Essays

Genetic Data Sharing in the European Health Data Space: An Urgent Call for Coordinated Action by the Member States

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GENETIC DATA SHARING IN THE EUROPEAN HEALTH DATA SPACE: AN URGENT CALL FOR COORDINATED ACTION BY THE MEMBER STATES

ABSTRACT: In the European Health Data Space, there are still loose ends to be tied up. Regarding the secondary use of genetic data, the failure of Member States to reach a consensus during the EHDS negotiations led to a regulatory exception. Once again, in application of Article 9(4) GDPR, Member States may introduce additional safeguards for the secondary processing of genetic data in the EHDS. This paper analyses the risks of this exception for genetic research and personalised medicine, while proposing policy alternatives that would allow Member States to enhance institutional control over the genetic data lifecycle and boost individual autonomy and trustworthiness.

KEYWORDS: EHDS; genetics; opt-in; opt-out; consent; EDIC

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1. Introduction

On 26 March 2025, the Regulation (EU) 2025/327 on the European Health Data Space entered into force, marking the beginning of the transition phase towards its application. The secondary use of data in the EHDS aims to enable the secure and trustworthy reuse of health data for research, innovation, policy-making, and regulatory activities.[1] Although in line with other

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[1] Art. 53(1) EHDS.

EU regulations such as Regulation (EU) 2022/868 (Data Governance Act) and Regulation (EU) 2023/2854 (Data Act), secondary use of data in the EHDS represents a significant step forward for the healthcare sector.[2]

In this short piece, we focus on the secondary use of genetic data for scientific research purposes. Under the EHDS, through a regulated procedure mediated by the Health Data Access Bodies, all kinds of Health Data Holders should make their electronic health data available to any researcher who appropriately justifies the need for access to certain data for scientific research purposes. Individuals will be able to refuse secondary use of their data through an opt-out mechanism. Indeed, the new scientific research regime under the EHDS involves a paradigm shift from a consent-based approach to what might be called a general or public interest approach, with opt out safeguards.[3]

However, as has repeatedly occurred in contemporary legal history, what has become known under the umbrella of 'genetic exceptionalism' gave rise to a polarised debate.[4] As we will see, differently from the other categories of data, secondary access to genetic data in the EHDS can be limited by each Member State. In other words, while for the secondary use of the other categories of data the maintenance or introduction of additional conditions set out in Article 9(4) of the GDPR is prohibited, MSs are allowed to establish such additional conditions to the sharing of genetic data in the EHDS. For instance, by limiting secondary use upon the explicit consent (opt-in) of the data subject.

Throughout this paper, we are critical of the particular regime ('genetic exceptionalism') given to the secondary use of genetic data in the EHDS. For our criticism to be constructive and based on economic, scientific and individual rights protection grounds, we argue that Member States take coordinated action on the implementation of such particularity, while considering that a way forward can be offered by the process of construction of a European Digital Infrastructure Consortium. As part of the Digital Decade Policy Programme 2030, EDICs are legal instruments established by a Commission decision upon the application of at least three MSs, aimed at setting up and implementing multi-country projects. Of course, EDIC as a tool is only an example of possible coordination mechanisms. In other words, if further safeguards for the use of genetic data in this European area are deemed necessary, our approach is to adopt such safeguards on a rational basis in the interests of science and society and in a coordinated manner between the EU Member States to allow maintaining the highest fundamental rights protection.

We are aware that such a concert among MSs did not go through during the negotiation phase of the EHDS and that MS have a high interest in keeping a certain degree of control over genetic data. Still, we argue that the form of the EDIC can technically offer a "setting" with sufficient regulatory and political flexibility to allow at least a starting group of MSs to experiment effective genetic data sharing within EU borders empowering research and other uses without diminishing the protection of fundamental rights and, actually, enhancing the security of these data. It is a form of pragmatic federalism that does not

[2] F. Cascini, *Enabling Factors and Opportunities to Maximize Health Data Reuse*, in F. Cascini (Ed.), *Secondary Use of Electronic Health Data: Public Health Perspectives, Use Cases and Challenges*, in *Springer Nature Switzerland*, 2025, 101-119.

[3] E. Santamaria Echeverria, *The European Health Data Space: A New Paradigm for Secondary Uses of Health Data for Scientific Research?*, in S. Slokenberga, K. Ó Cathaoir, M. Shabani (Eds.), *The European Health Data Space: Examining A New Era in Data Protection*, 2025, 162-178.

[4] S. Slokenberga, *You can't put the genie back in the bottle: on the legal and conceptual understanding of genetic privacy in the era of personal data protection in Europe*,in *BioLaw Journal - Rivista Di BioDiritto*, 1S, 2021, 223–250.

undermines the general principles but effectively enhance and reinforces areas of reinforced cooperation among interested MSs. It would be a form of reinforced cooperation among the "willing" and interested, able to experiment innovative solutions within an already shared common framework.

2. Genetic Data Sharing in the EHDS: Back to the Spirit of Article 9(4) GDPR

The GDPR definition maintained by the EHDS understands genetic data to be: «personal data relating to the inherited or acquired genetic characteristics of a natural person which give unique information about the physiology or the health of that natural person and which result, in particular, from an analysis of a biological sample from the natural person in question».[5] Regarding the secondary use, among the 'genetic data', we include the following minimum categories: human genetic, epigenomic and genomic data; other human molecular data and omics; and health data from biobanks and associated databases.[6]

When discussing genetic data, it should not be forgotten that the individual -personal data- perspective is not sufficient for a complete analysis of the risks involved in its processing. Individual risks and interests must be properly balanced with the interests of families and communities.[7] Particularly, with regard to genetic discrimination and stigma which are inextricably linked and cannot be viewed in isolation from other structural inequities.[8] This helps to understand the different sensitivities -genetic exceptionalism- in the regulation of genetic data processing by Member States.

Back in 2016, the GDPR included a clause that allowed Member States to introduce additional restrictions on the processing of health and genetic data. From the very beginning, this exception was regarded as particularly challenging for the collaborative genetic research.[9] According to Recital 53 GDPR, this provision should not hamper the free flow of personal data within the EU. However, evidence shows that its application by the Member States has negatively influenced cross-border data sharing.[10] Over the years, this provision has become the main regulatory constraint to the free data sharing both at the EU level and

[5] Art. 4(13) GDPR

[6] Arts. 51(1)(f), (g) and (q) EHDS. For the purposes of this paper, we include all these categories under the umbrella of genomics. However, it should be noted that not all omics are genetic data, nor should the organizational, technical, and security measures be the same to preserve their privacy.

[7] World Health Organization, *Guidance for human genome data collection, access, use and sharing*, 2024.

[8] A. RUD, E. PORTER, Y. JOLY, et al., *Addressing genetic discrimination and its stigmatizing effects through human rights*, in *Journal of Community Genetics*, 17, 2026, 1-7.

[9] M. SHABANI, P. BORRY, *Rules for processing genetic data for research purposes in view of the new EU General Data Protection Regulation*, in *European Journal of Human Genetics*, 26(2), 2018, 149–156.

[10] F. MOLNÁR-GÁBOR, J. SELLNER, S. PAGIL, S. SLOKENBERGA, O. TZORTZATOU-NANOPOULOU, K. NYSTRÖM, *Harmonization after the GDPR? Divergences in the rules for genetic and health data sharing in four member states and ways to overcome them by EU measures: Insights from Germany, Greece, Latvia and Sweden*, in *Seminars in Cancer Biology*, 84, 2022, 271–283; F. KERTESZ, *Collaboration in Healthcare: Implications of Data Sharing for Secondary Use in the European Union*, in *European Journal of Health Law*, 31(5), 2024, 497-517.

across borders,[11] even if not the only one,[12] leading to unequal secondary access to genetic data depending on the State of origin of the processing.[13]

In the Commission's May 2022 proposal, the governance of secondary data use did not distinguish between different categories of health data.[14] Later, as reflected in Recital 18 EHDS, particularities with respect to genetic data were included in the EHDS due to the 'different sensitivities in the Member States on the degree of patients' control over their health data'. Regarding the secondary use of data, while Member States were banned from maintaining or introducing further conditions established under Article 9(4) GDPR, genetic data was excluded from this general rule.[15]

Put another way, Member states may or may not establish additional safeguards to the sharing of genetic data, for instance by limiting secondary use upon the explicit consent (opt-in) of the data subject.[16] Thus, expanding on the fragmentation generated by the GDPR and its exception in Article 9(4),[17] and missing the opportunity to address the unequal secondary access to genetic data in the EU.

3. The Economic Rationale

Given the possibility of such fragmentation under the EHDS, we believe there are good reasons to avoid it by the EU Member States. The first of them is economic. Indeed, we are investing a lot of money in making this EU space functional.

Under the Recovery and Resilience Facility (RRF), Member States have budgeted EUR 14 billion for investments in digital health, while the Commission will provide over EUR 810 million for its implementation under the EU4Health Programme, the Digital Europe Programme, the Connecting Europe Facility and Horizon Europe.[18] The impact assessment of the proposal of the EHDS regulation estimated an overall cost of EUR 0.4-0.7 billion for public authorities just for the rollout of health data access bodies and the necessary

[11] R. Becker, D. Chokoshvili, G. Comandé, E. Dove, A. Hall, C. Mitchell, F. Molnár-Gábor, P. Nicolàs, S. Tervo, A. Thorogood, *Secondary Use of Personal Health Data: When Is It "Further Processing" Under the GDPR, and What Are the Implications for Data Controllers?*, in *European Journal of Health Law*, 30(2), 2022 129-157.

[12] B.M. Knoppers, A. Bernier, S. Bowers, E. Kirby, *Open Data in the Era of the GDPR: Lessons from the Human Cell Atlas*. In *Annual Review of Genomics and Human Genetics*, 24, 2023; D. Peloquin, M. DiMaio, B. Bierer, M. Barnes, *Disruptive and avoidable: GDPR challenges to secondary research uses of data*, in *European Journal of Human Genetics*, 28(6), 2020, 697–705.

[13] A. Vlahou, D. Hallinan, R. Apweiler, et al., *Data Sharing Under the General Data Protection Regulation*, in *Hypertension*, 77(4), 2021, 1029–1035; EIT Health Think Tank, *Implementing the European Health Data Space Across Europe*, April 2024. Report available here: https://eithealth.eu/think-tank-topic/implementing-the-european-health-data-space/.

[14] COM/2022/197 final. Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space.

[15] Art. 51(4) EHDS

[16] Recital 52 EHDS

[17] DG Food and Health Safety, *Assessment of the EU Member States' Rules on Health Data in the Light of GDPR. Assessment of the EU Member States' Rules on Health Data in the Light of GDPR*, Brussels, 2021.

[18] Directorate-General for Health and Food Safety - European Commission, *EU funding for digital health*, 2025. Available here: https://health.ec.europa.eu/ehealth-digital-health-and-care/eu-funding-digital-health_en.

digital infrastructure connecting these bodies, research infrastructures and EU bodies, and the promotion of interoperability and data quality.[19]

Another calculation from the mentioned impact assessment that is worth mentioning, are the estimated costs related to getting the consent by data re-users in health for cross-country research as opposed to the EHDS access: EUR 2.7 billion over 10 years.[20] Where Member States' safeguards for access to secondary genetic data make it necessary to obtain this consent as well, an additional cost not foreseen in these initial calculations will necessarily be added.

Following the calculations of the Commission, the whole rationale for investing in secondary access in the EHDS would be based on avoiding the costs of secondary access through re-consent for the secondary use. Therefore, by implementing 'safeguards' that require the use of re-consent, while investing in the implementation of the EHDS, Member States will be duplicating costs. Possible reactions to restrictions by others are likely to feed back into this duplication of costs.[21]

In other words, the Commission establishes economic calculations based on the cost of re-consent to justify the expenditure. This is a political decision, and it means that the money is invested in other administrative safeguards (SPEs, HDABs, etc.) rather than in an effective infrastructure to enable express consent. In our view, what seems contradictory is that, at the same time, the EHDS establishes a regulatory exception that would generate the extra costs it wishes to avoid. Only for certain categories of data, and at the discretion of Member States.

Moreover, fragmented legislation corresponding to fragmented access to health and genomic data reverberates on several key internal markets. The inability to effectively and timely access data hampers innovation and research, harm the industrial capacity and international role of EU champions and contribute preventing the emergence of such European champions. Counterintuitively, the mentioned investments should call for efficient ways of capitalizing data sharing while sustaining a rigorous fundamental-rights-oriented approaches. The social cost of waiting political general momentum for innovating in these domains might be too high. Once again experimental approaches coalescing a minimum of MS in a specific cross border project could, ironically, even leverage genomic exceptionalism – the regulatory prerogatives of MS- to coordinate a levelling of legal bases at national level, for instance.

4. The Scientific Rationale

Science provides the basis for our second argument concerning the risks of fragmentation of secondary genetic data sharing in the EHDS. As stated by the European Society of Human Genetics, the opt-in mechanism for genetics is not only arbitrary but could substantially hinder progress in the field of human

[19] EUROPEAN COMMISSION, *Impact Assessment Report accompanying the document Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space*, 2022 [SWD(2022) 131 final].

[20] EUROPEAN COMMISSION, *op. cit*.

[21] That is: if you limit the access to 'your' genetic data but you can access 'mine', I will therefore also limit your access to mine. A slippery slope against the mutual trust of EU member states. In our view, this is one of the worst scenarios that could result from the exception for secondary use of genetic data in the EHDS. Meaning that not only did the parliamentary negotiations fail in the first place, but Member States would subsequently adopt increasingly divergent positions on the construction of the EHDS.

genetics within Europe, preventing patients -especially those exposed to rare diseases- from obtaining the significant benefits of the EHDS.[22]

The position of the European Society of Human Genetics seems reasonable if we look at the literature on the effects that opt-in can have as opposed to opt-out. Participants in studies with an opt-out procedure are more likely to be representative of the study population than those with studies with an opt-in procedure.[23] Furthermore, people with vulnerable conditions are underrepresented in studies using opt-in.[24] Once again, this draws attention to the possibility of having a greater impact on research on rare diseases, the vast majority of which are genetically based. Where an opt-in procedure and an opt-out procedure are directly compared using an RCT design, the differences in consent rates were statistically significant (21% in the opt-in group vs. 95.6% in the opt-out group),[25] and opt-out yields more data availability while opt-in risks bias due to non-response tendencies.[26]

We do not intend to be reductionist in this argument. Certainly, other factors will affect the availability and representativeness of the data. Our point is that, other things being equal, availability and representativeness are different in opt-in and opt-out contexts, which will differently affect the databases available in each Member State.

5. The Patients' Rights Protection Rationale

Last but not least, we must focus on the protection of patients' rights and the respective exercise of their autonomy. Undoubtedly, individual autonomy and its possible exercise through an opt-in or opt-out -which were excluded at the Commission's first version in May 2022- became one of the most important topics of legislative discussion of the EHDS.[27]

The prevalence of opt-in consent in a secondary use context, in our view, should not be such. On one side, the centrality of consent in this kind of context risks shifting the burden of responsibility from institutions to individuals, meaning that transparency, security and equity should be at the core of the EHDS.[28] This is even more true, when we are talking about particularly sensitive data. On the other side, it should not be

[22] Opting-in to data sharing in the European Health Data Space will disadvantage research on personalised medicine, says ESHG. Available here: https://www.eshg.org/news/news-details?tx_news_pi1%5Baction%5D=detail&tx_news_pi1%5Bcontroller%5D=News&tx_news_pi1%5Bnews%5D=66&cHash=ef055b33ea95d43b17185ff76101996f (Last visited 09/09/2025).

[23] Y. DE MAN, Y. WIELAND-JORNA, B. TORENSMA, et al., *Opt-In and Opt-Out Consent Procedures for the Reuse of Routinely Recorded Health Data in Scientific Research and Their Consequences for Consent Rate and Consent Bias: Systematic Review*, in *Journal of Medical Internet Research*, 25, 2023.

[24] Y. DE MAN, Y. WIELAND-JORNA, B. TORENSMA, et al., *op. cit*.

[25] J.G. BERRY, P. RYAN, M.S. GOLD, A.J. BRAUNACK-MAYER, K.M. DUSZYNSKI, VACCINE ASSESSMENT USING LINKED DATA (VALID) WORKING GROUP, *A randomised controlled trial to compare opt-in and opt-out parental consent for childhood vaccine safety surveillance using data linkage*, in *Journal of medical ethics*, 38(10), 2012, 619–625.

[26] M. HERMUS, C.H. SCHARLOO-KARELS, M.A. IKRAM, et al., *Opt-In versus opt-out for the secondary use of routinely recorded health data: A randomized controlled trial*, in *European Journal of Internal Medicine*, 133, 2025, 100–105.

[27] M. SALOKANNEL, *Opting-in or -out or Not at All: Secondary Use of Health Data in the EHDS Framework*, in *European Law Blog,* 2024.

[28] J. DE FRUTOS LUCAS, H.T. HAUGO, *Moving forward with the European health data space: the need to restore trust in European health systems*, in *The Lancet Regional Health – Europe*, 40, 2024.

forgotten that individuals' autonomy is already there as opt-out and fits better for secondary use purposes.[29] However, in this context, governance frameworks and processes on the re-use of the data should always be informed by community engagement and appropriate oversight and monitoring.[30] Rather than holding to traditional care-research distinction and its governance models and consent mechanisms, it is essential to identify the complexities of data processing that arise from secondary uses of data and to adopt appropriate safeguards (also regarding individual autonomy) in response to the associated risks.[31]
Following this logic, opt-out became the main expression of consent in the EHDS governance model for secondary data use. Still, as we see it, it's also key to look at how this opt-out is configured from an individual perspective, beyond the safeguards and accountability mentioned above. What emerges here is the importance of information provision and the procedure itself as the basis for meaningful autonomy. In order to be justifiable, opt-out consent should at least include awareness that the data is included in the EHDS, sufficient and simple information about the data processing, and an accessible mechanism to object (opt-out).[32] The provision of ongoing information, rather than just at outset of processing, with more contextual and granular content, the combination of in-person and virtual approaches, or addressing linguistic and cultural barriers, are some of the challenges that the EHDS should face. However, the need to devise ongoing mechanisms for keeping constantly informed patients to enable their autonomy in an opt out system requires a technological approach capable to avoid what we could term "dissent fatigue", a similar result observed for the personal costs of continuous reconsenting, which would come at the expenses of individual fundamental freedoms. Clearly the balancing between affordable protection of autonomy, via continuous information, should be balanced with the general interests related to research, innovation, collective health and so on. Such a balancing is not easily predetermined and predetermined once and forever. These considerations encourage the kind of pragmatic experimentalism we are proposing in this contribution while offering de facto sandboxing under the shelter of appropriate safeguards. These safeguards could be adopted at the higher level (e.g. coordinated legislative attempts among several member states under the aegis of an EDIC), or within a strict ethics board control, or in other ways able to guarantee among else, reversibility of the adopted solution.
More importantly, we shall not forget that the patients' rights protection is not completed at the EU regulation level of the EHDS. Indeed, the actual assessment of the requirements of data protection safeguards for granting a data permit is regulated at the minimum level, hence, the gaps will be filled by the different national laws.[33] This could be a perfect occasion for such a coordinated approach.
Therefore, there is still considerable room for national implementation in the EHDS that affects the protection of individual and collective rights and their control over personal data. On one hand, this means

[29] D. HORGAN, M. HAJDUCH, M. VRANA, et al., *European Health Data Space—An Opportunity Now to Grasp the Future of Data-Driven Healthcare*, in *Healthcare*, 10, 2022.
[30] World Health Organization, *Guidance for human genome data collection, access, use and sharing*, Geneva, 2024. Available here: https://www.who.int/publications/i/item/9789240102149
[31] M. SHABANI, *Collection and sharing of genomic and health data for research purposes: Going beyond data collection in traditional research settings*, in *BioLaw Journal - Rivista Di BioDiritto*, 1S, 2021, 251–260.
[32] These criteria have been sourced from here: N.A. GIESBERTZ, A.L. BREDENOORD, J.J. VAN DELDEN, *Inclusion of residual tissue in biobanks: opt-in or opt-out?*, in *PLoS biology*, 10(8), 2012, e1001373.
[33] J. REICHEL, *Administrative tools for balancing societal and individual interests: Data protection safeguards and administrative procedural guarantees in secondary use in the European Health Data Space*, in *The European Health Data Space: Examining A New Era in Data Protection*, 2025, 207–228.

that specific safeguards on genetic data-sharing might be added at the national level without the need to move from opt-out to opt-in. These safeguards by Member States could strengthen the autonomy of participants in line with certain provisions already contained the European Regulation itself (e.g. by promoting citizen participation through the role of Health Data Access Bodies,[34] or by reinforcing the ethical control through existing Research Ethics Committees,[35] whose members could also include experts in genetics).

On the other hand, where those measures are not aligned with the EHDS governance model, we run the risk of replicating the lack of legislative consensus in the EHDS negotiations at this level of national implementation as well. Thus, we may need to put in place alternative coordination mechanisms to avoid further mismatches on genetic data control between different EU countries. This could be the case of a Genomic EDIC as discussed here.

6. The Whole Spectrum on Personal Control Over Data: Opt-In, Opt-Out, Dynamic Consent and Data Altruism

Even if European citizens show heterogeneity in their consent preferences, establishing processes that guarantee access to transparent information on data sharing and provide mechanisms for citizens to express consent seems non-negotiable.[36] For consent to be satisfactory from a legal and normative standpoint -whether opt-out or opt-in-, patients need to be certain about what they can expect in terms of benefits, outcome, and future usage of their data.[37] In other words, Europeans want to have control over their data.

Until now, the implementation of consent processes that adequately reflect and incorporate patients' needs has been slow and insufficient.[38] We find the EHDS to be an extraordinary opportunity to enhance the citizens' experience in exercising their autonomy and control over their health data. However, as a double-edged sword, a lack of trust in its governance model may turn the EHDS into a failure, regardless of the consent mechanism chosen.

6.1. Consent to Participate in Research vs. Consent as a Legal Basis for Data Processing

If we consider data control as a spectrum rather than an opt-in vs. opt-out dichotomy, the possibilities are endless for consent processes.

Under this data-control spectrum, we should not forget that consent as an ethical or even legal requirement in research, in this case as an expression of individual autonomy in the context of secondary use of

[34] Art. 58(4) EHDS

[35] Recital 73 EHDS. As also proposed by P. Cervera de la Cruz, T. Lalova-Spinks, M. Shabani, *Implementation of the European health data space: a qualitative study on expectations of health data experts from 23 countries*, in *Health Policy*, 161, 2025.

[36] R. Biasiotto, J. Viberg Johansson, M.B. Alemu, et al., *Public Preferences for Digital Health Data Sharing: Discrete Choice Experiment Study in 12 European Countries*, in *Journal of Medical Internet Research*, *25*, 2023.

[37] R. Horn, J. Merchant, The UK-FR GENE Consortium, *Managing expectations, rights, and duties in large-scale genomics initiatives: a European comparison*, in *European Journal of Human Genetics*, 31, 2023.

[38] I. Kassam, D. Ilkina, J. Kemp, H. Roble, A. Carter-Langford, N. Shen, *Patient Perspectives and Preferences for Consent in the Digital Health Context: State-of-the-art Literature Review*, in *Journal of Medical Internet Research*, 25, 2023.

data under the EHDS, does not require consent as the legal basis for data processing.[39] Indeed, the right to opt-out under the EHDS is independent not only from the legal basis under the GDPR, but also from its right to object under Article 21.[40] Furthermore, the GDPR does not privilege consent as a lawful basis in the scientific research context.[41]

Hence, the spectrum of personal data control also comprises the spectrum of legal bases for data processing. Meaning that the introduction of an opt-in mechanism may also introduce consent as the legal basis for data processing but also could not (see examples 1 and 2 in Table 1). Moreover, Member States could even establish a specific opt-out mechanism for genomics, while maintaining the general opt-out mechanism for the rest of the data categories. In other words, providing an extra degree of autonomy in the control of genomic data, without the need to change from an opt-out to an opt-in mechanism or to alter the legal basis for processing (see example 3 in Table 1).

Furthermore, none of the possibilities included here are an obstacle to initial genetic testing being obtained under express opt-in consent, as established by most national legislation in Member States. This is, while initial genetic testing may be obtained through opt-in consent, and on a legal basis that may, for example, respond to a diagnostic or healthcare need, the secondary use of the genetic data obtained may be based on opt-out consent and on a different legal basis. In any case, we believe that the implementation of the EHDS is a welcome opportunity for Member States to review their national legislation and establish appropriate governance of genetic data throughout its entire lifecycle.

Table 1. How the spectrums of individual control and legal basis may interplay in the EHDS

	General secondary data sharing for scientific research purposes	**Further conditions that could be established by Member States according to Art. 51(4) EHDS**		
		Example 1	**Example 2**	**Example 3**
Individual control	OPT-OUT	OPT-IN	OPT-IN	OPT-OUT FOR GENOMICS

[39] C. STAUNTON, S. SLOKENBERGA, A. PARZIALE, D. MASCALZONI, *Appropriate Safeguards and Article 89 of the GDPR: Considerations for Biobank, Databank and Genetic Research*, in *Frontiers in Genetics*, 13, 2022.

[40] TEHDAS2, M8.1 Draft Guideline to Health Data Access Bodies "How to implement opt-out from secondary use of electronic health data", 7 September 2025. Available here: https://tehdas.eu/public-consultations/

[41] E. DOVE, J. CHEN, *Should consent for data processing be privileged in health research? A comparative legal analysis*, in *International Data Privacy Law*, 10(2), 2020; see also S. SLOKENBERGA, *You can't put the genie back in the bottle: on the legal and conceptual understanding of genetic privacy in the era of personal data protection in Europe*, in *BioLaw Journal - Rivista Di BioDiritto*, 1S, 2021, 223–250.

Legal basis for including data in the EHDS by the Data Holder	LEGAL OBLIGATION Art. 6(1)(c) + 9(2)(i) and (j) GDPR	CONSENT Art. 6(1)(a) + 9(2)(a) GDPR	LEGAL OBLIGATION Art. 6(1)(c) + 9(2)(i) and (j) GDPR	LEGAL OBLIGATION Art. 6(1)(c) + 9(2)(i) and (j) GDPR
Legal basis for data processing by the Data User	TASK IN PUBLIC INTEREST OR LEGITIMATE INTEREST Art. 6(1)(e) or (f) + Art. 9(2)(j) GDPR	CONSENT Art. 6(1)(a) + 9(2)(a) GDPR	TASK IN PUBLIC INTEREST OR LEGITIMATE INTEREST Art. 6(1)(e) or (f) + Art. 9(2)(j) GDPR	TASK IN PUBLIC INTEREST OR LEGITIMATE INTEREST Art. 6(1)(e) or (f) + Art. 9(2)(j) GDPR

6.2. Expanding the Possibilities of Data Control in the EHDS

Still, the spectrum of personal data control offers even greater scope within the EHDS.[42] The financial investment in EHDS can offer a great opportunity to adopt dynamic consenting models, which provide patients more granular control over their data,[43] and allow them to adjust their consent preferences over time.[44] It also offers the opportunities to move beyond dynamic consent leveraging other legal basis and presenting the occasion to revise legal interpretations in light of regulatory novelties (e.g. the DGA and its implications for data altruism as a legal and technical vehicle for art. 9(2)(e) GDPR). In our view, the integration of these technologies into the consent process and into the empowerment of other legal basis -that fit better with the secondary use of data-,[45] should always be subject to the provision of adequate information, also by the health services to which citizens have in-person access, and which will subsequently share their data as data holders. A different interpretative mood emerges also in the latest decisions of the EUCJ focusing on the safeguards needed to ensure effective personal data processing, opening to a spectrum in leveraging pseudonymization.[46]

Lastly, the limitations that Member States may wish to impose in the form of an opt-in should at least consider that the EU envisioned data altruistic organizations to serve citizens wishes under the Data Governance Act. The interplay between data altruism in the DGA, the GDPR and the EHDS, still remains

[42] The aspects mentioned here deserve a more thorough analysis than is possible within the scope of this text. We will however address them in a future work that is still in progress.

[43] A model that has already been tested in genomics research and biobanking research, see R. BIASIOTTO, P. P. PRAMSTALLER, D. MASCALZONI, *The dynamic consent of the Cooperative Health Research in South Tyrol (CHRIS) study: broad aim within specific oversight and communication*, in *BioLaw Journal - Rivista Di BioDiritto*, 1S, 2021, 277–287.

[44] T.K. ALHASAN, *Managing legal risks in health information exchanges: A comprehensive approach to privacy, consent, and liability*, in *Journal of Healthcare Risk Management*, 44(4), 2025, 12–24.

[45] P. QUINN, and L. QUINN, *Big genetic data and its big data protection challenges*, in *Computer Law & Security Review*, *34*(5), 2018, 1000–1018.

[46] EUCJ, C-413/23 P, *EDPS v SRB*, 4 September 2025

unclear and under discussion.[47] Nevertheless, it appears that the DGA has major implications for the current legal framework and could provide a chance to harmonize the application of the research exemption and the legal basis of consent by creating a data altruism mechanism at the EU level.[48] Indeed, regarding scientific research, Recital 50 DGA suggests that further processing for scientific purposes -secondary uses- should not be considered incompatible with the initial purposes, regardless of whether the initial legal basis was consent or another.[49] Despite the limited success of the DGA so far, we believe that Member States' actions in the EHDS cannot represent a further barrier to altruistic data sharing, further considering that the participation of data altruism organisations is already envisioned in the Regulation.[50]

7. The Construction of a Genome EDIC: Putting Into Practice New Ways of Controlling Personal Genetic Data

European Digital Infrastructure Consortiums (EDICs) are legal entities established by the Commission that are meant to speed up and simplify the setup and implementation of multi-country digital infrastructures and projects under the Digital Decade Programme.[51] An EDIC is established through a Commission decision at the request of a group of MS. The decision grants the EDIC full legal capacity, recognising its existence and authority across all MS.[52] With its legal independence, EDICs also assume financial responsibility and their budget will be based on their members' contributions complemented by other sources of revenues, which may include EU and national grants.[53] Pragmatically, participation to an EDIC requires direct MS involvement and is normally channelled by relevant ministerial power, similarly to another EU based institution the European Research Infrastructure Consortia[54], offering direct access to governmental initiated national legislation processes for which the eric can offer a proper coordination and planning forum. Only five EDICs have been created so far, however, many others are in preparation. Among them, the Genome EDIC. On March 2023, the special group of national representatives in the 1+ Million Genomes initiative endorsed the principal approach of creating an EDIC, and by June 2023 nine Member States (Belgium, Bulgaria, Croatia, Czechia, Denmark, Estonia, Finland, Luxembourg and Spain) pre-notified an

[47] On this matter and closely related to the processing of genetic data in the EHDS, see L. CENTENO, *The dilemma between data protection and data altruism within the context of rare diseases in the European Health Data Space*, in *European Journal of Health Law*, forthcoming.

[48] M. CHRISTOFIDOU, T.N. ARVANITIS, D. KALRA, et al., *Data altruism and the "consent" question: a study into the "consent" models used under the GDPR and how the data altruism mechanism can act as a potential solution for the research community in the reuse of health data*, in *Frontiers Medicine*, 11, 2025.

[49] T. LALOVA-SPINKS, J. MESZAROS, I. HUYS, *The application of data altruism in clinical research through empirical and legal analysis lenses*, in *Frontiers Medicine*, 10, 2023.

[50] Art. 73(4) EHDS

[51] EU Decision 2022/2481

[52] For a more detailed explanation on the organizational nature and the governance model of the EDICs, see E. TAN, D. DU SEUIL, *European Digital Infrastructure Consortium (EDIC): A New Governance Framework for the European Blockchain Services Infrastructure (EBSI)*, in J. GOOSSENS, E. KEYMOLEN, A. STANOJEVIĆ (Eds.), *Public Governance and Emerging Technologies: Values, Trust, and Regulatory Compliance*, 2025, 83–101.

[53] Arts. 16, 17 and 18, EU Decision 2022/2481.

[54] https://research-and-innovation.ec.europa.eu/strategy/strategy-research-and-innovation/our-digital-future/european-research-infrastructures/eric_en.

EDIC application[55]. The Genome EDIC aims to ensure the sustainable operation of the -also in construction- European Genomic Data Infrastructure (GDI), with the support of other projects also funded by the Commission under the 1+MG initiative, such as the Genome of Europe (GoE) and the Beyond One Million Genomes (B1MG) projects.

Regarding the aim of this text and the challenges of genetic data sharing in the EHDS, we propose to consider the potential of the Genome EDIC in different layers.

First, the Genomic Data Infrastructure is being designed to mitigate the particular risks associated with genetic data and its sensitivity, and those tools are specifically designed to become reusable in the context of the EHDS.[56] National interest in the particular sensitivity of genetic data and the difficulty of anonymizing it were key factors in the legislative negotiations to give genetic data this special status.[57] Appropriate technology adapted to these categories of data is essential to minimize the risks of sharing them and they might effectively leverage an updated reading of pseudonymization as it can possibly emerge after EDPS v SRB.

This infrastructure can help build mutual trust among Member States, preventing them from putting further governance obstacles in place for the secondary sharing of genetic data to protect its sensitivity.

Second, the Genome EDIC might be useful as a de facto regulatory sandbox for allowing new ways of personal control over personal data. As we have noted above, control over personal data is more of a spectrum than an opt-in vs. opt-out dichotomy, which also includes a wide variety of legal bases for processing. In this context, our view is that a mixed model technologically based can be designed to enable certain degrees of automation in opting in or opting out. In other words, we can rely on technology to design new consent practices within that spectrum of possibilities. A coordinated establishment of a Genome EDIC can technically and legally kick start such practices with interested and willing MS.

And third, such a solution can be useful to achieve significant milestones for genomics that are out of the scope of the EHDS. For instance, a Genome EDIC would also open possibilities for secondary uses of data beyond the EHDS, such as enabling findability and information of data subjects on the possibility to be included in clinical trials or observational studies, or contributing data for the diagnosis, prognosis or therapeutic decisions on similar patients. These coordinated efforts are particularly relevant in the field of rare diseases, where the EHDS could fall short.

8. A Path to Leverage Genomic Data Secondary Uses Protecting Fundamental Rights and Autonomy

Concluding, our brief explorative journey confirms that there is still work to be done in the implementation of the EHDS for a secondary use of genetic data that is both trustworthy, secure and respectful of fundamental rights and research needs. However, considering the aforementioned reasons, the introduction of an opt-in consent seems like the worst possible outcome for the Member States.

[55] SWD (2025) 292 final, *Progress report on multi-country projects*, in *Commission staff working document*, Brussels, 16.6.2025. More recently, both France and Italy submitted their pre-notifications.

[56] L. EBERMANN, R. BECKER, A. CAMBON-THOMSEN, et al., *GDI D2.9 Evaluation of data governance experiences – Report*, in *Zenodo*, 2023.

[57] M. SALOKANNEL, *op. cit*.

Since MS did not reach an agreement on a different regime during EHDS regulation negotiations we claimed that, without hampering the positive results settled in the EHDS regulation there are additional paths that MSs can follow to open the lead for experimenting innovative ways to balance fundamental rights protection and securing the needs of research.

One option could be the opportunity for MS (from a minimum of 3 up to all of them) to experiment coordination mechanisms of their implementing rules for the EHDS, eventually leveraging technology powered solutions to empower, within the framework of Multicounty project (EDIC) effective data sharing. Within this framework it is possible to coordinate as compatible as possible measures with the governance structure of the EHDS.

These coordinated measures would be implemented in each MS according to internal rules with the appropriate legislative nature, where needed; some MS could require "stricter measures" in the sense of Article 51(4) EHDS, while others could simply be part of the state-level implementation of the EHDS. In this example, the Genome EDIC could serve as a testing ground and the instrument through which these measures are implemented in a coordinated manner. This way, the consensus that was not possible in the legislative discussion of the EHDS could be achieved by demonstrating the usefulness of Genome EDIC for the implementation of the new regulation by a smaller number of MS (minimum 3)."

As an ancillary note, the agreed upon implementation measures could even be useful in secondary data sharing beyond genetic categories offering an example of a best practice. The very same solutions adopted within a multicounty project for the Genome EDIC could be conceived as a regulatory and technological sandbox example. Finally, content-wise, these policy alternatives are meant to: enhance institutional control over the genetic-data lifecycle, boost individual autonomy and trustworthiness, and implement specific technical and organisational measures for genetic data-sharing.