

Towards
European
Health
Data
Space

Milestone M8.5

Overview about the results of EU-wide multi stakeholder workshops, with a special regard to updated definitions, needs, solutions, experiences, and good practices of data altruism structures and functions for the future EHDS

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1 Executive summary

The aim of 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.

The current document (M8.5) is the first deliverable of T8.5. It builds on (and presents) the results and learnings of the multi-stakeholder workshops organised in the framework of T8.5 on 17, 18, and 19 January 2022.

The present document seeks to respond to the following questions:

- What are the most important features for defining health data altruism structures and functions?
- What are the key lessons from best practices in data sharing structures and functions for future EHDS, focusing on the most relevant use cases?

This document contains preliminary findings to help understanding differences and analogies between data altruism and other data sharing practices, and how data altruism systems ensure citizen-centric approach, so that citizens can benefit from the value created by the secondary use of health data.

Some of the main conclusions of the discussions during the three days can be summarised as follows:

- Consensus should be reached on the nature of data altruism, its relation to other types of data sharing, as well as to the uncertainties about the meaning of general and public interest.
- Citizens have a central role in sharing their data and building trust with citizens is the main prerequisite from which we should start any consideration of the possibility of sharing data.
- Citizen and patient engagement are much wider than stakeholder engagement, and there are various active or more passive mechanisms for citizen engagement.
- Also, it is necessary to encourage the involvement of citizens to the EHDS.
- Data valorisation or monetisation need further discussion with focus on key questions including how to anticipate the value created with data, different models, what would be acceptable model for citizens, and ethical issues.
- Methods and tools for sharing health data need to be simple and user-friendly, and they must guarantee the privacy of citizens when sharing their data, as well as data security.
- Participants agreed that there's a need for an essential element for building trust, e.g., via platforms or applications, to give citizens an overview of using their data shared.
- Issues of reward for data sharing, and profit or not for profit use of the citizens' health data should also be considered.
- The FAIR principle should be applied (data shall be findable, accessible, interoperable and reusable) and the structures shall be fair (transparent, equal, trustworthy and righteous).

Final conclusions will be drawn in the further work to carry out by M8.6 and D8.2 (primary and final recommendations on data altruism functions, structures, and governance).

2 Context

“The Joint Action Towards the European Health Data Space (TEHDAS) helps the Member 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.” 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.

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 was M8.4 “Presentation of a first set (catalogue) of data altruism definitions, use cases and findings about consent and accessibility issues (30.9.2021).

To prepare the 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), two documents (milestones M8.5 and M8.6) will be produced. These documents take as a starting point the above mentioned M8.4 document.

The next – actual – milestone, delivered by Task 8.5 (T8.5), is M8.5 “Publication of an overview (prepared to launch a communication campaign) about the results of EU-wide multi stakeholder workshops, with a special regard to updated definitions, needs, solutions, experiences, and good practices of data altruism (altruism structures and functions) for the future EHDS (means of verification: published in TEHDAS webpage)”. The current M8.5 document is the first deliverable of T8.5. It builds on (and presents) the results and learnings of the multi-stakeholder workshops organised in the framework of T8.5 in January 2022.

Results presented in this document will be used to launch a communication campaign to engage citizens, researchers and service providers for data sharing, to become active players of data altruism structures.

Final conclusions will be drawn in the further work to carry out by M8.6 and D8.2 (primary and final recommendations on data altruism functions, structures and governance).

3 Introduction and Methodology

TEHDAS Work Package 8 (WP 8 - Citizens) invited wider TEHDAS stakeholder community and TEHDAS partners to meet WP8 Advisory Group members and WP8 key contributors at 3 interactive online workshops on 17-19 January 2022.

The purpose of the workshops was to discuss some of the most challenging topics on citizen-centric solutions and models for use cases of health data altruism/intermediary systems for data sharing, structures, and functions for the future EHDS.

Task 8.5 took into account the following findings presented in M8.4, to prepare the debate and discussions and consultation to prepare the development of suggestions for the definitions of data altruism:

- data altruism can be a tool, way, use case, organisation, system or educational pathway, cultural shift and empowerment perspective for sharing and controlling health (or health-related) data specifically for secondary uses by citizens;
- citizens shall be allowed to choose the purpose, the entity or the research topic and type for which their consent has been given.

Therefore, to meet the purpose of the workshop, participants were invited to:

- 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.

Based on the results of the workshops, Task 8.5 has summarised most important features for defining health data altruism structures and functions, as well as the experiences and learnings from best practices in data sharing structures and functions for future EHDS, focusing on the most relevant use cases.

4 TEHDAS WP8 Online Workshops 17-19 January 2022

4.1 General information about the workshops

Key topics

DAY 1 - Jan 17 (10:00-12:00 CET):

- Citizens' control over data - How data altruism/intermediary systems ensure citizen-centric approach;
- Real-life and citizen-centric solutions or models for use cases of data sharing;
- How citizens can influence distribution of the revenues generated by secondary use of health data - e.g., improve health or benefit to society;
- Optimising benefits from data sharing mechanisms - How citizens' participation in planning/implementation of data use can contribute to optimising benefits.

DAY 2 - Jan 18 (14:00-16:00 CET):

- Differences and analogies between data altruism and other data sharing practices;
- SWOT of data sharing through data altruism and/or other data intermediary organisations.

DAY 3 - Jan 19 (14:00-16:00 CET):

- Update definitions, needs, solutions, experiences, and good practices of data altruism as tool, way, use case, organisation, system or educational pathway, cultural shift and empowerment perspective for sharing health (related) data for secondary use purposes by and control of citizens;
- Activities, structures and functions for the future EHDS - Why dedicated health(care) specific regulation of altruism/intermediary systems is required for EHDS;
- Enablers and obstacles;
- Sustainability.

Stakeholder engagement

Stakeholders were asked if they were interested in making a short presentation at one of the events. Finally, 9 experts presented his/her pitch during the 3 days.

To engage others than TEHDAS partners and advisory group members, the online workshops and the registration link were promoted by information published on the TEHDAS website under the Events page: [Online workshops: Health data altruism and citizens' control - Tehdas](#) (see figure 1).

TEHDAS project partners, advisory group members and most active TEHDAS stakeholders were contacted by email and newsletter invitation on 16 December 2021 (see figure 2).

A tweet about the events was also posted from [TEHDAS Twitter account](#) (see figure 3).

Thanks to the invitations through direct e-mails, newsletter project website publication and social media posts, more people were reached than expected. The 3 events were held on 3 consecutive days, which also helped to attract a large number of people to register and attend the workshops. The events were held online, which also helped to reach a higher number of participants.

99 people registered for the three events, most of them attended all the three workshops, only some attended one or two. Distribution of participants per workshop: day1: 84, day2: 78 and day3: 77. Participants represented 21 European (18 EU) countries and the USA. Great majority (87%) of the attendees came from 4 sectors (see Table 1).

Figure 1 – Invitation published at the tehdas.eu website

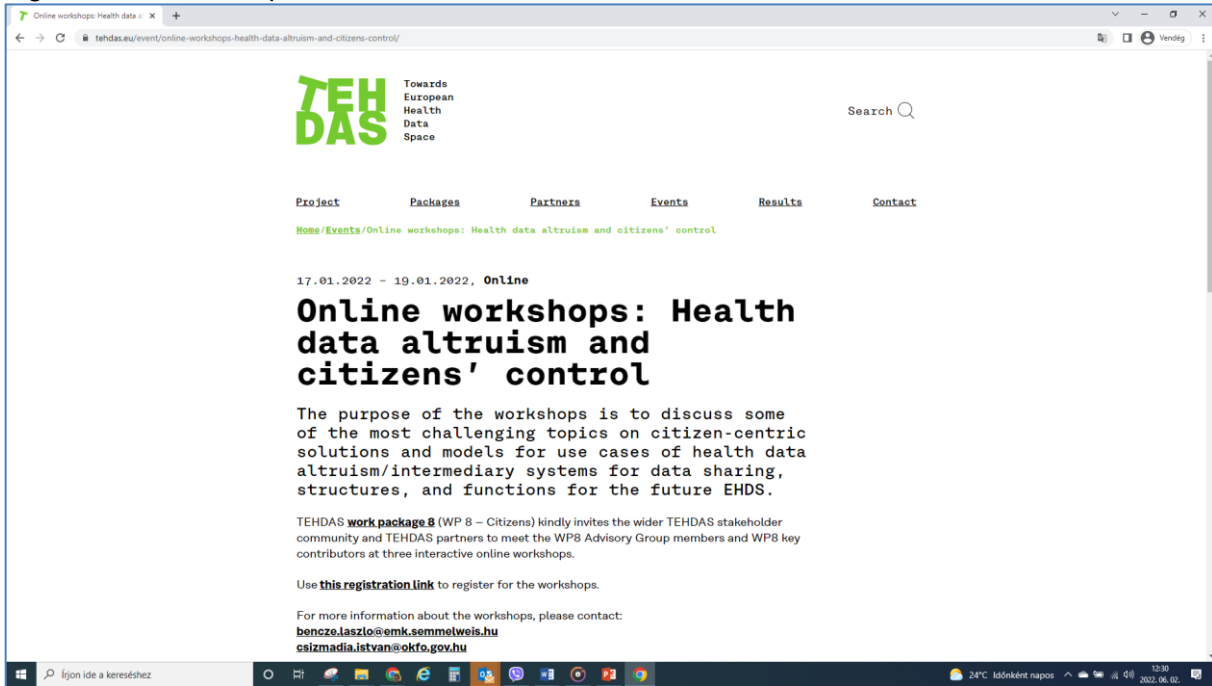


Figure 2 – TEHDAS Newsletter (16 December 2021)

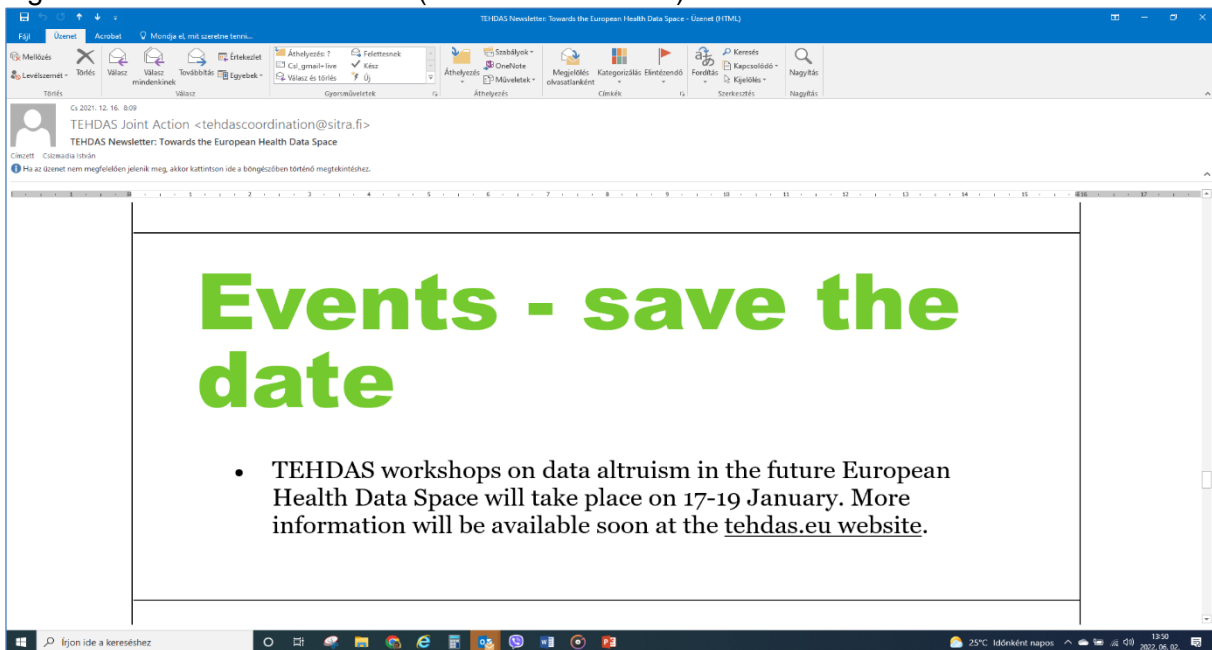


Figure 3 – Invitation published at the Twitter account

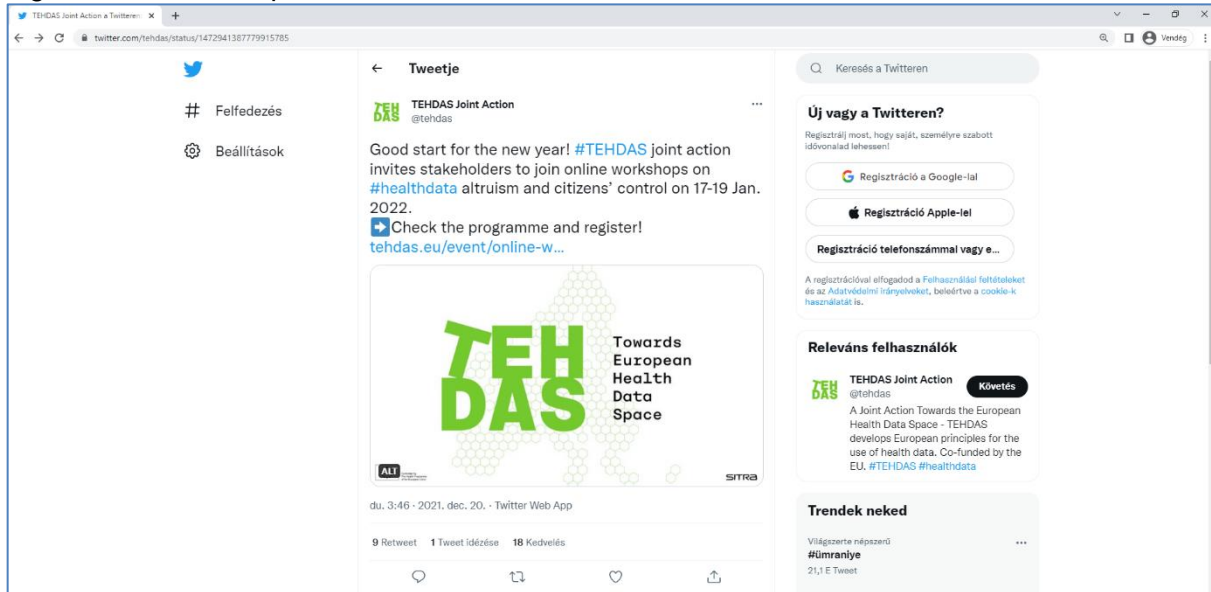


Table 1 – Represented sectors

SECTOR	%
Scientific Community (Higher Education, Research)	27%
Civil Society (Patient, health, professional association/society/other organisation)	23%
Policy Makers, Government, Public authority, EU	19%
Industry	18%
Other	10%
Media	1%
Customers (individual patients, professionals, scientists, non-professionals)	1%
General Public	1%
Investors	0%
TOTAL	100%

4.2 Summary of day 1

4.2.1 Presentations

4.2.1.1 Izabelle De Zegher:

Managing Personal Data as an asset – parallelism with Online Banking

The starting point of the presentation was that from a high-level perspective data altruism is the easier but suboptimal model of data sharing because individuals lose control on their data and have no incentive to manage their data for their own benefit or health. For EHDS, data altruism represents a simplified process where a longitudinal view of the data set on an individual is not possible.

From a democratic perspective, data intermediary which is described in the DGA is more optimal but also more complex than data altruism. Through a data intermediary, individuals keep control of their data, can be incentivised to maintain their data across time (longitudinal health record).

The proposal was to come with a personal data sharing app. The business architecture of online banking can be an example of individual data sharing.

Data intermediary (accredited by the governing organisation) plays the central role between the data individual and the data consumer e.g., healthcare provider, pharma, insurer. The national ID registry approves the person's identity. Consent management would be the data intermediary's role. Aggregated data are anonymised and, in this way, qualify as non-personal data.

Business architecture includes payment and reward for transactions, where health reward may include additional health services.

A choice should be made between pay-for-service and give-data-for-service. Market potential for give-data-for-service is growing. The question is, how citizens can be incentivised to share data.

The vision for the future is health data trusts. Data monetisation model needs to be clarified, and ethical issues to be taken into consideration

The conclusion of the presentation was that data trust or data intermediary is more democratic than data altruism, and more respectful of citizens' freedom. New business model and new technology solution need to be set up.

4.2.1.2 Dominik Geller:

Building trust with patient held EHR and dynamic consent

Basically, EHDS relies on trust of individuals. The key factors of trust are security and privacy, transparency, added value, self-determination, engagement.

A potential block of current sharing practice includes consent issues, de-identification or anonymisation of personal data, controls, and issues of secondary use for research and data transfer.

The presentation included proposals in relation to challenges:

EHDS is critically dependent on trust, so that citizens are ready to share their data via the hubs and nodes. Key elements are that data need to be secure and private, transparent, and need to perceive the value in data being shared collectively and maybe personally, too.

As regards engagement and inclusion, citizens need to be enabled to determine and control what data they share and with whom.

The second challenge is how to ensure citizens' rights like access or transfer of data, and in case of transfer how data will be observed on the other end.

Third challenge is a block we see in current industry data sharing practice. With broad consent at the beginning of data collection people are asked whether they are willing to share their data. This approach falls short of the GDPR requirement to have consent for all purposes of data use. Data are often de-identified which is not equivalent to anonymisation and there is a risk of re-identification of personal data. De-identification is not equal to anonymisation.

Industry practices use standard contractual clauses or binding contractual rules but there is a risk that current practices of secondary use of data will be interpreted by courts.

A key issue is that personal data sharing must be non-discriminating by data intermediary.

The proposal is the creation of a citizen platform e.g., via mobile devices. In this way data requests can be presented to citizens and downloaded. This solution contributes to patient/citizen empowerment as it would increase acceptance and trust being transparent, increase preparedness to share, and handle legal risks.

Proposals as regards EHDS were the following:

- Increase acceptability of central EHDS nodes across EU/within MS;
- Increase citizen's preparedness to share their data;
- Legally and ethically robust consent to concrete processing/study request;
- Efficiently handle request of citizen to their own information;
- Full citizen/patient empowerment.

As a complementary to EHDS effort and architecture, it was proposed to include private-public collaboration building on existing initiatives like the Innovative Health Initiative (IHI, Horizon Europe) with the involvement of patient organisations and academia, and a platform to be operated by a dedicated not-for-profit organization.

4.2.1.3 Zoltán Lantos:

Social innovation for community health value

The presentation discussed the topic of data sharing from a human approach. It was stated that data are considered a renewable resource, and data asset is a misleading expression as data re-use generate more data.

The proposed European data model would be based on the data capital triangle: Utility, Privacy, and the FAIR principle.

An important aspect is that for individuals, personal benefit is more important than public good. Regarding the value of data, metrics need to be introduced so that value-set and reward can be better designed.

For data sharing, key issues are:

- Outreach, engagement, and sustainability. A dialogue has to be initiated with national health authorities, international stakeholders;
- Excellence in data quality;
- Auditing data holders;
- Transparent data processing;
- Meta data catalogues;
- Trusted Research Environment.

The role of data intermediation organisations is key.

4.2.2 Discussion

The discussion started from the issue of data monetisation and data valorisation. There was general agreement that they are key issues which need to be discussed. In the field of health data, data valorisation was considered a better term, than monetisation. It was added that novel metrics need to be found because there is a lack of common understanding on values, and the 'data for service' approach can be defined based on the new metrics. From a broader perspective, a new social contract on data valorisation was proposed.

It was also added that if service is made part of the system in return of data, then as a result data sharing will no more be voluntary and free. Service can be provided in return of the data but linking the two is unsustainable, and raises data protection concerns, as data can only be used for the purposes of the service under GDPR but not in return.

In addition to service, information will also be important for patients in return for data. Reliable and well-designed information is also a service.

The European context was also mentioned, and it was proposed to consider other models. In most European countries healthcare is free and as a result the value of data has less importance for citizens than in the US. If patients can pay for service with data instead of money, then the value is different. Value also should be linked to the quality of data, and citizens should be given help to improve the quality. Reward for sharing data is a key question of EHDS which is missing for the moment.

The role of data intermediaries as another topic was discussed. Under the DGA, there is no clear assignment as intermediary. In principle anyone can be data intermediary who shares data on behalf of a data holder or an individual, including sponsors or Contract Research Organisations (CRO). If more EHRs will be used, then CROs will become a more important intermediary. Data altruism can be considered as a special form of data intermediation.

Data market should be in the interest of and controlled by citizens. Data market should be based on robust grounds such as consent to make citizens have control over what is happening with their data. Data being an asset, it is difficult when it comes to personal data because citizens have rights over their data. Consent is a license given by an individual and therefore licensing contracts and the types of consent have to be examined. Consent should not be bundled together with service, especially for rare disease patients who do not really have a choice.

Other components than data sharing was also mentioned like data portability and bringing value.

Regarding the banking model, as one possible model, it was highlighted that parallelism with banking can simplify many issues like consent forms, especially from the citizens' perspective. Citizens can feel safe to manage transactions like in a bank. Data portability could be similar like changing a bank. However, data bank may not be a good term, but it can be data trust. A further question to be discussed will be if data trusts can be for profit or non-profit.

As a challenge for using online applications was mentioned that they are easy interface but not fully secure, therefore control by legislators and data protection authorities is necessary. In addition to authorities, the role of patient organisations was mentioned. Multi-stakeholder participation and representation will be important for robust policymaking on data sharing.

In the last part of the discussion, the results of the survey conducted by the M8.5 team were presented. It was a preliminary survey, not a research or wide survey. Analogy from banking and from other sectors can be seen, too, at least four of five solutions. The variety gives a choice for citizens and stakeholders to select from different solutions depending on motivation, ability, readiness, skills, and empowerment. Multiple answers show different sets of combination of possibilities but data sharing is in the centre. The message is that participants of the survey found that data sharing alone or with other solutions could somehow be a guarantee of citizens' control and active role.

On the other side, the results show uncertainty, that is why experience should be designed and conducted, and use cases specified to understand the model. Currently, good reference is not available but TEHDAS will be good establishment for experimenting.

The uncertainty also emphasises the need for understandable and easy-to-access communication with patient involvement and representation to explain what data sharing means. Patients know best what unmet needs are, or what is not ethical or safe for patients. Independent patients like bloggers and influencers can give valuable feedback. Digital and literacy must also be considered. In addition to patient participation and representation, being consumer and user centric is also important.

As an argument for applications, it was added that applications on smartphones can be user friendly that is why a lower level of digital literacy may be sufficient. Differentiation should be made according to needs and education, and help is important, not only education. Internet and smartphones will evolve, e.g., intelligent bots can be helpful.

Commenting the TEHDAS literature review and evaluation, the co-creation approach was considered to be missing as health value can only be achieved with co-creation.

4.2.3 Conclusion and next steps

Important learning from Day 1 of the workshops is the issue of service, information or other return for data, connected to different groups and needs of citizens. It is also important for selecting the possible intermediation ways provided by the legal setup.

There was agreement that data valorisation or monetisation need further discussion with focus on key questions including how to anticipate the value created with data, different models, what would be acceptable model for citizens, and ethical issues.

It was proposed that citizens should be helped in relation of EHDS, like in a form of an app, with different scenarios to help citizens and make willing to share data.

Further next steps proposed were disease-specific or situation-specific use cases that would provide a basis for an application. The landscape of services for citizens should be examined.

For the next steps, the WP8 Team will present barriers and opportunities based on DGA and EHDS. Stress will be put on trust, consent, portability, active role and control of citizens. Special attention will be given to main groups of citizens' needs, communication, information, co-creation and literacy. In relation to new opportunities, security, capacities and responsibilities should be considered, too.

4.3 Summary of day 2

The objective of the day was to discuss the following two main topics:

- Differences and analogies between data altruism and other data sharing practices;
- SWOT of data sharing through data altruism and/or other data intermediary organisations.

The Report on the literature review prepared by WP8 under milestone M8.4 served as background material for the discussion. The Report covered the first set of definitions of data altruism, as well as certain use cases and findings on consent and accessibility.

An important question was that data altruism may not exclusively apply to citizens, but health systems, public and private sector organisations as well. Other important issues were the sharing of data and data protection rules including the withdrawal of consent or portability of data.

The discussion of Day 1 pointed out that data sharing is not a synonym with data altruism as data altruism is narrower and gives less control for citizens over their personal data. The draft Data Governance Act (DGA) provides a mixture concerning altruism as it addresses data altruism and data altruism organisations, building on altruistic motivation. Citizens are rather passive once agreed to share data in altruistic view, more proactive role should be considered in the new data economy, which requires other models than data altruism. Therefore, citizen perspective and patient perspective has to be considered.

The results of the preliminary survey prepared by the WP8 team were presented.

4.3.1 Presentations

Pitches were presented introducing specific projects, and in relation to those projects, various issues of sharing health data were discussed.

4.3.1.1 Anne Moen: Citizens' engagement in secondary use of their health data

The presentation covered aspects related to adding a clinical health use value of secondary use of health data.

The first and obvious paradox is that citizens and patients are core actors present in most health or wellness activities, but there is limited support for active personal health management and there is lack of coordination tools.

Patients and citizens add personal contributions, and there is value, knowledge and expertise in health data related to a person's health situation. A support network can also become an expert on personal health. A personal health data space can transform personal health management and make the patient support networks fulfil a coordination role and also to some extent control and update the available information.

Opportunities and value in personal health data for cross border scenarios was also added to the discussion, which is increasingly important when mobility across Europe starts again after the pandemic.

The presentation also introduced the Gravitare Health project, a public-private partnership in the framework of the Innovative Medicines Initiative (IMI) whose objective is: Add value of digital access to health data, facilitate for understanding of relevant health information, and apply for personal health management and adherence to treatment.

4.3.1.2 James Maddock: The importance of data altruism and citizen engagement to the European Health Data Space

Terms of data altruism, data donation and data solidarity were discussed by the presentation. The presentation emphasised the problem of ownership issues.

Based on a survey conducted in Belgium, France and the UK including about 60 expert interviews, active mechanisms of citizen engagement were introduced, including citizen assemblies/juries, access/advisory committees and content panels, representative organisations, community groups and organisations.

A SWOT analysis of data altruism was presented. Among strengths, belonging to a community was highlighted. The ability to empower citizens and patients make use of greater data sources was mentioned as an opportunity. The risk of over reliance on donated data and varying uses of consent through European countries was emphasised. The issue of equity of access is a major weakness, related to digital literacy.

4.3.1.3 Antal Bódi: Future cyber security challenges and controls for secure processing environment

The presentation discussed cyber security issues with a special regard to quantum computers. It was proposed as a solution to reorganise IT systems according to the Zero Trust principle where authentication is required for every transaction and collect, analyse and retaliate against everything by the security log. Zero Trust covers users, devices, network traffic, applications and their source code, and most importantly, data systems.

It was highlighted that algorithms currently in use are not unbreakable by quantum computers, and quantum resistant algorithms are not yet widespread.

The growth of data spaces and data sharing, AI and the cloud technology are great opportunities but we have to concentrate on how to preserve privacy when sharing data and prevent abuse. The following methods were proposed:

- Fully homomorphic encryption: data is encrypted before it is shared. It can be analysed, but not decoded into the original format;
- Differential privacy: noise is added to the dataset so that it is impossible to reverse-engineer the original inputs;
- Functional encryption: select users have a key that allows them to view some parts of encrypted text;
- Federated analysis: parties share insights from their analysis without sharing the data itself;
- Zero-knowledge proofs: User can prove their knowledge of a values without revealing the value itself.

4.3.1.4 Mikael Rinnetmäki: Sensotrend, making sense of diabetes trends

The basic idea of the application presented in the pitch is the recognition that people with chronic conditions want to share their health data for research in hope of better treatment in the future, and both pharma companies and healthcare organisations need the data as part of the transition towards value-based medicine.

These kind of wellness apps and digital health tools have a unique position in the value chain because they have a trusted relationship and an ongoing conversation with the users. Data processed by the apps are shared with electronic health record systems.

A market mechanism is emerging where citizens allow their data through apps for primary and secondary use, and organisations pay fees for access to their data. The fees are mainly shared by operators and the apps. In some cases, some part of the monetary reimbursement might reach the citizens, but especially with the chronic conditions the main benefit for the citizens would be that they have a selection of apps and more control over their data. Medical research or use of data by registers is always based on specific request.

Instead of uploading data to a centralised repository citizens may want to decide who gets access to their data on a case-by-case basis but it needs an active discussion with the users. The information gathered from the patients e.g., on the effectiveness of medicines may also be helpful in negotiations on setting the prices for medications. If there are already apps in place and use, it would enable this kind of an ecosystem.

4.3.1.5 Zdenek Gütter: Data altruism classification

The aim of the presentation was to review classification in order to help consider various aspects of data altruism in healthcare. Various criteria or viewpoints on data altruism processes exist:

Data Originator (data subjects) – Possible entities: Public Institutions, companies, other entities, individuals.

Methods of providing access to the data:

1. Data subject to give consent with sharing data that are technically collected by an operator of an ICT system used by the individuals;
2. Providing agreed access to own database of the data subject, otherwise protected for access;
3. Individuals bring/transfer/push data from their own repository to a data altruism organization.

Period of time for sharing:

1. Sharing (disclosure) only of a given set (sets) of the data subject, created in a defined period of time;
2. Sharing of historical data only;
3. Sharing of future data only;
4. Sharing without time limitation, even for future („all data in a specified repository“) (withdrawing the consent is still possible).

Scope of the consent related to kind of users of the data:

1. Only single propose consent to share data of the data subject by a given user;
2. Multipurpose consent to use the data in a restricted range (geographical, research or policy, kind of research, defined users) only;
3. Universal consent to use the data by any user.

Scope of the consent in terms of purpose of the use of the data:

1. Only for specified activities (specific medical research, statistics);
2. For group of similar activities (several research projects, e.g., consecutive ones);
3. Unlimited.

Scope of the shared data in terms of types of data records:

1. Only selected specified records (e.g., CT images only, but no other modalities and data);
2. All records related to one disease or condition but not to other ones;
3. Complete (medical) records available in a given database(s).

Scope in terms of GDPR (personal data):

1. Only duly anonymized data;
2. Data with some personal data (e.g., age - date of birth, gender, location);
3. Disclosure of the data as is, incl. personal information.

Reward for data sharing:

1. For free;
2. Reward for costs associated with sharing, incl. e.g., transport, media used and data quality assurance;
3. Additional reward e.g., to motivate data subjects to provide data, moreover in a specific period of time.

4.3.2 Discussion

Several questions and comments were added to the presentations, and issues including social pressure, interests of data subjects, access to data, as well as mechanisms and services were discussed.

As regards social impact, it was mentioned that there is a risk of marginalisation of citizens who decide not to participate in altruistic systems, that is why the social implications of the term 'data altruism' needs to be understood, especially as it will be part of the legislation.

Reaching the population is necessary in order to make use of mechanisms or platforms. The role of social media is important in engaging with people, but also the specifics of social media as not everyone engages in social media in the same way. There is a risk that people are left behind who have lower level of digital literacy and in this way not engaged.

Performant thing to do when you have apps, so we have logging mechanisms and each time the third party uses your data they are required to report that.

Using pieces of data brings several technical and legal aspects like enforcing what happens with data, the purposes of sharing data, time-limit of data usage, duration of consent, and degree of personal information. Regarding European data consent forms are needed not only on European but also on national level.

The issue of sharing data for free was discussed and it was acknowledged data sharing data involves certain costs which is an important aspect of the definitions in the DGA.

Methods of data collection or sharing may be various including systems used by individuals, or giving access by individuals to their own database e.g., fitness device, or the citizens can transfer their data which is a more complex option.

Trust in the services was considered a key issue and there was agreement that usability and security cannot be compromised.

4.3.3 Conclusion and next steps

The main learning of the day was that citizens have a central role in sharing their data, and building trust with citizens is the main prerequisite from which we should start any consideration of the possibility of sharing data.

Citizens must be able to decide whether they want to share their data, be informed that their data is being used and who is using their data.

From the perspective of citizens, it is extremely important that information on the possibilities of sharing their health data is accessible, i.e., clear, that the information clearly communicates the meaning of sharing data, and in this sense, it is extremely important to educate citizens.

Also, it is necessary to encourage the involvement of citizens and for these purposes there are active and more passive mechanisms for citizen engagement. On the one hand, methods and tools for sharing health data must be simple, user-friendly, and on the other hand, it is necessary to respect the legal, economic, IT or security requirements regarding data sharing, security and privacy of citizens.

Efforts need to be made in terms of taking measures and techniques that ensure the privacy of citizens when sharing their data, i.e., data security, and reconcile this with the requirements for ease of use and accessibility of citizens because if there is no security there is no trust.

4.4 Summary of day 3

At the beginning of the workshop, Željka Gluhak (HZZO, HR) summarised the most important results and lessons learned from the previous day. Among these, she highlighted that the main learning of the day was that citizens had that central role in sharing their data, so building trust with citizens is the main prerequisite from which to start. Citizens must be able to decide whether they want to share their data, be informed about the fact that their data is being used, and they should know who is using their data. There was a fruitful discussion about the differences between data donation and data solidarity. Some of these differences relate to the issue of ownership, or rather control, of the shared data. From the perspective of citizens, it is extremely important that information about the possibilities of sharing health data is available, accessible and clear. Citizens should be clearly communicated and educated about the significance and possible outcomes of sharing their data. On the one hand, methods and tools for sharing health data must be simple and user-friendly, and on the other hand, it is necessary to respect the legal, economic, identification and security requirements regarding data sharing, security and privacy of citizens.

The starting point for the third day was thus that the clarity of 'data altruism' depends on the extent to which it becomes clear that sharing data does not in itself change the right to dispose of the data, and in particular does not affect ownership (since data in the classical sense has no owner). The relationship of data altruism to the public good or gratuitousness is also a decisive factor.

Task 8.5 drawn the attention to the definition of data altruism in the draft DGA legislation (Data Governance Act COM/2020/767 final, 25.11.2020) and the Council's comment on it (Council of the European Union 14606/21, 10 December 2021 provisional political agreement reached at the second trilogue). While the original proposal emphasised the significance of consent by data subject or permission of data holders, the Council's version highlighted the significance of voluntary data sharing.

In this regard, the workshop participants highlighted that the concept was not clear within the DGA, as it basically defined one concept with another unknown concept. Altruism was explained by a concept that was not clear.

4.4.1 Presentations

4.4.1.1 Dr. Mona Nasser DDS, MSc, PgCert, PhD, FHEA, Associate Professor in Evidence based Dentistry

Impact of data altruism on systematic review production/ research priority setting

Systematic reviews are secondary research projects. They start with a research question(s) and use transparent and systematic approaches to address the question(s). This involves systematic searches, screening of the studies, appraisal and synthesis of the studies. They are key to inform practice and policy, and more and more countries use it as an integral part of their policy-making. However, systematic reviews are only as good as the available data. People often forget that there's a lot of decisions made in shaping assessment review beyond the clinical trial data. It is important to understand how the topics of the systematic review and the focus of the research question affect the availability of evidence for decision-making.

So, in addition to the obvious option that if people are more altruistic about data sharing, it would increase possibility that they would participate in research, and if people start sharing more personal data about themselves, it would help us understand how to make decisions, engage people or how we prioritise outcome measures for assessment reviews. Because how we prioritise them can make a difference whether some health care intervention gets approved or not approved.

Systematic reviews mostly have used synthesized data. However, there are several types of systematic reviews that use individual patient data. E.g., systematic reviews using individual patient

data meta-analysis. There are other types of data that affect a systematic review, e.g., views of patients on what outcome is important or should be prioritised or how the view of stakeholders affect the interpretation of the final results.

This makes it important to know what people's needs and priorities are, what they are willing to give information about, and what and how they choose to give information about. All this information reflects the value judgments people make around it, and it might shape how we approach data altruism and who we advertise this information for. So, it is worth making it clear to policy makers and citizens alike that learning how to use data for and provided by systematic reviews can make a huge difference. The change we are trying to influence would come from this change.

4.4.1.2 Brendan Barnes, Director Data protection, EFPIA - European Federation of Pharmaceutical Industries and Associations

Citizens' perception of and engagement with health data secondary use and sharing in Europe - a literature review - identification of multiple models of consent

In this presentation, also taking into account the results of the literature review presented in the M8.4 report, a number of risks and concerns were outlined.

At the beginning of the presentation, the importance of accountability and how that is built into the future system as a sort of counterpoint to any sort of data donation and data altruism concept was clearly emphasized.

It is also important to draw attention to public concerns that there is no consensus on the nature of data altruism. There is therefore a need for further discussion on how to make use of the many practical experiences that are available but not reflected in the literature.

From EFPIA's perspective, there has always been some reservation about linking the idea of donation in the concept of altruism with the idea of no reward, the idea that data is used, but by a particular type of organisation and entity. There are some concerns about the introduction of the idea of reward, as it raises the question of whether people should be rewarded. For sharing data through other channels, which is not generally the case today, linking these three concepts would raise some concerns and therefore needs to be looked at more carefully. The distinction between the public and private sectors may also raise concerns. There is now a lot of overlap and cooperation between the public and private sectors, which is important because private sector organisations understand what people want. For example, that they are expected to be accountable.

In the next part of the presentation, the speaker also drew attention to other risks:

- We can understate the importance of preserving already created datasets, both for further scientific research and for the question in relation to consent. Do we allow the withdrawal of consent to change existing datasets? Or do we make a sort of wider societal case for saying there's an interest in preserving those datasets if they're appropriately safeguard? That case could be made on the basis of the needs of research, industry, policy or citizens.
- We also have some legal obligations that mean that we need to retain data in its original form.
- Is there any risk of affecting the individual? Essentially what can be the harm here? This risk probably becomes quite important when one tries to bottom out what data altruism should mean.
- A differentiated level of accountability would be important when trying to get people to engage with how and in what ways their data is used. In cases where there is a very close relationship between the data user and the individual, it is conceivable that the individual could be, become or could remain identifiable to the data user. At the other extreme, you have got the situation where people are only for their purposes needing data. That is, you know, essentially aggregate or genuinely anonymous like not really linkable to the individual. You have got a vast range of uses in between.
- At some point, somehow, we need to find a way of making sure people understand to some degree those different uses and the safeguards that are attached to them. We do not just have anonymous and personal data; we have a whole graduation in the middle. Inevitably, the

literature focuses on consent. I think as we go forward with altruism, we need to look at other safeguards.

- The aspect of trust is also an important issue, the establishment and maintenance of which, is threatened by a number of factors. One of the absolutely critical elements is the role of intermediaries in the relationship with individuals and society. For this reason, we cannot avoid the fact that data users will also have accountability obligations. The previous day, we also talked about public education, how we educate people about something of this magnitude and, in that context, how we can get a clearer picture of public attitudes and risk-taking. The previous day, we also talked about public education, how we educate people about something of this magnitude and, in that context, how we can get a clearer picture of public attitudes and risk-taking. We see a possible role for things like accreditation of research reports, accreditation of implementing agencies to facilitate accountability and self-regulation. So, one of the things we are working on is a code of conduct under GDPR for our sector. We hope that this will go some way to helping people to be clear about how we use their data, which will build some confidence in how we use it.

4.4.2 Discussion

The first issue discussed was the general (public) interest. Workshop participants pointed out that the DGA does not clearly define what this means. This was also examined in the literature review sources presented in the M8.5 report. The conclusion was that there are several approaches to the public interest. A key distinction is that some consider that the public interest can only be linked to public activities or to sound scientific activities. On the other hand, there is another approach according to which, public interest can include for-profit activities of companies when they serve the interests of society, such as therapeutic development. Participants of the workshop agreed that it is essential to clarify that the meaning and content of the terms we define and use, are widely understood and accepted. In this way, the difference between public interests and general interests needs further clarification, definition and communication, since these terms can mean so many things and can leave so many things to the imagination. The solution is to apply GDPR, which clearly states whose personal data is in the public interest. It is important that the benefits are proportionate to the risks and that the risks to individuals can be weighed against the general or public interest. The draft DGA also lists some examples of public interest in health and scientific research.

In the next part of the workshop, the participants first discussed the differences and similarities between data altruism and other data sharing practices, as well as the advantages and disadvantages for the stakeholders. They also discussed the sustainability of different possible business models and systems that could be understood in terms of data altruism.

The first question was whether citizens could receive a reward or payment for sharing their data or whether they could receive a service in return. In this context, it was also raised whether it is conceivable that the data sharing model of a for-profit company could be altruistic from the citizen's point of view, and thus the model could be regulated accordingly. By tracking the company's activities and behaviour, would the citizen be able to decide on a case-by-case basis on his/her own behaviour: E.g.: Does he/she grant or maintain access to his/her data or its secondary use? Does he/she ask or expect anything in return? Can citizens choose between altruistic (or other intermediary) companies? Can they give their consent to one company for one purpose and another company for another? Do citizens give their data just to non-profit organisations or do they give it also to profit organisations like the pharmaceutical industry or something like that end? Participants then discussed whether it is possible to make it easier for citizens to decide on this choice or whether it is possible to create a simple solution for them. It was asked by the patent side whether a platform could be created to give citizens an overview of where, how and to whom they can share or donate their data, and what the advantages of cooperating with one (for/non-for-profit) organisation are. This platform could provide citizens with a complete overview to make it easier for them to see and understand a specific situation and project (and the goals and activities of the data intermediary/data altruism organisation). In

addition to the idea of a platform, it was also suggested that information on patient safety and quality could be made available to the public, based on existing good practices. Patients or citizens could then choose between private and public (for profit or not for profit) data custodians, based on various criteria that are important to them. The data custodians could be evaluated and ranked, and this information would provide further useful feedback to citizens, public authorities and policy makers before making their decisions. Participants agreed that this kind of platform is indeed an essential element for building trust. However, it was emphasised that there's the challenge, which derived from the way the DGA has been built, is that we might have to rely quite heavily on the Data Innovation Board to drive consistency of the approach across Member States and within Member States. The other observation was that data intermediaries have to have high standards of cybersecurity as well as high standards of accountability. Otherwise, the system is going to be harmed by loss of confidence, because there will be data breaches and failures. Therefore, the system has to be robust enough to deal appropriately with those things when they happen and explain to the public why they happened.

On the research side, it was emphasized that when talking about altruism and citizen control, it would be an interesting dimension if we could exploit the fact that people are able to make and control their decisions and make quite sophisticated trade-offs in their decisions. The methods to engage citizens will defer, depending on how they have been involved or engaged in a direct relationship, including digital relationship. People have different motivations or different understanding of the question, so flexibility is an important factor in the system. One possible solution is for the citizen to agree on the general principles of data sharing and use, and then on the specific final terms. This might be a two-pronged approach to giving consent. It would first refer to a number of general (broadly defined) conditions (towards the data custodians), e.g., categorisation of data and which kind of stakeholders could use data. Then detailed final consent could be provided to a specific use as soon as a given research organisation directly contacts the citizen. In this dual approach, both the intermediary/altruistic organisation and the researcher should be informed about the other parties. This could be a time consuming but promising way to build trust between the different parties. It was also highlighted that there would be registers of intermediaries who are competing in a market to gain business as intermediaries in a new data sharing market that EU is establishing. So, they have all interests to have a competent offering that respects the needs of the citizens, so the market forces hopefully would do that element. Based on the offers, it would be possible to choose between intermediaries and, depending on the intermediary, citizens would receive data requests, which they would either accept or not. However, intermediary institutions that are being set up by the Data Governance Act, need to be trustworthy. Trust is a very important condition for those who do not want to be actively involved in making concrete decisions about the use of their data and for all those parties who do not want to get involved in the difficulties of withdrawing consent.

Participants also reviewed a case where a hospital provides data free of charge to an associated university for scientific purposes. This means that they can create databases for scientific purposes and these databases can be the subject of agreements with industry for further research or even licensing and access to the data. It is therefore important to understand the difference in altruism of the actors. In the model under discussion, the patients agree to the hospital using their data for research, the hospital makes the data available to the university, and ultimately the university can make the data available to industry, even for a fee. In this case, we are talking about a complex level of not simply non-profit or for-profit use of the public and private sectors, but an interlocking system of these relationships. Therefore, it was also underlined that we should avoid falling into the trap of thinking that a distinction should be made between private and for-profit, or public and non-profit organisations, because public benefit organisations can work for profit just as well.

During the discussion, participants also paid attention to the opportunities offered by technology, including advanced data protection technologies such as federated analytics, where data does not really move from the location of the data owner or data provider. Therefore, intelligent services can be created on the data without moving the data or using homomorphic encryption. Additional security and protection services can be built on top of an interesting technological response that can also create stronger safeguards in healthcare. However, in the meantime, it was also found important to realise that data economy today is not fair as such and how all these services are built according to big platform companies. Many service providers entice their customers to share their data on the

basis that they, and other customers or users, can get better, more accurate, personalised and secure services at the same or even cheaper prices. However, this business model may ultimately be perceived by the customer as providing (some) acceptable quality and price only if he shares his data and gives up the right to control it. Therefore, in order to gain, strengthen, maintain or regain trust, there is also a need to talk about how to make data altruism fair. There is therefore a need for fair and FAIR principles and rules to be applied too. These principles and rules should help both the consumer and the service provider to avoid situations, where a consumer sees no reason not to use a particular service because all of his or her groups (or even an entire local or even wider community) use it and would be excluded from those groups or communities. At the same time, he or she may be reluctant to use the service because he or she fears, rightly or wrongly, that his or her data will not be used in a truly fair way. Encouraging data altruism not only requires data that is findable, accessible, interoperable and reusable, but also fairness is part of this broader concept of Fairness.

In this area, it is important to consider that data sharing solutions based on different technological tools and business models are implemented primarily through human contact points. At the same time, we feel that we are a little disconnected from the data and there is always the danger that we will not be able to trace back where our data is going and where it is being told what. Yet it is important to know where my data and results are and to understand what happened to my data. However, the different people who make relationships are not able to handle the technology equally well, which can also be a cause for concern, as it has a negative impact on trust in the data management technology and business model and data quality.

In the end of the discussion session, brief information was provided to the participants about TEHDAS WP8 online consultation on the use of citizen data. Link to the survey was shared, and participants were asked to disseminate it.

4.4.3 Conclusion and next steps

The most important learning of the day was that differences and similarities between data altruism and other data sharing practices, as well as the advantages and disadvantages for the stakeholders, can be understood if it would be clear that the patient and citizen engagement is much wider than the stakeholder engagement, and it can be used in many ways. However, there are some reservations on the idea of no reward linked with data altruism, while distinction between the public and private sectors or for-profit and non-for-profit business models, may also raise concerns. It is worth to know what people's needs and priorities are, what they are willing to give information about, and what and how they choose to give information about.

The importance of accountability and how that is built into the future system as a sort of counterpoint to any sort of data donation and data altruism concept was clearly emphasized.

Attention was drawn to public concerns that there is no consensus on the nature of data altruism, as well as to the uncertainties about the meaning of general and public interest.

Participants agreed that there's a need for an essential element for building trust (e.g., through a platform) to give citizens an overview of where, how and to whom they can share or donate their data, and what the advantages of cooperating with one (for/non-for-profit) organisation are. This could facilitate to exploit the fact that people are able to make and control their decisions and make quite sophisticated trade-offs in their decisions. The idea of creating such a platform can be followed by another possible solution for the citizens to agree on the general principles of data sharing and use, and then on the specific final terms. This might be a two-pronged approach to giving consent. It would first refer to a number of general (broadly defined) conditions (towards the data custodians), e.g., categorisation of data and which kind of stakeholders could use data. Then detailed final consent could be provided to a specific use as soon as a given research organisation directly contacts the citizen.

Information about the opportunities offered by technology, including advanced data protection technologies such as federated analytics, where data does not really move from the location of the data owner or data provider, shall be disseminated too. However, technology enables (partly) unfair business models, therefore, in order to gain, strengthen, maintain or regain trust, there is also a need for fair and FAIR principles and rules to be applied too.

5 Data altruism – definition and use cases

Identifying the most important features for defining health data altruism structures and functions, it shall be underlined that from a high-level perspective many stakeholders can look at data altruism as the easier but suboptimal model of data sharing because individuals lose control on their data and have no incentive to manage their data for their own benefit or health. (While, from a democratic perspective, data intermediary which is described in the draft Data Governance Act (DGA) seems to them more optimal but also more complex than data altruism.)

There are several elements to be considered in this stakeholder statement, even if the definition in DGA change compared to the initial draft published by the European Commission:

“Article 2 (16) ‘data altruism’ means the voluntary sharing of data on the basis of the consent of data subjects to process personal data pertaining to them, or permissions of data holders to allow the use of their non-personal data without seeking or receiving a reward that goes beyond compensation related to the costs that they incur where they make their data available for objectives of general interest as provided for in national law, where applicable, such as healthcare, combating climate change, improving mobility, facilitating the development, production and dissemination of official statistics, improving the provision of public services, public policy making or scientific research purposes in the general interest”¹

From a functional point of view, it therefore makes sense to implement the DGA in a way that allows individuals keep control over their data and do not exclude the use of their data for their own benefit or health. Also, in parallel with data altruism organisations, the establishment of other types of data intermediary organisations should be promoted.

The starting point for understanding the clarity of ‘data altruism’ depends on the extent to which it becomes clear that sharing data does not in itself change the right to dispose of the data, and in particular does not affect ownership (since data in the classical sense has no owner).

Beyond the issue of control over the data and sharing in the value that can be created from its use, the willingness and ability of the individual to do so, and the skills required, are also fundamental. In this context, data shall be FAIR (findable, accessible, interoperable and reusable) and the structures shall be fair (transparent, equal, trustworthy and righteous), to increase and maintain trust in the structure among all actors. Trust, in addition, shall be strengthened by cyber security means and technologies for privacy protection. However, establishment and maintenance of trust depend on accountability (obligations related to accreditation) of intermediaries in the relationship with individuals and society. Building trust can also be supported through a platform to give citizens an overview of where, how and to whom they can share or donate their data, and what the advantages of cooperating with one (for/non-for-profit) organisation are.

An important consideration is that for individuals, personal benefit is more tangible than the public good. This is counterbalanced by regulatory instruments in the case of altruism, as its main characteristics include not only voluntarism, selflessness and (possibly) compassion, but also the pursuit of the public interest. However, while GDPR clearly states whose personal data is in the public interest, there are concerns that some uncertainties exist about the meaning of general and public interest. It is important that the benefits are proportionate to the risks and that the risks to individuals can be weighed against the general or public interest, and public interest does not necessarily be linked to public activities or to sound scientific activities and can include for-profit activities of companies.

¹ <https://data.consilium.europa.eu/doc/document/PE-85-2021-INIT/en/pdf>

Citizens' approach to the public interest can be improved by taking into account result of the SWOT on data altruism prepared and presented at the 2nd workshop in January 2022 (see table 2). Belonging to a community (as strength) and the ability to empower citizens and patients that makes use of greater data sources (as opportunity) can be built upon. At the same time, the risk of over reliance on donated data and varying uses of consent through European countries should be avoided or reduced, and the weakness in equity of access, which stems from low levels of digital and health literacy, should be countered.

While the 'data for direct service' approach can raise data protection concerns, as data can only be used for the purposes of the service under GDPR but not in return, the recognition that people with chronic conditions want to share their health data for research in hope of better treatment in the future, can help understanding how public interest contributes to data altruism.

Table 2 – Data altruism SWOT

<p style="text-align: center;">Strengths</p> <ul style="list-style-type: none"> • More choice in ways for engaging • Over time can generate feelings of belonging & community 	<p style="text-align: center;">Weaknesses</p> <ul style="list-style-type: none"> • Over reliance on donated data • Challenges in access and use of data • Variations in use of consent
<p style="text-align: center;">Opportunities</p> <ul style="list-style-type: none"> • Opening pre-existing data sources • Individuals become their 'own point of care' • Opportunities to combine health data with other social data 	<p style="text-align: center;">Threats</p> <ul style="list-style-type: none"> • How to maintain right to modify or remove consent • Economic costs • Equity of access

6 Next steps

Task 8.5 will prepare and launch a communication campaign to engage citizens, researchers and service providers for data sharing, to become active players of data altruism structures.

WP8AG members as well as Work Package 2 and Task 8.3 contributors will be involved in the preparation of the campaign, which is planned to be launched in September 2022.

The campaign will include the next WP8 workshop that will be organised in October 2022 and will end after the autumn Policy Forum of TEHDAS in November 2022.

Task 8.5 will prepare the next report on milestone M8.6 "Primary recommendations to foster GDPR-compliant data altruism mechanisms for the EHDS" by October 2022. In this work results introduced in the previous and the current documents (M8.4 and M8.5) will be utilized and completed by additional findings about broad consent and data altruism consent form.