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Faculty of Law

Governance and data access mechanisms for secondary use within the European Health Data Space (EHDS)

Case ONCOVALUE on secondary use of electronic health data in value-based oncology care

Intellectual Property and Beyond
Master's thesis

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8.9.2025

UNIVERSITY OF TURKU
Faculty of Law

Abstract page

Master's thesis

Subject: Intellectual Property and Beyond
Author: Tiia Hautaniemi
Title: Governance and data access mechanisms for secondary use within the European Health Data Space (EHDS) - Case ONCOVALUE on secondary use of electronic health data in value-based oncology care
Supervisors: Tuomas Mylly, Heidi Härkönen
Number of pages: XV + 64 pages
Date: 8 September 2025

The European Health Data Space (EHDS) is the first sector-specific data space within the European Union. Together with other strategic sectoral data spaces, it will eventually form a European single market for data. The EHDS is governed by the European Health Data Space Regulation, which entered into force in March 2025. The aim of the Regulation is to establish a common framework for the use and exhange of electronic health data throughout the European Union. Within the EHDS, the secondary use of electronic health data allows access to certain health data for legally defined purposes, such as research or policymaking.

This thesis examines the secondary use of electronic health data in accordance with the Regulation, with particular emphasis on its governance and mechanisms for such use. The study seeks to investigate the structures created by the EHDS for secondary use and to understand the role of EU-funded projects and initiatives in the phased implementation of the Regulation. The topic is approached from the perspective of the ONCOVALUE project and its need to map the current state of affairs.

The research is conducted as a contextual doctrinal study, which incorporates elements beyond traditional legal scholarship. This approach provides a multidisciplinary perspective and practical relevance to the subject under exploration by combining legal sources with materials from other fields.

The study demonstrates how EU-projects and initiatives, particularly in cross-border contexts, actively participate in the implementation of the EHDS and influence the practical solutions associated with its use. Based on the findings, it can be concluded that such projects and initiatives play a central role in the successful implementation of the EHDS and in ensuring consistent governance of secondary use. Accordingly, it is essential that the development and operationalisation of the EHDS continue to involve applicable EU-projects and initiatives.

Key words: European Health Data Space, EHDS, secondary use

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Tiivistelmä

Tutkielma

Oppiaine: Immateriaalioikeudet ja informaation muu sääntely
Tekijä: Tiia Hautaniemi
Otsikko: Hallinto ja mekanismit tervesystietojen toissijaista käyttöä varten Eurooppalaisella terveystietoalueella - Case ONCOVALUE sähköisten terveystietojen toissijaisesta käytöstä vaikuttavuusperusteisessa syöpähoidossa
Ohjaajat: Tuomas Mylly, Heidi Härkönen
Sivumäärä: XV + 64 sivua
Päivämäärä: 8.9.2025

Eurooppalainen terveystietoalue, European Health Data Space (EHDS), on ensimmäinen Euroopan union yhteinen data-avaruus, joka yhdessä muiden strategisten sektoreiden data-avaruuksien kanssa tulee lopulta muodostamaan Euroopan unionin yhteisen datamarkkinan. Kyseistä terveystietoaluetta sääntelee maaliskuussa 2025 voimaantullut asetus eurooppalaisesta terveystietoalueesta, jonka tavoitteena on muodostaa yhteinen kehys sähköisten terveystietojen käytölle ja vaihdolle Euroopan Unionissa. Eurooppalaisen terveystietoalueen puitteissa tapahtuva sähköisten terveystietojen toissijainen käyttö mahdollistaa pääsyn tiettyihin terveystietoihin laissa määriteltyjen käyttötarkoitusten, kuten tutkimuksen- tai päätöksenteon, perusteella.

Tässä tutkielmassa tarkastellaan asetuksenmukaista terveystietojen toissijaista käyttöä ja etenkin siihen liittyvää hallinnointia ja mekanismeja. Tarkoituksena on tutkia eurooppalaisen terveystietoalueen luomia rakenteita toissijaiseen käyttöön ja ymmärtää EU-rahoitteisten projektien ja aloitteiden merkitystä asetuksen asteittaisessa toimeenpanossa. Aihetta lähestytään ONCOVALUE -hankkeen lähtökohdista ja tarpeesta kartoittaa nykytilannetta.

Tutkimus on toteutettu kontekstuaalisena lainopillisena tutkimuksena (contextual doctrinal research), jonka metodeita hyödyntäen tutkimukseen on sisällytetty perinteisen lainopin ylittäviä elementtejä. Näin tutkittavaan aiheeseen on saatu monitieteistä näkökulmaa ja tarvittavaa käytännönläheisyyttä yhdistämällä lähteitä eri aloilta.

Tutkimus osoittaa, miten etenkin rajat ylittävissä tilanteissa projektit ja aloitteet ovat aktiivisesti mukana eurooppalaisen terveystietoalueen toimeenpanossa, vaikuttaen siihen, millaisia ratkaisuja sen käyttöön liittyy. Tulosten perusteella voidaan siten päätellä, että projektit ja aloitteet ovat keskeisessä asemassa yhteisen eurooppalaisen terveystietoalueen toimeenpanon onnistumisessa ja toissijaisen käytön yhdenmukaisessa hallinnassa. Tästä syystä myös jatkossa on varmistettava, että eurooppalaisen terveystietoalueen kehitykseen ja toiminnallisuuksien käyttöönottoon sisältyy tarkoituksenmukaisia EU-projekteja ja aloitteita.

Avainsanat: Eurooppalainen terveystietoalue, EHDS, toissijainen käyttö

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TEHDAS2, Second Joint Action Towards the European Health Data Space – TEHDAS2. https://tehdas.eu/ (Accessed 2 September 2025).

Cases

Judgement 26 April 2023, *Single Resolution Board v European Data Protection Supervisor*, T-557/20, not published, EU:T:2023:219

List of Abbreviations

AI	Artificial Intelligence
CJEU	Court of Justice of the European Union
DA	Data Act (EU) 2023/2854
DARWIN EU	Data Analysis and Real World Interrogation Network®
DGA	Data Governance Act (EU) 2022/868
EHDS	European Health Data Space
EHDS2 Pilot project	Pilot for a European Health Data Space on secondary use of health data
EMA	European Medicines Agency
EU	European Union
GDPR	General Data Protection Regulation (EU) 2016/679
HDAB	Health Data Access Bodies
HTA	Health Technology Assessment
HUS	Helsinki University Hospital
IoT	Internet of Things
IPR	Intellectual Property Rights
OMOP CDM	Observational Medical Outcomes Partnership Common Data Model
PET	Privacy Enchancing Technologies
RWD	Real-World Data
RWE	Real-World Evidence
SPE	Secure Processing Environment
TEHDAS1	Joint Action Towards the European Health Data Space
TEHDAS2	Second Joint Action Towards the European Health Data Space

Appendices

Appendix 1 AI Usage Disclosure

All research design, analysis, interpretations and conclusions are the author's own, and AI tools were not used to generate original content.

Scite.ai's **Assistant by scite** (scite.ai/assistant) was used to discover relevant research articles cited in this thesis.

OpenAI's **ChatGPT** models GPT-4.1 Mini and GPT-5 Mini (chatgpt.com) and **DeepL Write** (deepl.com/en/write) were used to finalise the text by checking grammar and readability. The author further edited the text.

1 Introduction

The European Union (EU) has created Common European Data Spaces to benefit the European economy and society. Currently, these spaces cover fourteen strategic sectors, ranging from agriculture to health, and it is envisaged that the spaces will become increasingly interconnected, ultimately forming the single market for data.[1]

Within this digital ecosystem, the maturity of data spaces varies, with some still in the preparation stage and others already in the deployment phase.[2] Among them, the European Health Data Space (EHDS)[3] stands out as the first sector-specific data space by entering into force in March 2025 and currently undergoing phased implementation.[4] Its ambition is to provide an ethically governed, secure and interoperable digital environment for health data, and improve access of individuals and public institutions to high-quality data.[5]

The EHDS Regulation sets out, among other things, governance and common mechanisms to access electronic health data for secondary use.[6] Alongside this, multiple EU-funded initiatives and research projects work actively toward its harmonised implementation and explore practical ways of operating in this new regulatory environment.[7] While the Regulation encourages to increase collection and access to electronic health data, challenges persist.[8] These arise from different levels of readiness within Member States to align with the EHDS requirements of secondary use, complicated further by its cross-border nature.[9]

Although the EHDS is expected to bring substantial progress for medical research through improved use of electronic health data, its implementation has raised concerns. Much of the discourse relates to the growing intricacy of the data regime within the EU and the practical

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[1] European Commission, Common European Data Spaces. For the original initiative, in which the European Commission puts forward the European Data Strategy, including the original data spaces, see Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions (European Strategy for Data), COM(2020) 66 final (COM[2020] 66 final).
[2] Commission Staff Working Document on Common European Data Spaces, SWD(2024) 21 final, p. 4.
[3] In this thesis, the ”EHDS” refers to the data space, while the ”EHDS Regulation” or ”Regulation” refers to the Regulation (EU) 2025/327 which establishes the space.
[4] See the “Explanatory Memorandum” in Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space, COM/2022/197 final. For the regulation on the Health Data Space (EHDS), see Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847 (EHDS).
[5] European Commission, European Health Data Space Regulation (EHDS).
[6] Recital 52 of the EHDS. For governance and mechanisms for secondary use, see Section 2 of the EHDS.
[7] See for instance European Commission, Projects supporting EHDS.
[8] COM/2022/197 final, p. 2.
[9] See for instance Recital 7 & 55 of the EHDS; EIT Health Think Tank 2024.

difficulties of the harmonised implementation of the EHDS, especially regarding secondary use.[10]

At the centre of this thesis is the EHDS governance and common mechanisms for secondary use of electronic health data. In addition, it covers four EU-projects and initiatives that support the implementation of the EHDS. The thesis argues that research projects already underway have a tangible impact on the implementation of the EHDS at the Union level and their contributions prove to be of considerable value to it. Yet sustained cooperation across stakeholders remains important to make governance structures and operational mechanisms for secondary use truly effective.[11]

The relevance of the findings in this thesis extends even further than the projects included. Healthcare providers, policymakers and other actors within the health sector will all be affected as the EHDS gradually becomes fully applicable. The study therefore offers useful observations regarding the current situation and its implications for different stakeholders.

This work also serves as preparatory research for a forthcoming summary report on governance models and legal requirements for ONCOVALUE, an EU-funded project focused on the secure use of harmonised, hospital-based real-world data (RWD) in cancer care. Accordingly, the discussion is adapted to reflect this perspective.[12]

In order to provide a coherent analysis, the thesis proceeds as follows. After explaining the methodology, Sections 3 and 4 introduce the EHDS and core aspects of its regulation. Sections 5 and 6 turn to the provisions concerning secondary use. After these, Section 7 examines selected EU-based projects and how they help to build compliant governance for the secondary use of electronic health data. Section 8 contains a brief discussion, and the final section presents concluding observations.

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[10] See for instance Davidovics – Kovács – Gaál 2023; Kessissoglou et. al. 2024; Marelli et. al. 2023; Quinn 2025; Shabani 2022; Terzis 2023.
[11] See also Kessissoglou et al. 2024, p. 1106; Hussein et al. 2024, p. 14.
[12] For more information of the project, see ONCOVALUE, Implementing Value-based Oncology Care at European Cancer Hospitals.

2 Methodology

2.1 Background of the study

The European Heath Data Space (EHDS) represents a new legal instrument which provides a unified legal and technical framework for the access, exchange and use of electronic health data across the EU.[13] Conceptually, the Regulation distinguishes between two modes of data use: primary and secondary. Primary use centres on strengthening individuals' rights by improving their ability to access and control their personal electronic health data. Secondary use, by contrast, involves the reuse of specific categories of health data for broader societal benefit, particularly in the context of scientific research, policymaking and regulatory purposes.[14] This distinction does not imply that the two modes exist in isolation.[15] Instead, through its governance rules and provisions on secondary use, the Regulation defines who may access data, what categories of data may be used, and for which purposes.

A number of research projects and initiatives seek to contribute to the creation of compliant governance for the secondary use of electronic health data.[16] Two projects, ONCOVALUE and the EHDS2 Pilot project, which take different approaches to the EHDS, have been selected for closer examination. ONCOVALUE is a consortium of cancer institutes and commercial businesses collaborating to advance value-based cancer care. The project leverages Real-World Data (RWD) for secondary use and aims to enhance cross-border collaboration in cancer care.[17] The EHDS2 Pilot, as its name suggests, tested the EHDS infrastructure in a real-world settings and evaluated user experience in accessing and using electronic health data. The piloted process is now incorporated into the EHDS Regulation with only minor adjustments.[18]

In addition to these projects, two key initiatives, were chosen for further investigation. These are TEHDAS initiatives and DARWIN EU, which are working to expand opportunities for the secondary use of electronic health data. The first is designed to support Member States,

[13] Recital 1 of the EHDS; European Commission, European Health Data Space Regulation (EHDS).
[14] Ibid. The Chapter II of the EHDS concerns primary use and the Chapter IV the secondary use.
[15] EIT Health Think Tank 2024, pp. 12, 22–24.
[16] See for instance European Commission, Projects supporting EHDS.
[17] ONCOVALUE, Implementing Value-based Oncology Care at European Cancer Hospitals.
[18] European Commission, Pilot for a European Health Data Space on secondary use of health data.

the research community and other stakeholders to align with the EHDS.[19] The latter promotes better exchange and access to different types of health data, including RWD, which is of interest to policymakers, regulators and research field.[20]

While these projects and initiatives are advancing the operationalisation of the EHDS, the primary focus here is on its cornerstone, the EHDS Regulation. In contrast to the projects, which have already produced a wide range of deliverables and reports, relatively little attention has been given to the Regulation by legal scholarship so far.[21] Most publications on the topic appear in other fields, such as medical, health research, scientific or technological journals. This leaves a clear gap and an evident need for practical analysis of the legal aspects of the subject.

Moreover, the origins of this research stem from ONCOVALUE's efforts to align with the development of the EHDS. Accordingly, the thesis has been written to be accessible to readers from diverse disciplines and countries, making it relevant to anyone in the health sector and beyond. For this reason, a broad perspective on the EHDS Regulation has been prioritised, rather than limiting the analysis to a few specific provisions.

2.2 Objectives and research questions

The thesis aims to provide a comprehensive, contextual overview of secondary use within the established EHDS. It covers the relevant legal components of governance and mechanisms designed for secondary use. These are combined with a variety of efforts of EU-projects for a harmonised implementation of the EHDS. Since secondary use is at the core of this study, provisions of primary use are excluded for the most part of the study.

The main objective of the thesis is to examine the governance system introduced by the EHDS Regulation and consider how research projects can support its implementation. The findings are intended to inform not only the ONCOVALUE project, but also other ongoing

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[19] TEHDAS initiatives refers to two consecutive Joint Actions, which are the Joint Action Towards the European Health Data Space (TEHDAS1) and its successor the Second Joint Action Towards the European Health Data Space (TEHDAS2). See TEHDAS1, Joint Action Towards the European Health Data Space – TEHDAS1; TEHDAS2, Second Joint Action Towards the European Health Data Space – TEHDAS2.

[20] DARWIN EU is an abbreviation for the Data Analysis and Real World Interrogation Network® which is established within the European Union. For more information on the initiative, see DARWIN EU, Home.

[21] At the time of writing, however, some of the most active legal scholars in this field are Quinn (professor of law at the Vrije Universiteit Brussel), Shabani (assistant professor in privacy law at Ghent University), Slokenberga (senior lecturer in administrative law at Uppsala University) and Terzis (lecturer in digital law at King's College), all of whom are cited in this thesis.

and future projects, since the EHDS will thoroughly transform the accessibility of electronic health data for secondary use within the EU.

Considering the above, the guiding research question in this paper is:

- How can research projects and initiatives support the harmonised implementation of governance and data access mechanisms for secondary use of electronic health data, consistent with the European Health Data Space (EHDS) Regulation?

To answer this question, it is broken down into three sub-questions, examined in the following order:

- What is the European Health Data Space (EHDS), and what is its regulatory framework?
- How does governance and the mechanism for secondary use function within the EHDS?
- How can EU research projects and initiatives foster compliant governance for secondary use in terms of the harmonised implementation of the EHDS Regulation?

The paper begins by introducing the EHDS and its regulatory framework in the broader context. It then shifts to governance arrangements and mechanisms for secondary use, by explaining how these function within the Regulation. Finally, the role of EU research projects and initiatives is explored by demonstrating how they can support compliant governance and the harmonised implementation of the EHDS.

Keeping the EHDS Regulation in the centre of this study, contextual doctrinal research was chosen for best achieving its objectives.

2.3 Data and method

The methodology employed in this thesis is contextual doctrinal research, as presented by Sanne Taekema, professor of legal theory, and Wibren van der Burg, professor of legal philosophy and legal theory. Like traditional doctrinal research, this also focuses on a doctrinal core, by placing primary emphasis on the analysis of legal texts and principles. The contextuality comes from the simultaneous incorporation of insights and outputs from other disciplines to provide context and strengthen understanding.[22] It is worth noting that

[22] Taekema – van der Burg 2024, p. 13.

contextual doctrinal research does not directly apply the methods of these other disciplines, but rather integrates their findings to inform and supplement legal analysis.[23]

In this study, the examination of the EHDS Regulation forms the foundation, serving as the main reference point for exploring governance and mechanisms for the secondary use of electronic health data. To complement the legal analysis, relevant findings and data are incorporated from fields such as digital health, informatics and data analytics, which offer practical and empirical perspectives.

Contextual doctrinal research involves the systematic collection and interpretation of source materials.[24] The sources used in this thesis consist of a combination of primary and secondary sources.[25] Primary sources consist of EU legislation, such as the EHDS Regulation and other regulations concerning Common European Data Spaces, alongside relevant case law from the Court of Justice of the European Union (CJEU). Secondary sources comprise additional materials other than legal texts, most notably preparatory materials of the EHDS Regulation, journal articles and documents from official sources related to the topic of the thesis.

The search for source materials focused selectively on the secondary use of health data within the EHDS framework. Direct searches were conducted through Volter, the library database of University of Turku, using the keywords “secondary use” and “health data” in combination with “European Health Data Space” or “EHDS”. These queries produced between 52 and 153 peer-reviewed journal articles in English. In selecting the articles, preference was given to publications within the field of law and regulation, as opposed to those in medicine, medical research, science or technology. In addition, the Scite was used to discover and verify the most relevant articles with similar keywords and preferences. Duplicates were removed where results overlapped.

A preliminary screening of the retrieved materials narrowed the selection to 52 articles for detailed review. At this stage, more articles were excluded due to lacking a legal perspective or insufficient relevance to the research question. Supplementary materials were identified through citations in the selected articles. In total, this search and screening process produced 29 articles for inclusion in the thesis.

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[23] Taekema – van der Burg 2024, p. 94.
[24] Taekema – van der Burg 2024, pp. 10, 62.
[25] On the categorisation of the primary and secondary sources, see Taekema – van der Burg 2024, pp. 66–67.

Besides this, the law-in-context method was utilised when collecting and anaysing materials. Contrary to the purely doctrinal approach, which is confined to recognised legal sources and interpretative techniques, the law-in-context method makes it possible to transcend boundaries of the discipline of law.[26] Consequently, this study draws on non-legal materials, including project deliverables and reports published by ONCOVALUE, TEHDAS1 and TEHDAS2. For the EHDS2 Pilot project, already concluded and without an active website, the official portal of the European Commission was used to access final reports and related documentation.

As Taekema & van der Burg explain, "To understand law, researchers must understand the society in which it is embedded; therefore, they need all kinds of empirical information about that society. -- To understand the regulation of biotechnology, they must understand biotechnology and thus may need to access medical publications. Which materials are relevant can only be decided in the light of the research questions and subquestions."[27] Accordingly, this thesis has kept legal materials at its core while also incorporating complementary applied sources to achieve its objectives and provide comprehensive answers to the research questions.

[26] Taekema – van der Burg 2024, p. 112.
[27] Ibid.

3 EU legislation governing the Common European Data Spaces

3.1 EHDS Regulation and other EU legislation

Within the EU, Common European Data Spaces have been created to leverage the value of data for the benefit of the economy and society. These Data Spaces span several strategic sectors, including agriculture, energy, green deal, finance, health, manufacturing, mobility, public administration and skills, among others. Since the initial proposal, additional domains have emerged, bringing the total number of sectors to fourteen.[28] Collectively, the Common European Data Spaces are intended to become progressively interconnected and ultimately form a single market for data.[29]

As envisaged by the European Commission, the single market for data will ensure security for both personal and non-personal data while providing broad access to high-quality, reliable data. Its objectives are to drive economic growth and sustainability, guarantee compliance with EU law and support data-based innovation.[30] To realise this vision, the EU is combining governance with fit-for-purpose legislation, most notably the Data Governance Act (DGA)[31] and the Data Act (DA)[32], together with investment in standards, infrastructure and the skills required for effective data use.[33]

The DGA and the DA aim to establish a single market for data across the European Union[34] and directly govern all Common European Data Spaces, including the European Health Data Space.[35] The European Health Data Space (EHDS) Regulation entered into force on March 2025,[36] after years of regulatory development, which involved consultations with numerous stakeholders and preparations through EU initiatives.[37]

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[28] European Commission, Common European Data Spaces. See also COM(2020) 66 final.
[29] European Commission, Common European Data Spaces.
[30] Ibid.
[31] 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, DGA).
[32] Regulation (EU) 2023/2854 of the European Parliament and of the Council of 13 December 2023 on harmonised rules on fair access to and use of data and amending Regulation (EU) 2017/2394 and Directive (EU) 2020/1828 (Data Act, DA).
[33] COM(2020) 66 final, pp. 4-5.
[34] See for instance European Commission, Data Act Explained.
[35] As noted, there are 14 sector-specific data spaces, including the health data space. While the Data Act applies to all of them, at the time of writing the EHDS is the only one formally established.
[36] Art. 105 of the EHDS.
[37] For a general overview of stakeholder consultations, see "3 Results of Ex-Post Evaluations, Stakeholder Consultations and Impact Assessments" in COM/2022/197 final. With respect to stakeholder perspectives, the

Being a sector-specific act, the EHDS Regulation builds on several foundational EU legislations.[38] However, some of the recent legal acts, including the Digital Market Act (DMA)[39] and the Digital Services Act (DSA)[40], fall outside the scope of this thesis on the grounds that they hold limited relevance for the secondary use of health data.[41] Since the study centres on the secondary use of health data, these acts would not contribute to the analysis.

Complementing the DGA and the DA, the General Data Protection Regulation (GDPR)[42] is examined, as it constitutes the primary regulation on processing of personal data and on the free movement of such data, making it highly relevant to the EHDS. As a sectoral legislation, the EHDS Regulation builds on these regulations by introducing additional provisions for the health sector where necessary.[43] To outline their interrelationship, the DGA, DA and GDPR are briefly investigated with reference to the EHDS Regulation.

3.2 Data Governance on the Common European Data Spaces

The DGA supports the setup and development of the Common European Data Spaces across strategic domains, including the health sector.[44] As a horizontal legislative instrument, it seeks to improve conditions for data sharing within the EU internal market by creating a harmonised framework for data exchange and defining essential requirements for data

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Joint Action Towards the European Health Data Space (TEHDAS1) was started to assist Member States and the European Commission in developing and promoting concepts for the secondary use of health data. See TEHDAS1, Joint Action Towards the European Health Data Space – TEHDAS1. For a comprehensive overview of more than two decades of EU-level efforts to harmonise and integrate health data, see Schmitt et al. 2023.

[38] In addition to the three core legal instruments briefly analysed in this thesis, the EHDS Proposal states that it is also based on the Regulation (EU) 2017/745 on medical devices (Medical Devices Regulation), the Regulation (EU) 2017/746 on in vitro diagnostic medical devices (In Vitro Diagnostics Regulation) , the Regulation (EU) 2024/1689 on artificial intelligence (Artificial Intelligence Act), the Directive (EU) 2016/1148 on security of network and information systems (NIS Directive) and the Directive (EU) 2011/24 on the application of patients' rights in cross-border healthcare (CBHC Directive). See the "Explanatory Memorandum" in COM/2022/197 final.

[39] Regulation (EU) 2022/1925 of the European Parliament and of the Council of 14 September 2022 on contestable and fair markets in the digital sector and amending Directives (EU) 2019/1937 and (EU) 2020/1828 (Digital Markets Act, DMA).

[40] Regulation (EU) 2022/2065 of the European Parliament and of the Council of 19 October 2022 on a Single Market For Digital Services and amending Directive 2000/31/EC (Digital Services Act, DSA).

[41] This statement originates from TEHDAS1 and is followed in this thesis. For the observation, see Sprengers et. al. 2023, p. 7.

[42] 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, GDPR).

[43] European Commission, European Health Data Space Regulation (EHDS).

[44] European Commission, European Data Governance Act.

governance.[45] Building on the DGA, the EHDS Regulation establishes a specialised structure for managing health data within the EU.[46]

A central component of the DGA is the regulation of the re-use of certain categories of data held by public sector bodies.[47] It lays down rules for how public sector bodies make data available, extending also to data protected by third-party intellectual property rights (IPRs) or trade secrets.[48] Making data available is not mandatory, in the sense that the DGA does not impose an obligation on public sector bodies to permit the re-use of data.[49] The decision to make data available remains at the discretion of each Member State.[50]

Contrary to that, the EHDS Regulation requires health data holders, without distinguishing between public sector bodies or private sector entities, to make certain defined categories of data available for secondary use.[51] Unlike the DGA, where data sharing is voluntary, the EHDS Regulation imposes a legal obligation to provide access. Another difference arises in terms of the coverage of the data. The DGA applies, in principle, to all electronic data held by public sector bodies, whereas the EHDS Regulation specifies minimum categories of electronic health data that must be made available for secondary use.[52]

Regarding the sector-specific Union legislation, the DGA allows these laws to build on and complement its provisions.[53] An example of this can be found in the approach of the EHDS Regulation to data altruism. Data altruism occurs when individuals or companies voluntarily give their consent to make data they generate available for use in the public interest, without receiving any reward. Such data can significantly advance studies and the development of products and services in the health sector.[54] Within the DGA, data altruism offers a complementary mechanism to enable the use of personal health data for research, especially when patients give their consent. The EHDS Regulation then further clarifies that when a data

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[45] Recital 3 of the DGA.
[46] Peolsson et. al. 2025, p. 11.
[47] Recital 10 & Art. 1(1)(a) of the DGA.
[48] For the categories of data, see Art. 3(1) of the DGA.
[49] Art. 1(2) of the DGA. See also Directorate-General for Health & Food Safety (DG SANTE) 2025, p. 41.
[50] Recital 11 of the DGA.
[51] Art. 50(1) & 51(1) of the EHDS. Defining the health data holders, the EHDS Regulation excludes only two categories: 1) natural persons and 2) legal persons that qualify as microenterprises. See Art. 50(1) of the EHDS.
[52] Art. 51(1) of the EHDS. See also DG SANTE 2025, p. 42.
[53] Recital 3 & Art. 1(2) of the DGA.
[54] European Commission, European Data Governance.

altruism organisation makes personal health data available in a secure processing environment (SPE), the SPE must adhere to the same security standards as SPEs under the EHDS.[55]

Another example of the DGA enabling emerging EU data regulation to complement its provisions can be seen in the ongoing development of national datasets for the European Health Data Space. This work is steered by the legal and technical provisions set out in both the DGA and the EHDS Regulation. Both instruments stress the importance of establishing metadata management processes to facilitate efficient data discoverability and usability for secondary purposes, including research and policymaking. In this context, the EHDS serves as the main legal and operational basis for health metadata catalogues, while its implementation is reinforced by the DGA and other EU data governance frameworks.[56]

Overall, aligning the requirements of the EHDS Regulation with the principles of the DGA ensures coherence with the broader EU data governance policies.[57] The next legislative instrument to be discussed is the DA, which entered into force after the DGA and will become largely applicable from September 2025.[58] Building on the foundations of the DGA, the DA supplements the EU data regime.

3.3 Data Act and a competitive data market

The Data Act is designed to strengthen the EU's data economy and promote a competitive data market by making data easier to access and use.[59] Opportunities to share data were not excluded under the pre-existing EU legislation. However, the applicable rules, for instance rendering from the GDPR, were often perceived as restrictive and thus insufficiently conducive to innovation and research. In response, both the DA and the EHDS Regulation were put forward to provide complementary mechanisms for secure data access and use.[60]

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[55] DG SANTE 2025, p. 42.
[56] Peolsson et. al. 2025, p. 11.
[57] Ibid.
[58] Art. 50 of the DA. The DGA entered into force in June 2022 and has been applicable since September 2023. See Art. 38 of the DGA.
[59] European Commission, Data Act Explained. For a detailed account of the scope of the Data Act and its relation to personal data protection, see Art. 1(1)(a) & 1(5) of the DA. The Internet of Things (IoT) devices belonging to the scope of the Act are determined under its preamble. See Recital 14 of the DA.
[60] See for instance Peolsson et. al. 2023, p. 14; Casarosa – Gennari 2025, p. 21; European Commission, Rules on fair access to and use of data (Data Act).

In particular, the DA seeks to simplify business access to large volumes of high-quality industrial data, especially that generated through connected products, commonly referred to as the Internet of Things (IoT).[61] The DA sets out obligations to make data of IoT devices directly accessible to its users,[62] and grants them the right to, under certain conditions, share it with third parties of their choice.[63] With regard to electronic health record (EHR) systems and wellness applications, these fall primarily under the remit of the EHDS Regulation.[64] However, where such equipment or application qualify as IoT device, the rights and obligations of the DA apply.[65] This means that patients, who own or rent medical IoT devices, may voluntarily make their health data available by sharing it with third parties, thereby enabling access and secondary use of such data within the EHDS framework.[66]

The approach to public sector access to data differs between the DA and EHDS Regulation. Under the DA, public authorities may request access to data held by private entities only on basis of an exceptional need, and even then, access to personal data is subject to strict conditions.[67] In contrast, the EHDS Regulation takes a broader approach by allowing public authorities to access electronic health data when such access is necessary for the fulfilment of legal tasks assigned to them.[68] It is worth noting, that in situations where data can be made available through secondary use under the EHDS Regulation, the option of emergency access pursuant to the DA does not apply.[69]

Another striking difference between the acts lies in the mechanisms for accessing data. The EHDS Regulation encompasses a centralised and administratively governed data access procedure, which is expected to facilitate more streamlined access to electronic health data compared with the contractual and decentralised mechanisms favoured by the DA.[70] Nevertheless, the contract-based approach adopted by the DA may offer greater practical flexibility.[71]

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[61] European Parliament, Boosting data sharing in the EU: what are the benefits?
[62] Art. 3(1) of the DA.
[63] Art. 5(1) of the DA. See also DG SANTE 2025, p. 42.
[64] See Chapter III of the EHDS.
[65] DG SANTE 2025, p. 43; Recital 56 of the EHDS.
[66] DG SANTE 2025, p. 43.
[67] Art. 14 of the DA. In certain conditions, the access to personal data could be permitted only in the case of an exceptional need related to a public emergency response. See Art. 15(1)(a) & Recital 72 of the DA.
[68] Terzis 2023, p. 348. See also Art. 57(3–4) & Recital 61 of the EHDS; European Commission 2025, pp. 42–44.
[69] DG SANTE 2025, p. 43.
[70] Casarosa – Gennari 2025, p. 22. See also Recital 5 of the DA.
[71] Casarosa – Gennari 2025, p. 22.

In summary, the EHDS Regulation is built to a large extent upon the DA, specifically in its provisions on the secondary use of electronic health data.[72] While the DA lays the foundation for a more open and accessible data ecosystem, the EHDS Regulation extends it by enacting sector-specific rules and infrastructure for the access, governance and secondary use of electronic health data within that broader ecosystem.

3.4 GDPR as the main regulation on personal data in the EHDS

The primary objective of the GDPR is to protect the fundamental rights and freedoms of natural persons, especially their right to the protection of personal data.[73] When such data concerns a natural person's physical or mental health and reveals information about their health status, its processing is, in principle, prohibited.[74] The processing of these special categories of personal data, also known as sensitive data, falls under the article 9 of the GDPR and requires a strict legal basis and merit specific protection.[75]

The EHDS Regulation confirms that the processing of personal electronic health data remains subject to the provisions of the GDPR and adopts equivalent definitions for certain key terms, for example "personal data" and "processing".[76] Importantly, the EHDS Regulation does not amend or replace the GDPR, even though its understanding of data differs; the GDPR is rooted in the protection of fundamental rights related to personal data, whereas the EHDS adopts an approach that emphasises data sharing and innovation, treating electronic health data as a valuable economic resource. Rather than overriding the GDPR, the EHDS adapts and interprets its provisions to meet the specific needs and challenges associated with health data.[77]

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[72] See the "Explanatory Memorandum" in COM/2022/197 final.
[73] Art. 1(1) & (2) of the GDPR.
[74] Art. 4(15) & 9(1) of the GDPR.
[75] See Art. 9 of the GDPR; Recital 51 of the GDPR.
[76] Art. 1(3) & Recital 5 of the EHDS. For the definitions, see Art. 2(1) of the EHDS.
[77] Recital 8 of the EHDS; Casarosa – Gennari 2025, p. 17. See also Becker – Chokoshvili – Dove 2024. Another perspective is presented by Terzis, who interprets the EHDS Proposal as a shift away from the stringent data protection framework of the GDPR towards a model of administrative governance. He considers access to health data to be an administrative matter. Terzis argues, that although this approach may weaken data protection, it is not necessarily harmful and could benefit society by facilitating research and enabling rapid responses to public health issues. See Terzis 2023, p. 361.

During the drafting phase of the EHDS Regulation, considerable debate centred on its interaction with the GDPR.[78] The Proposal was criticised for lacking sufficient clarity to fully comply with the GDPR, particularly regarding the processing of sensitive data.[79] As a general rule, Article 9(1) of the GDPR prohibits the processing of sensitive data, including health-related data. The same article, nonetleless, contains certain exceptions under which such processing may lawfully take place, requiring that the defined legal conditions are satisfied and sufficient safeguards are ensured.[80] Doubts arose over whether the EHDS Proposal complied with these exceptions for processing sensitive data.[81]

Legal scholars, such as Meilak Borg & Caruana and Kertesz, argued that although the EHDS Proposal allows for a broad range of secondary uses, it fails to provide a clear explanation of how these uses correspond to the legal exceptions stipulated in the GDPR.[82] Similar concerns were raised by the European Data Protection Board (EDPB) and the European Data Protection Supervisor (EDPS), who notified that the Proposal did not demonstrate the consistency of such uses with GDPR requirements. These oversight bodies jointly recommended revising the Proposal for greater coherence with both EU and national data protection legislation.[83]

The adopted EHDS Regulation prescribes that EU Member States may no longer create or keep additional rules about how personal electronic health data is used for secondary purposes unless those rules are meant to add stronger protections for sensitivity and value of certain data as laid down in the EHDS Regulation. Applicants seeking access electronic health data must prove that they have a valid legal reason under the GDPR and must also comply with all conditions set by the EHDS Regulation. Furthermore, the Regulation obliges health data holders, like hospitals, to make electronic health data available to Health Data Access Bodies (HDABs), the national authorities, when requested. However, this obligation does not alter the original legal basis under which data were first collected, in this case for the provision of healthcare.[84]

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[78] Multiple legal scholars have expressed their concerns about the compatibility of the EHDS with the provisions of the GDPR. See for instance Becker – Chokoshvili – Dove 2024; Meilak Borg – Caruana 2024; Kertesz 2024; Quinn – Ellyne – Yao 2024.
[79] EDPB–EDPS 2022, p. 23; Kertesz 2024, pp. 500-501; Meilak Borg – Caruana 2024, p. 22.
[80] Art. 9(1) of the GDPR. For the list of the exceptions that enable processing personal data of special categories, see Art. 9(2) of the GDPR.
[81] EDPB–EDPS 2022, p. 23; Kertesz 2024, pp. 500-501; Meilak Borg – Caruana 2024, p. 22.
[82] Kertesz 2024, pp. 500-501; Meilak Borg – Caruana 2024, p. 22.
[83] EDPB–EDPS 2022, p. 23.
[84] Recital 52 of the EHDS.

What the EHDS Regulation provides in addition to the GDPR are specifications and completions to the rights of natural persons, predominantly with regard to the primary and secondary use of their personal electronic health data.[85] The main difference in material scope between the EHDS Regulation and the GDPR is that the GDPR applies only to personal data, whereas the EHDS covers both personal and non-personal electronic health data.[86]

Within the EHDS, the secondary use of electronic health data is permitted only when data has been either anonymised or pseudonymised, in order to prevent the identification of data subjects.[87] In research , anonymisation is routinely applied to allow datasets to be shared and reused more widely, particularly for large-scale studies and cross-border collaboration.[88] It is important to recognise that from legal perspective, anonymous and pseudonymised data are subject to distinct requirements.

Pseudonymised data continues to qualify as personal data, and is therefore subject to the full array of data protection safeguards and compliance obligations set out in the GDPR. Pseudonymisation refers to the processing of personal data in a way that prevents this data to be attributed to a specific data subject without additional, separately kept information.[89]

In contrast, anonymous data and their processing are not subject to the GDPR and thus its principles of data protection do not apply. Anonymous information, defined in the GDPR as data that does not relate to an identified or identifiable natural person, or that has been rendered anonymous so that the data subject can no longer be identified, is excluded from the reach of data protection rules.[90]

Recent case law indicates that the classification of pseudonymised data under the GDPR may vary depending on the context. In *Single Resolution Board v the European Data Protection Supervisor*, which has been appealed to the Court of Justice of the European Union (CJEU) and remains unresolved, the focus is on whether the recipient has the practical capability to re-identify individuals, rather than placing emphasis on the initial act of pseudonymisation by

[85] Art. 1(2)(a) of the EHDS.
[86] For the material scope of the GDPR, see Art. 2 of the GDPR. In this matter, for the scope of the EHDS Regulation, see Art. 1(1) & 2(2)(c) of the EHDS.
[87] Recital 53 of the EHDS.
[88] Auñón et. al. 2024, p. 8.
[89] Art. 4(5) of the GDPR.
[90] Recital 26 of the GDPR.

the sender.[91] In other words, data that is pseudonymised from the perspective of one entity (in this case the sender) may be considered anonymous from the perspective of another (the recipient), depending on its access and technical capabilities.[92] Until the CJEU provides further clarification, it is prudent to treat pseudonymised data equally as personal data for the purposes of complying with GDPR requirements and avoiding potential legal risks.

Besides this, anonymisation also presents certain challenges. The technology community increasingly acknowledges that data which is considered anonymised can be re-identified, particularly through the use of advanced Artificial Intelligence (AI) techniques.[93] From a legal standpoint, the re-identification of anonymised data is not prohibited under the GDPR. While the suggestion has been made by certain scholars to impose criminal penalties for such actions, there are currently no legal ramifications for them.[94]

The EHDS Regulation marks a step forward when it comes to re-identification. The Regulation prohibits data users from re-identifying, or even attempting to re-identify, natural persons when processing data for secondary purposes. Such actions constitute a serious infringement under the EHDS Regulation and may result in administrative fines. Thereby the Regulation sets a legal safeguard that did not previously exist.[95]

3.5 Data regime of the Common European Data Spaces

This section examined the legislation surrounding the Common European Data Spaces Despite it being widely recognised that the data regime within the EU has become increasingly complex,[96] the analysis here only referred to a small number of EU legislative

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[91] See Judgement 26 April 2023, *Single Resolution Board v European Data Protection Supervisor*, T-557/20, not published, EU:T:2023:219 (*SRB v European Data Protection Supervisor*); Para. 59 of Opinion of Advocate General Spielmann, 6 February 2025, European Data Protection Supervisor v Single Resolution Board, C-413/23 P,. The case concerns the distinction between anonymisation and pseudonymisation. The ruling shifts the focus from the sender's perspective to whether the recipient can reasonably identify an individual. The decision acknowledges that, depending on access and technical context, pseudonymised data can be anonymous for one party but not for another. In this case, pseudonymised data was not considered personal data where the third-party recipient lacked the means to re-identify the individuals. The decision has been appealed, and at the time of writing this thesis, the case is pending before the Court of Justice of the European Union (CJEU).
[92] *SRB v European Data Protection Supervisor*, paragraph 105.
[93] Auñón et. al. 2024, p. 8. See also Raposo 2025, p. 14.
[94] Raposo 2025, p. 14.
[95] Recitals 54 and 103 of the EHDS.
[96] See for instance EIT Health Think Tank 2024, p. 29. Although the EHDS and DA are grounded in the principles of the GDPR, Casarosa & Gennari argue that the two regulations reveal inconsistencies and lack in their coordination. According to them, several interrelated issues across these legislations exist, including the use of inconsistent terminology and the overall complexity of their application. See Casarosa – Gennari 2025, pp. 2, 17–18.

acts. The reviewed regulations can be summarised as follows. The DGA facilitates the establishment and development of the Common European Data Spaces in strategic domains, such as health.[97] The DA complements this by setting out requirements to promote interoperability both within and across data spaces.[98] Meanwhile, the GDPR lays down rules governing the processing of personal data and its free movement within the European Union.[99] Finally, building on these, the EHDS Regulation defines the rules applicable to a single sector-specific domain, the Common European Health Data Space.[100]

What is common to these the legal instruments, the DGA, the DA, GDPR and the EHDS Regulation, is that they are all EU regulations. This means they are directly applicable in all Member States and binding in their entirety.[101] Although EU regulations generally create a uniform legal framework across the Union, certain facultative clauses within the legislation allow for variation at the Member State level. For example, the GDPR establishes a harmonised set of rules for the protection of personal data but contains specific provisions relating to the processing of health data.[102] As discussed, this has raised questions of the alignment of the EHDS Regulation with the GDPR. More broadly, variations also arise in how data are collected, stored and accessed across Member States. In each country, these processes are governed by a combination of national, European and international rules, which has led to considerable differences throughout the EU.[103]

Therefore, it is not surprising that every step of progress towards the realisation of Common European Data Spaces concerns have been raised, both in academia and among Member States, about the need for consistency in legal definitions and substantive provisions. The introduction of the EHDS has brought these worries to the forefront once again.[104]

It has been argued, that a failure to ensure coherence may lead to legal ambiguity, which, in turn, can impede research and innovation.[105] Especially, from the perspective of smaller companies, the EHDS has been viewed with some caution if it further complicates the already

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[97] European Commission, European Data Governance Act.
[98] Art. 33 of the DA.
[99] Art. 1(1) of the GDPR.
[100] Art. 1(1) of the EHDS.
[101] Art. 288 of the Consolidated version of the Treaty on the Functioning of the European Union [2016] OJ C 202/47.
[102] DG SANTE 2022, pp. 10–11
[103] DG SANTE 2022, p. 10; Abboud – Cosgrove – Kesisoglou 2023, p. 12.
[104] Shabani 2022, p. 1359; EIT Health Think Tank 2024, p. 29
[105] Ibid..

dense regulations. This could hinder collaboration and slow innovation within the field.[106] Furthermore, social scientists such as Marelli et al., have cautioned that initiatives like the EHDS could potentially obstruct rather than support the re-use of health data by researchers.[107] This statement has been reinforced by Åm et. al., who assert that their analysis justifies the observations made by Marelli et al.[108]

Following the entry into force of the EHDS Regulation, other scholars have emphasised the role of Member States. Calls have been made for clearer definitions and harmonised policies to prevent the risks of regulatory fragmentation across jurisdictions.[109] Accordingly, the European Commission has emphasised that while a one-size-fits-all approach is not feasible within the Common European Data Spaces, it is possible to adapt and apply common governance principles and models in different sectors.[110]

Despite these challenges, there is a broad consensus among Member States and stakeholders that the EHDS will ultimately lead to the more widespread use of European health data for scientific research. It is also anticipated that the EHDS will enhance interoperability across administrative levels, organisations and other actors.[111] In this sense, the Regulation is seen not merely as a legal instrument but as a strategic enabler of cross-border collaboration in digital health as well.

[106] van Drumpt et. al. 2025, pp. 6, 10.
[107] See Marelli et. al. 2023, p. 2.
[108] Åm et. al. 2025, p. 10.
[109] van Drumpt et. al. 2025, p. 11.
[110] COM(2020) 66 final, p. 21.
[111] Abboud – Cosgrove – Kesisoglou 2023, p. 13; Kessissoglou et al. 2024, p. 1106.

4 The European Health Data Space Regulation on secondary use

4.1 Data and data use in general

As part of broader legislative action at EU level, the EHDS Regulation aims to improve data sharing across the Union.[112] The European Commission states that the European Health Data Space (EHDS) aspires to create an ethically governed, secure and interoperable digital environment for health data. It further seeks to ensure that both individuals and public institutions benefit from improved access to high-quality, reliable data.[113]

The EHDS Regulation represents a new legal instrument developed in response to the well-recognised need for secure and interoperable systems for exchanging health data in healthcare across the EU.[114] Especially within the biomedical research community, enabling secondary uses of health data for scientific studies has long been a key objective. This has been pursued not only through the development of standards and best practices but also through the establishment of data-sharing initiatives, platforms and infrastructures. An increasing number of these efforts involve cross-border activities backed by European governments.[115]

Now in force, the EHDS Regulation pursues two core objectives: first, to strengthen individuals' rights by granting them better access to and control over their personal electronic health data; and second, to facilitate the reuse of specific categories of data for broader public interests.[116] The former objective corresponds to the primary use of electronic health data, while the latter relates to its secondary use.

The EHDS Regulation covers a wide range of health data types, from clinical data to automatically generated ones.[117] The thesis does not aim to discuss all of these categories that may fall within its scope. Instead, particular attention is given to Real-World Data (RWD), which has gained growing interest in the recent years. Accordingly, research and innovation activities relating to RWD have expanded, with the European Commission also contributing

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[112] Recital 1 of the EHDS; Becker – Chokoshvili – Dove 2024, p. 224.
[113] European Commission, European Health Data Space Regulation (EHDS). See also Recital 1 of the EHDS.
[114] See for example Slokenberga – Cathaoir – Shabani 2025, p. 4; Terzis – Santamaria Echeverria 2023, p. 369. The results of over 100 case studies in 2022 revealed that European data users face numerous barriers to cross-border health data sharing for secondary use, primarily due to legal and data management issues, which arise from misaligned interpretations and implementations. For the case studies, see Abboud et al. 2022.
[115] Becker – Chokoshvili – Dove 2024, p. 224.
[116] Recital 1 of the EHDS; European Commission, European Health Data Space Regulation (EHDS).
[117] Recital 56 of the EHDS. For the list of data categories for the secondary use, see Art. 51(1) of the EHDS.

to the field.[118] One of its Horizon Europe projects, ONCOVALUE, aims to enhance the use of RWD for secondary purposes in value-based cancer care. Hence, it is useful to consider what is meant by RWD and how it is applied within the health sector. Although this thesis primarily refers to electronic health data in general terms, it does not always explicitly distinguish RWD as a separate category. For the purposes of this discussion, whenever electronic health data is mentioned, it should be understood as encompassing RWD as one of its data types.

4.2 Real-World Data (RWD) as electronic health data

Electronic health data are assumed to hold considerable potential for delivering societal benefits. Notably, the EHDS Regulation stresses the importance of RWD and Real-World Evidence (RWE), which can complement the already available health data.[119] Moreover, access to RWD has significantly improved lately, with advancements occurring across multiple levels from local hospital research databases to large-scale international collaborations.[120]

RWD refers to data which are collected during routine healthcare and may encompass patient demographics, disease, treatment, interactions with the healthcare system and social or environmental factors affecting health status.[121] In clinical research, especially in the development of cancer treatments, RWD offers complementary data beyond traditional clinical trials,[122] because unlike data generated in controlled research settings, RWD is collected in real-world environments.[123] RWD originates from numerous sources. It can be obtained either through primary collection, where data are specifically gathered for a particular study, or through secondary use, meaning the data were initially recorded for other purposes, such as patient care or administrative needs.[124]

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[118] For projects on Real-World Data (RWD) funded by the European Commission, see European Commission, New methods for the effective use of real-world data and/or synthetic data in regulatory decision-making and/or in health technology assessment.
[119] See Recital 53 of the EHDS.
[120] Price et al. 2025, p. 2.
[121] EMA 2024a, p. 4.
[122] For the results of the analysis of the approvals by European Medicines Agency (EMA), see for example Wang et al. 2023. The EHDS Regulation also acknowledges the potential of Real-World Data and Real-World Evidence to complement the health data currently available. See Recital 53 of the EHDS.
[123] Cascini 2025, p. 3. See also Price et al. 2025, p. 2; Katkade – Sanders – Zou 2018, p. 300
[124] EMA 2024a, p. 4; Solà-Morales et al. 2023, p. 33; Katkade – Sanders – Zou 2018, p. 297.

In practice, RWD sources often include electronic health records (EHRs), medical claims, billing systems, disease and product registries and digital health technologies such as mobile devices.[125] With most of these sources now digitised, advances in technology have made it easier to collect and standardise data systematically. As a result, the integration of data from diverse sources has become increasingly feasible.[126] However, inconsistencies in data entry across healthcare providers and information technology systems add intricacy, which makes it difficult to compile complete and high-quality datasets for secondary use.[127] In this context, the EHDS Regulation offers a potential solution by establishing a uniform legal and technical framework for EHR systems, which aims to minimise fragmentation, heterogeneity and disparities across Member States.[128]

As the volume of RWD continues to grow, several global databases have emerged to aggregate this information, often covering data from large patient populations. There are efforts to link and harmonise these datasets to maximise their value for research and decision-making.[129] In Europe, European Medicines Agency (EMA), a decentralised body which is responsible for the scientific evaluation of medicines within the Union, maintains a catalogue of RWD sources. This catalogue primarily consists of secondary data, while primary data are generally included only when patient registries are involved.[130] Now as the EHDS gradually becomes applicable, it is important that datasets intended for secondary use are as comprehensive and complete as possible to maximise their utility.[131]

Over the past years, RWD has gained substantial attention in oncology care due to its potential to accelerate advancements in the field.[132] Yet, despite the strong prevalence of RWD-based studies in the literature, its tangible impact on clinical practice remains limited.[133] Within the EU, research projects such as ONCOVALUE are actively working to increase the use of high-quality RWD.[134] These efforts are in line with the EHDS Regulation,

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[125] Solà-Morales et al. 2023, p. 33.
[126] Katkade – Sanders – Zou 2018, p. 297.
[127] Cascini 2025, p. 3. For the encouragement to prepare comprehensive datasets, see Recital 53 of the EHDS.
[128] See Recital 1 & 7 of the EHDS.
[129] Katkade – Sanders – Zou 2018, p. 297. For concrete efforts in this field, see European Commission, Projects supporting EHDS.
[130] EMA, Good Practice Guide for the use of the HMA-EMA Catalogues of real-world data sources and studies, p. 7. See also European Medicines Agency (EMA), About us. For the catalogues, see EMA, RWD Catalogues.
[131] See Recital 53 of the EHDS.
[132] Katkade – Sanders – Zou 2018, p. 297.
[133] Price et al. 2025, p. 2.
[134] See for instance European Commission, CORDIS.

which encourages the uptake of RWD and RWE for research, health technology assessment (HTA), evidence-based regulation and policymaking as well as for clinical decision-making. The Commission further notes that RWD and RWE can meaningfully complement existing health data sources by increasing their utility for various secondary purposes. [135]

4.3 Concepts of the primary and secondary use

The EHDS Regulation lays down common rules and mechanisms for primary and secondary use of electronic health data.[136] Chapter II of the Regulation sets out provisions for primary use and Chapter IV regulates secondary use. Together, these provisions are intended to enhance collaboration among Member States through the cross-border digital infrastructure for health data exchange.[137]

To begin with, the primary use refers to the processing of a natural person's electronic health data for providing healthcare. This can involve assessing, maintaining or restoring their state of health.[138] The EHDS Regulation brings several rights for individuals concerning this primary use. Pursuant to the Regulation, they have right to access[139], manage[140] and share their health information, in particular when seeking medical treatment across different Member States.[141]

Natural persons may choose to opt-out of granting access to their personal electronic health data. Nevertheless, this option is only possible where the respective Member State has decided to make it available. This means that in Member States which do not enact an opt-out mechanism, individuals have no legal means to refuse the primary use of their health data.[142] Where opting out is permitted, the Member State must also ensure that this right can be reversed.[143]

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[135] Recital 53 of the EHDS.
[136] Art. 1(2)(c) of the EHDS.
[137] Davidovics – Kovács – Gaál 2023, p. 6; COM/2022/197 final, p. 100.
[138] Art. 2(2)(d) of the EHDS.
[139] Art. 3 (Right of natural persons to access their personal electronic health data) of the EHDS.
[140] Art. 5 (Right of natural persons to insert information in their own EHR), 6 (Right of natural persons to rectification) & 8 (Right to restrict access) of the EHDS.
[141] Art. 7 (Right to data portability for natural persons) of the EHDS.
[142] Art. 10(1) of the EHDS; European Commission, European Health Data Space Regulation (EHDS).
[143] Art. 10(1) of the EHDS.

Secondary use, instead, concerns the processing of electronic health data for purposes beyond those for which the data were originally collected or generated.[144] Despite the terminological delineation between primary and secondary use, the secondary use of health data cannot be considered in vacuum. This is because the effectiveness of such data use is inherently dependent on the quality and completeness of data collected for primary use.[145]

Contrary to the opt-out from primary use, which will be determined by the national laws of each Member State, the right to opt-out from secondary use is guaranteed by the EHDS Regulation. Natural persons may exercise this right at any time without a reason.[146] This implies that the more individuals opt-out across EU Member States, the less health data will be available for research through secondary use. This could also lead to variations in data availability between countries, particularly if citizens of certain Member States are more inclined to exercise their opt-out rights. Furthermore, secondary use does not cover all electronic health data of natural persons, since only specific types categorised in the Regulation are included.

The categories of electronic health data, which must be available for secondary use, are defined in the EHDS Regulation. Member States may add further categories if they wish.[147] In the EHDS, processing electronic health data for secondary use requires prior authorisation from a Health Data Access Body (HDAB), which each Member State is expected to establish.[148] The responsibilities of the HDABs involve reviewing applications submitted by health data applicants and thus contribute to the consistent implementation of the EHDS Regulation throughout the European Union.[149]

In the application, the health data applicant must demonstrate a legal basis for requesting access to electronic health data.[150] In other words, the access cannot be sought for undefined or purely commercial interests but must correspond to a specific and legitimate legal purpose

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[144] Art. 2(2)(e) of the EHDS; European Commission, European Health Data Space Regulation (EHDS).
[145] EIT Health Think Tank 2024, pp. 12, 22–24.
[146] Art. 71(1) of the EHDS. The right to opt out of the secondary use of personal electronic health data is not absolute, as Article 71(4) of the EHDS allows Member States to make such data available under national legislation.
[147] Art. 51 of the EHDS.
[148] Recital 64 & Art. 55(1) of the EHDS; European Commission, European Health Data Space Regulation (EHDS).
[149] Recital 65 & Art. 55(1) of the EHDS.
[150] Art. 67(2)(b) of the EHDS.

for processing data for secondary use. Under the EHDS, these purposes range from scientific research to policymaking and regulatory activities supporting health authorities.[151]

As was discussed earlier in this thesis regarding the compatibility of the EHDS Regulation with the General Data Protection Regulation (GDPR), a similar issue arises here. The legal grounds for secondary use have not been interpreted or applied uniformly across Member States, particularly regarding the scientific research exemption for sensitive data. For this, each Member State has imposed varying requirements. Therefore, the lack of uniformity could cause difficulties in interpreting and applying the norms that establish the legal basis for data processing.[152] In addition to this, Member States may encounter further challenges once the EHDS becomes applicable.

4.4 Member State readiness for secondary use in the EHDS

Before the EHDS Regulation came into force, a range of EU-level policy initiatives had already contributed to its development.[153] In recent years, many Member States have also shown political commitment to advancing the digital transformation of healthcare, with their governments taken a positive and proactive stance in relation to the EHDS.[154] Before that, the situation was more fragmented.[155]

A few years ago, nearly half of the Member States had introduced national or regional interoperability policies that enabled health data to be exchanged between healthcare professionals or integrated into multiple databases for secondary use. However, approximately one third of the Member States had not adopted any such policies at either the national or regional level, revealing notable disparities in readiness across the Union.[156]

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[151] Art. 53(1) of the EHDS. For prohibited secondary use, see Art. 54 of the EHDS.
[152] Peolsson et. al. 2023, p. 15; Raposo 2025, p. 11.
[153] DG SANTE 2022, p. 10. One example of an initiative is the eHealth Digital Service Infrastructure (eHDSI), which was set up to guarantee continuity of care for persons travelling from one Member State to another. See DG SANTE 2022, p. 10. A further example is the eHealth Network, which made some progress, notably in facilitating cross-border data exchange for healthcare. However, the efforts regarding the secondary use of electronic health data were rather limited and ineffective. Within the Member States, other actors emerged on secondary use than the ones represented in the eHealth Network. Ultimately, the EHDS Proposal concluded that the eHealth Network's structure was no longer suitable. See COM/2022/197 final, p. 9; DG SANTE 2020, p. 2.
[154] EIT Health Think Tank 2024, p. 27.
[155] DG SANTE 2022, p. 24; DG SANTE 2021, p. 38.
[156] Ibid.

A major challenge for EHDS lies in the uneven maturity of digital health systems among Member States.[157] National levels of digitalisation vary noticeably and interoperability between healthcare systems has continued to be limited.[158] Multiple technical factors currently influence the extent to which health data can be digitised across the EU.[159] The EHDS Regulation applies exclusively to electronic health data, which in practice means, that health data in non-digital formats falls outside the scope of the EHDS.[160]

At the heart of this digitalisation issue is that some healthcare providers or registeries in couple of countries still rely on paper-based records, while others provide digital access to patient data for healthcare professionals and individuals.[161] The EHDS Regulation does not oblige existing non-electronic health data to be converted into digital form before its application, meaning the amount and timespan of data available for secondary use will vary across Member States.[162] In cases where paper records persist until the start of the application of the Regulation, only data collected or generated from that point onwards will be accessible for secondary use.

Various mechanisms and procedures for accessing health data for secondary use have existed in Member States even before the EHDS Regulation.[163] Nonetheless, the EU-wide infrastructure supporting the secondary use of electronic health data is still considered relatively underdeveloped and appears to be focused primarily on specific categories of data.[164] This uneven development suggests that European countries are not yet consistently aligned with the requirements for secondary use, and consequently, the accessibility of electronic health data for research, innovation and policymaking may vary across Member States.

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[157] DG SANTE 2022, p. 24.
[158] DG SANTE 2020, p. 2. For detailed country factsheets concerning health data management systems in different Member States, see Abboud – Cosgrove – Kesisoglou 2023.
[159] DG SANTE 2022, p. 24.
[160] The Regulation covers only electronic health data. See Art. 1(1) & Recital 1 of the EHDS; European Commission, European Health Data Space Regulation (EHDS).
[161] DG SANTE 2022, p. 24; Abboud – Cosgrove – Kesisoglou 2023, p. 11. For country factsheets, see Abboud – Cosgrove – Kesisoglou 2023.
[162] In general, not only in this context, data imbalance, where different healthcare providers have uneven volumes of data, is common. See for example study of Auñón et. al. 2024.
[163] Petročnik 2025, p. 189.
[164] DG SANTE 2022, p. 17

In essence, the EHDS provisions on secondary use seek to address longstanding challenges in accessing and utilising health data for research, innovation and policymaking.[165] For Member States, the EHDS Regulation establishes, for the first time, a comprehensive legal framework governing the secondary use of electronic health data.[166] Previously, only a few European countries had clear frameworks enabling such use, although many governments had already invested in health data infrastructure.[167]

The EHDS Regulation introduces a common system of data governance, accompanied by rules and guidelines for data exchange in the health sector. However, as has become apparent, the adoption of this common framework will face diverse national realities.[168] For example, the study by Åm et al. reveals that even in Nordic countries, which are relatively similar, notable differences in approaches and practices exist. The authors emphasise that the EHDS's requirements for regulatory and organisational changes will affect each Member State differently.[169]

A group of stakeholders has suggested that the implementation of the EHDS Regulation requires revising legal provisions that are overly restrictive or ambiguous, as well as the data-sharing policies and practices these provisions have produced in different organisations over time. They also agree that cross-border data sharing for secondary use will necessitate greater consistency among all Member States when interpreting the GDPR, particularly with regard

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[165] Recital 55 of the EHDS. See also the "Explanatory Memorandum" in COM/2022/197 final. For an overview of the anticipated benefits of the EHDS, see European Commission, European Health Data Space Regulation (EHDS).
[166] Abboud – Cosgrove – Kesisoglou 2023, p. 12; Terzis 2023, p. 348.
[167] Terzis 2023, p. 347.
[168] EIT Health Think Tank 2024, p. 8. Regarding concerns about the implementation of the EHDS, a survey of stakeholder expectations conducted by TEHDAS1 indicates that stakeholders view the operationalisation of the Regulation as its most significant challenge. Out of 153 respondents, 125 identified "implementation after the legislative proposal has been adopted" as the most pressing issue associated with the EHDS Proposal. See TEHDAS1, Joint Action Towards the European Health Data Space – TEHDAS1. This concern is reinforced by Casarosa & Gennari, who anticipate that the EHDS is likely to require a longer transitional period than currently stipulated in the Regulation before reaching full implementation. See Casarosa – Gennari 2025, p. 22. Kessissoglou et al. similarly report that stakeholders share this expectation of possible delay. See Kessissoglou et al. 2024, p. 1106
[169] Åm et. al. 2025, p. 5. In Finland, Findata is currently the closest equivalent to an HDAB and, contrary to the article, should not be understood as a HDAB itself. Instead, Findata merely reflects the future role of a HDAB. The website of Findata clarifies that no decisions have yet been made regarding national implementation. Pursuant to Art. 105 of the EHDS Regulation, the HDABs will be designated by March 2027. See Findata, EHDS.

to anonymisation and pseudonymisation. Therefore, stronger coordination and collaboration between the national bodies responsible for EHDS governance are thus needed.[170]

To support harmonised and effective implementation of the EHDS for secondary use, a number of complementary EU-projects and initiatives, such as the EHDS2 Pilot project and TEHDAS initiatives, are especially dedicated to developing the necessary infrastructure, processes and governance structures.[171] Since the application of the EHDS Regulation starts gradually, there are opportunities for these projects and initiatives to develop, test and refine processes before compliance becomes mandatory. The Regulation itself sets out the overall timeframe for implementation and thus it provides a structured pathway for Member States and stakeholders to prepare for full-scale deployment.[172]

4.5 Application timeline of the EHDS Regulation

Based on the policy and regulatory background of the EHDS, the development of digital health has progressed more slowly compared with digitalisation in other sectors. There is also significant variation across EU Member States in the maturity of their digital health systems, as discussed in the previous section.[173] The EHDS Regulation now establishes the key principles and objectives for the operation of the European Health Data Space by providing a unified legal and operational framework. It maps out a timeline for implementation, including the adoption of delegated and implementing acts and the deployment of infrastructure and governance mechanisms.

The EHDS Regulation entered into force on 26 March 2025 and its adoption marks the beginning of a gradual implementation process.[174] As is typical with EU legislation, the Regulation will not immediately apply; its general application is scheduled to begin in 2027.[175] This phased approach is intended to support not only the successful implementation of the Regulation but also the creation of effective conditions for cooperation on European health data.[176]

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[170] EIT Health Think Tank 2024, p. 8.
[171] European Commission, Projects supporting EHDS.
[172] On the phased application timeline of the EHDS Regulation, see Art. 105 of the EHDS.
[173] See also DG SANTE 2022, p. 10.
[174] See Art. 105 of the EHDS.
[175] On the fixed timeline, see Art. 105 of the EHDS; European Commission, European Health Data Space Regulation (EHDS).
[176] Recital 115 of the EHDS.

With the EHDS comes plenty of technical details which are to be specified through implementing acts.[177] The Regulation demands the European Commission to adopt the core implementing acts within two years of its entry into force, and in certain cases at a later stage, depending on the categories of health data concerned.[178] These acts will encompass a wide range of matters, including technical specifications, detailed system requirements and security measures necessary for secure processing environments (SPEs).[179] Essentially, they lay down more detailed rules required for the practical application of the Regulation.[180] For adopting delegated acts to supplement the EHDS Regulation, the Commission has been empowered already from the date the EHDS Regulation came into force.[181]

From March 2029, several key provisions of the EHDS Regulation, together with the corresponding implementing acts, will begin to apply, including the rules on the secondary use of most categories of electronic health data, such as data derived from EHRs. By March 2031, these rules on secondary use will be extended to cover the remaining categories of data.[182]

At the moment, several practical matters are still to be clarified by secondary legislative instruments, in order for the EHDS to function as envisioned. In spite of that, the overall framework has now been established by the EHDS Regulation to provide the necessary legal certainty and strategic direction to guide Member States and other stakeholders in the preparatory phase across the European Union.

[177] Art. 97 of the EHDS; European Commission 2025, p. 8.
[178] Art. 105 of the EHDS.
[179] Art. 97 of the EHDS; European Commission 2025, p. 8.
[180] European Commission, European Health Data Space Regulation (EHDS).
[181] Art. 97(2) of the EHDS.
[182] For detailed steps for starting the application, see Art. 105 of the EHDS. See also European Commission, European Health Data Space Regulation (EHDS).

5 Governance and mechanisms for secondary use under the EHDS Regulation

5.1 Overview of the EHDS in action

From the legislative perspective, turning the vision of Common European Data Spaces into reality requires a solid regulatory basis to govern their operation. According to the European Commission, governance structures should clearly define the conditions under which data may be used, enable cross-border data flows and prioritise interoperability standards both within and across sectors.[183] In line with this approach, the EHDS Regulation establishes a governance framework that enables the secondary use of electronic health data.[184]

The governance system of the European Health Data Space (EHDS) is organised around the mechanisms and actors engaged in secondary use. New entities specifically dedicated to the EHDS involve health data holders, health data users, health data access bodies (HDABs) and trusted third parties. A health data holder is a natural or legal person legally processing or controlling electronic health data.[185] A health data user, on the other hand, is any natural or legal person who has been granted access to use such data for secondary purposes.[186] An HDAB is a competent national authority responsible for granting access.[187] In close cooperation with the HDAB, a trusted health data holder is an entity designated to simplify and manage data access applications and requests.[188]

Cross-border access to electronic health data for secondary use will be enabled through HealthData@EU.[189] More broadly, HealthData@EU is intented to operate in an interoperable manner with other Common European Data Spaces, which are expected to become interconnected over time.[190] Accordingly, HealthData@EU should support the secondary use of multiple categories of electronic health data, including the potential to link health data with

[183] COM(2020) 66 final, p. 12.
[184] Art. 1(1) of the EHDS.
[185] Art. 2(2)(t) of the EHDS.
[186] Art. 2(2)(u) of the EHDS.
[187] Art. 57(1)(a) of the EHDS.
[188] Recital 76 of the EHDS. See also Art. 57 of the EHDS.
[189] Art. 75(7) of the EHDS. HealthData@EU is a cross-border infrastructure for multi-country secondary use. See Recital 80 of the EHDS.
[190] Art. 75(11) & Recital 80 of the EHDS.

information from other domains, such as environmental or social datasets. This cross-sector interoperability could offer important insights into the wider factors that influence health.[191]

Being the first sector-specific regulation of its kind, the EHDS Regulation contains some novel concepts. In this regard, scholars have stressed need for precise conceptual clarity, as its absence could lead to unintended consequences.[192] Rak, for example, cautions that stakeholders may face legal uncertainty and potential risks if central concepts within the EHDS Regulation are vaguely defined. He stresses that this is critically relevant in light of the ambitious and largely untested common data governance mechanism for the secondary use.[193]

The EHDS infrastructure and mechanisms for secondary use were trialled in real-world settings prior to the Regulation being adopted. The EHDS2 Pilot project, also known as HealthData@EU Pilot, had participants from seven Member States and was conducted in cooperation with the European Commission. The Commission received practical feedback from the project on how to refine and guide the development of the EHDS prior to the adoption of the Regulation.[194]

5.2 Health data holders and access to electronic health data

A health data holder could be any natural or legal person, or any public authority, agency or body operating within the healthcare or care sector. The definition also encompasses natural or legal persons involved in the development of products or services related to health, care or healthcare, the development or manufacture of wellness applications, or the conduct of research in the field of healthcare or care. EU institutions, bodies, offices and agencies may likewise qualify as health data holders.[195]

To qualify as a health data holder, a subject mentioned above must have either a legal right or a legal obligation to process personal electronic health data for a purpose specified in the EHDS Regulation, including public health, research or policymaking.[196] In short, a data

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[191] Recital 80 of the EHDS.
[192] Rak 2024, p. 938. See also for example Slokenberga – Cathaoir – Shabani 2025; Meilak-Borg – Caruana 2024; Marelli et al. 2023; Shabani – Yilmaz 2022;
[193] See Rak 2024. Also Raposa argues that operational clarity of the health data access bodies (HDABs) is lacking. See Raposa 2025, p. 17.
[194] See European Commission, Pilot for a European Health Data Space on secondary use of health data.
[195] Art. 2(2)(t) of the EHDS.
[196] Ibid. According to Art. 50(1) of the EHDS, even though falling into definition of a health data holder, natural persons, including individual researchers, and legal persons that qualify as microenterprises, are exempt from the

holder is the one that originally collected the health data for its own purpose and continues to retain control over it.[197] Examples of health data holders are hospitals, research institutions and application developers.

In the light of the EHDS Regulation, research projects, such as ONCOVALUE, which use electronic health data for secondary purposes without having collected it themselves, do not qualify as data holders. Instead, the coordinator of the ONCOVALUE project, Helsinki University Hospital (HUS), and its consortium members – cancer centres and institutions including IPO Porto, IRST-IRCCS, The Netherlands Cancer Institute, Rigshospitalet and Rijnstate – may fall within this category.[198] As a health data holder, the entity is bound by the obligations set out in the EHDS Regulation.

Health data holders are required to make certain categories of electronic health data available for secondary use. The EHDS Regulation establishes a minimum set of such categories and Member States may define additional categories beyond this core set.[199] The minimum categories of the EHDS Regulation comprise, among others, electronic health data from electronic health records (EHRs) and data from medical registries, clinical trials and wellness applications .[200]

The duty of health data holders is to provide access to their data when requested by the HDAB. Such requests may take the form of a data permit issued by the HDAB or a health data request authorised by the same authority. In either case, the health data holder must make the data available in accordance with the conditions specified in the relevant permit or request.[201] The health data holders do not have the right to refuse access, even if there are potential grounds for objection, such as intellectual property rights (IPRs) or trade secrets. As Raposo concludes, it is foreseeable that health data holders might delay the delivery of data.[202] Nevertheless, the HDAB has the authority to intervene and may impose fines for non-

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obligations on health data holders regarding the secondary use. However, Member States may decide otherwise and, in their national laws, stipulate that these obligations apply to them as well. See Art. 50(2) of the EHDS.
[197] Raposo 2025, p. 9.
[198] On the ONCOVALUE Consortium, see ONCOVALUE, The ONCOVALUE Consortium.
[199] Art. 51(1–2) of the EHDS.
[200] Health data holders should make data from research cohorts, questionnaires and surveys available for secondary use once the related results have been published for the first time. See Art. 51(1)(p) of the EHDS.
[201] Art. 60(1) of the EHDS.
[202] Raposo 2025, p. 13.

compliance, ensuring thus adherence to the Regulation.[203] In this capacity, HDABs serve a central function in protecting the effective secondary use of electronic health data and enabling a mechanism to mitigate possible risks arising from data access delays.

5.3 HDABs and trusted health data holders

HDABs will support access to electronic health data across the Union, which is necessary for promoting its secondary use.[204] By 26 March 2029, each Member State must have at least one HDAB operational.[205] In academic and research communities, some have disagreed with designating multiple HDABs at the national level, as this may not resolve the fragmentation issues between Member States that have posed challenges to date.[206] Conversely, the Regulation leaves it to the Member States to decide how many of such bodies they wish to have. The identities of these bodies should be communicated to the European Commission by 26 March 2027, two years before their operations are scheduled to commence.[207]

Member States may designate existing public sector bodies as HDABs or establish new ones for this purpose. While at least one HDAB per Member State is mandatory, multiple bodies may be created, in which case one must be appointed as the national coordinator.[208] HDABs are required to operate independently, avoid any conflicts of interest and be free from external influence in their decision-making regarding access to electronic health data for secondary use.[209]

A key responsibility of HDABs is the management of data permits and health data requests. They are tasked with evaluating applications for access to health data (pursuant to Article 67 of the EHDS), authorising and issuing data permits for secondary use (pursuant to Article 68) and deciding on submitted health data requests (pursuant to Article 69). Once a data permit is issued or health data request approved, the HDAB obtains the relevant electronic health data

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[203] Art. 63(4) of the EHDS; Raposo 2025, p. 13. In addition, Member States may impose further penalties for refusal under Art. 99 of the EHDS.
[204] Recital 64 & 65 of the EHDS. Against this goal, Raposo claims that the EHDS Regulation appears to designate HDABs as the principal gatekeepers of health data. She states that the Regulation does not provide a precise definition of these bodies and their role is defined more by function than by formal description. See Raposo 2025, p. 10.
[205] Art. 55(1) & art. 105 of the EHDS.
[206] Sprengers et. al. 2023, p. 22; Åm et. al. 2025.
[207] Art. 55(6) of the EHDS.
[208] Art. 55(1) of the EHDS.
[209] Art. 55(5) of the EHDS; Recital 64 of the EHDS.

from the appropriate health data holders. Moreover, when issuing a data permit, the HDAB provides access to electronic health data for health data user within a secure processing environment (SPE).[210]

To reduce the administrative burden associated with managing access requests, Member States may designate trusted health data holders to assist in a simplified permit procedure. [211] When the requested data is held by a single trusted health data holder, HDABs can forward data access applications and health data requests to them for review. The trusted health data holder then issues a non-binding recommendation and a proposed decision to the HDAB, which may take it into account when making a final decision.[212] Ultimately, the HDAB retains exclusive authority to approve or deny access permits and health data requests.[213]

As set out in the Regulation, HDABs must provide access to electronic health data in accordance with a data permit exclusively through an SPE.[214] Processing of personal health data within this environment must comply with the General Data Protection Regulation (GDPR) and must not allow the direct transfer of electronic health data to users.[215] Health data users may only download non-personal electronic health data from the SPE, including electronic health data in anonymised statistical format. Before any non-personal electronic health data can be downloaded, the request must first be reviewed and approved by the HDAB.[216]

Regarding infrastructures for processing data for secondary use, the study conducted by Åm et al. offers a noteworthy example. The authors observed that tensions have arisen in the development of health data spaces[217] in Finland, Norway and Denmark. One reason is the presence of long-established data infrastructures, which have fostered professional and organisational environments with a strong sense of ownership over the data they collect and use. Each infrastructure applies its own guidelines for data collection, storage and usage. Furthermore, many also provide dedicated analytical platforms as secure environments for

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[210] Art. 57(1)(a) of the EHDS.
[211] Recital 76 of the EHDS.
[212]Art. 72(1-5) & Recital 76 of the EHDS.
[213] Art. 57(1)(a) of the EHDS; Recital 76 of the EHDS.
[214] Art. 73(1) of the EHDS.
[215] Recital 77 of the EHDS.
[216] Art. 73(2) of the EHDS. See also Recital 77 of the EHDS
[217] Unlike the EHDS, which is formally established by law, data spaces can generally be set up through a contract between organisations.

processing data. Consequently, various actors in these countries prefer to maintain the systems they have relied upon for years or, alternatively, pursue to lead and define any new centralised structure themselves.[218]

With the implementation of the EHDS, practices will be harmonised and requirements for SPEs established at Union level. For data users, this is expected to standardise the processing of electronic health data for secondary purposes.

5.4 Transition from Health Data Applicant to User

A health data user is a natural or legal person, or an EU institution, body, office or agency, entitled to access and process electronic health data for secondary use in accordance with an issued data permit, an approved health data request or an access approval granted by an authorised participant in HealthData@EU.[219] Within the EHDS, research projects such as ONCOVALUE can become health data users by applying for access to electronic health data for secondary use. The EHDS Regulation offers two mechanisms for such access: health data access applications and health data requests. In cross-border situations, where a health data applicant seeks access to electronic health data stored in more than one Member State, a single application is sufficient. Once submitted, the application is automatically forwarded to the relevant authorities in the other Member States.[220]

The application process for secondary use has been tested by the EHDS2 Pilot project in real-world settings, and a draft guideline has been published by TEHDAS2 to support its implementation.[221] The guideline, "Guideline for Data Users on Good Application Practice for Data Access and Requests", provides step-by-step instructions for health data applicants and describes the application procedures. It was published in January 2025, when the EHDS Regulation was still at the proposal stage and not yet in force. The guideline introduces a common platform for the application process, encompassing both health data access

[218] Åm et. al. 2025, p. 10.
[219] Art. 61(1) of the EHDS.
[220] Art. 67(3) of the EHDS.
[221] TEHDAS2 has published a series of guidelines which underwent public consultation at the beginning of 2025. The final versions will be published in autumn 2025, but these were not yet available at the time of writing the thesis. This section specifically refers to the draft "Guidelines for Data Users on Good Application Practice for Data Access and Requests", which also functions as an introductory guide to the EHDS Regulation from the perspective of health data applicants and users. Further updates to the guidelines are expected. For the draft guideline, see Dudová. et. al. 2025.

applications and requests.[222] The difference is that health data access applications are used to obtain access to anonymised or pseudonymised individual-level electronic health data, whereas health data requests are intended for anonymised, aggregated data or statistical results.[223] Both approaches are examined below.

The first option, a health data access application, should be selected when health data applicants require individual-level personal data to fulfil their objectives and aggregated statistical results are insufficient. This pathway applies to two types of datasets: 1) anonymised datasets, when direct access to such datasets is necessary for analysis, and 2) pseudonymised datasets, when anonymised data alone are inadequate to meet the processing objectives.[224]

Following the issuance of a data permit, all secondary use of electronic health data must take place within a SPE. Data users may only use the data in accordance with the conditions set out in the permit.[225] Although they are legally permitted to access and process electronic health data, users are not authorised to further disclose or share it with third parties, unless such third parties are explicitly identified in the data permit. Only under these conditions may access or availability be extended to others. [226] An exception applies if a health data user discovers a significant finding related to the health of an individual when processing data within the SPE. In such cases, the health data user must inform the HDAB of the finding.[227] Health data users are strictly prohibited from re-identifying, or attempting to re-identify, the individuals to whom the data relate.[228]

The second option, a health data request, results in a response provided in an anonymised statistical format and no other formats are available through this pathway.[229] If a data user's objectives can be met with aggregated data, this mechanism is appropriate. While the EHDS provisions allow a response in anonymised statistical form, they prevent the data user from

[222] For the guideline, see Dudová et. al. 2025.
[223] Dudová et. al. 2025, pp. 9–10.
[224] Dudová et. al. 2025, p. 11.
[225] Recital 77 & Art. 68(11) of the EHDS.
[226] Art. 61(2) of the EHDS
[227] Art. 61(5) of the EHDS.
[228] Art. 61(4) of the EHDS
[229] Recital 72 of the EHDS.

accessing any underlying personal electronic health data.[230] The HDAB remains the sole controller of all personal data associated with the response to the health data request.[231]

In both cases, secondary use of data entails specific obligations for health data users. After completing data processing within an SPE or receiving a response to a health data request, health data users must make their results or outputs of such secondary use publicly available in anonymised form.[232]

Health data users are able to locate and assess data for secondary use through datasets. Compiled at the national level, these structured collections provide detailed information on the types of data available, their location and the conditions for access. This infrastructure makes secondary use of electronic health data both accessible and effective across Member States.

5.5 Datasets and dataset catalogues

Within the EHDS, dataset catalogues are intended to provide a well-organised system that enables, most importantly, health data users to ascertain existence, location and conditions of access to electronic health data. At the ground level, a dataset, held by a data holder, refers to a structured collection of electronic health data.[233] Health data holders are obliged to communicate the descriptions of their datasets to the HDAB, which maintains a national dataset catalogue. The datasets themselves are not disclosed in this process.[234] The national dataset catalogue compiles the descriptions in the form of metadata, detailing the available datasets and their characteristics.[235] Each national dataset catalogue is subsequently interconnected into a federated EU dataset catalogue.[236] In practice, dataset catalogues provide health data users, including research projects such as ONCOVALUE, with the

[230] Raposo 2025, p. 11. Pursuant to Art. 69(1) of the EHDS Regulation, the health data user will not have access to the electronic health data used to generate the response.
[231] Recital 72 of the EHDS.
[232] Art. 61(4) of the EHDS.
[233] Art. 2(2)(w) of the EHDS. The term ”dataset” can have different definitions in different fields. In this thesis, however, it is understood as stipulated in the EHDS Regulation.
[234] Art. 60(3) &77(1) of the EHDS. According to Art. 77(1) of the EHDS, the description of the dataset must include information about its source, coverage, key features and the nature of the electronic health data it contains, as well as the conditions for making that data available.
[235] Art. 77(1) of the EHDS.
[236] Art. 79(1) of the EHDS.

information necessary to evaluate the suitability of specific datasets for their intended secondary use.[237]

Prior to the entry into force of the EHDS, it was acknowledged that many datasets remained non-harmonised. Such fragmentation impeded comparability and limited the potential for cross-border research.[238] To respond to these concerns, the European Commission is mandated, through forthcoming implementing acts, to define the minimum dataset elements and their characteristics.[239] Such definitions are expected to enable the trustworthy and reliable secondary use of electronic health data.[240]

Implementation efforts are progressing through collaboration between professional organisations, the European Commission and other relevant institutions. Among the most recent documents are draft guidelines prepared by TEHDAS2 on dataset descriptions and on the technical specifications of national metadata catalogues.[241] Especially the first one might be useful for those ONCOVALUE consortium members which qualify as data holders and are thus required under the EHDS to communicate their dataset descriptions to the national HDAB.[242]

The "Guideline for Health Data Holders on Data Description" promotes a unified standard that enables health-related datasets to be easily catalogued and understood regardless of their origin or system. The document involves practical instructions for health data holders on using the HealthDCAT-AP,[243] a metadata model which is designed to improve the management and interoperability of datasets within the EHDS.[244] In addition, health data

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[237] Recital 84 of the EHDS.
[238] Recital 87 of the EHDS.
[239] Art. 77(4) of the EHDS; Recital 105 of the EHDS. It is worth to note, that certain datasets are prioritised with respect to implementation efforts and further improvements. In general, priority will be given to datasets which are most likely to generate scientific, societal and innovative value. According to the EHDS Regulation, this will enhance the efficiency of the secondary use of electronic health data and support the realisation of the benefits envisaged by the Regulation. See Recital 58 of the EHDS.
[240] Recital 87 of the EHDS.
[241] For the draft guideline on data descriptions, see Schutte et. al. 2024 and for the draft guideline for technical specifications on the national metadata catalogues, see Peolsson et. al. 2025. Both guidelines were produced by TEHDAS2. The public consultation on these documents took place in early 2025, and the final versions will be published in autumn 2025. At the time of writing, the final publications were not yet available.
[242] See Art. 60(3) of the EHDS.
[243] Schutte et. al. 2024, pp. 6–7.
[244] Schutte et. al. 2024, p. 13; Peolsson et. al. 2025, p. 8.

holders can already generate metadata to describe their own datasets through the HealthDCAT-AP editor.[245]

Within the EHDS, these descriptions of datasets will be published in dataset catalogues.[246] The health data holders should at least once a year review that their descriptions in the national dataset catalogue are updated and accurate and correct them if necessary.[247] As the first guideline focuses on dataset descriptions, the second guideline deals with national metadata catalogues. At the national level, the responsibility for developing and maintaining these catalogues rests with national HDABs, which is why the guideline is specifically targeted at them. Since HDABs operate in every Member State, their national catalogues will inherently differ from each other. Therefore, a central EU dataset catalogue will be established to interconnect them,[248] and thereby improve the discoverability of datasets across the EHDS.[249]

The main objective of the second draft, "Guideline for HDABs on Technical Specifications for the National Metadata Catalogue", is to define technical specifications for national dataset catalogues that allow their seamless integration into a federated EU dataset catalogue.[250] The guideline notes that a remarkable challenge is to ensure that all Member States implement a minimum set of functionalities to achieve interoperability across national catalogues. Such harmonisation is central for the exchange of health data for secondary use and for supporting a unified EHDS.[251]

Some attention must be directed towards the datasets themselves. In particular, an important challenge concerns real-world data (RWD) in datasets. This stems from the expanding volume

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[245] Schutte et. al. 2024, p. 37.
[246] Art. 2(2)(y) of the EHDS.
[247] Art. 60(3) of the EHDS.
[248] Art. 79(1) of the EHDS; Recital 86 of the EHDS.
[249] Recital 84 of the EHDS.
[250] Peolsson et. al. 2025, p. 8. Note that this guideline is a draft version and may contain inconsistencies. An example can be found in Annex 2 "Key Terminology – Glossary", which will be aligned across all TEHDAS2 deliverables later. This glossary contains explanations of terms that do not in all respects correspond to the definitions in the EHDS Regulation. For example, even the central term "dataset" is defined in the Glossary as "any organised collection of data. Ref. OECD" whereas the EHDS Regulation and its predecessor, the EHDS Proposal (already available at the time of the guideline's preparation), define dataset as "a structured collection of electronic health data". For the definitions, see Art. 2(2)(w) of the EHDS & Art. 2(2)(ab) EHDS Proposal.
[251] Peolsson et. al. 2025, p. 9. Also HDABs–CoP, which supports voluntary collaboration and knowledge sharing among HDAB's development before the EHDS is fully applicable, mentions that Health DCAT-AP metadata standard specifications developed by the EHDS2 Pilot project should be considered. See HDABs Community of Practice (HDABs-CoP) 2024, p. 18.

of RWD use within the health sector and the increasing support it has received from regulatory bodies and agencies such as the European Commission and the EMA.[252] While the use of RWD in secondary use grows, as Cascini explains, significant ethical and privacy concerns arise. These datasets frequently contain sensitive information, including medical histories, disease status and even financial details. Privacy risks are further amplified when records from different databases are linked, which is a common practice in RWD analyses. All these factors stress the need for ethical considerations and privacy safeguards in RWD use because the outcomes of data analysis can affect both individuals and communities beyond scientific research.[253]

The EHDS Regulation might resolve, or at least mitigate, some of these challenges concerning the secondary use of RWD and related datasets. The Regulation imposes strong safeguards for the secondary use of electronic health data, particularly requiring datasets to be anonymised or pseudonymised before being made accessible to data users. This approach reduces the risk of identifying data subjects while allowing researchers and regulators to generate high-quality RWD.[254] Anonymisation and pseudonymisation of data are, in general, central elements and requirements within the EHDS, especially in secondary use which builds on those measures.

5.6 Anonymisation and pseudonymisation within the EHDS

The secondary use of electronic health data relies on anonymised or pseudonymised data to prevent the identification of data subjects.[255] Anonymisation and pseudonymisation refers to data protection techniques which are intended to protect personal information. These terms are not defined within the EHDS Regulation, but where the processing of personal data is involved, the GDPR applies. Moreover, with regard to anonymisation and pseudonymisation of electronic health data, the European Commission is under a duty to establish the relevant procedures and requirements and provide the necessary technical tools to enable a harmonised approach where appropriate.[256]

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[252] Recital 53 of the EHDS; EMA, Real-world evidence; Katkade – Sanders – Zou 2018, p. 297.
[253] Cascini 2025, p. 4.
[254] Recital 53 of the EHDS.
[255] Recital 53 of the EHDS.
[256] Recital 65 of the EHDS.

Within the EHDS, the responsibility of anonymisation or pseudonymisation of data lies with HDABs. Their responsibility is to anonymise or pseudonymise electronic health data which is intended for secondary use.[257] Since personal electronic health data must be anonymised or pseudonymised as early as possible for its secondary use, health data holders can also perform these tasks.[258] When the health data holder is capable of undertaking anonymisation or pseudonymisation, it may deliver strengthened data security safeguards. This is because the data holder is often in a more suitable position than the HDAB to perform these processes, given its familiarity with the circumstances of the original processing and associated data protection considerations.[259] Both HDABs and health data holders are allowed to delegate anonymisation or pseudonymisation to processors at their discretion.[260]

With regard to geographical location, personal electronic health data intended for anonymisation or pseudonymisation should be stored and processed within the EU. These activities, whether undertaken by HDABs, trusted health data holders or entities acting on their behalf, should deploy either SPEs or the HealthData@EU infrastructure.[261] Limiting access to electronic health data exclusively to SPEs ensures, for its part, strict data protection and prevents unauthorised re-identification.[262] Moreover, data processed in these environments will be archived by the HDABs for reproducibility reasons, as re-analysis might be necessary for example in peer-review processes.[263] Instead – although data are stored, processed and archived within these environments – the EHDS does not establish a centralised data repository. As stipulated by the EHDS Regulation, it functions as a data-sharing framework governed by rules for electronic health data access and use.[264]

Bearing in mind the sensitivity of electronic health data, the principle of data minimisation must be applied to reduce risks to the privacy of natural persons. Within the EHDS this means that whenever the provision of non-personal electronic health data is sufficient, only non-personal electronic health data should be made available.[265] In other words, for secondary use,

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[257] Art. 57(1)(b) of the EHDS.
[258] Recital 72 of the EHDS.
[259] Rak 2024, p. 936.
[260] Recital 72 & Art. 74(1) of the EHDS.
[261] Art. 87(1) of the EHDS.
[262] Dudová et. al. 2025, p. 11.
[263] Dudová et. al. 2025, p. 41.
[264] Kalliola – Drakvik – Nurmi 2023, p. 7.
[265] Recital 72 of the EHDS. See also Art. 66(2) of the EHDS.

HDABs must provide data in an anonymised format by default.[266] However, as Quinn, Ellyne & Yao point out, fully anonymised datasets often have constrained research utility, as personal data typically carry greater analytical value. Consequently, it is likely that many health data access applications will pertain to datasets containing personal information.[267] As the EHDS2 Pilot project recommends, health data applicants should articulate a solid research question or objective, so the application of the data minimisation principle would be easier.[268]

If the purpose of processing electronic health data cannot be achieved with anonymised data, that is, if the use of personal electronic health data is necessary, health data applicants must clearly justify this requirement in their application.[269] In general, applicants for health data access are obligated explain why the data, whether anonymised or pseudonymised, are necessary for their stated purpose and demonstrate compliance with the principle of data minimisation. The HDAB evaluates each application to assess both compliance and necessity and to determine whether the justification is valid.[270]

It is important to note that personal electronic health data can only be made available in pseudonymised format.[271] Pseudonymisation, according to the GDPR, involves processing personal data in such a way that the data can no longer be attributed to a specific data subject without accessing additional information. This additional information must be kept separately and protected through appropriate technical and organisational measures to prevent identification of the individual.[272] The EHDS Regulation further clarifies who should possess the additional information.

When pseudonymised data are provided, the information necessary to reverse pseudonymisation must remain solely with the HDAB or an entity acting as a trusted third party.[273] The information is thus not disclosed to the health data holders who process the electronic health data for secondary purposes. Furthermore, health data users are strictly prohibited from re-identifying or attempting to re-identify any natural persons whose data have been accessed under a data permit or a health data request.[274] Within the EHDS, de-

[266] Art. 66(2) of the EHDS.
[267] Quinn – Ellyne – Yao 2024, p. 8.
[268] EHDS2 Pilot ("HealthData@EU pilot") 2024, p. 58.
[269] Recital 72 of the EHDS. See also Art. 67(2)(e) of the EHDS.
[270] Art. 66(3) & Recital 72 of the EHDS; Dudová et. al. 2025, p. 11.
[271] Recital 72 of the EHDS. See also Art. 66(2) of the EHDS.
[272] Art. 4(5) of the GDPR.
[273] Art. 66(3) & Recital 72 of the EHDS.
[274] Art. 61(3) of the EHDS.

identification is permitted in one situation only, and even then, the task of re-identification is not assigned to health data users.

De-identification arises in situations where a health data user, while processing electronic health data within a SPE, identifies a significant finding related to an individual whose data are included in the dataset. Since all data for secondary use must be in anonymised or pseudonymised format, health data users in this situation are obligated to report the finding to the HDAB.[275] When a HDAB receives such information from a health data user, it should further notify the relevant health data holder. The health data holder then informs the individual or their treating health professional, unless the individual has opted not to receive such findings.[276]

It is evident that this mechanism functions only when the data are pseudonymised, as anonymised data cannot be reversed to identify individuals. Consequently, information on significant findings cannot reach the individual when the data have been anonymised for secondary use. This creates a paradoxical situation in which a person cannot be informed of a significant finding concerning their health, even if they have not declined to receive such information.[277] Also, in the case of pseudonymised health data, the HDAB may not have access to the additional information required to re-identify the individual if the pseudonymisation is performed by the data holder or delegated to another processor. The EHDS Regulation does not specify the procedures to follow in such circumstances.[278]

In conclusion, as anonymisation and pseudonymisation are not explicitly defined in the EHDS Regulation, it would be beneficial if Member States adopt a consistent interpretation and application of the GDPR. In this regard, relevant CJEU case law, including *Single Resolution Board (SRB) v. European Data Protection Supervisor*, may offer additional clarification. For actors within healthcare, for example research projects such as ONCOVALUE, it would be suitable to apply the strictest standards to ensure compliance and minimise risk, as long as legal uncertainties remain.

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[275] Art. 61(5) of the EHDS. This exception applies to Art. 61(2) of the EHDS, which states that users of electronic health data should not provide access to, or make available, those data to third parties not mentioned in the data permit. In this case, however, health data users are obligated to inform the HDAB, even though it is not explicitly mentioned in the data permit.
[276] Art. 58(3) & Recital 67 of the EHDS.
[277] See Art. 58(1) & Recital 67 of the EHDS.
[278] Also the ”Draft guideline for data users on good application and access practice” by TEHDAS2 assumes that HDABs have the additional information to re-identity the individual in quesion. See Dudová et. al. 2025, p. 34.

5.7 Governance in brief and critical observations

In summary, the EHDS establishes rules for secondary use of electronic health data in the EU and provides the necessary infrastructures to facilitate the reuse of such data across borders. The governance framework and mechanisms for secondary use introduced by the EHDS Regulation function in the following manner. A health data applicant submits a health data access application to the competent HDAB to request access to electronic health data for secondary purposes. If the applicant demonstrates a justified purpose and provides sufficient safeguards, the HDAB may issue a data permit. This permit authorises the applicant, now identified as a health data user, to access and process anonymised or pseudonymised electronic health data within a SPE. Alternatively, an applicant may file a health data request to receive a response in an anonymised statistical format.

Among these central actors – health data holders, users and access bodies – the HDABs have drawn most attention from both academia and the research community.[279] A closer look at the responsibilities assigned to HDABs reveals several practical challenges.[280] Concerning the mechanisms for secondary use within the EHDS, scholars stress the importance of rigorously applying the safeguard methods embedded in it. With regard to the potential privacy risks associated with the secondary use of electronic health data, they bring to the fore the critical function of HDABs. When managing secondary use, HDABs are granted considerable discretion under the Regulation to approve or reject health data access applications and requests.[281] Concerns stem from the competencies of HDABs when assessing these applications and requests. Beyond a formal review of the stated purpose, the assessment requires a thorough substantive analysis of the proposed secondary use as well, including the nature and sensitivity of the requested data, the technical methods and tools intended for its processing and the specific research or regulatory objectives of the use.[282] Indeed, this entails a comprehensive evaluation.

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[279] For instance, the EHDS2 Pilot Project's survey reveals that, with regard to Legal and Regulatory Compliance, 55% of the respondents foresee a big challenge when implementing the future national HDABs, compared to 5% who anticipate no challenge at all. For the results, see Jensen et. al. 2025, p. 12.
[280] See for example Petročnik 2025; Quinn – Ellyne – Yao 2024.
[281] Quinn – Ellyne – Yao 2024, p. 1.
[282] See Petročnik 2025; Quinn 2025; Quinn – Ellyne – Yao 2024. Additionally, in their article on data sharing in the Internet of Medical Things (IoMT), Casarosa & Gennari argue that HDABs will need to conduct more than a formal check of the purpose of secondary use. For instance, concerning IoMT, the authors assert that HDABs must also perform a thorough evaluation of the documentation required for non-compliant EHR systems that are subject to market bans. See Casarosa – Gennari 2025, p. 21.

For their steady functioning, HDABs will need to mobilise a wide range of highly specialised expertise to fulfil their responsibilities. This encompasses not only technical knowledge of the data and its processing but also the ability to interpret and apply Member State legislation within their own jurisdiction and, where applicable, in other Member States, since health data access applications and requests may originate from multiple EU countries.[283] The EHDS Regulation appropriately requires that Member States ensure that each HDAB is sufficiently staffed or has access to expertise to fulfil its regulatory role and responsibilities.[284] Competencies from various disciplines are needed, among others, legal professionals, privacy and data security specialists, domain experts familiar with health systems, IT architects and data scientists. Additionally, Member States should build expertise and establish processes at levels below the HDAB, particularly within trusted data holders.[285] From a legal compliance perspective, core competencies for future national HDABs includes knowledge of the EHDS Regulation, GDPR and relevant national law.[286]

From a practical perspective, the fixed timelines for issuing data permits and approving requests, combined with data access procedures that are already considered complicated, risk making the process overly slow.[287] Swift delivery of data permits and datasets therefore remains a challenging issue. Taking more optimistic stance, Jensen et. al. note that the health data request mechanism is anticipated to streamline access procedures and reduce approval bottlenecks that often slow down research. By responding to such requests, HDABs can provide applicants with aggregated datasets, enabling preliminary analyses and refinement of study parameters before submitting a full application for a data permit.[288] At the same time, it should be emphasised that health data users may continue to rely on existing systems for

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[283] Quinn – Ellyne – Yao 2024, pp. 13– 14; Quinn 2025, pp. 78– 79. In his recent article, Quinn notes that Art. 9(4) of the GDPR allows Member States to maintain divergent national rules related to the processing of health, genetic or biometric data. All of these categories may fall within the scope of "electronic health data" under the EHDS and therefore be in demand. Consequently, HDABs will need to frequently evaluate applications in situations where national legislation imposes additional conditions on the processing of such data. See Quinn 2025, p. 70.
[284] Recital 64 of the EHDS. After testing the pilot version of the EHDS in real-world settings, the EHDS2 Pilot project stated in their evaluation report that they faced significant challenges in mobilising the necessary technical and legal expertise. This stemmed especially from the cross-disciplinary nature of their project. See Benderra 2025, p. 9. While the observation is valid, this cross-disciplinary challenge itself should not come as a surprise in the field of research, since projects employing experts from multiple disciplines are probably the norm rather than the exception. Furthermore, the EHDS is designed to increase access to electronic health data for a variety of users and purposes.
[285] Jensen et. al. 2025, p. 16.
[286] Jensen et. al. 2025, pp. 16-17.
[287] See for example Raposo 2025, p. 17.
[288] Jensen et. al. 2025, p. 26.

secondary use if they wish. The EHDS does not replace these systems, rather it complements them by introducing a more unified structure for secondary use.

6 Intellectual property rights (IPRs) and trade secrets under the EHDS

6.1 IPR approach in the EHDS Regulation

For the European economy, the pharmaceutical industry represents a key strategic asset. The pharmaceutical (prescription) market of the EU is the second largest globally, accounting for 22.7% of the world market, behind North America with 54.8%.[289] Currently, increasing competition is arising from emerging economies, especially China, whose rapid growth in both market size and research capacity is leading to the relocation of economic and research activities outside Europe.[290]

The pharmaceutical sector involves multiple stakeholders, for whom the protection of intellectual property rights (IPR) remains a central concern. These stakeholder groups include pharmaceutical and medtech companies, academic researchers and healthcare institutions that hold assets on valuable data.[291] Notably, all of these groups are represented in the ONCOVALUE project. The project brings together consortium members not only from cancer institutes and hospitals but also commercial businesses such as BC Platforms (technology company specialised in Real-World Data), IQVIA (health information technology company) and Siemens Healthineers AG (medical technology company).[292]

In order to reconcile stakeholder interests with the broader benefits for the EU market, the European Health Data Space (EHDS) must incorporate safeguards that both prevent the creation of distorted incentives during its implementation and ensure that the European research ecosystem is protected from unfair competition.[293] To this end, the Regulation

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[289] European Federation of Pharmaceutical Industries and Associations (EFPIA), The Pharmaceutical Industry in Figures – Key Data 2025, pp. 3, 14. See also Kertesz 2024, p. 514.
[290] EFPIA, The Pharmaceutical Industry in Figures – Key Data 2025, p. 9.
[291] EIT Health Think Tank 2024, p. 30.
[292] ONCOVALUE, Implementing Value-based Oncology Care at European Cancer Hospitals. During its running, ONCOVALUE is generating outcomes that can be promoted and test-marketed. Certain outcomes have potential for joint exploitation, while others will be pursued independently by the respective partners. At the end of the project, the outcomes of the ONCOVALUE are intended to exploit by the consortium and/or its partners, depending on the IPR arrangements in place. Additionally, ONCOVALUE may produce new technological solutions or product innovations over its course. The consortium also explores opportunities to transfer these results into other applicable sectors and thereby expanding their potential market reach. ONCOVALUE aims to assess how the results align with current market demands or with areas of interest in other European R&I initiatives at the European level. See Zocchi 2024, p. 27.
[293] EIT Health Think Tank 2024, p. 30.

contains Article 52, which lays down specific provisions on IPR and trade secrets in relation to the secondary use of data within the EHDS. Notably, unlike the Data Act (DA), which explicitly states that it does not affect Union or national legal acts that protect intellectual property, the EHDS contains no comparable reference.[294]

During the draft stage of the EHDS Regulation, industry stakeholders called for legal certainty regarding which datasets must be shared, who would be obliged to share them and who could gain access. For example, some demanded that the obligation to share data should apply only to completed clinical trials, allowing trial sponsors to retain priority access. This is because if companies were forced to disclose commercially sensitive data to their competitors, it could lead to market distortions. Several non-industry stakeholders agreed with that, noting that early public disclosure of trial results could trigger bias, for instance by influencing patient selection, before a product reaches the market. The consequences of such data-sharing requirement would be significant in the medtech sector, where small and medium-sized enterprises (SMEs) rely on investor support to bring innovative solutions to market.[295]

The EHDS Regulation adopted a starkly different approach from the position advocated by industry stakeholders. Contrary to the industry-driven proposals for limited data sharing to protect commercial interests, the EHDS Regulation emphasises that data protected by IPRs, trade secrets or regulatory data protection rights should be made available for secondary use.[296] This reflects a deliberate prioritisation of public interest and innovation over exclusive control.[297] This approach is supported in academic literature, where number of scholars have advocated for shifting the focus of IPRs from private gain toward their intended purpose of serving the public interest.[298]

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[294] See Art. 1(8) of the DA. By contrast, within the EHDS Regulation, Art. 52 is the sole provision that directly addresses intellectual property rights (IPRs).
[295] EIT Health Think Tank 2024, p. 30.
[296] See Recital 60 of the EHDS; COM(2020) 66 final. For instance, both The European Federation of Pharmaceutical Industries and Associations (EFPIA) and European Confederation of Pharmaceutical Entrepreneurs (EUCOPE) made demands regarding datasets. They stated that datasets containing trade secrets or commercially confidential information should not be included in catalogues. Furthermore, they concluded that the EHDS Regulation should include a process that empowers health data holders to prevent such publication of their data. See EFPIA, EFPIA response to EHDS report adopted by ENVI/LIBE committee in the European Parliament; European Confederation of Pharmaceutical Entrepreneurs (EUCOPE), Common statement on the European Health Data Space and the Amendment Proposals of the Council of the European Union and the European Parliament.
[297] See Recital 60 of the EHDS; COM(2020) 66 final.
[298] In the context of cancer care, see for example Zakout 2025.

In this way, the EHDS Regulation signals a strong EU policy stance that access to health data and its secondary use are essential for stimulating innovation and improving patient care.[299] Despite this emphasis on public interest, the protection afforded by IPRs and trade secrets cannot be reduced or bypassed. Quite the opposite, all essential measures to safeguard IPRs and trade secrets must remain in effect during secondary use.[300] To maintain this balance, Health Data Access Bodies (HDABs) are tasked with upholding IPR protection while providing access to electronic health data for secondary purposes.[301]

6.2 Health Data Access Bodies and IPR

The EHDS Regulation places a responsibility on HDABs to maintain the appropriate protection of data holders' IPRs and trade secrets for data they are required to make available for secondary use. In practice, health data holders must notify the HDAB of any electronic health data containing content or information protected by IPRs, trade secrets or regulatory data protection rights.[302] To comply with these obligations, they must identify the relevant portions of their datasets and explain the justification for the specific protection of each portion. This information should accompany the initial description of the dataset submitted to the HDAB. If not supplied at that stage, the data holder must provide it at the latest upon receiving a request from the HDAB regarding such data.[303]

One of the regulatory responsibilities of HDABs is to implement all necessary measures to maintain the confidentiality of IPRs, trade secrets and regulatory data protection rights.[304] The Regulation does not prescribe specific measures, but it mandates that any actions taken must be appropriate and proportionate and could involve measures of a legal, organisational or

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[299] See Recital 60 of the EHDS; COM(2020) 66 final. The European Commission has expressed its aspiration that with the EHDS, the use and re-use of health data will be strengthened and extended. This is regarded as highly important for innovation in the healthcare sector. See COM(2020) 66 final, p. 29.
[300] Recital 60 of the EHDS.
[301] Recital 60 of the EHDS.
[302] Art. 52(3) of the EHDS. The regulatory data protection refers to results of toxicological tests, pharmacological tests and clinical trials as well as authorised medicinal products for human use. See Art. 10(1) of the Directive (EC) 2001/83 of the European Parliament and of the Council on the Community code relating to medicinal products for human use (Directive 2001/83/EC); Art. 14(11) of the Regulation (EC) 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (Regulation 726/2004/EC).
[303] Art. 52(2) of the EHDS.
[304] Art. 57(1)(c) of the EHDS.

technical kind.[305] Whatever measures the HDAB implements to safeguard data holders' IPRs, trade secrets or regulatory data protection rights, it is obliged to weigh the rights of both the health data holder and the health data user. [306]

Data permits may also be issued on a conditional basis. When granting access for secondary use, HDABs can attach legal, organisational or technical conditions to certain datasets. These conditions may involve contractual arrangements between data holders and users governing the sharing of information or content protected by IPRs or trade secrets.[307] An example of when a contractual agreement may be necessary, is described in a guideline for data users on good application and access practices, published by TEHDAS2.[308]

In this example, a researcher (health data applicant) seeks access to electronic health data from clinical trials to evaluate the effectiveness of a new cancer treatment. These trials, conducted by a biotech company (data holder), consist of sensitive information protected by IPRs. The HDAB does not refuse access, but rather makes it conditional when issuing the data permit. A direct contractual agreement is thus made between the biotech company and the researcher to ensure that intellectual property is protected while allowing access to anonymised data.[309]

As a last resort, if granting access to electronic health data would pose a serious risk of infringing IPRs, trade secrets or regulatory data protection rights that cannot be adequately mitigated, an HDAB must refuse access to the health data applicant. In that situation, the HDAB is required to notify the applicant and provide a justification for the refusal. Both health data holders and applicants retain the right to lodge a complaint against such decisions.[310]

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[305] See Art. 52(3) of the EHDS. The EHDS mentions some measures in Recital 60. According to the Recital, measures to protect intellectual property rights (IPR) or trade secrets can encompass: contractual arrangements for common electronic health data access; defined requirements within data permits relating to such rights; pre-processing the data in order to generate derived data that protect trade secrets, but do not have any use for health data users; or configuration of secure processing environments (SPEs) in a way that such data are not accessible to users. See Recital 60 of the EHDS.
[306] Art. 57(1)(c) of the EHDS.
[307] Art. 52(4) of the EHDS. HDABs will have models of contractual terms available. The European Commission is responsible for developing and recommending these models, but their non-binding nature means that HDABs retain discretion over whether to adopt them in practice. See Art. 52 (4) of the EHDS.
[308] For the "Draft guideline for data users on good application and access practice", see Dudová et. al. 2025.
[309] Dudová et. al. 2025, p. 35. See also Art. 52(3–4) of the EHDS.
[310] Art. 52(5) of the EHDS.

6.3 Access obligations and IPR protection in the EHDS

It is claimed that current IPR laws, with their exclusivity rules, often limit access to data and information that could be valuable for early-stage (upstream) research. This creates tension between the protection of private rights and the advancement of the public interest. particularly in the field of scientific progress. Considering the enormous human, social and economic burden posed by diseases such as cancer, it is often contended that collective interest should prevail over the pursuit of short-term private profits.[311]

In criticism of the emphasis on public interest, some stakeholders and scholars have condemned the compulsory data-sharing introduced under the EHDS Regulation. Their arguments focus on how these obligations may interact with existing mechanisms for the protection of intellectual property and commercially confidential information.[312] Kertesz explains that one of the principal challenges posed by the EHDS for pharmaceutical firms and medical technology manufacturers lies in the potential erosion of their competitive edge. A decline in competitiveness could harm these companies directly and may also reduce incentives for investment in research and development. Ultimately, this could slow the pace of innovation in the EU and weaken its influence on the global stage.[313]

The approach in EHDS Regulation unavoidably thus generates a legal and practical dilemma. On one side, IPRs and trade secrets are designed to protect economic interests, foster innovation through private investment and preserve competitive advantage. On the other, the Regulation now imposes mandatory data-access duties that can override these protections in the name of public interest and innovation. Zakout points out that this confrontation rises a question whether the EHDS Regulation risk weakening long-standing IPR regimes by mandating the disclosure of information traditionally regarded as proprietary. Furthermore, she insists that any limitations on IPRs must be justified as necessary to promote public welfare and should interfere as little as possible with the legitimate interests of rights holders.[314]

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[311] Zakout 2025, pp. 16-17.
[312] See for instance EFPIA, EFPIA response to EHDS report adopted by ENVI/LIBE committee in the European Parliament; Rak 2024.
[313] Kertesz 2024, pp. 514–515. The article by Kertesz was published during the EHDS Proposal, which did not include provisions on protection of Intellectual Property Rights (IPRs) or trade secrets. The Art. 52 was only added later and is now included in the EHDS Regulation.
[314] Zakout 2025, pp. 16–17.

7 Research projects and initiatives supporting the implementation of the EHDS

7.1 Selected research projects and initiatives

The research community is actively preparing for the transition to the European Health Data Space (EHDS). This final section discusses four major undertakings – two research projects (ONCOVALUE and the EHDS2 Pilot Project) and two broader initiatives (TEHDAS initiatives and DARWIN EU) – to illustrate the concrete steps being taken in this direction.

For a harmonised and coordinated implementation of the EHDS, especially its secondary use, multiple complementary initiatives and projects are developing and testing the governance and infrastructure models foreseen in the Regulation. The European Commission has been driving much of this progress by funding numerous projects and joint actions that are helping to set the stage for the EHDS to become a reality.[315]

ONCOVALUE is one of these projects, funded under the Horizon Europe programme "New methods for the effective use of real-world data and/or synthetic data in regulatory decision-making and/or in health technology assessment".[316] The programme itself focuses on advancing innovative methods for leveraging real-world data (RWD) and synthetic health data to support regulatory decision-making and health technology assessment (HTA). It also connects to broader European efforts around the EHDS and DARWIN EU.[317] Specifically, ONCOVALUE seeks to achieve value-based assessment of novel cancer therapies by incorporating high-quality RWD in regulatory and reimbursement decision-making.[318] While its primary focus lies outside the direct construction of the EHDS, its methodologies and outcomes are highly relevant to the ecosystem surrounding it.

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[315] European Commission, Projects supporting EHDS.
[316] See European Commission, New methods for the effective use of real-world data and/or synthetic data in regulatory decision-making and/or in health technology assessment.
[317] For ongoing projects under the Horizon Europe programme "New methods for the effective use of real-world data and/or synthetic data in regulatory decision-making and/or health technology assessment", see European Commission, New methods for the effective use of real-world data and/or synthetic data in regulatory decision-making and/or in health technology assessment. On Commission's commitment to invest in the Horizon Europe programme, which supports technologies that are crucial for the next stages of the data economy, see COM(2020) 66 final, p. 19.
[318] ONCOVALUE, Implementing Value-based Oncology Care at European Cancer Hospitals.

The EHDS2 Pilot Project, which has already been finished, was more directly aimed at preparing for the EHDS. It created and tested the infrastructure needed to assess how the EHDS might function in real-world conditions. This pilot provided important lessons on both technical and organisational aspects by offering a first glimpse of what large-scale secondary use of electronic health data across the EU could look like.[319]

The TEHDAS initiatives have taken place in two stages. The first, Joint Action Towards the European Health Data Space (TEHDAS1), defined common European principles for the secondary use of health data. The second, Second Joint Action Towards the European Health Data Space (TEHDAS2), is now turning those principles into practice by working on ways to ensure that health data can be reused across borders in a consistent and reliable way. In doing so, TEHDAS2 is laying much of the groundwork for how the EHDS will eventually function.[320]

Finally, DARWIN EU brings together multiple actors, including Data Partners, Coordination Centre, the European Medicines Agency (EMA), the EU Medicines Regulatory Network and several other organisations.[321] The network is designed to provide a steady flow of high-quality Real-World Evidence (RWE) that can support regulatory decision-making and medicines evaluation. By doing so, DARWIN EU not only strengthens regulatory capacity of Europe but also directly contributes to the EHDS vision.[322]

Taken together, these projects and initiatives show how the pieces of the EHDS are gradually coming together, and before moving into the conclusion, this section captures the current stage of these efforts.

7.2 ONCOVALUE pioneering new ways to share data

Led by Helsinki University Hospital (HUS), ONCOVALUE comprises six leading European cancer hospitals and three technology companies.[323] By combining clinical and technological

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[319] See European Commission, Pilot for a European Health Data Space on secondary use of health data.
[320] See TEHDAS1, Joint Action Towards the European Health Data Space – TEHDAS1; TEHDAS2, Second Joint Action Towards the European Health Data Space – TEHDAS2.
[321] DARWIN EU, Home.
[322] DARWIN EU, European Health Data Space.
[323] These are HUS, IPO Porto, IRST-IRCCS, The Netherlands Cancer Institute, Rigshospitalet, Rijnstate, BC Platforms, IQVIA and Siemens Healthineers AG. For short introduction of each, see ONCOVALUE, The ONCOVALUE Consortium.

expertise, the consortium focuses on developing methods to enable cross-border sharing of harmonised hospital-based RWD within the EU.[324] The ultimate objective is to expand access to high-quality, structured health data that can support research, regulatory evaluation and decision-making in cancer care.[325]

To achieve its goal, ONCOVALUE has adopted a two-track approach. The first track concentrates on improving the quality of health data entered in electronic medical records (EMRs) in hospitals.[326] The second focuses on developing Artificial Intelligence (AI) tools capable of transforming unstructured information into structured datasets suitable for analysis. Once trained and validated, these AI models process real-world unstructured data to produce information that supports HTA and regulatory decision-making.[327]

The first track aims to improve the data quality and data entry into the health systems in hospitals. It is widely acknowledged that clinical data entry practices frequently vary across institutions and even among departments within the same facility. Such inconsistencies make it difficult to integrate health data and the discrepancies become even more intensified data is shared across borders.[328] Consequently, datasets are often highly heterogeneous, as the collection protocols, formats and standards differ among providers. This lack of uniformity poses obstacles to effective collaboration in secondary use.[329]

As a response to this challenge to harmonise RWD, ONCOVALUE decided to employ the Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM), an open community data standard. The OMOP Common Data Model seeks to standardise data in a way that enables it to be compared and combined with other datasets effortlessly.[330] By using this CDM, ONCOVALUE can perform data analyses across institutions without the need to transfer patient-level data to a centralised database.[331] Although the OMOP Common Data Model is widely used,[332] and was incorporated into the EHDS infrastructure pilot with

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[324] ONCOVALUE, Implementing Value-based Oncology Care at European Cancer Hospitals.
[325] ONCOVALUE, Implementing Value-based Oncology Care at European Cancer Hospitals.
[326] Ibid.
[327] ONCOVALUE, First milestones reached in project aiming to enable value-based oncology care in Europe.
[328] For the data quality and data entry challenges, see van Drumpt et. al. 2025, p. 7.
[329] Auñón et. al. 2024, pp. 10, 16.
[330] ONCOVALUE, Implementing Value-based Oncology Care at European Cancer Hospitals. For the Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM), see OHDSI, The Observational Health Data Sciences and Informatics.
[331] ONCOVALUE, Implementing Value-based Oncology Care at European Cancer Hospitals.
[332] OHDSI, Our Journey – Where The OHDSI Community Has Been And Where We Are Going; Auñón et. al. 2024, pp. 10, 16.

DARWIN EU, it is not a formal requirement within the EHDS framework.[333] Still, because ONCOVALUE aims to standardise and automatise data collection, the technology and methods being built in the project benefit from the OMOP standardisation.[334] The OMOP CDM ecosystem has already proven valuable for cancer research, especially in collaborative studies similar to those ONCOVALUE pursues.[335]

Taking this into account, ONCOVALUE encourages healthcare professionals to record patient information in a structured and standardised format during routine clinical practice. Concretely, it guides cancer hospitals to collect and harmonise high-quality RWD.[336] Data collection here aligns with the EHDS concept of primary use, since it arises from activities directly related to patient care.[337] The consortium itself does not interact directly with patients but rather works to improve the data quality and usability in cancer hospitals.

The second track of ONCOVALUE concentrates on developing AI tools, which are capable of extracting structured data from unstructured sources.[338] In the project, these cover medical images and free-text notes written by clinicians.[339] Research has shown that a substantial portion of clinically relevant cancer information exists in unstructured form.[340]. Within ONCOVALUE, once AI tools are trained, they convert these real-world, unstructured records into structured datasets suitable for research, HTA and regulatory decision-making.[341] In the terminology of the EHDS, this type of use represents secondary data use, since the data are processed in these circumstances for purposes other than those for which they were originally collected.[342]

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[333] DARWIN EU, European Health Data Space. At present, the EHDS Regulation does not prescribe specific Common Data Models (CDMs) or data standards for secondary use of health data. Recommendations are though expected to come from TEHDAS2, which builds on lessons learned from the use cases tested in the EHDS2 Pilot project. These recommendations aim to provide practical steps to ensure interoperability and their unified use across datasets used for secondary purposes. See EHDS2 Pilot ("HealthData@EU pilot") 2024, pp. 53–54.
[334] See ONCOVALUE, Working towards automated evaluation of the effectiveness of cancer treatment.
[335] Wang et. al. 2025, p. 1. Since the Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM) ecosystem remains under active development, with continuous updates, improvements are projected to support cancer research. See Wang et al. 2025, p. 6.
[336] ONCOVALUE, Implementing Value-based Oncology Care at European Cancer Hospitals.
[337] See Art. 2(2)(d) of the EHDS.
[338] ONCOVALUE, Implementing Value-based Oncology Care at European Cancer Hospitals.
[339] European Commission, Implementing value-based oncology care at European cancer hospitals: An AI-based framework for assessing real-life effectiveness of novel cancer therapies in real-time.
[340] Wang et. al. 2025, p. 6.
[341] European Commission, Implementing value-based oncology care at European cancer hospitals: An AI-based framework for assessing real-life effectiveness of novel cancer therapies in real-time.
[342] See the definition of secondary use in Art. 2(2)(e) of the EHDS.

The effectiveness of secondary use of data depends on the quality and completeness of data collected for primary use, making this two-track strategy beneficial.[343] By improving the quality of RWD at the point of entry, ONCOVALUE simultaneously increases its value for secondary use. This dual approach reflects the EHDS idea that primary and secondary data uses are interdependent.[344]

Since ONCOVALUE operates across national borders, both national and international aspects need to be considered in the legal and technical matters. At Helsinki University Hospital (HUS), collected electronic health data are transmitted in real-time to a centralised data lake, which allows data to accumulate continuously. Comparable technical infrastructures are applied by the partner institutions as well.[345] RWD are thus collected and harmonised locally and the original datasets remain in national repositories. Analyses of the common use cases within ONCOVALUE are carried out by using a federated approach.[346]

From a legal perspective, this decentralised approach entails that the members of the ONCOVALUE consortium must comply only with the data protection rules of their respective jurisdictions, as no cross-border transfer of data takes place. The adopted model simplifies cross-border data governance by mitigating some of the difficulties associated with international data transfers and facilitates compliance with national and local requirements.[347]

From a technical standpoint, cross-site data processing requires all the partners to harmonise their datasets which are utilised in the common use cases. In this way, ONCOVALUE also aligns with the objectives of the EHDS, which underscores the importance of comprehensive datasets of RWD and RWE. Since the EHDS recognises that RWD and RWE can greatly

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[343] It has even been suggested that systems for collecting primary data should be designed with downstream reuse in mind. See EIT Health Think Tank 2024, p. 12.
[344] EHDS2 Pilot ("HealthData@EU pilot") 2024, p. 56.
[345] ONCOVALUE, Implementing Value-based Oncology Care at European Cancer Hospitals.
[346] Federated analysis was also employed in the EHDS2 Pilot Project, which recommended that guidelines for this should be made. The guidelines should cover how to perform the analysis without the need of pooling data (e.g., the use of common data models [CDMs], procedures for federated analysis, standardisation of pipelines or scripts). This would assist health data users to define when pooling data is necessary and when it can be omitted. In addition, according to the project, legal and technical support would be needed in order to perform the studies in a federated way. See EHDS2 Pilot ("HealthData@EU pilot") 2024, p. 54.
[347] ONCOVALUE, Implementing Value-based Oncology Care at European Cancer Hospitals. See also EHDS2 Pilot ("HealthData@EU pilot") 2024, p. 54.

enrich existing health data, this potential can only be realised if the datasets available for secondary use are as comprehensive as possible.[348]

All in all, ONCOVALUE seeks to release the full value of RWD which are collected in European cancer hospitals by expanding the availability of structured, high-quality RWD suitable for analysis and the generation of RWE.[349] This RWE is intended to support not only hospital administrators but also regulatory authorities and HTA bodies. By promoting standardised data collection and transforming heterogeneous, unstructured RWD into harmonised datasets, ONCOVALUE strengthens its value for secondary use.[350] In addition, by sharing best practices and developing guidelines for effective data collection, harmonisation and analysis, the consortium contributes to the wider research community.[351]

The ONCOVALUE consortium actively engages with a range of European initiatives to optimise impact and foster innovation in cancer care.[352] Beyond bilateral networking, it participates in collaborative clusters that bring together multiple projects that share common goals and interests.[353] Moreover, with respect to ongoing initiatives, ONCOVALUE maintains regular meetings with TEHDAS2, ensuring continuous dialogue and alignment with the latest developments in European health data governance. The consortium also closely follows the progress of DARWIN EU. Through these interactions, ONCOVALUE is able to refine its strategies in response to evolving European developments and thereby strengthen the relevance of its research outputs.

7.3 TEHDAS initiatives advancing harmonised EHDS implementation

TEHDAS1 and its successor, TEHDAS2, both coordinated by the Finnish Innovation Fund Sitra, are large-scale projects aimed at advancing the cross-border secondary use of electronic health data in Europe. TEHDAS1, which ran from 2021 to 2023, developed European-level

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[348] See Recital 53 of the EHDS.
[349] ONCOVALUE, Implementing Value-based Oncology Care at European Cancer Hospitals.
[350] Cascini 2025, p. 3. See also Price et al. 2025, p. 2; Katkade – Sanders – Zou 2018, p. 300.
[351] For outcomes, see ONCOVALUE, The Results; European Commission, Implementing value-based oncology care at European cancer hospitals: An AI-based framework for assessing real-life effectiveness of novel cancer therapies in real-time. For the claims to share best practices and develop guidelines for using Real-World Data (RWD), see for example Katkade – Sanders – Zou 2018, p. 297.
[352] ONCOVALUE, European AI Security Network (EASiNet); ONCOVALUE, News & events.
[353] Zocchi 2024, p. 33. In the deliverable ”Stakeholder Analysis”, ONCOVALUE identified the most important stakeholders relevant to its innovations and evaluated their positions within the project’s value chain. This assessment enables the project team to develop more targeted stakeholder engagement strategies. See Zocchi 2024.

principles for secondary use. TEHDAS2, launched in 2024 and continuing until 2026, is building on this foundation by preparing the ground for harmonised implementation of secondary data use within the EHDS.[354]

TEHDAS1 was essentially a preparatory initiative which involved 25 European countries. It laid the groundwork for the EHDS Regulation with a particular focus on the secondary use of electronic health data.[355] Its leading objective was to support EU Member States and the European Commission by developing shared principles for the cross-border secondary use of health data.[356]

The contributions of TEHDAS1 have been widely utilised in various initiatives.[357] One of the most prominent was a User's Journey, a process developed to describe how data users interact with the decentralised infrastructure for secondary use.[358] It was incorporated into the EHDS2 Pilot project which tested the first version of the EHDS infrastructure in a limited group of Member States.[359] During the pilot, a central component was to evaluate the User's Journey in real-world conditions. Following this, the model was ultimately adopted in the EHDS legislative framework, with only minor modifications by the European Commission.[360]

The influence of TEHDAS1 was reflected in the European Commission's proposal for the EHDS Regulation and now that the Regulation is in force, its legacy continues through the work of TEHDAS2. TEHDAS2, for its part, promotes the harmonised implementation of the Regulation by having 29 European countries involved [361]

TEHDAS2 builds on and expands upon the work initiated under TEHDAS1 and the EHDS2 Pilot project.[362] In practical terms, TEHDAS2 produces concrete guidelines and technical

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[354] See TEHDAS1, Joint Action Towards the European Health Data Space – TEHDAS1; TEHDAS2, Second Joint Action Towards the European Health Data Space – TEHDAS2.
[355] TEHDAS1, Joint Action Towards the European Health Data Space – TEHDAS1; Kalliola – Drakvik – Nurmi 2023, p. 24.
[356] Kalliola – Drakvik – Nurmi 2023, p. 7. See also TEHDAS2, Second Joint Action Towards the European Health Data Space – TEHDAS2. In their study of six data-driven EU projects focusing on cancer, Gyrard et. al. observed that all these projects utilised the recommended standards for interoperability identified by the TEHDAS1. This indicates that despite their varied areas of focus, the projects collectively relied on interoperability. See Gyrard et al. 2025, p. 10.
[357] Kalliola – Drakvik – Nurmi 2023, p. 24.
[358] Kalliola – Drakvik – Nurmi 2023, p. 18.
[359] For the outcomes of the pilot project, see European Commission, Pilot for a European Health Data Space on secondary use of health data.
[360] Kalliola – Drakvik – Nurmi 2023, p. 18.
[361] Kalliola – Drakvik – Nurmi 2023, p. 9.
[362] TEHDAS2, Second Joint Action Towards the European Health Data Space – TEHDAS2.

specifications for Member States and the European Commission. The first set of guidelines has already been through public consultation and will be published in autumn 2025.[363] Three of the four draft guidelines from this set have been cited in this thesis, as they demonstrate the practical application of the EHDS and represent the most concrete reference point so far.[364] As implementation progresses and additional practical experience is gained, further refinements and developments can naturally be expected.[365]

The main goal behind these outputs is to deliver common, actionable guidelines and develop technical specifications that strengthen European collaboration in using data efficiently. The results of TEHDAS2 are intended to support data holders, users and HDABs as they prepare to take on new responsibilities under the EHDS Regulation.[366]

The purpose is that Member States can make use of the results to guide their own national implementation efforts concerning the EHDS Regulation and its implementing acts. Simultaneously, the work of the TEHDAS2 will assist the European Commission in the preparation of those acts.[367]

7.4 EHDS2 Pilot project in collaboration with DARWIN EU

The EHDS2 Pilot project, conducted over 2022–2024, built and tested the first version of EHDS by linking data provider platforms across Europe for secondary use. This setup allowed the project to trial the User's Journey, a process originally created under TEHDAS1, to guide health data users through the application process to access data for secondary use.[368] Throughout the pilot, the EHDS2 Pilot project collaborated with TEHDAS2 team, so that the findings of the EHDS2 Pilot directly informed the ongoing work of TEHDAS2.[369]

To evaluate the entire User's Journey, the EHDS2 Pilot project run five use cases, covering the path from electronic health data discovery to its access and analysis. Participants came

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[363] The next wave of draft guidelines is scheduled for release in autumn 2025, with the next ones due in summer 2026. See TEHDAS2, Second Joint Action Towards the European Health Data Space – TEHDAS2.
[364] These are the "Draft guideline for data users on good application and access practice" by Dudová et. al. 2025, the "Draft technical specification on the national metadata catalogue" by Peolsson et. al. 2025 and the "Draft guideline on data description" by Schutte et. al. 2024.
[365] TEHDAS2, Second Joint Action Towards the European Health Data Space – TEHDAS2.
[366] Ibid.
[367] Ibid.
[368] For the project page, see European Commission, Pilot for a European Health Data Space on secondary use of health data.
[369] Benderra 2025, p. 9.

from France, Finland, Belgium, Denmark, Norway, Croatia and Hungary. Several agencies, institutions and initiatives, including EMA and DARWIN EU, were involved to the project and conducted its use cases as well.[370]

EMA joined the consortium as a partner and led one of the EHDS2 Pilot use cases, with DARWIN EU serving as a flagship "pathfinder" to test the EHDS in a practical setting.[371] DARWIN EU, which became fully operational in 2024, is a European initiative coordinated by EMA and rooted in the concept of the secondary use of healthcare data.[372] Within the EHDS2 Pilot, it contributed to the ongoing development of the EHDS and built upon the work of TEHDAS1 to support the European principles for the secondary use.[373] Even though these two projects, DARWIN EU and EHDS2 Pilot project, are distinct entities, they complement one another in advancing the secondary use of electronic health data.[374] DARWIN EU continues to coordinate with relevant initiatives and policies at both the European and national levels.[375]

After the completion of the EHDS2 Pilot project, its lessons learned stated that alignment with the EHDS Regulation negotiations and continuous monitoring of legislative developments were essential.[376] At that stage, the EHDS Regulation was in progress, which inevitably contributed to a degree of ambiguity. Nonetheless, coordination with the European Commission proved critical for managing the uncertainties arising of a constantly evolving regulatory environment.[377]

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[370] European Commission, Pilot for a European Health Data Space on secondary use of health data; Benderra 2025, p. 7. Other participants were the European Centre for Disease Prevention and Control (ECDC), Biobanking and Biomolecular Resources Research Infrastructure – European Research Infrastructure Consortium (BBMRI–ERIC) and ELIXIR / Barcelona Supercomputing Center (BSC). For specific use cases, see for instance the deliverables at European Commission, Pilot for a European Health Data Space on secondary use of health data.
[371] European Commission, Pilot for a European Health Data Space on secondary use of health data; Benderra 2025, pp. 7–8; EMA, Initiation of DARWIN EU® Coordination Centre advances integration of real-world evidence into assessment of medicines in the EU.
[372] DARWIN EU, Home. The coordination centre of DARWIN EU was established by the European Medicines Agency (EMA) and the European Medicines Regulatory Network (EMRN). Its purpose is to provide timely and reliable evidence on medicines for human use from real-world healthcare databases across the EU. For more information, see DARWIN EU, Home.
[373] DARWIN EU, European Health Data Space; EMA, Data Analysis and Real World Interrogation Network (DARWIN EU); Oyen – Catalano 2022, p. 14.
[374] DARWIN EU, European Health Data Space.
[375] EMA 2024b, p. 7.
[376] Benderra 2025, p. 17.
[377] Ibid.

The EHDS2 Pilot noticed that the shifting nature of the EHDS legislation added considerable complexity for research. As commented by the leader of its Work Package 7, "The moving target of the EHDS Regulation, including delays in the regulation and changes to the entire framework, has made it complicated to achieve concrete advances".[378] Consequently, the project recommended to develop such flexible strategies, which accommodate unstable legislative structures, alongside fostering strong interdisciplinary collaboration between scientific, technical and legal teams.[379]

This characterisation of the EHDS as a "moving target" resonates across all current EU-based projects and initiatives in the Europe. While the Regulation is now in force, the absence of delegated and implementing acts leaves uncertainty but also gives research projects and initiatives opportunity to explore innovative solutions and prepare for the emerging EHDS.

7.5 Outcomes and implications

Over the past few years, ONCOVALUE, TEHDAS1, TEHDAS2, the EHDS2 Pilot and DARWIN EU have done more than run projects side by side. Collectively, they have helped to bring Europe closer to a coherent European Health Data Space and offered practical guidance for aligning with its Regulation. While each of these projects and initiatives functions independently, their orientation towards an interoperable EHDS underscores the value of collaboration. Broadly speaking, such action is widely regarded essential for the development and successful implementation of the EHDS Regulation.[380]

Collaboration across EU-level initiatives is particularly important because these projects are uniquely positioned to guide a coordinated and legally sound transition to EHDS adoption. As seen in the EHDS2 Pilot, which employed a wide range of actors, the model designed by TEHDAS1 for the User's Journey, ultimately influenced the EHDS Regulation itself.

Nevertheless, as Fröhlich et al. point out, current projects have succeeded in producing practical solutions under the existing EU legislation, but the impact of upcoming legislative changes remains uncertain. They maintain that considerable progress is still needed before the

[378] Benderra 2025, p. 13.
[379] Benderra 2025, p. 18.
[380] van Drumpt et. al. 2025, p. 10; Oyen – Catalano 2022, p. 17.

EHDS can fully realise its ambition of a more integrated and efficient health data ecosystem across Europe.[381]

[381] See Fröhlich et al. 2025.

8 Discussion

This thesis has explored the recently established European Health Data Space (EHDS) and examined the ways in which EU-projects and initiatives can contribute to its harmonised implementation. At the core of the study has been an analysis of the governance and data access mechanisms introduced by the EHDS Regulation for the secondary use of electronic health data. Placing the emphasis on areas where the interaction between EU-funded projects and the evolving development of the EHDS is the most clearly visible, the main findings can be summarised as follows.

In order to translate the regulatory ambitions of the EHDS into practical solutions, EU-projects and initiatives can serve as experimental platforms. Initiatives such as TEHDAS1, TEHDAS2 and the EHDS2 Pilot project demonstrate how high-level objectives can be transformed into tangible infrastructures, metadata frameworks and governance templates. The EHDS infrastructure, which was set up in the EHDS2 Pilot project, shed light on its technical feasibility for data access cross the borders, whereas a set of draft guidelines to support actors involved in secondary use, was produced by TEHDAS2 and launched for public consultation. These outcomes show that projects, besides providing input for EU-level policy design, also engage Member States and thereby prepare them for the phased implementation of the EHDS and reduce the risk of fragmentation across national systems.

Real-world data (RWD) and innovation appear as central components in the EHDS ecosystem. RWD has been recognised by both the EU legislator and stakeholders as a valuable resource for research, regulatory decision-making and health technology assessment (HTA). The European Commission's investments in projects which focus on RWD reflect this priority. ONCOVALUE provides a concrete example of how such projects can improve the quality and standardisation of RWD and develop AI tools to increase its usability for secondary purposes, such as value-based oncology care. This indicates that RWD is not merely a technical or methodological issue but also a governance concern at the EU level, as its integration into the EHDS depends on ensuring reliability and legal compliance.

In the end, the success of the EHDS will rest on achieving harmonisation across Member States. This requires paying attention to legal consistency, as well as adopting shared standards and governance practices. Research and pilot projects are essential in this process, as they provide the opportunity to test and validate tools before they are scaled up in the EU.

For instance, HealthDCAT-AP, a metadata model developed within TEHDAS2, could be widely used to standardise dataset cataloguing for secondary use. These technical building blocks are important for making national datasets discoverable and accessible across borders and avoiding fragmentation within the EHDS.

This thesis has approached the EHDS from a legal perspective, a standpoint where research on EHDS Regulation remains relatively limited. Much of the existing academic work has concentrated narrowly on the interaction between the EHDS and the GDPR, especially regarding the legal basis for processing personal health data, or on the role and tasks of Health Data Access Bodies (HDABs), national authorities responsible for managing data access for secondary use. By contrast, this thesis has sought to offer broader and more contextual view by deliberately integrating the outcomes of EU-projects to capture the current state of secondary use within the EHDS. In doing so, it contributes to legal scholarship by linking legal analysis with ongoing project-based experimentation and thus giving insights how law and practice co-evolve in the development of the EHDS.

The study has its limitations, most notably in relation to developments within the Member States. By adopting a broad EU-wide perspective, it has inevitably underrepresented the diversity of national approaches and practical challenges that Member States will face during the implementation of the EHDS Regulation. The real test of the EHDS will take place in domestic contexts, where preparedness for secondary use varies significantly. Future research should therefore examine Member State practices in greater depth and assess how the framework for secondary use, as designed in the EHDS, is translated into concrete action.

9 Conclusion

The findings of this thesis suggest that EU-projects and initiatives represent intermediaries in operationalising the European Health Data Space (EHDS). In this capacity, they are essential enablers for translating the abstract language of regulation into the concrete realities of secondary data use within the European Health Data Space. These projects and initiatives function as experimental arenas where infrastructures, governance mechanisms and legal principles are tested and refined before being adopted into binding practice.

The EU-projects and initiatives are not passive actors, rather they hold an active and central position in guiding the future of the EHDS. In practice, they assess what is workable, expose where tensions arise and aim to find practical solutions that can be scaled up across the EU. By connecting the gap between regulatory ambitions and operational realities, these projects and initiatives can ensure that the EHDS develops in a harmonised and innovation-friendly manner throughout Europe.

Finally, this leaves us with a cautious optimism. The EHDS framework, supported by ongoing EU-projects and initiatives, offers a possible route leading to a more interoperable European health data ecosystem. Although the EHDS is the first sector-specific European data space to be formally established, this does not directly imply that it is the most mature. Consequently, continued cooperation and cross-border engagement remains necessary to make sure that the EHDS functions effectively and achieves its objectives.