors. [74]

Fifth risk can be associated with technologies and practices of data generation, exchange and sharing, as they are unevenly spread through society. [15]

A good practice identified is related to the fact that the spectrum of new sharing relationships is getting wider, e.g., "prosocial behaviour" is an umbrella term that describes activities undertaken to benefit other individuals or society as a whole. Sharing personal data, similar to the way we donate blood, could become a new act of digital economy prosocial behaviour. There is also a potential of opening up vast untapped pre-existing data resources that could advance health research. Now it is possible for citizens to transfer personal data (collected by any commercial entity) to an academic researcher in a machine-readable format if the right to data portability applies to personal data that an individual has given to a data controller, when the processing is carried out by automated means and includes observed data about the individual. [88] However, there can be some limitations to this opportunity, e.g. timescales.

Another solution for methods of granting access to data is by creating a synergy between individuals and the system which offers better access to comprehensive health data from citizen registers managed by the public sector and enriching it with analytical insights from other organisational partners or additional behavioural data offered by individuals, as well as a transfer of resources and autonomy to healthcare professionals, communities, and citizens to ensure that health systems more accurately reflect the needs and goals of those they serve. [94]

With regards to how consent can be implemented in data altruism systems, members of functioning health data cooperatives, determining which data they want to share for example with doctors or to contribute to research for the benefit of their health and that of society, can also decide how the revenues generated should be invested in research, information or education. [2]

The significance of GDPR related use cases is clearly highlighted by the circumstances in which patients' health and genetic data can be processed. A good practice identified by the literature review is that if data altruism is wanted to gain strength, research needs to show the value back to the citizens from the research, e.g. feedback to subjects as to the results generated from their data.
A guidance on GDPR and patients highlights the importance of understanding that now data needs to be seen as an asset similar to money. Example could be taken from NGOs that emphasise communication about their activities and results to "money donors". [99]

Finally, taking into consideration another aspect, it is also worth mentioning the importance of "platforms". While many companies have large reservoirs of data, some 25 internet companies control vast amounts of this data. Many of these companies do not just analyse data; they act as both intermediaries and infrastructure for data. Scholars refer to them as "platforms," or venues where market actors can exchange ideas, goods, and services. The platforms take advantage of what economists call network effects: the more users utilise the platform, the more valuable the platform becomes to users and investors. The more valuable the platform, the greater its ability to acquire, control, and analyse data. Users often become reluctant to leave platforms because they flock to sites where they can find people with whom they want to connect. [98]

5.3 Examples

There are a few projects (examples) that has seen some success at the national, European, and international levels offering good practices for altruism structures and functions for the future EHDS in all the twelve groups of data altruism use cases. Furthermore, they are good practices on how to implement several use cases of the same classification group at the same time.

- The **DATA for GOOD Foundation (Denmark)**, has the aim to ensure citizen control and privacy, while providing citizens, service providers, researchers, innovative companies and data integrators access to data to promote knowledge, dissemination and use of data-based development, health promotion, prevention and disease management. Its goal is to contribute to development, growth and public health locally, nationally, and globally. [40] Their solution breaks down the silos between traditional behavioural and register-related areas by providing a personal online data store for (the consent management for) citizens. They translate anonymised or pseudonymised data into new insights and knowledge using a number of advanced calculation methods, including big data, algorithms and cognition methods.

- **REFINIO GmbH (Germany)** has delivered a software foundation for a secure, decentralized, data protecting solution for federated data management (FDM). [47] Custom applications can added to the software stack based on the central "Refinio ONE" architecture, which is an ubiquitously available meta database providing the same runtime environment on servers, on PCs, in browsers, and on mobile and embedded devices for any software application requiring communication and storage. FDM extends the concept of the Blockchain to individual data and software. Collected data only gets shared with other users if the user explicitly grants access.

- **TEAM-X project**: The aim of Trusted Ecosystem of Applied Medical Data Exchange Application. (TEAM-X) is to establish a protected and trustworthy digital data ecosystem based on the *GAIA-X infrastructure* for the development of data-driven business models, products and services. Two GAIA-X use cases are to be developed in the areas of nursing and women's health. [49]

- **Smart4Health,** a Horizon 2020 research project develops a mobile software application that allows users to collect, manage, share, and donate their health-related data throughout the EU. The Smart4Health platform is developed along citizen use cases (CUCs) to feedback to platform development, to assess implemented functionalities and feed into validation. [89] [67] [68]

- **The Yale University Open Data Access (YODA)** Project currently collaborating with 4 Data Partners in pharmaceutical and medical device science to facilitate sharing and access to their clinical trial program data as well as external access by third party Data Partners. The Project developed a data-sharing platform to a controlled data access where data are supplied only in a closed, secure system. [50] [51]

- **Through the Data Release Pilot Project of YODA** a few months were spent determining how best to handle some specific questions, situations, risks, or issues. (E.g., Requested data were generated many years ago and are not in shareable data files; Data requests for which the privacy and confidentiality of research participants and their data cannot be protected; Clinical trial informed consent does not allow the sharing of de-identified data for public health research or educational purposes; Data requests from external partner will require agreement on data sharing from all involved partners before a request can be approved; How much time and effort is required for appropriate data de-identification as per current regional standards to protect patient privacy as well as preparation of the necessary accompanying documentation before the data are made available?) [50]

- **The Nivel Study**, in addition to data altruism systems, lists examples of data cooperatives (citizen-owned non-profit cooperatives in which citizens can share personal data for research purposes):
    - Switzerland: MiData, HealthBank
    - Spain: Salus Co-op
    - Denmark: National Experimental Therapeutic Partnership (NEXT)

This is an interesting development as E. Hafen; D. Kossmann; A. Brand found in 2014 that no functional Health Data Cooperatives existed yet. [2]

- **MyData Global,** is a project that presents itself as having the aim to "empower individuals by improving their right to self-determination regarding their personal data". It is based on the MyData Declaration. Its functioning is based on hubs formed by its members who provide recommendations on the development of a health data infrastructure that would be based on personal data management and governance. In their vision, individuals would collectively support and manage an operator as members through the legal forms of associations, cooperatives, or data trusts by running their own personal data store (PDS). [95] [96]

- **The Health Outcomes Observatory (H2O)** project aims to set-up patient-centric pan-European and national observatories. H2O is a strategic partnership between the public and private sectors that seeks to provide patients with digital tools, including an app, to report their health outcomes in a standardised way. The Data collected will be thereafter anonymised, aggregated and tracked so that individual patients and their clinicians can compare their progress with other patients with similar health issues through establishing health outcomes observatories in Germany, Spain, Austria and the Netherlands focusing on three disease areas: Diabetes, Inflammatory Bowel Disease, and Cancer. [52] [53] [54]

- **Personal Health Train (PHT)** based on the principle of connecting different data "stations": the research question of data users would in this system travels to the data source "stations" rather than data from various sources having to be transported to the research question.[55]

- **GRAVITATE HEALTH** is an Innovative Medicines Initiative (IMI) project that offers citizens digital information tools that make them confident, active, and responsive in their patient journey. It engages citizens in their own health (management) and encourages safe use of medicines for better health and quality of life through offering a route for patients to access trustworthy, up-to-date information that better meet their individual needs. The project also delivers recommendations how to strengthen access to, risk minimization for, as well as understanding and future use of digital services. These recommendations can be useful for building future altruism systems. The project is an early stage, however, acknowledging its objectives and approach, it can potentially be considered as a good example in the coming years.

5.4   Potential learnings for successful governance

There are general data governance tools, however, different use cases (of data altruism) may require additional specific solutions. The definition provided by the Organization for Economic Development and Cooperation (OECD), the term "Data governance" covers principles, policies, standards, laws, regulations, and agreements designed to control, manage, share, protect, and extract value from various types of data. Policymakers should create rules both to facilitate an appropriate enabling environment for data-driven growth and to protect their citizens and firms from harm. [98]

Understanding altering risks and issues behind data altruism use cases can help to find common ground on shared international data governance. Therefore, use case centric approach can assist preparing international agreements and development of mechanisms to bridge regulatory differences between countries. As platforms, playing leading role as channels for collecting and sharing data in altruistic mechanisms, they may be governed as altruism organisations recognised in the EU.

Values and preferences of citizens are key factors to be taken into account by data altruism organisations and to be taken into account in governance. Moreover, they are not static factors, but change over time, and therefore need to be constantly monitored at management and governance level.

Solutions, results and learnings to develop requirements for European data altruism organisations, as well as to encourage citizens to share health data through such recognised organisations, can be taken into consideration to facilitate the access to health data (for research, innovation, policy-making and regulatory decision) by public bodies and/or trusted/certified organisation, who should collect the consent of individuals to share their health data for specified societal uses ("data altruism") and manages their health data.

6   First set (catalogue) of findings about consent and accessibility issues

6.1   Description

In recitals (6) of DGA it is emphasised that privacy-friendly technologies are available such as anonymisation, pseudonymisation, differential privacy, generalisation, or suppression and randomisation and their application should ensure privacy and confidentiality. This case especially applies for consent and accessibility issues of data altruism.

This in itself raises the questions of who gives consent to whom, about what, and under what conditions, when his/her data are not being used for his/her own benefit but for the public good. Conditions likely depend on the motivations of the interested parties (as well as many other reasons or factors). Therefore, assessing (maybe also improving) definition of data altruism in healthcare is a prerequisite to any actions in the field.

In engaging citizens, we assume, there is a risk or problem that citizens may be forced to meet certain digital technical, security and literacy requirements and have the necessary digital literacy and skills. Giving informed consent for secondary uses of Personal Health Records (PRHs) or other health/wellness data therefore depends on full information not only about the purpose and means of accessing the data, but also about the implications of meeting the technical and literacy requirements. The content of the full information and the expectations may discourage many citizens or make it impossible for many to join an altruistic system of data sharing, even if they would otherwise participate. Furthermore, citizens with insufficient digital (health) literacy may withdraw (partially or fully) the consent they have already given when they perceive the burden of cooperation. They may then opt out of the system, or even simply stop providing data (or its technical connection) without a formal act.

In countries where citizens possess an electronic national identity card (eIDAS conform) including a microchip, many public services (healthcare, voting, etc.) and private services (electronic banking, signing contracts, etc.) can allow the use of these microchips as electronic identification means for citizens. In a mature ecosystem where every citizen has a contact smart card reader (NFC compatible mobile phone), they can use their electronic national identity card to access those electronic services and they can control they own data usage too. In Europe, most countries provide their citizens with electronic identity cards and allow citizens to access all of e-gov services with digital identities based on these identity cards. This solution is better than normal second factor authentication token because the citizens never will delegate to someone else they own ID cards. As far as the relation between "eID" and "consent" is concerned, it must be emphasised that:

- On the one hand, users should be able to exercise control over the personal data they share for the purposes of identification/authentication.
- On the other hand, eID solutions increasing efficiency of and trust in data altruism systems by helping to identify who is giving, modifying or erasing consent (for what, to whom, when, how long, etc.).

6.2   Key findings and results of literature assessment

Key issues associated with data sharing, such as consent, anonymity and trust are important not only because they offer participants a level of protection in the research, but also because the way these issues are managed has significant implications for patients' perspectives on research and their willingness to engage. Consent is also referred to as "a social agreement", adding that decisions about research are not automatically conferred to the research teams or ethics panels. [29]

Main forms of consent described in the IMI BD4BO project document, empirical investigation of current informed consent practices, based on a literature review, are the following with references [93]:

Table 1 – Current informed consent practices

Type of consent	Description	Source
Dynamic consent	Ongoing communication allowing participants to provide or revoke consent over time, obtain information about how their data is being used, and learn about outcomes of the research. Electronic systems such as web interfaces are often used to support this form of consent. Similar: ongoing consent, a continuous process controlled by the participant who is able to withdraw at any time.	(Grady, et al., 2017); (Dixon, et al., 2014); (Kaye, 2012); (McCaughey, et al., 2016); (D'Abramo, 2015)
Partnership model	Similar to dynamic consent. Bidirectional communication process for consent that provides opportunities for researchers and participants to update consent over time.	(McGuire & Beskow, 2010); (Driessnack & Gallo, 2011)
Tiered consent	Allows participants to personalise consent based on a range of factors including preferences for future uses of their data and whether or not they wish to be recontacted before any future use.	(Bradbury, 2015); (Hudson, 2011)
Layered consent	Often refers to a form of consent that allows participants to choose between options.	(Groisman, et al., 2014)
Targeted consent	Disclose extra information during a standard informed consent procedure.	(Wendler, 2015)
Broad consent	Open in terms of data re-use. Broad consent proposals often include other processes working alongside them. For example, one suggestion was to have broad consent with certain limits set on the future use of samples which could be judged by IRBs. Others proposed broad consent in a well-regulated environment with safeguards, and with mechanisms used to monitor communication with donors.	(Tabor, et al., 2011); (Wendler, 2013); (Otlowski, 2012) *(hybrid model)*; (Menikoff, et al., 2017); (Grady, 2015); (Hudson & Collins, 2015); (Lancet, 2014); (Hudson, 2011); (Lo & Barnes, 2016)
Universal consent	Similar to broad consent. Proposed to be used in situations where the entire healthcare organisation (e.g. a hospital) is affected by an intervention, such as quality improvement or quality improvement research.	(Fiscella, et al., 2015)
Opt-out forms	The participant is given brief information about the treatment and told they will be part of the research study unless they do not wish to take part. Another opt-out model put forward an 8-point model of consent with opt-out based on Fiona Caldicott's recommendations (Perrin, 2016; Caldicott, 2016). These points, aimed at participants, tell participants of the importance of information, the role of law in protecting participants, the right to opt out, and the suggestion that opt out does not apply to anonymised information or exceptional when there is a "mandatory legal requirement" or "over-riding public interest".	(Kass, 2016) (Perrin, 2016; Caldicott, 2016)

It can be added to the above list that meta-consent systems allow individuals to choose which type of consent they would like to use in the future to express their preferences on the secondary use and sharing of their health data [3]. Citizens' expectations are central to the drivers of the economy, so how people perceive the future and the theories of how expectations are formed also matter.

The EU Consortium Smart4Health, deliverable 1.3 includes the 1st Specification of user requirements and performance criteria [67]. Some of the user requirements which seem to be especially important from the point of view of data donation, are:

- information to users on access to data
- understandable terminology
- funding and potential economic benefits
- information on the purpose or domain the data is used for,
- character of public good,
- guarantees on exercising data protection rights and access to healthcare.

Deliverable 1.4 on the 1st Citizen/User Consent Language Report [68] stressed that discussions on the ethics of using medical data tend to take a system-centric perspective and focus on what researchers and the health service may or may not do with data that are placed within their trust. Rarely, if ever, is the question of the data subjects' preferences addressed beyond practical matters of obtaining valid consent.

In regard to the receiving-end of the data donation/provision, the question was raised on which basis researchers are authorized, by which criteria, who exactly decides on this, and what makes a researcher qualified.

As regards informed consent, it is emphasised that for both the platform for personal health data storage and for the donation of health data for research, it needs to be clarified what will happen to the data that has been collected after the withdrawal of consent to data collection/participation.

From a data security perspective, the ENISA report on eIDAS compliant eID Solutions [97] provides an overview of the legislative framework under eIDAS for electronic identification and presents the landscape of notified and pre-notified eID schemes and identifies key trends in the electronic identification field. Moreover, it discusses preliminary security considerations and recommendations related to the underlying technologies used for eID means and makes a proposal on the role that ENISA could play in the eIDAS compliant eID ecosystem. Since Germany notified in September 2017 the first European eID scheme under the eIDAS Regulation, an increasing number of countries have started an eID scheme notification process. Other schemes are pre-notified and more will undoubtedly follow, thus demonstrating the success of eID across the European Union. The report also draws attention to the risks and limits of using smartphone-embedded biometrics directly operated by the mobile operation system.

Considerations on access to data: EPF's position was that, although informed consent is a fundamental right and should be the rule, in some cases exemptions to consent for sharing data are needed to make research possible. In these cases, other safeguards need to be in place to ensure patients' rights are upheld. Examples of such cases are available on the "data saves lives" campaign website. In many cases studies, researchers used data collected by healthcare systems or previous studies and re-consenting all the participants would have represented a disproportionate effort, considering safeguards such as key-coding were in place to protect the data.

Depending on the uses projected for the accessed data, consent, as basis of the data altruism model, may be challenged, especially in the use cases of "data recording time period" and "scope of the consent related to future users".

For instance, as DIGITALEUROPE warns, it is not always easy to outline in great details at the time of data collection why such data is needed for research purposes. Consent withdrawal or modification may also create legal uncertainty for businesses, which have obtained data through registered data altruism organisations. [37]

Priority areas that need to be addressed to enable and improve data donation research were identified by the Health Data Exploration (HDE) Project under the theme "Enabling Personal Data Donation for Public Good Research". [15]

1. Participant Protections: There is a need to explore new models and procedures for informed consent, and the practical management of consents. There are also deeper questions about what it means to give consent when a dataset is going to be public and can be used for any purpose. Data donation projects (as they were referred to in the document) also highlight issues of time and duration with regard to research datasets, including the timeframe of data processing and data subjects' rights.
2. Representativeness of Data: Some groups of people likely donate less or no data, because not everyone has data available to donate as technologies and practices of data generation and sharing are unevenly spread through society, regardless their consent could be obtained if capturing and/or transferring data would not be blocked by technical or financial barriers.
3. Incentives and value for participation, benefits: to develop robust data donation projects, it is critical to consider how the participants will relate to the project, especially if there is a goal of fostering ongoing donation over a longer term. Presenting value for participants is highly important.

6.3 Potential learnings for successful governance

The protection of individuals' rights, including data protection, is a key aspect, closely related to the issue of trust, when it comes to the governance of systems using personal data. One of the essential elements of data protection is consent. As it is described in the literature review, while consent is defined by the legislation, in fact, more approaches exist towards the consent of individuals / patients / data subjects to the use of their personal data. Opt-out approaches or systems are discussed under the types of consent. These approaches need to be taken into account and the appropriate method of consent will need to be selected for any systems of data altruism.

The potential impacts of successful governance in general have been analysed in detail by TEHDAS Task 5.4, while governance shall find solutions to the specific issues explored in section 6 to effectively build data altruism systems on the consent by data.

Legal uncertainty related to consent withdrawal or modification may be a risk that can be mitigated by a guidance under the data altruism framework.

Considering the findings of the literature review, the Health Data Exploration (HDE) Project raised certain relevant questions related to governance, as one of its priority areas. For data donation projects, it will be important to consider issues surrounding the long-term use of the data as it raises a number of questions: how individuals can restrict the use of their data, time-limit of the storage of data, distribution of the data, and the responsibilities of those who use the data. [15]

In cross-border and cross-organisational data exchange, parties may face challenges due to different forms of consent. Therefore, ethical, legal and technical issues that can emerge are recommended to be indicated in a matrix of the consent forms to assist players avoiding them. Recognised data altruism organisations can have an important role in updating and disseminating the content of this issue-matrix, as well as offering solutions to avoid and/or mitigate them.

7   Results from stakeholder consultation

On the 7th of July 2021, WPAG8 members virtually met to discuss:
- definitions related to data altruism (donation, solidarity)
- consent issues from data subjects or permissions to process data
- recognised data altruism organisations
- voluntary sharing of data
- collecting data
- data for purposes of general interest (common good)
- allowing data sharing
- data gathering for public interest.

As regards the definition of data altruism, it was raised during the discussion that data altruism may not exclusively apply to citizens but health systems, public and private sector organisations, as well. The definition of altruism might be narrow and can even undermine data sharing. In the frames of the workshop, WP8AG members begun discussion if "data altruism" definition of Draft DGA article 2 paragraph (10) should be amended, at least to a certain extent, to avoid inconsistencies with other regulations (e.g. GDPR) and legal uncertainty.

There were varying views if data could be owned, possessed, provided and/or donated. Regarding the issue of donation and ownership, it was emphasised that data altruistic organisations have the role to ensure consent, but data cannot be owned. It is also a question of consistency with GDPR, not clarification.

Concerning use cases, key issues are public good and social responsibility. ERNs, the EU Cancer Plan, organ, and blood donation were examples mentioned. It is important to look at why certain initiatives or organisations are successful. Foundations need to be established, trust to be built, benefits need to be simply presented and clarified. Mechanisms for success should be proposed.

It was also discussed if altruism, in general, contributed to the belief that there is an ethical obligation to allow health information to be used for research, or it was based on the belief that this obligation exists. Most WPAG members stressed that such an ethical obligation did not depend on altruism, but different motivations drove people sharing their health data for secondary purposes. The main aim of any further work is to look at the benefit of citizens. Citizens can be passive in a data altruism mechanism, but they should be empowered in the data economy. Data collection mechanism is not only a one-sided strategy to collect data but citizens to use the process. Citizen involvement mechanisms range from the passive altruism to more active data co-operatives, trusts, citizen decision-making. Typology could be developed. Data cooperatives can be a solution. There are mechanisms not altruistic in nature as there is always a return for sharing data, like in taxpaying. Use of data needs to be controlled. A different mind-set is needed to find solutions. Citizens are willing to share their data to be used for public benefit to patients and health systems) with safeguards. Trust is a link to willingness; it should be added as a key word to the review.

The draft DGA provides a mixture considering altruism, as it addresses "data altruism" and "data altruism organisations" and builds on altruistic motivations. Relevant legislation includes mainly GDPR and the draft DGA. DGA is being negotiated and a review of GDPR is foreseen but the scope of the work in is not comment the legislation of the relationship between pieces of legislation. While views were divided on whether an EU body should have wide mandate for certifying, licencing or permitting altruism organisations, WPAG members agreed that data altruism could increase effectiveness of data governance structures and functions of primary and secondary use of citizens' health and health-related data through the following means (in priority order):

1. Use case specific rules for health data altruism organisations.
2. Use case specific and general codes of conduct.
3. Special and distinct rules for health data altruism organisations in general.

All the experts agreed that there were data altruism use cases that should be dealt health sector specific. They found that donation of EHR/PHR (or other form of) data managed by the care provider of the data subject and donation of health and wellbeing data captured and shared by the data subject, as well as sharing genetic/ genomic data are the most important health specific use cases. Further use cases could be sharing health status data, care/treatment/service data or posthumous medical data donation. In addition, further use cases might be donation to public and non-profit or business/commercial data/biobanks, or donation to HEI/RDI organisations or their data/biobanks.

WPAG members emphasised that EU citizens need to remain informed of what is happening with their data, and there were different ethical, societal and technical impact of these different use case due to the specific nature of health data, its importance for health care and biomedical research. There should be direct correlation between the data altruistic consented for health research and the research made (transparent and accountable).

In summary, the work should more concentrate on mechanism, less on commenting DGA. Fields need to be looked at where gains can be shown and how those gains can be accepted by citizens. It can be also looked how data altruism organisation may be enlarged to data hubs in order to increase focus and gains.

WPAG8 members made further comments and suggestions during the written consultation phase of document M8.4. Their contribution is reflected in the information about next steps (section 8).

8   Next steps

Task 8.4, taking into account findings of current document as well as the comments and suggestions of WP8AG members on M8.4 version 0.3, (in the context of the preparation of M8.5) will:

- further investigate how data altruism (and/or other intermediary) systems can ensure that citizens remain in control regarding data they shared;
- seek further real-life and citizen-centric solutions or models for use cases of data sharing (i.e. not only "for" the citizen, but by the citizen);
- consider potential differences and analogies between data altruism and other data sharing practices through (personal) data intermediaries;
- study how, under each alternative data sharing option, citizens can also influence the distribution of the revenues generated by secondary use of health data to facilitate research and education, improve information, or for their own benefit, e.g. to improve their health or to benefit society;
- analyse opportunities, as well as strengths, weaknesses and threats of data sharing through data altruism and/or other data intermediary organisations;
- consider how citizens' participation in the planning and/or implementation of data use can contribute to optimising the benefits from the use of their shared data through different data sharing mechanisms;
- take findings of analyses and discussions into consideration to update definitions, needs, solutions, experiences, and good practices of data altruism (altruism structures and functions) for the future EHDS;
- organise further discussions at the level of the whole work package to identify all relevant enablers and obstacles, which are at the core of WP objectives, including findings in Task 8.1;
- share, debate and consult the results of the discussions and analyses with key players at the EU-wide multi stakeholder workshops that will be organised in the end of 2021 and beginning of 2022;
- think through the lessons and results of the workshops with EU-wide multi stakeholders;
- develop suggestions for the definitions of data altruism as tool, way, use case, organisation, system or educational pathway, cultural shift and empowerment perspective for sharing specifically health (related) data for secondary use purposes by and control of citizens, who shall be allowed to choose the purpose, the entity or the research type for which the consent has been given;

Task 8.4 will also co-operate with WP5 and further discuss with stakeholders to provide inputs for Task 8.5 to prepare primary recommendations to foster GDPR-compliant data altruism mechanisms for the EHDS (milestone M8.6). For instance to address topics such as voluntary sharing of personal data (even if identifiable). Such data should be protected in order to ensure that even the most sensitive ones (e.g. data of deceased or OMICS data) could be shared, if and when consent is given, and if, together with the use of privacy-preserving techniques, "anonymous", "de-identified" or "pseudonymous" sharing in line with the GDPR could be ensured. It shall be further investigated if consent under the GDPR may also apply to the possibility to notify an individual, if necessary, that there is a need to authenticate the data shared, and the citizen is at risk of a health risk, based on the results of research or analysis.

9 Appendices

9.1 Appendix 1 – List of reviewed literature

No.	Reference of the source (Title, Author, Published in, Doi, etc.)
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