The European Health Data Space and the GDPR – A problem of Compatibility for the "Donation" of Health Data

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Abstract: The technological gap within the European Union and of the EU Single Market is hindering its economic competitiveness. To address this issue, the European Commission, has launched various regulatory initiatives aiming to promote the availability and quality of data and fostering the development and use of new technologies, such as AI, as well as the healthcare services and research in the EU. The Commission's proposal for a European health data space is an important step towards facilitating the sharing and reutilization of health and health-related data. However, the need for guidance and harmonization with the EU data protection framework must be addressed to ensure the success of the European health data space.

Keywords: *common EU health data space; personal data protection; health data sharing; data reutilization.*

Resumo: O fosso tecnológico dentro da União Europeia e do Mercado Único da UE está a dificultar a sua competitividade económica. Para contrariar esta questão, a Comissão Europeia lançou iniciativas regulamentares para promover a disponibilidade e qualidade de dados e

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fomentar o desenvolvimento e utilização de novas tecnologias, como os sistemas de IA, bem como os serviços de saúde e a investigação na UE. A proposta da Comissão para um espaço de dados de saúde é uma iniciativa importante para facilitar a partilha e reutilização destes dados. Contudo, a necessidade de orientação e harmonização com o quadro de proteção de dados da UE devem ser endereçados para garantir o sucesso do espaço de dados de saúde.

***Palavras-Chave**: espaço europeu comum de dados de saúde; proteção de dados; partilha de dados de saúde; reutilização de dados.*

1. The Symptoms and the Diagnosis (pun intended)

The economic competitiveness of the European Single Market is a struggle that has been fought for many years and possibly for the years to come, particularly in what regards to the technological market. The challenges to the EU in this field are manifold: (*i*) to improve the economic stability; (*ii*) to become more competitive; and (*iii*) to create more and better jobs in a sustainable way.[3]

As recognised by the European Commission,[4] the business and economic growth associated with digital transformation and technological development are already moving at a rapid pace in China and in the United States. Consequently, if the European Union wishes to join the *"grown-ups'" table* of the digital and technological world, it must

[3] MONCADA.PATERNÒ-CASTELLO, Pietro; GRASSANO, Nicola; "The EU vs US corporate R&D intensity gap: investigation key sectors and firms"; Industrial and Corporate Change; volume 31; 2022, pages 19 to 38. Available at: https://www.researchgate.net/publication/340138938_The_EU_vs_US_corporate_RD_intensity_gap_Investigating_key_sectors_and_firms.

[4] European Commission; Communication from the European Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions "A European Data Strategy"; COM(2020) 66 final; 19 February 2020; page 3.

develop its own initiatives to foster the internal market and reduce EU technology gap.[5]

In this regard, the European institutions have been working on multiple actions to encourage and promote both the commercial value of European technology companies, as well as the use of digital tools and new business models across sectors.[6] Pivotal to this end, as recognized by the Commission,[7] is the upgrade of a data-agile economy, able to simultaneously encourage the availability of large quantities of data, while ensuring their quality, trustworthiness, and reliability.

As largely highlighted in research, data are the essential tool that fosters new technologies, as a *sine-qua-non* of artificial intelligence ("AI"), Internet of Things (IoT) or cloud edge computing.[8] Thus, data is a fundamental pre-requisite for the technology development and innovation. Additionally, it is also worth pointing out that data are a great investment, as they are non-exclusive (they can be used, simultaneously, by multiple entities, independently and for different purposes) and (at least in most cases, except if contractually agreed otherwise) non-rival goods, while also being easy and cheap to replicate.

As addressed by the European Commission,[9] there are large quantities of data generated within the EU which are not utilised, particularly

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[5] AKANDE, Adeoluwa; CABRAL, Pedro; CASTELEYN, Sven; "Assessing the Gap between Technology and the Environmental Sustainability of European Cities"; Information Systems Frontiers; 2019; Available at: https://research.unl.pt/ws/portalfiles/portal/11905837/Akande_Cabral.pdf.

[6] In this regard, multiple legislative packages and industrial incentives have been announced, namely: the Competitive Digital Markets (within the European Digital SME Alliance), the Digital Europe organization; the Digital Services Act package (comprehending the Digital Services Act and the Digital Markets Act); the Cybersecurity Strategy (comprehending the NIS 2 Directive and the Cybersecurity Act); among many others.

[7] European Commission; Communication from the European Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions "A European Data Strategy"; COM (2020) 66 final; 19 February 2020; page 6.

[8] For instance, CURRY, Edward; SCERRI, Simon; TUIKKA, Tuomo; *Data Spaces – Design, Deployment and Future Directions*, Springer, 2022.

[9] European Commission; Communication from the European Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions "A European Data Strategy"; COM(2020) 66 final; 19 February 2020; page 7.

due to legal, operational, and commercial barriers. Such barriers are imposed either in the relation between public entities and businesses (government-to-business) or between businesses (business-to-business).

However, before immediately considering the ways that such barriers can be minimised or even taken down, the EU standards should be taken into consideration. The EU is inextricably linked with human rights protection, which concomitantly occupy a central position within the EU legal order.[10] The European Treaties declare "that the EU is founded on respect for human rights, they give binding effect to the Charter of Fundamental Rights and Freedoms (…)".[11] Consequently, any solution founded to break through the barriers identified to the data sharing initiatives and data-driven economy must take into consideration fundamental rights protection in particular, and unavoidably, the protection of personal data, established in Art. 8 of the Charter of Fundamental Rights of the European Union.

2. The Prescription

In order to overcome the shortcomings of the lack of competitiveness of the EU economy in what regards the development and use of new technologies, the European Commission has announced several legislative initiatives:[12] *(i)* the Data Governance Act[13] (approved on the 30th May 2022), which establishes, among other topics, the conditions for the re-use, within the Union, of certain categories of data held by public bodies (Art.

[10] CRAIG, Paul and BÚRCA, Gráinne de; *EU Law – texto, cases and materials;* 6th edition, Oxford University Press, 2015.

[11] *Ibidem.*

[12] European Commission; Communication from the European Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions "A European Data Strategy"; COM(2020) 66 final; 19 February 2020.

[13] 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). Available at: https://eur-lex.europa.eu/eli/reg/2022/868/oj.

1(1)(a)); [14] *(ii)* an Implementing Act on high-value data sets, under the Open Data Directive,[15,16] which establishes a list of sectorial high-value datasets held by public bodies as well as the arrangements needed for publishing and reusing such datasets; (*iii*) the Data Act[17] approved on the [27]th November 2023 and, at the time of writing, pending publication on the Official Journal of the European Union, aiming to foster data sharing with individuals and between businesses; (*iv*) the signature of a Memoranda of Understanding with Member States on cloud federation,[18] promoting secure and competitive and secure cloud offering; and lastly the (*v*) creation of an EU (self-) regulatory cloud rulebook, to establish common grounds and standards ruling the offer and use of cloud services throughout the Union, both by public and private entities.[19]

In addition to the initiatives listed above, the Commission has also proposed the creation of multiple sectorial Data Spaces,[20] as part of the Common European Data Spaces. Data Spaces in general can be defined as "an ecosystem of data models, datasets, ontologies, data sharing contracts, and specialized data management services together with soft competencies including governance, social interactions, and business

[14] Such categories are detailed in Art. 3(1) of the Data Governance Act and include data protected on grounds of commercial and statistical confidentiality; as well as data protected under intellectual property rights of third parties and as personal data.

[15] Directive (EU) 2019/1024 of the European Parliament and of the Council of 20 June 2019 on open data and the re-use of public sector information. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32019L1024.

[16] The Proposal for the implementing act was presented on the 21December 2022. Available here: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12111-Open-data-availability-of-public-datasets_en.

[17] Proposal for a Regulation of the European Parliament and of the Council on harmonised rules on fair access to and use of data (Data Act). Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2022%3A68%3AFIN, presented on the 23rd February 2022.

[18] Signed by the 27 Member-States on the 15 October 2020. Available at: https://digital-strategy.ec.europa.eu/en/news/towards-next-generation-cloud-europe.

[19] The EU Cloud Rulebook is not yet published, but more information about it is available at: https://digital-strategy.ec.europa.eu/en/library/cloud-and-edge-computing-different-way-using-it-brochure#Rule.

[20] European Commission; Communication from the European Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions "A European Data Strategy"; COM(2020) 66 final; 19 February 2020.

processes."[21] or as "(…) an umbrella term to an ecosystem, benefiting data sharing technologies, a suitable regulative framework, and innovative new business aspects",[22] being mainly considered, in the EU, as infrastructures that will foster data sharing and data reutilisation, without compromising the applicable legal framework.

The Commission's Strategy[23] foresees nine European Data Spaces, each governed by each one sector-specific regulation: Health, Industrial, Agriculture, Finance, Mobility, Green Deal, Energy, Public Administration and Skills. These sectors were selected due to their strategic significance for the EU Single Market but also due to their specific legal, economic, and business characteristics, risks, and requirements.

The first[24] Proposal for a Common European Data Space is the one for the Common European Health Data Space ("EHDS").[25] It should be noted that the Financial Data Spaces proposal was also originally expected in 2022,[26] while the Financial Data Spaces already mentioned as one of the strategic objectives set out in the EU Digital Finance Strategy.[27]

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[21] CURRY, Edward; SCERRI, Simon; TUIKKA, Tuomo; *Data Spaces – Design, Deployment and Future Directions*, Springer, 2022.

[22] *Ibidem.*

[23] European Commission; Communication from the European Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions "A European Data Strategy"; COM(2020) 66 final; 19 February 2020.

[24] And at the time of writing, the only proposal published.

[25] Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space. Available at: https://eur-lex.europa.eu/resource.html?uri=cellar:dbfd8974--cb79-11ec-b6f4-01aa75ed71a1.0001.02/DOC_1&format=PDF.

[26] European Commission; Communication from the European Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions "A European Data Strategy"; COM(2020) 66 final; 19 February 2020.

[27] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on a Digital Finance Strategy for the EU, COM(2020) 591 final. Nonetheless, it should be noted that the Report on Open Finance by the Expert Group on European Financial Data Spaces was published on 24 October 2022, available here https://finance.ec.europa.eu/publications/report-open--finance_en. Therefore, some development in this field are expected in the coming months.

2.1. The Formula of the EHDS

The EHDS is described as "essential for advances in preventing, detecting and curing diseases as well as for informed, evidence-based decisions to improve the accessibility, effectiveness and sustainability of the healthcare systems".[28] With an enhanced importance after the COVID-19 public health crisis, the EHDS intends to foster data access to individuals, researchers, policy makers and innovators. As referred in this Proposal, "EHDS will create a common space where natural persons can easily control their electronic health data. It will also make it possible for researchers, innovators and policy makers to use this electronic health data in a trusted and secure way that preserves privacy".[29]

The main objectives of the EHDS, besides the ones already mentioned, are to: (*i*) contribute to a single market for digital health products and services; (*ii*) support a harmonised and common EU approach to use of electronic health data, increasing the free movement of natural persons and promote the EU a global standard in digital health; (*iii*) encourage the exchange and access to different types of electronic health data (as health records and genomics data); and (*iv*) establish mechanisms for data altruism in the sector.[30]

To achieve these goals, the Proposal for the EHDS presents nine chapters, establishing rules, common standards, practices, infrastructures, and a governance framework, both for the primary use and the reuse of "*electronic health data*".

In the first chapter, the scope and subject matter are presented, as well as the definitions. In this regard, the broad concept of *"personal electronic health data"* must be highlighted, as it includes: "(…) personal data related to the physical or mental health of a natural person, including the provision of health care services, which

[28] Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space. Available at: https://eur-lex.europa.eu/resource.html?uri=cellar:dbfd8974--cb79-11ec-b6f4-01aa75ed71a1.0001.02/DOC_1&format=PDF.

[29] *Ibidem*.

[30] *Ibidem.*

reveal information about their health status, 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, as well as data determinants of health, such as behaviour, environmental, physical influences, medical care, social or educational factors (…) The electronic health data concern all categories of those data, irrespective to the fact that such data is provided by the data subject or other natural or legal persons, such as health professionals, or is processed in relation to a natural person's health or well-being and should also include inferred and derived data, such as diagnostics, tests and medical examinations, as well as data observed and recorded by automatic means."[31]. All these categories of data (among others) can be processed either for (*i*) primary use – the provision of healthcare services[32] – or for (*ii*) secondary use – the purposes foreseen in Art. 34 of the Proposal.

In more detail, the primary use can be considered as the process of data to support or provide direct healthcare to the data subject, while the secondary use (or reuse) will consist of the processing of personal or non-personal data, as part of aggregated datasets or not, for research, innovation, policy making, regulatory activities or other purposes.[33]

The following chapter sets out several obligations for healthcare professionals in relation to the electronic health data. In detail, professionals are obliged to: (*i*) have access to the electronic health data of the

[31] Recital 5 of the Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space. Available at: https://eur-lex.europa.eu/resource.html?uri=cellar:dbfd8974-cb79-11ec-b6f4-01aa75ed71a1.0001.02/DOC_1&format=PDF.

[32] Art. 2(2)(d) of the Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space. Available at: https://eur-lex.europa.eu/resource.html?uri=cellar:dbfd8974-cb79-11ec-b6f4-01aa75ed71a1.0001.02/DOC_1&format=PDF.

[33] MARCUS, J Scott; MARTENS, Bertin; CARUGATI, Christophe; BUCHER, Anne; GODLOVITCH, Ilsa; "The European Health Data Space – Study requested by the ITRE Committee", 2022. Available at: https://www.europarl.europa.eu/RegData/etudes/STUD/2022/740054/IPOL_STU(2022)740054_EN.pdf.

patient, independent of the Member State; and (*ii*) ensure the update of the information in relation to their patients.

Furthermore, this second chapter also focus on the rights of data subjects, broadening the scope of the right to data portability, foreseen in Art. 20 of the General Data Protection Regulation ("GDPR").[34] Data portability under the GDPR consists of the right of the data subject to receive the personal data provided to the controller, as long as the processing is based on the data subject's consent or needed for the performance of a contract or for pre-contractual diligence, and only if the processing is carried out by automated means.[35] As it can be understood, the data portability right is subject to strong legal requirements under the GDPR, which are considerably reduced by the Proposal for the EHDS.

As referred in Recital 11 of the Proposal, portability under the EHDS lowers the obstacles regarding:[36] (*i*) the legal ground for processing that allows a portability request. In this case for instance, the processing can occur on the basis of compliance with a legal obligation; (*ii*) the categories of data that can be requested as to cover not only personal data directed provided to the controller by the data subject, but also inferred and indirect data; and (*iii*) the obligations of interoperability. Under the GDPR, controllers shall transmit the data when technically feasible, while under the EHDS Proposal, such technical feasibility is mandatory.

Under Art. 3(1) and 3(2) of the Proposal, all natural persons shall have the right to access and to receive an electronic copy of the electronic health data processed for primary use (the technical specifications

[34] 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). Available at: https://eur-lex.europa.eu/eli/reg/2016/679/oj.

[35] Art. 20 of GDPR.

[36] MARCUS, J Scott; MARTENS, Bertin; CARUGATI, Christophe; BUCHER, Anne; GODLOVITCH, Ilsa; "The European Health Data Space – Study requested by the ITRE Committee", 2022. Available at: https://www.europarl.europa.eu/RegData/etudes/STUD/2022/740054/IPOL_STU(2022)740054_EN.pdf.

of the format of transmission is still to be determined by the Commission).[37] Furthermore, data subjects can also request the transmission of such data to a recipient of their choice, from the health or social security sector, "immediately, free of charge and without hindrance".[38]

Moreover, the chapter also foresees the creation of a digital health authority, which is entrusted, amongst others, with the implementation of the rights and obligations provided in the Proposal.[39] Interestingly, data subjects will also be entitled to complain to such authority, which then it shall be able to communicate with the relevant national data protection authority, if necessary, when the matter in discussion regards the protection of personal data.

Lastly, the second chapter addresses the creation of the cross-border infrastructure – MyHealth@EU – that will facilitate the exchange of the electronic health data between contact points that are nationally defined.[40] For this purpose, the Proposal establishes that in what regards this structure, the national contact points are to be qualified as joint controllers (meaning both will define together the purposes and essential means for the personal data processing), and the Commission shall be qualified as a processor (processing the personal data on the behalf of the national contact points).

Moving on to chapter three, its provision outline an essential framework for the success of the EHDS, establishing the desired interoperability and security requirements applicable to the electronic health

[37] Art. 6(1) of the Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space. Available at: https://eur-lex.europa.eu/resource.html?uri=cellar:dbfd8974-cb79-11ec-b6f4-01aa75ed71a1.0001.02/DOC_1&format=PDF.

[38] Art. 3(8) of the Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space. Available at: https://eur-lex.europa.eu/resource.html?uri=cellar:dbfd8974-cb79-11ec-b6f4-01aa75ed71a1.0001.02/DOC_1&format=PDF.

[39] Art. 10 of the Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space. Available at: https://eur-lex.europa.eu/resource.html?uri=cellar:dbfd8974-cb79-11ec-b6f4-01aa75ed71a1.0001.02/DOC_1&format=PDF.

[40] Art. 12 of the Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space. Available at: https://eur-lex.europa.eu/resource.html?uri=cellar:dbfd8974-cb79-11ec-b6f4-01aa75ed71a1.0001.02/DOC_1&format=PDF.

records systems ("EHR Systems"). Only through such requirements it is possible to ensure the efficient data sharing amongst the different systems. In this regard, the subjective scope of the chapter is mostly directed to the providers of such systems instead of the health professionals that were targeted in the previous subdivision. The Proposal's framework is mostly based on self-certification and compliance obligations for the manufacturers of EHR Systems, entrusting the oversight to the newly created market surveillance authorities, which will have the powers to oblige a certain provider to bring a system into conformity with the applicable requirements. These authorities will also be responsible for red flagging any EHR Systems which present a risk to the health or safety of natural persons or to the public interest. In addition, this chapter also provides a framework for wellness applications – which is defined as an "(…) appliance or software intended by the manufacturer to be used by a natural person for processing electronic health data for other purposes than healthcare, such as well-being and pursuing healthy life-styles" – that wish to be interoperable with the EHR Systems, regulating the use of a label for that end, issued by the manufacturer of the application. Both the EHR Systems and the wellness apps are subject to registration in the EU database.[41]

As for the fourth chapter, it is dedicated to the secondary use of electronic health data, establishing the minimum categories of data that can be reused, as well as permitted and prohibited purposes of such reutilisation. Furthermore, the chapter also provides a governance model for the secondary use, creating a health data access body which is responsible for granting the access to the data recipient entities, subject to a fee. However, these bodies are also subject to transparency measures towards data subjects, as they shall make publicly available, amongst other information, the legal basis for granting access, the security measures put in place to protect the data and the rights of the data

[41] Art. 32(2) of the Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space. Available at: https://eur-lex.europa.eu/resource.html?uri=cellar:dbfd8974-cb79-11ec-b6f4-01aa75ed71a1.0001.02/DOC_1&format=PDF.

subjects. However, and surprisingly, these bodies do not have to comply with Art. 14 of the GDPR, thus, they do not have to inform the data subjects regarding the personal data they are receiving and sharing, as well as about the terms of the processing.

Naturally, the chapter establishes obligations towards the data holders and data recipients. In relation to the first, the obligations mainly focus on data quality and on ensuring the good faith of the *"data providers*". In relation to the latter, data recipients must prepare the application for access, including pointing out the legal grounds for processing, when needed. In this regard, also the secondary use occurring cross-borders, through the HealthData@EU infrastructure – created specifically for this purpose – and mediated by the national contact points is regulated.

In a nutshell, the process for the reuse of electronic health data will consist of:

(*i*) the entity offering healthcare services that is a holder of electronic health data will have the obligation to provide information regarding these data to the national entity acting as a health data access body;

(*ii*) the national entity will aggregate, compile and publicize a dataset catalogue that will describe the source and nature of the electronic health data, as well as the requirements of access;

(*iii*) any natural or legal person can submit an application to the national entity, requiring access to the dataset; and

(*iv*) if the conditions are fulfilled, the data permit shall be granted, in such terms that the national entity and the data user (the entity accessing the data) will be considered joint controllers, for the purposes of the GDPR.[42]

Chapter five plays a critical role in the current globalized world, as it establishes the rules governing the transfer of personal and

[42] TERZIS, Petros; "Compromises and Asymmetries in the European Health Data Space"; *European Journal of Health Law*; 29; 2022; page 1 to 19.

non-personal electronic health data to third countries. Although the transmission of personal data to third countries presents greater legal challenges due to heavy regulation in the GDPR, the transmission of non-personal data under the Proposal is also severely restricted. The primary concern is to ensure that non-personal data cannot be relinked to a specific individual, ensuring that any anonymization techniques employed are pre-approved by the Commission. Additionally, Member States are authorized to introduce further impediments to the transfer of personal data to third countries, as stipulated in Art. 9(4) of the GDPR.

The sixth chapter establishes the EHDS Board, an entity that shall facilitate the cooperation and exchange of information among Member States; while chapters seven[43], eight[44] and nine[45] deal with miscellaneous legal topics that notwithstanding their importance, are not that relevant for the present analysis.

Overall, the formula proposed by the Commission's for the EHDS is coherently structured, notwithstanding the challenges that are posed by the Data Spaces in general and to the one dedicated to the health sector in particular, resulting from the particular sensitive nature of health and health-related data.

3. The complications

As anticipated in the previous sections, the European Data Spaces face multiple challenges: technical (as the sharing design and the security of the infrastructure); business and organisational (as the dynamic

[43] This chapter concerns the delegation of powers to be conferred to the Commission, regarding specific matters that will be further regulated in the future.

[44] This chapter details that the rules on the penalties to be applied under the future Regulation are to be determined by Member States. Additionally, it also foresees an evaluation and review process, after 5 and 7 years of the entrance into force.

[45] Chapter ten details the deferred application, as not all the provisions of the Regulation would enter into force at the same time, in accordance with the Proposal.

ecosystem and skills and the trust in the information which is made available); as well as national and regional obstacles (based on local resistance to change and different workforce skills).[46] As highlighted by the European Economic and Social Committee: *"[The EESC]* calls on the Commission to clearly reflect on the pros and cons of the initiative to reduce the risks before moving forward. One must realise that there are too many challenges ahead when we talk about the Member States' health systems. There are different paces, different views about public and private health systems and citizens must realise that this proposal means investment and public policy choices*"*.[47]

Naturally, as it is possible to understand from the Proposal of the EHDS, the legal issues arising from such a disruptive initiative are multiple. More specifically, the compatibility between the obligations and rights arising from the Proposal and the legal regime applicable to data protection is particularly interesting, due to: (*i)* the strict obligations established under the GDPR for the processing of personal data; (*ii*) the conservative approach that multiple national data protection authorities have been following; and (*iii*) the fact that "electronic health data" will mostly consist, as it can be anticipated, of health and genetic data, which are special categories of personal data, that shall not be processed unless one of the (stringent) exceptions of Art. 9 of the GDPR apply. Thus, even though the Explanatory Memorandum of the Proposal claims that *"*Considering that a substantial amount of electronic data to be accessed in the EHDS are personal health data relating to natural persons in the EU, the proposal is designed in full compliance (…) with the GDPR (…)*"*, it is possible to highlight several pertinent inconsistencies and obstacles.

The first challenge is the one stemming from Art. 51 of the Proposal and is posed by the qualification of national body controlling the access

[46] CURRY, Edward; SCERRI, Simon; TUIKKA, Tuomo; *Data Spaces – Design Deployment and Future Directions*, Springer, 2022.

[47] European Economic and Social Committee; Opinion of the European Economic and Social Committee on the Communication from the Commission to the European Parliament and the Council – A European Health Data Space: harnessing the power of health data for people, patients and innovation; COM(2022) 196 final; 21 December 2022.

to health data and data users as joint controllers for secondary use. First of all, the qualification of the parties involved in a data processing activity should be determined considering the facts and the effective control over the decisions underlying the processing.[48] Even though one can also argue that such control can be inferred or directly established in legal provisions (as it would be the case), a relationship between joint controllers has multiple consequences which can hinder the goals of the EHDS. Firstly, joint controllers shall determine and agree on the terms that rule their relationship,[49] especially regarding the data subjects' rights and the provision of information under Art. 13 and Art. 14 of the GDPR. This document has not been drafted yet.[50] However, its scope cannot prejudice the data users' interests, an aspect that would prove particularly challenging, since one of the controllers is a public entity. Secondly, national authorities are not bound by the roles attributed to each joint controller under the referred agreement.[51] Concomitantly, there is a risk that different national data protection authorities may have different deliberations in this matter, undermining the harmonised approach and EU-wide data-agile objective of the EHDS. This risk may be further aggravated considering that specific measures in relation to the health and health-related data may be in place subject to sector--specific national laws as well as due to possible specific provisions included in the GDPR national implementation laws.[52] The fact that

[48] European Data Protection Board; Guidelines 07/2020 on the concepts of controller and processor in the GDPR; 2 September 2020; Available at: https://edpb.europa.eu/sites/default/files/consultation/edpb_guidelines_202007_controllerprocessor_en.pdf.

[49] Art. 25 of 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). Available at: https://eur-lex.europa.eu/eli/reg/2016/679/oj.

[50] Art. 51(2) of the Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space. Available at: https://eur-lex.europa.eu/resource.html?uri=cellar:dbfd8974-cb79-11ec-b6f4-01aa75ed71a1.0001.02/DOC_1&format=PDF.

[51] European Data Protection Board; Guidelines 07/2020 on the concepts of controller and processor in the GDPR; 2 September 2020; Available at: https://edpb.europa.eu/sites/default/files/consultation/edpb_guidelines_202007_controllerprocessor_en.pdf.

[52] For instance, this is the case in Portugal were specific technical and organisational measures are posed in Art. 29 of Law 58/2019 of 8 August, and Law 12/2005 of 26 January, as amended.

each of the joint controllers is also liable for the activities of the other controller[53] may also present high risk to entities who could be potentially interested in reusing the data, especially due to the volume and sensitivity of the personal data processed in this context.

In light of the above, it is also relevant to highlight the lawful bases for processing of personal data that can be used under the EHDS Proposal, in particular for the secondary use. In accordance with Recital 37, a data user will request access to the electronic health data (when applying for a permit) based on Art. 6(1)(e) or Art. 6(1)(f) of the GDPR, thus, either considering that processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller; or that processing is necessary for the purposes of the legitimate interests pursued by the controller or by a third party, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal data.

In what regards the first lawful basis, it is doubtful if it is applicable to private entities that do not have public authority powers. In this regard, it should be noted that that it is the prevailing opinion that *"*Article 6(1)(e) deals with data protection in the context of the performance of intrinsically state or public functions *(...)"*[54], and as such it has an extremely reduced scope. Following the case law of the Court of Justice of the European Union, the processing has to be necessary in the sense that it should facilitate activities that are foreseen in the law, in the public interest.[55] Therefore, data users should rely mainly on Article 6(1)(f) GDPR for the processing of personal data in this context. This

[53] MILLARD, Christopher; KAMARINOU, Dimitra; "Article 26 – Joint Controllers"; *The EU Data Protection Regulation – A Commentary;* Oxford University Press; 2020; pages 582 to 588.

[54] KOTSCHY, Waltraut; "Article 6 – Lawfulness of Processing"; *The EU Data Protection Regulation – A Commentary;* Oxford University Press; 2020; pages 321 to 344.

[55] Court of Justice of the European Union, Case C-524/06, REFERENCE for a preliminary ruling under Article 234 EC from the Oberverwaltungsgericht für das Land Nordrhein-Westfalen (Germany), made by decision of 15 December 2006, received at the Court on 28 December 2006; Heinz Huber v Bundesrepublik Deutschland; 16 December 2008.

will pose many obstacles to the flexible and easy process that underlined the draft of the EHDS Proposal. More specifically, a balancing exercise that must be performed by the data controller before the beginning of the processing activity. Notwithstanding Recital 37 of the Proposal establishes that "If the lawful ground for processing by the user is Art. 6(1), point (f), of Regulation (EU) 2016/679, in this case it is this Regulation that provides the safeguards.". However, this statement does not appear sufficient in fulfilling the balancing obligation, since it does not provide any guidance regarding the obligation of carrying a balancing test. It should be noted that such test must be tailor-made to the processing activity evaluated and should be documented by the controller. In particular, the balancing test should take into account:[56] (*i*) an assessment of the legitimacy of the interest of the controller which in this case and considering the purpose limitation for reuse of the electronic health data[57] may be possible; (*ii*) an assessment on the impact of the processing activities for the data subjects which can be particularly difficult to establish for secondary use, especially considering the amount of personal data processed and the sensitivity of the health and health-related data which is required; (*iii*) a provisional balance; and (*iv*) additional safeguards applied to mitigate the impact for data subjects. Therefore, such exercise may create an additional compliance obstacle to the secondary use provided in the EDHS Proposal.

The second problem posed with using Art. 6(1)(f) as a lawful basis for the processing related to the right to object, established in Art. 21 GDPR (which applies when the legal ground for processing is either line (e) or (f) of Art. 6). The data subjects must be able to object to the processing activity that may only continue if the data controller is able

[56] Article 29 Data Protection Working Party; Opinion 06/2014 on the notion of legitimate interests of the data controller under Article 7 of Directive 95/46/EC; 9 April 2014. Available at: https://ec.europa.eu/justice/article-29/documentation/opinion-recommendation/files/2014/wp217_en.pdf.

[57] As detailed before, the EHDS Proposal determines the purposes that can be pursued by electronic health data reutilisation, under Art. 34(1).

to demonstrate compelling legitimate grounds for the processing which override the interests, rights, and freedoms of the data subject or for the establishment, exercise, or defence of legal claims. However, the data subjects will not be informed by the data access body of the processing activity under Art. 38(2) of the Proposal (which exempts these entities of the obligation to inform) and the data user may not be able to provide the required information (which would also be exempt under Art. 14(5)(b) GDPR). This means that the data subjects may lose power over their personal data, in such way that is inconsistent with the GDPR.[58]

Furthermore, besides the legal ground for processing, there is also a challenge in the restrictions established in Art. 9 GDPR. In accordance with this Article, special categories of personal data – as health data – shall not be processed, unless one of the conditions foreseen in Art. 9(2) GDPR applies. In this regard, the Proposal lists several exclusions that may be appropriate in the context of EDHS.[59] Firstly, Art. 9(2)(g) GDPR applies when processing is necessary for reasons of substantial public interest as long as it is based in law and that such law is proportionate for the specific purposes pursued while respecting the right to data protection and providing suitable and specific measures to safeguard the fundamental rights and the interests of the data subject. To be able to use such exception for secondary use, the data user will be required to perform a balancing test, between the substantial public interest pursued and the risks for data subjects. Such analysis is not carried in the Proposal. Thus, it will be up to each data user to perform it.

The second exception listed is Art. 9(2)(h) allows processing of special categories of data, if necessary, for the purposes of preventive

[58] As noted by the European Data Protection Board and the European Data Protection Supervisor in their Joint Opinion 03/2022 on the Proposal for a Regulation on the European Health Data Space, 12 July 2022, available at https://edpb.europa.eu/system/files/2022-07/edpb_edps_jointopinion_202203_europeanhealthdataspace_en.pdf, in some topics the Proposal weakens the protection of the rights to privacy and data protection.

[59] Recital 37 of the Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space. Available at: https://eur-lex.europa.eu/resource.html?uri=cellar:dbfd8974-cb79-11ec-b6f4-01aa75ed71a1.0001.02/DOC_1&format=PDF.

or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems and services on the basis of law or pursuant to contract with a health professional. This exception will certainly be extremely useful for processing for the primary use of health data. However, this exception may not always be applicable for secondary use.

Furthermore, the third listed exception mentioned in Art. 9(2)(i) GDPR is probably the most useful for secondary uses. This exception allows the processing of health data, if necessary, for reasons of public interest in the area of public health, for instance to fight serious cross-border threats to health or to ensure high standards of quality and safety of health care and of medicinal products or devices on the basis of law, provided that such law offers suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy. Nonetheless, it is doubtful whether the Proposal is a sufficient basis to trigger the application of this exception, especially considering the strict interpretation of this Article and the lack of clarity of the Proposal to this effect.

Lastly, the fourth and last exception to be taken into consideration is Art. 9(2)(j), allowing processing, if necessary, for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Art. 89(1) GDPR, based on law and provided that it is proportionate for the objectives pursued and as long as it provides for safeguards to the fundamental rights and the interests of the data subject, including data protection. Once again, the text of the Proposal will have to pass the strict test of the legal interpretation. Even if such test is successfully passed, this exception will serve innovators and researchers, however, it may be difficult to apply to commercial entities, in general.

Naturally, and even though the European Data Protection Board ("EDPB") and the European Data Protection Supervisory ("EDPS") have correctly stated that several of the permitted purposes for the

secondary use are included in one of the mentioned exceptions,[60] such exclusions must be interpreted objectively and narrowly. As such, additional difficulty and risks for data users arise. For instance, the use of secondary health data for training AI systems by commercial and profit-seeking entities[61] will be difficult to frame within the mentioned exceptions.

Furthermore, it should be noted that the Proposal does not oblige the data user to disclose to the national data access body what is the exception under Art. 9(2) of the GDPR it is relying on for the processing. Considering the sensitivity of the data reuse and following the same rationale that obliges the data user to disclose the legal ground of Art. 6 GDPR in the data permit application, the exception in which the data user is relying when requiring access to personal health data (or to other special categories of data) shall also be disclosed to and taken into consideration by the national data access body when deciding to grant, or not, the permit.[62]

Another important data protection topic impacted by the Proposal for the EHDS related to the data subjects' information rights. As established in Art. 38(2) of the Proposal, the national data access bodies are not obliged to provide the information foreseen in Art. 14(1) GDPR to data subjects in what regards the use of their data for projects subject to a data permit. This means that, in practice, data subjects will not be informed of the processing of their sensitive personal data, since data users will, most likely, rely on the exception foreseen in Art. 14(5)(b)

[60] European Data Protection Board and the European Data Protection Supervisor in their Joint Opinion 03/2022 on the Proposal for a Regulation on the European Health Data Space, 12 July 2022, available at https://edpb.europa.eu/system/files/202207/edpb_edps_jointopinion_202203_europeanhealthdataspace_en.pdf.

[61] As foreseen in Art. 34(1)(g) of the Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space. Available at: https://eur-lex.europa.eu/resource.html?uri=cellar:dbfd8974-cb79-11ec-b6f4-01aa75ed71a1.0001.02/DOC_1&format=PDF.

[62] European Data Protection Board and the European Data Protection Supervisor in their Joint Opinion 03/2022 on the Proposal for a Regulation on the European Health Data Space, 12 July 2022, available at https://edpb.europa.eu/system/files/202207/edpb_edps_jointopinion_202203_europeanhealthdataspace_en.pdf.

GDPR, due to the absence of a method to inform these data subjects and because the process for notifying the data subject would be disproportionally difficult. As the EDPB and the EDPS have mentioned, this derogation undermines the powers of the data subjects.[63] Furthermore, it is not clear, and the Proposal does not address this matter, if such derogation is indeed necessary and proportionate for the purposes of the Proposal.

Finally, there are multiple challenges that will be posed at a national level, in particularly due to: (*i*) national laws and specific provisions applicable to the processing of health and health-related data; and (*ii*) the relationship between the national authorities and bodies involved in the EHDS. In what regards the first point, the GDPR specifically foresees, in Art. 9(4), that Member States are free to introduce additional conditions and restrictions to the processing of health data. Naturally, considering that there is some fragmentation already in this regard from a GDPR perspective, further tension is expected with Proposal for the EHDS.[64] Such fragmentation in implementation may also hinder the objectives of the cross-border infrastructures foreseen in the Proposal (as MyHealth@EU and HealthData@EU). In what regards the relationships among different national bodies and authorities, the Proposal foresees the creation of national digital health authorities, market surveillance authorities and health data access bodies, that will have to coexist with the national data protection authorities (among others that exist to regulate and supervise the health sector). The potential overlap of functions and inconsistencies amongst these entities and the possible tensions in their relationship with the various relevant stakeholders will be an additional challenge, aggravated by the possible fragmentation amongst the different Member States substantially hindering the objectives of the EHDS.

[63] *Ibidem.*
[64] *Ibidem.*

4. A Full Recovery?

The EHDS, as presented, has undoubtedly merit and may significantly contribute in boosting the competitiveness of the EU data-driven and technology economy, by addressing:[65] (*i*) the increased focus on public health, particularly due to the COVID-19 crisis; (*ii*) the desire to expand data subject's rights in the health sector, taking into account the limitations still applicable under the GDPR; (*iii*) the necessity of making a large volume of data available for commercial and non-commercial purposes, especially for AI training; and (*iv*) the fact that voluntary--based programs were insufficient to promote the data-agile economy in the sector.

Moreover, the EHDS represents the first attempt to establish a European framework for the secondary use of health data.[66] It imposes obligations on healthcare providers and EHR Systems to contribute and collaborate towards this goal, and as such significantly departing from other voluntary initiatives.[67]Despite the potential benefits and positive outcomes of the EHDS, the Proposal still presents legal challenges, as outlined above. One of the main obstacles in reusing electronic health data is establishing the legal basis for processing such data, particularly regarding the balancing test required when basing data processing on the controller's legitimate interests. Additionally, Art. 9 of the GDPR presents difficulties for processing activities that underpin each of the permitted purposes of secondary use. These issues, although not addressed currently in the Proposal, can still be addressed in its final text by including further details on the applicability of the exceptions listed in Art. 9(2) of the GDPR and on the obligation of the data users

[65] MARCUS, J Scott; MARTENS, Bertin; CARUGATI, Christophe; BUCHER, Anne; GODLOVITCH, Ilsa; "The European Health Data Space – Study requested by the ITRE Committee", 2022. Available at: https://www.europarl.europa.eu/RegData/etudes/STUD/2022/740054/IPOL_STU(2022)740054_EN.pdf

[66] TERZIS, Petros; "Compromises and Asymmetries in the European Health Data Space"; *European Journal of Health Law*; 29; 2022; page 1 to 19.

[67] *Ibidem.*

to inform the national data access bodies of the applicable condition.[68] This will ensure that the legal provisions of the Proposal meet the requirements established in Art. 9 (2): (*i*) proportionality when considering the objectives pursued, (*ii*) respect of the data protection right, and (*iii*) appropriate and specific measures to safeguard the fundamental rights and interests of the data subjects.

In addition to the challenges already mentioned, there are further legal obstacles that should be addressed to ensure the success of the EHDS. One of the main concerns is the derogation to the information obligations provided for in Art. 38(2) of the Proposal. To overcome this issue, alternative solutions such as limiting the derogation to specific situations or enhancing transparency obligations may be considered. Additionally, mechanisms to facilitate the exercise of the right of access under Art. 15 of the GDPR could be created to ensure data subjects have access to relevant information about the processing of their personal data.

Furthermore, it is crucial to establish a uniform understanding among all the national data protection supervisory authorities (existing and created based on EHDS) regarding the EHDS and its data protection implications to ensure its success. Uncertainty surrounding the approach of different authorities and possible fragmented implementation may deter data users from participating in the EHDS, ultimately hindering its goals, in particular due to the high fines that data users may face subject to the GDPR.

In conclusion, the legal obstacles and challenges presented in the EHDS Proposal must be addressed to create a better and more effective EHDS Regulation. Overcoming these obstacles will not only contribute to the success of the EHDS but also to the development of robust European Data Spaces, creating technological opportunities and

[68] As suggested by the EDPB and the EDPS, in European Data Protection Board and the European Data Protection Supervisor in their Joint Opinion 03/2022 on the Proposal for a Regulation on the European Health Data Space, 12 July 2022, available at https://edpb.europa.eu/system/files/202207/edpb_edps_jointopinion_202203_europeanhealthdataspace_en.pdf

offering a competitive advantage to EU companies, especially start-ups and SMEs in line with the EU´s strategic objectives.