Maastricht University

Institute for Transnational and Euregional cross border cooperation and Mobility / ITEM

Cross-Border Impact Assessment 2022

Dossier 1: European Health Data Space: Ex-ante analysis of the cross-border effects on the Euregio Meuse-Rhine

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Dossier 1: European Health Data Space – Ex ante analysis of the cross-border effects on the Euregio Meuse-Rhine

Joint research collaboration with Care and Public Health Research Institute (CAPHRI)

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ITEM is an initiative of Maastricht University (UM), the Dutch Centre of Expertise on Demographic Changes (NEIMED), Zuyd University of Applied Sciences, the City of Maastricht, the Euregio Meuse-Rhine (EMR), and the Dutch Province of Limburg

Contents

Abbreviations

CBS	Centraal Bureau voor de Statistiek
EC	European Commission
EPD	Elektronisch patiëntendossier
EHDS	European Health Data Space
EU	European Union
EMR	Euregio Meuse-Rhine
GDPR	General Data Protection Regulation
GGD	Gemeentelijke gezondheidsdienst
GP	General practitioner
TEU	Treaty on European Union
TFEU	Treaty on the Functioning of the European Union

1. Introduction & Method

Sharing health data has an extra dimension in border regions such as the Euregio Meuse-Rhine, where individuals, healthcare professionals and healthcare services move across the border more frequently[1] and collaborations between healthcare institutions from two or more countries are more frequent. For instance, the university hospitals in Aachen and Maastricht have longstanding collaborations[2] and currently intend to cooperate with the university clinic in Liege more closely in paediatric surgery. In order to ensure quality and continuity of care, it is crucial that healthcare professionals can access the medical data of their patients.[3] Data is also essential in the provision of digital health services. One example is the cooperation between the university hospitals of Maastricht and Aachen on large vessel surgery, where surgeons operate on a patient at Aachen Hospital while a neurophysiologist in Maastricht monitors the patient's condition real-time from a distance.[4] In addition, health data is valuable for research, innovation and policymaking, particularly to strengthen the resilience of healthcare systems. Resilience is especially key in border regions with deteriorating socioeconomic conditions, a shorter life expectancy and an aging population.[5] Moreover, as the COVID-19 pandemic has demonstrated, health data also plays a crucial role in providing efficient crisis management in border regions. Indeed, the Euregio-Meuse Rhine was negatively affected by the lack of relevant cross-border data to ground policy decisions. The diverse monitoring systems on infection rates produced incompatible data, with each country applying its own definitions and indicators.[6] Although border closures as an *ad-hoc* crisis measure had a negative social and economic impact on the region, they were found to have no impact on infection numbers.[7]

The fragmented standards and specifications for storing and sharing data, legal and administrative rules, insecurity about the application of data-protection provisions and limited interoperability pose obstacles to the exchange of health data.[8] The European Commission addressed this issue at EU level in 2020 within the context of the European Strategy for Data, which was the first attempt to create *Common European data spaces*. With these data spaces, the EU intends to establish a single market

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[1] 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, p. 2.

[2] IA. Glinos, N Doering and H Maarse Local roots, European dreams: evolution of the Maastricht–Aachen university hospital collaboration (the Netherlands–Germany) (2013) in Hospitals and Borders Seven case studies on cross-border collaboration and health system interactions IA. Glinos and M Wismar (eds.) World Health Organization

[3] Find more at https://www.maastrichtuniversity.nl/research/item/research/euregional-centre-for-paediatric-surgery, Prof. dr. H. Schneider, Dr. N. Büttgen, Dr. L. Kortese R. Tans, LL.M. M. Unfried, M.A., 'De Weg Vrijmaken voor een Euregionaal Kinderchirurgisch Centrum Toekomstbestendige Grensoverschrijdende Zorgsamenwerking in de Euregio MaasRijn' October 2020.

[4] European Commission, Directorate-General for Health and Food Safety, Lupiáñez-Villanueva, F., Gunderson, L., Vitiello, S., et al., Study on health data, digital health and artificial intelligence in healthcare, Publications Office of the European Union, 2022, https://data.europa.eu/doi/10.2875/702007.

[5] For instance, see ITEM Cross-Border Impact Assessment 2021 Dossier 4: "Is the EU Patient's Rights Directive fit for providing well-functioning healthcare in cross-border regions? An ex-post assessment", European Commission, 'Boosting growth and cohesion in EU border regions' {SWD(2017) 307 final, p. 4.

[6] Covid-19 Crisis-management in the Euroregion Meuse-Rhine: Study on lessons learned of cross border cooperation in the field of healthcare during the Pandemic crisis (PANDEMRIC, 2021), retrieved via: https://pandemric.info/wp3-studies-and-legal-advice/.

[7] See for instance, *Onderzoek: Sluiten van grens had geen effect op coronapandemie en was vooral voor de bühne,* retrieved via https://www.gelderlander.nl/home/onderzoek-sluiten-van-grens-had-geen-effect-op-coronapandemie-en-was-vooral-voor-de-buhne~a1d73d08/.

[8] See: EUHealthSupport consortium (2021), Assessment of the EU Member States' rules on health data in the light of GDPR, https://ec.europa.eu/health/ehealth/key_documents_en#anchor1.

for data, in which data can freely flow within the EU and across sectors for the benefit of businesses, researchers and public administrations.[9] In light of the European Commission's priorities in the areas of health and building the European Health Union[10], the European Commission published a proposal for Regulation on European Health Data Space ('EHDS') on 3 May 2022 as the first of these data spaces. The proposal addresses health-specific obstacles to electronic health-data access and sharing and advances the development of a digital health single market. The purpose of the Regulation is to facilitate a more secure and safe exchange of health data without barriers.[11] The European Health Data Space intends to support the work of European Health Emergency Preparedness and Response Authority (HERA)[12], the Europe's Beating Cancer Plan[13], and the Pharmaceutical Strategy for Europe.[14] Moreover, the proposal also emphasises the importance of well-functioning health-data exchange in cross-border regions[15], allowing the exploration of the potential of cross-border regions as pilot regions for innovative solutions to European integration, as suggested in the Commission report "EU Border Regions: Living labs of European integration" [16].[17]

Under the themes of European Integration, Sustainable and Socio-economic Development and Euregional Cohesion (see Table 1), this dossier aims to analyse by means of an *ex-ante* assessment the possible effects of the proposed Regulation on the European Health Data Space on the Euregio Meuse-Rhine (EMR). This dossier provides an overview of the EU proposal and, through a literature review and interviews, evaluates the current practices of health-data exchange within national borders, as well as in the cross-border EMR context. Based on these findings, the dossier provides conclusions as to the potential effects of the European Health Data Space on the EMR from a border-regional perspective.

[9] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, "A European strategy for data" COM(2020) 66 final.
[10] Communication from the Commission to the European parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, "Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats" COM(2020) 724 final.
[11] Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space, COM(2022) 197 final.
[12] See more at https://ec.europa.eu/info/departments/health-emergency-preparedness-and-response-authority_en.
[13] Communication from the commission to the European Parliament and the Council, 'Europe's Beating Cancer Plan'.
[14] Communication from the commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, 'Pharmaceutical Strategy for Europe' COM/2020/761 final.
[15] Recital 24: "Access to and transmission of electronic health data is relevant in cross-border healthcare situations, as it may support continuity of healthcare when natural persons travel to other Member States or change their place of residence. Continuity of care and rapid access to personal electronic health data is even more important for residents in border regions, crossing the border frequently to get health care. In many border regions, some specialised health care services may be available closer across the border rather than in the same Member State […]"
[16] Report from the commission to the european parliament, the council, the european economic and social committee and the committee of the regions eu border regions: 'Living labs of European integration', COM(2021) 393 final.
[17] Explanatory memorandum, Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space, COM(2022) 197 final.

1.1 Research themes, definitions and demarcation

Ex-ante evaluation

This dossier will contribute to the 'ex-ante' mapping of potential cross-border effects of proposed policies and legislation, mainly those of the Regulation on the European Health Data Space. The Regulation dovetails with several other policy initiatives and legislative acts (at both EU and national levels[18]), but for the feasibility of this research, this dossier mainly explores the proposed legislation on the European Health Data Space.

Geographical demarcation

As regards the geographical delimitation of the analysis, this dossier focuses on identifying and analysing obstacles of health-data exchange in the Euregio Meuse-Rhine. Nevertheless, as the dossier examines an EU-level proposal, arguably some of the aspects of the dossier are also applicable to other (cross-border) regions within Belgium, Netherlands and Germany, as well as elsewhere in the EU. Also, some of the findings are applicable in a purely national context too. Due to the fact that the majority of interviews for this study was conducted with actors based in the south of the Netherlands, special emphasis is placed on health-data exchange from the perspective of that area.

[18] For instance, in the Netherlands see *Wet Elektronische Gegevensuitwisseling In de Zorg (Wegiz)*, that was recently (on 27 September 202) unanimously passed by the House of Representatives.

The Research Themes, Principles, Benchmarks and Indicators of the Dossier

Table 1: Research themes, principles, benchmarks, and indicators for assessing the cross-border effects of the proposed Regulation on European Health Data Space

Theme	Principles	Benchmarks	Indicator
European Integration	Public health Art. 168 TFEU Art. 35 EUCFR Free movement of patients Regulation 883/2004 Regulation 987/2009 Directive 2011/24 Data protection Article 16 TFEU General Data Protection Regulation (GDPR)	Health data is shared within the national borders, for both primary use (healthcare delivery) and secondary use (research and policy-making)	Is health data exchanged in cross-border situations? What are the current shortcomings and challenges in (cross-border) health-data exchange?
Sustainable Development/Socio-Economic Development	Internal market Art. 114 TFEU Free movement of services Art. 56 TFEU	Well-functioning healthcare in border regions from the aspects of economic, social, and territorial development and sustainability	Could the proposed European Health Data Space solve the challenges of health-data exchange identified under the theme of European integration?
Euregional Cohesion	Strengthening economic, social and territorial cohesion Art. 174 TFEU Mutual assistance and cooperation between Member States Art. 4(3) TEU Art. 10 Directive 2011/24 Rec. 50 Directive 2011/24 Art. 76 Regulation 883/2004	Organisation of well-functioning healthcare provision and data exchange in border regions supported by cooperation of the regional actors Care in the cross-border territory is equal to that in the national territory	What are the benefits of the proposed European Health Data Space for border regions such as the Euregio Meuse-Rhine?

The dossier will first examine and provide a description of the key aspects of the proposed EU Regulation on the European Health Data Space. Secondly, the dossier will provide a rapid review of the academic literature, exploring what challenges were reported with regard to health-data exchanges, and how the initiative for an EHDS and Commission proposal has been received in the academic community. In the third section, the results of interviews will be presented. These results will explore the state of play of health-data exchange in the Euregio Meuse-Rhine from a practical point of view. Finally, these findings will be evaluated on the basis of the three research themes covered in this dossier. Under the theme **European Integration**, the dossier analyses the interview findings in light of the proposed EU Regulation on the European Health Data Space – evaluating the state of play and current obstacles on health-data exchange in a national and cross-border (EMR) setting. Under the theme of **Sustainable and Socio-economic Development**, the dossier attempts to answer whether these obstacles could be avoided or mitigated by the proposed Regulation. Finally, in the assessment

of **Euregional Cohesion**, the dossier examines the benefits of the European Health Data Space from a (cross-border) regional perspective.

2. Proposal Regulation on the European Health Data Space

2.1 Background

With the proposed Regulation on the European Health Data Space (EHDS), the EU intends to establish a common, trusted, and secure space where individuals have control over their electronic health data and where health data can be utilised for research, innovation, and policymaking. The proposal seeks to address the current barriers on health-data exchange in both national and cross-border contexts.

Although this dossier focuses solely on the EHDS, it is important to note that the Regulation is linked with other legal and policy initiatives. The EHDS supports and complements the General Data Protection Regulation (GDPR), the Data Governance Act[19], the Data Act[20], the Directive on security of network and information systems (NIS Directive)[21], the Medical Device Regulations[22] as well as the Artificial Intelligence Act[23] by specifying the rights and obligations regarding the use of electronic *health* data.[24]

The European Health Data Space is not the EU's first initiative involving electronic health data.[25] For instance, the 2011 Patients' Rights Directive (also known as the Cross-Border Healthcare Directive)[26] provides a voluntary eHealth network as a basis for an electronic health-data system.[27] As a result of the eHealth network's efforts, a platform called MyHealth@EU has been established, under which electronic prescriptions and patient summaries can be exchanged cross-borders. Nevertheless, due to the exact voluntary nature of this provision, its effectiveness has been rather limited. The uptake of this framework has been slow and, until now, it has only been (partially) implemented by 10 Member States,[28] not including the Netherlands, Germany or Belgium.[29] As will be discussed below, the EHDS Regulation proposes to make this infrastructure mandatory and extend it to other types of health data.

[19] 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).
[20] Data Act: Proposal for a Regulation on harmonised rules on fair access to and use of data.
[21] Directive (EU) 2016/1148 of the European Parliament and of the Council of 6 July 2016 concerning measures for a high common level of security of network and information systems across the Union.
[22] Regulation (EU) 2017/745 of the european parliament and of the council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.
[23] Proposal for a Regulation of The European Parliament and of the Council Laying Down Harmonised Rules On Artificial Intelligence (Artificial Intelligence Act) And Amending Certain Union Legislative Acts COM/2021/206 final.
[24] Article 1(4)-(5) Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space, COM(2022) 197 final.
[25] Another recent example of a mandatory framework introduced the EU-level is the EU Digital COVID Certificate adopted during the COVID-19 crisis, Adopted by Regulation 2021/953.
[26] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare OJ L 88, 4.4.2011, p. 45–65.
[27] *Ibid,* Article 14.
[28] Section 3 Proposal for a Regulation on the European Health Data Space COM/2022/197 final.
[29] Under the infrastructure of Myhealth@Eu, the Netherlands is only mentioned to able its doctors to access health data from Czech Republic, Portugal, and Luxembourg. Patient summaries or ePrescripions are not enabled for any of the three countries

Using the legal basis of the internal market (Art. 114 TFEU) and data protection (Art. 16 TFEU), the Regulation on European Health Data Space proposes a legal framework, common standards, a governance framework and a mandatory cross-border infrastructure for the use of electronic health data.[30] A distinction is made between primary and secondary use of such data. The Regulation refers to **primary use** when the data is used directly for providing healthcare at national and cross-border levels.[31] This also include data on prescriptions, dispensation and provision of medicinal products and medical devices, as well as data relevant for social-security, administrative or reimbursement services.[32] **Secondary use**, on the other hand, refers to situations where health data is used for research purposes, for instance to assess public health policies or to develop new medicines, medical devices or products.[33] This includes, for instance, data obtained from clinical trials, registries for medicinal products or medical devices, and data from biobanks.[34]

Table 2: The use of electronic health data as categorised by the proposed EHDS Regulation

Primary use of health data	Secondary use of health data
• Improve access to and control by persons over their personal electronic health data	• Rules on the use of health data for the benefit of society as a large: research, innovation, policy-making, statistics
• Sharing data with and among healthcare providers for treatment purposes	• Data stored in a closed, secure environment where non-personal data can be accessed via data permits (only for limited use)
• MyHealth@EU: central platform for digital health, facilitating exchange of health data between Member States	• HealthData@EU: platform that creates a link between national access points for the secondary use of electronic health data

2.2 Scope of the Regulation

Regarding its material scope, the Regulation applies to both personal and non-personal electronic health data. **Personal electronic health data** refers to health data, genetic data and biobank data, as well as data referring to determinants of health or data processed in relation to the provision of healthcare services.[35] Data that falls outside of the scope of personal data, is defined as **non-personal electronic health data**.[36]

under this infrastructure. See https://health.ec.europa.eu/ehealth-digital-health-and-care/electronic-cross-border-health-services_en.

[30] Articles 1(1)-(2) Proposal for a Regulation on the European Health Data Space COM/2022/197 final.

[31] *Ibid*, Chapter II.

[32] *Ibid,* Article 2(2)(d).

[33] *Ibid,* Chapter IV.

[34] *Ibid,* Article 33.

[35] *Ibid,* Article 2(2)(a).

[36] *Ibid,* Article 2(2)(b).

As to the geographical scope, the Regulation applies to data controllers and processors established in the EU who process electronic health data of EU citizens or third-country nationals legally residing in the EU[37], as well as to data users to whom health data is made available by data holders[38] in the EU.[39] The Regulation is also is applicable to third countries that are connected to or interoperable with the MyHealth@EU infrastructure (see Section 2.3).[40] Moreover, the Regulation applies to manufacturers and suppliers of electronic health record (EHR) systems[41] and wellness applications[42] brought to market in the EU, as well as the users of such products.[43]

2.3 Primary use of electronic health data

Rights in relation to personal electronic health data

Regarding primary use, the Regulation provides a set of rights and obligations for individuals (patients) and healthcare professionals in respect to the use of personal electronic health data.[44] Patients have the right to access their own health data in a readable, consolidated and accessible format.[45] This refers to the **European electronic health record exchange format,**[46] to be used and updated by health professionals in the course of treatment of their patients, irrespective of the Member State of affiliation and the Member State of treatment.[47] Patients have a right to transfer their data within and across national borders to their healthcare professional of choice immediately and free of charge.[48]

The Regulation proposes a priority list of data that must be made accessible and exchangeable first.[49] Priority categories of personal electronic health data consist of patient summaries, electronic prescriptions and dispensations, medical images and image reports, laboratory results and discharge reports.[50] Member States are only obliged to provide the personal electronic health data after the application of the Regulation in an electronic format, but the national authorities may also choose to let the requirement regarding these data take effect prior to this moment.[51]

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[37] *Ibid,* Article 1(3)(b).
[38] *Ibid,* Article 2(2)(y): 'Data holder' means any natural or legal person, which is an entity or a body in the health or care sector, or performing research in relation to these sectors, as well as Union institutions, bodies, offices and agencies who has the right or obligation, in accordance with this Regulation, applicable Union law or national legislation implementing Union law, or in the case of non-personal data, through control of the technical design of a product and related services, the ability to make available, including to register, provide, restrict access or exchange certain data.
[39] *Ibid,* Article 1(3)(d).
[40] *Ibid,* Article 1(3)(c).
[41] 'EHR system' (electronic health record system) means any appliance or software intended by the manufacturer to be used for storing, intermediating, importing, exporting, converting, editing or viewing electronic health records, Article 2(2)(n).
[42] *Ibid,* Article 2(2)(o): 'Wellness application' means any 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 lifestyles.
[43] *Ibid,* Article 1(3)(a).
[44] *Ibid,* Article 3.
[45] *Ibid,* Article 3(1).
[46] *Ibid,* Article 6. See also Commission Recommendation of 6.2.2019 on a European Electronic Health Record exchange format, C(2019) 800 final.
[47] *Ibid,* Article 4.
[48] *Ibid,* Article 3(8).
[49] *Ibid,* Article 3(2).
[50] *Ibid,* Article 5(1).
[51] *Ibid,* Article 3(4).

The access of health professionals to personal electronic health data is covered under Article 4. When data is stored in an electronic format, health professionals have access to the data of their patients,[52] at least to the priority categories of electronic health data.[53] However, patients may restrict the access to their health data, in which event the healthcare provider(s) may not access the content without the prior authorisation of the person concerned. Only when protecting the vital interest of a person may the healthcare provider(s) access these data without the patient's consent.[54]

Infrastructure and governance

To enable sharing of health data, the Regulation established common requirements and standards for interoperability, security, and privacy. Under the **European electronic health record exchange** format (EHRxF), the electronic health records contain specific datasets, coding systems and technical specifications, aiming for seamless exchange of records.[55] To satisfy interoperability and security requirements, electronic health-record systems are subject to standardisation and mandatory certification. Manufacturers of wellness applications are given the option to apply for a label on a voluntary basis if they seek to claim interoperability with electronic health-record systems.[56]

Regarding telemedicine services, if a Member State accepts the provision of such services, it must, under same conditions, accept the provision of services of the same type by healthcare providers located in other Member States.[57] With the aim of facilitating transferability of electronic health data in a cross-border context, such telemedicine services or other personal health-data-access services may be accessed by electronical identification means, in accordance with Regulation 910/2014 (EIDAS). Such a **cross-border identification and authentication mechanism** will be implemented by the digital health authorities and the Commission, at both the levels of the Member States and the European Union.[58]

A central platform called **MyHealth@EU** will facilitate the cross-border exchange of electronic health data for primary use.[59] This platform is already in use in some countries for prescriptions and patient summaries, but with this proposal, the EU seeks to make it mandatory and extend its use to other personal health data, such as discharge reports and medical images. The Member States are expected to have implemented the platform by 2025.[60]

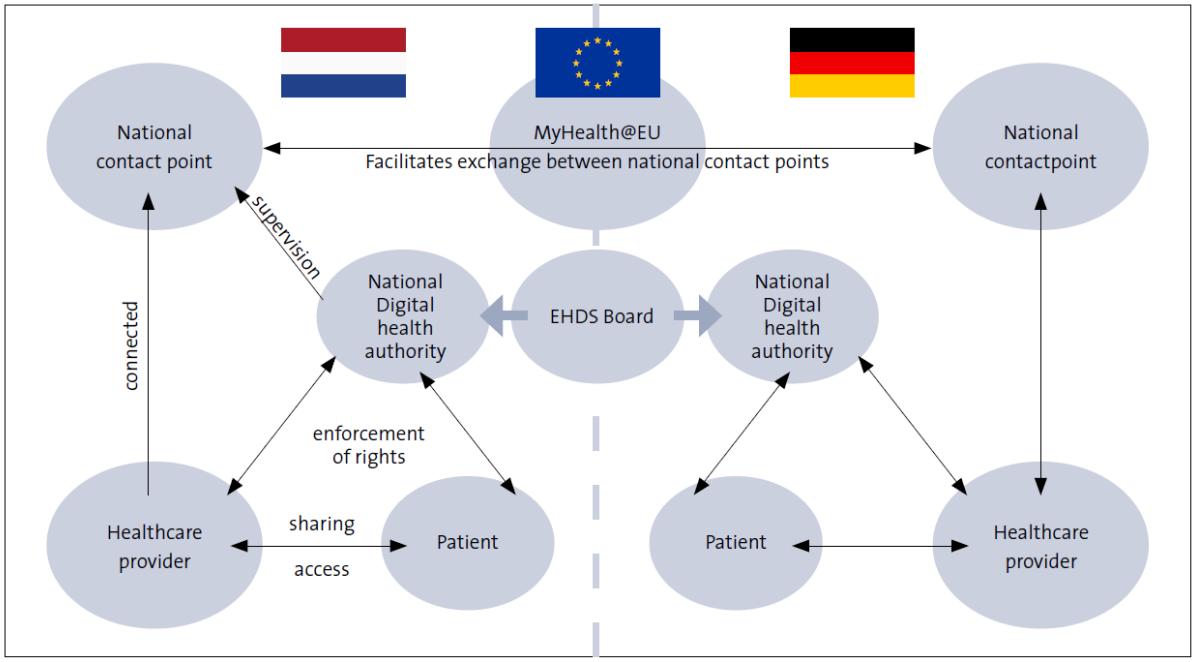
It is important to note that the Regulation does not propose a centralised European database, but rather the exchange of personal health data via **national contact points**, which currently exist on a voluntary basis under the eHealth network. Healthcare providers are directly connected to the national contact points. Pharmacies, for instance, may share and access e-prescriptions via these contact points.[61] MyHealth@EU may also be used to provide supplementary services, for instance exchange

[52] *Ibid,* Article 4(1).
[53] *Ibid,* Article 4(3).
[54] *Ibid,* Article 4(4).
[55] *Ibid,* Article 6.
[56] *Ibid,* Article 30.
[57] *Ibid,* Article 8.
[58] *Ibid,* Article 9.
[59] *Ibid,* Article 12.
[60] *Ibid,* S.3 Explanatory Memorandum.
[61] *Ibid,* Article 12.

and verification of health certificates, such as vaccination certificates.[62] MyHealth@EU may also be used to facilitate the exchange of data with other infrastructures, such as those related to social security.[63] Furthermore, the proposal requires each Member State to designate a **digital health authority**, which will supervise the national contact points and implement as well as enforce the Regulation at national level.[64] Natural and legal persons may also lodge complaints with the digital health authority, relating to their rights under the regulation.[65] The rights of individuals are monitored by the same authority as for the GDPR, which cooperates closely with the digital health authorities set up in the Member State.[66]

At EU-level, cross-border cooperation between the established national authorities will be facilitated by a new **European Health Data Space Board**, which will be composed of representatives of the digital health authorities and new health-data access bodies from all Member States and of the Commission.[67]

Table 3: Illustration of the governance system for primary use of health data



2.4 Secondary use of electronic health data

Data permits for secondary use of data

Health data **for secondary use** will be governed at the national level by **health-data access bodies**, which will be designated by each Member State. For this purpose, one or more new public sector

[62] *Ibid,* Article 13.
[63] *Ibid,* Article 13(2).
[64] *Ibid,* Articles 10(1)-(2).
[65] *Ibid,* Article 11.
[66] *Ibid,* Article 3(11).
[67] *Ibid,* Article 64.

bodies may be established; however, where several access bodies are designated, one body must act as coordinator with the responsibility to coordinate requests among the other health-data access bodies.[68] In the case of cross-border registries and databases, the health-data access body in which the data holder is registered shall have the authority to decide on requests for access to electronic health data.[69] These health-data access bodies are tasked with authorising and issuing data permits and access to data users. For this service, a fee may be charged by the health-data access body.[70] The data permit will specify for which purposes the data may be used. Furthermore, the data is always to be provided in an unidentifiable form that cannot be traced back to the data subject.[71]

The use of secondary data is limited to certain purposes. Health-data access bodies only provide access when the data is intended to be used in the public interest, for instance, in the areas of public and occupational health (such as protection against serious cross-border threats to health), to support public-sector bodies, to produce official statistics, for education or teaching activities in the health or care sectors, scientific research, or development and innovation activities for products or services contributing to public health or social security.[72] On the other hand, Article 35 lists purposes for which the use of secondary health data is prohibited. These include uses such as taking decisions detrimental to a natural person based on their electronic health data (i.e. legal decisions), modifying their insurance contract, contributions or insurance premiums; advertising or marketing activities; or developing products or services that are harmful to individuals and society as a whole, such as drugs, alcoholic beverages, and tobacco products.

The proposal also requires holders of health data (such as hospitals, public authorities, and research institutes) to make specific categories of data available for secondary use.[73] These include, for instance, health-related administrative data (including claims and reimbursement data), public health registries, and data obtained from clinical trials.[74] In general, the data holder has to provide the data to the health-data access body within two months from receiving the request.[75]

The proposal also includes provisions on the quality and utility of health data for secondary use. The health-data access bodies have the obligation to inform data users about the available datasets and their characteristics.[76] Datasets made available may have a Union data-quality and utility label, provided by the data holders. This label ensures compliance with several elements regarding data documentation, technical quality, data-quality management processes, coverage, information on access and provision, and information on data enrichments.[77] The Commission will establish an EU

[68] *Ibid,* Article 36.
[69] *Ibid,* Article 53.
[70] *Ibid,* Article 42.
[71] *Ibid,* Article 44: In anonymised or pseudonymised format.
[72] *Ibid,* Article 34(1).
[73] *Ibid,* Article 33.
[74] *Ibid,* Article 33(1), Article 41.
[75] *Ibid,* Article 41(4).
[76] *Ibid,* Article 55.
[77] *Ibid,* Article 56.

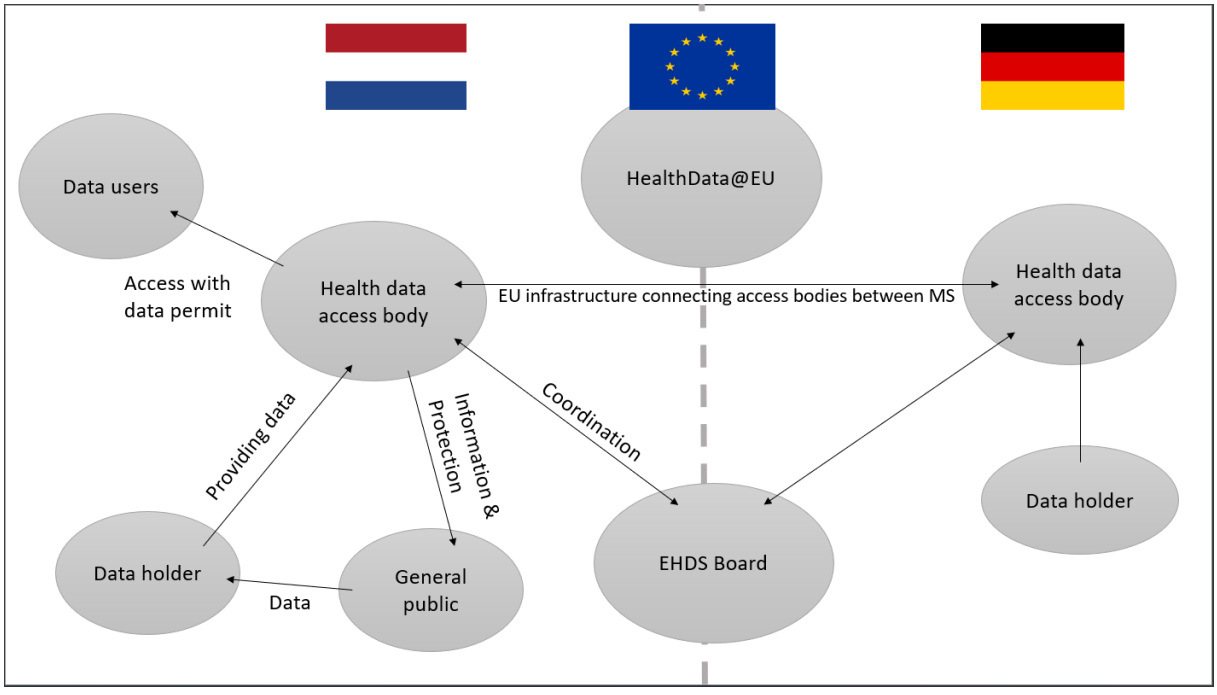
Datasets Catalogue that connects the national catalogues of datasets established by participants in the HealthData@EU infrastructure.[78]

Infrastructure and governance

The health-data access bodies are also tasked with the cooperation between and supervision of data holders, as well as facilitating cross-border access to data for secondary use by cooperating with the Commission and other Member States through an infrastructure designed specifically for secondary use of health data, **HealthData@EU**.[79] Each Member State will designate a national contact point for the secondary use of electronic health data, which is responsible for making data available in a cross-border context.[80] The health-data access bodies also participate in the above-mentioned European Health Data Space Board.

The health-data access bodies may revoke data permits and impose fines when the rules, such as time periods to provide data under the Regulation, are not respected.[81] The access bodies are also obliged to provide annual reports and publicly available information on the conditions under which health data is made available for secondary use, the legal basis on which access is granted, the measures taken to protect the rights of natural persons, and the results of the projects for which electronic health data were used.[82]

Table 4: Illustration of the governance system for secondary use of health data



[78] *Ibid,* Article 57.
[79] *Ibid,* Article 37.
[80] *Ibid,* Article 52.
[81] *Ibid,* Article 43.
[82] *Ibid,* Article 38.

3. Literature review

A concise narrative review of relevant literature sources was conducted to understand which challenges have been reported with regard to health-data exchange and how the initiative for an EHDS and the Commission proposal have been received in the academic community. The insights supported the specification as well the interview questions. The Google Scholar and Web of Science databases were screened using the exact query "European Health Data Space" and variations of "cross-border", "health", "data", and "Europe".

The retrieved sources reveal three streams of literature in the debate: Firstly, **health care and public health researchers** reporting about innovation projects and the status quo from practice. Secondly, **legal academics** addressing legal matters pertaining to privacy, data security, GDPR and consent. Thirdly, **health/medical information scientists** addressing interoperability issues and potential technical (IT) solutions. Very few of the retrieved sources address all of these issues in one contribution, and few studies are data driven.

Many publications reporting on innovation projects are demonstration projects, pilot or test-of-concept studies eluting to an early phase of innovation XXXX and limited scaling. With regard to European data exchanges, only e-prescription, hospital discharge, and patient summary seem to have been scaled to include more countries of application now. Data and interoperability standards/formats like FAIR, HL7, SNOWMED-CT, etc. seem to have a large area of application, according to multiple publications. Lastly, contributions addressing the EHDS specifically are largely descriptive, with few studies being concrete or providing options on how the EHDS should remedy the current challenges.

3.1 The challenges involved in health-data exchange

Reported challenges that impede health-data exchange generally involve three aspects (1) limited data interoperability, (2) fragmented legal provisions to access data for research and (3) limited data-science literacy and technical skills among citizens and healthcare professionals.[83]

Limited data interoperability

Contextual factors to limited health-data interoperability involve, on the one hand, a huge number of stakeholders' interactions in healthcare regarding healthcare provisions, financing and governance, coupled with a multitude of linked flows of diverse data. This results in several stakeholders developing their own particular interoperability solutions, for instance for providing a specific service (e.g. radiology imaging), financing operations (e.g. reimbursement of hospital care through insurances) or taking regulatory action (e.g. post-market surveillance of pharmaceuticals). Secondly, the governance of the data flows and standards or the structure for interoperability evolves in a mixture between governmental decision-making and solutions left to the market. This leads to a variety of standard data models and coding systems, such as SNOMED CT, OMOP, FIHR, LOINC and others, existing in parallel.[84] Interoperability is further hampered by different IT platforms (providers) operating in the sector and a

[83] M Shabani, "Will the European Health Data Space change data sharing rules?" (2022) Science 375 (6587), DOI: 10.1126/science.abn4874; E Tacconelli et al. Challenges of data sharing in European Covid-19 projects: A learning opportunity for advancing pandemic preparedness and response. (2022) The Lancet Regional Health – Europe 21: 100467

[84] Idid, Tacconelli et al.

heterogeneity of data stemming from various collection methodologies, such as clinical trials, cohort studies, electronic patient records, billing data, omics data, biobanks, etc.[85]

Finally, implementation of the FAIR data principles is meagre in the healthcare sector and could address interoperability issues.[86] The penetration of these FAIR Principles is hampered by gaps in the alignment between the biomedical and health-data terminology standards and FAIR. There is a lack of evaluation of usages of the FAIR principles in health research and of models to transform the health sector towards the FAIR-ification of data structures and processes.[87]

Fragmented legal provisions to access data for research

Despite the GDPR, the rules for access and exchange of data are unclear or are interpreted too restrictively.[88] The GDPR as such leaves room for many so-called Opening Clauses that allow for diverging and imposing stricter domestic rules, i.e. beyond the level that the GDPR provides. For example, the national rules for genomic and health-data processing and exchange differ in Germany, Greece, Latvia and Sweden, among others with regard to conditions for the lawful processing and the use of healthcare data for scientific research purposes, the rights of data subjects, or data sharing.[89]

Limited data-science literacy and technical skills among citizens and healthcare professionals

The relationship between provisions for health-data access and (re-)use and the relevant legislation is complex. A greater understanding is needed among health care providers and citizens/patients of the value and benefits of data use and of the safeguards that should be in place. It would benefit the management of data to facilitate better quality, availability and accessibility.[90] While polls among citizens/patients hint at a preference for data sharing and (re)use for research purposes, the terms and conditions, safeguards and benefits involved remain rather opaque for laypersons. Clinical health professionals may likewise lack understanding of and insight in data collection (structured data), sharing needs, data processing and, finally, its influence on clinical decision-making. Data controllers and legal experts need to strike a balance between creating adequate safeguards for citizens' privacy – ensured by technical or organisational means (i.e. ethical/research review boards, data commissions)[91] – and enabling the re-use of data through current legislative frameworks, so as to enable the use of data that serves the public interest.

3.2 Perceived solutions proposed by the EHDS Regulation

The EHDS needs to fulfil two purposes to address the general challenges of data sharing: First, EHDS regulation needs to provide ***legal clarity*** on access to and use of health data vis-a-vis the GDPR for secondary purposes such as research, innovation, regulatory and policy decision-making. Second, the

[85] Ibid.
[86] Ibid.; CL Parra-Calderón, F Sanz, LD McIntosh. The Challenge of the Effective Implementation of FAIR Principles in Biomedical Research. (2020) Methods Inf Med 59(04/05): 117-118.
[87] Ibdi, Parra-Calderón eta l.
[88] M Shabani.
[89] F Molar-Gabor et al. 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 (2022) Seminars in Cancer Biology 84, 271-283.
[90] Tacconelli et al.
[91] M Shabani.

EHDS needs to provide the ***infrastructure and processes*** for appropriate data governance, data quality and interoperability.[92] In this regard, the EHDS proposal foresees three lines of action to address the above challenges for health-data exchange.

The creation of a unified governance system and clear rules for data exchange

For primary healthcare-related purposes, the established eHealth Network and its digital infrastructure eHDSI – used under the brand name **MyHealth@EU** – constitute the designated system for data exchange, whereby the currently voluntary contact points will, in the future, serve as interlocutors, mediating the data exchange between the domestic e-health systems. This would involve the extension and upscaling of existing specific data-exchange systems to include e-prescriptions, patient summaries, lab results and medical imaging.[93]

For secondary purposes, *health-data access bodies*[94] for data exchange and *national contact points for secondary use of electronic health data*[95] are the designated bodies within the EHDS to facilitate data exchange in a cross-border context.[96] The TEHDAS (Towards European Health Data Space) Joint Action was launched to identify solutions for the creation of these bodies. The TEHDAS also covered options for the contact points' governance models for the exchange between countries.[97] As a follow up, the EHDS2 pilot project aims to suggest and test legal and technical framework standards on data governance for data-sharing purposes. EHDS2's work specifically involves making recommendations for the operation of both data-access bodies and contact points.[98]

Guarantees for high data quality and technical as well as semantic interoperability between infrastructures

For secondary purposes, the TEHDAS aims to ensure trustful use of health data by suggesting directions for data quality, including guidelines for data anonymization and data variety. Moreover, TEHDAS provides options for technical interoperability,[99] while EHDS2 specifically involves a proposal for metadata standards and guidelines for data interoperability, quality, and protection.[100]

In addition, the FAIR4HEALTH project developed a technical platform for accessing health-data sets via algorithms. This technical platform uses the HL7 FHIR standard and the FAIR implementation guidelines increasingly to arrive at FAIR data sets. HL7 FHIR builds on Application Programming Interfaces and drives the integration of the health systems' various IT platforms while supporting data quality. In addition, the EHRxF -European EHR exchange format is used as a specification to improve the

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[92] Tacconelli et al.; M Hendolin, TOWARDS THE EUROPEAN HEALTH DATA SPACE: FROM DIVERSITY TO A COMMON FRAMEWORK (2021) Eurohealth 27 No.2
[93] F Molar-Gabor et al.
[94] EHDS Regulation, Article 36, one or more health-data access bodies [are] responsible for granting access to electronic health data for secondary use.
[95] EHDS Regulation, Article 51, *a national contact point for secondary use of electronic health data*, [is] responsible for making electronic health data available for secondary use in a cross-border context
[96] A Kouroubalia and DG Katehakisa, Policy and Strategy for Interoperability of Digital Health in Europe (2022) MEDINFO 2021: One World, One Health – Global Partnership for Digital Innovation P. Otero et al. (Eds.)
[97] *TEHDAS Website* https://tehdas.eu/
[98] EHDS2 Press release https://www.sciensano.be/en/projects/european-health-data-space-pilot-secondary-use-health-data
[99] *TEHDAS Website* https://tehdas.eu/
[100] EHDS2 Press release.

interoperability of patient summaries, e-prescriptions, laboratory results, medical imaging and hospital discharge reports. EHRxF can be used for both primary and secondary purposes.[101]

The development of digital infrastructures

As previously described, the digital infrastructures – both for primary and secondary purposes – are currently being built and scaled up. For primary purposes, the eHDSI digital infrastructure, coined as **MyHealth@EU**, under auspices of the eHealth network is the designated infrastructure for primary purposes regarding healthcare. The infrastructure for secondary purposes is being developed through current pilot projects such as TEHDAS and EHDS2.

4. State of play of (cross-border) health-data exchange in the Euregio Meuse-Rhine

To find out how health-data exchange is currently functioning in the Euregio Meuse-Rhine, nine interviews were conducted between September and November 2022 with experts involved in healthcare delivery or handling cross-border care (projects) in the EMR. Two experts were employed by a health insurance company[102], two by organisations focused on cross-border cooperation[103], and six experts worked in a hospital setting.[104] Relevant experts or institutions were identified via the network of the authors. Participants received an information sheet, consent form and a semi-structured question guide before the interview. The interview guide covered topics such as general introduction to the person and institution, data-exchange practices within the country, data exchange across borders, and if and how they had received the EHDS proposal. The interviews were conducted online via the Microsoft Teams or Zoom platforms and lasted between 45 to 75 minutes. Memos were created afterwards, which formed the basis for a thematic analysis.

This section will discuss the findings in the light of the thematic analysis. First, the general findings on the importance and challenges of health-data exchange in the Euregio Meuse-Rhine will be discussed. Then, the experiences of the interviewees will be separately examined in a national and a cross-border context. This section concludes with a discussion of the interviewees' perspectives on the European Health Data Space. A selection of specific examples on health-data exchange provided by the interviewees is included in Annex I.

4.1 The importance and need for health data in the Euregio Meuse-Rhine

The interviews confirmed that health data play a crucial role in the Euregio Meuse-Rhine, both in healthcare delivery (primary use of health data), in research and in policy-making (secondary uses of health data).

[101] FAIR4HEALTH Website https://www.fair4health.eu/; CE Chronaki, FAIR Health Data and HL7 FHIR in the European Health Data Space (2021) Appl Med Inform 43 (Suppl. S1).
[102] One health insurance company was based in the Netherlands, the other one in Germany.
[103] Both organisations were based in the Netherlands, with a strong focus on cooperation with actors in Belgium and Germany.
[104] Five of them worked in a hospital in the Netherlands, one in Belgium.

The interviewees noted that there is a need for (cross-border) exchange of health data in the Euregio Meuse-Rhine. One of the interviewed organisations indicated that obtaining data within the national borders is, in fact, of less importance to them; in their view, comparing the figures from two remote regions in the same country, such as Limburg and North Holland in the Netherlands, reveals little about life in a cross-border region. For this reason, the interviewee held that obtaining and comparing data from neighbouring (cross-border) regions, such as Maastricht-Aachen, is more valuable for research and policy-making in the Euregio Meuse-Rhine. However, despite the need for access to health data, from the interviews it became quickly clear that data exchange is subject to several challenges, within and across the national borders in the Euregio Meuse-Rhine. In general, for both primary and secondary use, cross-border data exchanges are based on EU agreements, standards or pilot initiatives, and regional as well as bilateral cooperation projects. These take place on a limited scale, however, and with hurdles. The interviews revealed three types of obstacles: legal, infrastructural and technical obstacles. The barriers to cross-border data exchange are in line with those identified in the literature, whereby the interviewees emphasised the legal obstacles.

Overall, the interviews show that health-data exchange is perceived as a time-consuming and complex process, subject to the General Data Protection Regulation (GDPR) and privacy laws with a fragmented application and interpretation. Depending on the nature of the data, the interviewees described that the procedure frequently involves obtaining patient consent, approval from a medical and ethical review committee and a review of data-management plans. The difficulty of obtaining health data depended on the sensitivity of its nature – whereby the process was perceived as more burdensome when the data included personal information on a specific patient. On the other hand, data exchange based on non-personal numerical data was perceived as functioning well.

The interviewees indicated encountering infrastructural obstacles, in that health data for research purposes frequently had to be extracted from fragmented data sources in the absence of a centralised point of contact. One interviewee noted that, in these data-storage questions, two “schools of thought” could be identified: Some stakeholders would be in favour of "data trains", whereby data is stored in the original location (e.g., a hospital) and the required data is collected and transferred by an algorithm. The other school of thought advocates a single large data centre where data is stored and cleansed for research purposes. In the interviewee’s opinion, it would be advantageous to learn from both, as both approaches have unique strengths and weaknesses. Interoperability was also viewed as a barrier; The interviewees noted that technical systems and interfaces were often incompatible, which hindered health-data exchange in both national and cross-border contexts.

The main obstacles to health-data exchange identified by the interviews, however, were not only associated with data accessibility, but also with data quality. It was noted that, especially in a cross-border context, there may be inconsistencies in the data's underlying indicators and terminology. Due to these differences in methodology and data collection, data is not always comparable and useful for research purposes, even when it can be accessed. In order to achieve effective health-data exchange, the interviewees noted that the definitions of the data must be aligned. As an example of good practice, intensive hospital care in the Netherlands was mentioned. However, a similar alignment of the definitions could not be found in Belgium, for instance. Another example involved ambulance care, where the three countries may have a different understanding of “urgency” when comparing the numbers of urgent ambulance transfers.

4.2 Obstacles to health-data exchange in a national context

Three of the interviewees working in a hospital in the Netherlands found that **health-data exchange for primary use** did not always function optimally, especially when it concerned transfers between hospitals.

In the Netherlands, patients must first obtain a referral from their general practitioner (GP) before they may consult a specialist in a hospital. This referral, accompanied by the medical history – and in some cases a list of medications taken by the patient – is sent electronically to the hospital in the form of a letter. Hospitals in the Netherlands process patient information in an Electronic Patient Dossier (EPD) system. However, there is fragmentation as to the types of EPD systems used in hospitals, meaning that the systems are not always compatible. Consequently, information can neither be shared nor accessed via these systems and can only be utilised internally by individual hospitals.

These EPD-systems also show the referral and the information sent by the general practitioner. However, it is up to the GP to ensure that it is regularly updated. If, for example, a hospital specialist makes a change to a patient's medication, this is not always recorded by the general practitioner, so the patient's medical file may not be accurate. For this reason, there has been a development in the Netherlands whereby information on patient medication is instead requested from the pharmacies, which are now also connected to these EPD systems.

Although the transfer of patient data takes place electronically between the GPs and hospitals, there may be complications in emergency situations. In these events, the general practitioner calls the hospital first and sends the patient to the hospital with a brief accompanying letter if a specialist consultation is necessary. According to a doctor interviewed, these letters tend to be extremely brief, however, and do not always provide the complete patient history, particularly when emergencies occur in the evening or at night.

The most prominent difficulties arise when the hospital receives a patient that is not known to their hospital and information must be obtained from another hospital. In these situations, only brief information in form of a letter is exchanged, and the receiving hospital must rely on the doctor in the other hospital to have included all the pertinent details. On some occasions, obtaining this information may be complicated by the fact that the patient is known in several hospitals. This information is not always accessible directly via electronic means due to the variety in EPD systems, as outlined above. In these cases, treating doctors rely on the patients themselves or their family members for more extensive information and consult colleagues in other hospitals via standard means of communication such as telephone or email and may ask them to exchange relevant patient data subsequently.

As solutions to these shortcomings, the hospital representatives commonly agreed that greater efficiencies and fewer barriers in national data exchange for primary purposes between hospitals are easiest to achieve by purchasing from the same EPD software provider, as some local networks of hospitals in the Netherlands and Belgium have already done. In Belgium, technical solutions called “hubs”, which allow for data exchange between different EPD platforms, are in their infancy. Moreover, these hubs impose massive requirements on clinical personnel, who need to select the right properties in the system to allow data extraction. This leads to late and incomplete availability of data

to other care providers, whereas even incomplete discharge letters can be viewed in hospitals using the same EPD platform.

The interviewees referred to several other specific healthcare providers, such as Flemish pharmacies and a German network of radiology praxes and hospital departments (*Westdeutscher Teleradiologie Verbund*), as good practises that have achieved easy data exchange regionally by using the same IT platforms. The exchange of medical images is facilitated by the DICOM® standard (Digital Imaging and Communications in Medicine), a worldwide standard for processing aspects of transmission and storage of medical images and radiology pictures. For laboratory data, LOINC (Logical Observation Identifiers Names and Codes) provides a common language for the structure and processes of such data, though this has not become a unified global standard, according to the interview partners.

Regarding the exchange of health data for secondary use, several interviewees indicated that there are challenges in obtaining these health data. One of the obstacles mentioned related to the absence of a central data-access point; the interviewees experienced the process of requesting data from multiple sources and adhering to certain data-protection procedures as time consuming. One interviewee's organisation, for instance, requires access to regional or municipal data and statistics due to the nature of its research. However, data sources may be hesitant to provide the relevant information due to their perception that data sharing and subsequent procedures are time intensive. In the Netherlands, for example, municipalities rarely provide this information directly. Rather, this information is collected and has to be requested from other public-health authorities (such as GGD[105]and CBS[106]).

Another obstacle that was frequently mentioned in relation to secondary use of health data referred to the fragmented interpretation of the GDPR. One interviewee observed differences in what was required before data could be accessed for research purposes between hospitals. For instance, the interviewee's department uses an "opt-out" system – whereby the patient's family may opt out on the patient's behalf if the patient is unable to provide consent for their data to be used for research due to their serious condition. He indicated that other hospitals may adhere to a more relaxed or stricter approach to patient consent.

The national exchange of data is perceived to go well between **health insurances** in the Netherlands and Germany. Data from care providers comes in a readable format and detailed level for reimbursement purposes. After processing, insurances send special datasets to the respective government agencies,[107] which pool the data from all domestic insurances either for research or quality-assurance purposes or for the calculation of the risk-equalization scheme in the given countries.

When it comes to improving national data exchange, the attention points varied per interview partner. Interviewees referred to a need for "uniformity of language", more widely used "structured data", "interoperability of data contents and data structures" or "use of ontologies" (i.e. standards for documenting and coding medical data), such as SNOMED CT. Alongside technical aspects, one

[105] Gemeentelijke Gezondheidsdienst.
[106] Centraal Bureau voor de Statistiek.
[107] Such as Vektis in the Netherlands or BfArM/DIMDI in Germany.

interviewee mentioned the operational needs to demonstrate to doctors/clinical personnel the practical relevance of data entry, data exchange and pooling, as well as the advancement of medicine, for example by data input into an AI. This interviewee mentioned ***"What is in it for me***?" as an important question. In addition, this interviewee sees that financial incentives might play a role for doctors to improve the reporting levels in the EPD using structured entry fields.

4.3 Obstacles to health-data exchange in a cross-border context

Cross-border health-data exchange for primary use was found especially important for the Euregio Meuse-Rhine, where patients and healthcare professionals move across the border more frequently. However, the interviewees working in a hospital setting noted that it is difficult to share patient data across the border. Patients' medical histories are, in most cases, only shared via letters. This is not only inefficient, but it also entails a risk of error if these letters are manually filed in the respective hospital's system. Furthermore, the interviewees referred to the lack of exchange of medical images as causing losses in cost-effectiveness. Sometimes, for instance, an MRI scan is performed twice as the doctor cannot simply review the images already taken at the other hospital. Another interviewee points out that there has been a bilateral collaboration between the hospitals in Maastricht and Aachen regarding the transfer of medical images since the Dutch hospital joined the *Westdeutscher Teleradiologie Verbund*. Getting to that point has not been easy though. According to the interviewee, the next step, and challenge, is to do this with more than two hospitals and across different medical specialists and departments. Being a member of the *Westdeutscher Teleradiologie Verbund* should at least provide the technical infrastructure and interoperability standards to achieve this.

One example of the difficulties and implications of limited cross-border health-data exchange was given in relation to patients that were transported during the COVID-19 crisis. Due to their limited intensive care capacity, a hospital in the south of the Netherlands transported patients to Germany. As soon as the patient's condition had stabilised, they were returned to the Netherlands. Even in this instance, the exchange of patient data was limited to written, printed letters, despite the fact that, in the absence of the data, it would be challenging to monitor and coordinate the patient's follow-up care. In the experience of the interviewee, images were shared only in a few instances, and only via CD-ROM or DVD; data was not exchanged electronically.

Another obstacle in cross-border health-data exchange for primary use related to language. Not only was patient information shared through letters in the absence of electronical means, but they were often also written in a foreign language. The interviewee based in a hospital in the Netherlands indicated that this was a challenge when receiving patients from Germany or the French-speaking regions of Belgium. Before the patient information could be accessed, it would have to be professionally and carefully translated. Furthermore, the data mentioned in these letters was not always comparable and directly interpretable. The interviewee gave an example related to blood samples, where the units of measurements are standardised within the Netherlands but may be different in Germany.

Health insurance companies prefer to rely on their trusted insurance counterparts in the other countries of the EMR to check bills of their insured patients accessing healthcare across the border before readable datasets of reduced depth are shared with them. EU standards provide very rudimentary datasets to base reimbursements on. Also, the different structures and organizations of

healthcare in the respective countries was perceived to have complicated the submission of insurance claims in certain instances. An example is provided regarding ambulance transport, which in Belgium is distinct from hospital care. While the patient's health insurance can directly reimburse hospital care, this is not the case for ambulance transport, so the invoice is sent to the patient.

Regarding cross-border health-data exchange for secondary use, the interviewees emphasized that there is still much to learn from health data in order to improve treatments and public health. However, it was noted that laws on data (protection) are not clear cut in the sense of being "black or white". The fragmented implementation of the GDPR leads to unclarity and uncertainty regarding the legal provisions, complicating the exchange of health data for research, innovation and policy-making purposes. Due to this obstacle, health data is not always accessible, or it involves a long procedure including reviews of ethical considerations and data-management procedures. All interviewees agreed there were benefits to data pooling and sharing of health data within the Euregio Meuse-Rhine. As an example of a successful collaboration effort, the COVID-19 data dashboard was mentioned, which collected and compared the number of infections, hospitalisations and ICU admissions in the EMR. Additional benefits were also seen in a wider EU-context, with some interviewees referring to the use of AI and its development independent of other economies such as the US and China.

4.4 Perspectives on the European Health Data Space

Awareness of the European Health Data Space varied to a great extent between the interviewees. Most of them indicated to be unaware of such a proposal. However, after being briefed on the content of the EHDS, the initial reception among the interviewees was generally positive, and they saw potential for the EHDS to overcome (some of) the obstacles they are currently experiencing.

Nevertheless, the interviews revealed scepticism about how far existing data-exchange arrangements within the bi-or trilateral setting of the EMR (i.e. accommodating data infrastructures and legal provisions from two or three jurisdictions) can be scaled and generalised to 27 Member States and still remain practical, implementable and meaningful at the same time. Indeed, some interviewees were uncertain as to how health-data exchange could be established at EU level, given that it does not always function at national level. Other concerns were expressed in relation to data privacy and cybersecurity. The interviewees identified risks regarding privacy, leakage and data abuse if health data were to be used at a larger scale.

When asked what would be essential for the successful implementation of the EHDS, it was noted that effective health-data exchange requires the data to be both accessible and comparable. In addition, the focus should also be placed on the quality of the data, both in primary and secondary use. Many interviewees also highlighted the importance of knowing and trusting actors across borders – one interviewee noted that it would be essential to have "everyone on board" in order to ensure successful implementation of the EHDS. This requires not only the participation of national, regional, or local actors, but also of operational actors, as well as clarification of the obligations and rights proposed by the Regulation to everyone falling under its scope. Also, effective current practices should not be discarded, but rather used as a foundation upon which to build.

Concrete proposals for priorities when implementing the EHDS were only set out in one interview, in which quality of data and questions around the "contact points" (nodes) were highlighted. Questions regarding norms and governance processes for answering data requests were regarded as key for contact points. More generally, the EHDS proposal was seen as *"embrac[ing] the current developments in countries".*

5. Evaluation of the European Health Data Space

This section will evaluate the findings from the interviews (Section 4) and the literature review (Section 3) in light of the proposed Regulation on the European Health Data Space (Section 2). First, the state of play of health-data exchange in the Euregio Meuse Rhine and its impact on the theme of **European Integration** will be discussed. Secondly, it will be evaluated how the EHDS Regulation would impact the **Sustainable and socio-economic position** of the region. Finally, the EHDS Regulation will be discussed, taking the overall perspective of cross-border regions and specifically assessing the proposal's impact on **Euregional Cohesion** in the Euregio Meuse-Rhine.

5.1 Evaluation of the theme of European Integration

The interviews with healthcare stakeholders in the Euregio Meuse-Rhine discussed in Section 4 revealed obstacles to the cross-border exchange of health data**. The absence of a well-functioning health-data exchange may be an impediment to European integration**, as health data cannot be utilised to its full potential. In addition, the limited exchange of health data impedes the freedom of movement of persons, patients, and healthcare services. Additionally, it was discovered that comparable obstacles exist at national level.

The research found that **electronic exchange of patient data was infrequent in cross-border settings.** The exchange of patient data did not always occur electronically, but rather via written letters or, in some instances, via a CD-ROM. This was primarily due to the fact that **hospital-operated electronic patient-information systems were not interoperable**. Similar obstacles could also be found at national level when hospitals made use of different (incompatible) EPD systems. Nevertheless, the interviews found that several actors in the Euregio Meuse-Rhine had, in recent years, engaged in collaborations allowing the exchange of patient data. However, these collaborations were limited to highly specific instances or bilateral agreements between specific hospitals.

Despite the need for the exchange of patient data, its absence was cited as a hindrance to optimal patient care and, in emergency situations, as a potential cause of life-threatening outcomes if the patient's medical records could not be accessed in a timely manner. In addition to the **time-consuming task** of accessing patient data, re-entering data manually into the respective hospital's system was also indicated to pose **a risk of error**. Specific obstacles in a cross-border setting related to the **absence of standardisation of data** as well as **linguistical barriers**. Patient data would not always be directly interpretable; for instance, the results of blood samples were presented in different units across countries. Also, patient information presented in a foreign language required a careful, professional translation process. This was seen as particularly problematic in the Euregio Meuse-Rhine, where

patients travel more frequently across the linguistic borders between Dutch and German and (to a lesser extent) French.

Regarding the secondary use of health data, the lack of interoperability and a centralised data point were found to complicate data exchange. Data for research purposes often had to be extracted from **various, fragmented sources**. Also, the variety in **implementations of the GDPR** was mentioned as a common issue, both in national instances, and in a cross-border setting. The interviewees found that the rules on **privacy and data protection varied greatly**, resulting in ambiguity and a time-consuming process. Not only data accessibility, but also **data quality** was identified as an obstacle during the interviews. Even if the obstacles to accessibility (i.e. the legal hurdles as well as the technical, interoperability issues) were resolved, the issues of data comparability and understanding potential biases would remain. This was especially experienced as an obstacle in a cross-border context, where inconsistencies in the data's underlying indicators and terminology are more common, so that data cannot always be utilised for research purposes.

As will be explored in the next section, the European Health Data Space has the potential to overcome (some of) these obstacles, **fostering the principles of free movement and European Integration in health-data exchange.**

5.2 Evaluation of the theme Sustainable and Socio-economic Development

The literature review in Section 3 found obstacles that could be categorised into (1) obstacles regarding limited data interoperability, (2) fragmented legal provisions for accessing data for research purposes and (3) limited data-science literacy and technical skills. As confirmed in Section 4 of this dossier, these obstacles were also familiar to the stakeholders involved in healthcare in the Euregio Meuse-Rhine. Section 2 of this dossier explored in detail how the proposal for Regulation on the European Health Data Space intends to address the current shortcomings and obstacles in health-data exchange. Based on these findings, this study concludes that the legal framework and infrastructure proposed by the European Health Data Space could provide solutions to overcome (certain) obstacles in both national and cross-border settings. Moreover, the Regulation has the potential to contribute to a **well-functioning healthcare in border regions in terms of economic, social, and territorial development as well as sustainability.**

The Regulation on the European Health Data Spaces proposes mandatory requirements for electronic health-record systems, requires certain categories of patient data to be made available in the European electronic health-record exchange format, and requires the Member States to participate in the use of a cross-border infrastructure, MyHealth@EU, for the exchange of health data. This system has the **potential to solve the problems** faced by hospitals that operate different, non-interoperable patient information systems in the national and EMR contexts. The platform and format are not new but are currently implemented on a voluntary basis only in a limited number of Member States, excluding those of the Euregio Meuse-Rhine. The EHDS Regulation takes a step forward from the current framework by making it mandatory and expands the use of these health records to include medical imaging and laboratory results alongside patient histories. With this framework, **patient data could be shared more easily by healthcare providers**, improving **the quality and continuity of care**,

reducing the administrative burden, and contributing to **cost-effective healthcare services**. The proposal also aims to **overcome linguistic obstacles**, so that patient records can be accessed in the language of the country of destination.

Regarding health data for secondary use, the obstacle related to the absence of a centralised database **could be mitigated to some extent** by the creation of "health-data access points", as proposed by the European Health Data Space. These access points would be designated by each Member State, and their main task would be to provide data permits, allowing access to data for research and policymaking purposes. The proposal also **seeks to address the obstacle on the fragmented implementation** of the GDPR by establishing specific rules for the use of health data, an issue that was frequently raised by the interviewees. Nonetheless, resolving this issue is not obvious. The EHDS Regulation may face similar obstacles as the GDPR if its interpretation and implementation are not harmonised across the Member States. Specific risks could be identified in relation to the fact that the scope of the EHDS is even broader than that of the GDPR as it also applies to non-personal data. The room for interpretation of the conditions for granting data-access permits is another example. In fact, **one of the concerns raised in the interviews was that the Regulation might not lead to a single European Health Data Space, but rather to 27 distinct spaces.**

Concerning the obstacles posed by poor data quality and comparability, the question arises to **which extent the EHDS Regulation could provide solutions** to these matters. Although the Regulation seeks to establish an interoperable and common infrastructure and stipulates rules on providing information about data quality, it appears to emphasise access to and transferability of data. However, as mentioned in the interviews, a European Health Data Space is of no use if it means having access to incomparable data.

5.3 Evaluation of the theme Euregional Cohesion

If adopted in its proposed form, the Regulation on the European Health Data Space could provide numerous benefits for the Euregio Meuse-Rhine. If implemented, it is recommended that the EHDS Regulation consider **the perspective of border regions and the objectives of Euregional Cohesion**.

Due to the wide scope of the proposal, the **Regulation would impact many healthcare actors in the Euregio Meuse-Rhine**, including citizens, healthcare providers, policymakers, researchers, industry, businesses, health insurance companies and public authorities. Since border region inhabitants are characterised by high mobility, the Regulation on the European Health Data Space could ensure that the inhabitants of the Euregio Meuse-Rhine, as well as their healthcare providers, have access to the necessary data in the course of treatment(s). The EHDS Regulation also has the potential to support the current and envisaged cross-border cooperation frameworks in the region as well as their objectives, e.g. the ones that the previously mentioned Euregional Paediatric Surgery Centre seeks to achieve. Furthermore, better use of health data for research purposes could help to strengthen the resilience of health systems in the border region, as well as the region's socio-economic position. It should also be noted that, alongside the benefits that can be identified from a regional perspective, the EHDS Regulation could improve the exchange of health data at national level and, as part of a larger EU-level objective, increase European global competitiveness on international markets.

Despite the clear benefits and opportunities that the European Health Data Space holds for border regions, **its adoption also entails a level of hesitancy among the stakeholders.** Some of the

stakeholders interviewed in course of the research stated that the EHDS should not overrule the existing frameworks where collaboration is currently effective and should preserve operational federated networks. Other stakeholders, on the other hand, lean towards more harmonisation of data processes and infrastructure in the form of non-federated networks. When implementing the EHDS, it is recommended that the **best practices and experiences of actors in border regions** be used as a foundation to build upon.

Other concerns related to data protection and privacy, although the primary aim of the EHDS proposal is to increase trust in and the security of health-data exchange. However, given that health-data exchange is still, in some instances, in its infancy at national level in the countries of the Euregio Meuse-Rhine, the EHDS represents a significant step forward. **The question is whether the proposal is too ambitious and realistically achievable in its envisaged timeframe.** According to the interviewees, the reason for the current "old-fashioned" data-exchange practises is not necessarily the lack of technological advancements, but rather a concern for privacy, particularly in relation to health data, which is by definition considered sensitive. All interviewees identified risks of exchanging health data associated with data breaches, data abuse, and loss of privacy. The challenge, and perhaps the solution, is to strike a balance between privacy on one hand, and access to data on the other hand.

To ensure scalability and usability, the successful **implementation of the EHDS Regulation would necessitate strong partnerships and infrastructural investments**. This requires not only the participation of national, regional, or local actors, but also of operational actors. **Regional stakeholders should also have a position in its governance structure.** Therefore, it is recommended that the perspective of (cross-)border regions be considered in the implementation of the EHDS, if adopted.

6. Conclusions and recommendations from a Euregional perspective

6.1 Substantive conclusions

This dossier examined the recent proposal Regulation on the European Health Data Space, with the aims of considering the proposal from the perspective of a border region (the Euregio Meuse-Rhine) and raising awareness of the EU initiative among regional actors. The dossier concludes that **the European Health Data Space may have a positive impact on health-data exchange, both for primary and secondary purposes, in the Euregio Meuse-Rhine, but also in a national context**. The dossier found that, in the current situation, the absence of functioning electronic health-data exchange is an impediment to European integration. The European Health Data Space has the potential to overcome the obstacles to health-data access for primary and secondary use, which would foster the principles of free movement and contribute to well-functioning healthcare in border regions in terms of economic, social, and territorial development as well as sustainability. However, its success will also depend on whether the Regulation is implemented harmoniously across the Member States. If the Regulation is adopted, it is recommended that the perspective of border regions and the objectives of Euregional Cohesion be considered in its implementation.

6.2 Outlook

This dossier has focused solely on the recent proposal for the European Health Data Space. To get a full picture, it is necessary to examine health-data exchange with a larger scope, taking into account other EU, national, and regional initiatives. The Electronic Data Exchange in Healthcare Act (*Wet elektronische gegevensuitwisseling in de zorg*) in the Netherlands or the Digital healthcare and nursing modernisation act (*Digitale-Versorgung-und-Pflege-Modernisierungs-Gesetz – DVPMG*) in Germany, for example, have many similar objectives to the European Health Data Space, and it would be interesting to assess their (cross-border) impact.

The Regulation on the European Health Data Space is presently being reviewed by the Council and the European Parliament. It remains to be seen whether, and in what form, it will be adopted.

ANNEX I.

This Annex provides a selection of examples on health-data exchange and its related obstacles provided by the interviewees.

- One interviewee explained how the absence of electronic health-data exchange could have dangerous consequences in emergency situations. When a hospital receives an unidentified patient, they must first determine in which hospital the patient is known. Then, they must contact that hospital and hope the requested information can be provided quickly, either via phone or email. However, in some emergency situations, patients may be unconscious or unable to answer questions related to their medical history and regular hospital(s) where they are known. This puts the doctors in a situation where they do not know anything about the patient, nor about their potential contraindications, allergies, or medication taken, which may be life-threatening.
- The transports of patients during the COVID-19 crisis were mentioned as another example demonstrating how "old-fashioned" the Dutch health-data exchange system was perceived to be. Due to the limited capacity of intensive-care beds, patients were transported to other hospitals in the Netherlands. When doctors received confirmation that their patient had been accepted for transport to another hospital, they had to quickly compose a letter containing vital information about this patient. This letter would then be printed and transported with the patient in the ambulance. When asked why this file was not sent via electronic means, the answer was that it was believed that sending the data along with the patient was the most secure method, as the document would remain and travel with the patient. If they had sent the file by email, there was the risk that the receiving doctor's shift might have ended before it arrived and no information would have reached the hospital simultaneously with the arrival of the patient.
- As an example of data incomparability, one interviewee mentioned BMI (Body Mass Index) data. Although there is a universal method for calculating BMI values, there may be variations in data collection, for example as to how a patient is weighed. Whereas some doctors weigh patients while they are dressed, others weigh patients while they are only wearing shoes. As a result, BMI data are not always comparable.