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CHALLENGES OF GDPR COMPLIANCE WITH THE DATA ALTRUISM CONCEPT UNDER THE DATA GOVERNANCE ACT: LESSONS FROM THE ESTONIAN X-ROAD MODEL

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ABSTRACT

The introduction of the Data Governance Act (DGA), which entered into force on 23 June 2022, has marked a significant development in the European data landscape.[1] This landmark legislation aims to reshape data governance practices within the European Union, setting the stage for a

[1] Here you European Data Governance Act, Retrieved from: https://digital-strategy.ec.europa.eu/en/policies/data-governance-act

new era of data utilization and regulation[2]. However, it presents a complex challenge – how shall these goals be aligned with the strict data protection standards outlined in the General Data Protection Regulation (GDPR)? This research is driven by the recognition that understanding and addressing the compliance challenges that arise when balancing data altruism, data sharing, and data protection in the European data landscape are more crucial than ever. By increasing data availability, the European market seeks to gain a competitive advantage, stimulate innovation, and foster economic growth[3]. This article addresses the question of how GDPR-compliant approaches can be established to facilitate efficient, secure, practicable, and simple data exchange under the DGA, especially in the context of data altruism, and drawing from the experiences of the Estonian X-Road.

KEYWORDS

Data Governance Act, Data Altruism, Data Altruism Consent, GDPR.

INTRODUCTION

At the core of our modern technological era lies the centrality of the data, a fundamental element that maintains its critical importance and is set to continue shaping future advancements[4]. To improve data-sharing in the internal market, a standardized framework for data exchanges and governance was needed, with a focus on Member State collaboration. Thus, the European Commission adopted the Data Governance Act (DGA), effective from September 2023. This regulation aims to advance the digital market while prioritizing human values, rights, trust, and security, highlighting the Commission's commitment to unified data governance across the EU [5].

The Data Governance Act represents a significant milestone within the scope of data utilization and the digital market. One of these essential concepts of this act is "data altruism," along with the establishment of data altruism organizations, which are integral components of the DGA. According to Article 2, Part 16 of the Act, "data altruism" refers to the voluntary sharing of data, either personal or non-personal, based on the consent of data subjects or the permissions of data holders. This sharing is undertaken without seeking or receiving any reward beyond compensation for incurred costs. Such data sharing serves objectives of general interest, as outlined in national law, including but not limited to healthcare, environmental conservation, transportation improvement, statistical analysis, public service enhancement, policy formulation, and scientific research. These objectives underscore the Act's commitment to promoting social welfare and advancing public interest initiatives.[6]

Despite the benefits of data altruism for research and collective good, there are potential compliance issues with the GDPR. The DGA is relatively new, and its full implications are not yet clear. This article explores the challenges of data sharing under the DGA and its compliance with GDPR provisions. The key question is whether secure and ethical data sharing is possible under the DGA, given the risks of voluntary personal data sharing. While GDPR sets strong guidelines for data protection, breaches still occur, raising the question of whether the DGA needs stricter regulations. It is crucial

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2 *Ibid.*
3 A European strategy for data, Brussels, 19.2.2020 COM (2020) 66 final.
4 A European strategy for data, Brussels, *supra nota* 3, p.1.
5 Regulation (EU) 2022/868 of the European Parliament and Council, of 30 May 2022 on European data governance and amending Regulation (EU) 2018/1724 (Data Governance Act), *OJ L 152*, 3.6.2022, p. 1–44.
6 *Ibid.*

to compare the GDPR's focus on personal data protection with the DGA's broader data governance approach to assess the DGA's effectiveness, especially concerning data altruism. Moreover, with the GDPR already in force, the necessity of the DGA and the concept of data altruism comes into question. There is also a question of whether the DGA offers significant added value in terms of data governance[7], or whether it risks duplicating efforts already covered by the GDPR.

The research here focuses on the Data Governance Act, especially data altruism and sharing, in relation to GDPR. Given the newness of the legislation, understanding its compliance and challenges is vital. The study offers Estonia's X-Road as a case of effective data sharing, analyzing its alignment with GDPR to identify challenges and lessons.

DATA GOVERNANCE ACT

To promote the use of data for European research and innovation purposes by both public and private entities, it was imperative to establish clear and consistent conditions governing access to and utilization of such data throughout the Union[8]. The European Union adopted the DGA to standardize data access, a move justified despite criticisms of overregulation. However, the Act overlaps with the GDPR, often referencing it and introducing new definitions and consent type, raising concerns about the need for additional consent forms when the GDPR already provides a framework.

Examining the link between the Data Governance Act and the Data Act is crucial. The Data Act builds on the Data Governance Act, aligning with the EU's data strategy to clarify data value and access and promote cross-sector data sharing. While the DGA regulates general data-sharing practices, the Data Act focuses on data sharing within the Internet of Things (IoT)[9]. These legislative initiatives align with the broader goal of promoting and developing a data economy within the EU by facilitating efficient and compliant data-sharing practices.

The DGA establishes a legal framework for data intermediaries, ensuring compliant and ethical data sharing within the EU. It provides guidelines for intermediaries, data sharing, and dispute resolution, promoting access, research, innovation, and economic development. In contrast, the Data Act focuses on data-sharing practices in the IoT sector, tackling issues of ownership, interoperability, and security[10].

The EU's introduction of numerous new legislations is aimed at achieving the goals outlined in the EU Data Strategy. The objective of this regulation is to encourage data sharing within the internal market by establishing a standardized legal framework for data exchanges, while still adhering to the principles outlined in the GDPR[11]. It is important to note that the DGA does not introduce new data processing methods but references GDPR regulations. Article 1 of the DGA sets the regulation's principles and objectives. It establishes conditions for reusing data held by public sector bodies in the EU, introduces a framework for supervising data intermediaries, and outlines voluntary

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7 Ferrè, G. R. (2023, April 26). *Data donation and data altruism to face algorithmic bias for an inclusive digital healthcare*. https://doi.org/10.15168/2284-4503-2624

8 Regulation (EU) 2022/868, *supra nota* 5, Recital (6).

9 Carovano, G., & Finck, M. (2023). *Regulating data intermediaries: The impact of the Data Governance Act on the EU's data economy*. https://doi.org/10.1016/j.clsr.2023.105830.

10 *Ibid.*

11 Bravo. (2022). Data Governance Act and Re-Use of Data in the Public Sector. *European Review of Digital Administration & Law - Erdal, 3*(2), 13–22.

registration for organizations processing data altruistically. It also creates the European Data Innovation Board to foster data innovation[12].

This article clarifies that the regulation does not require public sector bodies to permit data re-use or exempt them from confidentiality obligations under Union or national law. It also specifies that existing Union or national laws on data access and re-use, as well as sector-specific requirements, will take precedence.[13] This ensures that the regulation operates within the existing legal framework and respects confidentiality obligations and specific provisions in Union or national law.

Despite this, uniformity challenges persist. Each member state has its own GDPR-compliant laws, but data reuse governance remains uncertain. The DGA's effectiveness depends on member states' willingness to allow data reuse and integrate it into their legal frameworks, as well as public acceptance of voluntary data sharing with its risks. Addressing these concerns requires significant effort from member states to establish governance frameworks and assure citizens of GDPR compliance, though achieving complete safety remains difficult even with strict data protection rules.

In contrast to GDPR, the Data Governance Act extends beyond personal data to encompass data in general. It introduces the concept of a "data holder," described as a legal entity, including public sector bodies and international organizations, or a natural person who is not the subject of the data in question. This data holder possesses the authority, as per applicable Union or national law, to grant access to or share certain personal or non-personal data[14].

It is essential to discuss the connection of definitions with other regulations as well. The definition of 'data' in the EU Regulation on the free flow of non-personal data and the Data Governance Act appears similar but has subtle differences that could lead to confusion about the scope and applicability of the regulations. In the EU Regulation on free flow of personal data, 'data' is defined as all data other than personal data, as outlined in Article 4(1) of the GDPR.[15] This definition excludes personal data, focusing on non-personal data. Alternatively, Article 2 of the DGA defines 'data' broadly as any digital representation of acts, facts, or information, including various formats like sound, visual, or audiovisual recordings. Article 2(1) of the Data Act aligns with this broad definition and adds specific definitions like product data and related service data.[16] This definition covers a broader range of data, including both personal and non-personal data. The DGA's broader definition may cause confusion since it includes personal data, while the EU Regulation on the free flow of non-personal data focuses only on non-personal data, leading to potential misunderstandings about the applicable regulations.

The DGA sets rules for voluntary data sharing and introduces concepts like data altruism. According to Article 2(10), data sharing involves providing data to a user based on voluntary agreements or legal frameworks, directly or through intermediaries, under arrangements like open or commercial licenses, with or without a fee.[17] In parallel, Data altruism, as per Article 2(16), involves voluntarily sharing data with consent or

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12 Regulation (EU) 2022/868, *supra nota* 5, Article 1.
13 *Ibid.*
14 Regulation (EU) 2022/868, *supra nota* 5, Article 2 (8).
15 Regulation (EU) 2018/1807 of the European Parliament and of the Council of 14 November 2018 on a framework for the free flow of non-personal data in the European Union (Text with EEA relevance.) *OJ L 303*, 28.11.2018, p. 59–68, Article 2(1).
16 Mylly, U. M. (2024). *Trade Secrets and the Data Act. IIC – International Review of Intellectual Property and Competition Law*. https://doi.org/10.1007/s40319-024-01432-0.
17 Regulation (EU) 2022/868, *supra nota* 5, Article 2 (10).

permissions, aimed at contributing to public interests like healthcare, climate change, mobility, statistics, public services, policy-making, and scientific research.[18] Nevertheless, the practical implementation remains largely theoretical, and the effectiveness of these measures in practice is yet to be seen. While safeguards are theoretically in place, the question of their reliability and trustworthiness remains unanswered.

The DGA functions alongside the GDPR without modifying its scope, allowing both regulations to operate simultaneously. As certain elements of the DGA have implications for personal data, its provisions are designed to fully comply with data protection laws and enhance individuals' authority over their data[19]. This is particularly crucial for regulations like the Data Governance Act, which are relatively new and lack extensive practical implementation or case law.

For these abovementioned reasons, it is essential to ensure alignment with the GDPR. To ensure compliance with GDPR and clarity in the provisions of the DGA, several approaches can be adopted, with a focus on defining key terms. Firstly, it's crucial to define what falls under "general interest." While Recital 45 of the DGA provides examples such as healthcare, combating climate change, and supporting scientific research,[20] there remains a need for a comprehensive definition to address scenarios where data usage extends beyond these examples. This definition clarifies the scope of activities in the general interest and helps data subjects understand the purposes of data use. It is crucial to distinguish "public interest" in the GDPR from "general interest" in the DGA, as they may overlap but also differ in concepts and objectives. Clear differentiation is needed to avoid confusion and ensure data subjects are informed about how their data is used.

The need for a new consent form under the DGA, given the GDPR's existing practices, raises concerns about overlap. With limited practical experience with the DGA's consent form, its implementation and effectiveness remain uncertain. Balancing clarity with practical challenges is crucial. Exploring solutions like dynamic consent—offering personalized engagement for clinical and research purposes—could address these concerns.[21] The dynamic consent form allows participants to give and revoke consent over time based on their changing circumstances and preferences, making choices adaptable and flexible.[22] The technology-based consent platform offers flexibility beyond paper forms, allowing participants to consent to different sample and data uses, case-based approvals, and specific research contexts.[23] Dynamic informed consent boosts participant engagement by letting individuals express their preferences and stay informed through clear consent updates and simplified findings summaries.[24] In the context of data altruism, this approach enhances transparency, ensuring individuals understand data use. It allows flexible consent modifications and separate approvals, and provides information on research outcomes, fostering trust and encouraging future data sharing.

It also should be noted that data altruism under the DGA may conflict with GDPR principles like purpose limitation and data minimization by potentially leading

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18 Regulation (EU) 2022/868, *supra nota* 5, Article 2 (16).

19 Garske, B., Holz, W., & Ekardt, F. (2024). Digital twins in sustainable transition: exploring the role of EU data governance. *Frontiers in Research Metrics and Analytics, 9*. https://doi.org/10.3389/frma.2024.1303024.

20 Regulation (EU) 2022/868, *supra nota* 5, Recital 45.

21 Kaye, J., Whitley, E. A., Lund, D. J., Morrison, M., Teare, H., & Melham, K. (2014, May 7). *Dynamic consent: a patient interface for twenty-first century research networks*. https://doi.org/10.1038/ejhg.2014.71.

22 *Ibid.*

23 Kaye, Whitley, Lund, Morrison, Teare, & Melham, K. (2014, May 7), *supra nota* 21, p. 142.

24 De Sutter, E., Barbier, L., Borry, P., Geerts, D., Ioannidis, J. P. A., & Huys, I. (2024, January 1). P*ersonalized and longitudinal electronic informed consent in clinical trials: How to move the needle?* https://doi.org/10.1177/20552076231222361.

to excessive data collection. Understanding the relationship between these concepts is vital to ensure compliance with regulations and prevent unintended overlap or confusion in their implementation.

DATA ALTRUISM CONCEPT

The DGA governs activities such as facilitating data sharing, providing data intermediation services, promoting data altruism, and safeguarding data protection and commercial confidentiality, extending beyond the GDPR's conventional data protection scope.[25] Aligned with Recital 35 of the DGA, data voluntarily shared with informed consent can advance social goals like improving healthcare, addressing climate change, enhancing transportation, refining statistics, bettering public services, and supporting evidence-based policies and technological development,[26] while also encouraging technological development. Additionally, supporting scientific research is highlighted as another important aspect. The legislative aim is to encourage the development of large data pools sourced from altruistic contributions, which can then be used for robust data analysis and machine learning across Europe.[27]

Acknowledging criticisms is also important. Relying solely on altruism might not motivate enough participation, potentially limiting data pools. Some may be unwilling to share data, especially if disclosure is seen as stigmatizing or harmful. Additionally, concerns about data management and security are widespread, with worries about inappropriate access or leakage.[28]

In general, altruistic data sharing is important not only for data governance but also for advancing data analytics and machine learning through large datasets.[29] This implies that selfless data contributions impact data management and significantly enhance analytical and learning systems that rely on large datasets.[30] Different actors may see the significance and risks of data collection, sharing, and reuse differently due to their roles, context, or perceptions. Thus, the value and risk of data are subjective and depend on individual viewpoints[31]. But the issue is that the DGA lacks clear guidelines on donating to data altruism organizations or specifying data use, causing hesitation among creators, providers, and users due to uncertainties about risks and costs. Regulatory gaps and unclear GDPR application for public interest data sharing add to legal and compliance expenses, deterring potential data providers.[32]

According to the DGA, to facilitate the gathering of data through the principle of data altruism, the Commission must create implementing acts that introduce and refine a standardized European data altruism consent form. This consent form will

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[25] Pathak, M. (2024). Data Governance Redefined: The Evolution of EU Data Regulations from the GDPR to the DMA, DSA, DGA, Data Act and AI Act. *Social Science Research Network*. https://doi.org/10.2139/ssrn.4718891.

[26] Regulation (EU) 2022/868, *supra nota 5,* Recital 45.

[27] *Ibid.*

[28] Skovgaard, L. L., Wadmann, S., & Hoeyer, K. (2019). 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*(6), 564–571. https://doi.org/10.1016/j.healthpol.2019.03.012.

[29] Ferrè, G. R. (2023, April 26). *Data donation and data altruism to face algorithmic bias for an inclusive digital healthcare*. https://doi.org/10.15168/2284-4503-2624

[30] *Ibid.*

[31] Grafenstein, M. (2022). Reconciling Conflicting Interests in Data through Data Governance. An Analytical Framework (and a Brief Discussion of the Data Governance Act Draft, the Data Act Draft, the AI Regulation Draft, as well as the GDPR). *SSRN Electronic Journal*. https://doi.org/10.2139/ssrn.4104502.

[32] Finck, M., & Mueller, M.-S. (2023). Access to Data for Environmental Purposes: Setting the Scene and Evaluating Recent Changes in EU Data Law. *Journal of Environmental Law*, 35(1), 109–131. https://doi.org/10.1093/jel/eqad006.

adopt a modular structure, enabling customized adaptations to suit various sectors and objectives.[33] Furthermore, when personal data is involved, the European data altruism consent form will guarantee that individuals can provide and revoke consent for a particular data processing activity. This process must adhere to the stipulations outlined in GDPR.[34]

The DGA does not specify if its consent mechanism is an additional requirement for data exchange or an alternative model for general interest activities. This contrasts with GDPR, where consent is a clear, informed, and unambiguous expression of the data subject's wishes, given through a statement or affirmative action.[35] This discrepancy underscores the need for further clarification and alignment between the DGA's provisions and the established principles of consent outlined in the GDPR.[36]

Concerning anonymized statistics, GDPR is seen as advantageous because it promotes and defines the sharing of anonymized data. While GDPR imposes strict regulations on sharing identifiable data, it does not impede the sharing of anonymized data.[37] On the contrary, while the DGA encompasses various types of data, including personal and non-personal data, there exists potential ambiguity regarding the classification of non-personal data.[38] The DGA lacks detailed definitions regarding non-personal data, which may lead to uncertainty regarding its interpretation and application. According to Article 2 of the DGA, non-personal data is defined as data that does not qualify as personal data under the GDPR. To ensure alignment with the GDPR and establish robust safeguards and measures for anonymization of data, it is imperative to have comprehensive definitions in place within the DGA.

The purpose limitation principle is one of the fundamental principles outlined in the GDPR, but specifying the purpose alone does not determine the risk involved. Even if the controller misstates the purpose, the actual risk can be assessed based on factors like data nature and processing context. Nonetheless, the controller's stated purpose is a key indicator of the potential harm to individuals' fundamental rights.[39] This emphasizes the significance of clearly defining the purpose of data processing, even in the presence of stringent consent regulations. Ensuring that data subjects understand how their data is utilized and preventing any misuse of their information is paramount. This is particularly crucial in the context of data altruism, where trust is fundamental as data is shared voluntarily. Those contributing their data must have confidence that it will be handled accurately, highlighting the utmost importance of transparency.

Furthermore, adhering to the principle of data minimization is essential, considering the challenges associated with managing large volumes of data. In research contexts, where data is utilized for public good and general interest, it must be directly relevant to the intended purpose. Data employed in research should not merely be readily available but should specifically serve the precise objectives to advance public welfare.

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[33] Regulation (EU) 2022/868, *supra nota* 5, Article 25 (1).
[34] Regulation (EU) 2022/868, *supra nota* 5, Article 25 (3).
[35] 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) *OJ L 119*, 4.5.2016, p. 1–88.
[36] Vardanyan, L., & Kocharyan, H. (2022). The GDPR and the DGA proposal: Are they in controversial relationship? *European Studies, 9*(1), 91–109. https://doi.org/10.2478/eustu-2022-0004..
[37] Vukovic, J., Ivankovic, D., Habl, C., & Dimnjakovic, J. (2022). Enablers and barriers to the secondary use of health data in Europe: general data protection regulation perspective. *Archives of Public Health, 80*(1). https://doi.org/10.1186/s13690-022-00866-7.
[38] Skovgaard, Wadmann, & Hoeyer (2019), *supra nota* 28.
[39] Von Grafenstein, M. (2021). Refining the Concept of the Right to Data Protection in Article 8 ECFR – Part II. *European Data Protection Law Review, 7*(2), 190–205. https://doi.org/10.21552/edpl/2021/2/8.

Article 5 of the GDPR outlines key obligations for data controllers, emphasizing that personal data must be processed lawfully, fairly, and transparently. It must also be collected for specific, explicit, and legitimate purposes, reflecting the principle of purpose limitation. Furthermore, only data that is adequate, relevant, and necessary for those purposes should be collected, in line with the principle of data minimization.[40] Although defining research objectives and ensuring that data use serves public or general interests can be complex, there is always a risk of overstepping these boundaries. This raises concerns, especially regarding the safeguarding of data subjects' rights, as their personal information is at stake. Ambiguities in regulatory frameworks may lead to uncertainty or even misuse of data.

To address these risks, regulatory approaches must prioritize the protection of data subjects, ensuring transparency and legal certainty. One practical measure would be the introduction of data protection impact assessments specifically tailored to data altruism initiatives. These assessments could help identify potential risks and ensure alignment with existing data protection standards. Notably, while the Data Governance Act references data protection impact assessments in its recitals, it lacks concrete provisions on the matter in its operative text. Considering the wide range of purposes for which personal data may be used under data altruism frameworks, incorporating explicit data protection impact assessment requirements within the DGA would be a significant step toward enhancing accountability and safeguarding individual rights.

When discussing purpose limitation, it is essential to address the ambiguity surrounding the concept of purpose, particularly concerning public interest in GDPR and general interest in the DGA. While the main purpose of processing in these cases revolves around these interests, there is a lack of clarity regarding whether the terms are synonymous or their differences. For example, the introduction of the concept of processing for purposes of general interest in the DGA suggests that it may permit, under certain circumstances, the processing of personal data for research purposes that are not strictly defined but serve the general interest.[41] By contrast, GDPR Recital 159 offers a more detailed explanation of scientific research purposes, encompassing technological development, fundamental research, and studies that serve public health. Given the close alignment between the GDPR and the DGA, it is reasonable to apply the GDPR's interpretation of scientific research purposes to the DGA. Ensuring consistency between the two regulations is essential for coherent EU legislation and the smooth conduct of cross-border research. Similarly, the notion of general interest should be interpreted broadly, in line with the objectives of the DGA and the illustrative examples in Recital 35.[42]

It is essential to include definitions within the regulations that clarify the concept of general interest and outline the specific areas that fall under this concept. Furthermore, considering the distinction between general interest and public interest, legislation should encompass the term "public interest" alongside "general interest." However, due to the broad nature of these definitions, it is advisable to establish limitations to ensure they are applied appropriately. These limitations would define the boundaries

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[40] Regulation (EU) 2016/679, Article 5.

[41] Gefenas, E., Lekstutiene, J., Lukaseviciene, V., Hartlev, M., Mourby, M., & Cathaoir, K. Ó. (2021). Controversies between regulations of research ethics and protection of personal data: informed consent at a crossroad. *Medicine, Health Care and Philosophy*. https://doi.org/10.1007/s11019-021-10060-1.

[42] Kruesz, C., & Zopf, F. (2021). European Union · 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. *European Data Protection Law Review, 7*(4), 569–579. https://doi.org/10.21552/edpl/2021/4/13

within which these interests can be utilized. Firstly, it helps to emphasize the exact purpose of data sharing, providing clarity and transparency for all stakeholders involved. Secondly, it empowers data subjects to make informed decisions about sharing their data and understanding the broad concepts under which their data may be utilized.

DATA ALTRUISM CONSENT

The ambiguity around data altruism poses challenges, particularly in aligning its consent model with the GDPR's stringent consent requirements. The added value of data altruism is questionable given the existing GDPR framework.[43] This framework sets specific conditions for valid consent, but its ambiguity creates confusion for data subjects and controllers. Without clear guidelines on data altruism and its regulatory alignment, data rights may be inadequately protected, and implementation of data altruism initiatives may be delayed. Clarifying data altruism is crucial for effective integration into the data protection framework.[44]

The DGA's definition of consent is complex. While it references GDPR Article 4, it introduces a specialized consent form for data altruism under Article 25, which allows modular approach, and for customization different sectors and purposes.[45] But ambiguity remains about distinguishing consent for personal versus non-personal data in data altruism. While the DGA references GDPR consent requirements, the need for a separate consent form is unclear. However, the DGA's modular approach, allowing tailored consent options, is ultimately a positive feature.[46]

The GDPR already sets strict rules for consent forms. The necessity of a new, specific consent form for data altruism under the DGA is debatable. While the DGA introduces a modular form with options for research and general interest, it is unclear if this is needed or if the existing GDPR consent form suffices. Introducing separate forms could complicate matters for organizations. Practical implementation and experimentation are needed to assess if the new form effectively supports data altruism. Clarifying consent requirements is essential for clear communication and trust between participants and organizations.[47]

ESTONIAN X-ROAD

Estonia's X-Road is a key e-government platform that ensures secure, seamless data exchange and communication across various organizations and administrative levels.[48] Developed by the Estonian government, X-Road ensures 24/7 database availability, reflecting the Republic of Estonia Information System Authority's commitment to seamless data accessibility and exchange.[49] Access to the X-Road empowers users to leverage the services and data of fellow members, thereby enhancing their own business processes.

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43 *Ibid.*
44 *Ibid.*
45 Regulation (EU) 2022/868, *supra nota* 5, Article 25.
46 Regulation (EU) 2022/868*, supra nota* 5, Recital 52.
47 Rivas Velarde, M. C., Lovis, C., Ienca, M., Samer, Caroline., & Hurst, S. (2024). Consent as a compositional act – a framework that provides clarity for the retention and use of data. *Philosophy, Ethics, and Humanities in Medicine, 19*(1). doi:10.1186/s13010-024-00152-0.
48 Paide, K., Pappel, I., Vainsalu, H., & Draheim, D. (2018). On the Systematic Exploitation of the Estonian Data Exchange Layer X-Road for Strengthening Public-Private Partnerships. *Proceedings of the 11th International Conference on Theory and Practice of Electronic Governance*. https://doi.org/10.1145/3209415.3209441.
49 Tropp, E. M., Hoffmann, T., & Chochia, A. (2022). Open Data: A Stepchild in e-Estonia's Data Management Strategy? *TalTech Journal of European Studies*, *12*(1), 123–144. https://doi.org/10.2478/bjes-2022-0006.

However, it is worth noting that private entities must obtain explicit prior consent to access personal data[50].

A key feature of the X-Road is the incorporation of the 'once-only principle' (OOP), mandated by Estonian law.[51] This principle dictates that individuals provide their personal data to the state just once, with subsequent data processing operations being handled exclusively by public authorities accessing this centralized repository.[52] This approach not only streamlines administrative processes but also enhances data privacy by minimizing unnecessary data exchanges. By centralizing personal data access, the 'once-only principle' reduces the risk of data breaches and fosters greater trust in the handling of sensitive information by government agencies.

The challenges of ensuring compliance with GDPR arise concerning the Estonian data protection framework, particularly regarding the X-Road and the 'once-only principle' (OOP). While these mechanisms may initially raise concerns about adherence to the GDPR's principle of purpose limitation,[53] Estonia's approach emphasizes transparency to address data subject interests. Despite potential issues with consent at the access level, robust transparency measures ensure comprehensive oversight at the processing level.[54] Through the state portals, individuals can access real-time, detailed information on who accessed their data, under what authorization, and for what specific purpose.[55] This transparency not only fosters accountability but also empowers data subjects with greater control over their personal information, thus aligning with Estonia's commitment to data protection and transparency in governance.

The success story of Estonian ICT began with the establishment of X-Road.[56] As evidenced by practice, Estonia remains a leader in e-governance and digitalization, highlighting its effective approach. Exploring the Estonian model for data altruism is valuable for insights on implementing it with a focus on individuals' trust. As data altruism is new and lacks established practices, comparing it with existing models is crucial to addressing this gap.

Despite Estonia's success with the 'once-only' principle and X-Road, the 'exactly once open' principle may not suit data altruism. The 'once-only' principle works within a single country's unified system, while data altruism's broad scope serves general interests. Achieving the 'once-only' principle in Estonia depends on its alignment with EU data protection law, especially GDPR's purpose limitation principle.[57] This principle mandates that personal data be collected and processed for specific purposes. However, challenges arise with data altruism, where purposes are broad and vague. Purpose limitation ensures transparency, predictability, and user control, enabling data subjects to exercise their rights, including the right to object.

Transparency examples from Estonia are instructive. In the case of Estonia, transparency regarding data usage plays a crucial role in fostering trust. When individuals have insight into how their data is accessed and processed, they are more likely to trust the system. In Estonia, the state portal allows individuals to request real-time

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50 *Ibid.*
51 *Ibid.*
52 *Ibid.*
53 *Ibid.*
54 Hoffmann, T. (2020). The Impact of Digital Autonomous Tools on Private Autonomy. *Baltic Yearbook of International Law Online*, 18, 18–31., Available at SSRN: https://ssrn.com/abstract=3771306.
55 Tropp, Hoffmann, & Chochia (2022), *supra nota*, 47.
56 Kerikmäe, T., Pärn-Lee, E. Legal dilemmas of Estonian artificial intelligence strategy: in between of e-society and global race. *AI & Soc 36*, 561–572 (2021). https://doi.org/10.1007/s00146-020-01009-8.
57 Mikiver, M., & Tupay, P. K. (2023). *Has the GDPR killed e-government? The "once-only" principle vs the principle of purpose limitation*. https://doi.org/10.1093/idpl/ipad010.

information about who accessed their data, when, and for what purpose, creating transparency and accountability. This level of transparency is essential for building trust, as individuals can see exactly how their data is being used.[58] Aligning with this example, the Data Governance Act should prioritize transparency, providing detailed information for data subjects about how their data is utilized. It would be beneficial for data altruism organizations to have a portal where individuals can access information about how, when, and by whom their data is used, especially for research or clinical trials. This portal should establish a dynamic system capable of adapting over time,[59] consistently reinforcing trust through its responsiveness to evolving needs and circumstances.

CONCLUSION

The European Commission's Data Governance Act, designed to foster data sharing by establishing a trustworthy digital ecosystem among diverse stakeholders,[60] represents a significant advancement toward aligning with the European data strategy. The primary contribution of this research is to propose ideas on how data altruism within the Data Governance Act should function effectively. The main findings consist of several key aspects. The research identifies challenges related to definitions and highlights issues with consent mechanisms. Additionally, the study examines data-sharing practices among various authorities and suggests strategies for improvement. Given that the legislation is relatively new, the research draws upon existing experiences, such as those from the Estonian X-Road, to enhance trust and ensure the successful implementation of data altruism initiatives.

When it comes to defining terms, it is essential to recognize that various legislations, such as the Data Governance Act, Data Act, and GDPR, offer differing definitions for data. Therefore, it becomes crucial to comprehend which definition applies in a given context. In light of this, it's advisable to incorporate the definition of data into consent agreements to ensure alignment with the scope of the Data Governance Act.

Another significant aspect of the definition challenge involves clarifying the concept of "general interest." The definition should clearly distinguish between the general interest in the Data Governance Act and the concept of public interest within the GDPR framework to prevent confusion. Notably, the term "general interest" is not explicitly defined in the text of the regulation but can only be inferred from the recitals. Due to the broad nature of the definition and the potential for it to encompass every aspect, it may be challenging to ensure regulatory compliance and maintain a clear purpose for data processing. To ensure clarity and guidance for all parties involved, it is recommended to establish limitations within the definition, as discussed above. This involves structuring the definition to explicitly outline what is not included in the general interest definition. These exclusions should encompass personal preferences or individual desires unrelated to broader societal welfare, private commercial interests not aligned with public welfare objectives, discriminatory policies favoring specific groups, actions undermining data privacy or violating individuals' rights to data protection, decisions prioritizing short-term gains for certain stakeholders, initiatives compromising data security or

[58] Tropp, Hoffmann, & Chochia (2022), *supra nota, 47.*

[59] Jain, S., Spelliscy, C., Vance-Law, S., & Moore, S. (2023). AI and Democracy's Digital Identity Crisis. *SSRN Electronic Journal*. https://doi.org/10.2139/ssrn.4593685.

[60] Laamech, N., Munier, M., & Pham, C. (2022). IdSM-O. *Proceedings of the 14th International Conference on Management of Digital EcoSystems*. https://doi.org/10.1145/3508397.3564825.

contributing to cyber threats and vulnerabilities, and any activities conflicting with established legal and ethical standards regarding data usage and management.

Informational exchange between data altruism organizations and data protection authorities can greatly benefit the practical implementation of the data altruism concept. This exchange fosters better compliance and understanding, particularly considering the GDPR exemptions regarding data reuse for research purposes.[61]

Another significant challenge lies in the landscape of data altruism consent. While the Data Governance Act offers a modular approach to consent, which is highly beneficial, the primary issue remains ensuring that the entire system encourages data subjects to share their data voluntarily, as data altruism revolves around voluntary data sharing. Legislation must prioritize building trust, which necessitates providing detailed information. In the context of data altruism, it is crucial to develop consent mechanisms in a way that aligns with the modular approach while also being dynamic. This means that dynamic consent forms should be adaptable and capable of evolving over time. Data subjects should have the flexibility to give or revoke consent at any time, reflecting changes in circumstances or preferences. For instance, they may initially withhold consent but later decide to provide it based on evolving factors. Dynamic consent is particularly crucial in scenarios where research purposes may change, empowering data subjects to adjust their consent accordingly.

The practices and lessons from Estonia when addressing data altruism are instructive. Reflecting this example, the Data Governance Act should prioritize transparency, ensuring that data subjects receive detailed insights into how their data is utilized. To achieve this, establishing a portal within data altruism organizations would be advantageous, enabling individuals to access comprehensive information regarding the utilization of their data, especially in research or clinical trial settings. This portal should operate dynamically, adapting over time to maintain transparency throughout the data processing journey.

As the legislation is still in its early stages of development, there is no established practice yet. Although new legislations have been adopted within the European data strategy, it remains questionable how all these regulations will harmonize and function together. The registration of data altruism organizations is ongoing and given that the adoption of the DGA and its essential parts such as data altruism is optional for countries, there is uncertainty about how it will operate, with practices potentially varying widely. Despite these uncertainties, the approaches and findings of this research set a foundation for the practical implementation of data altruism. However, as the concept is put into practice, new challenges may emerge, necessitating further research to address them effectively.

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