

Towards
European
Health
Data
Space

Deliverable 8.2
**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
(including broad consent)**

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Contents

1 Executive summary	4
2 Overview of TEHDAS data altruism work.....	5
2.1 Introduction.....	5
2.2 Context.....	5
2.2.1 The European Union and international context	5
2.2.2 TEHDAS context.....	7
2.2.3 TEHDAS Work Package 8	7
2.3 Methodology	10
3 Lessons learnt.....	11
3.1 Main findings of the previous three TEHDAS data altruism reports.....	11
3.1.1 Main findings on data altruism definitions.....	11
3.1.2 Main findings of the stakeholder workshops.....	12
3.1.3 Main findings on GDPR-compliant data altruism mechanisms	13
4 Further analysis	16
4.1 Business models further analysed	16
4.1.1 Citizen science	24
4.2 GDPR-compliant application of data altruism practices further analysed	24
4.2.1 Privacy aspects of data sharing	24
4.2.2 An outline of the legal basis	25
4.2.3 The definition of data altruism in light of the EHDS Proposal	28
4.2.4 Technical and organisational aspects	31
4.3 The use of consent further analysed with a focus on broad consent	32
4.3.1 Types of consent	33
4.3.2 Broad consent	36
4.3.3 Examples from Member States and projects.....	42
4.4 Forward look.....	44
5 Recommendations to foster GDPR-compliant data altruism mechanisms for the EHDS... 46	46
5.1 Recommendations for the European policy makers in the health sector	46
5.2 Recommendations for the health data altruism organisations	47
6 Glossary	49
7 References	52
Annex 1 List of relevant projects, initiatives and use cases.....	55
Annex 2 Results from the stakeholder workshop 2023.....	59

1 Executive summary

The overarching aim of the Joint Action Towards the European Health Data Space (TEHDAS) is to develop the future policy, legal and technological framework for the sharing and secondary use of health data in the European Union. TEHDAS has a dedicated work package (work package 8) entitled Citizens (formerly called iCitizen), which specifically facilitates policy development on the role of citizens in the European Health Data Space (EHDS).

The objectives of work package 8 are to:

- better understand citizens' knowledge of, expectations, and trust in health data sharing and secondary use systems.
- empower citizens around health data and enable them to become actors of innovation as part of the future EHDS, including through enhanced data altruism practices.

This Report is informed by earlier reports prepared by work package, under Milestones 8.4, 8.5 and 8.6. which we briefly summarise. The original documents are available in full on the TEHDAS web page¹.

This Report builds on the above mentioned earlier documents, in particular the TEHDAS Milestone report 8.6 entitled '*Primary recommendations to foster GDPR-compliant data altruism mechanisms for the EHDS*' (hereinafter: Primary recommendations). In the Primary recommendations we summarised the main work package 8 findings on the engagement and involvement of citizens, data altruism definitions and mechanisms, as well data altruism organisations in the health sector. It did not yet include a more detailed analysis of certain fields, namely business models, aspects of the compliance with GDPR, and the use of consent with a focus on broad consent. It is this further analysis of the above-mentioned topics that is covered by this report. Finally, the report captures the main conclusions of our work and the discussions with our partners and stakeholder in the past two years, in the form of recommendations.

The European Commission's plan is the development of nine Common European data spaces, the first being the EHDS. Our focus in work package 8 is on citizens' engagement in general and health data altruism specifically.

In this report we specify recommendations to foster GDPR-compliant data altruism mechanisms for the EHDS, including how to adopt and harmonise identified good practices for **the construction of national or European health data spaces**, followed by specific recommendations for **data altruism organisations and policymakers**. Following the publication of the EHDS legislative proposal and as defined in the amended project proposal, the report also includes an analysis of the use of consent including broad consent in relation with data altruism practises. The authors of this report are alert to the fact that the framework

¹ TEHDAS web page: <https://tehdas.eu>

of EHDS and the secondary use of health data is evolving, thus we have tried to focus on some of the key issues and considerations for future work in this field. The conclusions of this report are clear that it will still be necessary to further examine the added value of health data altruism, and also how data altruism can best work for the secondary use of health data for scientific research or health policy purposes.

2 Overview of TEHDAS data altruism work

2.1 Introduction

The Joint Action Towards the European Health Data Space (TEHDAS) is an EU funded project of 25 EU/EAA and associated countries whose task is to work to improve cross-border use of health data for the benefit of citizens' health, for public health, research and innovation.²

The project was launched on February 1, 2021. It is funded by the Third Health Programme of the European Union and the European countries involved, and co-ordinated by the Sitra.³ The joint collaboration and work on the tasks of TEHDAS helps the member states, the European Commission and associated countries to develop and understand ideas and concepts which will help the achievement of the overarching aim of the JA TEHDAS; to develop future policy, legal and technical framework related to the secondary use of health data, and which also contribute to establishment of the EHDS.

2.2 Context

2.2.1 The European Union and international context

In the last few years, we have seen that our society is changing rapidly in response to new digital developments, technologies and innovations. As we use these new technologies, more and more data are created, to which individuals, as one of the data generators, also contribute.

To facilitate the creation of innovations based on data, and to also ensure, that the citizens benefit from these innovations, it is necessary to place the interests of the individual high on the agenda, in accordance with European values, fundamental rights and rules. Citizens' trust and accept data-driven innovations only if they are confident that any personal data sharing in the EU will be subject to full compliance with strict data protection rules.⁴

² TEHDAS project pages <http://tehdas.eu>

³ Joint Action for the European Health Data Space – TEHDAS. Sitra. <https://www.sitra.fi/en/projects/joint-action-towards-the-european-health-data-space-tehdas/>

⁴ European Commission. A European strategy for data. <https://digital-strategy.ec.europa.eu/en/policies/strategy-data>

As a result of great challenges and changes, which after the World War II affected the whole world, including the European continent, the Universal Declaration of Human Rights⁵ was created, shortly followed by the European Convention on Human Rights⁶.

The aforementioned historical legal documents state that no individual should be subjected to arbitrary interference in their private life, i.e., that everyone has a legal right to a private life.

Article 8 of the Charter of the European Union on Fundamental Rights⁷ defines the right for personal data to be protected, and that such data must be processed fairly for specified purposes and based on the consent of the person concerned or another legitimate basis laid down by law, as well as the right of access to data and to their rectification. Article 3 of the Charter states that everyone has the right for their physical and mental integrity to be respected. In medicine and biology, free and informed consent forms the basis of legal and ethical norms and practices regulating research and healthcare.

After the European Data Strategy laid the foundations for data altruism in various sectors, in 2022 the Data Governance Act (DGA)⁸ entered into force. The DGA creates trusted tools for data sharing based on data altruism, including recognised data altruism organisations, their establishment, and their responsibilities. The DGA creates a common minimum legal regime and governance in the EU in three key areas:

- 1) the re-use and secondary use of certain data held by public sector bodies,
- 2) the provision of data intermediation services; and
- 3) the provision of services based on “data altruism”, by data altruism organisations recognised in the Union.⁹

In addition to the European Data Strategy, related acts like the Digital Markets Act (DMA), the Digital Services Act (DSA), and the Artificial Intelligence Act (AIA) and the Data Act are useful in considering data altruism.^{10, 11}

In the European Data Strategy it is foreseen that “the Commission will promote the development of Common European Data Spaces in strategic economic sectors and domains

⁵ United Nations. The Universal Declaration of Human Rights. 10.12.1948
<https://www.un.org/en/about-us/universal-declaration-of-human-rights>

⁶ European Court of Human Rights. European Convention on Human Rights.
<https://www.echr.coe.int/Pages/home.aspx?p=basictexts&c>

⁷ Charter of Fundamental Rights of the European Union. OJ C 326, 26.10.2012, p. 391–407.
https://eur-lex.europa.eu/eli/treaty/char_2012/oj

⁸ European Commission. European Data Governance Act. <https://digital-strategy.ec.europa.eu/en/policies/data-governance-act>

¹⁰ Trust and Legal Certainty for the data-driven Economy? A look into the EU Data Governance Act - Osborne Clarke | Osborne Clarke. <https://www.osborneclarke.com/insights/trust-and-legal-certainty-data-driven-economy-look-eu-data-governance-act>

¹¹ Tobias Bräutigam et al. EU regulation builds a fairer data economy. Sitra working paper, 7.6.2022.
<https://www.sitra.fi/app/uploads/2022/06/sitra-eu-regulation-builds-a-fairer-data-economy.pdf>

¹² Milestone 8.6 Primary recommendations to foster GDPR-compliant data altruism mechanisms for the EHDS TEHDAS. 5.12.2022. <https://tehdas.eu/app/uploads/2022/12/primary-recommendations-to-foster-gdpr-compliant-data-altruism-mechanisms-for-the-ehds.pdf>

of public interest”, in practice the European Commission will support the development of nine Data Spaces, the first of which is “a Common European Health Data Space (EHDS), which is essential for preventing, detecting and curing diseases as well as for facilitating informed, evidence-based decisions to improve the accessibility, effectiveness and sustainability of the healthcare systems”.¹² Other data spaces may be set up to complete this initial list, such as the cross-lateral data space of Space Cooperative Europe supported by the EU which will target health data among other sectoral data and will have a vocation to connect itself with other health data spaces.¹³

The EHDS Proposal¹⁴ was developed to provide the legal framework for the EHDS. In Article 40, the Proposal refers to the provisions of the DGA relating to the regulation of data altruism practices, i.e., the processing of personal electronic health data by recognised data altruism organisations.

The DGA is the basis for the development of consent-based altruism with respect to individuals' health data. As stated in the European Data Strategy, the subsequent proposals for developing altruism reflect “European values, fundamental rights and the conviction that the human being is and should remain at the centre”.

2.2.2 TEHDAS context

TEHDAS is delivered through eight work packages focusing on involving stakeholders and citizens in the dialogue about the EHDS and the secondary use of health data. Topics covered under the work packages include the development of a governance model for cross-border cooperation on the secondary use of health data, ensuring sustainability and promoting reliability and compatibility of health data and access for secondary use.

This Joint Action is grounded on the principles of transparency, trust and citizen empowerment and has a dedicated citizen work package.

2.2.3 TEHDAS Work Package 8

TEHDAS aims to clarify the role of individuals in the secondary use of health data by including them in dialogue about the use of health data for research and policymaking.

To achieve this aim TEHDAS has set up the work package 8, Citizens. The work package aims to better understand citizens' perceptions towards the sharing of their health data, to

¹³ COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS A European strategy for data. COM 2020/66 final. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020DC0066>

¹³ <https://dhde.spacecoop.eu/>

¹⁴ European Commission, Directorate-General for Health and Food Safety. Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space. COM/2022/197 final. CELEX: 52022PC0197. Proposal for a regulation. 03/05/2022. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022PC0197>

improve citizens capacity to engage with data, and to improve citizen trust in data sharing by identifying ways to better inform, engage and empower citizens when it comes to the use of their health data¹⁵. The purpose of the work package is to provide evidence for decision-makers and healthcare professionals in Europe so that they can more effectively promote the secondary use of health data and the acceptance thereof by citizens. Work package 8 was led by the French Health Data Hub (France) and the National Directorate General for Hospitals, formerly called the National Healthcare Service Centre (Hungary).

Work package 8 explored and focused on two important areas, one is citizens' engagement in general, and the other is health data altruism specifically. Accordingly, the work was divided into the following tasks:

Task 8.1: Preparatory phase of online consultation in three pilot countries

Task 8.2: Conduct online consultation to collect citizens' perceptions

Task 8.3: Develop recommendations for the EHDS to ensure citizen sensitisation and engagement with health data

Task 8.4: Overview of national data altruism definitions and systems

Task 8.5: Recommend ways to foster GDPR-compliant data altruism mechanisms for the EHDS.

¹⁵ TEHDAS Work Packages. <https://tehdas.eu/packages/>

Within the framework of TEHDAS, milestone reports were published in which the aforementioned tasks were elaborated.^{16, 17, 18, 19, 20} The milestone report supports the two main deliverable documents of work package 8:

Deliverable 8.1: Qualitative citizen consultation conducted amongst key stakeholders (public, private actors, and patient / citizen groups) to assess citizen's perception of health data²¹, published on the TEHDAS website 31st March 2023.

Deliverable 8.2: 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 (including broad consent) (this Report): the final document of work package 8 which is a product of previous work focused on data altruism.

The basis of **Deliverable 8.1** took the form of a consultation platform, designed and commissioned by TEHDAS, using a mixture of qualitative and quantitative methods to better understand participants' attitudes towards the sharing of health data for secondary use, specially relating to how this could inform engagement with the EHDS, named the 'Healthy Data Consultation'.

The study found that individuals felt intrinsically tied to their own data and therefore should be respected as a partner in decision-making around the use and sharing of their data. As such, it was felt that inclusion of individuals in the governance of their own data could be a

¹⁶ Zoé Perrin, Louise Mathieu. Citizens' perception of and engagement with health data secondary use and sharing in Europe – a literature review. Milestone M8.1. Joint Action Towards the European Health Data Space – TEHDAS project. 25.11.2021. <https://tehdas.eu/app/uploads/2021/11/tehdas-citizens-perception-of-and-engagement-with-health-data-secondary-use-and-sharing-in-europe.pdf>

¹⁷ James Maddocks, Louise Mathieu, Nathan Courbon, Rosie Richards, Marlies Saelaert, Wannes Van Hoof. Healthy Data, an online citizen consultation about health data reuse – intermediate report. Milestone M8.2. Joint Action Towards the European Health Data Space – TEHDAS project. 30.7.2022. <https://tehdas.eu/results/tehdas-consultation-people-support-health-data-use-with-solid-safeguards/>

¹⁸ Marianne Bårtvedt van Os, László Bencze, Peter Bezzegh, Antal Bódi, István Csizmadia, Nanna Alida Grit Fredheim, Željka Gluhak, Zdeněk Gütter, Andrija Hermanović, Saara Malkamäki, Tatjana Pavešković, Marja Pirttivaara, Kornél Tóth. Presentation of a first set of data altruism definitions, use cases and findings. Milestone M8.4. Joint Action Towards the European Health Data Space – TEHDAS project. <https://tehdas-presentation-of-a-first-set-of-data-altruism-definitions-use-cases-and-findings.pdf>

¹⁹ László Bencze, István Csizmadia. 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. Milestone M8.5. Joint Action Towards the European Health Data Space – TEHDAS project. 5.7.2022. <https://tehdas.eu/results/tehdas-consults-stakeholders-on-data-altruism/>

²⁰ Zsófia Bulla, Zeljka Gluhak, Réka Kovacs, James Maddocks, Tatjana Paveskovic, Marja Pirttivaara, Rosie Richards. Primary recommendations to foster GDPR-compliant data altruism mechanisms for the EHDS Milestone 8.6. Joint Action Towards the European Health Data Space – TEHDAS project. <https://tehdas.eu/app/uploads/2022/12/primary-recommendations-to-foster-gdpr-compliant-data-altruism-mechanisms-for-the-ehds.pdf>

²¹ Published: <https://tehdas.eu/results/tehdas-consultation-citizens-support-the-secondary-use-of-health-data-when-it-matches-their-ethical-values/>

valuable way to ensure a working relationship could foster trust and promote the use of the EHDS. The final results can be found on the TEHDAS website²².

Citizens' desire for a clear framework for health data reuse demonstrated a general call for an overarching safeguard and included a general question for clarity and transparency regarding the framework in which health data reuse takes place. Therefore, it seems that the call for a framework was also a request to increase public awareness about or involvement in health data reuse and the way it is regulated.

There were a variety of statements on how this awareness should be realised and to what extent citizens should be involved in the establishment of a framework for health data reuse. Participants emphasised confidentiality, equality, individual freedom, solidarity and avoiding discrimination as the most important values.

It was concluded that a well-thought-out framework, taking into consideration ethical, legal, and societal dimensions is needed. The framework should be developed by policy makers, experts, and stakeholders in an open dialogue with citizens. The report about the online citizen consultation which was conducted within this work package can and hopefully will serve as starting point for discussions with European policy makers, experts, and stakeholders about the EHDS. The results of **Deliverable 8.1** should have provided „evidence for decision-makers and healthcare professionals in the European Union so that they can promote more effectively the secondary use of health data and the acceptance thereof by citizens”.^{23 24}

To achieve this, the deliverable was dedicated to identifying citizens' perceptions and attitudes on health data, ways of engaging citizens around their health data, defining health data altruism practices in the EU, as well as identifying key features, conditions, and determinants of integrating health related data captured and shared by individuals and data altruist organizations, in close alignment with the DGA.

2.3 Methodology

The methodology for the tasks related to data altruism (Deliverable 8.2) within work package 8 Citizens is comprised of four main elements:

- **Literature review** for mapping existing theory and best practice on data altruism in Europe. Key issues and keywords describing health data altruism were identified, according to the scope of literature review, relevant resources were selected and summarised.

²² TEHDAS consultation: Citizens support the secondary use of health data when it matches their ethical values <https://tehdas.eu/results/tehdas-consultation-citizens-support-the-secondary-use-of-health-data-when-it-matches-their-ethical-values/>

²³ Healthy Data, an online citizen consultation about health data reuse – intermediate report. TEHDAS Milestone 8.2 report 30.6.2022. <https://tehdas.eu/app/uploads/2022/07/tehdas-healthy-data-an-online-citizen-consultation-about-health-data-reuse-intermediate-report.pdf>

²⁴ EU Project Grant Agreement number 101035467 — TEHDAS, Annex 1, p. 34.

- **Stakeholder workshops and consultations** for discussing the most challenging topics on citizen-centric solutions and models for use cases. Partners and the Advisory Group of TEHDAS, as well as the wider stakeholder community were invited to interactive online workshops on 17-19 January 2022 to discuss citizen-centric solutions and models for use cases of health data altruism and systems for data sharing, as well as structures and functions for the future EHDS.
- **Consolidation and realignment**, including the Primary recommendations, for combining the extensive research and results of the consultations from the preparatory stages, and for re-evaluating data altruism priorities for TEHDAS following the publication of the EHDS Proposal.
- **Final recommendations** developed in alignment with stakeholders' views, based on applicable legislative instruments especially the GDPR, the DGA, and the EHDS Proposal, as well as taking into consideration best practice examples. The final recommendations included in this Report were discussed at a workshop on health data altruism organised in Brussels on 27 April 2023.

All the deliverables were prepared with the support of the Advisory Group of TEHDAS work package 8.

3 Lessons learnt

Three TEHDAS milestone documents (Milestones 8.4, 8.5 and 8.6) were published before the preparation of this Report. The main findings of these milestone documents are presented in the following chapters. In this Report, where the term data altruism is mentioned, we refer to data altruism in health.

3.1 Main findings of the previous three TEHDAS data altruism reports

3.1.1 Main findings on data altruism definitions

The Milestone 8.4 document contained basic findings to help understand obstacles and enablers to improve policymaking and to facilitate decisions on what data generated and held by citizens can be used, how and by whom in a manner compliant with GDPR.

The document contributed to improving the capacity of citizens 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 in health.

The document aimed to respond to the questions on the specificities of data altruism in health compared to many other fields, on the obstacles and enablers for achieving specific objectives of work package 8, but also to the question of why governing data altruism in the context of Common European data spaces requires dedicated legislation in EHDS.

The available literature on this topic, as well as the number of use cases and examples are relatively limited. The work on Milestone 8.4 was carried out before the final adoption of the DGA, and therefore it also covered the definition of data altruism. The adopted definition of data altruism in DGA, as well as further provisions of the DGA addresses the purposes of

data sharing in detail, and, although the range of data subjects is not specified in it, several provisions apply to rights and procedures pertaining to them.

The set of classified use cases contains twelve groups, from the health data types through the organisations in charge of the data altruism system, to the tools of citizen involvement in the system.

Milestone 8.4 identified a few projects (examples) that have already seen some success at the national, European, and international levels offering good practices for altruism structures and functions for the future EHDS. As consent was discussed as a key topic, it was concluded that in cross-border and cross-organisational data exchange, parties may face challenges due to different forms of consent. It was also agreed that final conclusions would be drawn in the further work (Milestones 8.5 and 8.6).

3.1.2 Main findings of the stakeholder workshops

January 2022 workshops

An important milestone of work package 8 (Milestone 8.5) was the EU-wide multi stakeholder workshop, discussing updated definitions, needs, solutions, experiences, and good practices of data altruism structures and functions for the future EHDS. A 3-day workshop was organised in January 2022 where nine experts gave presentations, and participants came from 21 European countries and the USA.

The document summarising the workshop tried to answer certain questions about the most important features for defining health data altruism structures and functions, and about the key lessons from best practices in data sharing structures and functions for future EHDS.

Key conclusions from the workshop include: the need for reaching consensus on the nature of health data altruism, the central role of the citizens in sharing their data; taking into consideration various active and/or passive mechanisms of citizens engagement; encouraging the involvement of citizens to the EHDS; the need to further discuss data valorisation or monetisation; the need to have simple and user-friendly methods and tools for sharing health data; the need for an essential element of building trust that would help citizens see how their data is used; and, that data collected should be in line with the FAIR principles (findable, accessible, interoperable and reusable).

As a starting point, it was clear that it is necessary to encourage the involvement of citizens in the EHDS. It was also added that citizen and patient engagement is much wider than stakeholder engagement, and there were various active or more passive mechanisms for citizen engagement which should also be considered.

An important conclusion from the workshops on health data altruism is that the establishment and maintenance of trust depend on accountability of intermediaries in the relationship with individuals and society. An essential element for building trust is the facilitation of citizens' and patients control over their data, as well as transparency on where, how and with whom health data are shared, and what the benefits and risks of data sharing are.

Another important conclusion was that the establishment of various types of data sharing organisations should be promoted. Under various data sharing options, it will also be important to study how citizens can influence the distribution of the revenues generated by secondary use of health data.

It was recommended that the DGA should allow individuals to keep control over their data and to use their data for their own benefit or health. Individual benefit is an important aspect for citizens and patients, beside the secondary use of health data for purposes of public interest. In addition, the perception of general or public interest may be different in various groups or countries. The issue of data valorisation or monetisation was discussed but not into details, and further discussion on this topic seems to be useful, as well as on value created with data.

The importance of social media in engaging with people was discussed, as well as the specifics of social media, given that not everyone uses social media in the same way. The risk was emphasised that people with lower level of digital literacy could be left behind and, in this way, not engaged.

April 2023 workshop

The final recommendations in this Report have been developed in alignment with stakeholders' views including via a dedicated workshop in Brussels on 27 April 2023. The workshop to discuss the recommendations was hosted by the Hungarian team with support from the Hungarian Permanent Representation, the European Commission and partners from Belgium, Finland, France, and the UK.

The interactive workshop focused on three topic areas, discussed in sections 4.1, 4.2 and 4.3 below. These topic areas were health data altruism organisations and business models, citizens' involvement, GDPR-compliant health data altruism practices, and consent as a legal basis. These topics areas were key to the development of the final recommendations and required further stakeholder engagement, feedback and testing to best inform the recommendations. For each topic, stakeholders were invited to vote on a series of statements aimed at helping to refine the draft recommendations. This was followed by a guided discussion to draw out the nuances and supporting evidence behind the poll results. The full list of statement and poll results can be found at Annex 2. Stakeholders' views and the poll results are included in the preceding sections of this report which discussed each of these topics in detail and draws together policy, legal and research analysis alongside stakeholders' views. Together these information sources form the evidence base for the final recommendations in this report.

3.1.3 Main findings on GDPR-compliant data altruism mechanisms

The Primary recommendations document (referred to in Chapter 1) dealt with the issues of citizen science and with different forms of consent, where this topic is described in detail however the main findings are summarised below.

It was the DGA that for the first time legally defined the term 'data altruism' founding these organisations and the scope of their responsibility. The Primary recommendations dealt with

the term ‘data altruism’ in detail, as well as setting out the responsibilities of data altruism organisations and the role of competent authorities in the health sector.

The document further discussed the issue of the Union register of recognised data altruism organisations, and the conditions that a legal person needs to fulfil for the registration. It also deals with the obligations of recognised data altruism organisations in health including the manner their work is performed, the requirements for safeguarding rights and interests of data subjects and data holders regarding their health data as special category of data, and security measures for the storage and processing of non-personal data that they have collected based on data altruism. The competent authorities will monitor and oversee the compliance of recognised data altruism organisations with the requirements laid down in DGA.

It was stated that recognised data altruism organisations should be able to collect relevant data directly from natural and legal persons or to process data collected by others. Processing of collected data could be done by recognised data altruism organisations for objectives of general interest which they establish themselves which may include various processing purposes. Processing by third parties can also be allowed. In cases where recognised data altruism organisations are data controllers or processors as defined in GDPR, they have to comply with that Regulation.

It was recommended that the clear procedures by which recognised data altruism organisations give natural or legal persons the possibility to process the data in its possession (and especially the health data) were not left to the national legislation of each individual member state, but rather that the standardisation of these procedures be at the level of EU legislation. It was also stressed that the success of the EHDS will depend on a strong legal basis for processing in line with EU data protection law, on the establishment of a strong data governance mechanism and effective safeguards for the rights and interests of natural persons that are fully compliant with the GDPR. Besides, all requirements in relation to giving or withdrawal of the consent, need to be fulfilled. Within the compliance with the GDPR, the issue of the legal basis including consent is a key issue. The meaning of consent is a highly context dependent term, with a number of different legal frameworks defining consent, each with nuanced but important differences. Member states have adopted different approaches to consent, which may be an obstacle to cross-border data sharing. Under certain circumstances, consent may also not be the relevant legal basis and legitimate interest or others, may be more appropriate.

The main ethical point discussed was the commercialisation of health data. Citizens want to see benefits to society from the reuse of health data, but they do not want to see a market for the buying and selling of the same data. This was also a key finding of the WP8 citizen consultation which concluded that the valorisation or monetisation of data requires further discussion, particularly on key issues including how to predict the value created with data, different models, a model acceptable to citizens, and ethical issues.

The WP8 citizen consultation also found that in spite of recognising certain benefits or need to involve commercial actors, it was a common trend among citizens to voice concerns about their involvement. Many citizens consulted associated commercial actors with a higher risk of abuse and negative impact on the public. They also frequently put into question the compatibility between pursuing both the common good and financial interest and doubt

commercial actors' good intentions. These concerns about commercial actors' intentions and potential misalignment with what citizens considered an appropriate and desirable secondary use prompted some citizens to suggest that conditions and safeguards in place should change depending on the actor involved. Therefore, citizens suggested conditions should change when this type of user is involved. For example, they mentioned different limitations that should be in place, such as the purposes for which they can access data, their involvement in some data management respects (such as data governance, data storage or data processing), or their access to only certain types of data e.g., only anonymised data. Furthermore, they called for more transparency on how these conditions are fulfilled. Another important matter was how to guarantee that benefits could be shared or returned in some way to society and individuals. There, citizens considered that a control over benefits generated should be ensured, and that some benefits should flow from these actors' access to data, such as free services, affordable treatments, or publication of results. Some also referred to financial reward for individuals or payment to public services. Finally, they required information and transparency over the involvement of commercial actors, their intentions, and the results of their use of data. In essence, citizens expected certain conditions for accessing data to be in place to guarantee that the intention behind the secondary use is in line with their values. For further information, please consult Deliverable 8.1; Qualitative study to assess citizens' perception of sharing health data for secondary use and recommendations on how to engage citizens in the EHDS (see tehdas.eu website). Whereas stakeholder views on the participation of private sector entities from the April workshop were generally more positive. When asked "whether private sector entities should be encouraged to increase their participation in and contribute to the secondary use of health data" 72% of the respondents voted "agree". It must be noted that the workshop was attended by a small sample of individuals and organisations and is not necessarily representative of all stakeholders, however the poll result does tally with existing research and commentary on stakeholders' views on the use of health data, such as the expert interviews carried out under Deliverable 8.1.

The follow-up discussion provided an opportunity to dissect the vote, allowing us to draw the following conclusions on why citizen and stakeholders may have different levels of receptiveness to the involvement of private sector entities. Firstly, stakeholders communicated that they accept that private sector entities will have a role (of some sort) in the EHDS as well as recognised health data altruism organisations under DGA. From the WP8 consultation it was evident that citizens have not reached the same conclusion and are still debating whether there should be a role for industry. However, both stakeholders and citizens were united in their views that private sector entities should be subject to appropriate safeguards, which may be more stringent than those required of public sector bodies and the need for reciprocity. By "reciprocity" citizens and stakeholders meant that they expect private entity organisations to feed their findings (as appropriate based on IP rules) back into the system and ensure that benefits are shared between all parties. For both groups reciprocity was an expected condition of private sector entities using health data in data altruism and beyond. Attention should therefore be paid to communication and information sharing methods, as health data altruism practices governed by the DGA should be available equally to different groups of people.

4 Further analysis

In the preceding chapters we outlined the main findings of the work package with regards to the engagement and involvement of citizens, and issues that the DGA regulates such as data altruism definitions and mechanisms, as well recognised data altruism organisations. The Primary recommendations (Milestone 8.6) did not include a more detailed analysis of certain fields, namely business models, the certain aspects of the compliance with GDPR, and the use of consent with a focus on broad consent. This further analysis is part of the following chapters of the present Report.

4.1 Business models further analysed

DGA covers three main areas: access to data held by public sector bodies, regulation of data sharing services through data intermediaries, encouraging data altruism and sharing data for the objectives of general interest.

Data intermediaries connect data subjects or data holders with data users and facilitate the flow of data. They will function as neutral third parties that connect individuals and companies with data users. Data intermediaries cannot monetise the data and will have to comply with strict requirements to ensure neutrality and avoid conflicts of interest. Data altruism is about individuals and companies giving their consent or permission to make available data that they generate voluntarily and without reward to be used in the public interest including the fields of research or health. Entities that make available relevant data based on data altruism will be able to register as 'data altruism organisations recognised in the Union'.²⁵

Both data intermediation and data altruism can lead to new business models and further development of data space ecosystems. Data altruism organisations recognised in the Union and data intermediaries are close to each other and in some cases their business models might be overlapping. Two clear differentiators under the DGA are that recognised data altruism organisations must be not-for-profit organisations and that notification for Data Intermediaries is mandatory rather than voluntary. Other differences include that recognised data altruism organisations are based on 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, furthermore, that there is no direct benefit for sharing the data.

Various business models of recognised data altruism organisations and data intermediaries are given in Table 1. The reason business models of both data altruism organisation and data intermediaries are presented is that the main difference is the non-profit requirement for

²⁵ European Commission. Data Governance Act explained. <https://digital-strategy.ec.europa.eu/en/policies/data-governance-act-explained#ecl-inpage-l4ihmeih>

recognised data altruism organisations. So, business models of intermediaries can be business models of recognised data altruism organisations as well, in a non-profit form.²⁶

Table 1. Business models for recognised data altruism organisations and data intermediaries.

Business model	Description	Source
Crowdfunding model – relevant for data intermediaries	Utilising crowdfunding platforms to raise funds. Supporters can get rewards or other perks. In accordance with Article 2(16) of the DGA, recognised data altruism organisations should not be ‘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’.	European Commission, Directorate-General for Education, Youth, Sport and Culture, De Voldere, I., Zeqo, K., Crowdfunding: reshaping the crowd’s engagement in culture, Publications Office, 2017
Data controls model – relevant for data intermediaries	Intermediary offers a solution for sharing data (including sensitive data) in a secure, targeted, and controlled manner with full insight into who uses the data. Data owners are offered a menu of options what (or parts of) data to share with whom, for what purpose and for what period. The value comes from the technical excellence of the product and the data expertise of the intermediary. Therefore, the intermediary is dependent on buy-in from key stakeholders and on	Susha et al. Towards Generic Business Models of Intermediaries in Data Collaboratives From Gatekeeping to Data Control. 2020.

²⁶ Pilar del Castillo. Regulation of the European Parliament and of the Council on harmonised rules on fair access to and use of data (Data Act) Compromise amendment (EPP, S&D, Renew, Greens, ECR) 7.2.2023.

https://www.europarl.europa.eu/meetdocs/2014_2019/plmrep/COMMITTEES/ITRE/DV/2023/02-09/06_CA_DataAct_EN.pdf

	<p>standardisation and interoperability efforts.</p> <p>In the case of both recognised data altruism organisations and data intermediaries, if personal data is involved the proposed needs to be specific and comply with GDPR.</p>	
Data cooperative – a special type of data intermediary	<p>Intermediaries that collect data from its members, process and monetise the pooled data, and compensate the members for their individual contributions. These cooperatives establish an ecosystem of trust among its members and are attractive to consumers for three basic reasons: control, bargaining power, and compensation. Enables shared data spaces controlled by data subjects. However, it should be noted that data intermediaries in the meaning of the DGA cannot transform, enrich or aggregate data for adding substantial value to it without establishing a commercial relationship between data holders and data users (Article 2(11)(a) DGA). It also may not work for not-for-profit data altruism organisations (Art. 2(16) DGA).</p>	<p>Mehta et al. Can data cooperatives sustain themselves? 2021.</p> <p>Data cooperative: A new intermediary on the horizon. Emre Bayamlioğlu, KU Leuven, 2021</p>
Data custodian – relevant for data intermediaries	<p>Enables privacy-protecting analysis or attribute checks of confidential data, for example, via the application of Privacy Enhancing Technologies (PETs).</p>	<p>Centre for Data Ethics and innovation. Unlocking the value of data: Exploring the role of data intermediaries. 2021.</p>
Data exchange – relevant for data intermediaries, or	<p>Operates as an online data platform where datasets can be advertised and accessed -</p>	<p>Centre for Data Ethics and innovation. Unlocking the value of data: Exploring the</p>

<p>registered data altruism organisations (not-for-profit basis)</p>	<p>commercially or on a not-for-profit basis.</p>	<p>role of data intermediaries. 2021</p>
<p>Data gatekeeper model – relevant for data intermediaries</p> <p>NB: Gatekeeper here is the general term and is not in the meaning of gatekeeper in the Digital Markets Act.</p>	<p>Intermediary serves as a trusted third party that negotiates terms of access to previously closed data by users selected through a call for proposals. Value comes from the legitimacy of the process.</p>	<p>Susha et al. Towards Generic Business Models of Intermediaries in Data Collaboratives From Gatekeeping to Data Control. 2020.</p>
<p>Data trust – relevant for data cooperatives</p>	<p>Provides fiduciary data stewardship on behalf of data subjects. In data trusts, individuals or entities take on a fiduciary duty to control and make decisions on data. Data subjects authorise the individual or entity stewarding their data on their behalf for the benefit of a wider group.</p> <p>Regarding recognised data altruism organisations, there is no fiduciary duty in the DGA.</p>	<p>Centre for Data Ethics and innovation. Unlocking the value of data: Exploring the role of data intermediaries. 2021.</p>
<p>Donation-based model – relevant for data intermediaries</p>	<p>Rely on donations from individuals and organisations to fund the operations. Possibly also seeking out grants and funding from foundations or government agencies supporting their mission.</p> <p>It should be noted that ‘data donation’ has different purposes and way of operating than data altruism.</p>	<p>Bietz, M., Patrick, K. and Bloss, C., 2019. Data Donation as a Model for Citizen Science Health Research. Citizen Science: Theory and Practice, 4(1), p.6.</p>

<p>(Industrial) data platforms – relevant for data intermediaries</p>	<p>Provide shared infrastructure to facilitate secure data sharing and analysis between companies.</p>	<p>Centre for Data Ethics and innovation. Unlocking the value of data: Exploring the role of data intermediaries. 2021.</p>
<p>Information-as-a-service model – relevant for data intermediaries</p>	<p>Intermediary provides data visualisations to targeted segments to ease the understandability of data for decision-makers. Value comes from ease-of-use and quality of decision support; therefore, the intermediary is dependent on users.</p> <p>Data intermediaries have to connect supply and demand through creating commercial relationships between data subjects/holders and data users.</p>	<p>Sushi et al. Towards Generic Business Models of Intermediaries in Data Collaboratives From Gatekeeping to Data Control. 2020.</p>
<p>Membership model – relevant for data intermediaries</p>	<p>Individuals and organisations pay membership fees and receive benefits like access to data and tools, networking opportunities.</p>	<p>ChatGPT April 2023</p>
<p>One-stop-shop model</p>	<p>Intermediary aggregates previously siloed data from multiple sources into a central data repository to ease discoverability, comparability, and analysis of data. Value comes from scale; therefore, the intermediary is dependent on data providers contributing data. It should be noted that data intermediaries in the meaning of the DGA cannot transform, enrich or aggregate data to add substantial value to it without establishing commercial relationships</p>	<p>Susha et al. Towards Generic Business Models of Intermediaries in Data Collaboratives From Gatekeeping to Data Control. 2020.</p>

	between data holders/data subjects and data users (Article 2(11)(a) DGA).	
Partnership model – relevant for data altruism organisations or data intermediaries	<p>Partnering with other organisations like academic organisations or governmental agencies for data and resource sharing, thus achieving common goals. Also, recognised data altruism organisations need to make their data available for purposes of general interest</p> <p>Data intermediaries have to connect data supply and demand through creating commercial relationships between data subjects/holders and data users.</p>	Global Partnership for Sustainable Development Data
Personal information management system – relevant for data intermediaries	Seek to give data subjects more control over their personal data.	Centre for Data Ethics and innovation. Unlocking the value of data: Exploring the role of data intermediaries. 2021.
Service model – relevant for data intermediaries	Offer independent data-related services like data collection, analysis and visualisation, either for fee or pro bono, without commercial relations. This model may not be appropriate for registered data altruism organisations, as they have to be separate from any entity that operates on for-profit basis, due to their not-for-profit structure.	European Commission, Directorate-General for Informatics, Publications Office of the European Union, Data sharing as a service: will data services remove intellectual property rights from the picture, and at what cost? Publications Office of the European Union, 2021
Trusted third party – relevant for recognised data altruism organisations	Provides assurance to those looking to access confidential datasets that the data is fit-for-purpose (e.g., in terms of	Centre for Data Ethics and innovation. Unlocking the value of data: Exploring the

	quality or ethical standards), without commercial relations.	role of data intermediaries. 2021.
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As data altruism organisations are not-for-profit according to the DGA, they must prioritise social impact over profit, and their business models should reflect this, compared to intermediaries’ business models. Data altruism organisations recognised in the Union should be transparent about funding sources and ensure that they do not accept funding that can create conflicts of interest.

Some of the obstacles for these business models and the data ecosystems are lack of knowledge, lack of incentives for data sharing, cost of data sharing and access, missed opportunities to use data in the public interest, regulatory and ethical risks, commercial and reputational risks, and balancing privacy and transparency.^{27, 28} E.g., there are risks associated with unfair business models where companies may start pooling and selling health datasets shared by recognised data altruism organisations²⁹. In addition, it is also important to take into account the quality of health data which needs to be ensured before sharing the data. As a result, recognised health data altruism organisations established under the DGA should further study the possible business models and choose the models that best suits them. During the April 2023 workshop 75% of respondents voted that data altruism organisations in health should define their role in the future legal framework. According to stakeholders, the role of data altruism organisations could complement the EHDS, providing different and supplementary data. For example, by providing personal data and playing a role in improving data quality or enriching the datasets during the data donation process.

Furthermore, it was concluded by stakeholder consultation within Milestone 8.5, that the establishment of various types of data sharing organisations should be promoted including incentives for individuals and organisations. An important question is how citizens can be incentivised to share data. It was concluded by the literature review presented in the TEHDAS Milestone 8.4 document, that in order to develop robust data sharing 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 and presenting value for participants is highly important.

In general, incentive is a thing that motivates or encourages someone to do something. They are external measures designed and used to influence motivation and behaviour of

²⁷ Centre for Data Ethics and innovation. Unlocking the value of data: Exploring the role of data intermediaries. 2021. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1004925/Data_intermediaries_-_accessible_version.pdf

²⁸ Data-driven business models. the role of legal teams in delivering success. A pan-European study. ECLA & Osborne Clark. 2023. https://www.osborneclarke.com/system/files/documents/22/09/30/DDBM_Study_20220930.pdf

²⁹ In addition, it is also important to take into account the quality of data which needs to be ensured before sharing the data. T’odora Lalova-Spinks et al. The application of data altruism in clinical research through empirical and legal analysis lenses. Front. Med. 30.3.2023. 10:1141685. doi: 10.3389/fmed.2023.1141685

individuals, groups, or organisations.³⁰ Incentives are all the rewards and punishments that providers meet in the institutions they work or under which they operate and the specific interventions they provide.³¹ Impacts of incentives are different in different contexts and situations. The core idea is around tangible or intangible compensation, explicit or implicit ways to influence individuals or groups of people to exert more time and effort in order to achieve personal as well as organisational goals.³² In the private sector the key issue of incentives is to develop a competitive edge over competitors, while in the public sector it is to increase customer value for the target groups and reduce costs for taxpayers. Incentive-driven work can be entrepreneurship, employment, or volunteering – or health data-sharing based on data altruism.³³

It can be rewarding the patients themselves or incentivising the healthcare professional in convincing the patients to share their data for a secondary use such as taking part to a given health research program on a given disease.

The different categories of incentives include monetary and non-monetary, financial, and non-financial, direct or indirect, internal or external, formal or informal, positive or negative, material incentives, solidary incentives and purposive incentives, administrative incentives, economic incentives and reputational incentives, and competitive or collaborative.³⁴ The possibility to contribute to the general good and wellbeing is viewed by citizens as a true incentive. Nevertheless, another clear incentive for patients is in general having high quality data to improve their own health but this aspect rather falls outside of the scope of data altruism. The question of data sharing and data altruism incentives in health is certainly difficult and important.³⁵ In the era of artificial intelligence and machine learning, the need of non-biased data is crucial and thus understanding possible impacts of incentives is needed.³⁶

The data altruism mechanism as a concept and data altruism organisations in health can provide incentives for data sharing to individuals and other organisations, based on e.g.:

- Access to data
- Access to analysis tools

²⁹ Incentive Systems: Incentives, Motivation, and Development Performance. UNDP 2015. <https://www.undp.org/publications/incentive-systems-incentives-motivation-and-development-performance>

³⁰ WHO. The World Health Report 2000 -Health Systems: Improving Performance. 2000. <https://reliefweb.int/report/world/world-health-report-2000-health-systems-improving-performance>

³² Oun Tep. Exploring the importance of employee incentives and their effectiveness in improving quality performance in Cambodian public organisations. Master thesis. Victoria University of Wellington. 2015. <https://researcharchive.vuw.ac.nz/bitstream/handle/10063/4152/thesis.pdf>

³²Marja Pirttivaara. Incentives in the renewal of the public sector and services. Internal report. Sitra. 2015.

³⁴ *ibid.*

³⁵ Anisa Rowhani-Farid, Michelle Allen, Adrian G. Barnett. What incentives increase data sharing in health and medical research? A systematic review. *Res Integr Peer Rev.* 2017 May 5;2:4. doi: 10.1186/s41073-017-0028-9. Erratum in: *Res Integr Peer Rev.* 2017 May 23;2:7. PMID: 29451561; PMCID: PMC5803640.

³⁶ B. Carballa-Smichowski, N. Duch-Brown. To pool or to pull back? An economic analysis of health data pooling. JRC Technica Report. JRC Digital Economy Working Paper 2021-06. <https://joint-research-centre.ec.europa.eu/system/files/2021-12/jrc126961.pdf>

- Information about incidental findings
- Collaboration opportunities
- Learning and understanding opportunities
- Recognition with appreciation
- Social impact when encouraging participation and partnership
- Possible tax benefits.

It was highlighted by the stakeholders that the control of individuals over their data, societal benefits as well as individual benefits of data sharing are important factors. During the April workshop, stakeholders also highlighted the citizens wish for granularity in their control of their health data as a key incentive to their involvement in data altruism. Therefore, it can be concluded that the implementation of the DGA should allow individuals keep control over their data and do not exclude the use of their data for their own benefit or health. It would also be important to assess how citizens can influence the distribution of the revenues generated by the secondary use of health data.

4.1.1 Citizen science

Data altruism and recognised data altruism organisations regulated by the DGA can support citizen science in health as these practices facilitate individuals' contribution and participation in scientific research, by creating, collecting, and analysing health data and contributing to health research projects.

Data altruism and recognised data altruism organisations in health can support citizen science by:

- providing data-sharing platforms,
- offering data analysis tools,
- ensuring data privacy and security, and
- promoting data literacy.

This means helping the democratic development of scientific research and scientific results will be better available to the public. In general, this can help to develop positive attitude and deeper understanding of citizens towards science and innovations and will also promote scientific and digital literacy of health data and various advanced tools.

4.2 GDPR-compliant application of data altruism practices further analysed

4.2.1 Privacy aspects of data sharing

The chapter below first covers general considerations on the legal requirements of data sharing followed by an analysis of some of the data protection aspects of data altruism regarding health data as special category of data. The analysis relies on the relevant legal regulations such as the GDPR, the horizontal framework established by the DGA, and the sectoral rules of the EHDS Proposal. The DGA is relevant because it creates the legal ground for the provision of services based on data altruism and by recognised data altruism organisations which is the scope of the present document. The use of certain technological solutions based on advanced cryptographic techniques is also discussed as a privacy factor.

First, it seems useful to give an overview of the general privacy aspects of sharing health data. The protection of personal data is an integral part of the trust and confidence that individuals and organisations place in the development of data sharing ecosystems. Success will also depend on the development of strong data governance and effective safeguards for the rights and interests of individuals that are fully compliant with the GDPR.

The recent EU legislative initiatives and measures to facilitate data sharing are sectoral and cross-sectoral instruments that aim to make data accessible by regulating the re-use of data, including personal data. The group of data users has expanded to include new actors such as private sector data sharing platforms, data marketplaces, government data repositories and other types of organisations, as outlined by the DGA. Rules for these types of entities can be found in the GDPR, the DGA and the EHDS Proposal. Under the GDPR, they must ensure that data subjects' rights are enforced, which requires, among other aspects, a clear legal basis for data processing. The conditions for data use must be clearly defined for data subjects before data sharing activities start and updated, as necessary.

Enforcing the rights of data subjects can be a challenge in a shared environment with multiple actors, data processors, IT service providers, etc. What makes this challenge even more complex are the possible changes over time. The data subject may decide at any time to withdraw consent to data processing or to restrict data processing for certain data users. Art. 89 of the GDPR contains rules on possible derogations from data subjects' rights in the research context.

Data processing policies, consent forms, contractual commitments over secondary use between data controllers or between data controllers & data processors (when having a vocation to themselves become data controllers) and codes of conduct can be useful tools in implementing data protection requirements.

4.2.2 An outline of the legal basis

A widely agreed conclusion of the discussions in the framework of TEHDAS was that data altruism as defined and regulated by the DGA relies on the trust of individuals, taking into consideration the special nature of health data when it comes to health data altruism. Using health data brings several technical and legal aspects such as the question of what happens with data, the purposes of sharing data, time-limit of data storage, duration of consent, and amount of personal information. The key factors of trust from a legal perspective are privacy, security, and transparency.

From the privacy perspective, one of the fundamental requirements is the valid legal basis. At the same time, we must keep in mind that ensuring the data protection rights of individuals, is a fundamental requirement of all data management, also in the context of the future EHDS. Nevertheless, the present analysis focuses on the issue of the legal basis, which is also important for the interpretation of data protection rights. This outline of the legal basis is also intended as an introduction to the analysis of consent in the context of health data altruism in the next chapters.

In the following paragraphs, we briefly outline certain aspects of the legal basis with a particular focus on the secondary use of health data.

The term ‘secondary use of data’ does not appear in the GDPR which refers to the further processing of data. The definition of secondary use is included in the EHDS Proposal however, it was recommended by the EDPB-EDPS joint opinion to be further reconciled with the GDPR.³⁷ The definition covers several purposes and activities, of which in the following, we focus on the purposes of scientific research only, but keeping in mind the broader meaning of secondary use.

The GDPR sets out a number of specific rules concerning data protection in scientific research, including how to choose the proper legal basis:

- Under Recital 50, further processing for scientific or historical research purposes or statistical purposes is considered to be compatible with the initial purpose of the data collection.
- Under Recital 159, processing of personal data for scientific research purposes should take into account the Union's objective of achieving a European Research Area” [Article 179(1) TFEU] which can be interpreted as a requirement of balance between privacy and scientific research.
- Various legal grounds may apply to the processing of health data as a special category of data: substantial public interest, healthcare provision and management, public health, and scientific research [GDPR 9(2) (g)-(j)].in connection with Article 6 i.e., legal obligation, vital interest, legitimate interest of the data controller like researcher or a third party may also serve as legal grounds.
- The choice of the legal basis is also important for certain data protection rights e.g., the ‘right to be forgotten’ is not applicable if personal data are processed based on public interest or legal obligation, or for research purpose but in those cases, the legal basis would usually establish a retention period [GDPR Article 17].

For the interpretation of GDPR, it is important to refer to the opinion of the European Data Protection Board (EDPB). The EDPB has stated³⁸ that ethical standards cannot be interpreted to mean that only the explicit consent of data subjects can be used to legitimise the processing of health data for scientific research purposes, and that it is not incompatible with ethical standards that other legal grounds can be invoked for the processing of health data for scientific research purposes. The EDPB added that the requirement of informed consent can be understood as an additional safeguard of the GDPR for scientific research purposes. In the field of clinical trials, the EDBP discouraged the use of consent as a legal

³⁶ EDPB-EDPS Joint Opinion 03/2022 on the Proposal for a Regulation on the European Health Data Space.

³⁸ EDBP Document on response to the request from the European Commission for clarification on the consistent application of the GDPR, focusing on health research (adopted on 2 February 2021) https://edpb.europa.eu/our-work-tools/our-documents/other-guidance/edpb-document-response-request-european-commission_en

basis, as the freely given characteristic of the consent may be a challenge, and a power imbalance may occur between the data controller and the data subject.³⁹

Within the recent legislative developments, it is important to examine the provisions on the legal basis for the processing of health data for secondary use. The EHDS Proposal specifies certain provisions of the GDPR but does not modify them. Recitals 37 and 50 of the EHDS Proposal detail the legal bases for secondary use of health data, which will be: substantial public interest, healthcare provision and management, public health and scientific research [GDPR 9(2) (g)-(j)], and the legal basis for requesting access to data is the performance of a task carried out in the public interest or for reasons of legitimate interest. Article 34 of the EHDS Proposal lists the legitimate purposes of the secondary use of data while Article 35 defines the prohibited purposes.

As regards the issue of the legal basis of the secondary use of health data, although not part of data altruism, it should be noted that the draft report of the European Parliament on the EHDS Proposal⁴⁰ introduced a new aspect, namely the right to opt-out, in part or in full, for some or all of the purposes of secondary use, which is a significant new element compared to the Proposal and therefore needs careful analysis.

As regards the national legislation on the legal basis, it is worth recalling an earlier TEHDAS recommendation, that member states should aim to allow the collection and use of health data in the form of a public interest or legal obligation through a legal basis for primary use, which would allow for a higher level of secondary use, if necessary.⁴¹

To sum up, various legal bases can be applied for the secondary use of health data based on GDPR, and a shift towards data processing based on public interest can be observed. Nevertheless, in case of data altruism the legal ground is consent as defined in the DGA, in the meaning that processing of personal data within data altruism is based on the consent of the data subjects. In practice, different types of GDPR consent may be applied as described in the chapter on consent below. Data subjects may choose to limit their consent to certain conditions or purposes which is also an interesting aspect of broad consent. When considering the most appropriate type(s) of consent for data altruism it is important to narrow the scope of the analysis to recognised data altruism organisations covered by the DGA that operate in the health sector. This specific use case must be separated from the wider European debate on legal basis for secondary use of data in general. In doing so, we are able to be more precise and suggest options which while suitable for health data altruism, may not be suitable as a wholesale solution.

As regards the introduction of an opt-out in the legal framework for secondary uses of health data, as it was proposed during the negotiations on the EHDS Proposal, it is recommended

³⁹ The application of data altruism in clinical research through empirical and legal analysis lenses. Teodora Lalova Spinks, Janos Meszaros, Isabelle Huys. *Front. Med.*, 30 March 2023 *Sec. Regulatory Science* Volume 10 – 2023. <https://doi.org/10.3389/fmed.2023.1141685>

⁴⁰ 2022/0140 (COD), 10.2.2023

https://www.europarl.europa.eu/doceo/document/CJ43-PR-742387_EN.pdf

⁴¹ TEHDAS D5.2 Document “Recommendations for European countries when planning national legislation on secondary use of health data”, Recommendation 12.5

to study its administrative burden, as well as practical implementation, especially in cases where individual consent is difficult to manage. Such cases are for example data processed in large databases, aggregated data, or when previously processed data cannot be removed from the research process at the time of the opt-out notification. It is important to note that opt-out is not the same as the legal basis of consent. Also, it needs to be taken into account that the right to erasure (also known as the ‘right to be forgotten’) is not applicable for certain legal grounds like public interest [GDPR Article 17], and that EU or national legislation may restrict certain data protection rights [GDPR Article 23].

4.2.3 The definition of data altruism in light of the EHDS Proposal

In the DGA, the concept of data altruism refers to the voluntary and proactive consent of data subjects to the use of their data for objectives of general interests, such as scientific research or the improvement of public services. Thus, the legal basis for data processing is typically the consent of the data subjects. This does not imply a waiver of privacy and data protection rights, either for the data subject or for the organisation processing the data. The principle of accountability requires that recognised data altruism organisations have to document and, where necessary, justify the origin of the data and the availability of consents given by the data subjects.

As regards data altruism in health, Article 40 of the EHDS Proposal states that when processing personal electronic health data, recognised data altruism organisations shall comply with the rules set out in Chapter IV of the DGA. Where recognised data altruism organisations process personal electronic health data using a secure processing environment, such environments shall also comply with the requirements set out in Article 50 of this Regulation. Health data access bodies shall support the competent authorities designated in accordance with Article 23 of the DGA in the monitoring of entities carrying out data altruism activities.

The *interplay between the DGA and the proposed EHDS Regulation* requires further analysis which also affects data altruism covered by the DGA in the health sector⁴². In this document, we can only attempt to point out some key issues on how the definition of data altruism under the DGA can be applied in the context of the EHDS.

The main characteristic elements of the definition of data altruism under the DGA are the following ones:

- voluntary sharing of data, by data subjects or data holders,
- based on consent, or in case of data holders, a permission,
- without seeking reward (beyond compensation for costs),
- for public interest purposes (as provided for by national law).

The main issue we focus on from the perspective of compliance with the GDPR is the legal basis for processing health data as special category of data. According to Recital 37 of the EHDS Proposal, as described above, the legal basis for the purpose of the initial processing

⁴¹ EDPB-EDPS Joint Opinion 03/2022 on the Proposal for a Regulation on the European Health Data Space, Chapter 3.3. and point 97.

remains intact which means that in data altruism the voluntary sharing of health data can be considered as the initial purpose, based on the consent of the data subjects.

As regards data altruism, this is regulated by the DGA, therefore, when discussing health data altruism, we have to start from the provisions of the DGA, but it is a key issue how recognised health data altruism organisations will function within the framework to be created by the proposed EHDS. Therefore, this issue is discussed below. In line with data protection rights, data subjects can specify or limit their consent. Individuals may decide for what purposes or for what types of activities they may or may not give consent to. However, if recognised data altruism organisations qualify as data holders in the EHDS, then the data altruism organisation will have a legal obligation to provide the data to the health data access body, and the data applicant will have to prove a legitimate purpose.

In this way, we see the interplay between the DGA and EHDS at work (as illustrated in the diagram below).

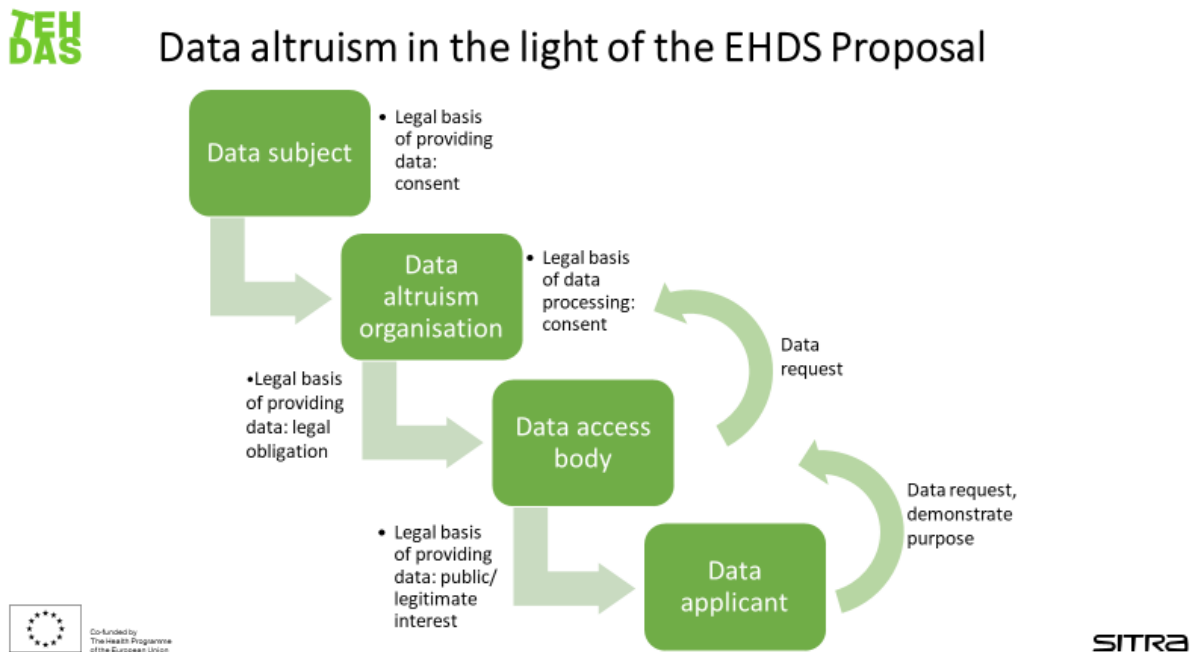


Figure 1: The interplay between the DGA and the EHDS.

Another issue to be considered is the relevance of voluntary data sharing in the framework of the EHDS, as large data sets will be available to data applicants based on grounds such as public interest or public health. Therefore, recognised data altruism organisations should examine what added value they can provide, for example in terms of quality of health data, or availability for health research.

Citizens who participated in the consultations within work package 8 expressed a strong sense of altruism which included a fair and equitable benefit for all, regardless of the choices of others. They strongly disagreed that only those who choose to share their data should benefit from health research resulting from the re-use of their data, and that those who chose not to allow access to their unidentified data should pay more for medical care. The

disagreement with these two statements shows a strong sense of altruism among participants and suggests that although the public may have rather complex and nuanced view about how and when to share and reuse their health data, they strongly believe in societal benefit from that use. Ensuring that public and private research is for the public good should clearly be a priority for decision-makers seeking to increase support for health data sharing. In addition, policy makers should seek to ensure that policies do not unintentionally disadvantage those who do not participate in research or the reuse of their health data.

Barriers to citizens' support for health data altruism can be identified in a number of areas, ranging from concerns about privacy and security to a lack of understanding of the concepts of data altruism and sharing health data as special category of data. These findings highlight the importance of active and ongoing public engagement on health data altruism and the importance of strong governance and transparent data altruism processes.

The DGA provides the strong governance and legal framework required by citizens. For example, it sets out that the European Commission should adopt, by means of delegated act, a rulebook for recognised data altruism organisations which will provide for information, technical and security requirements as well as communication roadmaps and interoperability standards.

Compliance with that rulebook will be a requirement for the registration of recognised data altruism organisation. The rulebook will also include clear and transparent information on the use of data, the tools for giving and withdrawing consent or permission, and measures taken to avoid misuse of data shared with a data altruism organisation, and in this way, the rulebook can be a useful tool to further clarify the data protection aspects of data altruism, also in the health sector. This rulebook shall be prepared in close cooperation with recognised data altruism organisations and relevant stakeholders. The European Commission is working on the delegated act that will establish the rulebook.

Public interest or general interest is also a core issue, both as a possible legal basis for data processing and as an important aspect for citizens when they decide to share their personal data. The GDPR and the DGA include several references to the public interest or general interest, but no precise definition is provided. Under the GDPR, where processing is necessary for the performance of a task carried out in the public interest, it should have a basis in EU or member state law (Recital 45), and it follows that a task assigned by law to entities as public interest will mean such a task.

The GDPR provides guidance on the types of personal data that fall within the scope of public interest and clarifies that data may be processed not only by public but also by private bodies for reasons of public interest (Recitals 128, 158). The DGA states that “support to scientific research should also be considered to be an objective of general interest” (Recital 45), and, within the definition of data altruism lists examples of general interest such as healthcare and scientific research (Article 2 para. 16.).

It was emphasised during the discussions within work package 8 that the benefits of data processing should be proportionate to the risks, and that risks to individuals should be weighed against the general or public interest.

One of the conclusions of the literature review presented in the Milestone 8.4 report was that there are several approaches to the public interest. A key distinction is that some people believe 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 the public interest can include for-profit activities of companies when they are in the interest of society, such as therapeutic development. The Citizen consultation also pointed out: “While the EHDS proposal refers to the ‘public interest’, it seems that this concept does not grasp the entire scope of what citizens have in mind when they refer to ‘common good’.” Clarifying concepts such as data ownership, privacy, public interest, commercial interest, common good, is “essential for citizens to understand how secondary use happens, but also to ensure collective agreement on all aspects of the data relationship.” It was also emphasised that “major ethical principles that should be respected included the realisation and support of, on the one hand, the common good and inclusion, and, on the other hand, autonomy and control. These values reflect the dual nature of health data, as being both a social asset and an individual, very personal entity.”

Ethical issues of public interest should also be mentioned. The primary recommendations highlighted that the role of private sector organisations in the re-use of health data is an ethical issue that deserves attention. The results of work package 8 showed that many citizens perceive a conflict of interest between the commercial interests of for-profit organisations and individual and societal benefits, while others recognise the need for private sector participation. The legal, technical and governance separation of data sharing operations from the for-profit organisations to which they are associated could be a possible solution.

4.2.4 Technical and organisational aspects

Although technical and organisational aspects are not the main scope of the present report, they are an important aspect of compliance with the GDPR. In relation to technical and organisational aspects, as well as data security, the TEHDAS Milestone 7.6 document “Report on architecture and infrastructure options to support EHDS services for secondary use of data”, published on the TEHDAS website, provides a detailed analysis, including computation (e.g., secure processing environment) and communication infrastructure options.

Although the issue of technical and organisational measures is not directly within the scope of this document, it seems important to mention some of its aspects due to its relevance in processing health data as special category of data in the context of health data altruism.

Despite the potential of the concept of data sharing and EU policy and law in this area, appropriate technical and organisational measures and how to implement them in practice still need to be considered. European legislative initiatives on data sharing involve the processing of large amounts of data, including personal data. Therefore, in addition to the need to be in line with the GDPR, it is important to remove legal uncertainty about roles and obligations with regard to data sharing. Furthermore, in order to exploit the potential of data sharing within the EU, practitioners could be provided with guidance on which technologies and techniques are appropriate to ensure compliance with data protection and data security principles.

The DGA provides for a secure processing environment, and a key principle of the EHDS Proposal is to ensure the secure and free movement of electronic health data across the Union, as declared in Recital 27, including the mandatory self-certification scheme for EHR systems and compliance with the EU-wide cybersecurity certification framework.

There are a number of commonly used cryptographic techniques (asymmetric encryption, pseudonyms, etc.) that are already been recognised as being capable of mitigating privacy risks. With the emergence of new concepts such as data spaces and data intermediaries, the emerging risks cannot always be adequately managed by such techniques alone. This is because data subjects want to preserve the confidentiality of the data they share, as they may not know in advance with whom they are sharing data or may want to share datasets.

It is important to note that, in addition to legal compliance (e.g., GDPR), the majority of technologies rely on PKI-based (public key infrastructure) asymmetric cryptography, the emergence of quantum computing and the impact on the security of asymmetric encryption currently in use must be taken into account. Once data-sharing infrastructures and services are in place, we cannot expect them to be discontinued due to possible inadequacies of asymmetric ciphers. This is where cryptographic agility with the quantum resistance becomes important, as it allows switching between algorithms, cryptographic primitives, and other encryption mechanisms without the need for significant changes to the entire IT system or process.

In order to ensure of preventive protection and reduce the risk of data leakage, it should be assumed that, whether market companies or public organisations, there are no longer any real secrets and no fully useful cryptography protection. This requires entirely new protection strategies, and the trend is increasingly towards zero trust.

As far as recognised data altruism organisations under DGA are concerned, it is important to ensure that high quality and non-biased health data is accessible and available for research and public good purposes, for example via data sharing platforms and tools. In relation to data security, it means that health data as special category of data is stored securely and can be easily accessed by researchers and other stakeholders. Also, methods and tools for sharing health data need to be simple and user-friendly, and they must guarantee the privacy of citizens, as well as data security.

4.3 The use of consent further analysed with a focus on broad consent

The preceding chapter discussed certain aspects of the legal grounds applied under the GDPR and the EHDS Proposal, and the analysis continues below with the topic of the consent of the data subjects, which is typically the legal basis for sharing and processing personal data in data altruism, under Article 2(16) of the DGA.

Within data altruism under the DGA, the scope of the present document is health data altruism. The aim of this chapter is to explore the use of consent in health data altruism, as consent is one of the main aspects of trust for individuals when it comes to special categories of data such as health data. As a starting point, it is important to emphasise that we perceive consent primarily an ethical issue, and it can be considered as a legal topic in the light of ethics. As a reminder, Article 4 (11) of the GDPR requires that “consent shall be freely given, specific, informed and the unambiguous indication of the data subject’s wishes by which he

or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her (...)"

4.3.1 Types of consent

The literature review in Milestone 8.4 provided an initial set of findings concerning how requirements for consent and accessibility are dealt with by distinct types of data altruism practices (incl. identification of potential barriers and opportunities). It was concluded that in practice, several types of consent are applied in health research. In the document the main forms of consent used in practice were also identified. It should be noted that some of the forms may differ from the GDPR concept consent and may thus not function as a GDPR legal basis.⁴³ For the present analysis, it seems useful to include this list again, amended at some points, as follows.

Table 2: Types of consent

Broad consent	A comprehensive and generally formulated consent. Open in terms of data re-use, usually in the context of secondary use of data for research purposes. Possible definitions are described in the sections of this Report on broad consent.
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 can withdraw at any time.
Electronic consent	Electronic consent (eConsent), also known as electronic informed consent (eIC), is a system that obtains informed consent from a research subject or their legally authorised representative (LAR) using electronic-based processes and systems. The information is presented via computers, tablets, websites, smartphones rather than on paper. The digital format makes it easier to educate subjects about the study using a

⁴² Based on especially the IMI Big Data for Better Outcomes Programme (BD4BO):
<https://bd4bo.eu/index.php/publications/>

	variety of media, such as text, graphics, audio, video, podcasts, and passive and interactive websites. ⁴⁵ Electronic consent form is often understood as a digital version of a clinical trial informed consent form.
Layered consent	Often refers to a form of consent that allows participants to choose between options.
Meta-consent systems	It can be added to the list of the types of consent 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.
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. In the context of secondary use for the purposes of scientific research, it is also important to take into account the approach of the opt-out, where the participants are given brief information about taking part in a research study unless they do not wish to participate. A possible model is the 8-point model developed in the UK, the consent with opt-out where participants are informed of the importance of information, the role of law in protecting participants, the right to opt out, and the suggestion that opting out does not apply to anonymised information or exceptionally when there is a mandatory legal requirement or over-riding public interest. ⁴⁴
Partnership model	Similar to dynamic consent. Bidirectional communication process for consent that provides opportunities for researchers and participants to update consent over time.
Targeted consent	Disclose extra information during a standard informed consent procedure.
Tiered consent	Allows participants to personalise consent based on a range of factors including

⁴⁴ National Data Guardian for Health and Care | Review of Data Security, Consent and Opt-Outs. 6.7.2016. <https://www.gov.uk/government/publications/review-of-data-security-consent-and-opt-outs>

	preferences for future uses of their data and whether or not they wish to be recontacted before any future use.
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.

In certain sectors, assumed consent (also implied or implicit consent) is known but it is not included into the above list as it is considered incompatible with the GDPR. One of the available definitions is: informational consent done in the absence of any formal recorded or verbal indication of agreement or any overt action (or inaction) on the part of the data subject.⁴⁵

Further to the above list, there are other aspects which can be taken into account in relation to the types of consent, like scope of consent related to users of the data, the purpose of the use of the data, the types of data records, or the level of de-identification. The Citizen consultation has pointed out that anonymisation was the most discussed safeguard by citizens, but this concept will need more clarification.

The stakeholder discussions within Milestone 8.5 of TEHDAS raised further ideas regarding consent like the banking model. It was mentioned that parallelism with banking could simplify many issues, e.g., data portability, especially from the citizens' perspective.

An important question in the context of health data altruism under the DGA is which types of consent are the most appropriate to use in practice, e.g., modular consent, multi-layer consent forms, or broad consent. Regarding the European data altruism consent form referred to in Article 25 of the DGA, it will be adopted as an implementing act, in line with the requirements of GDPR. It is not expected that the European data altruism consent form would specify any of the consent types mentioned above, because they are not defined in legislation. In practice, however, recognised data altruism organisations under the DGA that operate in the health sector will probably have the flexibility to consider choosing between the types of consent they use, which will be constrained by the consent requirements in the GDPR.

An ethical challenge is, as it was described by the Primary recommendations that consideration also needs to be given to those who make an informed choice not to engage in health data altruism. As such, data altruism practices in health covered by DGA cannot be implemented in ways that limit the benefits or impact upon the equality of service provision.

Another important aspect for the implementation of consent rules in health data altruism will be the interplay between the DGA, the EHDS Proposal, and the GDPR, which is not yet

⁴³ Assumed Consent. Digital Health Europe. <https://digitalhealtheuropa.eu/glossary/assumed-consent/>

entirely clear. According to the DGA, consent for data altruism falls under the provisions of the GDPR, however, data altruism consent is sometimes understood as a new model in the literature reviewed.⁴⁶ Legally, consent as a legal basis for data altruism is governed by the GDPR, while the European data altruism consent form under the DGA will be a tool to facilitate data exchange, not a legal basis.

Under the GDPR, personal data cannot be collected for unspecified future purposes, however, in case of the secondary use of data it is not always possible to foresee the further use of data, and the same question can be raised in the context of health data altruism. Furthermore, as we explained in relation to the legal basis, the secondary use of health data will mainly be based on public interest or similar legal grounds under EHDS Proposal. While data altruism is consent-based, making data available under the EHDS will be based on legal obligation. Therefore, the interplay between the DGA, the GDPR and EHDS Proposal (see Figure 1 above) would need further analysis, as was recommended by the EDPB-EDPS Joint Opinion on the EHDS.⁴⁷

4.3.2 Broad consent

In the following sections, we will examine the type of broad consent, which has become increasingly important in the secondary use of health data, especially for scientific research, and compare it with some of the above listed consent types.

With broad consent at the beginning of data collection people are asked whether they are willing to share their data. While broad consent is not defined by law, various definitions are available, just to mention the following ones:

- The act of gaining one consent for multiple potential future research projects.⁴⁸
- A process whereby participants consent to the use of their samples and data for future unspecified research.⁴⁹
- Describing potential future use of data for research and healthcare in very general terms when a patient/participant declares consent⁵⁰.

In this document we use the definition quoted in the glossary: “Consent for an unspecified range of future research subject to a few contents and/or process restrictions”. Broad consent is less specific than consent for each use, but more narrow than open-ended permission

⁴⁶ The application of data altruism in clinical research through empirical and legal analysis lenses. Teodora Lalova Spinks, Janos Meszaros, Isabelle Huys. *Front. Med.*, 30 March 2023 Sec. Regulatory Science Volume 10 – 2023. <https://doi.org/10.3389/fmed.2023.1141685>

⁴⁶ EDPB-EDPS Joint Opinion 03/2022 on the Proposal for a Regulation on the European Health Data Space

⁴⁷ Hallinan, D.: Broad consent under the GDPR: an optimistic perspective on a bright future. *Life Sciences, Society and Policy* (2020) 16:1 <https://doi.org/10.1186/s40504-019-0096-3>

⁴⁹ Thomas Zima, David N. Weisstub (Editors): *Medical Research Ethics Challenges in the 21st Century*. Springer Nature Switzerland AG 2023 <https://link.springer.com/book/10.1007/978-3-031-12692-5>

⁴⁹ Medizin Informatik Initiative – Medical Informatics Initiative, Germany. <https://www.medizininformatik-initiative.de/en/start>

without any limitations. In principle, there can even be several types of broad consent, ranging from a simple general formulation to complex structures that allow for a number of conditions.

Broad consent is not referred to as such in the GDPR but can be derived from its Recital 33, in line with the interpretation of the EDPB⁵¹: as it is often not possible to fully identify the purpose of personal data processing for research purposes at the time of data collection, data subjects can give their consent to certain areas of scientific research or only parts of research projects to the extent allowed by the intended purpose.

The usual interpretation of the EDPB opinion is that broad consent can only be used in exceptional cases. However, according to a different interpretation the text of the GDPR suggests that the legislator aimed to support broad consent.⁵²

The EDPB has added that the GDPR cannot be interpreted to allow for a controller to navigate around the key principle of specifying purposes for which consent of the data subject is asked. The EDPB's interpretation also suggests that where purposes for data processing cannot be specified at the outset, Recital 33 allows for a more general description of the purpose, however, it cannot be applied to undefined future projects.⁵³ Therefore, when research purposes cannot be fully specified, a controller must seek other ways to ensure the essence of the consent requirements are served best, for example, to allow data subjects to consent for a research purpose in more general terms and for specific stages of a research project that are already known to take place at the outset. In addition, adequate safeguards should be in place.

Recital 33 of GDPR is taken further by Recital 50 of DGA by saying that in accordance with GDPR, scientific research purposes could be supported by consent to certain areas of scientific research where in keeping with recognised ethical standards for scientific research or only to certain areas of research or parts of research projects, however the DGA does not provide for further clarification.

The EDPB and the EDPS in their Joint Opinion 03/2021 on the DGA draft proposal noted that the content of Recital 38 of the draft should be part of the substantive part of the regulation, namely the specification of broad consent, accompanied by a clear distinction between (1) consent to areas of scientific research, (2) further processing for scientific or historical, or statistical purposes, and (3) the processing for the purposes of general interest. This has not been changed in the adopted version, as it is only part of Recital 50.

⁵¹ EDPB Document on response to the request from the European Commission for clarifications on the consistent application of the GDPR, focusing on health research. February 2021. https://edpb.europa.eu/our-work-tools/our-documents/other-guidance/edpb-document-response-request-european-commission_en

⁵¹ Dara Hallinan, D. Broad consent under the GDPR: an optimistic perspective on a bright future. *Life Sci Soc Policy* 16, 1 (2020). <https://doi.org/10.1186/s40504-019-0096-3>

⁵³ EDPB Guidelines 05/2020, para 156; also in: EDPB Document on response to the request from the European Commission for clarifications on the consistent application of the GDPR, focusing on health research, para 26

We can observe a slight difference between the wording of GDPR when mentioning purposes, for which consent is to be used, and the wording of DGA saying data processing operation, without further defining its meaning. The relation of these two expressions has to be further clarified, as a study also concluded⁵⁴.

The stakeholder discussions within Milestone 8.5 of TEHDAS identified an ethical challenge, that in certain current data sharing practices with broad consent may fall short of the GDPR requirement to have consent for all purposes of data use.

Consent to be used for data altruism in general may be based on a harmonised consent form, as regulated in Article 25 of DGA. It says that where personal data are provided, the European data altruism consent form shall ensure that data subjects are able to give consent to and withdraw consent from a specific data processing operation in compliance with the requirements of the GDPR. This is where the question arises, which type of consent will be used. In the following, we review and compare some of the types of consent that are dealt with in the literature in the field of health research reviewed.

As regards dynamic consent, this model was proposed as a solution, which would allow patients to maintain control over their data and receive information about the uses of their data in medical research, as opposed to opt-out. The reason is that a dynamic consent model would be a transparent, flexible, and user-friendly means to maintain public trust in the use of electronic patient records in medical research⁵⁵. Another publication, on the contrary, argues that dynamic consent poses additional risks, like the withdrawal of consent by patients in response to project-specific information and does not offer substantial benefits over broad consent⁵⁶.

An overview of various consent models also states that dynamic consent options through interactive interfaces have the potential to accommodate different consent approaches in healthcare, protect individuals' interests over time and make individuals equal partners in research-related activities, while criticism includes the administrative burden of dynamic consent, and concerns about patients' potentiality to interfere with the research processes and their ability to express their preferences in related activities.⁵⁷

⁵⁴ The application of data altruism in clinical research through empirical and legal analysis lenses. Teodora Lalova Spinks, Janos Meszaros, Isabelle Huys. *Front. Med.*, 30 March 2023 Sec. Regulatory Science Volume 10 – 2023. <https://doi.org/10.3389/fmed.2023.1141685>

⁵⁵ Williams H, Spencer K, Sanders C, Lund D, Whitley EA, Kaye J, et al. Dynamic consent: a possible solution to improve patient confidence and trust in how electronic patient records are used in medical research. *JMIR Med Inform.* 2015;3 (1):e3. Epub 2015/01/15. doi: 10.2196/medinform.3525. PubMed PMID: 25586934; PubMed Central PMCID: PMC4319083.

⁵⁶ Sven Zenker et al. Data protection-compliant broad consent for secondary use of health care data and human biosamples for (bio)medical research: Towards a new German national standard. *J Biomed Inform.* 2022 Jul; 131:104096. doi: 10.1016/j.jbi.2022.104096. Epub 2022 May 25. PMID: 35643273.

⁵⁷ Workshop Proceedings: Informed Consent in Biobanking—from the Key Barriers, Challenges, and Perceptions to Digital Innovations: ISBER Virtual Annual Meeting and Exhibit, May 14–16, 2021. [Desislava Ivanova; Panagiotis Katsaounis. *Innovations in Digital Health, Diagnostics, and Biomarkers* \(2022\) 2 \(2022\): 16–26. https://doi.org/10.36401/IDDB-21-07](https://doi.org/10.36401/IDDB-21-07)

Dynamic specific consent allows participants, by using an online platform for the consent process, to decide on a case-by-case basis on their participation in research activities, and in this way respects their autonomy but it carries the risk of 'consent fatigue' in requiring participants to routinely click to agree. Similarly, like dynamic specific consent, the meta consent model is also considered as an alternative to broad consent as research subjects can choose between consent options, thus it respects individual autonomy more adequately, however, it also carries risks related to the 'consent fatigue', the digital divide, as well as its administrative burden.⁵⁸

The model of tiered consent, sometimes also referred to as multi-layered consent, can be regarded as a compromise between specific consent and broad consent. The main difference is that tiered consent provides the possibility to choose the broadness of the individual consent. In the consent procedure, questions are asked to determine the scope of the individual consent, which can range from study specific to broad consent. The options are formulated along the lines of issues of ethical relevance, individual or societal, e.g., disease types in the scope of future research, sharing data with other institutions, or the return of information about incidental findings. Administrative burden, 'consent fatigue', and the digital divide can again be mentioned, as potential risks.⁵⁹

A study of 838 German cancer patients showed that they were in favour of the secondary use of their clinical data. Most participants expressed acceptance of the broad consent model, 59 %.⁶⁰ In another study with 1580 respondents in Japan, 61 % preferred autonomy-based consent (specific or dynamic consent) and 24 % preferred broad-type consent (opt-out or broad consent), and marital status, gender, and privacy concerns were significantly associated with the preference.⁶¹ There might be a big variation of attitude measurement results, depending on the way of what is explained and asked as consent issues might be difficult to understand for the big audience. Future work is needed.^{62, 63}

Also, the question of possible bias of health data due to attitudes towards different consents (and incentives) is important. Opt-in procedures resulted in more consent bias compared with

⁵⁷ Wiertz, S., Boldt, J. Evaluating models of consent in changing health research environments. *Med Health Care and Philos* 25, 269–280 (2022). <https://doi.org/10.1007/s11019-022-10074-3>

⁵⁸ Wiertz, S., Boldt, J. Evaluating models of consent in changing health research environments. *Med Health Care and Philos* 25, 269–280 (2022). <https://doi.org/10.1007/s11019-022-10074-3>

⁶⁰ Anja Köngeter et al. Patients' Willingness to Provide Their Clinical Data for Research Purposes and Acceptance of Different Consent Models: Findings From a Representative Survey of Patients With Cancer. *J Med Internet Res*. 2022 Aug 25;24(8):e37665. doi: 10.2196/37665. PMID: 36006690; PMCID: PMC9459939.

⁶¹ Oikawa M, Takimoto Y, Akabayashi A. Attitudes of the Public Toward Consent for Biobank Research in Japan. *Biopreserv Biobank*. 2022 Dec 19. doi: 10.1089/bio.2022.0041. Epub ahead of print. PMID: 36576410. Attitudes of the Public Toward Consent for Biobank Research in Japan

⁶² Cumyn A, Ménard JF, Barton A, Dault R, Lévesque F, Ethier JF. Patients' and Members of the Public's Wishes Regarding Transparency in the Context of Secondary Use of Health Data: Scoping Review. *J Med Internet Res*. 2023 Apr 13;25:e45002. doi: 10.2196/45002. PMID: 37052967; PMCID: PMC10141314.

⁶³ Antonia Vlahou et al. Time to Harmonize Law and Research Ethics? *Hypertension*. 2021 Apr;77(4):1029-1035. doi: 10.1161/Hypertension.AHA.120.16340. Epub 2021 Feb 15. PMID: 33583200; PMCID: PMC7968961.

opt-out procedures. In one recent Dutch publication opt-in consenting led more likely to individual being males, with higher level of education, higher income, and higher socioeconomic status.⁶⁴

Finally, it is worth referring to a publication where it is recommended to assemble a shared toolkit for existing consent models.⁶⁵

A comparison of advantages and risks of the types of consent highlighted, based on our primary findings, can be found in the table below:

Table 3: Advantages and risks of certain consent types

Consent types	Advantages	Risks
Specific consent	Individual autonomy	Power balance Interference with research process
Dynamic consent	Accommodate different consent approaches	Administrative burden Interference with research process
Dynamic specific consent Meta consent	Individual autonomy Possibility to choose between consent options	Administrative burden 'Consent fatigue' Digital divide
Tiered consent Multi-layered consent	Compromise between specific and broad consent Possibility to choose the broadness of individual consent	Administrative burden 'Consent fatigue' Digital divide

⁶⁴ Yvonne de Man Y et al. Opt-In and Opt-Out Consent Procedures for the Reuse of Routinely Recorded Health Data in Scientific Research and Their Consequences for Consent Rate and Consent Bias: Systematic Review. *J Med Internet Res*. 2023 Feb 28;25:e42131. doi: 10.2196/42131. PMID: 36853745; PMCID: PMC10015347.

⁶⁵ Loosman I, Nickel PJ. Towards a Design Toolkit of Informed Consent Models Across Fields: A Systematic Review. *Sci Eng Ethics*. 2022 Aug 30;28(5):42. doi: 10.1007/s11948-022-00398-x. PMID: 36042065; PMCID: PMC9427926.

Furthermore, the mix of opt-in and opt-out solutions can also be applied where preferences for different types of data and purpose of use can be specified, like: always share = opt-in / never share = opt-out / ask for consent.

It can be concluded that there are arguments *pro* and *contra* the different types of consent, and to select the optimal one, the characteristics of the given research should be considered, as well as other aspects like ethics and the given cultural background where the research is conducted. Equity must also be a primary factor so that the use of consent remains unbiased. This conclusion should also be taken into account when a European data altruism consent form or forms will be designed for data altruism in the health sector, as regulated by the DGA.

As regards broad consent, based on our above analysis, it seems to be a possible solution to reconcile scientific research and data protection. It facilitates future unspecified research, and at the same time provides individuals with control over their personal data. A further advantage is its relatively low administrative burden. A legal risk is however, that broad consent may fall short of the requirement to have consent for all purposes of data use for using the legal basis of consent under GDPR, and in this way the control of citizens over their personal data may be hindered. Furthermore, the necessary clarification is a prerequisite for informed consent⁶⁶, and in case of broad consent it may be a risk if the data subject is not fully informed, in other words, there is a risk of not meeting the threshold that informed consent needs to actually be informed. When data subjects give their broad consent, the specificities of data sharing and the given situation should be taken into account, including especially the following aspects:

- the type of data to be shared,
- the data sources e.g., EHRs or public sources,
- the purpose of each data processing activity,
- the data controller (possibly ex data processor) with whom the data will be shared,
- needs of specific groups of individuals like patient groups or vulnerable groups,
- in addition, it seems also important to take the cultural context in account, although it does not stem from the legislation.

Based on our primary findings, a list of advantages and risks of broad consent can be found in the table below:

⁶⁶ Loosman I, Nickel PJ. Towards a Design Toolkit of Informed Consent Models Across Fields: A Systematic Review. *Sci Eng Ethics*. 2022 Aug 30;28(5):42. doi: 10.1007/s11948-022-00398-x. PMID: 36042065; PMCID: PMC9427926.

Table 34: Advantages and risks of broad consent

Advantages	Risks
Compliance with the legal requirements for consent: Clear and explicit consent in line with the GDPR.	Legal risk: Broad consent may fall short of the requirement to have consent for all purposes of data use under GDPR.
Flexibility: Data subjects may provide their consent to process their personal data for a wide range of purposes in research projects.	Transparency: Requirements on specificity of consent may not be fulfilled completely.
Control: Data subjects have control over their personal data, including the right to withdraw their consent at any time.	Informed consent: The necessary clarification is a prerequisite for informed consent, and in case of broad consent the data subject may not be fully informed
Facilitating research: Reducing the need for multiple consent for different purposes within research projects.	Applicability: According to EDPB's interpretation, broad consent should only be used in exceptional circumstances.
Consent management: Relatively low administrative burden, in comparison with other types of consent.	Specificities: Needs to be adapted to the circumstances where the data are shared e.g., type of data, purpose, data controller.

To conclude, in the context of data altruism under DGA using the type of broad consent may be an effective solution for the legal basis of sharing health data, but during implementation and practical application, policy makers and recognised health data altruism organisations should take into account its specifics, including its advantages and risks, with special regard to the nature of health data as special category of data, and should take steps to mitigate these risks. Also, independent data security controls have to be in place to prevent abuse. They should also take into consideration other types of consent or the possibility to combine them as most appropriate to the data use.

4.3.3 Examples from Member States and projects

Below are a few consent regulations and practices, based on publications and information in TEHDAS. Some of them are not related to data altruism under the DGA, but they are meant as examples on how to apply consent in the secondary use of health data.

The UK introduced a national data opt-out on 25 May 2018, enabling patients to opt out from the use of their data for research or planning purposes, in line with the recommendations of the National Data Guardian in her [Review of Data Security, Consent and Opt-Outs](#). In the

UK patients can view or change their national data opt-out choice at any time by using the online service⁶⁷ or via the NHS Application.

In **Finland** the Healthy Finland survey aims to produce up-to-date information on the health and welfare, and the factors affecting them for adults living in Finland. Participating in the survey provides participants with important knowledge about their health, and also allows participants to make an impact by supporting the prevention of diseases and care research, promoting functional capacity and welfare, and improving health and welfare services. The survey is carried out by the Finnish Institute for Health and Welfare (THL) as a part of its statutory duty. The Healthy Finland survey has received a favourable statement from the competent regional Research Ethics Committee. Participation is voluntary and relies on broad consent. Participants sign a consent form where they confirm their participation in the survey and give their voluntary consent to serve as a research subject. Furthermore, there is a separate biobank consent form for the THL Biobank and its biobank research. Individuals have the ability to withdraw their consents.

In **Germany**, a working group of the national Medical Informatics Initiative⁶⁸ conducted a requirements analysis and developed a GDPR-compliant broad consent standard. The development included consensus procedures within the Medical Informatics Initiative, a documented consultation process with all relevant stakeholder groups and authorities, and the ultimate submission for approval via the national data protection authorities. The GDPR-compliant broad consent for secondary use of health care data and biosamples for (bio)medical research can fulfil the requirements of research ethics committees and federal- and state-level data protection authorities.^{69, 70, 71}

Although not data altruism in the sense of DGA, it is also worth mentioning research clauses, as defined in the Federal Data Protection Act of Germany (BDSG). Research clauses permit the execution of research projects on the basis of personal data, if the interest in the implementation of the project considerably outweighs the individual interest of the data subjects in the exclusion of their data from the processing and the project would not be feasible otherwise as it relies on the data, under Section 27(1) of the BDSG.⁷² On regional level, the Saarland Hospital Act provides that patient data may in principle be used for

⁶⁶ Choose if data from your health records is shared for research and planning. NHS.

www.nhs.uk/your-nhs-data-matters

⁶⁷ Medical Informatics Initiative Germany: <https://www.medizininformatik-initiative.de/en/template-text-patient-consent-forms>

⁶⁹ Data protection-compliant broad consent for secondary use of health care data and human biosamples for (bio)medical research: Towards a new German national standard:

<https://www.sciencedirect.com/science/article/pii/S1532046422001125>

⁶⁹ Secondary research use of personal medical data: attitudes from patient and population surveys in The Netherlands and Germany: <https://www.nature.com/articles/s41431-020-00735-3>

⁷¹ Sven Zenker et al. Data protection-compliant broad consent for secondary use of health care data and human biosamples for (bio)medical research: Towards a new German national standard. J Biomed Inform. 2022 Jul;131:104096. doi: 10.1016/j.jbi.2022.104096. Epub 2022 May 25. PMID: 35643273. <https://pubmed.ncbi.nlm.nih.gov/35643273/>

⁷¹ Federal Data Protection Act. Germany. Translated. https://www.gesetze-im-internet.de/englisch_bdsq/englisch_bdsq.html

research within the specialist department, unless there is a corresponding objection by the person concerned.⁷³

As regards **France**, the legal basis for the legislation is “public interest”, but there is no definition of public interest in the law.⁷⁴ It is stipulated in the law that the ethical review board is the authority in France who decide whether or not a project involving health data is in the public interest. The French law states that when there is a public interest, there is no need for consent from the data subjects, but their prior specific information is required by the GDPR. Legitimate interest could be an alternative if the required conditions are met.

In **Austria**,^{75, 76} broad consent to process personal data for scientific research is permitted by the Federal Research Organisation Act. Data subjects can consent to processing their personal data for a research area, several research areas, research projects, or parts of research projects. The Ethics Commission has published model information sheets including consent forms for participants in clinical trials.

4.4 Forward look

To conclude the analysis chapter, we would like to look ahead to the the potential next steps that the work of TEHDAS has highlighted as necessary or important to further develop the subject of altruism and the findings of this report. We therefore recommend the following aspects should be examined as part of future work on data altruism:

With the establishment of the EHDS framework, a large amount of health data will be available through data access bodies. Large datasets like national level EHR databases become available for secondary data use. It will be necessary to examine the added value of altruism in this framework. It may be taken into account that the requirement of voluntary consent, which is a conceptual element of altruism based on the DGA, may provide scope for increasing access to data. Voluntary data sharing by individuals can, for example, enable personalised analysis of health data to a depth more than in EHR databases. The EHDS framework is likely to facilitate the sharing of de-identified health data. Overall, altruism appears to have a potential for broader data access.

⁷³ Saarländisches Krankenhausgesetz (SKHG), Article 14

https://www.uniklinikum-saarland.de/fileadmin/UKS/Einrichtungen/Kaufm_Direktion_Verwaltung/Dezernat_V/Justitiariat/2022-03-16_-_SKHG_-_Saarlaendisches_Krankenhausgesetz.pdf

⁷⁴ Recommendations for European countries when planning national legislation on secondary use of health data, Appendix 2 Summary of country specific interview answers includes information from selected Member States. TEHDAS Deliverable D5.2. <https://tehdas.eu/app/uploads/2023/03/tehdas-recommendations-for-european-countries-when-planning-national-legislation.pdf>

⁷⁵ Austria: Health and Pharma Overview. <https://www.dataguidance.com/opinion/austria-health-and-pharma-overview>

⁷⁶ National Regulation on Processing Data for Scientific Research Purposes and Biobanking Activities: Reflections on the Experience in Austria: <https://link.springer.com/article/10.1007/s41649-022-00231-4>

Another key question likely to need further consideration is how attractive altruistic organizations will be to individuals. If it is possible to create trust and motivation for citizens, the number of individuals involved in altruism and the amount of data available will make a qualitative step towards secondary use. Along with the fundamental issue of citizens' trust, the equity dimension will also need an in-depth analysis.

Linked to this, data altruism cannot be successful without the buy in (via consent) of individuals and therefore more work is needed to develop robust citizen information about data altruism organisation and active engagement and empowerment campaigns to encourage their involvement.

In addition, as it was discussed during the stakeholder consultations and mentioned in the milestone 8.5 report, 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.

Further work seems necessary to explore how data altruism organisations will differ and add value beyond HDABs – and the accompanying governance needs to support the development of data altruism organisations.

5 Recommendations to foster GDPR-compliant data altruism mechanisms for the EHDS

The above chapters of this document have reviewed and further analysed the results and conclusions of the work completed in the field of data altruism in the framework of TEHDAS work package 8. Based on the work carried out, this document makes the following recommendations, which are proposed to be taken into account in the design and future implementation of the EHDS. Specific recommendations on consent and broad consent have been developed at the request of the European Commission and following the publication of the EHDS Proposal.

5.1 Recommendations for the European policy makers in the health sector

The following recommendations are at European policy makers in Brussels and national administrations and have been developed and informed by the TEHDAS literature review (Milestone 8.4⁷⁷), stakeholder workshops (Milestone 8.5⁷⁸) and on-going policy development.

1. **Involvement, engagement, and empowerment of citizens in data altruism in the field of health should be strongly encouraged.** Citizen and patient engagement and empowerment go beyond informing and educating citizens, and these more active mechanisms should be employed in accordance with the needs of the groups concerned, and with regard to the nature of health data as special category of data.
2. **Digital literacy and public awareness of the secondary use of health data should be promoted and supported, to increase responsible and ethical data use.** This includes providing training and resources e.g., on data management and data privacy, and social media use as well as raising awareness of the benefits of data sharing for public good purposes such as research. It is vital that people with of all digital literacy levels can be equally engaged. Especially the move towards digital applications like smart devices or public health applications to collect and process health data requires the consideration of digital literacy so that no one is left behind as it would undermine equity and public trust.
3. **Transparency and accountability of data altruism organisations in the health sector must be ensured in order to build public trust in the use of health data.** Essential elements for building public trust include facilitating citizen and patient control over the use of their health data, the strong accountability for data altruism organisations in the relationship with individuals and society, as well as transparency on where, how and to whom health data are shared, what the advantages of data sharing are, and what will be the value created.

⁷⁸ TEHDAS probes matrix of data altruism definitions. 430.9.2021. TEHDAS.
<https://tehdas.eu/results/tehdas-probes-matrix-of-data-altruism-definitions/>

⁷⁹ TEHDAS consults stakeholders on data altruism. TEHDAS. 5.7.2022.
<https://tehdas.eu/results/tehdas-consults-stakeholders-on-data-altruism/>

4. **A wide range of business models should be encouraged and promoted for voluntary data sharing including health data altruism.** The advantages and risks of the different models need to be taken into account in order to choose the optimal models for given data sharing operations. Consideration should be given on how these models can support and interoperate with each other.
5. **Within the scope of the proposed EHDS framework, private sector entities should increase their contribution in the secondary use of health data, ensuring that they engage in benefit sharing and contribute back to the data system. Their participation should be based on reciprocity.** Cooperation between the public and the private sector can further promote the creation of value from their datasets, in a reciprocal way.
6. **The Rulebook for data altruism organisations should be prepared in cooperation with the relevant EU projects and initiatives, as well as stakeholders.** The Rulebook will be an important tool for the interpretation of the provisions of the DGA, as well as its implementation. It will help data altruism organisation recognised in the Union in the health sector to operate and to define their role, and to be prepared for the EHDS framework, find the business model etc.

5.2 Recommendations for the health data altruism organisations

The following recommendations, aimed at data altruism organisations, have been developed and informed by the TEHDAS literature review, stakeholder workshops and on-going policy development. These are meant for the health sector but can serve as orientation for other sectors, too

7. **Data altruism organisations should establish collaborations and partnerships with other organisations and institutions to facilitate health data sharing and to promote the exchange of knowledge and resources.** This includes working with academic institutions, public authorities, and not-for-profit organisations e.g., health charities or health research institutes to identify data gaps and develop data-driven solutions to societal problems.
8. **Data altruism organisations should provide incentives for individuals and organisations to engage in data sharing activities.** This includes for example offering recognition for data contributions, providing access to data and data analysis tools. As regards sharing health data for the public good, motivation is of high importance including that individuals should be informed on how and for what purposes their data will be used. The control of individuals over their data, feedback on their data used, benefits for the society, as well as individual benefits are important factors of motivation and incentives for voluntary data sharing.
9. **Data altruism organisations should ensure that high quality and non-biased data is accessible and available for research and public good purposes.** This includes developing data sharing platforms and tools that promote open and accessible data, as well as ensuring that data is stored securely and can be easily accessed by researchers and other stakeholders. Methods and tools for sharing

health data need to be simple and user-friendly, and they must guarantee the privacy of citizens, as well as data security.

10. **Data altruism organisations should choose the most appropriate type of consent, based on the characteristics of the data sharing and data use, including ethical aspects and individual needs.** There are several types of consent used in the practice of health research. Some types of consent, such as broad consent, dynamic consent, tiered consent, or meta consent may be appropriate for health data altruism in the majority instances while specific consent for each data use is unlikely to be appropriate. Opt-out can also be a tool to address privacy concerns but its application has to be based on specific and detailed rules. There are arguments *pro* and *contra* the different types of consent, and to select the optimal types or types used in combination, the characteristics of the given research should be considered. This includes other aspects such as ethics and the cultural background where the health research is conducted, as well as the expectations and needs of the individuals involved, with a view to the special nature of health data as special category of data. Given this, health data altruism organisations are recommended to consider the type of consent they use and flex their approach based on the characteristics of the data sharing and data use.
11. **Data altruism organisations should complement the EHDS, providing different and supplementary data to health data access bodies.** Large databases will be accessible for data applicants, and therefore, it would be important to examine what added value the voluntary sharing of data can provide e.g., in terms of data types, and improving data quality. The valorisation of health data for data altruism in the context of the planned EHDS framework should be further analysed as part of the future work based on the results of TEHDAS. Initial findings suggest that health data altruism organisations can provide richer data as a result of the voluntary participation and consent of individuals.

6 Glossary

Key terminology: terms and definitions and their sources are given in the Table 1, Glossary. The Glossary is an updated version from the Primary recommendations.

Table 1: Glossary

Term	Definition	Source
Altruism	Intentional and voluntary actions that aim to enhance the welfare of another person in the absence of any quid pro quo external rewards.	David Steinberg. Altruism in medicine: its definition, nature, and dilemmas. 2010..
Broad consent	Consent for an unspecified range of future research subject to a few contents and/or process restrictions. Broad consent is less specific than consent for each use, but more narrow than open-ended permission without any limitations.	Christine Grady et al. Broad Consent for Research with Biological Samples: Workshop Conclusions. Am J Bioeth. 2015;15(9):34-42.
Citizen science	General public engagement in scientific research activities when citizens actively contribute to science either with their intellectual effort or surrounding knowledge or with their tools and resources.	Green paper on Citizen Science (2013)
Consent	Consent of the data subject means any freely given, specific, informed, and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her.	GDPR Article 4
Data altruism	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	DGA, Article 2(16) EHDS Proposal, Article 2.1(c): "the definitions of 'data', 'access', 'data altruism', 'public sector body' and 'secure processing environment',

	<p>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.</p> <p>(In the present Report, under data altruism, health data altruism is understood usually.)</p>	<p>pursuant to Article 2 (1), (8), (10), (11) and (14)” of DGA.</p>
<p>Data Altruism Organisation (recognised in the Union)</p>	<p>Organisation that carries out data altruism activities; is a legal person, operates on a not-for-profit basis and is legally independent from any entity that operates on a for-profit basis, and carries out its data altruism activities through a structure that is functionally separate from its other activities.</p>	<p>DGA Articles 17-21</p>
<p>Data Intermediation Service /Data intermediary</p>	<p>In short: Neutral organiser of personal and non-personal data sharing or pooling to increase trust.</p> <p>In detail: Service which aims to establish commercial relationships for the purposes of data sharing between an undetermined number of data subjects and data holders on the one hand and data users on the other, through technical, legal, or other means, including for the purpose of exercising the rights of data subjects in relation to personal data, excluding at least the following:</p> <p>(a) services that obtain data from data holders and aggregate, enrich, or transform the data for the purpose of adding substantial value to it and license the use of the resulting data to data</p>	<p>DGA, Article 2(11)</p>

	<p>users, without establishing a commercial relationship between data holders and data users.</p> <p>(b) services that focus on the intermediation of copyright-protected content.</p> <p>(c) services that are exclusively used by one data holder in order to enable the use of the data held by that data holder, or that are used by multiple legal persons in a closed group, including supplier or customer relationships or collaborations established by contract, in particular those that have as a main objective to ensure the functionalities of objects and devices connected to the Internet of Things.</p> <p>(d) data sharing services offered by public sector bodies that do not aim to establish commercial relationships.</p>	
Delegated act	Non-legislative act adopted by the European Commission that serve to amend or supplement the non-essential elements of the legislation.	EUR-Lex glossary
European Data Innovation Board EDIB	European Data Innovation Board will be created to advise and assist the European Commission in enhancing the interoperability of data intermediation services and ensuring consistent practice in processing requests for public-sector data, among other tasks.	DGA, Article 29.
Incentive	External measures that are designed and established to influence motivation and behaviour of individuals, groups or organisations. Incentives are not just monetary or financial incentives.	Incentive Systems: Incentives, Motivation, and Development Performance UNDP 2015
Informed consent	A subject's free and voluntary expression of his or her willingness to participate in a particular clinical trial, after having been	Regulation 536/2014 on clinical trials on

	<p>informed of all aspects of the clinical trial that are relevant to the subject's decision to participate or, in case of minors and of incapacitated subjects, an authorisation or agreement from their legally designated representative to include them in the clinical trial.</p>	<p>medicinal products for human use.</p>
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7 References ⁷⁹

1. Marianne Bårtvedt van Os et al. Presentation of a first set of data altruism definitions, use cases and findings. Milestone M8.4. Joint Action Towards the European Health Data Space – TEHDAS project. <https://tehdas-presentation-of-a-first-set-of-data-altruism-definitions-use-cases-and-findings.pdf>
2. Centre for Data Ethics and innovation. Unlocking the value of data: Exploring the role of data intermediaries. 2021. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1004925/Data_intermediaries_-_accessible_version.pdf
3. Digital Health Europe. Better Utilisation of Data Infrastructures to Support Secondary Uses of Health Data. White Paper. March 2020. <https://digitalhealthurope.eu/wp-content/uploads/2020/10/Better-Utilisation-of-Data-Infrastructures.pdf>
4. Johannes Drepper: Data protection in biobanks from a practical point of view: what must be taken into account during set-up and operation? J Lab Med 2019; 43(6): 301–309.
5. Sebastian Hoffmann: Forschungsklausel statt *Broad Consent*. Datenschutz und Datensicherheit 12/2022
6. Thomas Zima, David N. Weisstub (Editors): Medical Research Ethics: Challenges in the 21st Century. Springer Nature Switzerland AG 2023. <https://link.springer.com/book/10.1007/978-3-031-12692-5>
7. IMI Big Data for Better Outcomes (BD4BO) Programme, Publications <https://bd4bo.eu/index.php/publications/>

⁸⁰ A more detailed reference list can be found in the TEHDAS literature review on data altruism: <https://tehdas.eu/results/tehdas-probes-matrix-of-data-altruism-definitions/>

8. Morshed Mannan. Data Cooperatives in Europe: A Legal and Empirical Investigation. 14.2.2022. Robert Schuman Centre. Florence School of Regulation. <https://fsr.eui.eu/data-cooperatives-in-europe-a-legal-and-empirical-investigation/>
9. Medical Informatics Initiative Germany: <https://www.medizininformatik-initiative.de/en/template-text-patient-consent-forms>
10. Sameer Mehta et al. Can data cooperatives sustain themselves? Blog. 2.8.2021. London School of Economics LSE. <https://blogs.lse.ac.uk/businessreview/2021/08/02/can-data-cooperatives-sustain-themselves/>
11. Karen Patrias, Dan Wendling. Citing medicine: the NLM style guide for authors, editors, and publishers [Internet]. 2nd ed. Wendling DL, technical editor. Bethesda (MD): National Library of Medicine (US); 2007 - [updated 2015 Oct 2; cited Year Month Day]. Available from: <http://www.nlm.nih.gov/citingmedicine>
12. Saarländisches Krankenhausgesetz (SKHG), Article 14: http://www.lexsoft.de/cgi-bin/lexsoft/justizportal_nrw.cgi?t=167811069853502735&sessionID=11865256741011615113&templateID=document&source=lawnavi&chosenIndex=Dummy_nv_68&xid=612597,15
13. Iryna Sussha et al. Towards Generic Business Models of Intermediaries in Data Collaboratives From Gatekeeping to Data Control. Electronic Government - 19th IFIP WG 8.5 International Conference, EGOV 2020, Proceedings. DOI: 10.1007/978-3-030-57599-1_23
14. Sven Zenker et al. Data protection-compliant broad consent for secondary use of health care data and human biosamples for (bio)medical research: Towards a new German national standard. J Biomed Inform. 2022 Jul; 131:104096. doi: 10.1016/j.jbi.2022.104096. Epub 2022 May 25. PMID: 35643273.
15. N. Garrison, N.A. Sathe, A.H.M. Antommaria, I.A. Holm, S.C. Sanderson, M. E. Smith, M.L. McPheeters, E.W. Clayton, A systematic literature review of individuals' perspectives on broad consent and data sharing in the United States, Genet. Med. 18 (7) (2016) 663–671.
16. C. Grady, L. Eckstein, B. Berkman, D. Brock, R. Cook-Deegan, S.M. Fullerton, H. Greely, M.G. Hansson, S. Hull, S. Kim, B. Lo, R. Pentz, L. Rodriguez, C. Weil, B. S. Wilfond, D. Wendler, Broad Consent for Research With Biological Samples: Workshop Conclusions, Am. J. Bioethics 15 (9) (2015) 34–42.
17. D. Strech, S. Bein, M. Brumhard, W. Eisenmenger, C. Glinicke, T. Herbst, R. Jahns, S. von Kielmansegg, G. Schmidt, J. Taupitz, H.D. Troger, " A template for broad consent in biobank research. Results and explanation of an evidence and consensus-based development process, Eur. J. Med. Genet. 59 (6-7) (2016) 295–309.
18. R. Jahns, J. Geiger, I. Schlünder, D. Strech, M. Brumhard, S. Graf von Kielmansegg, Broad donor consent for human biobanks in Germany and Europe: a strategy to facilitate

cross-border sharing and exchange of human biological materials and related data, JLabMed. 43 (6) (2019) 291–299, <https://doi.org/10.1515/labmed-2017-0064>.

19. The application of data altruism in clinical research through empirical and legal analysis lenses. Teodora Lalova Spinks, Janos Meszaros, Isabelle Huys. *Front. Med.*, 30 March 2023 Sec. Regulatory Science Volume 10 – 2023. <https://doi.org/10.3389/fmed.2023.1141685>
20. EDPB-EDPS Joint Opinion 03/2021 on the Proposal for a Regulation of the European Parliament and of the Council on European Data Governance (Data Governance Act). (2021). https://edpb.europa.eu/system/files/2021-03/edpb-edps_joint_opinion_dga_en.pdf
21. Loosman I, Nickel PJ. Towards a Design Toolkit of Informed Consent Models Across Fields: A Systematic Review. *Sci Eng Ethics*. 2022 Aug 30;28(5):42. doi: 10.1007/s11948-022-00398-x. PMID: 36042065; PMCID: PMC9427926.
22. Workshop Proceedings: Informed Consent in Biobanking—from the Key Barriers, Challenges, and Perceptions to Digital Innovations: ISBER Virtual Annual Meeting and Exhibit, May 14–16, 2021. [Desislava Ivanova](#); [Panagiotis Katsaounis](#). *Innovations in Digital Health, Diagnostics, and Biomarkers* (2022) 2 (2022): 16–26. <https://doi.org/10.36401/IDDB-21-07>
23. Wiertz, S., Boldt, J. Evaluating models of consent in changing health research environments. *Med Health Care and Philos* 25, 269–280 (2022). <https://doi.org/10.1007/s11019-022-10074-3>
24. Anna Berti Suman et al, When Concerned People Produce Environmental Information: A Need to Re-Think Existing Legal Frameworks and Governance Models? *Citizen Science: Theory and Practice*, 8(1), 2023. p.10. DOI: <http://doi.org/10.5334/cstp.496>
25. Anna Berti Suman et al. Reimagining health services provision for neglected groups: The “personalization from below” phenomenon. *Frontiers in Sociology*. 2.2.2023. <https://www.frontiersin.org/articles/10.3389/fsoc.2023.1052215/full>
26. Data Governance Act explained. European Commission, 30 August 2022. <https://digital-strategy.ec.europa.eu/en/policies/data-governance-act-explained>

Annex 1 List of relevant projects, initiatives and use cases

A Projects, and initiatives and use cases, with site links, based on the TEHDAS M8.6⁸⁰ report.

1. All of Us initiative (USA) <https://allofus.nih.gov/>
2. Belgian DNA debate <https://www.ipaac.eu/res/file/outputs/wp6/belgian-dna-debate.pdf>
3. Biobanks, see e.g. List COVID-ready samples and data on the BBMRI-ERIC Directory. BBMRI-ERIC: <https://www.bbmri-eric.eu/services/isber-biobank-collaboration/> Finnish Biobanks. <https://www.biopankki.fi/en/finnish-biobanks/>
4. Centre for Data Ethics and Innovation. <https://www.gov.uk/government/organisations/centre-for-data-ethics-and-innovation>
5. Centre for Effective Altruism <https://www.centreforeffectivealtruism.org/>
6. Connected Health Cities (UK) <https://connectedhealthcities.github.io/>
7. DATA for GOOD Foundation (website) <https://dataforgoodfoundation.com/>
8. Data Trusts & Trustees
9. DSSC Data Spaces Support Centre (DIGITAL) <https://dssc.eu/>
10. EH DEN European Health Data and Evidence Network Project (H2020) <https://www.ehden.eu/>
11. European Ethical Code for Data Donation project (funder: Microsoft) <https://www.oii.ox.ac.uk/research/projects/a-european-ethical-code-for-data-donation/>
12. EUHealthSupport Consortium, supporting EU and DG SANTE <https://www.nivel.nl/en/project/euhealthsupport-consortium-supporting-eu-and-dg-sante>
13. EU-Citizen.science project (H2020) <https://eu-citizen.science/>, platform for sharing citizen science projects, resources, tools, training etc.
14. GRAVITATE HEALTH public–private partnership (website) <https://www.gravitatehealth.eu/>
15. HDE Health Data Exploration Project <http://hdexplore.calit2.net/about/>
16. Health data cooperatives <https://digitalhealthurope.eu/glossary/health-data-cooperative/>

⁸⁰ Milestone 8.6 Primary recommendations to foster GDPR-compliant data altruism mechanisms for the EHDS TEHDAS. 5.12.2022. <https://tehdas.eu/app/uploads/2022/12/primary-recommendations-to-foster-gdpr-compliant-data-altruism-mechanisms-for-the-ehds.pdf>

17. Health Outcomes Observatory (H2O) Project (Innovative Medicines Initiative IMI / Horizon 2020) <https://health-outcomes-observatory.eu/>
18. Health-RI Initiative: Personal Health Train - PHT (website) <https://www.health-ri.nl/initiatives/personal-health-train>
19. MyData Global <https://www.mydata.org/>
20. National Data Guardians <https://www.gov.uk/government/organisations/national-data-guardian>
21. Norwegian Health Data Programme <https://helsedata.no/> and <https://www.ehelse.no/programmer/helsedataprogrammet>
22. Open Humans Foundation (non-profit organisation) and Open Humans (platform) <http://openhumansfoundation.org/> and <https://www.openhumans.org/>
23. OpenSNP and other genome data sharing platforms based on Direct-To-Consumer (DTC) genetic testing <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5423632/>
24. Quantified flu. Community and platform for data and tools sharing. A citizen science project. <https://quantifiedflu.org/>
25. REFINIO GmbH (Germany) <https://refinio.net/>
26. Smart4Health project (Horizon 2020) <https://smart4health.eu/> and <https://sts.univie.ac.at/en/research/current-research-projects/smart4health/>
27. Understanding Patient data <https://understandingpatientdata.org.uk>
28. Yale University Open Data Access (YODA) project <https://yoda.yale.edu/>
29. Zooniverse, people-powered research, online citizen science platform, by Oxford University <https://www.zooniverse.org/>
30. 1+ Million Genomes <https://b1mg-project.eu/> .European '1+ Million Genomes' Initiative <https://digital-strategy.ec.europa.eu/en/policies/1-million-genomes>
31. Data Collaboratives Explorer <https://datacollaboratives.org/explorer.html>
32. MyData.org <https://oldwww.mydata.org/mydata-operators/>

B Publications

33. Aline Blankertz. Designing Data Trusts. Why we need to test Consumer Data Trusts Now. Stiftung Neue Verantwortung. 2020. https://www.stiftung-nv.de/sites/default/files/designing_data_trusts_e.pdf
34. Caldicott, F. (2020). *The National Data Guardian for Health and Social Care Annual Report 2019-2020*. <https://www.gov.uk/government/publications/national-data-guardian-2019-2020-report>

35. Cameron. D, Pope.S, Clemence. M, Ipsos MORI Social Research Institute (2014). *Exploring the public's views on using administrative data for research purposes*. London: Ipsos Mori. 2–57
36. Centre for Data Ethics and Innovation. (2020). *Addressing trust in public sector data use*. <https://www.gov.uk/government/publications/cdei-publishes-its-first-report-on-public-sector-data-sharing/addressing-trust-in-public-sector-data-use>
37. Connected Health Cities. (2017). *A report of two citizens' juries designed to explore whether the planned and potential uses of health data by Connected Health Cities are acceptable to the public*. https://www.connectedhealthcities.org/wp-content/uploads/2016/08/CHC-juries-report-Feb-2017_2.pdf
38. Connected Health Cities. (2018). *Citizens' Jury 2018*. <https://www.connectedhealthcities.org/chc-hub/public-engagement/citizens-juries-chc/citizens-jury-2018/>
39. Data trustee: the independent mediator between data providers and data users <https://www.bundesdruckerei-gmbh.de/en/solutions/data-trustee>
40. Flavio D'Abramo. Biobank research, informed consent, and society. Towards a new alliance? *J Epidemiol Community Health*. 2015 Nov;69(11):1125-8. doi: 10.1136/jech-2014-205215. Epub 2015 Feb 10. PMID: 25669218.
41. Malik Ghallab et al. Data Trusts A new tool for data governance. Element AI. NESTA. https://hello.elementai.com/rs/024-OAQ-547/images/Data_Trusts_EN_201914.pdf
42. GPAI. Enabling data sharing for social benefit through data trusts. 2020. <https://gpai.ai/projects/data-governance/data-trusts/enabling-data-sharing-for-social-benefit-through-data-trusts.pdf>
43. Jeremiah Lau et al. The Basics of Private and Public Data Trusts. NUS Law Working Paper No. 2019/019 EW Barker Centre for Law & Business Working Paper 19/03. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3458192
44. Louise Locock, Anne-Marie Boylan. Biosamples as gifts? How participants in biobanking projects talk about donation. *Health Expect*. 2016 Aug;19(4):805-16. doi: 10.1111/hex.12376. Epub 2015 Jun 12. PMID: 26072951; PMCID: PMC5152721
45. Mantombi Maseme. Commodification of biomaterials and data when funding is contingent to transfer in biobank research. *Med Health Care Philos*. 2021 Dec;24(4):667-675. doi: 10.1007/s11019-021-10042-3. Epub 2021 Jul 20. PMID: 34286415.
46. Open Data Institute ODI. (2018). *ODI survey reveals British consumer attitudes to sharing personal data*. <https://theodi.org/article/odi-survey-reveals-british-consumer-attitudes-to-sharing-personal-data/>
47. Open Data Institute ODI. Attitudes towards data sharing. Survey. ODI – YouGov poll results. Open Data Institute, 29 November 2017. <https://theodi.org/article/odi-survey-reveals-british-consumer-attitudes-to-sharing-personal-data/>

48. Putting Good into Practice A public dialogue on making public benefit assessments when using health and care data.
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/977737/PGiP_Report_FINAL_1304.pdf
49. SOCIENTIZE. Green Paper on Citizen Science. Citizen Science for Europe. Towards a better society of empowered citizens and enhanced research. 2013. <https://digital-strategy.ec.europa.eu/en/library/green-paper-citizen-science-europe-towards-society-empowered-citizens-and-enhanced-research>
50. Louisa Spect-Riemenschneider, Wolfgang Kerber. Designing Data Trustees – A Purpose-Based Approach. Konrad Adenauer Stiftung. 2022.
<https://www.kas.de/documents/252038/16166715/Designing+Data+Trustees.pdf>
51. Hazel Thornton. The UK Biobank project: trust and altruism are alive and well: a model for achieving public support for research using personal data. *Int J Surg*. 2009 Dec;7(6):501-2. doi: 10.1016/j.ijssu.2009.09.001. Epub 2009 Sep 10. PMID: 19748601.
52. Understanding Patient Data. (2020). *Foundations of fairness: views on uses of NHS patients' data and NHS operational data*.
<https://understandingpatientdata.org.uk/sites/default/files/2020-03/Foundations%20of%20Fairness%20-%20Full%20Research%20Report.pdf>
53. Waind. E. (2020). *Trust, Security and Public Interest: Striking the Balance*.
https://www.adruk.org/fileadmin/uploads/adruk/Trust_Security_and_Public_Interest_Striking_the_Balance-ADR_UK_2020.pdf
54. UK Health Data Research Alliance. (2020). *Trusted Research Environments (TRE) A strategy to build public trust and meet changing health data science needs*.
<https://ukhealthdata.org/news/next-steps-on-the-journey-to-trusted-research-environments/>
55. OneLondon. (2020). *Public deliberation in the use of health and care data*.
<https://www.onelondon.online/wp-content/uploads/2020/07/Public-deliberation-in-the-use-of-health-and-care-data.pdf>

Annex 2 Results from the stakeholder workshop 2023

List of statements and poll results from the stakeholder workshop on health data altruism, Brussels, 27 April 2023.

Statements on compliance with GDPR

Private sector entities should be encouraged to increase their participation in and contribution to the secondary use of health data.

I agree	18
I have doubts	6
I disagree	1

Data altruism, under the DGA, means the consent by data subjects to process their personal data, however, in the EHDS framework health data for secondary use will be processed based on public interest.

I agree	14
I have doubts	9
I disagree	0

To ensure the control of citizens over their personal data, the possibility of opt-in/consent should be part of the EHDS legislative framework, at least for certain data categories.

I agree	13
I have doubts	3
I disagree	7

Statements on broad consent

In the context of data altruism broad consent has to be used as the main rule in case of secondary use of health data as its advantages outweigh the risks involved.

I agree	0
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I have doubts	14
I disagree	8

Broad consent is a solution which strikes a balance between scientific research for the common good and the protection of individuals' data protection rights.

I agree	3
I have doubts	12
I disagree	9

Opt-out can solve the privacy concerns when the secondary use of health data is based on broad consent.

I agree	9
I have doubts	11
I disagree	3

Statements on data altruism organisations and business models

Data altruism organisations should define their roles in the future legal framework, as large datasets will also be available based on the proposed EHDS Regulation, e.g., via understandable and practical business models.

I agree	18
I have doubts	6
I disagree	0

The Rulebook for the Data altruism organisations, prepared by the European commission, has to be prepared and later updated in close cooperation with stakeholders, especially EHDS stakeholders, projects and initiatives.

I agree	19
I have doubts	3
I disagree	0

Transparency and accountability of data altruism organisations must be ensured in order to build public trust in data use.

I agree	21
I have doubts	0
I disagree	0

Let's collect names together - Please name data altruism organisations, existing or under preparation.

understanding patientdata
 some biobanks mitz question mark
 we are health midata mydata global
 donate your data foundati
 health-ri question mark www saluscoop org
 data saves lives salus coop
 open humans foundation

Figure 2: Examples of data altruism organisations in health