Milestone 8.6

Primary recommendations to foster GDPR-compliant data altruism mechanisms for the EHDS

5 December 2022

This project has been co-funded by the European Union's 3rd Health Programme (2014-2020) under Grant Agreement no 101035467.

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1.2 Keywords

Keywords	TEHDAS, Joint Action, health data, European Health Data Space, data space, data altruism, data altruism organisation(s), consent, broad consent, citizen science, GDPR, EHDS, Data Governance Act, public trust

The document was accepted in Project Steering Group on 25 October 2022.

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1. Executive summary

The overarching aim of the Joint Action Towards the European Health Data Space (JA TEHDAS) is to develop the future policy, legal and technological framework for the sharing and secondary use of health data in the European Union. The JA TEHDAS has a dedicated citizen engagement work package (WP) called *iCitizen*, which specifically facilitates policy development on the role of citizens in the EHDS and data altruism. This milestone document will add to this debate by outlining the key issues and considerations for data altruism, in preparation for the final TEHDAS report on recommendations to foster GDPR-compliant data altruism mechanisms for the European Health Data Space (EHDS), due in May 2023.

The terms *data altruism* and *data altruism organisation(s)* were legally defined for the first time by the Regulation (EU) 2022/868 of the European Parliament and of the Council of 30 May 2022 on European Data Governance and Amending Regulation (EU) 2018/1724 (Data Governance Act [DGA]). As of the 20th of October 2022, there are currently a total of 41 European Union documents in the EUR-Lex of the European Commission[1], mentioning "data altruism".

For data altruism to come to life, the DGA sets out the necessity for each Member State to appoint one or more competent authorities for the registration of data altruism organisations. The recognised data altruism organisation shall use the data collected solely for the objectives of general interest for which the data subject or data holder allows the processing. They shall also take measures to ensure an appropriate level of security for the storage of the data they have collected and shall inform data holders of any unauthorised transfer, access, or use of the data they have shared. For the processing of personal data related to the health of individuals in the context of data altruism organisations to be in accordance with the GDPR, it must be based on one of the legal bases prescribed by the GDPR.

Crucial to the ethical development of data altruism are the communication, engagement and information sharing methods used by its proponents. Should communication, engagement and information sharing be poor, there is a risk of unreflective or biased analysis, and increased marginalisation.

To this end, this deliverable deals with the issue of citizen science and various forms of consents, especially broad consent. GDPR consent to processing and medical informed consent to treatment / participation in clinical trials / research involving human subjects. (page 4) Consents are used in various contexts like General Data Protection GDPR, medical informed consent to treatment, participation in clinical trials and research involving human subjects, such as bio-banking.

[1] Publications office of the European Commission. EUR-Lex. 2022. https://eur-lex.europa.eu/homepage.html

GDPR consent should not be conflated to e.g. medical informed consent to treatment / participation in clinical trials or research involving human subjects. [2], [3]

The second aim of this milestone report is to combine and synthesise the extension research and consultation results from the preparatory stages of that part of the WP8 that focuses on data altruism to prepare for the final TEHDAS report.

This final report will be published in May 2023 and will set out final recommendations on GDPR-compliant application of data altruism mechanisms and practices. This includes how to adopt and harmonise identified good practices for the construction of national or European health data spaces, as well as analysis of the use of consent forms and the use of broad consent with data altruism practices. The final deliverable will focus *inter alia* on the DGA data altruism definition in the context of EHDS and provide suggestions and mechanisms to facilitate data altruism and forms of consent in the context of health data.

2. Context

According to the vision of TEHDAS, European citizens, communities and companies will in the future benefit from secure and seamless access to health data regardless of where it is stored. A collaborative effort of 25 EU/EEA and associated countries, the JA TEHDAS project helps both Member States and the European Commission in the development and promotion of concepts related to the secondary use of health data, contributing to the establishment of the European Health Data Space (EHDS).

The iCitizen Work Package (WP8), under which this milestone sits, aims to "provide evidence for decision-makers and healthcare professionals in the European Union so that they can more effectively promote the secondary use of health data and the acceptance thereof by citizens"[4] in the EHDS.

2.1 European Union and international context

The European Strategy for Data[5], [6] (2020) has laid the basis on the present data altruism work in the European Union and in various sectors and connected data altruism to consent

[2] EDPB. Guidelines 05/2020 on consent under Regulation 2016/679 Version 1.1 Adopted on 4.6.2020. European Data Protection Board. https://edpb.europa.eu/sites/default/files/files/file1/edpb_guidelines_202005_consent_en.pdf

[3] EDPB. Document on response to the request from the European Commission for clarifications on the consistent application of the GDPR, focusing on health research. European Data Protection Board. 2.2.2021. https://edpb.europa.eu/our-work-tools/our-documents/other-guidance/edpb-document-response-request-european-commission_en

[4] Grant Agreement number 101035467 — TEHDAS, p. 34.

[5] European Commission. A European Strategy for data. https://digital-strategy.ec.europa.eu/en/policies/strategy-data

[6] European Commission, Directorate-General for Communications Networks, Content and Technology. COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT,

issues. According to the European Parliament's resolution on the European Strategy for the Data[7]:

> *"The European Parliament … supports the Commission's initiative to create a strictly defined, EU-wide approach to data altruism and to establish a clear definition and rules on data altruism in accordance with EU data protection principles, notably purpose limitation, which requires that data be processed for 'specified, explicit and legitimate purposes'; supports the Commission's proposal that data altruism should always be conditional on informed consent and revocable at any time; underlines that data donated under data altruism is meant to be processed for the purposes of .*

The Data Governance Act (DGA)[8] further strengthens and clarifies data altruism and brings the concept of data altruism organisation into use through its characteristics.[9] The Proposal for the Regulation on the European Health Data Act[10] explains data altruism in health, its mechanisms, technical requirements, and implementation, primarily in Article 40.

In addition to the Data Strategy and the Data Governance Act (DGA), related Acts like the Digital Markets Act (DMA), the Digital Services Act (DSA), and the Artificial Intelligence Act (AI Act) and the Data Act are useful in considering data altruism.[11]

THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS A European strategy for data. COM/2020/66 final. CELEX: 52020DC0066. 19/02/2020 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020DC0066

[7] European Parliament, Committee on Agriculture and Rural Development, Committee on Civil Liberties, Justice and Home Affairs, Committee on Culture and Education, Committee on Employment and Social Affairs, Committee on Industry, Research and Energy, Committee on International Trade, Committee on Legal Affairs, Committee on Transport and Tourism, Committee on the Environment, Public Health and Food Safety, Committee on the Internal Market and Consumer Protection. European Parliament resolution of 25 March 2021 on a European strategy for data (2020/2217(INI)). CELEX: 52021IP0098. Own-initiative resolution. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021IP0098

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

[9] Julie Baloup et al. White Paper on the Data Governance Act (June 23, 2021). CiTiP Working Paper 2021, https://ssrn.com/abstract=3872703 or http://dx.doi.org/10.2139/ssrn.3872703

[10] 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

[11] Tobias Bräutigam et al. EU regulation builds a fairer data economy. The opportunities of the Big Five proposals for businesses, individuals and the public sector. Sitra working paper. 2022. https://www.sitra.fi/en/publications/eu-regulation-builds-a-fairer-data-economy/

Furthermore, the Charter of Fundamental Rights of the European Union (2012) includes Articles that can be linked to data altruism, and e.g. its Article 3 refers to "informed consent".[12, 13]

Looking further back, the Nuremberg Code[14] (1947) and the Declaration of Helsinki[15] (1967) have established the idea and importance of free and informed consent. The Nuremberg Code is broad in scope, including all experimentation involving human subjects. The Declaration was designed with a focus on clinical research. Together the Code and the Declaration provide the ethical basis and principles for research involving human subjects, including research on identifiable human material and data.

The Code and the Declaration are not laws but their impact has been long-lasting and of great importance. In the United States, the Code and the Declaration influenced the drafting of regulations to ensure ethical treatment of human subjects in research, known as the Common Rule, and it now codified in Part 46 of Title 45 of the Code of Federal Regulations CFR[16].

Moreover, the Oviedo Convention and its Protocols[17] (1997), drawn on the principles of the European Convention on Human Rights (ECHR)[18] (1953), is an international legally binding instrument protecting human rights in the biomedical field.[19] Consent issues are not mentioned in the ECHR but are included in the Oviedo Convention. The EU Clinical Trials Regulation[20] makes a distinction between the consent for participating in the clinical trial, and consent relating to further research using of data derived from such trial. Altogether, this

[12] 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

[13] Evelien De Sutter et al. Digitizing the Informed Consent Process: A Review of the Regulatory Landscape in the European Union. Front Med (Lausanne). 2022 May 25;9:906448. doi: 10.3389/fmed.2022.906448. PMID: 35692551; PMCID: PMC9174519.

[14] Jonathan D Moreno et al. The Nuremberg Code 70 years later. JAMA. 2017. Sep 5;318(9):795-796. doi: 10.1001/jama.2017.10265. PMID: 28817743.

[15] The World Medical Association (WMA). Declaration of Helsinki - ethical principles for medical research involving human subjects. https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

[16] Code of Federal Regulations. 2022. https://www.ecfr.gov

[17] Council of Europe. Oviedo Convention and its Protocols. https://www.coe.int/en/web/bioethics/oviedo-convention

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

[19] Council of Europe. Oviedo Convention and its Protocols. https://www.coe.int/en/web/bioethics/oviedo-convention

[20] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC. In force. This act has been changed. Current consolidated version: 31/01/2022. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0536

regulatory and ethical landscape presents a challenge for e.g., consent in biobanking.[21] In general, donating tissue like blood means that also access to data is included. This dynamic interlinkage means that e.g. a big picture of various health related consents is important.[22] [23]

Finally, Article 27 of the Universal Declaration of Human rights (UDHR)[24] (1948) can be linked to citizen science as it establishes human rights to science (HRS).[25], [26]

> *(1) Everyone has the right to freely participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits.*
>
> *(2) Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary, or artistic production of which he is the author.*

These legislative documents in combination with the 41 European Union documents mentioning "data altruism" set the basis and principles for the development of data altruism mechanisms. These documents have provided the starting point for TEHDAS's work to develop recommendations to foster GDPR-compliant data altruism mechanisms to support the creation of the EHDS.

2.2 TEHDAS context

2.2.1 TEHDAS in general

According to the TEHDAS Joint Action Towards the European Health Data Space Project Proposal[27], TEHDAS helps EU member states and the European Commission to develop and promote concepts for the secondary use of health data in Europe. The project is implemented by partners from 25 EU/EAA and associated countries with the co-ordination of

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[21] Marjut Salokannel et al. Legacy samples in Finnish biobanks: social and legal issues related to the transfer of old sample collections into biobanks. Human Genetics (2019) 138: 1287-1299. https://link.springer.com/content/pdf/10.1007/s00439-019-02070-0.pdf

[22] Bettina Schmietow. Property redux. Ownership of human tissue and the governance of post-genomic research biobanks. PhD thesis. European School of Molecular Medicine (SEMM) and University of Milan. 2012. https://air.unimi.it/retrieve/handle/2434/234151/301892/phd_unimi_R08920.pdf

[23] Michael A Lensink et al. Better governance starts with better words: why responsible human tissue research demands a change of language. BMC Med Ethics 23, 90 (2022). https://doi.org/10.1186/s12910-022-00823-7

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

[25] Effy Vayena et al. Research led by participants: a new social contract for a new kind of research. J Med Ethics. 2016 Apr;42(4):216-9. doi: 10.1136/medethics-2015-102663. Epub 2015 Mar 30. PMID: 25825527; PMCID: PMC4819634.

[26] Bastian Greshake Tzovaras et al. Open Humans: A platform for participant-centered research and personal data exploration. Gigascience. 2019 Jun 1;8(6): giz076. doi: 10.1093/gigascience/giz076. PMID: 31241153; PMCID: PMC6593360.

[27] https://tehdas.eu/project/

the Finnish Innovation Fund Sitra. TEHDAS is carried out through eight work packages focusing on:

- involving stakeholders and citizens in the dialogue about the European health data space, the secondary use of health data, clarifying their role.
- development of a governance model for cross-border cooperation on the secondary use of health data between European countries, ensuring sustainability.
- promoting reliability and compatibility of health data and access for secondary use.

2.2.2 TEHDAS Work Package 8

WP8 "seeks to obtain a better understanding of citizens' relationship with health data in the EU, to better inform and sensitize citizens regarding health data and recommend data altruism practices for the EHDS"[28].

WP8 work is divided into five tasks:

- T8.1 Preparatory phase of online consultation in three pilot countries,
- T8.2 Conduct online consultation to collect citizens' perceptions,
- T8.3 Develop recommendations for the EHDS to ensure citizen sensitization and engagement with health data,
- T8.4 Overview of national data altruism definitions and systems, and
- T8.5 Recommend ways to foster GDPR-compliant data altruism mechanisms for the EHDS.[29]

[28] Grant Agreement number 101035467 — TEHDAS, p. 21.
[29] Ibid., p. 47-48.

Tasks 8.1-8.3 focus on citizen engagement in general while Tasks 8.4-8.5 focus on data altruism specifically. The TEHDAS project has already published four milestone reports within the WP8 [30], [31], [32], [33]. After this report, the WP8 will produce three reports:

- M8.3 Publication of recommendations the European Health Data Space to ensure citizen sensitization and engagement with health data.
- D8.1 Qualitative study conducted amongst key stakeholders (public, private actors, and patient / citizen groups) to assess citizen's perception of health data.
- D8.2 Report on lessons learned to be applied and recommendations for data altruism practices in the implementation of construction of national and European health data spaces (including broad consent).

2.2.3 Tasks 8.5

The TEHDAS tasks relating to data altruism, including this report, are preparatory stages for the final report due in May 2023 on recommendations to foster GDPR-compliant data altruism mechanisms for the EHDS.

The Deliverables and milestones for the TEHDAS data altruism work are: M8.5, M8.6 and D8.2.

- M8.5: A publication of an overview (prepared to launch a communication campaign) about the results of EU-wide multi stakeholder workshops, with a special regard to updated definitions, needs, solutions, experiences, and good practices of data altruism (altruism structures and functions) for the future EHDS.
- M8.6: Recommendations to foster GDPR-compliant data altruism mechanisms for the EHDS.

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[30] 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

[31] James Maddocks et al. 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/

[32] 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

[33] 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/

- D.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).

Figure 1 below sets out the stages and timelines for the specific data altruism tasks, including delivery of:

1. A literature review of data altruism definitions, mechanisms, and literature to inform Milestone 8.4.
2. Milestone 8.4 report which presents a first set (catalogue) of data altruism definitions, use cases and findings about consent and accessibility issues.
3. Multi-stakeholder workshops to discuss new definitions, good practices of data altruism and altruism structures and functions for the future EHDS.
4. Milestone 8.5 which provides an overview of the results of EU-wide multi stakeholder workshops, with a special regard to updated definitions, needs, solutions, experiences, and good practices of data altruism.
5. A communication campaign to disseminate the results of the EU-wide workshops.
6. Milestone 8.6 (this report) which outlines the key issues and considerations for data altruism, in preparation for the final TEHDAS report.
7. Final TEHDAS report on 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, and it will also include an analysis of the use of consent forms including use of so-called broad consent with data altruism practises.

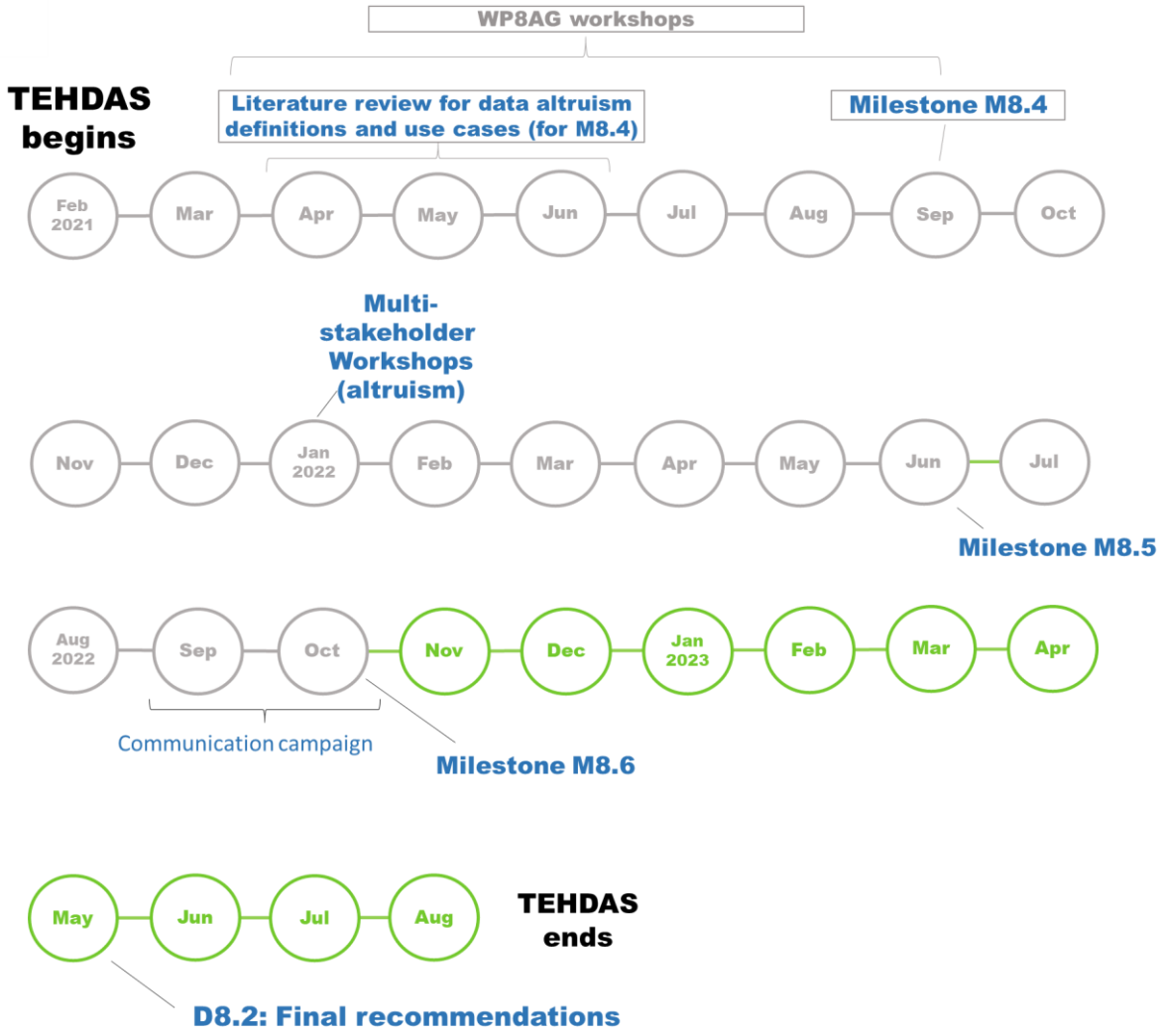

Figure 1: Work Package 8 data altruism specific tasks

2.2.4 Links with other TEHDAS work

The TEHDAS Work Plan (the Annex of the Grant Agreement) mentions data altruism, data altruism bodies and consent in two sections (other than WP8): Chapter 1, Problem analysis including evidence base, the objective text of the WP7.

> TEHDAS problem analysis:
>
> *"The use of data may not be transparent to citizens. No systematic mechanisms are in place for citizens to either give **consent** to the use of their data or to "opt out." In addition, there are many misconceptions and lack of trust in the use of health data, related to practices of misuse and failing cybersecurity and privacy issues. As a result, even in times of Covid-19, the practice of "data altruism" or data donation by citizens is still a rare practice and lacks an EU-wide regulatory framework."*

"Many problems of secondary use of health data remain similar in both advanced and less advanced European countries, such as ethical issues, consent, cyber security."

TEHDAS WP7 objective:

"The key concept for the envisaged EHDS is a federated peer-to-peer system, that interconnect node of different typologies (data permit authorities, European level health data providers, research infrastructures, data altruism bodies etc.). The EHDS nodes will operate regularly in an independent manner, providing services to their users, but as part of the federation they will be connected. The interconnection will be implemented through a series of specific EHDS services deployed on to provide federation-wide features, such as: announcement, authentication, data discovery, data retrieval, data analytics, etc."

The problem explained in the TEHDAS Project Plan is still valid. Indeed, the practice of "data altruism" or data donation by citizens is still a rare practice and lacks an EU-wide regulatory framework.

3. Methodology

The methodology for the data altruism is comprised of four tasks:

1. **Literature review:** The aim of the literature review was to map existing theory and best practice on data altruism practices across Europe. The review took place between April – June 2021. From July to September, the results of the literature review were compiled, analysed, summarised leading to the publication of Milestone 8.4, "Presentation of a first set of data altruism definitions, use cases and findings" [34]. Further detail on this milestone can be found at Chapter 2.1.

2. **Stakeholder workshops and consultations:** The purpose of the workshops was to discuss some of the most challenging topics on citizen-centric solutions and models for use cases of health data altruism/intermediary systems for data sharing with stakeholders. The workshops took place in January 2022, and contributed to the publication of milestone 8.5, "Summary of the EU-wide multistakeholder workshops"[35]. Further detail on this milestone can be found at Chapter 2.2.

3. **Consolidation and realignment:** A consolidation exercise has been planned for the mid-point of the project. The aim of this exercise is to combine and synthesise the extension

[34] 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

[35] 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. TEHDAS M8.5. 5.7.2022. https://tehdas.eu/app/uploads/2022/07/tehdas-overview-of-results-of-eu-wide-multi-stakeholder-workshops-on-data-altruism.pdf

research and consultation results from the preparatory stages as well as to reassess data altruism priorities for TEHDAS in line with the publication of the European Health Data Space proposal. Published in October 2022, this report is the result of the consolidation exercise, and clearly sets out the next steps to deliver the final stage of the data altruism work stream.

4. **Final recommendations:** The final recommendations for the European Commission will be developed in line with the views of stakeholders, best practice examples and with consideration to the European Health Data Space proposals, the Data Governance Act, and other seminal works on the subject. The final recommendations are scheduled to be published as the Deliverable D8.2 in May 2023.

3.1 Literature review

The literature review covers previous TEHDAS WP8 literature review work on data altruism, and search and analysis of EUR-Lex documents on data altruism, data altruism organisations, citizen science and broad consent.

The EUR-Lex run by the Publication Office of the European Union is "Access to the European Union Law" and “the online gateway to EU Law”[36]. According to the EUR-Lex Advanced search form, the EUR-Lex contains two main document collections (with subcollections), 1) EU-Law and caselaw: treaties, legal acts, consolidated texts, case-law, international agreements, preparatory documents related to EU legislation, EFTA documents, lawmaking procedures, parliamentary questions, and 2) National law and case-law: national transposition, national case-law, and JURE case-law.[37], [38]

Statistical query summaries are available by year of document, by collection, by type of act, and by author. The Date of document is given in the query results and sometimes a document contains extra clarification for the data, like Date of vote, Date of signature or Date of publication. In this M8.6 report the document dates of the query results are given as such, without further analysis what it means in that specific case.

3.1.1 Previous TEHDAS WP8 literature review work on data altruism

The WP of the TEHDAS project has executed literature review work. The Milestone 8.4 report includes an analysis of approximately one hundred documents relevant to data altruism[39].

[36] Publications office of the European Commission. About EUR-Lex. 2022. https://eur-lex.europa.eu/content/welcome/about.html
[37] Publications office of the European Commission. EUR-Lex Advanced search. 2022. https://eur-lex.europa.eu/advanced-search-form.html
[38] Publications office of the European Commission. Types of documents in EUR-Lex. 2022. https://eur-lex.europa.eu/content/tools/TableOfSectors/types_of_documents_in_eurlex.html
[39] Marianne Bårtvedt van Os, László Bencze Semmelweis, 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

Overall, the M8.4 report identifies twelve factors that illustrate the complexity and diversity of data altruism. They include the variety of data subjects such as patients or organisations, the scope of the consent can vary from one-time consent to giving a consent for multiple different purposes at a time, and value for data subjects for sharing data, such as being informed about how the data used benefitted research. We continue to update and modify the literature to supplement to previous work as time passes. As such we conducted an additional search of EUR-Lex[40] documents on data altruism.

3.1.2 EUR-Lex documents on data altruism

A EUR-Lex query with the search term "data altruism" was executed on the 16th of September 2022 to get an updated overview of the legislative documents related to data altruism. There were altogether 41 European Union legislative documents mentioning "data altruism". The documents are listed in Annex 1 of this report.

In the EUR-Lex, the query results are categorised by year, by collection, by type of act, and by author.

By year, all the data altruism documents are from three years: 2020 (15 documents), 2021 (11 documents) and 2022 (15 documents).

By collection, thirty-nine of the data altruism documents were from the EU law and case-law collection, and from these, one document — the Data Governance Act, DGA — belongs to a subcategory of Legal acts and thirty-eight were Preparatory documents. No query results were from the EUR-Lex National law and case-law collection.

By type of act, for example eight data altruism documents were cover notes, appr. ten various types of opinion documents, five impact assessments, three implementing decisions, two legislative acts, and one factual summary report of the public consultation (about European Health Data Space). The European Economic and Social Committee has given eight opinion documents referring to data altruism.

By author, seventeen data altruism documents were from the European Commission (EC). The Commission documents were from the Directorate-General for Communications Networks, Content and Technology (five documents), the Directorate-General for Health and Food Safety (four documents), the Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (one document), the Directorate-General for Justice and Consumers (two documents), and the Directorate-General for Research and Innovation (three documents). Twelve documents were from the European Council. Two documents were from European Data Protection Supervisor. The Regulatory Scrutiny Board and the European Data Protection Supervisor (EDPS) have both two opinion documents. The

altruism definitions, use cases and findings. Milestone M8.4. Joint Action Towards the European Health Data Space – TEHDAS project. https://tehdas.eu/app/uploads/2021/09/tehdas-presentation-of-a-first-set-of-data-altruism-definitions-use-cases-and-findings.pdf

[40] Publications office of the European Commission. EUR-Lex. 2022. https://eur-lex.europa.eu/homepage.html

European Data Protection Board (EDPS) and EDPS have also one common opinion paper on the Proposal for Regulation on the European Health Data Space. The Special Committee on Beating Cancer has got one document referring to data altruism.

The legislative data altruism documents from the query are related to the European Data Strategy, the European Data Spaces, especially European Health Data Space, the Data Governance Act, and the Horizon Europe programme.

The Data Governance Act (DGA)[41] gives a definition to "data altruism" (adopted on 30th May 2022):

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

3.1.3 EUR-Lex documents on data altruism organisations

An EUR-Lex query with the search terms "data altruism organisation(s)" was executed 16th September 2022 and gave sixteen legislative documents. The documents are listed in Annex 1 of this report, marked in Italics.

By year, all the data altruism documents are from three years, 2020 (two documents), 2021 (seven documents) and 2022 (seven documents).

"Data altruism organisation" can be defined through the General requirements for registration given in the DGA.

> *"In order to qualify for registration in a public national register of recognised data altruism organisations, an entity shall:*
>
> *(a) carry out data altruism activities.*
>
> *(b) be a legal person established pursuant to national law to meet objectives of general interest as provided for in national law, where applicable.*

[41] European Parliament, Council of the European Union. Regulation (EU) 2022/868 of the European Parliament and of the Council of 30 May 2022 on European data governance and amending Regulation (EU) 2018/1724 (Data Governance Act) (Text with EEA relevance). PE/85/2021/REV/1. OJ L 152, 3.6.2022, p. 1–44. In force. CELEX: 32022R0868. Regulation, 30/05/2022 Adopted. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022R0868

(c) operate on a not-for-profit basis and be legally independent from any entity that operates on a for-profit basis.

(d) carry out its data altruism activities through a structure that is functionally separate from its other activities.

(e) comply with the rulebook referred to Article 22(1), at the latest 18 months after the date of entry into force of the delegated acts referred to in that paragraph.

3.1.4 EUR-Lex documents on citizen science

In the EUR-Lex search conducted on 17 October 2022 “citizen science” gives 215 results, since 2011, and the trend for the annual amounts of documents is growing. Several more strictly defined searches were performed: "Citizen science" AND health gave 210 documents, “citizen science AND “health data” gave thirty-one documents, "citizen science" AND "data spaces" gave fourteen documents. “Citizen science” and “data altruism” gave two documents, both related to Horizon Europe programme [42, 43].

One of the documents, an INSPIRE evaluation document [44], has an interesting conclusion that has certain relevance to data spaces as well.

> *“When considering changes to the current INSPIRE infrastructure, it is important to not only consider the data but also to consider relevant technological developments and the role of new actors, including the private sector and citizen science initiatives.”*

Citizen science has many connections to regulation and soft regulation and ethics. E.g., informed consent, broad consent and dynamic consent are very important.

3.1.5 EUR-Lex documents on broad consent

A logical starting point to consider “broad consent” is to start from the concept of “consent” and “informed consent” in general. It is also worth of keeping in mind that although it is often

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[42] European Commission, Directorate-General for Research and Innovation. COMMISSION IMPLEMENTING DECISION amending Implementing Decision C(2021)1940 final on the adoption of the work programme for 2021-2022 within the framework of the Specific Programme implementing Horizon Europe – the Framework Programme for Research and Innovation and on its financing, as regards Missions. C/2021/9128 final. Implementing decision. 15/12/2021

[43] European Commission, Directorate-General for Research and Innovation. COMMISSION IMPLEMENTING DECISION amending Commission Implementing Decision C(2021)1940 on the adoption of the work programme for 2021-2022 within the framework of the Specific Programme implementing Horizon Europe – the Framework Programme for Research and Innovation and on its financing as regards the 2022 budget. C/2022/2975 final. Implementing decision. 10/05/2022. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=PI_COM%3AC%282022%292975

[44] European Commission, Directorate-General for Environment. COMMISSION STAFF WORKING DOCUMENT EVALUATION of DIRECTIVE 2007/2/EC establishing an Infrastructure for Spatial Information in the European Community (INSPIRE). SWD/2022/0195 final. 13/07/2022.

claimed that "data altruism" consent in the DGA is the same consent as the one foreseen under the GDPR, there are uncertainties and interpretation issues related to e.g. different consent types. The lack of clarity and the existence of uncertainties can have negative impacts on data altruism organisations as they are in charge of consents. [45]

The GDPR definition of consent is given in the GDPR Article 4[46]:

> *"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."*

The conditions for consent are more clarified in the GDPR Article 7:

> *"1. Where processing is based on consent, the controller shall be able to demonstrate that the data subject has consented to processing of his or her personal data.*
>
> *2. If the data subject's consent is given in the context of a written declaration which also concerns other matters, the request for consent shall be presented in a manner which is clearly distinguishable from the other matters, in an intelligible and easily accessible form, using clear and plain language. Any part of such a declaration which constitutes an infringement of this Regulation shall not be binding.*
>
> *3. The data subject shall have the right to withdraw his or her consent at any time. The withdrawal of consent shall not affect the lawfulness of processing based on consent before its withdrawal. Prior to giving consent, the data subject shall be informed thereof. It shall be as easy to withdraw as to give consent.*
>
> *4. When assessing whether consent is freely given, utmost account shall be taken of whether, inter alia, the performance of a contract, including the provision of a service, is conditional on consent to the processing of personal data that is not necessary for the performance of that contract."*

An EUR-Lex query with the search term "broad consent" was executed 16th September 2022, and it gave just two legislative documents.

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[45] Julie Baloup et al. White Paper on the Data Governance Act (June 23, 2021). KU Leuven CiTiP Working Paper 2021. https://ssrn.com/abstract=3872703 or http://dx.doi.org/10.2139/ssrn.3872703

[46] European Parliament, Council of the European Union. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation GDPR). In force. Current consolidated version. 04/05/2016 CELEX 32016R0679- Regulation. 27/04/2016. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32016R0679

From the two legislative documents mentioning broad consent only one was relevant and it is an impact assessment report on the European Health Data Space[47]. The report mentions "broad consent" in the Annex 8, Overview of the GDPR legal basis for processing health data for different purposes, based on an assessment[48].

In the Annex there were two separate questions that had produced answers with the term "broad consent."

> *"Please state if any specific legislation has been adopted that addresses the processing of health data that was originally collected for the purpose of providing care, by third-party public-sector researchers, i.e., by a different controller than that where the treating healthcare professionals were based. If yes, please indicate which legal base in Article 9(2) is relied upon when data are used for research by third-party public-sector researchers."*

> *"Please state if any specific legislation has been adopted that addresses the processing of health data that was originally collected for the purpose of providing care, by third party researchers not in the public sector – i.e., researchers based in not for profit organisations, researchers based in industrial or commercial research organisations and researchers based in other privately funded research organisations. If yes, please indicate which legal base in Article 9(2) is relied upon by such third-party researchers not in the public sector."*

Both these question tables included one specific row: "Broad consent as defined in national legislation, or in accordance with Recital 33". Austria, Finland, and Germany had answered positively. For Germany, there was a foot note "In the case of Germany there is no mention of broad consent legislation in the sense of legal acts, but this should become administrative practice as recently confirmed by a resolution of all supervisory authorities."

The Recital 33 mentioned above is in the GDPR,

> *"(33), It is often not possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection. Therefore, data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research. Data subjects should have the opportunity to give their consent only to certain areas of research or parts of research projects to the extent allowed by the intended.*

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[47] Council of the European Union. COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space Select: 2. ST 8751 2022 ADD 4. 06/05/2022 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CONSIL%3AST_8751_2022_ADD_4

[48] European Commission. Assessment of the EU Member States rules on health data in the light of GDPR. 2020. https://ec.europa.eu/health/sites/health/files/ehealth/docs/ms_rules_health-data_en.pdf (Annexes available at: https://ec.europa.eu/health/sites/default/files/ehealth/docs/ms_rules_health-data_annex_en.pdf)

3.2 TEHDAS WP8 stakeholder workshops and consultations

A wider TEHDAS stakeholder community and partners were invited to meet WP8 Advisory Group members and key contributors at workshops on 17-19 January 2022.

The aim of the workshops was to discuss the most challenging topics of citizen-centred solutions and models of health data altruism/data sharing intermediary systems, future EHDS structures and functions.[49]

The main conclusions of the discussions can be summarised as follows:

- Consensus needs to be reached on the nature of data altruism, its relationship to other types of data sharing, and the uncertainties surrounding what it means in the general and public interest.
- Citizens play a central role in sharing their data and building trust with citizens is the main prerequisite for any consideration of the possibility of data sharing.
- The involvement of citizens and patients is much broader than the involvement of stakeholders, and there are different active or more passive mechanisms for this.
- Citizen participation in EHDS should be encouraged.
- 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.
- Methods and tools for sharing health data should be simple and user-friendly and should guarantee the privacy of citizens when sharing their data, as well as data security.
- Participants agreed that a fundamental element of trust-building is needed, for example through platforms or apps, so that citizens have an overview of how their shared data is being used.
- Consideration should also be given to the issue of remuneration for data sharing, as well as the profit-making or non-profit use of citizens' health data.
- The FAIR principle must be applied (data must be findable, accessible, interoperable, and reusable), structures must be fair (transparent, equal, reliable and fair).[50]

[49] 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, p. 5. https://tehdas.eu/results/tehdas-consults-stakeholders-on-data-altruism/

[50] Ibid., p. 3.

3.3 Other relevant projects, initiatives and use cases

Some cooperation projects have produced reports related to data altruism, citizen science, consent, and health. [51], [52] A preliminary list of relevant projects, initiatives and use cases has been collected to the Annex 2.

4. Preliminary findings

4.1 Data altruism definitions

The official TEHDAS work plan, which set out the scope for the iCitizen Work Package was formulated in 2020. The plan set out defining data altruism as a key output. In 2021, TEHDAS published its first set (catalogue) of data altruism definitions, use cases and findings about consent and accessibility issues.

In 2022, the Data Governance Act (DGA) and the Proposal for a Regulation on the European Health Data Space were published. Both legal documents used the same definition on the data altruism (see the Glossary).

Following the publication of a legal definition of data altruism, one of our key objectives has been completed. Therefore, the context, needs and expectations for this report and the TEHDAS data altruism project have changed and evolved. For example. TEHDAS no longer needs to further analyse the definitions or basic mechanisms. Instead, the second phase of the TEHDAS data altruism project is focused on finding solutions to present and future needs related to data altruism.

The new focus of TEHDAS includes:

- To understand, apply and define the DGA and EHDS definitions and their characteristics and linkages with other sectors
- To prepare preliminary suggestions of mechanisms on data altruism for the EHDS and related issues.

4.2 Data altruism

The importance of data altruism and coordinated mechanisms to foster altruism are clearly expressed in the EC EHDS impact analysis:

“In the absence of coordinated EU action for the reuse of health data subject to rights of others and data altruism mechanisms, the societal and environmental benefits would be limited.”

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[51] EU Health Support. https://www.euhealthsupport.eu/

[52] Johan Hansen et al. Assessment of the EU Member States’ rules on health data in the light of GDPR. Nivel. EUHealthSupport. 2021. https://health.ec.europa.eu/system/files/2021-02/ms_rules_health-data_en_0.pdf

Research conducted by TEHDAS (T8.3) shows that individuals have distinct reasons and interests that encourage them to share their data. They may want to contribute to rare disease research, make local transportation more efficient, or share their data to get better advice related to their personal situation. It could also be human curiosity or citizen science, and its various forms and active participation, that is their driving force.

As the European Commission's 2020 online consultation showed, a considerable proportion of respondents (87%) consider that there are not sufficient mechanisms in place for altruistic data sharing, while 83.3% see the need for such enabling tools and mechanisms to be able to share their data for the common good. [53]

Until recently, i.e., until the adoption of the DGA, in most member states there were no clear rules and procedures regarding data altruism. Only Denmark has established data altruism mechanisms in relation to health data, and Germany plans to establish and launch them in 2023.

The goal of the DGA, as a mandatory legislative framework for data altruism, is to ensure and encourage society's trust in data altruism, which shall encourage companies and individuals to make their data available for the wider common good based on consent.

In this sense, it is crucial to ensure that data altruism mechanisms are truly altruistic, and to exclude any possibility of the misuse of data sharing in the processes regulating data altruism.

It is expected that by the year 2028 there would be around 1,250 intermediaries facilitating data altruism, with around five million citizens and five hundred companies participating in such schemes.[54]

It is the goal to provide with data altruism a high level of support for individuals in controlling their own data. For this purpose, it is necessary to find solutions that shall reconcile privacy rights with the use of data for the common good. Trust is the key.

It is also important that individuals have a clear legislative framework, fully compliant with the Regulation (EU) 2016/679 (better known to the public and hereinafter: GDPR) that will allow them to make their data available for altruistic purposes. Given that the GDPR already

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[53] COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on European data governance (Data Governance Act). ST 13351 2020 ADD 1. Cover note. 25/11/2020 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CONSIL%3AST_13351_2020_ADD_1&qid=1665976230981

[54] European Commission, Directorate-General for Communications Networks, Content and Technology. COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on European data governance (Data Governance Act) SWD/2020/295 final. CELEX 52020SC0295. Impact assessment. 25/11/2020. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020SC0295

prescribes principles and rules on consent, possibilities open up for the concept of data altruism.

In addition to trust, from the perspective of the individuals who share their data through data altruism mechanisms, transparency is of the utmost importance. Individuals, especially in relation to the sharing of their health data, should know for what purposes their data is used and they also should not be 'nudged' into sharing more data than they normally would by labelling such sharing data altruism.[55]

Finally, according to Commission Staff working document impact assessment report Accompanying the document Proposal for a Regulation of the European Parliament and of the Council on European data governance (Data Governance Act) individuals, especially in the context of EHDS, should also have the freedom to elect not to donate their health data and opt-out.

As Inception Impact Assessment on the Legislative framework for the governance of common European data spaces by the European Commission [56] states:

> *"In order to support individuals in making data available for the common good: Options to be assessed would examine whether main actions are best adopted at the national or European level. Options to be examined will range from obligations on Member States to ensure national data altruism mechanisms, to making available a common European consent form (which can be customised depending on areas), certification or labelling of tools or apps for communicating data and consent (including the option to withdraw) and tasking the European coordination mechanism (mentioned before) to maintain and disseminate such form;*
>
> *To tackle interoperability and standardisation needs, the establishment of (a) European coordination body/ies, structure(s) or process(es) is/are considered. Its/their role would be to better identify needs early on, also from an industrial policy perspective and which shall feed into the established mechanisms and processes for technical standardisation."*

Data altruism could prepare ground for new business models and further development of data ecosystems. Based on the DGA, there will be at least two key organisations in data ecosystems, data intermediation service providers and data altruism organisations. They are

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[55] Council of the European Union. COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on European data governance (Data Governance Act). ST 13351 2020 ADD 1. Cover note. 25/11/2020. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CONSIL%3AST_13351_2020_ADD_1

[56] European Commission, Directorate-General for Communications Networks, Content and Technology. Legislative framework for the governance of common European data spaces. Inception impact assessment. 02/07/2020. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=PI_COM%3AAres%282020%293480073

not identical (see e.g. Glossary)[57]. The European Data Innovation Board (EDIB) will integrate the national coordinating authorities acting as representative of the competent authorities for data intermediation services, and as the competent authorities for the registration of data altruism organisations.[58] One business model related to data altruism is data cooperative.[59]

4.3 Data altruism organisations

The term *Data altruism organisations*, the founding of the organisations, and their responsibility were legally defined for the first time by the DGA.

It is important to emphasise that Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space of 3 May 2022 (hereinafter referred to as: Proposal) in Article 40, paragraph 1 prescribes:

> *"When processing personal electronic health data, data altruism organisations shall comply with the rules set out in Chapter IV of Regulation […] [Data Governance Act COM/2020/767 final]. Where 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"*

The entire procedure for establishing data altruism organisations and bodies responsible for their registration is prescribed in Chapter IV entitled "Data altruism."

For data altruism to come to life, it is necessary that each Member State appoints one or more competent authorities for the registration of data altruism organisations (hereinafter referred to as: competent authorities). For this purpose, Member States may establish one or more new authorities or rely on existing entities. However, these bodies shall be legally separate from any recognised data altruism organisation, and functionally independent from them.

Competent authorities shall exercise their tasks in an impartial, transparent, consistent, reliable, and timely manner. In exercising their tasks, they shall safeguard fair competition and non-discrimination, and their top-level management and personnel shall not engage in any activity that may conflict with their independence of judgment or integrity in relation to evaluation activities assigned to them. Moreover, they shall have at their disposal the adequate financial and human resources to carry out the tasks assigned to them, including the necessary technical knowledge and resources.

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[57] European Commission. Data altruism / Data Governance Act explained / Shaping Europe's digital future. 2022. https://digital-strategy.ec.europa.eu/en/policies/data-governance-act-explained

[58] Committee on Legal Affairs. DRAFT OPINION of the Committee on Legal Affairs for the Committee on Industry, Research and Energy on the proposal for a regulation of the European Parliament and of the Council on harmonised rules on fair access to and use of data (Data Act) (COM(2022)0068 – C9 0051/2022 – 2022/0047(COD). 6.10.2022. https://www.europarl.europa.eu/doceo/document/JURI-PA-736696_EN.pdf

[59] Morshed Mannan. Data Cooperatives in Europe: A Legal and Empirical Investigation. Florence school of regulation. 14.4.2022. https://fsr.eui.eu/data-cooperatives-in-europe-a-legal-and-empirical-investigation/

The competent authorities of each Member State shall be responsible for the public national register of recognised data altruism organisations that they will maintain and regularly update, and where these tasks are related to the processing of personal data, they shall perform their tasks in cooperation with the relevant data protection authority, and with the relevant sectoral authorities of that Member State.

At the level of the European Union, the Commission will introduce the Union register of recognised data altruism organisations. Every Member State shall notify the Commission of the identity of their competent authorities by 24 September 2023, and after that of any subsequent change to the identity of those competent authorities.

One of the tasks of the national competent authorities is to evaluate the request of a subject or a legal person for the registration in the public national register of recognised data altruism organisations.

In order that a subject or legal entity, to be able to apply for registration in the public national register of recognised organisations for data altruism and to be registered in the same, in accordance with the DGA, it shall meet the following conditions:

- carry out data altruism activities
- be a legal person established pursuant to national law to meet objectives of general interest as provided for in national law, where applicable
- operate on a not-for-profit basis and be legally independent from any entity that operates on a for-profit basis
- carry out its data altruism activities through a structure that is functionally separate from its other activities
- comply with the rulebook referred to in Article 22(1), at the latest 18 months after the date of entry into force of the delegated acts referred to in that paragraph.

After the competent authority evaluates the application for registration and determines that the entity meets all prescribed requirements for registration, it will register the entity in the public national register of recognised data altruism organisations within 12 weeks from the receipt of the application for registration. Registration is valid in all Member States.

After that, the national competent authority shall inform the Commission about all registrations, which the Commission then includes in the public Union register of recognised data altruism organisations.

An entity that is registered in the public national register of recognised data altruism organisations can use for the written and spoken communication the label "data altruism organisation recognised in the Union", as well as a common logo.

To ensure that recognised data altruism organisations are easily identifiable throughout the Union, the Commission shall, by means of implementing acts, establish the design of the common logo to be clearly displayed by recognised data altruism organisations in any online and offline publication related to their data altruism activities. The common logo shall be

accompanied by a QR code with a link to the public Union register of recognised data altruism organisations.

The common logo, accompanied by the QR code, helps data subjects and data holders to easily identify the recognised data altruism organisations and thereby increase trust in them.[60]

The work of recognised bodies for data altruism must be transparent, so for that purpose the DGA also prescribes the specific requirements to ensure the transparency of their work.

In order to ensure the transparency of its work, the data altruism organisation is obliged to keep complete and accurate records of all natural or legal persons that were given the possibility to process data held by that recognised data altruism organisation, and their contact details; about the date or duration of the processing of personal data or use of non-personal data; about the purpose of the processing as declared by the natural or legal person that was given the possibility of processing; and about the fees paid by natural or legal persons processing the data, if any.

Moreover, another obligation of a recognised data altruism organisation which provides the transparency of its work will be the annual report on its activities that will be submitted to the relevant competent authority. The report shall contain at least the following: information on the activities of the recognised data altruism organisation; a description of the way in which the objectives of general interest for which data were collected have been promoted during the given financial year; a list of all natural and legal persons that were allowed to process data it holds, including a summary description of the objectives of general interest pursued by such data processing and the description of the technical means used for it, including a description of the techniques used to preserve privacy and data protection; a summary of the results of the data processing allowed by the recognised data altruism organisation, where applicable; information on sources of revenue of the recognised data altruism organisation, in particular on all revenue from allowing access to the data, and on expenditure.

The DGA prescribes specific requirements to safeguard rights and interests of data subjects and data holders regarding their data. Thus, a recognised data altruism organisation shall inform data subjects or data holders prior to any processing of their data in a clear and easily comprehensible manner on the objectives of general interest and, if applicable, the specified, explicit and legitimate purpose for which personal data is to be processed, and for which it permits the processing of their data by a data user; and on the location of and the objectives of general interest for which it permits any processing carried out in a third country, if the processing is carried out by the recognised data altruism organisation.

The recognised data altruism organisation shall not use the data for objectives other than those of general interest for which the data subject or data holder allows the processing, and it shall not use misleading marketing practices to solicit the provision of data.

[60] Recital 47 of DGA

It shall provide tools for obtaining consent from data subjects or permissions to process data made available by data holders, as well as the tools for easy withdrawal of such consent or permission.

It shall also take measures to ensure an appropriate level of security for the storage and processing of non-personal data that it has collected based on data altruism.
In case of unauthorised transfer of non-personal data that has been exchanged, unauthorised access to this data or its unauthorised use, the recognised data altruism organisation shall inform the data holders without delay.

If the recognised data altruism organisation facilitates data processing by third parties, including by providing tools for obtaining consent from data subjects or permissions to process data made available by data holders, it shall, where relevant, specify the third-country jurisdiction in which the data use is intended to take place.

The competent authorities shall monitor and supervise compliance of recognised data altruism organisations with the requirements laid down in Chapter IV of the DGA (hereinafter referred to as: Chapter IV). They may also monitor and supervise the compliance of such recognised data altruism organisations, based on a request by a natural or legal person.

In that sense, if the competent authority finds that a recognised data altruism organisation does not comply with one or more of the requirements from Chapter IV, it shall notify that organisation of its findings and give it the opportunity to state its views within 30 days of the receipt of the notification.

The competent authority shall have the power to require the cessation of the infringement found either immediately or within a reasonable time limit and shall take appropriate and proportionate measures with the aim of ensuring compliance.

If a recognised data altruism organisation does not comply with one or more of the requirements of Chapter IV even after the competent authority informed it on the infringement and sent a request for the cessation of the infringement, that recognised data altruism organisation shall lose its right to use the label data altruism organisation recognised in the Union' in any written and spoken communication, and it shall be removed from the relevant public national register of recognised data altruism organisations and from the public Union register of recognised data altruism organisations.

To facilitate the collection of data based on data altruism, the Commission shall adopt implementing acts establishing and developing a European data altruism consent form, after consulting the European Data Protection Board, considering the advice of the European Data Innovation Board, and duly involving relevant stakeholders. The form shall allow the collection of consent or permission in all Member States in a uniform format.
The European form for consent to data altruism shall, in the case of providing personal data, ensure that data subjects can give and withdraw their consent from a specific data processing operation in compliance with the requirements of GDPR.

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 data altruism organisations for purposes which they establish themselves or, where relevant, they could allow the processing by third parties for those purposes. Where recognised data altruism organisations are data controllers or processors as defined in GDPR, they have to comply with that Regulation. Data altruism will rely on consent of data subjects within the meaning of Article 6(1), point (a), and Article 9(2), point (a), of GDPR that should be in compliance with requirements for lawful consent in accordance with Articles 7 and 8 of that Regulation. Where it's about non-personal data, there's no data subject and no GDPR implications.

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. Article 5(1), point (b), of GDPR specifies that further processing for scientific or historical research purposes or statistical purposes should, in accordance with Article 89(1) of GDPR, not be considered to be incompatible with the initial purposes. For non-personal data, the usage limitations should be found in the permission given by the data holder.

The European Commission gives a practical explanation on data altruism organisations in its web pages.

> *"Entities that make available relevant data based on data altruism will be able to register as 'data altruism organisations recognised in the Union. These entities must have a not-for-profit character and meet transparency requirements as well as offer specific safeguards to protect the rights and interests of citizens and companies who share their data. In addition, they must comply with the rulebook (at the latest 18 months after it comes into force), which will lay down information requirements, technical and security requirements, communication roadmaps and recommendations on interoperability standards. The Commission will develop the rulebook, in close cooperation with data altruism organisations and other relevant stakeholders."*[61]

According to the EC web page explanation, the data altruism organisations must comply with the rulebook to be developed by the Commission, in close cooperation with data altruism organisations and other relevant stakeholders.

The DGA does not prescribe the procedure by which a recognised data altruism organisation gives natural or legal persons the possibility to process data in the possession of that organisation.

Chapter IV of the EHDS Proposal[62] entitled Secondary use of electronic health data, in its Section 1 prescribes the general conditions of the secondary use of electronic health data. In Section 2, there are provisions related to the governance and mechanisms for the

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[61] European Commission. Data altruism / Data Governance Act explained / Shaping Europe's digital future. 2022. https://digital-strategy.ec.europa.eu/en/policies/data-governance-act-explained

[62] 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: 52022PC0197Form: Proposal for a regulation. 03/05/2022. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022PC0197

secondary use of electronic health data, and the provisions of Section 3 prescribe the procedure of obtaining the permit for the secondary use of electronic health data.

However, from the provisions of Chapter IV of the Proposal the procedure by which a recognised data altruism organisation gives natural or legal persons the possibility to process data in the possession of that organisation is not clear. It is also not clear whether there are certain situations in which the said organisation refuses to give natural or legal persons the possibility of data processing, and what conditions must be met by a natural or legal person to gain the possibility of data processing. Namely, it is not clear how the provisions from Articles 44, 45, 46 and 47 of the Proposal refer to recognised data altruism organisations in the context of the European health data space.

Following the above said, it would be good if the clear procedures by which recognized data altruism organisations give natural or legal persons the possibility to process the data in its possession, especially the data donated by the individuals about their health, were not left to the national legislation of each individual member state, but that the standardization of these procedures be at the level of EU legislation. Knowing when the Commission will prepare the rulebook for data altruism organisations cooperation with the Data Spaces Support Centre DSSC EU Project[63] (DIGITAL) and other relevant EU projects and initiatives is needed. The DSSC project will explore the needs of data space initiatives, define common requirements, and establish best practices to accelerate the formation of sovereign data spaces as a key element of digital transformation at all levels. Information requirements, technical and security requirements, communication roadmaps and recommendations on interoperability standards for data from data altruism organisations are quite essential for data spaces and a dialogue is needed. The DSSC is also expected to be “an operational arm” of the European Data Innovation Board, which will be a key organisation in the fair data economy, also for data altruism organisations.[64]

4.4 Citizen science

Citizen science both supports and relays on data altruism and can be defined as:

> *“Citizen Science refers to the 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. Participants provide experimental data and facilities for researchers, raise new questions, and co-create a new scientific culture.”*[65]

[63] DSSC Data Spaces Support Centre EU Project (DIGITAL) https://dssc.eu
[64] The Council of the European Union. EU looks to make data sharing easier: Council agrees position on Data Governance Act. 1.10.2021. https://www.consilium.europa.eu/en/press/press-releases/2021/10/01/eu-looks-to-make-data-sharing-easier-council-agrees-position-on-data-governance-act/
[65] SOCIENTIZE Project. 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

Citizen science includes many possibilities to contribute to scientific knowledge and understanding, e.g., by donating one's own genome data, participating in research, with often altruism and curiosity being the strongest driving forces. Sometimes data altruism and citizen science can produce amazing scientific results, e.g., Analysis of Y chromosomes in an Afro-American man resulted in a scientific publication that caused a shift in the evolutionary timeline of the humankind.[66], [67]

The European Citizen Science Association ECSA defines citizen science through characteristics and has published the ten points of citizen science:[68]

1. *Citizen science projects actively involve citizens in scientific endeavour that generates new knowledge or understanding. Citizens may act as contributors, collaborators, or as project leader and have a meaningful role in the project.*
2. *Citizen science projects have a genuine science outcome. For example, answering a research question or informing conservation action, management decisions or environmental policy.*
3. *Both the professional scientists and the citizen scientists benefit from taking part. Benefits may include the publication of research outputs, learning opportunities, personal enjoyment, social benefits, satisfaction through contributing to scientific evidence e.g., to address local, national, and international issues, and through that, the potential to influence policy.*
4. *Citizen scientists may, if they wish, participate in multiple stages of the scientific process. This may include developing the research question, designing the method, gathering, and analysing data, and communicating the results.*
5. *Citizen scientists receive feedback from the project. For example, how their data are being used and what the research, policy or societal outcomes are.*
6. *Citizen science is considered a research approach like any other, with limitations and biases that should be considered and controlled for. However, unlike traditional research approaches, citizen science provides opportunity for greater public engagement and democratisation of science.*
7. *Citizen science project data and meta-data are made publicly available and where possible, results are published in an open access format. Data sharing may occur*

[66] Fernand L Mendez, Thomas Krahn, Schrack B et al. An African American paternal lineage adds an extremely ancient root to the human Y chromosome phylogenetic tree. AJHG VOLUME 92, ISSUE 3, P454-459, MARCH 07, 2013. https://www.cell.com/ajhg/fulltext/S0002-9297(13)00073-6

[67] Alan Boyle. African American's Y chromosome sparks shift in evolutionary timetable. NBC News. 6.3.2013. https://www.nbcnews.com/sciencemain/african-americans-y-chromosome-sparks-shift-evolutionary-timetable-1c8710411

[68] ECSA 10 Principles of Citizen Science. https://ecsa.citizen-science.net/ecsa-guidelines-and-policies/

during or after the project unless there are security or privacy concerns that prevent this.

8. *Citizen scientists are acknowledged in project results and publications.*
9. *Citizen science programmes are evaluated for their scientific output, data quality, participant experience and wider societal or policy impact.*
10. *The leaders of citizen science projects take into consideration legal and ethical issues surrounding copyright, intellectual property, data sharing agreements, confidentiality, attribution, and the environmental impact of any activities.*

The connection of data altruism and citizen science is many, and understanding this link, its driving forces, incentives, mutually beneficial solutions, challenges, risks, and possibilities for data spaces is key.

4.5 Broad consent in the EHDS

Based on the DGA, the European Commission shall establish the European Data Innovation Board. It will advise and assist the Commission with regard to developing the European data altruism consent form in accordance with the DGA Article 25, based on a modular approach.[69]

> *"The European data altruism consent form shall use a modular approach allowing customisation for specific sectors and for different purposes."*

On the 3rd of May 2022, the European Commission adopted the proposal on EHDS. Following which they submitted a number of requests to TEHDAS partners, asking for additional elements to be included into the scope of research and recommendations of the TEHDAS project to support the implementation of EHDS. These requests included for WP8 the examination of the data altruism consent forms and practices, including the possible use of the broad consent. This new research on broad consent will be carried out on the basis of work that has been already accomplished by TEHDAS, incorporating existing stakeholder opinions and analysis, as well as available literature including documents of the European Data Protection Board (EDPB)[70], [71] further scientific articles and also national solutions on broad concept such in Austria, Finland and Germany which have broad consent defined in their national legislation or mechanisms in 2020. [72]

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[69] DGA, Article 25 (1). https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022R0868

[70] Guidelines of the European Data Protection Board on consent under Regulation 2016/679 https://edpb.europa.eu/sites/default/files/files/file1/edpb_guidelines_202005_consent_en.pdf

[71] EDPB Document on response to the request from the European Commission for clarifications on the consistent application of the GDPR, focusing on health research. European Data Protection Board. 2.2.2021. https://edpb.europa.eu/sites/default/files/files/file1/edpb_replyec_questionnaireresearch_final.pdf

[72] 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.

This Milestone document summarises the work that the TEHDAS JA work has already started to examine consent practices which provides for a good basis for further work on the possible use of the concept of broad consent.

For example, in Milestone document *M8.4 "Presentation of a first set of data altruism definitions, use cases and findings"* [73] a literature review has been carried out with the aim to map options, use cases and good practices on how data altruism can increase effectiveness of data governance structures and functions of (primary and) secondary use of citizens' health and health-related data across Europe. This literature review 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).

In this milestone document the main forms of consent have been identified based on a literature review as the following:

- 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.
- Partnership model: Similar to dynamic consent. Bidirectional communication process for consent that provides opportunities for researchers and participants to update consent over time.
- Tiered consent: Allows participants to personalise consent based on a range of factors including preferences for future uses of their data and whether or not they wish to be recontacted before any future use.
- Layered consent: Often refers to a form of consent that allows participants to choose between options.
- Targeted consent: Disclose extra information during a standard informed consent procedure.
- Broad consent: Open in terms of data re-use. Broad consent proposals often include other processes collaborating with them. For example, one suggestion was to have broad consent with certain limits set on the future use of samples which could be judged by IRBs. Others proposed broad consent in a well-regulated environment with safeguards, and with mechanisms used to monitor communication with donors.

[73] 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

- 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.

- Opt-out forms: The participant is given brief information about the treatment and told they will be part of the research study unless they do not wish to take part. Another opt-out model put forward an 8-point model of consent with opt-out based on Fiona Caldicott's recommendations. These points, aimed at participants, tell participants of the importance of information, the role of law in protecting participants, the right to opt out, and the suggestion that opt out does not apply to anonymised information or exceptional when there is a "mandatory legal requirement" or "over-riding public interest."

It can be added to the above list that meta-consent systems allow individuals to choose which type of consent they would like to use in the future to express their preferences on the secondary use and sharing of their health data.

M8.4 also identified 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 European Health Data Space (EHDS). Consent is discussed as a key topic. It is concluded that in cross-border and cross-organisational data exchange, parties may face challenges due to different forms of consent.

In Milestone *M8.5 "Overview about the results of EU-wide multi stakeholder workshops, with a special regard to updated definitions, needs, solutions, experiences, and good practices of data altruism structures and functions for the future EHDS"* document the results and learnings of the multi-stakeholder workshops organised in the framework of T8.5 on 17, 18, and 19 January 2022 have been collected. These discussions have also contained references to the distinct types of consents, including the broad consent. For example, it has been identified as a challenge that in current industry data sharing practice with broad consent at the beginning of data collection people are asked whether they are willing to share their data, which approach falls short of the GDPR requirement to have consent for all purposes of data use. Ideas like the banking model, as one model, have also been mentioned in connection with consent forms, as parallelism with banking can simplify many issues, especially from the citizens' perspective. Citizens can feel safe to manage transactions like in a bank. Data portability could be similar to changing a bank. The discussion concluded that varying uses of consent through European countries should be avoided or reduced. Regarding European data, consent forms are needed not only on European but also on national level.

The European Commission also organised a *Workshop on the European data altruism consent form* on the 20th of June 2022, with the aim to bring together relevant stakeholders with knowledge and experience on consent to advise the Commission on the development of a European data altruism consent form, pursuant to Article 25 of the Data Governance Act. Despite the general scope of the workshop, discussion was focused on data altruism consent form for medical research, where most stakeholders have had direct experience so far.

Good practices were presented during the workshop about consent form used in different countries in the context of scientific research, with regard GDPR and the possibility of broad consent. The German Medical Informatics initiative presentation highlighted that the key issues when working in the consent form included heterogeneity of regulatory environment, weakness of harmonisation effect of the GDPR and selection bias.

The core of the discussion was around whether to use dynamic or broad consent, having voted finally for the use of the latter, arguing among others with the unpredictable nature of scientific research, the need to avoid bias and the inclusion of those who died. Rotterdam Research University presented also the consent form they use. The informed consent template is based on WHO template for qualitative research, and consists of three parts: practical info, voluntariness, privacy, and confidentiality. They also emphasised that informed consent in the perspective of ethics in research is different from the consent regulated in the GDPR (where consent or public interest are considered as legal grounds to process personal data). The Polish Hospital Federation introduced the 'Donate your data foundation,' now supported by more than twenty organisations, based on the idea that to decide how one own data is used is a human right. Data donation is based on blockchain technology, the IT solution facilitates that consent can be given and withdrawn at any time. Medical data is collected when needed, is anonymised and only after that shared (data is not stored). A poll has also been organised in Poland showing that 49% of citizens would be willing to share data with medical associations.

During the general discussion around consent participants formulated many ideas and proposals, which will be later examined in more depth by TEHDAS as well. These include the issue of building trust between consent provider and receiving organisation as well as trustworthy institutional structures. Flexible solutions are needed as the needs of data subjects may be diverse. It has also to be considered that what could make people more willing to be data altruistic is the certainty that data will be used for the benefit of society. There was an idea to make the consent form modular: pyramid system (short, accessible text with key content that people care about expressed in simple language. Then use links/ infographic/ QR code to give info to those who wants to know more). Further thinking is required about the differences between sharing data with data altruism organisations, with data intermediaries, or sharing it in a data space, plus how e.g., biometric data in one's personal data wallets relate to all this. The best technologies must be explored that could facilitate giving/withdrawing consent, and finally definition of public interest (or general interest) is needed to boost data altruism, which is not only about medical research.

4.6 GDPR compliance

The protection of personal data is an integral element of the trust that the individuals and organisations should have in the development of the digital economy and the access to equitable health care, in the context of processing health data within the EHDS framework. In this regard the European Data Protection Bord (hereinafter referred to as: the EDPB) and the European Data Protection Supervisor (hereinafter referred to as: the EDPS) underline that the success of the EHDS will depend on a robust legal basis for processing in line with EU data protection law, 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. Sufficient assurances of a lawful, responsible, ethical management anchored in EU values, including respect for fundamental rights, should be provided. In this regard, the EDPB and the EDPS consider that the EHDS should serve as an example of transparency, effective accountability, and proper balance between the interests of the individual data subjects and the shared interest of society as a whole.[74]

In that sense, Recital 4 of the Proposal prescribes that

> *"processing of personal electronic health data is subject to the provisions of Regulation (EU) 2016/679 of the European Parliament and of the Council and, for Union institutions and bodies, Regulation (EU) 2018/1725 of the European Parliament and of the Council. References to the provisions of Regulation (EU) 2016/679 should be understood also as references to the corresponding provisions of Regulation (EU) 2018/1725 for Union institutions and bodies, where relevant."*

In line with Article 1(4) of the Proposal,

> *"[t]he Regulation shall be without prejudice to other Union legal acts regarding access to, sharing of or secondary use of electronic health data, or requirements related to the processing of data in relation to electronic health data, in particular Regulations (EU) 2016/679, (EU) 2018/1725, […] [Data Governance Act COM/2020/767 final] and […] [Data Act COM/2022/68 final]." Moreover, in line with Article 1(5) of the Proposal, the "(...) Regulation shall be without prejudice to Regulations (EU) 2017/745 and […] [AI Act COM/2021/206 final], as regards the security of medical devices and AI systems that interact with EHR systems" DGA should be without prejudice to Regulations (EU) 2016/943.*[75]

The DGA in its Article 2 refers the terms personal data, consent, data subject, and data user to as well as the term processing, but it also refers to the definition of processing in Regulation (EU) 2018/1807 regarding non-personal data.

For the processing of personal data, and in particular personal data related to the health of individuals in the context of data altruism organisations, to be in accordance with the GDPR it is essential that the consent on which the collection of the said data is based be recognized as the legal basis of data processing from Article 6 paragraph 1 point a) and Article 9 paragraph 2 point a) of the GDPR. Data altruism related to personal data as in the DGA, it is by definition consent-based. It is essential that the consent on which the collection of the said data is based be recognised be recognized as the legal basis of data processing from Article 6 paragraph 1 point a) and Article 9 paragraph 2 point a) of the GDPR.

Such processing must also be accompanied by appropriate data protection safeguards. This means that the re-use of personal data should always respect the principles of lawfulness,

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[74] EDPB-EDPS Joint Opinion03/2022 on the Proposal for a Regulation on the European Health Data Space Adopted on 12 July 2022

[75] Recital 3 of DGA

fairness, and transparency as well as purpose limitation, data minimisation, accuracy, storage limitation, integrity, and confidentiality in line with Article 5 of the GDPR[76].

Considering that data altruism will rely on consent of data subjects, it must be clearly pointed out that the consent should be in compliance with requirements for lawful consent in accordance with Articles 7 and 8 of GDPR. In other words, all requirements related to giving and withdrawal of the consent, as set in the GDPR, need to be fulfilled.

Also, the requirements accompanying the registration regime should enhance but not replace the obligations of the data altruism organisations as controllers or processors under the GDPR[4] especially with regard to the obligation to implement appropriate technical and organisational measures to ensure an appropriate level of processing security, which sit with the controller or processor, in addition to other obligations prescribed by the GDPR.

According to the legislative financial statement which is a part of the Proposal, the general objective of the Intervention is "to establish the rules governing the EHDS to ensure natural persons' access and control over their own health data, to improve the functioning of the single market for the development and use of innovative health products and services based on health data, and to ensure that researchers, innovators, policy-makers and regulators can make the most of the available health data for their work, while preserving trust and security. This objective is expressed in Article 1(2)a of the Proposal which states that the Regulation strengthens the rights of natural persons in relation to the availability and control of their electronic health data.

To fulfil the stated goal of the Proposal, it is essential to harmonise the work of data altruism organisations with the provisions of the GDPR, especially regarding the possibility of exercising the rights of the data subject, the rights of natural persons, in accordance with Chapter III of the GDPR. However, that is a question for the implementation of DGA.

4.7 Ethics

As defined in the *Data Governance Act (DGA)*, data altruism involves:

> "*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...*"

Central to the successful development of this practice, the DGA has established data intermediaries and data altruism organisations. These two types of organisations will act as the means for achieving a society and data economy that engages in the practice of data sharing and data altruism.

The European Commission envisages that data intermediaries will function as:

[76] 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) Version 1.1

> *"…neutral third parties that connect individuals and companies on one side with data users on the other. They cannot monetise the data (e.g., by selling it to another company or using it to develop their own product based on this data) and will have to comply with strict requirements to ensure this neutrality and avoid conflicts of interest."*[77]

The European Commission also gives a practical explanation on what data altruism organisations are in its web pages:

> *"Entities that make available relevant data based on data altruism will be able to register as 'data altruism organisations recognised in the Union.' These entities must have a not-for-profit character and meet transparency requirements as well as offer specific safeguards to protect the rights and interests of citizens and companies who share their data. In addition, they must comply with the rulebook (at the latest 18 months after it comes into force), which will lay down information requirements, technical and security requirements, communication roadmaps and recommendations on interoperability standards. The Commission will develop the rulebook, in close cooperation with data altruism organisations and other relevant stakeholders."*

The first ethical point that needs to be raised concerns the commercialisation of health data. If the primary means for encouraging citizens and companies to share their health data is the monetisation of said data, there is a risk that citizens will view this as an unethical action and reject data altruism as a result.
Research conducted by TEHDAS Work Package 8 iCitizen into citizens preferences towards secondary data use of health data has highlighted the monetisation of data as an ethical risk because citizens do not wish to see a market created for the buying and selling of health data. Whilst they wish to see benefits to society from the reuse of data, such as improvements to services, diagnostics, and treatments, but they do not wish for this to happen through financial/commercial/market mechanisms.

As a result, by monetising health data, there is a risk of disincentivising citizen's participation in altruistic practices. Instead, practices should be developed that demonstrate the benefits of data sharing. These can be communicated consistently to encourage and incentivise the public to share their data.

Further ethical challenges are brought about by citizens views on the role of private sectors organisations in health data reuse. The results of WP8 iCitizen have demonstrated a strong opposition from citizens towards the participation of private sector organisations in health data reuse[78]. This is based on the perceived conflict of interest that citizens see between the commercial interests of for-profit organisations and individual and societal benefits.

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[77] https://digital-strategy.ec.europa.eu/en/policies/data-governance-act-explained#ecl-inpage-l4ihlgt9 (accessed on the 02/11/2022)

[78] Joe Perrin, Louise Matthieu. Citizens' perception of and engagement with health data secondary use and sharing in Europe – a literature review. TEHDAS M8.1. . 25.2021.

This opposition is not absolute though, and some citizens do recognise the need for private sector participation. The rules governing data intermediaries' operations may go some way to overcoming this opposing then. By being legally, technically, and managerially separate from any for-profit organisation to which they are associated; as well as being required to provide information on who has accessed data, data intermediaries do take practical steps towards demonstrating themselves to be trustworthy custodians of health data.

Ethics, communication, engagement and information

Crucial to the ethical development of data altruism are the communication, engagement and information sharing methods used by its proponents. Should communication, engagement and information sharing be poor there is a risk that only a subset of the population choses to participate and data sets remain incomplete and unreflective of the overall population as a result [79].

From this, two ethical risks arise:

1. Unreflective or biased analysis
2. Increased marginalisation

Should data sets remain incomplete, any analysis performed will only be based on a subset of the population, limiting its value to the overall population, and potentially resulting in the development of fewer services for non-participants and, more worryingly, potentially less efficacious services or even harmful services [80].

To the second point, should engagement and information sharing be poor it is likely that an understanding of data altruism, and therefore the ability to give informed consent, is limited to a subset of population and not those groups who have historically been marginalised in society. If this were to happen a situation could arise where the services offered to those excluded from participation in data altruism are of a reduced quantity or quality.

Consideration also needs to be given to those who make an informed choice not to engage in data altruism. Whilst effective information and engagement can limit the size of this group, it is unlikely to remove it in its entirety. As such, data altruism practices cannot be implemented in ways that limit the benefits to this group or impact upon the equality of service provision.

Data altruism must be socialised as a practice throughout the population with an understanding that baseline attitudes and preferred means of engagement vary dramatically across subsets of the population and between individuals. It is therefore a requirement that

https://tehdas.eu/app/uploads/2021/11/tehdas-citizens-perception-of-and-engagement-with-health-data-secondary-use-and-sharing-in-europe.pdf

[79] Dame Fiona Caldicott. Our new dialogue with the public about data for public benefit. UK Government. 14.4.2020. https://www.gov.uk/government/speeches/our-new-dialogue-with-the-public-about-data-for-public-benefit

[80] NHS. Pulse Oximeter Bias Highlighted in Rapid Review. NHS Race & Health Observatory. 14.4.2021. https://www.nhsrho.org/publications/pulse-oximeter-bias-highlighted-in-rapid-review/

proponents of data altruism use the resources at their disposal to reach out to citizens through diverse means and not expect citizens to come to them.

4.7.1 Ethics and data altruism organisations

Heavily linked to the concerns about poor engagement with the public is the current development of Data Altruism Organisations. Specifically, the DGA sets out the transparency mechanisms intended to build trusts in Data Altruism Organisations as being:

> *"The common logo, accompanied by the aforementioned QR code, helps data subjects and data holders to easily identify the recognised Data Altruism Organisations and thereby increase trust in them."*

This makes the transparency of Data Altruism Organisation dependent upon citizens already trusting these institutions, having the digital literacy to make use of a QR code, and the knowledge and desire to find this information for themselves. In a European society where there are low rates of digital literacy, low trust in data reuse, and a wide range of preferences towards engagement and information sharing mechanisms the current proposals for building trust risk missing large sections of the population.

5. Further steps towards the deliverable D8.2 and final recommendations

The aim of this milestone report was to combine and synthesise the extension research and consultation results from the preparatory stages of that part of the Work Package 8 that focuses on data altruism as well as to reassess data altruism priorities for TEHDAS in line with the publication of the European Health Data Space proposal.

A final report, D8.2 Report on lessons learned to be applied and recommendations for data altruism practices in the implementation of construction of national and European health data spaces (including broad consent), will be published in May 2023, including recommendations on GDPR-compliant application of data altruism practices, on how to adopt and harmonise identified good practices for the construction of national or European health data spaces, and it will also include an analysis of the use of consent forms including use of broad consent with data altruism practises.

The final recommendations for the European Commission will be developed in line with the views of stakeholders, best practice examples and with consideration to the European Health Data Space proposals, the Data Governance Act, and other seminal works on the subject.

The focus of recommendations for the final deliverable will be the following including to:

1. Understand, apply, and clarify the DGA data altruism definition in the context of EHDS and to health data.
2. Clarify roles and responsibilities of Data Altruism Organisations in health specific context, regarding health data.

3. Define role and responsibilities of citizens in the system of secondary use of health data and specifically in data altruism models and ecosystems.
4. Set out suggestions of mechanisms to facilitate data altruism and Data Altruism Organisations.
5. Support for collaborations, e.g. the European Health Data Space actors should start a dialogue and cooperate with the European Commission and the European Data Innovation Board, to support their DGA-based consent work, including the concept of broad consent and dynamic consent, so that the result fits to the EHDS purposes as far as possible.
6. Collaborate with data altruism work in other projects and initiatives, e.g. the DSSC Data Spaces Support Centre project.

6. Glossary

The Glossary in the Table 1 provides definitions for key terminology.

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 content 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 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."	DGA, Article 2. EHDS Regulation, Article 2.: "the definitions of 'data', 'access', 'data altruism', 'public sector body' and 'secure processing environment', pursuant to Article 2 (1), (8), (10), (11) and (14)" of DGA.
Data Altruism Organisation	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.	DGA; Article 2.
Data Intermediation Service	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: (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 users, without establishing a commercial relationship between data holders and data users; (b) services that focus on the intermediation of copyright-protected content; © services that are exclusively used by one data holder in order to enable the use	DGA, Article 2.

	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; (d) data sharing services offered by public sector bodies that do not aim to establish commercial relationships;	
European Data Innovation Board EDIB	European Data Innovation Board will be created to advise and assist the 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.
Informed consent	A subject's free and voluntary expression of his or her willingness to participate in a particular clinical trial, after having been 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.	Regulation 536/2014 on clinical trials on medicinal products for human use.

7. References and further reading

This section contains both the articles that are referenced in the text (in italics) as well as useful articles for further reading and to be used in the Deliverable work.

1. Aalto University. Citizen Science. 2022. https://www.aalto.fi/en/open-science-and-research/citizen-science
2. Afua Adjekum et al. Elements of Trust in Digital Health Systems: Scoping Review J Med Internet Res 2018;20(12): e11254 doi: 10.2196/11254 https://www.jmir.org/2018/12/e11254/
3. Mhain Aitken et al. Public responses to the sharing and linkage of health data for research purposes: a systematic review and thematic synthesis of qualitative studies. BMC Medical Ethics 17, 73, 2016. DOI: 10.1186/s12910-016-0153-x
4. Katja von Alfthan, Jaakko Hyry. European Wearables Survey: Measuring wellbeing citizen survey: Finland, Germany, the Netherlands, and France. Total 2020 report. Sitra, Helsinki, 2020
5. Marieke A R Bak et al. “Stakeholders' perspectives on the post-mortem use of genetic and health-related data for research: a systematic review.” European journal of human genetics. EJHG vol. 28,4 (2020): 403-416. doi:10.1038/s41431-019-0503-5
6. A. Ballantyne. How should we think about clinical data ownership? Journal of Medical Ethics 46:289–294, 2020. https://jme.bmj.com/content/medethics/46/5/289.full.pdf
7. Julie Baloup et al. White Paper on the Data Governance Act (June 23, 2021). KU Leuven CiTiP Working Paper 2021. https://ssrn.com/abstract=3872703 or http://dx.doi.org/10.2139/ssrn.3872703
8. Marianne Bårtvedt van Os, László Bencze Semmelweis, 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.eu/app/uploads/2021/09/tehdas-presentation-of-a-first-set-of-data-altruism-definitions-use-cases-and-findings.pdf
9. 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/
10. Matthew Bietz et al. Data Donation as a Model for Citizen Science Health Research. Citizen Science: Theory and Practice. 2019;4(1):6. DOI: http://doi.org/10.5334/cstp.178

11. Daniel Boulos et al. Acceptability of opt-out consent in a hospital patient population. Internal Medicine Journal 48(1): 84-87. January 2018. DOI: 10.1111/imj.13666

12. Caroline Brall et al. Public preferences towards data management and governance in Swiss biobanks: results from a nationwide survey. BMJ Open. 2022 Aug 26;12(8): e060844. doi: 10.1136/bmjopen-2022-060844. PMID: 36028266; PMCID: PMC9422864.

13. Tobias Bräutigam et al. EU regulation builds a fairer data economy. The opportunities of the Big Five proposals for businesses, individuals, and the public sector. Sitra working paper. 2022. https://www.sitra.fi/en/publications/eu-regulation-builds-a-fairer-data-economy/

14. Fiona Caldicott. Information: To share or not to share? The Information Governance Review, 2013. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/192572/2900774_InfoGovernance_accv2.pdf

15. Fiona Caldicott. 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

16. Dame Fiona Caldicott. Our new dialogue with the public about data for public benefit. UK Government. 14.4.2020. https://www.gov.uk/government/speeches/our-new-dialogue-with-the-public-about-data-for-public-benefit

17. Daniel Cameron, Sarah Pope, Michael Clemence. Exploring the public's views on using administrative data for research purposes. London: Ipsos Mori. 2-57., 2014. https://www.ipsos.com/sites/default/files/publication/1970-01/sri-dialogue-on-data-2014-census.pdf

18. Sarah Castell, Harry Evans. The one-way mirror: public attitudes to commercial access to health data. Ipsos Mori, Wellcome Trust, 2016. https://www.ipsos.com/sites/default/files/publication/5200-03/sri-wellcome-trust-commercial-access-to-health-data.pdf

19. 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

20. Committee on Legal Affairs. DRAFT OPINION of the Committee on Legal Affairs for the Committee on Industry, Research and Energy on the proposal for a regulation of the European Parliament and of the Council on harmonised rules on fair access to and use of data (Data Act) (COM (2022)0068 – C9 0051/2022 – 2022/0047(COD). 6.10.2022. https://www.europarl.europa.eu/doceo/document/JURI-PA-736696_EN.pdf

21. Council of the European Union. COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on European data governance

(Data Governance Act). ST 13351 2020 ADD 1. Cover note. 25/11/2020 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CONSIL%3AST_13351_2020_ADD_1&qid=1665976230981

22. Council of the European Union. COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space. ST 8751 2022 ADD 4. 06/05/2022 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CONSIL%3AST_8751_2022_ADD_4

23. Council of the European Union. EU looks to make data sharing easier: Council agrees position on Data Governance Act. 1.10.2021. https://www.consilium.europa.eu/en/press/press-releases/2021/10/01/eu-looks-to-make-data-sharing-easier-council-agrees-position-on-data-governance-act/

24. Council of the European Union. Promoting data sharing: presidency reaches deal with Parliament on Data Governance Act Press release. 30/11/2021. https://www.consilium.europa.eu/en/press/press-releases/2021/11/30/promoting-data-sharing-presidency-reaches-deal-with-parliament-on-data-governance-act/

25. Council of Europe. Oviedo Convention and its Protocols. https://www.coe.int/en/web/bioethics/oviedo-convention

26. Sandra Courbier, Rebecca Dimond, Virginie Bros-Facer V. Share and protect our health data: an evidence based approach to rare disease patients' perspectives on data sharing and data protection - quantitative survey and recommendations. Orphanet Journal of Rare Diseases, 2019. 14:175. https://ojrd.biomedcentral.com/articles/10.1186/s13023-019-1123-4

27. Zoe Crouch. Algorithms for altruism: How data is being used for good. Published on LinkedIn, 3 December 2018 Presentation of first set of data altruism definitions, use cases and findings 30. https://www.linkedin.com/pulse/algorithms-altruism-how-data-being-used-good-zoe-crouch/

28. Evelien De Sutter et al. Digitizing the Informed Consent Process: A Review of the Regulatory Landscape in the European Union. Front Med (Lausanne). 2022 May 25;9:906448. doi: 10.3389/fmed.2022.906448. PMID: 35692551; PMCID: PMC9174519.

29. DIGITALEUROPE's recommendations for the Data Governance Act. 13.4.2021. https://digital-europe-website-v1.s3.fr-par.scw.cloud/uploads/2021/04/DIGITALEUROPE-Data-Governance-Act-recommendations-April-2021.pdf

30. ECSA 10 Principles of Citizen Science. https://ecsa.citizen-science.net/ecsa-guidelines-and-policies/

31. EDPB Document on response to the request from the European Commission for clarifications on the consistent application of the GDPR, focusing on health research. European Data Protection Board. 2.2.2021.

https://edpb.europa.eu/sites/default/files/files/file1/edpb_replyec_questionnaireresearch_final.pdf

32. Mirelle van Eechoud. Study on the Open Data Directive, Data Governance and Data Act and their possible impact on research. Independent Expert Report. https://www.ivir.nl/publicaties/download/KI0822204ENN.en_.pdf

33. EIT Health. Contribution to the discussion on the European Commission's Data Strategy and AI White Paper, Report by the EIT Health Consultative Group, 31.5.2020. https://eithealth.eu/wp-content/uploads/2020/06/EIT-Health-Consultative-Group-on-EC-Data-Strategy-and-AI-White-Paper-31-May-2020.pdf

34. EPF. The new EU Regulation on the protection of personal data: what does it mean for patients? A guide for patients and patients' organisations. https://www.eu-patient.eu/globalassets/policy/data-protection/data-protection-guide-for-patients-organisations.pdf

35. European Commission. A European Strategy for data. 2022. https://digital-strategy.ec.europa.eu/en/policies/strategy-data

36. European Commission. Assessment of the EU Member States rules on health data in the light of GDPR. 2020. https://ec.europa.eu/health/sites/health/files/ehealth/docs/ms_rules_health-data_en.pdf (Annexes available at: https://ec.europa.eu/health/sites/default/files/ehealth/docs/ms_rules_health-data_annex_en.pdf

37. European Commission. Data altruism / Data Governance Act explained / Shaping Europe's digital future. 2022. https://digital-strategy.ec.europa.eu/en/policies/data-governance-act-explained

38. European Commission, Directorate-General for Communications Networks, Content and Technology. 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. CELEX: 52020DC0066. 19/02/2020 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020DC0066

39. European Commission, Directorate-General for Communications Networks, Content and Technology. Legislative framework for the governance of common European data spaces. Inception impact assessment. Document Ares(2020)3480073. 02/07/2020. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=PI_COM%3AAres%282020%293480073

40. European Commission, Directorate-General for Communications Networks, Content and Technology. COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on European data governance (Data Governance Act) SWD/2020/295 final. CELEX 52020SC0295. Impact assessment.

25/11/2020. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020SC0295

41. European Commission, Directorate-General for Environment. COMMISSION STAFF WORKING DOCUMENT EVALUATION of DIRECTIVE 2007/2/EC establishing an Infrastructure for Spatial Information in the European Community (INSPIRE). SWD/2022/0195 final. 13/07/2022.

42. 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

43. European Commission, Directorate-General for Health and Food Safety. COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space. SWD/2022/131 final. CELEX: 52022SC0131. Impact assessment. 03/05/2022. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022SC0131

44. European Commission, Directorate-General for Research and Innovation. COMMISSION IMPLEMENTING DECISION amending Implementing Decision C(2021)1940 final on the adoption of the work programme for 2021-2022 within the framework of the Specific Programme implementing Horizon Europe – the Framework Programme for Research and Innovation and on its financing, as regards Missions. C/2021/9128 final. Implementing decision. 15/12/2021

45. European Commission, Directorate-General for Research and Innovation. COMMISSION IMPLEMENTING DECISION amending Commission Implementing Decision C(2021)1940 on the adoption of the work programme for 2021-2022 within the framework of the Specific Programme implementing Horizon Europe – the Framework Programme for Research and Innovation and on its financing as regards the 2022 budget. C/2022/2975 final. Implementing decision. 10/05/2022. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=PI_COM%3AC%282022%292975

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

47. European Commission. European data strategy. 2022. https://ec.europa.eu/info/strategy/priorities-2019-2024/europe-fit-digital-age/european-data-strategy_en

48. European Commission. European Health Data Space. 2022. https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space_en

49. European Commission. Horizon Europe. 2022. https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe_en

50. European Commission. Summary report of the public consultation on the European strategy for data. Consultation Results, European Commission Publication 24 July 2020. https://digital-strategy.ec.europa.eu/en/library/summary-report-public-consultation-european-strategy-data

51. European Commission. Towards a European strategy on business-to-government data sharing for the public interest: Final report prepared by the High-Level Expert Group on Business-to-Government Data Sharing, Brussels, 2020. https://data.europa.eu/doi/10.2759/731415

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

53. European Economic and Social Committee. Opinion of the European Economic and Social Committee on 'Proposal for a Regulation of the European Parliament and of the Council on European data governance (Data Governance Act)' (COM(2020) 767 final). EESC 2020/05545. OJ C 286, 16.7.2021, p. 38–44. CELEX: 52020AE5545. Opinion. 27/04/2021. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020AE5545

54. European Parliament, Committee on Agriculture and Rural Development, Committee on Civil Liberties, Justice and Home Affairs, Committee on Culture and Education, Committee on Employment and Social Affairs, Committee on Industry, Research and Energy, Committee on International Trade, Committee on Legal Affairs, Committee on Transport and Tourism, Committee on the Environment, Public Health and Food Safety, Committee on the Internal Market and Consumer Protection. European Parliament resolution of 25 March 2021 on a European strategy for data (2020/2217(INI)). CELEX: 52021IP0098. Own-initiative resolution. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021IP0098

55. European Parliament. Proposal for a Regulation on European Data Governance In "A Europe Fit for the Digital Age." Legislative Train Schedule. https://www.europarl.europa.eu/legislative-train/theme-a-europe-fit-for-the-digital-age/file-data-governance-act

56. European Parliament, Council of the European Union. Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC. In force. This act has been changed. Current consolidated version: 31/01/2022. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0536

57. European Parliament, Council of the European Union. Regulation (EU) 2022/868 of the European Parliament and of the Council of 30 May 2022 on European data governance and amending Regulation (EU) 2018/1724 (Data Governance Act) (Text with EEA relevance). PE/85/2021/REV/1. OJ L 152, 3.6.2022, p. 1–44. In force. CELEX: 32022R0868. Regulation, 30/05/2022 Adopted. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022R0868

58. European Statistical System ESS. Position paper on the future governance framework for the common European data. November 2020. spaces https://ec.europa.eu/eurostat/documents/13019146/13405116/ESS+Position+paper+on+the+future+governance+framework+for+the+common+European+data+spaces.pdf/

59. Barbara J Evans. The First Amendment Right to Speak About the Human Genome. Univ Pa J Const Law. 2014 Feb 1;16(3):549-636. PMID: 25473380; PMCID: PMC4249692.

60. Edward S Dove, Jiahong Chen, Should consent for data processing be privileged in health research? A comparative legal analysis, International Data Privacy Law, Volume 10, Issue 2, May 2020, Pages 117–131. DOI: 10.1093/idpl/ipz023

61. Edward S Dove ES, Jiahong Chen. To What Extent Does the EU General Data Protection Regulation (GDPR) Apply to Citizen Scientist-Led Health Research with Mobile Devices? Journal of Law, Medicine & Ethics. Cambridge University Press; 2020;48(S1):187–95.

62. Edward S Dove, Jiahong Chen, What does it mean for a data subject to make their personal data 'manifestly public'? An analysis of GDPR Article 9(2)(e), International Data Privacy Law, Volume 11, Issue 2, April 2021, Pages 107–124, https://doi.org/10.1093/idpl/ipab005

63. EU Health Support project. https://www.euhealthsupport.eu/

64. 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) Version 1.1 https://edpb.europa.eu/our-work-tools/our-documents/edpbedps-joint-opinion/edpb-edps-joint-opinion-032021-proposal_en

65. EMA. Data anonymisation - a key enabler for clinical data sharing Workshop report 30 November – 1 December 2017, European Medicines Agency, London https://www.ema.europa.eu/en/documents/report/report-data-anonymisation-key-enabler-clinical-data-sharing_en.pdf

66. EMA. The General Data Protection Regulation: Secondary Use of Data for Medicines and Public Health Purposes. Discussion paper, 2020. https://www.encepp.eu/events/documents/Discussionpaper.pdf

67. European Data Protection Board. EDPB-EDPS Joint Opinion 03/2022 on the Proposal for a Regulation on the European Health Data Space. 12.7.2022. https://edpb.europa.eu/system/files/2022-07/edpb_edps_jointopinion_202203_europeanhealthdataspace_en.pdf

68. European Data Protection Board. Guidelines 05/2020 on consent under Regulation 2016/679. Version 1.1. 4.5.2020. https://edpb.europa.eu/sites/default/files/files/file1/edpb_guidelines_202005_consent_en.pdf

69. European Parliament, Council of the European. Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal

products for human use, and repealing Directive 2001/20/EC. In force. Current consolidated version: 31/01/2022 CELEX 32014R0536. Regulation 16/04/2014

70. European Parliament, Council of the European Union. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation GDPR). In force. Current consolidated version. 04/05/2016 CELEX 32016R0679- Regulation. 27/04/2016. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32016R0679

71. European Parliament. Policy Department for Citizens' Rights and Constitutional Affairs Directorate-General for Internal Policies. IPR and the use of open data and data sharing initiatives by public and private actors. May 2022. https://www.europarl.europa.eu/RegData/etudes/STUD/2022/732266/IPOL_STU(2022)732266_EN.pdf

72. Alberto Gago Fernandez. Data: an unused resource for the common good. The Technolawgist. 2020. https://www.thetechnolawgist.com/2020/07/22/data-an-unused-resource-for-the-common-good/

73. Alexis Galanis, Wim Nauwelaerts EU: Unpacking the EU's suite of new era digital legislation - Part three: the Data Governance Act. OneTrust Data Guidance. June 2022. https://www.dataguidance.com/opinion/eu-unpacking-eus-suite-new-era-digital-legislation-1

74. Eugenius Gefenas et al. Controversies between regulations of research ethics and protection of personal data: informed consent at a crossroad. Med Health Care and Philos 25, 23–30 (2022). DOI: 10.1007/s11019-021-10060-1

75. József Golovics. Bounded rationality and altruism: behaviourism in economics. Financial and Economic Review. 14. 2015. 158-172. https://www.researchgate.net/publication/305073595_Bounded_rationality_and_altruism_behaviourism_in_economics

76. Christine Grady et al. Broad consent for research with biological samples: workshop conclusions. Am J Bioeth. 2015;15(9):34–42. doi: 10.1080/15265161.2015.1062162.

77. Carlos Granell et al. Emerging approaches for data-driven innovation in Europe. EUR 30969 EN. Publications Office of the European Union. Luxembourg. 2022. ISBN 978-92-76-46936-0. doi:10.2760/511775. JRC127730.

78. Grant Agreement number 101035467 — TEHDAS.

79. Greshake Tzovaras B, Rera M, Wintermute EH, Kloppenborg K, Ferry-Danini J, Aidelberg G, Aronoff R, Lindner A, Misevic D. Empowering grassroots innovation to accelerate biomedical research. PLoS Biol. 2021 Aug 9;19(8): e3001349. doi: 10.1371/journal.pbio.3001349. PMID: 34370720; PMCID: PMC8351957.

80. Bastian Greshake Tzovaras et al. Open Humans: A platform for participant-centered research and personal data exploration. Gigascience. 2019 Jun 1;8(6):giz076. doi: 10.1093/gigascience/giz076. PMID: 31241153; PMCID: PMC6593360.

81. Christi J. Guerrini et al. Biomedical Citizen Science or Something Else? Reflections on Terms and Definitions. Am J Bioeth. 2019 Aug;19(8):17-19. doi: 10.1080/15265161.2019.1619880. PMID: 31544641; PMCID: PMC6786766.

82. Christi Guerrini et al. Core values of genomic citizen science: results from a qualitative interview study. Biosocieties. 2022 Jun;17(2):203-228. doi: 10.1057/s41292-020-00208-2. Epub 2020 Sep 28. PMID: 36032504; PMCID: PMC9400840.

83. Muki Haklay et al. Contours of citizen science: a vignette study. R Soc Open Sci. 2021 Aug 25;8(8):202108. doi: 10.1098/rsos.202108. PMID: 34457323; PMCID: PMC8385385.

84. Johan Hansen et al. Assessment of the EU Member States' rules on health data in the light of GDPR. Nivel. EUHealthSupport. 2021. https://health.ec.europa.eu/system/files/2021-02/ms_rules_health-data_en_0.pdf

85. Jack Hardinges. Data Trusts in 2020. Open Data Institute, 2020. https://theodi.org/article/data-trusts-in-2020/

86. Alexandra Heidel et al. Pricing through health apps generated data - Digital dividend as a game changer: Discrete choice experiment. PLoS One. 2021 Jul 26;16(7): e0254786. doi: 10.1371/journal.pone.0254786. PMID: 34310618; PMCID: PMC8312968.

87. Debbie Heywood. EC Data Governance Act will apply from 24 September 2023. Taylor Wessing. 20 June 2022. https://www.taylorwessing.com/en/insights-and-events/insights/2022/06/radar---ec-data-governance-act-will-apply-from-24-september-2023

88. Minna Hendolin. Towards the European Health Data Space: from Diversity to a common framework. Eurohealth 2021, Vol.27, No.2. https://apps.who.int/iris/bitstream/handle/10665/352268/Eurohealth-27-2-15-17-eng.pdf

89. How do people feel about their data being shared by the NHS? Briefing, Health Watch England. 17.5.2017. https://www.healthwatch.co.uk/news/2018-05-17/how-do-people-feel-about-their-data-being-shared-nhs

90. Tim Hulsen. Sharing Is Caring-Data Sharing Initiatives in Healthcare. Int J Environ Res Public Health. 2020 Apr 27;17(9):3046. doi: 10.3390/ijerph17093046. PMID: 32349396; PMCID: PMC7246891.

91. Patrik Hummel, Matthias Braun, Peter Dabrock. Data Donations as Exercises of Sovereignty. The Ethics of Medical Data Donation pp 23-54. 16 January 2019 Presentation of first set of data altruism definitions, use cases and findings 28 [30]

92. Laurence T. Hunt. The life-changing magic of sharing your data. Nature Human Behaviour volume 3, pages312–315 (2019). https://ideas.repec.org/a/nat/nathum/v3y2019i4d10.1038_s41562-019-0560-3.html

93. IPSOS. A public dialogue on genomic medicine: time for a new social contract? Report. UK Research and Innovation, Genomics England, Sciencewise. 25.4.2019. https://www.ipsos.com/en-uk/public-dialogue-genomic-medicine-time-new-social-contract-report

94. Maria Karampela, Sofia Ouhbi, Minna Isomursu. Connected Health User Willingness to Share Personal Health Data: Questionnaire Study. Journal of Medical Internet Research, 21(11), 2019. DOI: 10.2196/14537

95. Atte Karineva. Biopankkilain mukainen "laaja suostumus" EU:n yleisen tietosuoja-asetuksen näkökulmasta - jännite henkilötietojen tutkimuskäytön ja yksityisyydensuojan välillä. – ”Broad consent” in the Biobank Act from the perspective of the General Data Protection Regulation - Tension between the Use of Personal Data in Research and Personal Privacy. Turku University of Applied Sciences. https://www.theseus.fi/bitstream/handle/10024/156902/Karineva_Atte.pdf

96. Tomas Kaya, Laurent Kellera, Laurent Lehmanna. The evolution of altruism and the serial rediscovery of the role of relatedness. PNAS (2020). DOI: 10.1073/pnas.2013596117

97. Hee-Wan Kim, Hae-Kyung Rhee, Tai M. Chung, Ung-Mo Kim. A Transaction Length Sensitive Protocol Based on Altruistic Locking for Multilevel Secure Database Systems. https://link.springer.com/chapter/10.1007/3-540-45600-7_13

98. Corina Kruesz & Felix Zopf, The Concept of Data Altruism of the Draft DGA and the GDPR: Inconsistencies and Why a Regulatory Sandbox Model May Facilitate Data Sharing in the EU, 7 EUR. DATA PROT. L. REV. 569 (2021). https://edpl.lexxion.eu/article/EDPL/2021/4/13

99. Laws and regulation. Finnish Biobanks. 2022. https://www.biopankki.fi/en/laws-and-regulation/

100. Michael A Lensink et al. Better governance starts with better words: why responsible human tissue research demands a change of language. BMC Med Ethics 23, 90 (2022). https://doi.org/10.1186/s12910-022-00823-7

101. Giovanni Maccani et al. Scaling up Citizen Science, Publications Office of the European Union, Luxembourg, 2020, ISBN 978-92-76-25158-3, doi:10.2760/354206, JRC122219.

102. James Maddocks, Louise Mathieu, 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/

103. Alex McKeown et al. Ethical Issues in Consent for the Reuse of Data in Health Data Platforms. Sci Eng Ethics. 2021 Feb 4;27(1):9. doi: 10.1007/s11948-021-00282-0. PMID: 33538942; PMCID: PMC7862505.

104. MedTech Europe response to the open public consultation. Proposal for a Regulation on European Data Governance. 2020.. https://www.medtecheurope.org/wp-content/uploads/2021/02/210208_data-governance-act-_mteresponse_.pdf

105. Jonathan D Moreno et al. The Nuremberg Code 70 years later. JAMA. 2017. Sep 5;318(9):795-796. doi: 10.1001/jama.2017.10265. PMID: 28817743.

106. NHS. Pulse Oximeter Bias Highlighted in Rapid Review. NHS Race & Health Observatory. 14.4.2021. https://www.nhsrho.org/publications/pulse-oximeter-bias-highlighted-in-rapid-review/

107. Jakob Ohme, Theo Araujo. Digital data donations: A quest for best practices. Patterns (N Y). 2022 Apr 8;3(4):100467. doi: 10.1016/j.patter.2022.100467. PMID: 35465227; PMCID: PMC9023895.

108. Lauren Olsen, Lindsay DePalma, and John H. Evans. Self-Interested and Altruistic Motivations in Volunteering for Clinical Trials: A More Complex Relationship. Journal of Empirical Research on Medical Ethics (2020) 88. https://pubmed.ncbi.nlm.nih.gov/32363984/

109. Soyoung Q. Park, Thorsten Kahnt, Azade Dogan, Sabrina Strang, Ernst Fehr & Philippe N. Tobler. A neural link between generosity and happiness. DOI: 10.1038/ncomms15964, 11 July 2017. https://www.nature.com/articles/ncomms15964

110. 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

111. Robin Pierce, Mariana Evram. Getting it right: implementing data protection in citizen science research. Insights. 2022; 35:2. DOI: http://doi.org/10.1629/uksg.538

112. Ray Pinto et al. Improving lives and managing diseases through a data driven EU healthcare system, Paper of DIGITALEUROPE, 4.11.2020 https://digital-europe-website-v1.s3.fr-par.scw.cloud/uploads/2020/10/DIGITALEUROPE_Improving-lives-and-managing-diseases-through-a-data-driven-EU-healthcare-system-1.pdf

113. Marja Pirttivaara. Ethics of health and genomic data, Course: Digital Ethics, Session 6: Health and well-being, 28th May 2021, Aalto University.

114. Yves Poullot. Artificial Intelligence and Public Services – the Role of Public Authorities in the Service of the "Third Way" Drawn up by the European Commission. European Review of Digital Administration & Law - Erdal 2021, Volume 2, Issue 2, pp. 129-148 ISSN 2724-5969 - ISBN 979-12-5994-752-9 - DOI 9791259947529 13

115. Publications office of the European Commission. About EUR-Lex. 2022. https://eur-lex.europa.eu/content/welcome/about.html

116. Publications office of the European Commission. EUR-Lex. 2022. https://eur-lex.europa.eu/homepage.html

117. Publications office of the European Commission. Types of documents in EUR-Lex. 2022. https://eur-lex.europa.eu/content/tools/TableOfSectors/types_of_documents_in_eurlex.html

118. Minakshi Rajid, Raymond De Vries, Paige Nongid, Sharon L. R. Kardia, Jodyn E. Platt. Do people have an ethical obligation to share their health information? Comparing narratives of altruism and health information sharing in a nationally representative sample. PLOS ONE 31 December 2020

119. Vera Raivola et al. Attitudes of blood donors to their sample and data donation for biobanking. Eur J Hum Genet. 2019 Nov;27(11):1659-1667. doi: 10.1038/s41431-019-0434-1. Epub 2019 May 30. PMID: 31147625; PMCID: PMC6871534.

120. Gesine Richter et al. Secondary research use of personal medical data: patient attitudes towards data donation. BMC Med Ethics. 2021 Dec 15;22(1):164. doi: 10.1186/s12910-021-00728-x. PMID: 34911502; PMCID: PMC8672332.

121. Gesine Richter et al. Secondary research use of personal medical data: attitudes from patient and population surveys in The Netherlands and Germany. Eur J Hum Genet. 2021 Mar;29(3):495-502. doi: 10.1038/s41431-020-00735-3. Epub 2020 Oct 1. Erratum in: Eur J Hum Genet. 2021 Sep 30: PMID: 33005018; PMCID: PMC7940390.

122. Marjut Salokannel et al. Legacy samples in Finnish biobanks: social and legal issues related to the transfer of old sample collections into biobanks. Human Genetics (2019) 138: 1287-1299. https://link.springer.com/content/pdf/10.1007/s00439-019-02070-0.pdf

123. Sven Schade et al. Activity Report on Citizen Science – discoveries from a five year journey, EUR 30551 EN, Publications Office of the European Union, Luxembourg, 2020, ISBN 978-92-76-28370-6 (online),978-92-76-28369-0 (print), doi:10.2760/841551 (online),10.2760/172609 (print), JRC123500.

124. Bettina Schmietow. Property redux. Ownership of human tissue and the governance of post-genomic research biobanks. PhD thesis. European School of Molecular Medicine (SEMM) and University of Milan. 2012. https://air.unimi.it/retrieve/handle/2434/234151/301892/phd_unimi_R08920.pdf

125. Christophe Olivier Schneble et al. All Our Data Will Be Health Data One Day: The Need for Universal Data Protection and Comprehensive Consent. J Med Internet Res. 2020 May 28;22(5): e16879. doi: 10.2196/16879. PMID: 32463372; PMCID: PMC7290498.

126. Sebastian C. Semler, Wiebke Lesch. “Data donation” for medical research: Results of a German survey TMF e. V., TMF-FORSA Survey on Attitudes towards Data Donation, Berlin 27.8.2019. https://www.tmf-ev.de/EnglishSite/News/articleType/ArticleView/articleId/4461.aspx

127. Enric Senabre Hidalgo et al. Shared motivations, goals and values in the practice of personal science: a community perspective on self-tracking for empirical knowledge. Humanity Soc Sci Commun 9, 182 (2022). https://doi.org/10.1057/s41599-022-01199-0

128. Esther-Mirjam Sent. Rationality and bounded rationality: you cannot have one without the other, The European Journal of the History of Economic Thought, 2018, 25:6, 1370-1386, DOI: 10.1080/09672567.2018.1523206. https://www.tandfonline.com/doi/full/10.1080/09672567.2018.1523206

129. Timo Seppälä, Jari Juhanko, Juri Mattila. Data Ownership and Governance. FINNISH LAW PERSPECTIVE. ETLA The Research Institute of the Finnish Economy. 2018. https://www.etla.fi/wp-content/uploads/ETLA-Muistio-Brief-71.pdf

130. Mahsa Shabani. Will the European Health Data Space change data sharing rules? Science. 24 March 2022. Vol. 375, Issue 6587, pp. 1457-1359. https://www.science.org/doi/abs/10.1126/science.abn4874

131. Nisha Shah et al. Sharing data for future research engaging participants' views about data governance beyond the original project: a DIRECT Study. Genetics in Medicine, 21(5), 2019, 1131–1138. DOI: 10.1038/s41436-018-0299-7

132. David M Shaw, Juliane V Gross, Thomas C Erren. Data donation after death: A proposal to prevent the waste of medical research data. EMBO Rep. 2016 Jan;17(1):14-7. doi: 10.15252/embr.201541802. Epub 2015 Dec 10. PMID: 26658488; PMCID: PMC4718407.

133. Anya Skatova, James Goulding. Psychology of personal data donation. PLoS One. 2019 Nov 20;14(11): e0224240. doi: 10.1371/journal.pone.0224240. PMID: 31747408; PMCID: PMC6867598.

134. Anya Skatova, Esther Ng, James Goulding. Data Donation: Sharing Personal Data for Public Good? Conference paper. Conference: Digital Economy All Hands Meeting 2014 DOI:10.13140/2.1.2567.8405

135. Lea Skovgaard, Sarah Wadmann, Klaus Hoeyer. A review of attitudes towards the reuse of health data among people in the European Union: The primacy of purpose and the common good. Health Policy 123, 2019, 564–571. https://pubmed.ncbi.nlm.nih.gov/30961905/

136. Luz Smith. Report on Standardisation Landscape for the MIRACLE Project. H2020. 2020. https://miracleproject.eu/wp-content/uploads/2020/07/20180629_D7.16_Report-on-the-standardization-landscape.pdf

137. SOCIENTIZE Project. 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

138. Kristin Solum Steinsbekk et al. We are not in it for the money-lay people's moral intuitions on commercial use of 'their' biobank. Med Health Care Philos. 2013 May;16(2):151-62. doi: 10.1007/s11019-011-9353-9. PMID: 22028241; PMCID: PMC3617351.David Steinberg. Altruism in medicine: its definition, nature, and dilemmas. Camb Q Health Ethics. 2010 Apr;19(2):249-57. doi: 10.1017/S0963180109990521. PMID: 20226108.

139. 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

140. Oskari Stenius. Laaja suostumus biopankkitoiminnassa : erityisesti näytteenantajan itsemääräämisoikeuden ja henkilötietojen suojan valossa. Master's thesis. Helsinki University. Faculty of Law. 2017. http://urn.fi/URN:NBN:fi:hulib-201705304302

141. Jitka Stilund Hansen (ed.). Citizen Science for Research Libraries — A Guide. Citizen Science Skilling for Library Staff, Researchers, and the Public. LIBER. 2021. https://libereurope.eu/article/book-launch-citizen-science-skilling-for-library-staff-researchers-and-the-public/

142. Jessica Stockdale et al. “Giving something back": A systematic review and ethical enquiry into public views on the use of patient data for research in the United Kingdom and the Republic of Ireland. Wellcome open research. 2016. https://pubmed.ncbi.nlm.nih.gov/30854470/

143. Veronika Strotbaum et al. Your data is gold – Data donation for better healthcare? it - Information Technology, vol. 61, no. 5-6, 2019, pp. 219-229. DOI: 10.1515/itit-2019-0024

144. Study on Digital Health implementation in the EU Final Report. April 2022. https://esante.gouv.fr/sites/default/files/media_entity/documents/dns-pfue_final-report_digital-health-vf.pdf

145. TEHDAS Joint Action towards the European Health Data Space. https://tehdas.eu/project/

146. The Guild of European Research-Intensive Universities. Proposals for the European Health Data Space. Position Paper 28.6.2021. https://www.the-

guild.eu/publications/position-papers/the-guild_proposals-for-the-european-health-data-space_june-2021.pdf

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

148. Susheel Varma et al. Building Trusted Research Environments - Principles and Best Practices; Towards TRE ecosystems. UK Health Data Research Alliance; NHSX. https://zenodo.org/record/5767586#.Y1CBUfzP02w

149. Effy Vayena et al. Research led by participants: a new social contract for a new kind of research. J Med Ethics. 2016 Apr;42(4):216-9. doi: 10.1136/medethics-2015-102663. Epub 2015 Mar 30. PMID: 25825527; PMCID: PMC4819634.

150. Winfried Veil. Data altruism: how the EU is screwing up a good idea. Discussion Paper #1. Algorithm Watch. December 2021. https://algorithmwatch.org/de/wp-content/uploads/2022/01/2022_AW_Data_Altruism_final_publish.pdf

151. Elizabeth Waind. Trust, Security and Public Interest: Striking the Balance. Administrative Data Research (ADR). A review of previous literature on public attitudes towards the sharing and linking of administrative data for research. UK Strategic Hub, Economic & Social Research Council, May 2020. https://www.adruk.org/fileadmin/uploads/adruk/Trust_Security_and_Public_Interest-_Striking_the_Balance-_ADR_UK_2020.pdf

152. Nicole Wetsman. It is easier to donate your body to science than your medical records. Handing over your digital health data is still nearly impossible. The Verge, 28 May 2019. https://w.theverge.com/2019/5/28/18642621/medical-records-donate-science-digital-data-health-body-death

153. World Medical Association (WMA). Declaration of Helsinki - ethical principles for medical research involving human subjects. https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

154. 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.

Annex 1 EUR-Lex query results, data altruism and Data Altruism Organisation(s)

The list includes the forty-one results of the EUR-Lex query “data altruism” and Data Altruism Organisation(s) (September 2022). The sixteen documents that include the longer term “Data Altruism Organisation(s)” are in Italics.

1. *Council of the European Union. Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on European data governance (Data Governance Act). ST 13351 2020 INIT. Cover note. 25/11/2020. https://eur-lex.europa.eu/legal-content/AUTO/?uri=CONSIL:ST_13351_2020_INIT*

2. Council of the European Union. COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on European data governance (Data Governance Act). ST 13351 2020 ADD 1. Cover note. 25/11/2020. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CONSIL%3AST_13351_2020_ADD_1

3. Council of the European Union. COMMISSION STAFF WORKING DOCUMENT EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on European data governance (Data Governance Act). ST 13351 2020 ADD 2. Cover note. 25/11/2020. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CONSIL%3AST_13351_2020_ADD_2

4. *Council of the European Union. Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on European data governance (Data Governance Act) - Outcome of the European Parliament's first reading (Strasbourg, 4-7 April 2022). ST 7853 2022 INIT. Information note. 11/04/2022. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CONSIL%3AST_7853_2022_INIT*

5. *Council of the European Union. Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space. ST 8751 2022 INIT. Cover note. 06/05/2022. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CONSIL%3AST_8751_2022_INIT*

6. *Council of the European Union. COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space. ST 8751 2022 ADD 3, Cover note. 06/05/2022. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CONSIL%3AST_8751_2022_ADD_3*

7. Council of the European Union. COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space. ST 8751 2022 ADD 4. Cover note. 06/05/2022. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CONSIL%3AST_8751_2022_ADD_4

8. Council of the European Union. COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space. ST 8751 2022 ADD 5. Form: Cover note. 06/05/2022. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CONSIL%3AST_8751_2022_ADD_5

9. Council of the European Union. COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space. ST 8751 2022 ADD 6. Cover note. 06/05/2022. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CONSIL%3AST_8751_2022_ADD_6

10. European Commission, Directorate-General for Communications Networks, Content and Technology. 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. CELEX: 52020DC0066 19/02/2020. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020DC0066

11. European Commission, Directorate-General for Communications Networks, Content and Technology. Legislative framework for the governance of common European data spaces. Inception impact assessment. 02/07/2020. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=PI_COM%3AAres%282020%293480073

12. *European Commission, Directorate-General for Communications Networks. Content and Technology. Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on European data governance (Data Governance Act) COM/2020/767 final CELEX: 52020PC0767. 25/11/2020 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020PC0767*

13. European Commission, Directorate-General for Communications Networks. Content and Technology. Commission staff working document executive summary of the Impact assessment report. Accompanying the document Proposal for a Regulation of the European Parliament and of the Council on European data governance (Data Governance Act. SWD/2020/296 final). 25/11/2020. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020SC0296

14. European Commission, Directorate-General for Communications Networks. COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on European data governance (Data Governance Act) SWD/2020/295 final. CELEX: 52020SC0295. 25/11/2020. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020SC0295

15. European Commission, Directorate-General for Health and Food Safety. Proposal for Regulation [tbc] on the European Health Data Space, digital health services and products and the use of new technologies, including artificial intelligence (AI) in health. Inception impact assessment. 23/12/2020. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=PI_COM%3AAres%282020%297907993

16. European Commission, Directorate-General for Health and Food Safety. Proposal for Regulation [tbc] on the European Health Data Space, digital health services and products and the use of new technologies, including artificial intelligence (AI) in health. Factual summary report of the public consultation. 27/01/2022. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=PI_COM%3AAres%282022%29636543

17. *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*

18. *European Commission, Directorate-General for Health and Food Safety. COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space. SWD/2022/131 final. CELEX: 52022SC0131. Impact assessment. 03/05/2022. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022SC0131*

19. *European Commission, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs. COMMISSION STAFF WORKING DOCUMENT Strategic dependencies and capacities Accompanying the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Updating the 2020 New Industrial Strategy: Building a stronger Single Market for Europe's recovery. SWD/2021/352 final. CELEX: 52021SC0352. Staff working document. 05/05/2021. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021SC0352*

20. European Commission, Directorate-General for Justice and Consumers. COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL Data protection as a pillar of citizens' empowerment and the EU's approach to the digital transition - two years of application of the General Data Protection Regulation. COM/2020/264 final. CELEX: 52020DC0264. 24/06/2020. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020DC0264

21. European Commission, Directorate-General for Justice and Consumers. REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS Protecting Fundamental Rights in the Digital Age - 2021 Annual Report on the Application of the EU Charter of Fundamental Rights. COM/2021/819 final. CELEX: 52021DC081. Report. 10/12/2021. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021DC0819

22. European Commission, Directorate-General for Research and Innovation. COMMISSION IMPLEMENTING DECISION amending Implementing Decision C(2021)1940 on the adoption of the work programme for 2021-2022 within the framework of the Specific Programme implementing Horizon Europe - the Framework Programme for Research and Innovation and on its financing with regards to 21 actions for 'Digital, Industry and Space'. C/2021/7804 final. 28/10/2021. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=PI_COM%3AC%282021%297804

23. European Commission, Directorate-General for Research and Innovation. COMMISSION IMPLEMENTING DECISION amending Implementing Decision C(2021)1940 final on the adoption of the work programme for 2021-2022 within the framework of the Specific Programme implementing Horizon Europe – the Framework Programme for Research and Innovation and on its financing, as regards Missions. C/2021/9128 final. Implementing decision. 15/12/2021. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=PI_COM%3AC%282021%299128

24. European Commission. Regulatory Scrutiny Board. Opinion of the Regulatory Scrutiny Board. SEC(2020)405. 24/11/2020. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020DC0066

25. European Commission. Regulatory Scrutiny Board. Regulatory Scrutiny Board Opinion. Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space. SEC(2022)196. 03/05/2022. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=PI_COM:SEC(2022)196

26. European Commission, Directorate-General for Research and Innovation. COMMISSION IMPLEMENTING DECISION amending Commission Implementing Decision C(2021)1940 on the adoption of the work programme for 2021-2022 within the framework of the Specific Programme implementing Horizon Europe – the Framework Programme for Research and Innovation and on its financing as regards the 2022 budget. C/2022/2975 final. 10/05/2022. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=PI_COM%3AC%282022%292975

27. European Data Protection Supervisor. Summary of the Opinion of the European Data Protection Supervisor on EDPS Opinion on the European strategy for data (The full text of this Opinion can be found in English, French and German on the EDPS website www.edps.europa.eu) 2020/C 322/04. OJ C 322, 30.9.2020, p. 11–13. CELEX: 52020XX0930(01). 30/09/2020. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020XX0930%2801%29

28. European Data Protection Supervisor. Summary of the Preliminary Opinion of the European Data Protection Supervisor on the European Health Data Space (The full text of this Opinion can be found in English, French and German on the EDPS website www.edps.europa.eu) 2021/C 99/09. OJ C 99, 23.3.2021, p. 13–16. CELEX: 52021XX0323(02). 23/03/2021. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021XX0323%2802%29

29. European Economic and Social Committee. A European strategy for data. EESC-2020-01042-AS. Provisional opinion. 23/07/2020. https://eur-lex.europa.eu/legal-content/AUTO/?uri=PI_EESC:EESC-2020-01042-AS

30. European Economic and Social Committee. Opinion - European Economic and Social Committee - A European strategy for data EESC-2020-01042-AC. Adopted opinion https://eur-lex.europa.eu/legal-content/AUTO/?uri=PI_EESC:EESC-2020-01042-AC

31. European Economic and Social Committee. Opinion of the European Economic and Social Committee on '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) EESC 2020/01042. OJ C 429,

11.12.2020, p. 290–295. CELEX: 52020AE1042. 18/09/2020. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020AE1042

32. *European Economic and Social Committee. Data governance. EESC-2020-05545-AS. Provisional opinion. 31/03/2021. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=PI_EESC%3AEESC-2020-05545-AS*

33. *European Economic and Social Committee. Opinion of the European Economic and Social Committee on 'Proposal for a Regulation of the European Parliament and of the Council on European data governance (Data Governance Act)' (COM(2020) 767 final). EESC 2020/05545. OJ C 286, 16.7.2021, p. 38–44. CELEX: 52020AE5545. Opinion. 27/04/2021. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020AE5545*

34. *European Economic and Social Committee. Opinion - European Economic and Social Committee - Data governance. EESC-2020-05545-AC. Adopted opinion. 27/04/2021. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=PI_EESC%3AEESC-2020-05545-AC*

35. *European Economic and Social Committee. Economic and social opportunities of digitalisation EESC-2021-02564-AS. Provisional exploratory opinion. 15/06/2021. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=PI_EESC%3AEESC-2021-02564-AS*

36. *European Economic and Social Committee. Opinion of the European Economic and Social Committee on Exploiting the economic and social opportunities of digitalisation and improving the digital transformation of the economy, especially SMEs, focusing on human-centred artificial intelligence and data (Exploratory opinion). EESC 2021/02564. OJ C 374, 16.9.2021, p. 6–10. CELEX: 52021AE256. Exploratory opinion. EESC 2021/02564. 07/07/2021. https://eur-lex.europa.eu/legal-content/AUTO/?uri=CELEX:52021AE2564*

37. European Parliament, Committee on Agriculture and Rural Development, Committee on Civil Liberties, Justice and Home Affairs, Committee on Culture and Education, Committee on Employment and Social Affairs, Committee on Industry, Research and Energy, Committee on International Trade, Committee on Legal Affairs, Committee on Transport and Tourism, Committee on the Environment, Public Health and Food Safety, Committee on the Internal Market and Consumer Protection. European Parliament resolution of 25 March 2021 on a European strategy for data (2020/2217(INI)) OJ C 494, 08/12/2021, p. 37–53. CELEX: 52021IP0098. 25/03/2021. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021IP0098

38. *European Parliament. Council of the European Union. REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on European data governance and amending Regulation (EU) 2018/1724 (Data Governance Act).PE 85 2021 INIT. Legislative Act. 04/05/2022. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CONSIL%3APE_85_2021_INIT*

39. *European Parliament, Council of the European Union. Regulation (EU) 2022/868 of the European Parliament and of the Council of 30 May 2022 on European data governance and amending Regulation (EU) 2018/1724 (Data Governance Act) PE/85/2021/REV/1. OJ L 152, 3.6.2022, p. 1–44. In force. CELEX: 32022R0868. Regulation. 30/05/2022 Adopted. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022R0868*

40. *European Parliament, Council of the European Union. REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON EUROPEAN DATA GOVERNANCE AND AMENDING REGULATION (EU) 2018/1724 (DATA GOVERNANCE ACT), PE 85 2021 REV 1. Legislative acts. 30/05/2022 Adopted.* *https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CONSIL%3APE_85_2021_REV_1*

41. European Parliament, Special Committee on Beating Cancer. European Parliament resolution of 16 February 2022 on strengthening Europe in the fight against cancer — towards a comprehensive and coordinated strategy (2020/2267(INI)). OJ C 342, 6.9.2022, p. 109–147- CELEX: 52022IP0038. 16/02/2022. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022IP0038

Annex 2. Other relevant projects, initiatives and use cases

- All of Us initiative (USA)
    - https://allofus.nih.gov/
    - "Participants were primarily motivated by altruism, desire to know more about their health, and curiosity." Courtney L Scherr et al. What People Want to Know About Their Genes: A Critical Review of the Literature on Large-Scale Genome Sequencing Studies. Healthcare (Basel). 2018 Aug 8;6(3):96. doi: 10.3390/healthcare6030096. PMID: 30096823; PMCID: PMC6165341.
    - Bastian Greshake Tzovaras, Athina Tzovara. The Personal Data Is Political. In the Ethics of Medical Data Donation. 2019. https://www.ncbi.nlm.nih.gov/books/NBK554079/#ch8.Sec1
- Belgian DNA debate
    - Mayeur Chloé. The Belgian DNA debate. An online deliberative platform on the ethical, legal, and social issues of genomics. 25.3.2021. https://www.ipaac.eu/res/file/outputs/wp6/belgian-dna-debate.pdf
- Biobanks
    - 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.ijsu.2009.09.001. Epub 2009 Sep 10. PMID: 19748601.
    - 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.
    - 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.
    - 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.
- Centre for Data Ethics and Innovation. (2020).
    - https://www.gov.uk/government/organisations/centre-for-data-ethics-and-innovation
    - CDEI publishes its first report on public sector data sharing. Gov.uk. 20.7.2020. https://www.gov.uk/government/publications/cdei-publishes-its-first-report-on-public-sector-data-sharing
- Centre for Effective Altruism

- https://www.centreforeffectivealtruism.org/

- Connected Health Cities (UK)
  - https://connectedhealthcities.github.io/
  - Connected Health Cities (CHC) was a £20m, four-year pilot funded by the Department of Health to unite local health data and technology to improve care for patients in the North of England. https://www.innovationagencynwc.nhs.uk/connected-health-cities
  - Connected Health Cities Citizens' Juries Report 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 January 2017. https://connectedhealthcities.github.io/assets/hub/Section%202.5.1_Connected%20Health%20Cities%20Citizens'%20Juries%20Report.pdf
  - Connected Health Cities. Impact Report. 2016-2020. https://www.thenhsa.co.uk/app/uploads/2020/10/CHC-full-impact-report.pdf

- DATA for GOOD Foundation (website)
  - https://dataforgoodfoundation.com/
  - Danish not-for-profit organisation that promotes individual data rights and equip citizens with digital tools that allow them to exercise their right to data portability (GDPR, art. 20) and make more data available for common good purposes.

- Data Trusts & Trustees
  - Data trustee: the independent mediator between data providers and data users https://www.bundesdruckerei-gmbh.de/en/solutions/data-trustee
  - 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
  - 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

- DSSC Data Spaces Support Centre (DIGITAL)
  - https://dssc.eu/
  - DSSC "will explore the needs of data space initiatives, define common requirements and establish best practices to accelerate the formation of sovereign data spaces as a key element of digital transformation at all levels."

- EHDEN European Health Data and Evidence Network Project (H2020)
  - https://www.ehden.eu/
  - EHDEN Ethical Advisory Board & Colleagues. BLOG – Keeping data closed enough for citizen security, but open enough for research. 15.6.2021. https://www.ehden.eu/blog-data-security-research/

- European Ethical Code for Data Donation project (funder: Microsoft)
  - https://www.oii.ox.ac.uk/research/projects/a-european-ethical-code-for-data-donation/
  - Jenny Krutzinna, Luciano Floridi (eds). The Ethics of Medical Data Donation. Philosophical Studies Series. 2019. https://library.oapen.org/handle/20.500.12657/23112
  - Jenny Krutzinna, Mariarosaria Taddeo, Luciano Floridi. Enabling Posthumous Medical Data Donation: An Appeal for the Ethical Utilisation of Personal Health Data. Sci. Eng. Ethics. 25 (5) 1357-1387. 2018. DOI: 10.1007/s11948-018-0067-8. https://www.researchgate.net/publication/328490679_Enabling_Posthumous_Medical_Data_Donation_An_Appeal_for_the_Ethical_Utilisation_of_Personal_Health_Data

- EUHealthSupport Consortium, supporting EU and DG SANTE
  - https://www.nivel.nl/en/project/euhealthsupport-consortium-supporting-eu-and-dg-sante
  - Johan Hansen et al. Assessment of the EU Member States' rules on health data in the light of GDPR. Publications Office of the European Union, 2021. https://health.ec.europa.eu/system/files/2021-02/ms_rules_health-data_en_0.pdf

- EU-Citizen.science project (H2020)
  - https://eu-citizen.science/, platform for sharing citizen science projects, resources, tools, training etc.
  - 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

- GRAVITATE HEALTH public–private partnership (website)
  - https://www.gravitatehealth.eu/

- HDE Heath Data Exploration Project
  - Matthew Bietz, Kevin Patrick, Cinnamon Bloss. Data Donation as a Model for Citizen Science Health Research. Citizen Science Theory and Practice 4(1). March 2019. DOI: 10.5334/cstp.

- Health data cooperatives
  - https://digitalhealtheurope.eu/glossary/health-data-cooperative/
  - Ernst Hafen, D. Kossmann, Angela Brand. Health Data Cooperatives – Citizen Empowerment, Methods Inf Med 2/2014 pp 1-5. https://www.researchgate.net/publication/260153303_Health_Data_Cooperatives_-_Citizen_Empowerment

  - Ankit Singh Tanwar et al. Global Open Health Data Cooperatives Cloud in an Era of COVID-19 and Planetary Health. OMICS: A Journal of Integrative Biology. Mar 2021.169-175. DOI: 10.1089/omi.2020.0134. https://www.liebertpub.com/doi/10.1089/OMI.2020.0134

- Health Outcomes Observatory (H2O) Project (Innovative Medicines Initiative IMI / Horizon 2020)
  - https://health-outcomes-observatory.eu/
  - Innovative Medicines Initiative IMI https://www.imi.europa.eu/
  - Tanja Stamm et al. Building a Value-Based Care Infrastructure in Europe: The Health Outcomes Observatory. NEJM CAtalyst. 2021.https://catalyst.nejm.org/doi/full/10.1056/CAT.21.0146

- Health-RI Initiative: Personal Health Train - PHT (website)
  - https://www.health-ri.nl/initiatives/personal-health-train
  - Projects & Initiatives that support connecting, sharing and reuse of health data

- MyData Global
  - https://www.mydata.org/
  - Viivi Lähteenmäki (ed). MyData – an introduction to human-centric use of personal data 3rd, revised edition. 2022. https://www.mydata.org/wp-content/uploads/2022/07/mydata-white-paper-english-2020-2.pdf

- Norwegian Health Data Programme
  - https://helsedata.no/ and https://www.ehelse.no/programmer/helsedataprogrammet
  - The Health Data Programme – New solutions, services and interfaces for cooperation https://www.forskningsradet.no/siteassets/utlysninger/vedlegg-utlysninger/the-health-data-programme--new-solutions-services-and-interfaces-for-cooperation-.pdf
  - Reports: https://www.ehelse.no/programmer/helsedataprogrammet/bakgrunn-for-helsedataprogrammet#Publikasjoner

- One London Project
  - Public deliberation in the use of health and care data. One London Project 2020. https://www.onelondon.online/wp-content/uploads/2020/06/Public-deliberation-in-the-use-of-health-and-care-data.pdf

- Open Data Institute
  - 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/

- Open Humans Foundation (non-profit organisation) and Open Humans (platform)

  - http://openhumansfoundation.org/ and https://www.openhumans.org/
  - Community and platform for data and tools sharing, citizen science projects like Quantified Flu https://quantifiedflu.org/
  - Marta Fadda et al. User Perspectives of a Web-Based Data-Sharing Platform (Open Humans) on Ethical Oversight in Participant-Led Research: Protocol for a Quantitative Study. JMIR Res Protoc. 2018 Nov 28;7(11): e10939. doi: 10.2196/10939. PMID: 30487120; PMCID: PMC6291678.
  - Bastian Greshake Tzovaras et al. Open Humans: A platform for participant-centered research and personal data exploration. Gigascience. 2019 Jun 1;8(6): giz076. doi: 10.1093/gigascience/giz076. PMID: 31241153; PMCID: PMC6593360.

- OpenSNP and other genome data sharing platforms based on Direct-To-Consumer (DTC) genetic testing
  - Tobias Haeusermann et al. (2017) Open sharing of genomic data: Who does it and why? PLoS ONE 12(5): e0177158. DOI: 10.1371/journal.pone.0177158

- REFINIO GmbH (Germany)
  - https://refinio.net/
  - federated data management (website)

- Smart4Health project (Horizon 2020)
  - https://smart4health.eu/ and https://sts.univie.ac.at/en/research/current-research-projects/smart4health/
  - The EU Consortium Smart4Health: On the Path Developing a Mobile Health Record Application. https://smart4health.eu/the-eu-consortium-smart4health-on-the-path-developing-a-mobile-health-record-application/
  - Ulrike Felt, Susanne Oechsner, Robin Rae. 1st Specification of user requirements and performance criteria (Deliverable 1.3; Smart4Health - Citizen-centred EU-EHR exchange for personalised health. December 2019. DOI: 10.13140/RG.2.2.12383.07840
  - Ulrike Felt, Susanne Ochsner, Robin Rae. 1st Citizen/User Consent Language Report (Deliverable D1.4 - Smart4Health - Citizen-centred EU-EHR exchange for personalised health). 2019 DOI: 10.13140/RG.2.2.19093.96487.
  - Ulrike Felt, Susanne Öchsner, Robin Rae. "Citizens in Search for a Place in the Digital Health Data Space: A Case Study." In Stud Health Technol Inform 293: 127-136. 2022. doi.org/10.3233/SHTI220359.

- Understanding Patient data
  - https://understandingpatientdata.org.uk
  - Henrietta Hopkins et al. Foundations of fairness: views on uses of NHS patients' data and NHS operational data. A mixed methods public engagement programme with integrated Citizens' Juries. Findings Report Creating Conditions, 2020.

https://understandingpatientdata.org.uk/sites/default/files/2020-03/Foundations%20of%20Fairness%20-%20Full%20Research%20Report.pdf

- Yale University Open Data Access (YODA) project
  - https://yoda.yale.edu/
  - Enrique Vazquez et al. Characteristics of available studies and dissemination of research using major clinical data sharing platforms. Clin Trials. 2021 Aug 18:17407745211038524. doi: 10.1177/17407745211038524

- Zooniverse, people-powered research, online citizen science platform, by Oxford University
  - https://www.zooniverse.org/
  - Maria Vincenza Ciasullo et al. An open innovation approach to co-produce scientific knowledge: an examination of citizen science in the healthcare ecosystem. European Journal of Innovation Management. 28.9.2021. https://www.emerald.com/insight/content/doi/10.1108/EJIM-02-2021-0109/full/html

- 1+ Million Genomes
  - https://b1mg-project.eu/
  - European '1+ Million Genomes' Initiative https://digital-strategy.ec.europa.eu/en/policies/1-million-genomes
  - Mahsa Shabani. The Data Governance Act and the EU's move towards facilitating data sharing. Mol Syst Biol. 2021 Mar;17(3): e10229. doi: 10.15252/msb.202110229. PMID: 33755313; PMCID: PMC7985992.
  - In Shabani's publication: "One of the major obstacles for this and other pan-European projects is to coordinate regulatory frameworks, including consent requirement, among the partners. In this context, a harmonized approach to consent is particularly useful as the GDPR has left considerable room for implementation of the rules related to processing data for scientific research."