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Title:

Data Altruism, Personal Health Data and the Consent Challenge in Scientific Research: A Difficult Interplay between EU Acts

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Abstract:

The paper explores the challenges in implementing data altruism, focusing on personal health data altruism for scientific research purposes. The analysis highlights conceptual gaps and lack of clarity of the Data Governance Act (DGA) provisions and their unclear interplay with the General Data Protection Regulation (GDPR). Ethical considerations regarding the relationship between altruism and solidarity-based systems are discussed, along with legal issues surrounding the scope of data altruism and consent requirements in different scenarios of personal health data altruism for scientific research. The discussion extends to existing opt-out practices in scientific research and their recognition, pointing out potential drawbacks of an overly restrictive emphasis on consent in the context of data altruism. The conclusion highlights the conceptual and ethical shortcomings of data altruism, advocates for the development of an integrative approach to altruism within health data-sharing organisations encouraging collaboration and recognition of contributors to not-for-profit research in the public interest. Ultimately, the paper supports the development of new approaches to participation in research through dynamic opt-out mechanisms in health systems and emphasises the need for clearer regulatory guidance to unlock the full potential of health data altruism.

I. Introduction:

The European Union (EU) Data Governance Act¹ (DGA) paves the way for the future European Data Spaces (EDS) based on harmonised rules for the free movement of protected data in accordance with European values and fundamental rights, including privacy and personal data protection.² The DGA builds on the idea that data generated or collected by public sector bodies or other entities with public budgets should benefit society, in particular research or innovation in the public interest.³ This long-standing objective of EU policy continues to face legal, technical and organisational obstacles and a persistent culture of ‘ownership’ of protected data

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¹ Regulation (EU) 2022/868 on European data governance and amending Regulation (EU) 2018/1724 (Data Governance Act), PE/85/2021/REV/1, [2022] OJ L152.

² Charter of Fundamental Rights of the European Union (2000/C 364/01), C364/1 [2000], arts.7-8. Regarding personal data protection, see also the Treaty on the Functioning of the European Union, C326/47 [2012], art.16.

³ Rec.6 DGA.

by data holders leading to its under-utilisation. The DGA aims to facilitate the sharing⁴, access⁵ and reuse of data⁶ held by public sector bodies⁷ and subject to the rights of thirds, by setting out specific conditions for trustworthy governance and processing environment.⁸ This covers any type of data protected by either commercial confidentiality, statistical confidentiality, intellectual property or personal data protection. The DGA broadly defines a ‘reuse’ as the use, by natural or legal persons, of data held by public sector bodies, for commercial or non-commercial purposes other than the initial purpose within the public task for which the data were produced, except for the exchange of data between public sector bodies purely in pursuit of their public tasks.⁹ This meets the concept of ‘further processing’ of personal data fixed under the General Data Protection Regulation¹⁰ (GDPR) as ‘processing for a purpose other than that for which the personal data have been collected.’¹¹

The DGA creates new mechanisms for not-for-profit activities by increasing the availability and reusability of public sector data through trusted third parties responsible for managing data reuse. One of these is the Data Altruism governance model, which can apply to personal and non-personal data. ‘Data altruism’ is defined as ‘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 [...]’.¹² The DGA allows Member States to recognise existing systems or to establish new technical or organisational arrangements through public policies for data altruism.¹³

How can this model be envisaged in the perspective of further processing personal health data¹⁴ for research purposes, which is subject to stringent requirements¹⁵ and specific rules in the GDPR? This article provides a cross-sectional analysis of the provisions of the DGA and the GDPR in relation to personal health data altruism for scientific research, particularly in relation to the consent requirements. Where appropriate, we refer to the draft European Health Data Space Regulation¹⁶ (draft EHDSR) which will implement the mechanisms foreseen by the DGA in the health sector for facilitating the secondary use¹⁷ of health data, notably those contained in electronic health records. We highlight some of the remaining issues arising from the

⁴ As defined in Art.2(10) DGA.

⁵ As defined in Art.2(13) DGA.

⁶ As defined in Art.2(1) DGA.

⁷ ‘Public sector body’ means the State, regional or local authorities, bodies governed by public law or associations formed by one or more such authorities, or one or more such bodies governed by public law. Art.2(17) DGA. This definition includes public health establishments such as hospitals, public research organisations, biobanks and health registries ruled by public law.

⁸ Art.1 DGA.

⁹ Art.2(2) DGA.

¹⁰ Regulation (EU) 2016/679 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), [2016] OJ L119.

¹¹ Art.6(4) and Rec.50 GDPR.

¹² Art.2(16) DGA.

¹³ Art.16 DGA.

¹⁴ Meaning personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status. Art.4(15) GDPR.

¹⁵ Art.9(1) and rec.51 GDPR.

¹⁶ Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space, COM(2022) 197 final, 2022/0140(COD) [2022].

¹⁷ Art.2(2)(e) draft EHDSR.

interplay of these regulations to implement personal health data altruism for research and related consent.

II. Data altruism at the cross-road of the DGA and the GDPR

a. The primacy of the GDPR on the DGA and its consequences for data altruism

Articulating the DGA with the GDPR necessitates understanding the relationship between each act about personal data processing. In line with the joint opinion of the European Data Protection Supervisor (EDPS) and the European Data Protection Board (EDPB)¹⁸, the final version of the DGA provides some clarifications. First, the DGA confirms the primacy of the GDPR for regulating personal data processing. Its recitals state that the DGA should be without prejudice to other Regulations on data, particularly the GDPR.¹⁹ Where a data altruism organisation (DAO)^{20,21} is data controller or processor according to the GDPR, it ‘should’ comply with that Regulation²² and related national implementing acts. Article 1(3) DGA reinstates that statement and secures the powers and competences of supervisory authorities established by GDPR in the field. It also provides that in the event of a conflict between the DGA and the GDPR, ‘the relevant Union or national law on the protection of personal data shall prevail.’ Importantly, this Article states that the DGA ‘does not create a legal basis for the processing of personal data, nor does it affect any of the rights and obligations’ set out in these Regulations.²³ Additionally, Recital 4 specifies that the DGA ‘should not prevent cross-border transfers of data in accordance with Chapter V of GDPR’. These provisions are particularly important for health and scientific research as the GDPR set up specific rules for processing of personal health data in the domain while recognising Member States primary competence for adopting further conditions in National laws.²⁴ This includes the possibility for States to introduce novelties for framing personal data processing for altruistic purposes, as envisaged in the DGA.

This legal hierarchy has been challenged by some authors arguing for an ‘altruism privilege’ that should have been inscribed in the DGA and disconnected from the GDPR, such as with the creation of an ‘altruistic exemption’ in Article 2(2) of the GDPR associated to specific concepts developed within the DGA such as ‘altruistic controller’ or ‘data donation’. According to their analysis, mere GDPR compliance is seen as a disadvantage.²⁵

To date, the entire legal architecture of personal data sharing activities built at the EU level relies on a subordinate relationship with the GDPR. This includes those falling within the scope

¹⁸ EDPB-EDPS Joint Opinion 03/2021 on the Proposal for a regulation of the European Parliament and of the Council on European data governance (Data Governance Act) [2021] paras 13, 27, 28.

¹⁹ Rec.4 DGA.

²⁰ The European Commission gives examples of entities practicing data altruism in the meaning of the DGA, <<https://digital-strategy.ec.europa.eu/en/policies/data-governance-act-explained>> accessed 30 November 2023.

²¹ DAO “should not be considered to be offering data intermediation services provided that those services do not establish a commercial relationship between potential data users, on the one hand, and data subjects and data holders who make data available for altruistic purposes, on the other. Other services that do not aim to establish commercial relationships, such as repositories that aim to enable the re-use of scientific research data in accordance with open access principles should not be considered to be data intermediation services”. Rec.29 DGA.

²² Rec.50 DGA.

²³ Art.1(3) DGA.

²⁴ Art.9(4), Rec.10, 53 GDPR.

²⁵ Winfried Veil, ‘Data altruism: how the EU is screwing up a good idea.’ (2021). Available online at <https://algorithmwatch.org/en/data-altruism>

of the DGA and those related to the draft EHDSR, except if specified otherwise. This obliges to view these acts through the prism of the GDPR. Such legal subordination inevitably has an impact on data altruism practices, consent requirements and practices.

b. Envisaging data altruism as a personal health data processing for research purposes under the GDPR

A cross-reading of the DGA and the GDPR requires reflection on the legal qualification of the DAO and the characterisation of the processing at stake, in order to understand how the data protection rules can be implemented.

The first issue stems from the conceptual gaps in data altruism as an ethico-legal concept. Despite the definition provided in Article 2(16) DGA, the contours of this concept are blurry. The EU legislator should have provided further explanatory documentation on this concept and its implementation to found and highlight its role in the European data governance scheme. It is also surprising that the European Group on Ethics in Science and New Technologies (EGE) has not been asked to provide an opinion about data altruism as far as this broad concept involves foundational ethical values for data sharing, for scientific developments in the general interest, and potential for misunderstandings. Moreover, given the breadth of the concept and what it could encompass, the particular symbolic value of data altruism and its legal implications for citizens' rights and expectations should have been specifically examined and detailed as part of the explanatory memorandum of the DGA proposal²⁶ or of the recitals of the final act. The initial proposal refers to the preparatory stakeholder consultations which included 201 contributions from EU citizens and 7 from consumer organisations (out of a total of 806 contributions) and expressed a high level of support for the concept of data altruism. At this stage, we can only call for further ex-post study of this concept to clarify its social rationale, its underlying ethical values, the related perceptions of citizens and its operational perspectives²⁷. From an ethical perspective, the distinction and relationships between foundational values of altruism- and solidarity-based systems should be addressed. Both values allow personal data sharing for research purposes and general interest. Conceptual clarifications could be useful for improving the understanding of value-based data sharing contexts and for legitimating specific rules attached to one or the other value, including about consent to personal data sharing and to for-profit activities. Since the introduction of the notion of altruism by Comte A. as a moral force opposed to selfishness, an extensive bibliography has developed the concept in philosophy, sociology, psychology and economics, without succeeding in finding a precise universal definition.²⁸ In sociology for example there are two schools tackling altruism either as a social norm (Durkheim) or as an individual moral or psychological representation (Moscovici).²⁹ Three models have been identified, behavioural altruism, psychological altruism

²⁶ Proposal for a Regulation of the European Parliament and of the Council on European data governance (Data Governance Act), COM(2020) 767 final, 2020/0340(COD), [2020].

²⁷ The TEHDAS project ran stakeholders' workshops in 2022 which underlined the need for reaching consensus on the nature of health data altruism and the central role of the citizens in sharing their data, taking into consideration various active and/or passive mechanisms of citizens engagement. TEHDAS, Milestone M8.5, Overview about the results of EU-wide multistakeholders workshop with a special regard to updated definitions, needs, solutions, experiences, and good practices of data altruism structures and functions for the future EHDS, 5 July 2022.

²⁸ Michelle Harbour 'L'altruisme et le modèle coopératif' (2009) *La Revue des Sciences de Gestion* No 239-240, 87-95.

²⁹ François-Régis Mahieu, 'Altruisme et ingérence. Modalités de l'altruisme dans l'analyse économique' in François-Régis Mahieu (ed.) *Altruisme : Analyses économiques* Economica (1998) 113-137.

or instrumental altruism. Each implies different motivations and practical implications in terms of the voluntary mechanisms that could be associated with the desire to share something altruistically.³⁰ Economists have gradually incorporated altruism into their models by distinguishing between altruism that is driven purely by the well-being of others and altruism that is a source of personal utility. Both of these conceptual approaches have the potential to enrich economic models³¹ and source a paradigm change in which individuals can supplement the role of States in maximising the sharing of resources, passing from a normative economic to a positive economic model. In this approach, altruism, identified with the positive interdependence of utilities, can no longer be distinguished from its antonym, selfishness.³² When it comes to data altruism, it is unclear which conceptual standpoint has informed the regulatory framework. With the introduction of data altruism in law, the DGA is an opportunity to solidify an innovative conceptual approach to altruism that is ethically sounded and structurally meaningful for generating shared socio-economic value in the EU.

From a legal perspective, the scope of data altruism must be clarified. This could be achieved by defining the legal terms of ‘general interest’ and its relationships with ‘public interest’ and specifying the list of processing purposes in the general interest that would qualify altruism and those that would not. The DGA only provides examples,³³ including scientific research, and refers to national laws for further definition. Achieving harmonised definitions of key data processing purposes seems urgently needed and could irrigate the whole EU data law. Use-cases could help, in particular for understanding frontiers.³⁴ Specifications should use and conciliate existing legal terms agreed under the GDPR and the draft EHDSR. Referring to the list of purposes for which electronic health data can be processed for secondary use in the context of Art.34 draft EHDSR seems relevant. Other non-legal sources also use the term ‘common good’ in relation to altruism with more³⁵ or less³⁶ explicit reference to elements of definition. Among the issues to tackle, could data altruism concern data processing pursuing different reuse purposes horizontally (case where the DAO processes the same data across different sectors, for multiple purposes) and/or, vertically (case where the DAO concentrates on data processing in a single domain, for example biomedical research, ultimately for a single purpose of general interest)? How the rewarding notion is defined in data altruism? Does it exclude data monetisation but allow informational rewards?³⁷ Which criteria shall be used to define a not-for-profit activity? There are also questions about the nature and scope of data subject consent. Is consent the sole GDPR legal basis of altruistic processing? Is data altruism consenting to primary and secondary/further processing of personal data for scientific research uses? Is data altruism sufficiently defined to ensure specific GDPR-compliant consent, even by using provisions allowing enlarged consent for science?³⁸ Moreover, in light of the EDPB

³⁰ Christine Clavier ‘Chapitre 4. Trois sortes d'altruisme et leur rapport à la morale’ (2011) in Alberto Masala (ed.) *La morale humaine et les sciences* Éditions Matériologiques 137-164.

³¹ Jean Dubois ‘L'économie entre égoïsme et altruisme’ (2019) *LesEchos*. Critique.

³² Ozgür Gün ‘L'introduction de l'hypothèse d'altruisme dans la théorie économique contemporaine : causes, modalités et conséquences’ (Thesis in Economics, Université Paris 1 Panthéon-Sorbonne 2003).

³³ Art.2(16) DGA.

³⁴ For example, the case of a private entity requesting access to DAO data for developing a commercial product or service.

³⁵ L Skovgaard, S Wadmann, K 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’ (2019) *Health Policy* 123, 564–571.

³⁶ European Commission ‘A European strategy for data’ COM(2020) 66 final.

³⁷ In TEHDAS workshops op.cit. participants agreed that a fundamental element of trust-building is needed, for example through platforms or apps allowing to have an overview of how their shared data is being used.

³⁸ Recital 32-33 GDPR and Art.35 DGA.

criteria,³⁹ it appears that data altruism, in particular personal health data altruism, covers a range of further processing implemented for (broadly) defined altruistic purposes, potentially based on a large scale and on various sensitive personal data, and should therefore be considered as a high-risk processing by default, requiring data protection impact assessment (DPIA). Similarly, the mandatory appointment of a Data Protection Officer (DPO) in DAOs should take into account not only the sensitivity of the personal data, but also the breadth of altruistic processing in terms of nature, scope, purposes, and specific expectations of data use and trustworthy data management underpinned by altruism. Data altruism brings new challenges to essential GDPR principles such as data minimisation,⁴⁰ data quality⁴¹ and integrity⁴² that DPO and DPIA shall address. Malpractices in data altruism could highly be detrimental to public trust in the data economy and data governance system. Clear standards on key concepts, transparent and accountable governance measures (respectively in line with Articles 20 and 5 DGA) will be important incentives for stakeholders envisaging personal health data altruism. The rulebook⁴³ for DAO should respond to these needs.

The second complexity relates to the DAO legal qualification in the GDPR. Given the scope of the DGA and of data altruism, numerous public organisations, including municipalities and public associations, operating for-profit or not-for-profit, could participate in health data altruism, in parallel to traditional collectors such as healthcare institutions and public research organisations. Consequently, they may assume responsibility for managing sensitive personal data, including health information, that they are not accustomed to handling. In the DGA, a DAO should be able to collect relevant data directly from natural or legal persons or to process data collected by others to meet their purposes.⁴⁴ A DAO should be able to hold the data and comply with health data repositories and data sharing platforms requirements. From a liability perspective, collected health data will be governed by the DAO that will determine the purposes and means of the processing of personal data, thus acting as a data controller⁴⁵ subject to related data protection duties. Joint controllership with data users could be envisaged in certain circumstances. The DAO shall identify a proper legal basis for the processing of personal health data according to Articles 6 and 9 GDPR and respect specific measures applied to scientific research fixed under Articles 89(1) and (2) GDPR, by design and by default, throughout the data lifecycle and through contractual arrangements with the users. Compliance with sector-specific standards and requirements applicable to the domain in which data will be available for reuse is necessary.

The third complexity results from two related aspects: a) a lack of recognition regarding the activity of traditional actors already established for serving broad health data sharing in scientific research from a value-based perspective, in particular those enshrined within health systems such as biobanks, cohorts and registries, despite the draft EHDSR; b) the apparently

³⁹ Article 29 Data Protection Working Party, WP 248 rev.01, Guidelines on Data Protection Impact Assessment (DPIA) and determining whether processing is “likely to result in a high risk” for the purposes of Regulation 2016/679. Endorsed by the EDPB. [2017] p. 9-11.

⁴⁰ Necessity and proportionality in processing will be essential, notably because altruism could lead to extensive profiling.

⁴¹ Data from subjects or various connected devices may be biased by design and require specific quality management to benefit science.

⁴² Maintaining a high level of security and confidentiality of health data is crucial.

⁴³ Rec.46 para.2, art.22 DGA.

⁴⁴ Rec.50 DGA.

⁴⁵ EDPB, Guidelines 07/2020 on the concepts of controller and processor in the GDPR. V.2.1, [2021] p.3, 17-24.

conflicting legal basis mentioned in the DGA for personal data altruism, that is consent, and in the GDPR for processing personal health data for research purposes, that may be consent.

III. The DGA vs the GDPR on consent requirement for processing health data for (altruistic) research

a. Consent as the legal basis, always?

Personal health data, like other special categories of personal data mentioned under Article 9 GDPR, are sensitive data whose processing is particularly regulated and prohibited by principle, except where one of the derogatory legal bases fixed under Article 9(2) GDPR can be invoked, in addition to general legal grounds provided in Article 6 GDPR.

The DGA identifies two specific instances of data altruism that we will examine in relation to consent rules in the GDPR for the processing of personal health data for research purposes.

Case 1: Altruism concerning personal health data based on data subject's consent

In this case, the data subject is the main actor of altruistic data sharing. He directly provides the personal health data relating to him that he generates or has access to, and gives consent to the processing for defined altruistic purposes to an identified DAO. Modular consent form mentioned in the DGA⁴⁶ is understood in the meaning and validity conditions fixed by the GDPR.⁴⁷

The appropriateness of using consent as a legal basis⁴⁸ for processing personal sensitive data for research purposes has been questioned for some time. Its relevance for data altruism may also be questioned. Indeed, the GDPR allows relying on other grounds for processing such data for scientific purposes based on combinations of Articles. In particular, where the processing is based on Union or National law and is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller under Article 6(1)(e), in conjunction with Article 9(2)(i) for reasons of public interest in the area of public health,⁴⁹ or (j) for archiving purposes in the public interest, scientific or historical research or statistical purposes.^{50,51,52} Consent is also envisaged as a last resort in specific cases of data transfer to non-EU countries or international organisation in Article 49 GDPR.

Processing that can rely on alternative legal bases should not have to implement consent requirement for data altruism. Opt-out mechanisms and other data governance measures planned for protecting privacy in the GDPR and in the DGA ensure appropriate data protection in such data reuses. Moreover, in scientific research, in particular health research, ethics principles and guidelines play an important role for preserving data subject's rights, together

⁴⁶ Art.22 DGA.

⁴⁷ Art.4(11), 7, rec.32-33 GDPR.

⁴⁸ Arts.(6)(1)(a) and 9(2)(a) GDPR.

⁴⁹ Rec.54 GDPR provides for specific measures allowing the processing of special categories of personal data where 'necessary for reasons of public interest in the areas of public health without consent of the data subject', provided that such processing is 'subject to suitable and specific measures so as to protect the rights and freedoms of natural persons.'

⁵⁰ G Chassang, 'The impact of the EU general data protection regulation on scientific research' (2017) *ecancer* 11 709.

⁵¹ S Slokenberga, 'Scientific research regime 2.0? Transformations of the research regime and the protection of the data subject that the proposed EHDS regulation promises to bring along.' (2022) *Technol Regul.* 135–47.

⁵² The Council of Europe adopts a similar approach by stating that scientific research requires consent or law authorising the use of the data. Recommendation CM/Rec(2019)2 of the Committee of Ministers to Member States on the protection of health-related data [2019].

with independent ethical reviews. The EDPB clarified further that the ‘ethics standards cannot be interpreted in such a way that only explicit consent of data subjects can be used to legitimate the processing of health data for scientific research purposes. Articles 6 and 9 GDPR provide other options that can be relied on for processing health data for scientific research purposes’⁵³ without diminishing protection or data subject’s control over the data reuses. Alternative legal bases are subject to appropriate safeguards mentioned within Article 89(1) and do not exempt from obligations of accountability, processing fairness, lawfulness, transparency, data minimisation and respect of individual rights. For example, in the context of clinical trials, the EDPB made it clear that the requirement of informed consent for participation in a scientific research project [under the Clinical Trial Regulation⁵⁴] can and must be distinguished from explicit consent mentioned in the GDPR as a possible legal ground to legitimate the processing of personal health data for scientific research purposes.’⁵⁵

This distinction with consent established as a legal basis for personal (health) data processing in the GDPR extends from their primary use for the purpose of the clinical trial to their secondary use outside the trial protocol, for other scientific purposes.⁵⁶ Nevertheless, the EDPB states that GDPR-consent can be practiced voluntarily and could be considered as an additional safeguards foreseen in Article 89(1) GDPR for data controllers⁵⁷ provided that the consent is valid and ethically compatible with the condition of the data subject and with the research protocol. This consent ‘as a safeguard’ should be interpreted as an optional consent practice for personal data processing (whether initial/primary use or further/secondary use) used by the data controller for a set of similar processing operations. Such voluntary practice aims at allowing the direct expression of data subjects, as a mean ‘for giving individuals more control and choice and thereby for upholding society’s trust in science’⁵⁸ and facilitating accountable data management.⁵⁹ Consent as a further condition or limitation for processing personal health data can also be imposed by Member States laws according to Article 9(4) and recital 53 GDPR. Nevertheless, personal health data previously collected, possibly based on consent for primary use, benefit from a general presumption of compatibility for further uses in research⁶⁰ and from National regulations departing from the opt-in consent requirement.⁶¹ In most EU countries, the further uses of personal health data for scientific research and innovation from sources such as medical or e-health records, hospital information systems, health registries or even research biobanks are legally based on opt-out mechanisms attached to controlled access governance

⁵³ EDPB Document on response to the request from the European Commission for clarifications on the consistent application of the GDPR, focusing on health research. [2021] para 5.

⁵⁴ Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, [2014] OJ L158, art.28.

⁵⁵ EDPB Document focusing on health research, op.cit. [2021] para 5.

⁵⁶ EDPB Opinion 3/2019 concerning the Questions and Answers on the *interplay* between the Clinical Trials Regulation (CTR) and the General Data Protection Regulation (GDPR) (Art. 70.1.b)) [2019] Section 3.

⁵⁷ EDPB Document focusing on health research, op.cit. [2021] para 7.

⁵⁸ EDPS A Preliminary Opinion on data protection and scientific research. P.19-20. 6 January 2020.

⁵⁹ For instance, through the development and adoption of innovative approaches to consent practices such as dynamic consent, meta-consent, broad/governance consent, including through the use of chatbots.

⁶⁰ Art.5(b) and rec.50 GDPR.

⁶¹ Nivel Study for the European Commission DG Health and Food Safety, Assessment of the EU Member States’ rules on health data in the light of GDPR (2021) section 5.

systems.^{62,63} In limited cases, for example regarding genetic data, consent is still preferred for initial processing and, in certain cases, for further processing for research purposes.

This general legal approach of defocusing attention on the individual explicit and specific consent to concentrate on the conditions for responsible data reuses when it comes to scientific (re)uses, in particular in the field of health and biomedical research, has been supported by many scholars. These argue based on consent impracticalities^{64,65} in the context of modern complex data sciences,⁶⁶ on doubts as to the consent quality⁶⁷ and value⁶⁸ in digital world,⁶⁹ and on the existence of multiple strict ethical, technical and organisational safeguards imposed to data controllers for ensuring responsible health data reuses in the public interest.^{70,71,72} Additionally, the use of consent has implications regarding applicable individual rights in research that can eventually be derogated based on Articles 89(2) and (4) GDPR. Besides, the idea that there could exist an ethical duty of each to contribute to health data research benefiting to the general interest is also discussed.⁷³ This said, the latter individual's ethical duty has not reached a consensus and is not explicitly recognised through legislations or as a general principle in ethical best practices. If such a duty is recognised, underlying data sharing should not be considered as data altruism.⁷⁴

The current EU data protection acquis preserves data holders and data subjects' freedoms in data sharing and sets up specific conditions of trustworthy health data management and reuses. These conditions permit a flexible approach to personal health data sharing for scientific

⁶² See examples in the Nivel study (2021) op.cit. p.57-80.

⁶³ S Slokenberga, O Tzortzatou, J Reichel, (eds) 'GDPR and Biobanking: Individual Rights, Public Interest and Research Regulation across Europe' (2021) Springer Nature; Law, Governance and Technology Series, 43.

⁶⁴ A Vlahou, D Hallinan, R Apweiler et al. 'Data Sharing Under the General Data Protection Regulation: Time to Harmonize Law and Research Ethics?' *Hypertension*. 2021 Apr;77(4):1029-1035.

⁶⁵ SJ Laurijssen, R Van der Graaf, WB Van Dijk, et al. 'When is it impractical to ask informed consent? A systematic review.' *Clinical Trials*. (2022) 19(5), 545-560.

⁶⁶ Re-consenting problems are often raised in epidemiological and genomic studies.

⁶⁷ W Montalvo, E Larson 'Participant comprehension of research for which they volunteer: a systematic review.' (2014) *J Nurs Scholarsh*. 46(6), 423-31.

⁶⁸ For example, Chico notes that "the ability of consent to protect people's interests in the health and social care context has been questioned." Chico, V. 'The impact of the General Data Protection Regulation on health research' (2018) Volume 128 Issue 1 *British Medical Bulletin*, 109–118.

⁶⁹ K Clark, M Duckham, M Guillemin et al 'Advancing the ethical use of digital data in human research: Challenges and strategies to promote ethical practice.' (2019) *Ethics and Information Technology*, 21(1), 59-73.

⁷⁰ A Ballantyne, GO Schaefer 'Public interest in health data research: laying out the conceptual groundwork.' (2020) *J Med Ethics*. 46(9), 610-616.

⁷¹ R Faden, N Kass, D Whicher, W Stewart, S Tunis 'Ethics and informed consent for comparative effectiveness research with prospective electronic clinical data.' (2013) *Med Care*. 2013 Aug;51(8 Suppl 3):S53-7.

⁷² E Gefenas, J Lekstutiene, V Lukaseviciene et al. 'Controversies between regulations of research ethics and protection of personal data: informed consent at a cross-road.' (2022) *Med Health Care Philos* 25(1), 23-30.

⁷³ A Ballantyne, GO Schaefer, 'Consent and the ethical duty to participate in health data research' *Journal of Medical Ethics* (2018) 44 p.392-396. See also the connected publication from N Heggul, KE Sleeman, AM Firth et al 'In response to Ballantyne and Schaefer's 'Consent and the ethical duty to participate in health data research'' (2019) *Journal of Medical Ethics* 45, 351-352.

⁷⁴ While to date data subjects are free, by principle, to contribute to research activities under the GDPR, the draft EHDSR tends to affirm an 'obligation placed on data holders to make their data available for secondary use in the framework of EHDS' as a kind of duty to share health data for reuses applying indistinctly to public or private data holders, as a counter part of public EU or Member State's funding. See rec.40 draft EHDSR. This approach builds on ethical guidelines regarding the open research data movement and has consequences on the interplay between the draft EHDS, the DGA, and the GDPR, regarding consent. Indeed, the draft EHDSR constitutes a legal basis under art.6(1)(c), art.9(2)(j), (h) and (i) GDPR for sharing personal health data as a data holder's duty. This position raises challenges as the health data access bodies will rely on the obligations laid down in the EHDSR to provide access, overcoming then the other consent requirements, see art.33(5) draft EHDSR.

research reuses presenting a significant interest for society in the respect of specific data governance requirements. They must be considered in order to improve the DGA/GDPR/draft EHDSR interplay, to avoid confusions or restrictions in the recognition of data altruism in regulated fields, such as in health research, where consent is not always legally required, nor ethically desirable, for initial and further health data uses, while data subjects keep control over the use of the data.

Issues could arise for DAO which would have a broader sharing scope going beyond the health or scientific research area. In such cases, consent to data altruism could be an adequate legal basis for managing multiple altruistic purposes likely to entail more privacy risks for the data subject. One could understand this consent rule as an ethical standpoint deeming that the legal bases other than consent provided in Articles 6 and 9(2) GDPR are incompatible with the object of data altruism for processing health data for scientific research purposes in certain (yet unclear) cases. But this deserves further clarity and justifications.

Besides the need to further characterise data altruism purposes, a useful distinction could be made between personal health data sources⁷⁵ to legitimate mandatory GDPR-consent practice, depending on whether:

- the data is collected within health system, including reliable and structured data collection from public funding authorities and social security bodies, public or private healthcare establishments, social care establishments, health research organisations, autonomous health professions regulated under National health law and professional deontology, from medical or e-health records, from prescribed medical devices; or whether
- the data is collected outside the health system, in particular in cases of citizen-generated health data (e.g. through non-medical mobile devices and wellbeing applications, transport, other digital behavioural or consumption applications generating health data, and health data which are made publicly available by the data subject, notably online). These data sometimes evolve in grey areas of law, including about the implementation of personal data protection law, involve commercial entities privately running the processing devices and exploiting data for several purposes, often with many commercial partners.

For the former category of data sources, health systems already build on special regulations enforcing the solidarity principle⁷⁶ which includes a form of data altruism⁷⁷ being part of a more or less explicitly negotiated social contract between citizens and State governing institutions. This umbrella approach justifies special regimes essentially based on opt-out for sharing data for scientific research reuses in compliance with the GDPR (with some exceptions governed by specific National laws), whether the data are collected directly or indirectly with the data

⁷⁵ By reference to art.33 of the draft EHDSR.

⁷⁶ Solidarity is an overarching framework for European healthcare systems, as notably reaffirmed by the European Group on Ethics in Science and New Technologies, see: Palazzani L, Halila R, Dratwa J, et al. *'The ethical implications of new health technologies and citizen participation'*, (2016) eds. Dratwa J, Parkin J.

⁷⁷ Data altruism and data solidarity are close concepts, yet not universally defined, deserving more explanatory works regarding the digital world challenges. For example, some noted that solidarity is relational and bi-directional – that is, it takes place between people, acting in solidarity with others can empower both the giver and the receiver – whereas altruism is unidirectional, going only from a giver to a receiver. Prainsack B, et al. 'White Paper – Data Solidarity. Growing up in a digital world 2030. Governing Health Futures.' (2022) The lancet & financial times Commission, p.11.

subject. In these cases, the reuse of the data for health-related research purposes are presumably foreseeable from the side of the data subject as they are part of the solidarity-based systems subject to specific and well-established transparency and accountability measures. Sharing activities are governed by the health system legal entities and serve altruistic purposes essentially in the health research fields.

For the second category of data sources, relationships are essentially based on commercial contracts or consumer relationships (irrespective of whether a payment is required or not for having the application), on data exploitation models generating private profits, more or less directly, including where based on forms of altruism⁷⁸, and on direct data collection with the data subject.⁷⁹ This category could also usefully cover situations of indirect data collections performed on the Internet, where the data have been made public by the data subject. In such cases, personal health data are essentially generated for data subject's personal uses, for domestic purposes. The reuse of data in different research areas may be less obvious and less predictable to data subjects, which may justify relying more on the mandatory GDPR-consent practice⁸⁰. Challenges to GDPR data quality principles are also important to ensure compliance with the rigorous quality standards required for scientific uses.⁸¹ Similarly, regarding the data minimisation and risks of extensive profiling. Additionally, in this case, data altruism essentially relies on the right to data portability^{82,83} allowing data subject to autonomously decide to move the data from a data controller to another. This right applies to automated processing where a data subject provided the personal data based on GDPR-consent or where the processing is necessary for the performance of a contract. But this right entails some limitations and derogations in the context of research processing.⁸⁴ The role of the data subject consenting to data altruism will also need clarification. Will the data subject be requested to activate data portability for providing the data? Will the DAO be entitled to perform access requests based on a consented delegation from the data subject, the DAO acting on his behalf, as a data broker?⁸⁵

Of note, the ongoing works for constructing the EHDS, which in our opinion builds on a form of data altruism, aims at integrating both categories of data and to make them available for research reuses.⁸⁶ Bridges between DAO and EHDS should be clarified regarding the provisions included in the draft EHDSR.⁸⁷

⁷⁸ Isaac Getz, Laurent Marbacher, 'Altruism can be good for business, as these companies show.' (2019) World Economic Forum.

⁷⁹ Meaning that in this category the data provider is the data subject.

⁸⁰ BEUC 'Consumer attitudes to health data sharing. Survey results from eight EU countries.' [2023].

⁸¹ EDPB-EDPS Joint Opinion 03/2022 on the Proposal for a Regulation on the European Health Data Space [2022] p.3.

⁸² Art.20 and rec.68 GDPR.

⁸³ EDPB Guidelines on the right to data portability under Regulation 2016/679, WP242 rev.01 [2018].

⁸⁴ G Chassang, T Southerington, O Tzortzatou, M Boeckhout, S Slokenberga, 'Data Portability in Health Research and Biobanking' (2018) European Data Protection Law Review, Volume 4 3, 296–307.

⁸⁵ Rec.50 DGA states that DAO "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."

⁸⁶ Art.33 draft EHDSR. As it results from the current draft, health data access body and data altruism body are separated entities.

⁸⁷ The consistency assessment of the draft EHDSR mentions that the EHDS builds upon the DGA and the Data Act. "The proposed Data Act enhances portability of certain user-generated data, which can include health data,

Case 2: Altruism concerning non-personal health data based on data holder permission (and data subject's opt-out or consent?)

In this case, the data holder is the main actor of data altruism. The data holder is broadly defined in the DGA as a 'legal person, including public sector bodies and international organisations, or a natural person who is not a data subject with respect to the specific data in question, which, in accordance with applicable Union or national law, has the right to grant access to or to share certain personal data or non-personal data.'⁸⁸ In this case, the data holder gives permission⁸⁹ to the reuse of non-personal data only, including anonymous and anonymised data. The DAO shall ensure that the data is not used for other purposes than those of general processing for which they permit the processing.⁹⁰

This case differs from case 1 based on the data category. There is no longer a relationship between the practice of consent and data altruism. The altruistic approach is no longer principally based on the data subject but on the DAO. One could challenge this position as weakening the control and engagement of data subjects. An interesting point there concerns the anonymisation process. When data will be anonymised? By whom? Is anonymisation subject to consent in this scenario?

Anonymisation of personal data is a processing covered by the GDPR. There too, the legal possibilities offered by the Articles 6 and 9 of the GDPR shall be considered as exposed above when data processing for scientific research is envisaged, including in the context of data altruism. In most cases there is no legal obligation to practice consent for anonymisation⁹¹ but data subjects have a right to be informed about such a processing and can opt-out until the full anonymisation of the dataset. Should anonymisation be performed by the DAO based on consent, this processing would inscribe in case 1. The question remains where anonymisation is based on opt-out.⁹² Once anonymised in the respect of technical state-of-art, health data are not anymore personal data subject to the GDPR as they do not longer permit to identify the data subject. Moreover, the DGA specifies that reidentification through reuses shall be prohibited.^{93,94} This needs specific contextual risk assessment based on processing

but does not provide rules for all health data. Therefore, the EHDS complements these proposed legislative acts and provides more specific rules for the health sector [...]” Art.37(1)(h) and 40 draft EHDSR respectively mention contribution to and monitoring of data altruism activities among the tasks of the Health data access bodies composing the EHDS. Art.39(1)(b) obliges these bodies to publish a list of data permits involving access to electronic health data based on data altruism and a summary description of the general interest purposes pursued, where applicable, including the outcomes of the data permits granted; (h) set the basis for authorities' cooperation as to health data altruism. Interestingly, Art.40(1) states that a DAO processing personal electronic health data using a secure processing environment, such environments shall comply with the requirements set out in Art.50 draft EHDSR. Finally, chapter VII allows the Commission to adopt delegated acts on data altruism and related technical requirements in health sector.

⁸⁸ Art.2(8) DGA.

⁸⁹ Art.2(6) DGA.

⁹⁰ Art.21(2) DGA.

⁹¹ Khaled El Emam, Mike Hintze, 'Does anonymisation or de-identification require consent under the GDPR?' (2019) IAPP.

⁹² Except by considering the proposed case 1.5 below.

⁹³ Rec.8 DGA.

⁹⁴ Rec.15 DGA adds that non-personal data should be transmitted only where there is no reason to believe that the combination of non-personal data sets would lead to the identification of data subjects. In the event of the re-identification of data subjects, an obligation to notify such a data breach to the public sector body should apply in addition to an obligation to notify such a data breach to a supervisory authority and to the data subject in accordance with GDPR.

characteristics, purposes⁹⁵ and necessitates appropriate technical and organisational safeguards. Of note, where personal and non-personal data in a dataset are inextricably linked, this mixed dataset shall be considered as a personal dataset subject to GDPR.⁹⁶ Hence the importance to ensure that a DAO is really dealing with anonymous data or is performing appropriate anonymisation techniques according to recognised methods⁹⁷ which are in constant development⁹⁸ and challenging in certain contexts such as genomics.⁹⁹ It is unfortunate that the DGA did not liaise with the opt-out nor consent in this regard, in order to reflect the state of the law and to allow for an understanding of where altruistic behaviour lies.

It results from this analysis of the interplay of DGA and GDPR that an intermediary case (case 1.5) could have been envisaged under the DGA. Case 1.5 would be altruism concerning personal (health) data based on data holder permission and data subject's opt-out mechanism. This would have fostered the inclusion of existing sector-specific infrastructures for data collection and altruistic management, in particular in the field of health, and better liaised with the ongoing works on a EHDSR detailing specific conditions for allowing the sharing and reuse in research of pseudonymised personal health data. It would also have embraced existing National legislations favouring forms of data altruism in research using other legal bases than consent, with specific requirements such as for prior Research Ethics Committee's approval of research projects. Opt-out inclusion would also have addressed some concerns reported through literature regarding 'consent misconception' in the field of health research (in particular clinical research) and critics emerging as to the creation of new entities building on a recognised altruistic value while current efforts from actors in the field already allow access to quality health data through EDS.¹⁰⁰

In any cases, whether the personal health data collection is legally based on data subject's consent or opt-out, the data subject is granting to the DAO a data stewardship including obligations and rights regarding data reuses. Specific GDPR requirements regarding appropriate measures for protecting individual rights and freedoms, and research ethics rules applied to protect privacy in personal health data processing should be considered as compatible with a trustworthy data altruism environment, irrespective of whether consent or opt-out is used. The essential elements being data subject control capacities, transparency and accountability. The dedicated rulebook mentioned in the DGA could adequately recognise and operationalise this approach in the light of the existing health data sharing systems and norms supporting forms of data altruism.

b. Existing practices in scientific research and their recognition

⁹⁵ Analysts noted that 'this provision introduces a new concept of 'purpose' for the processing of non-personal data, as of yet unseen in EU law [...]', although rec.46 DGA 'clarifies that legal persons could give permission for 'a range of purposes not defined at the moment of giving the permission', which is obviously much broader than the 'specific purpose' within the meaning of the GDPR.' CiTip White Paper (2021) op.cit. p.42.

⁹⁶ Like in Regulation (EU) 2018/1807 on a framework for the free flow of non-personal data in the European Union, OJ L 303 [2018] art.2(2).

⁹⁷ Art.29 Data protection Working Party, Opinion 05/2014 on Anonymisation Techniques, 0829/14/EN WP216 (2014).

⁹⁸ Scott Quellhorst, Renata Valkova, 'A practical guide to anonymisation standards across the EU and UK.' (2023) IAPP.

⁹⁹ K Akyüz, M Goisauf, G Chassang et al. 'Post-identifiability in changing sociotechnological genomic data environments.' (2023) BioSocieties.

¹⁰⁰ T Lalova-Spinks, J Meszaros and I Huys 'The application of data altruism in clinical research through empirical and legal analysis lenses.' (2023) *Front. Med.* 10:1141685.

Data altruism foreseen in the DGA places a high level of emphasis on consent, leading to a restrictive approach of the concept. This approach could potentially attempt to the understanding of the complex scalability of obligations based on risks established by the GDPR and the special regime for scientific research. Over-emphasising consent as the ‘typical’¹⁰¹ legal basis in the context of data altruism and data reuses for scientific research could result in excluding many infrastructures (such as biobanks, health registries), although they are contributing to data altruism in science for decades. They are currently providing indispensable informational resources for health and biomedical research enabling breakthroughs in knowledge generation and innovation of significant societal importance. They implement strict ethical and legal requirements and could legitimately pretend pursuing altruistic purposes by making available quality resources for further uses in scientific research pursuing a public or general interest. Without necessarily relying on consent, they maintain data subject’s capacity to oppose the use of their data and ensure appropriate trustworthy governance including sustainable privacy-preserving mechanism and FAIR data management.^{102,103} These infrastructures are not always well known nor recognised despite their important contribution to the researches serving society as a whole. A restrictive approach could be detrimental to their deserved recognition and developments, suggesting that altruism is not there, while ethics and safeguard of individual rights in the general interest are at the heart of their custodianship role. Whether hosted by public hospitals, public research organisations or other entities, they typically operate on a not-for-profit basis. Such infrastructures enshrined into health systems architecture in the EU could, in their diversity, be considered as serving data altruism for a broad range of scientific researches. A legal criterion for recognising DAO statute based on the use of consent is questionable where applicable laws provide for other options. The sole processing purposes and guarantees ensured by the organisations should be considered. Maybe an alternative could be to integrate additional data altruism use conditions into the opt-out procedures already effective in health systems’ organisations. Whereas consent should not be the only way of practicing ‘official data altruism’, it appears interesting to ethically question the role of consent in this context. Why requiring GDPR-consent in the context of data altruism? Which are the perceived advantages of this practice? Why or in which cases opt-out mechanisms for personal health data sharing would be insufficient? Is the use of consent including an ethical duty for the DAO to actively share the data? Is it a precontractual step? All these issues could be addressed by the future European Data Innovation Board (EDIB) who will adopt interpretative documents regarding the DGA, in collaboration with the EDPB and the forthcoming EHDS Board.

Consent seems to be envisaged as a new participatory way of creating a set of 'intangible commons' for altruistic uses in research. As the DGA mentions, consent ‘may’ be used voluntarily as a legal basis for data altruism. The practice of consent certainly has a strong symbolic value for advancing digital data democracy, for demonstrating active, voluntary individual engagement in non-profit scientific activities and citizen science initiatives, in a logic of unlocking the potential of open data through a bottom-up approach for the public good. Nevertheless, new practices of dynamic opt-out and downsides of a systematic requirement for

¹⁰¹ Rec.50 DGA.

¹⁰² M Wilkinson, M Dumontier, I Aalbersberg *et al.* ‘The FAIR Guiding Principles for scientific data management and stewardship.’ (2016) *Sci Data* 3, 160018.

¹⁰³ Regarding biobank management system, see: Petr Holub *et al.* ‘Enhancing Reuse of Data and Biological Material in Medical Research: From FAIR to FAIR-Health.’ (2018) 97-105 *Biopreservation and Biobanking*.

consent must be considered for regulated sectors such as scientific and health research for which the provisions of the GDPR, even though imperfect, preserve important data sharing pipelines and leeway for trustworthy actors keeping privacy and human at the centre of personal data governance, regardless of data subject's opt-in requirement.

Conclusion:

Data altruism suffers from important conceptual and ethical shortcomings leading to difficulties in grasping its concrete application in relation to applicable regulations, such as the GDPR, and related consent rules applied to personal health data processing for research purposes.

The DGA emphasises consent as a pivotal legal basis, potentially setting aside initiatives using other lawful grounds and GDPR's research exception. This leads to a theoretical distinction potentially marginalising health data-sharing infrastructures of the EU's solidarity-based health systems that operate on ethical, transparent, accountable and potentially dynamic opt-out enabling effective individual control over data compared to other entities. The unclear interplay between the DGA/GDPR/EHDSR on consent requirement is a source of misunderstandings and regulatory ambiguities impeding the full realisation of personal health data altruism's potential for research.

We regret that the legislator has not consulted the EGE on data altruism before adopting the DGA to clarify potential synergies or distinctions in a value-based analysis. Through the future dedicated rulebook, the EDIB, the EDPB and the EHDS Board should definitely develop the foundations of this concept, preferably as an integrative concept fostering broad recognition of engagement in health data sharing for the common good.