

Lawfulness in secondary use of health data

Interplay between three regulatory frameworks of GDPR, DGA & EHDS

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In the recent years the importance of secondary uses of health data for clinical, research and policy making purposes has been further stressed in view of the availability of health-related data collected in traditional and non-traditional settings. However, processing health data - which are sensitive type of personal data - requires adopting adequate legal and ethical protections, to ensure that rights of the data subjects have been respected, while also facilitating responsible access to data. In this paper we aim to shed light on the interplay between the existing and emerging relevant European regulatory frameworks related to data processing, including the General Data Protection Regulation (GDPR), the upcoming Data Governance Act and the legislative proposal for European Health Data Space. In doing that, we will focus mainly on the legal bases for secondary uses of data in view of the overarching principles of data protection.

1. Introduction

Developments in information technologies have paved the way for innovative approaches for collecting and sharing of health-related data in traditional research settings. In addition, vast amounts of health-related data have been collected via wearable technologies, mHealth applications and online platforms, leading to so-called crowdsourcing data for various purposes.¹ Consequently, enhancing accessibility of the databases for clinical, research and policy making purposes has been pursued by research institutions, funding agencies and policy makers such as the European Commission and national funding agencies such as the US National Institutes of Health and Wellcome Trust in the UK. A need for access to health data has been further stressed during the COVID-19 pandemic both for public health and research purposes.

Processing health data, however, requires adopting higher protections provided by various regulatory frameworks, including those on personal data protection. One of the important aspects related to processing health data is ensuring that such processing is in line with the overarching principles of European data protection,

including lawfulness, fairness, and transparency, as stipulated under the EU General Data Protection Regulation (GDPR)². In addition to the existing regulatory frameworks, recently, the European Commission has embarked on developing two new regulatory frameworks with direct implications for primary and secondary uses of health data for research purposes, namely the Data Governance Act and the legislative proposal for European Health Data Space. While the Data Governance Act³ has been published in May 2022 and is set to come to force in 2023, only the first draft of the legislative proposal for EHDS⁴ (hereafter EHDS for the sake of brevity) has been published in May 2022.

The Data Governance Act (DGA), as a horizontal regulatory framework, aims to promote the availability of both personal and non-personal data held by public sector and build a trustworthy environment to facilitate its use for research and the creation of innovative new services and products. The DGA introduces new actors such as data intermediation services and data altruism organisations to assist

1 Kerri Wazny, 'Applications of crowdsourcing in health: an overview' (2018) 8(1) *Journal of Global Health* <https://doi.org/10.7189/jogh.08.010502> accessed 28 May 2022, p.1,2.

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2 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 2016 L 119/1.

3 Regulation (EU) 2022/868 of the European Parliament and of the Council of 30 May 2022 on European data governance and amending Regulation (EU) 2018/1724 (Data Governance Act), OJ L 152.

4 Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space, 3 May 2022, COM(2022)197 final Commission Proposal.

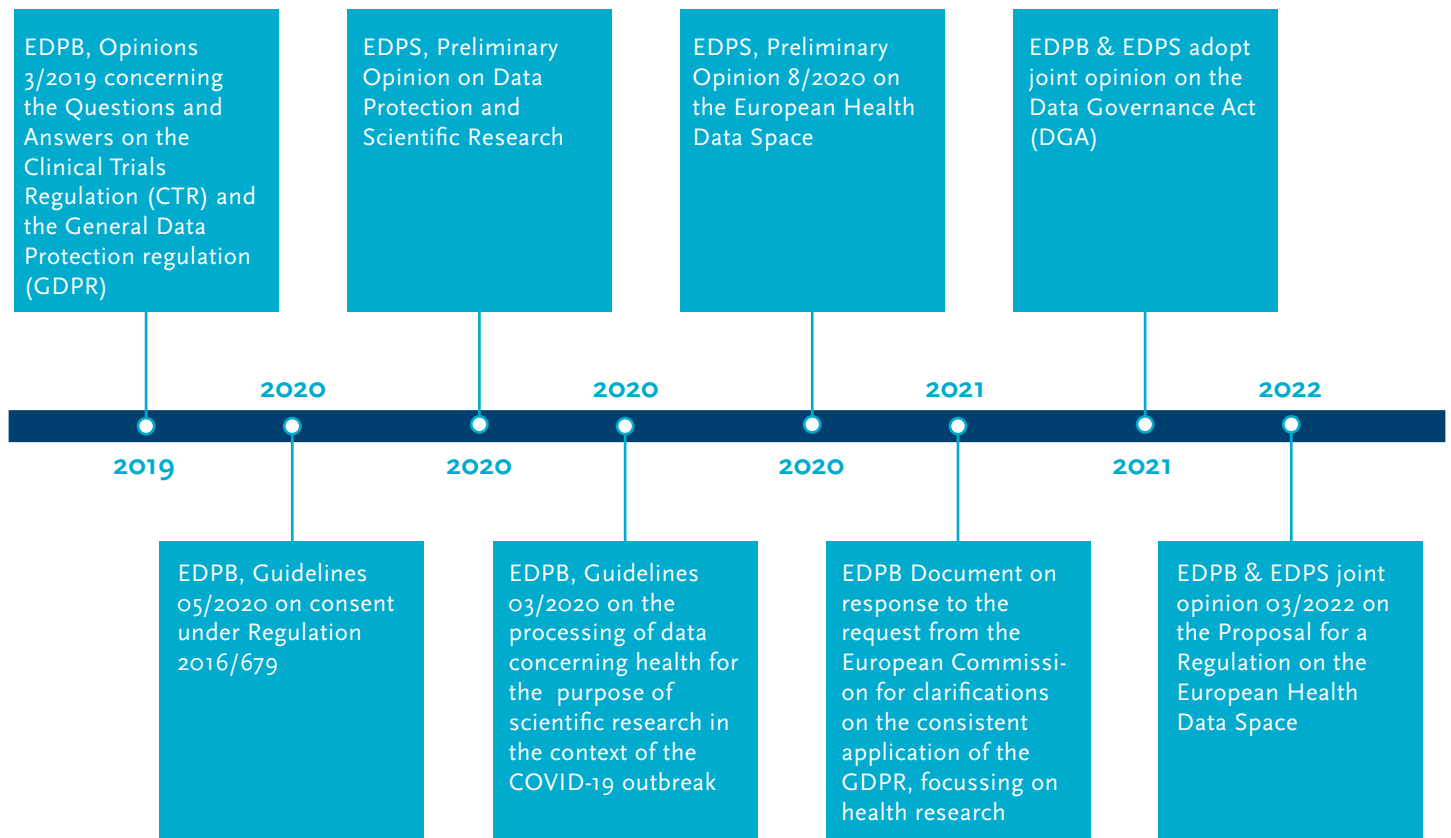


Figure 1. List of the published opinions and guidelines on the data protection rules relevant to scientific research by the European Data Protection Board & European Data Protection Supervisor (2019-2022)

in responsible organisation of data sharing. Also, the DGA foresees provisions to facilitate sharing data of businesses and individuals.

In contrast, the regulatory proposal for EHDS is health-sector specific, aiming to establish a legal, governance, data quality and operability framework for a common European Health Data Space in order to facilitate access to and sharing of health data to improve healthcare provision, health research, and policymaking.⁵ EHDS aims to regulate both primary and secondary uses of health data. The regulator states that EHDS builds upon relevant regulations such as the GDPR and DGA and aims to support the implementations of the data subjects' rights such as right to data access and data portability in the context of electronic health data.

While the GDPR, EHDS and DGA cover various aspects of data processing, in this paper we will focus on some key aspects related to secondary uses of health data for research purposes and the potential challenges in implementing the relevant provisions. In particular, we aim to discuss how the specific rules and legal grounds recognised under the DGA, for data sharing, and under the EHDS for secondary uses of health data, interplay with the existing rules under the GDPR applicable to processing of personal data for scientific research purposes. In doing that, we will first show the main legal bases recognised under the GDPR for processing data for research purposes, including consent and public interest. Then, we will discuss the newly proposed concept of data altruism consent for data sharing, and how this can interplay with consent as defined in the GDPR. At last, we will

review some of the main elements included in the legislative proposal for EHDS in the context of secondary uses of data. We will also refer to the additional guidelines and opinions published by the European data protection authorities, namely European Data Protection Board (EDPB) and European Data Protection Supervisor (EDPS) on various aspects of these existing and emerging regulatory frameworks. (see Figure 1)

2. GDPR and Legal Bases for Secondary Uses of Health Data for Scientific Research Purposes

Under the GDPR, various legal bases are foreseen for processing personal data for scientific research purposes. First, consent has been considered as one of the legal bases for processing personal data under articles 6(1)(a) and 9(2)(a) of the GDPR. Article 4(11) of the GDPR defines consent as a “freely given, specific, informed and unambiguous indication” of the data subjects' agreement on processing activities. Consent as a legal basis for data processing is considered to be advantageous, as it can bring more transparency on the intended data processing and allow data subjects to exercise a level of control on their personal data. However, previous investigations have shown that consent mechanism may not be always able to meaningfully and effectively involve data subjects in the governance of data sharing.⁶ This is partly due to the existing asymmetry of information between the individuals and the data controllers (researchers, institutions, etc.) who collect and process data.⁷ Especially, the complexity

5 Mahsa Shabani, 'Will the European Health Data Space change data sharing rules?' (2022) 375(6587) *Science* <https://doi.org/10.1126/science.abn4874> accessed 28 May 2022, pp. 1357–1359.

6 Sonja Erikainen, Phoebe Friesen, et al., 'Public involvement in the governance of population-level biomedical research: unresolved questions and future directions' (2021) 47 *Journal of Medical Ethics* <https://doi.org/10.1136/medethics-2020-106530> accessed 28 May 2022, pp. 522–525, p. 523.

7 Jiahong Chen, Edward S. Dove, and Himani Bhakuni, 'Explicit consent and alternative data protection processing grounds for health research' in

of health research projects with regard to their purposes, regulations, and governance make it difficult for individuals to make an informed decision about the processing of their personal data.⁸ Moreover, in most cases, individuals cannot exercise any negotiating power when it comes to agreeing to the terms and conditions of the use and re-use of data or signing a consent form, and face a take-it-or-leave-it option in reality.⁹

Additionally, obtaining a specific consent for scientific research which aim to share data for various purposes can be challenging. This is closely related to the principle of purpose limitation, which prohibits further processing of data in a manner that is incompatible with purposes specified at the time of data collection. Although in principle Recital 50 and Article 5(1)(b) of the GDPR foresee that processing data for scientific research may not be considered incompatible with the initial data collection purposes, conducting compatibility test under Article 6(4) may seem to be still necessary, depending on the context of data collection and sensitivity of data. In addition, further processing of data by the third parties for research purposes may still require a separate legal basis.

In view of the identified shortcomings of the specific consent, different forms of consent have also been envisaged in the literature. Among them, the broad consent model allows individuals to give consent to unspecified future research projects¹⁰, while other mechanisms such as review by ethics committees can ensure that downstream uses are in line with relevant ethical principles. However, compatibility of the broad consent model with the requirement of valid consent under the GDPR is still an open question.

According to the Recital 33 of the GDPR, it seems that broad consent has been permitted as “It is often not possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection. Therefore, data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research”.¹¹ However, it is practically impossible to meet the standards of specific consent as enshrined in Article 4(11) of the GDPR when consent is based on various and yet unknown purposes.¹² Besides, the EDPB is also of the opinion that “Recital 33 does not disapply the obligations with regard to the requirement of specific consent” which requires ‘purpose specification as a safeguard against function creep’, ‘granularity in consent requests’, and ‘clear separation of information related to obtaining consent for data processing activities from information about other matters’.¹³ Currently we are awaiting the further guidance from the European data protection authorities in processing health data for research

purposes, which will likely address some of the current unclarity regarding acceptability of broad consent.¹⁴

In addition, processing of personal data for scientific research purposes can fall on the grounds of so-called research exemption, which is based on public interest (Article 6(1)(e)) in conjunction with Article 9(2)(j) of the GDPR, which allows processing of sensitive personal data, including health data for scientific research purposes, in accordance with the requirements set in Article 89. Article 89 plays an important role in regulating processing of personal data for research purposes, because on one hand it allows certain derogations from data subjects’ rights such as right to object to certain processing, based on national laws. On the other hand, it requires adopting organizational and technical safeguards in protecting the rights of the data subjects.^{15,16}

Although the research exemption provisions of the GDPR could be considered to ease the strict regulatory framework for processing health data, in practice many have alluded to the limitations of such rules in making a real impact. This is partly due to fragmentations in the national laws, where the rules regarding research exemptions implemented differently, as shown by the Commission’s study on the “Assessment of the EU Member States’ rules on health data in light of the GDPR”¹⁷. These limitations have been further stressed during the COVID-19 pandemic, when sharing health data for public health research purposes appeared to be challenging due to the identified fragmentations.¹⁸

3. Data Altruism and the DGA

The concept of data altruism has been codified for the first time in the DGA, where it is defined as “voluntary sharing of data based on consent by data subjects to process personal data pertaining to them (...) without seeking or receiving a reward (...) for purposes of general interest, defined in accordance with national law where applicable, such as healthcare (...) or scientific research purposes in the general interest”. One of the main aims of introducing this concept in the DGA is to increase trust in personal and non-personal data sharing for the common good at large scale, including for scientific research.¹⁹

Eleni Kosta, Ronald Leenes, and Irene Kamara (eds), *Research Handbook on EU Data Protection Law* (Elgar 2022), pp. 474-502, p. 479.

8 TEHDAS, ‘Citizens’ perception of and engagement with health data secondary use and sharing in Europe – a literature review’ (2021) Milestone M8.1 <https://tehdas.eu/results/individuals-favour-data-sharing-and-use-if-benefits-are-clear/> accessed 28 May 2022, p. 14.

9 Mahsa Shabani, ‘The Data Governance Act and the EU’s move towards facilitating data sharing’ (2021) 17(3) *Molecular Systems Biology* <https://doi.org/10.15252/msb.202110229> accessed 4 April 2022, p. 2.

10 TEHDAS Milestone M8.1 (n 8) p. 18.

11 See Recital 33 of the GDPR.

12 Shabani (n 5) p. 1358.

13 European Data Protection Board (EDBP), ‘Guidelines 05/2020 on consent under Regulation 2016/679’ (2020) Version 1.1 adopted on 4 May 2020 https://edpb.europa.eu/sites/default/files/files/file1/edpb_guidelines_202005_consent_en.pdf accessed 28 May 2022, para 55, 156.

14 European Data Protection Board (EDBP), ‘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) https://edpb.europa.eu/sites/default/files/files/file1/edpb_replyec_questionnaire_research_final.pdf accessed 29 October 2022, para 31.

15 Mahsa Shabani and Pascal Borry, ‘Rules for processing genetic data for research purposes in view of the new EU General Data Protection Regulation’ (2018) 26(2) *European Journal of Human Genetics* <https://doi.org/10.1038/s41431-017-0045-7> accessed 9 October 2022, pp. 149-156, p. 154.

16 Ciara Staunton, Santa Slokenberga, and Deborah Mascalzoni, ‘The GDPR and the research exemption: considerations on the necessary safeguards for research biobanks’ (2019) 27 *European Journal of Human Genetics* <https://doi.org/10.1038/s41431-019-0386-5> accessed 9 October 2022, pp. 1159-1167, p. 1159.

17 European Commission, Consumers, Health, Agriculture and Food Executive Agency, Johan Hansen, Petra Wilson, Eline Verhoeven, et al., ‘Assessment of the EU Member States’ rules on health data in the light of GDPR’ (2021) Publications Office <https://data.europa.eu/doi/10.2818/546193> accessed 9 October 2022, p.58.

18 Regina Becker, Adrian Thorogood, Johan Ordish, and Michael Beauvais, ‘Covid-19 Research: Navigating the European General Data Protection Regulation’ (2020) 22 (8) *Journal of Medical Internet Research* <https://www.jmir.org/2020/8/e19799> accessed 29 October 2022.

19 Corina Kruesz and Felix Zopf, ‘The Concept of Data Altruism of the draft DGA and the GDPR: Inconsistencies and Why a Regulatory Sandbox Model May Facilitate Data Sharing in the EU’ (2021) 7(4) *European Data*

Certain elements of the concept of data altruism in the DGA require further clarification. Especially, the interplay between the rules and principles of data processing in the GDPR and voluntary sharing of personal data in the context of data altruism is not well-defined in the text of the DGA. Although the DGA is without prejudice to the GDPR and the latter prevails in the event of a conflict²⁰, ambiguities related to the notions of general interest, scientific research and consent need to be clarified further.

The Commission's study on "Assessment of the EU Member States' rules on health data in the light of GDPR" which has been published prior to publication of DGA, has made a reference to two national projects from Germany and Denmark, as examples using (or aiming to use) the data altruism approach. In the case of Denmark, Sundhed.dk is an independent agency governed by the Government and the Regions, and by using its platform, patients and health professionals can have access to electronic health records (EHRs). As it stands now, Sundhed.dk is mainly a display channel for individuals where they can find general information about their health. However, Sundhed.dk's strategy for 2019-2022 also includes transforming the platform in a way that supports active participation from individuals by allowing them to upload, register and store personal health data generated via smartphones or wearable technologies which can later be available for scientific research.²¹ In the case of Germany, insured persons will have the opportunity to voluntarily make their data stored in the electronic patient record (elektronische Patientenakte) available for research as of 2023 under the Patient Data Protection Act (Patientendaten-Schutz-Gesetz) dated 2020.²² Although these examples could be considered implementations of data altruism, their compatibility with the data altruism concept, as it has been introduced under the DGA should be investigated. Notably, these use cases are currently evolving, partly in response to the upcoming regulatory frameworks, including EHDS, and the visions for secondary uses of electronic health data, as will be explained later.

3.1 General Interest v. Public Interest

According to the DGA, altruistic data sharing should serve the purposes of general interest. Some examples are enumerated in the text of the DGA in a non-exhaustive manner. In their joint opinion on the proposal of the DGA, the EDBP and the EDPS urged that the Commission should better define the purposes of general interest.²³ In response, the final text of the DGA provides further specifications comparing to the previous version which had basically left the definition to the Member States by saying that the term is to be "defined in accordance with national law where applicable". The final version of the DGA further adds that such objectives of general interest should follow the provisions of national laws and provides a number of non-exhaustive examples such as for public policy making and scientific research purposes in the general interest. Although this wording

provides further information on how public interest should be defined in general, still the reference to "scientific research in the general interest" seems to go around in circles, raising the question of how to demark that general interest.

Similarly, the GDPR has already offered a margin of manoeuvre to the Member States to define the objectives of 'public interest', as one of the legal bases of processing data, in their national laws. It should also be noted that the DGA uses the term 'general' instead of 'public', and it does not explain the relationship between these two terms. This can lead to some confusions in implementations of the regulations.

3.2 Scientific Research, General Interest, and Private vs. Publicly Funded Research

One of the purposes of general interest provided in the DGA is scientific research. The DGA does not define what scientific research purposes in the general interest entail. While the previous version of the proposal provided examples of research falling under general interest "...including for example technological development and demonstration, fundamental research, applied research and privately funded research...", (Recital 35), the final text did not include those examples.

Nevertheless, the GDPR, in Recital 159, sheds some light on the definition of scientific research with a passing reference to inclusion of studies in public interest in the area of public health. The Recital reads: "the processing of personal data for scientific research purposes should be interpreted in a broad manner including for example technological development and demonstration, fundamental research, applied research and privately funded research. (...) Scientific research purposes should also include studies conducted in the public interest in the area of public health". Inclusion of privately funded research in the definition provided by the GDPR is particularly important because there has been an on-going discussion in the literature about whether the type of funding should impact the inclusion of the scientific research under the public interest. In particular, questions remain, regarding the driving force behind the scientific research, as to whether it is profit-oriented or conducted for the common good, and how to determine the predominant factor.²⁴

3.3 Data Altruism Consent

Data altruism applies to voluntary sharing of data based on consent by data subjects. Recital 50 of the DGA considers that data altruism consent can be based on consent as a legal basis prescribed in the GDPR by stating that "Typically, data altruism would rely on consent of data subjects in the sense of Article 6(1)(a) and 9(2)(a) of Regulation (EU) 2016/679 that should be in compliance with requirements for lawful consent in accordance with Articles 7 and 8 of that Regulation". However, such an assumption carries the risk of bringing or extending the uncertainties related to the GDPR consent to the DGA and its data altruism consent model.²⁵

A key question here is: what will be the intended added value of the data altruism consent? It seems that with the European data altruism consent, the legislator can promote trust, and bring additional legal certainty for individuals to give their consent to altruistic data sharing

Protection Law Review <https://doi.org/10.21552/edpl/2021/4/13> accessed 4 April 2021, pp. 569 - 579, p. 570.

²⁰ See Article 1(3) of the DGA.

²¹ See <https://www.sundhed.dk/borger/service/om-sundheddk/om-organisationen/hvem-er-sundheddk/sundheddks-strategi-2019-2022/>.

²² See <https://www.bundesgesundheitsministerium.de/patientendaten-schutz-gesetz.html>.

²³ European Data Protection Board and European Data Protection Supervisor, '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) Version 1.1 https://edpb.europa.eu/system/files/2021-03/edpb-edps_joint_opinion_dga_en.pdf accessed 15 May 2022, para 172.

²⁴ Shabani (n 5) p. 1358.

²⁵ Julie Baloup, Emre Bayamlioglu, Alike Benmayor, and et al., 'White Paper on the Data Governance Act' (2021) CiTiP Working Paper Series <http://dx.doi.org/10.2139/ssrn.3872703> accessed 29 May 2022, p.38.

in the context of scientific research.²⁶ We can also stipulate that data altruism consent can contribute to additional transparency for data subjects that their data will be accessed and used in accordance with their consent and also in full compliance with the data protection rules.²⁷ Notably, consent may not always be used as a legal basis for data processing. For example, in the context of promoting data sharing for scientific research purposes, public interest can be used as a legal basis. This approach has been endorsed by the EDPS in his preliminary opinion on the European Health Data Space, considering public interest as a legal basis for processing data in research.²⁸ Depending on the requirements of national laws, using public interest as a legal basis could remove the need for obtaining informed and specific consent to process data for scientific research purposes.²⁹ In that sense, data altruism consent can complement using public interest as a legal basis for processing data in health research by bringing additional transparency and empowering individuals in the health data governance. This can also be considered as an additional safeguard to respect the fundamental rights of the data subjects.

Despite its benefits, using a combination of public interest as a legal basis for data processing, and data altruism consent as an additional safeguard to introduce more transparency, among others, may still leave some uncertainties, in particular regarding the rights of data subjects to withdraw their consent. In fact, the possibility of withdrawing of consent is mentioned several times in the DGA.³⁰ However, acknowledging that the data can be processed on the basis of public interest and data altruism consent can only complement this legal ground, may implicate that whenever an individual withdraws his or her consent, data controller (such as research organization) can continue to use data under one of the legal grounds provided in the GDPR. Such a possibility for the data controllers could jeopardize the ultimate aim of the data altruism consent model introduced by the DGA to promote trust and bring additional legal certainty.

4. EHDS and Secondary Uses of Health Data

The recently proposed regulatory framework for European Health Data Space aims to introduce more clarity in processing health data both for primary and secondary uses. In terms of the secondary uses, multiple purposes have been recognized under Article 34(1) of the EHDS, including for scientific research, policy making and personalized medicine purposes. Also, of interest for biomedical research in the context of Artificial Intelligence (AI) is recognition of processing data for testing, training and evaluation of algorithms in medical devices, AI systems and digital health applications. As such the focus is on the purposes of the use, rather than the entities that can use the data for secondary purposes. However, it should be noted that in Recital 41, and not in the operative part of the proposal, it has been specified that the secondary uses of data under general interest of the society are permitted for the public, private & non-profit entities among others, raising questions whether access by for-profit entities is allowed or not. In that sense, the proposal does not offer further clarity compared to the previous relevant provisions by the GDPR and the DGA.

This approach has also been criticised in the recent joint-opinion by the EDPB-EDPS, where they strongly recommend that “for the Proposal to further delineate these purposes and circumscribe when there is a sufficient connection with public health and/or social security, in order to achieve a balance adequately taking into account the objectives pursued by the Proposal and the protection of personal data of the data subjects affected by the processing.”³¹

In addition, in terms of the terminology, the EHDS uses both general interest and public interest in the recitals and the body of the proposal respectively. As we discussed above, this can be potentially confusing, raising questions regarding whether these concepts can be used interchangeably under the three regulatory frameworks, namely the GDPR, DGA and EHDS.

Notably, the EHDS takes a step further and lists the prohibited purposes for secondary uses of health data under the EHDS regime, including various harmful uses against the data subjects, marketing, or what can be considered against public order or morality (Article 35). This seems to be helpful in addressing the existing uncertainties regarding what cannot be considered a legitimate use for secondary uses of health data.

In terms of the sources of health data that can be subject to secondary uses, Article 33(1) provides a long list, including health data from EHR, genomic data, person generated electronic health data, clinical trials, cohorts, and biobanks, among others. This gives a higher level of granularity to what is included in the definition of health data, than it has been previously provided under the GDPR. The approach of the regulator in not re-defining “data concerning health” can also avoid confusions arising from various definitions provided by relevant regulatory frameworks.

Furthermore, the EHDS is introducing new entities which play a role in coordinating and managing data sharing, including health data access bodies which are in charge of controlling access to health data for secondary uses in collaboration with data holders, and issuing data permits. Health data access bodies will grant access to a wide range of health data together with data holders, for the purposes of public interest, scientific research, statistical & educational purposes, training of the algorithms, personalized medicine, etc. Health data access bodies and single data holders may charge fees for making electronic health data available for secondary use. The Commission will publish the templates of the data access applications. It remains to be seen whether data access bodies fully take over the responsibilities of existing data access committees, which are often organized locally. In addition, data access bodies can benefit from the existing experiences of the current data access committees, and address the existing shortcomings in streamlining data access oversight, based on objective, fair and transparent access rules.³² In addition, as it has

²⁶ See Recital 52 of the DGA.

²⁷ See Recital 52 of the DGA.

²⁸ European Data Protection Supervisor (EDPS), ‘Preliminary Opinion 8/2020 on the European Health Data Space’ (2020) https://edps.europa.eu/data-protection/our-work/publications/opinions/preliminary-opinion-82020-european-health-data-space_en accessed 29 May 2022, paras 15 and 16.

²⁹ Shabani (n 9) p. 2.

³⁰ See for instance Recital 46, 52, Article 21(3) and Article 22(1)(a-b) of the DGA.

³¹ European Data Protection Board (EDPB) and European Data Protection Supervisor (EDPS), ‘EDPB-EDPS Joint Opinion 03/2022 on the Proposal for a Regulation on the European Health Data Space’ (2022) https://edpb.europa.eu/our-work-tools/our-documents/edpb-edps-joint-opinion/edpb-edps-joint-opinion-032022-proposal_en accessed 29 October 2022, para 85.

³² Mahsa Shabani, Stephanie O. M. Dyke, Yann Joly, and Pascal Borry, ‘Controlled Access under Review: Improving the Governance of Genomic Data Access’ (2015) 13(12) *PLoS Biology* <https://doi.org/10.1371/journal.pbio.1002339> accessed 29 May 2022; Mahsa Shabani and Pascal Borry, ‘“You want the right amount of oversight”: interviews with data access committee members and experts on genomic data access’ (2016) 18

been noted by the joint-opinion of EDPB-EDPS, the inclusion of legal expertise in data access bodies should be guaranteed, considering their role in assessing the legal grounds for processing health data by the data users.³³ The interplay between the data access bodies and the existing Data Protection Authorities (DPA) is another element which seemed to be in need of further clarifications, as stated by the joint-opinion.

In addition, the EHDS introduces a one-stop-shop for the data users to submit their data access requests to one data access body, even if data is stored in multiples countries. In operating this system, establishing the HealthData@EU (for secondary uses of health data) by the Member States and the Commission will be essential to support and facilitate the cross-border access to electronic health data for secondary use, connecting the national contact points for secondary use of electronic health data. Adopting this approach will inevitably lead to joint controllership among various data access bodies and data holders. It is important that the responsibilities of data holders and data access bodies in the data life cycle are clear and transparent, allowing the data subjects to understand where to direct their questions and potential complaints in case needed.

The data access bodies are also obliged to provide data subjects with information related to legal basis of data permit, the rights of the data subjects arising from the secondary use of electronic health data, the mechanisms available for data subjects to exercise their rights, the technical and organizational measures taken to protect data subjects' rights, and the results of the relevant health research. This obligation is not identical to the requirements under Article 13 and 14 of the GDPR, where provision of certain information to the data subjects on individual level has been foreseen in view of the overarching principle of transparency. As such, this can be considered as not strengthening transparency in secondary uses of health data, as granular information will not be provided to the data subjects. In response, in their joint opinion, the EDPB-EDPS recommend that the provision should be modified "...accordingly taking into account that the requirements set out in Article 14 GDPR may not be systematically overruled without adequate and relevant assessment and justification as to the need to rely on such exemption."³⁴

Finally, in terms of the legal basis for secondary uses of data, the general approach is not to rely on explicit consent from the data subjects. In fact, Recital 37 of the proposal outlines the legal basis for sharing or access to data, depending on the role of the parties in the data sharing ecosystem. Accordingly, data holders may make data accessible for sharing by data access bodies based on Article 6(1)(c) of the GDPR (compliance with a legal obligation). This must be in combination of one of the legal bases listed under Article 9(2), namely 9(2)(h) (i) (j) of the GDPR, for which EHDS regulation provides the basis.

For the data access bodies, the recognized legal basis for sharing data is Article 6(1)(e) of the GDPR (public interest), in combination with Article 9(2)(h) (i) (j) of the GDPR. For the data users, two options have been foreseen. First, access to data based on Article 6(1)(e) of the GDPR (public interest), which should be in combination with a national or EU law. The alternative option is processing based on

legitimate interest in Article 6(1)(f) of the GDPR (legitimate interests), which should be together with request for data permit from the data access bodies. In that sense, it seems that finding a basis under Article 9(2) of the GDPR is not required, a point which has been also scrutinized by the EDPS-EDPB in their joint opinion.

In relation with data altruism consent which has been introduced under the DGA for secondary uses of data for general interest purposes, the EHDS only re-states that this should be in line with this regulation (see Article 40 of the EHDS). As such, the newly proposed regulatory framework does not offer any clarifications regarding the points we raised above and in other places, regarding implementing data altruism consent in the context of secondary uses of data for general interest.³⁵

It should be noted that in principle the preferred approach for secondary uses of data under the EHDS is that data to be fully anonymized and be accessed within secure sharing environments, which could be considered as an example of organisational safeguards, as it has been also previously stipulated under the art 89 of the GDPR. In that case, secondary processing of data will not be considered as personal data. However, the EHDS does not rule out the possibility for sharing data in a pseudonymized way, which would require compliance with the GDPR, and the legal bases recognized under it. The EHDS also stipulates that in case of request to access data in pseudonymized way, besides compliance with Article 6(1) of the GDPR, "the following additional information shall be provided together with the data access application: [...] information on the assessment of ethical aspects of the processing, *where applicable* and in line with national law." Considering the importance of respecting ethical aspects of the processing health data, the EHDS can benefit from using stronger words, and demanding that the ethical aspects of the processing must be respected (see Article 45(4) EHDS). Ideally, the ethical aspects of data access requests should be dealt with by the specialized data ethics and access committees, and be integrated in the decision regarding issuing data permits.

5. Concluding Remarks

The secondary uses of health data are crucial for clinical, research and policy making purposes. At the same time, the regulatory and policy framework around processing health data should strike a balance on respecting individuals' control on their data on one hand and facilitating accessibility of data for general interest purposes on the other hand.

Although individual control over data is considered as a key factor in increasing acceptance of health data sharing for research purposes, there is no clear consensus on what such control implies. Besides, there is no well-developed conceptual and legal framework around the optimal level of individual control when data is collected in research, clinical, and public health settings. In addition to giving more control to individuals over how their health data to be used, transparency is equally considered essential in maintaining public trust in secondary uses of health data, and potentially lead to active involvement of the citizens in sharing health data.

As we have shown above, the current and emerging regulatory frameworks applicable to secondary uses of data include some aspects related to data control and transparency by using different

Genetics in Medicine <https://doi.org/10.1038/gim.2015.189> accessed 29 May 2022, pp. 892-897.

33 EDPB-EDPS Joint Opinion 03/2022 (n 31) para 93.

34 Ibid para 96.

35 Shabani (n 5).

instruments including consent or data altruism consent as a potential legal basis for data processing, and provision of granular and general information related to such secondary uses of data to citizens.

However, the recent legislative proposal for the EHDS seems to shift focus from consent as a legal basis and provision of information to the data subjects on an individual basis to the legal bases of public interest or legitimate interest and the provision of general information regarding secondary uses to citizens. This approach may be in response to the barriers on health data sharing which have been experienced since the implementation of the GDPR, when specific consent is recognized as a legal basis. In contrast, this may go against the goal of increasing control of the individuals on their data and encouraging their active involvement in data sharing.

Simultaneously, the data altruism consent may still be required for secondary uses of data, and consent as a legal basis can be considered necessary for secondary uses of data under public interest. The added value of such consent models then would be to help individuals to keep a level of control on their health data. However, for data altruism to work and not to be subjected to the same criticisms as the consent model of the GDPR, this would need to allow the potential implementation of broad consent. In addition, if the intention of European data altruism consent is pursued, this can also help to prevent introducing yet another fragmented approach to how specific/broad consent forms are formulated. In that sense, it will remain to be seen that how these provisions will interplay with each other, especially when it comes to exercising various rights of data subjects, including withdrawal of consent.

Finally, the newly proposed bodies could benefit from the existing experiences of local and central data access committees and strive to address the identified shortcomings in streamlining data access oversight. This seems to be a challenging task, as setting up centralized data access bodies may result in more administrative burden regarding data access applications and review of the data access requests. Therefore, the details of such data access review procedures should be determined carefully, to avoid causing unintentional delay in data access. At the same time, the ethical aspects of the data access request which should be reviewed by the authorized ethics committees need to be integrated in the decisions regarding issuing data permits.³⁶ In doing that, the ethical intricacies related to data-driven research must be reviewed by specialised committees.

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36 Mahsa Shabani, Edward S. Dove, Madeleine Murtagh, Bartha Maria Knoppers, and Pascal Borry, 'Oversight of Genomic Data Sharing: What Roles for Ethics and Data Access Committees?' (2017) 15(5) *Biopreservation and Biobanking* <http://doi.org/10.1089/bio.2017.0045> accessed 29 May 2022, pp.469-474.

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