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THE EUROPEAN HEALTH DATA SPACE (EHDS) AND OPENEHR: EVALUATION OF REQUIREMENTS AND PRINCIPLES

Master's thesis

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TERVISHOIU EUROOPA ANDMERUUM (EHDS) JA OPENEHR: NÕUETE JA PÕHIMÕTETE HINDAMINE

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Author’s declaration of originality

I hereby certify that I am the sole author of this thesis. All the used materials, references to the literature and the work of others have been referred to. This thesis has not been presented for examination anywhere else.

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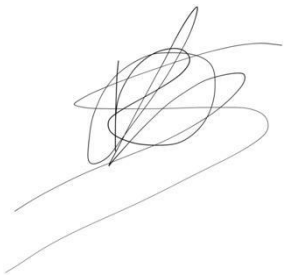

Abstract

The creation of a European Health Data Space (EHDS) is one of the priorities of the European Commission. Creating a common EHDS will support better exchange and access to health data between member states. The priority, combined with the recent recommendation from the World Health Organization (WHO) to use OpenEHR among others to develop a digital health platform, originated the aim of this thesis. This study aims to analyze if and how openEHR principles address the EHDS. A mixed methodology is applied to test the hypothesis of OpenEHR implementation being favorable toward the EHDS. A systematic literature review is conducted to define the EHDS requirements. Following analysis of the OpenEHR Architecture overview, the EHDS requirements are matched with the OpenEHR principles. The matching and resulted in: a total of 18 out of the 25 EHDS requirements are fully matching with selected OpenEHR principles, a total of 4 out of the 25 EHDS requirements do not match the selected OpenEHR principles, and a total of 3 out of the 25 EHDS requirements are potentially matching with selected OpenEHR principles.

The high level of matching between EHDS requirements and OpenEHR principles would correspond to the hypothesis and suggest that OpenEHR implementation would be advantageous. However, it is not justifiable to make such statements on the favorability of OpenEHR implementation for the EHDS thus far. The results of this study reveal that demand for a distinct definition of requirements is demanded before the establishment of the EHDS.

Nevertheless, the results of this study are valuable. This work revealed the lack of a current definition of the EHDS requirements. Additionally, it shows the potential of OpenEHR implementation and provided a framework to match healthcare infrastructures with EHDS requirements. The utilization of the framework should be considered in future studies. This all will be taken into account for input at the TEHDAS Joint Action.

This thesis is written in English and is 71 pages long, including 9 chapters, 3 figures and 1table.

Annotatsioon

TERVISHOIU EUROOPA ANDMERUUM (EHDS) JA OPENEHR: NÕUETE JA PÕHIMÕTETE HINDAMINE

Tervishoiu Euroopa andmeruum (EHDS) loomine on üks Euroopa Komisjoni prioriteetidest. Ühise EHDS'i loomine toetab paremat terviseandmetele vahetust ja juurdepääsu liikmesriikide vahel. Selle lõputöö eesmärk sai alguse Maailma Terviseorganisatsiooni (WHO) hiljutisest soovitusest kasutada digitaalse terviseplatvormi väljatöötamiseks teiste hulgas ka OpenEHR'i. Selle uurimustöö eesmärk on analüüsida, kas ja kuidas sobivad kokku openEHR põhimõtted EHDS'iga. EHDS'iga kokkusobiva OpenEHR'i rakendamise hüpoteesi testimiseks on kasutatud kombineeritud metoodikat. EHDS'i nõuete määratlemiseks viidi läbi süsteemne kirjanduse ülevaade. Peale OpenEHR'i arhitektuuri ülevaate analüüsi võrreldi EHDS'i nõudeid OpenEHR'i põhimõtetega. Võrdluse tulemus: 25 EHDS'i nõudest 18 vastas täielikult valitud OpenEHR'i põhimõtetele, neli ei vastanud valitud OpenEHR'i põhimõtetele ja kolm vastasid potentsiaalselt valitud OpenEHR'i põhimõtetele.

EHDS'i nõuete ja OpenEHR'i põhimõtete vastavuse kõrgetasemeline võrdlus vastas hüpoteesile ja viitas sellele, et OpenEHR'i rakendamine oleks kasulik. Sellise väite tegemine OpenEHRi rakendamise soodsuse kohta EHDS'i jaoks pole end seni õigustatud. Uurimistöö tulemused näitavad, et enne EHDS'i loomist on vajalik nõuete selge määratlemine.

Sellest hoolimata on selle uuringu tulemused väärtuslikud. See töö näitas EHDS'i nõuete praeguse määratluse puudumist. Lisaks näitas see OpenEHR'i rakendamise potentsiaali ja pakkus raamistiku tervishoiu infrastruktuuride sobitamiseks EHDS'i nõuetega. OpenEHR raamistiku kasutamist tuleks tulevastes uurimustöödes kaaluda. Seda kõike võetakse TEHDASe ühismeetme sisendina arvesse.

See lõputöö on kirjutatud inglise keeles ja on 71 lehekülge pikk, sealhulgas 9 peatükke, 3 joonised ja 1 tabeleid.

List of abbreviations and terms

AI	Artificial Intelligence
API	Application Programming Interface
AQL	Architype Quarry Language
CEF	Connecting Europe Facility
CKM	Clinical Knowledge Manager
EDPS	European Data Protector Supervisor
eHAction	2nd Joint Action supporting the eHealth Network
EHDS	European Health Data Space
eHDSI	eHealth Digital Service Infrastructure
eHN	eHealth Network
EHR	Electronic health record
EMR	Electronic Medical Record
EU	European Union
FAIR	Findable, Accessible, Interoperable, and Reusable
GDL	Guideline Definition Language
GDPR	General Data Protection Rules
HIS	Hospital Information Systems
HL7 FHIR	Health Level Seven Fast Healthcare Interoperable Recourses
IHE	Intergrading the Health Enterprise
ISO	International Organization for Standardization
IT	Information Technology
JAseHN	1st Joint Action to support the eHealth Network
RM	Reference Model
TEHDAS	The Joint Action Towards the European Health Data Space
WHO	World Health Organization

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1 Introduction

It is widely acknowledged that safe, efficient, and sustainable healthcare systems are highly dependent on data. [1] Data could support clinical decision-making, enable healthcare system planning, supervision, and improvement, and provide information to empower patients to engage actively in their healthcare and wellness management.

This data includes formally structured data in electronic health records (HER's), medical images, drug prescriptions, laboratory reports, claims and reimbursement data, patient-reported outcomes, and other healthcare systems' data management tools. [1]

The COVID-19 pandemic has significantly directed attention towards data sharing, both in the context of public health reporting of disease incidence and contact tracing and in the demand for accessible data for collaborative research across borders, both within and beyond the EU. However, the focus on improved availability and accessibility was already manifested in EU policy before being intensified by the COVID-19 crisis, and it established the basis of one of the priorities designated in the European Commission's mandate to develop a European Health Data Space (EHDS). [1], [2], [3]

The focus on improved availability is emphasised by Ursula von der Leyen, the current President of the European Commission, who stated the following at the World Health Summit (25 October 2020): [4]

'We cannot wait for the end of the pandemic to repair and prepare for the future. We will build the foundations of a stronger European Health Union in which 27 countries work together to detect, prepare and respond collectively.'

Additionally, the focus was emphasised by the European Council at the "Conclusions on COVID-19 lessons learned in health" event on 09/12/2020: [3]

'Calls upon the European Commission, the Member States, and all relevant public and private stakeholders to jointly collaborate in order to deliver a functioning European Health Data Space...'

Supported by these quotes, the development of the European Health Data Space (EHDS) has an urgency to secure and improve healthcare in Europe for the coming years.

To fulfil this urgency and begin the development of the environment, there will be a preliminary joint action, as predecessor programs have been developed in the same manner. [5], [6], [7]

The Joint Action Towards the European Health Data Space (the TEHDAS Joint Action project) develops European principles for the use of health data and infrastructure planning. The Finnish Innovation Fund Sitra is selected to coordinate the joint project conducted by 25 countries; this project began in February 2021. [8]
The outcome of this research will be used in the TEHDAS project (Appendix 2 confirmation of participation TEHDAS author thesis). To make the Joint Action successful and eventually develop a well-functioning EHDS, a significant number of topics require preliminary research. [9]

Recently, the World Health Organization (WHO) recommended OpenEHR, among others, for the development of a digital health platform, according to the 2020-published Digital Health Platform Handbook: Building a Digital Information Infrastructure (Infostructure) for Health. [10] As a result of this publication and given the chrematistics of OpenEHR as a standard used to build EHR systems, [11] this work aims, first, to study whether and how openEHR principles address the EHDS requirements and, second, to contribute to the understanding and development of the EHDS. To achieve this aim, four research objectives are established:

- Analyse the requirements for EHDS
- Analyse the OpenEHR principles
- Determine the correspondence of the OpenEHR principles with the EHDS
- Validate the correspondence with an expert

2 European Health Data Space

The creation of a European Health Data Space is one of the priorities of the Commission 2019–2025. Creating a collaborative European Health Data Space will encourage upgraded exchange and access to different types of health data (e.g., electronic health records, genomics data, data from patient registries). The improvement of access and exchange supports healthcare delivery (primary use of data), health research, and health policy-making purposes (secondary use of data). [12]

On 19 February 2020, the European Commission presented the communication for "A European strategy for data". This communication envisages the creation of a common space in the area of health, namely the European Health Data Space (EHDS). This is presented as an essential tool for the prevention, detection, and curing of diseases, providing evidence-based decisions and enhancing the healthcare systems' effectiveness, accessibility, and sustainability. [13]

The communication of the EHDS was part of a document package, including a Communication on Shaping Europe's digital future and a White Paper on Artificial Intelligence—A European approach to excellence and trust. [14], [15]

2.1 Types of health data use

Health data can be used to benefit individuals, public health, and medical research and development. [16] The uses of health data are classified as either primary or secondary.

2.1.1 Primary use of health data

Primary use occurs when health data is used to deliver healthcare to the individual from whom it was collected. [17]

2.1.2 Secondary use of health data

Secondary use occurs when health data is used outside of healthcare delivery for that individual (e.g., for health research and health policy-making purposes). [3], [17] The benefits of the secondary use of health data include the provision of better healthcare

services and personalised care, thereby saving lives and increasing business opportunities for companies and cost savings for societies. [18]

2.2 Pillars of EHDS

The European Health Data Space will be built on three main pillars: [12]

1) Strong system of data governance and rules for data exchange
2) Data quality
3) Strong infrastructure and interoperability

2.2.1 Governance of the European Health Data Space

To understand the need for governance within the EHDS, preparatory work was conducted in 2020 via workshops and a study. The preliminary work was completed to provide a framework for the primary and secondary use of health data in the Member States, particularly through the following:

• A mapping of how far GDPR is fulfilled in the health sector of different countries, including an overview of the legal and technical modalities applicable to health data sharing for primary and secondary uses in the EU countries.

• An overview of the existing governance structures for the secondary use of health data in the EU countries.

• Recommendations for possible actions, legislative and non-legislative, at the EU level to facilitate health data sharing across the EU for primary and secondary uses. [12]

2.2.2 Data quality and interoperability

To fully exploit the potential of exchanging health data, it is essential to ensure health data quality. The various health data sources (e.g., electronic health records, different registries, various IT or digital tools) can ‘talk’ to one another. This requires technical and semantic interoperability between the different infrastructures and IT systems.

It is likewise essential to ensure that the health data are findable, accessible, interoperable, and reusable (FAIR). The Commission supports mapping and making existing health data registries more FAIR. Additionally, other data sources should establish standard data sets for exchanges for health research and policy-making purposes. [12]

2.2.3 Infrastructure and technology

The infrastructure at the European level will support the overarching strategy of the European Data Space launched by the publication of the European strategy for data on 19 February 2020. Simultaneously, its directions provide an in-depth analysis of health sector specificities. It will build on and potentially scale up existing initiatives, such as the eHealth Digital Service Infrastructure, the European Reference Networks, and the Genomics project. [12]

2.3 European cross-border health data sharing

Several European cross-border health data sharing initiatives were conducted prior to EHDS. Such prior initiatives have developed the foundation for the development of EHDS.

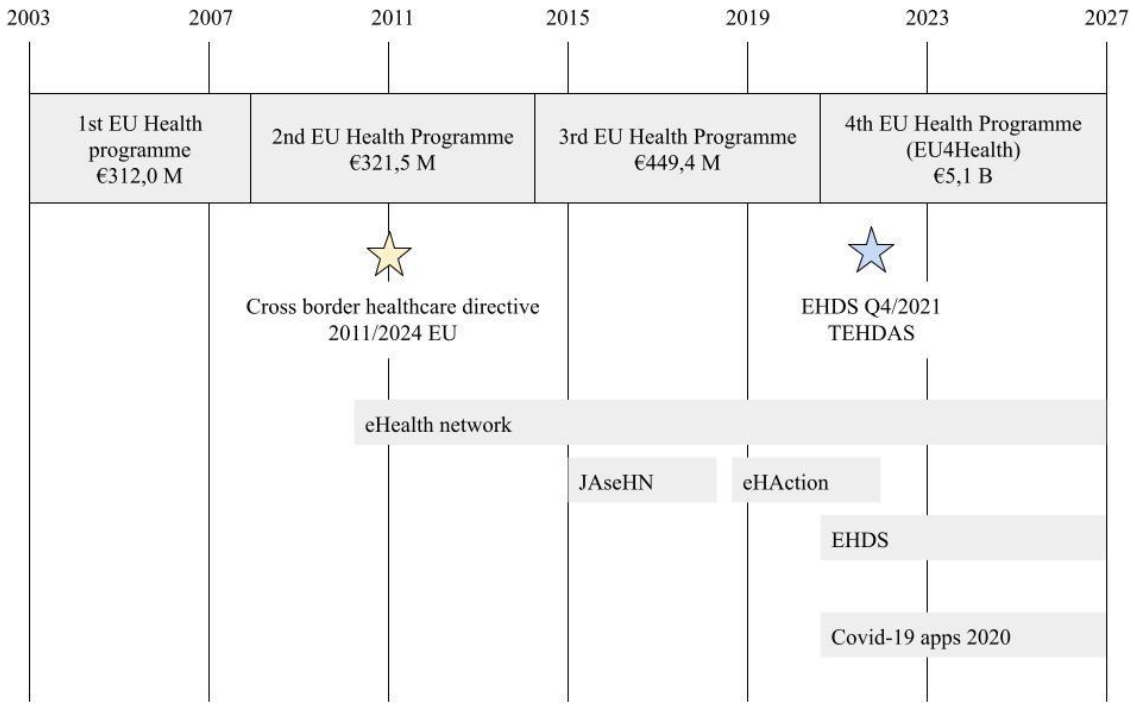

Figure 1. European eHealth timeline. Source: The author

In Figure 1, two initiatives are highlighted with star symbols. Both stars display an important event in European eHealth history and are of high relevance to this research. The first star (in yellow) is the directive 2011/24/EU of the European Parliament and the council on 9 March 2011 [13], [19]. At this event, the patients' rights in cross-border healthcare were announced. Meanwhile, the second star (in blue) is the start of the TEHDAS initiative. [8]

2.3.1 Past projects

JAseHN

The Joint Action to support the eHealth Network (JAseHN) was funded by the European Commission to serve as the main preparatory body for the eHealth Network. JAseHN was launched in May 2015, to facilitate the preparatory role of the 'eHealth Governance Initiative' to maintain this overall mechanism and ensure further joint political leadership and the ongoing integration of eHealth into health policy. [6]

JAseHN was in operation from May 2015 to June 2018. The objectives were to develop and submit several political recommendations and other instruments for cooperation to the eHealth Network regarding the Directive 2011/24/EU—specifically, on applying patients' rights in cross-border healthcare and the 2015–2018 Multiannual Working Plan of the eHealth Network, with the intention to organise a health data exchange between the EU Member States. [6]

The sole objective of JAseHN was to develop political recommendations and instruments for collaboration in the four specific priority areas specified in the eHealth Network's (eHN) Multi-Annual Work Plan 2015–2018, indicated as follows:

1) interoperability and standardisation,
2) monitoring and assessment of implementation,
3) exchange of knowledge and
4) global cooperation and positioning.

eHaction

The Joint Action supporting the eHealth Network, called eHAction, was launched in 2018. As the 3rd Joint Action of this type, it builds on the successful outcomes of predecessor programs. The primary aims were to support the eHealth Network by offering technical and scientific advice, facilitate cross-border healthcare across the EU, and provide the necessary policy support to the eHealth Digital Service infrastructure (eHDSI). [7]

eHAction develops strategic recommendations and tools to support the political discussions between the eHealth Network, EU countries, and the Commission on four priority areas, which are established on the eHealth Network Multiannual Work Programme for the period 2018–2021. It was financially supported through the EU Health Programme with the following declared aims: [7]

- Empowering people
- Contributing to the innovative use of health data

- Enhancing continuity of care
- Overcoming implementation challenges

2.3.2 Current and future projects

eHDSI

The eHealth Digital Service Infrastructure (eHDSI) is a framework that ensures the continuity of healthcare for European citizens as they travel abroad in the EU. It provides EU countries with the possibility to exchange health data securely, efficiently, and interoperably. European citizens can recognise the availability of the services under the brand 'MyHealth @ EU'. [20]

The following two electronic cross-border health services are currently introduced in all EU countries:

- **ePrescription (and eDispensation)** allows EU citizens to obtain their medication in a pharmacy located in another EU country. It enables the online transfer of citizens' electronic prescriptions from their country of residence to their country of travel. [20]
- **Patient Summaries** provide information regarding important health-related aspects (e.g., previous surgeries). This service is part of a more extensive collection of health data called the electronic Health Record. The digital Patient Summary is intended to provide doctors with essential information in their local language concerning the patient. It has already been stated that in the long term, medical images, lab results, and hospital discharge reports will also be available across the EU, forming the foundation of the EHDS. The exchange of ePrescriptions and Patient Summaries is accessible to all EU countries. [20]

Both services will be gradually implemented across 25 EU countries by 2025, namely: Austria, Belgium, Croatia, Cyprus, Czech Republic, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Slovenia, Spain, Sweden, Slovakia, Latvia, and Bulgaria. [20]

EHDS

The European Health Data Space will promote improved exchange and access to different types of health data. [12] The platform will be developed with three objectives in mind:

Objective 1: Assuring the access, sharing, and use of health data for healthcare delivery purposes and re-use for research and innovation, policy-making, and regulatory activities in a privacy-preserving, secure, transparent, and reliable manner:

a) Establishing an appropriate legal and governance framework to cover the access to and exchange of health data for healthcare provision, research, policy-making, and regulatory activities.

b) Reducing technical barriers limiting data use and re-use, particularly those related to infrastructure, interoperability, data quality, and standards in the health field.

c) Ensuring patients and citizens' access and control over their health data.

Objective 2: Creating a single market in digital health that covers digital health services and products, including telehealth, telemonitoring, and mobile health.

Objective 3: Magnifying the development, deployment, and application of reliable digital health products and services, including artificial intelligence. [21]

TEHDAS

Joint Action Towards the European Health Data Space (the TEHDAS Joint Action project) develops European principles for the use of health data and infrastructure planning. The Finnish Innovation Fund Sitra is selected to coordinate the joint project conducted by 25 countries. The project began in February 2021 [8] and will focus on the following areas:

- engaging other European projects and policy-makers in a discussion about the EHDS;
- ensuring the sustainability of the secondary use of health data in Europe;

- developing a governance model for cross-border cooperation regarding the secondary use of health data between European countries;
- promoting the reliability and compatibility of and access to health data for secondary use;
- clarifying the role of individuals in the secondary use of health data and including them in the dialogue about health data for research and policy-making. [9]

The outcome of this research will be used in the TEHDAS project, see Appendix 2.

2.4 Related EU financial support

To implement the policy in the field of eHealth, the European Commission relies on several financial instruments:

- The Connecting Europe Facility (CEF) supports trans-European networks and infrastructure, telecommunications, and energy sectors. It finances projects that address common challenges by providing technical and organisational expertise. The allocated budget proposed by the European Council for 2021–2027 is €28,396 million for the entire programme. [20]

- The Digital Europe Programme will invest in critical strategic digital capacities. It will complement other instruments in supporting digital transformation, with a budget of €6,761 million, as proposed by the European Council. [20]

- Horizon 2020, the EU's most extensive research programme, supports research, innovation, and cooperation for IT for health and wellbeing. Moreover, it encourages SMEs to scale up eHealth solutions and expand to markets abroad. The Horizon 2020 initiative was recently followed up by the next Horizon Europe programme, incorporating the period 2021–2027, with a budget of €75,900 million, as proposed by the European Council in July 2020. [20]

- The third Health Programme (2014–2020) supported the Joint Actions and has co-financed numerous eHealth projects. The upcoming EU4Health Programme (2021–2027) will continue to support the eHealth action of the European Union.

The European Council Conclusions in June 2020 provided it with a budget of €1,670 million. [20]

2.5 Regulations

2.5.1 GPDR

The EU General Data Protection Regulation (GDPR) represents the most important change in data privacy regulation in the past 20 years [22]. The GDPR replaces the Data Protection Directive 95/46/EC in an increasingly data-driven world that is immensely changed from when the 1995 directive was realised. The GDPR is designed to harmonise data privacy laws across Europe, protect all EU citizens' data privacy, and reshape how organisations in the union approach data privacy. The GDPR was adopted on 27 April 2016. [11]

According to the European Data Protector Supervisor (EDPS), processing operations under the EHDS will be lawful only if they are based on one or more of the six legal bases exhaustively listed in Article 6(1) GDPR. The scope of the EHDS's creation is to enhance access to health data to allow for evidence-based policy decisions and scientific research within the EU. EDPS does not consider Article 6(1)(a) GDPR to be the most appropriate legal basis to enhance such an aim. Instead, the EDPS considers that Article 6(1)(e) GDPR might be the most appropriate legal basis for the processing of personal data in the context of the functioning of the EHDS, as the platform's primary purpose is to serve the public interest. The processing should be done by an official authority named the controller. Additionally, it is recalled that health data are a 'special category of data', to which the GDPR affords special protection by establishing certain safeguards for its processing. In this regard, the EDPS considers that Article 9(2)(i) GDPR, which allows for the processing of sensitive data for reasons of public interest, could be considered a possible legal basis for the processing operations conducted within the EHDS. In addition, Article 9(2)(j) GDPR could serve as a possible legal basis for processing operations involving health data when the processing is necessary for scientific research purposes. The afore-mentioned processing must also be in accordance with Article 89(1) based on Union or Member State law, which requires the processing to be proportionate to the aim pursued, respect the essence of the right to data protection, and provide for suitable and

specific measures to safeguard the fundamental rights and the interests of the data subject. In this context, the EDPS would emphasise the recently adopted EDPB Guidelines on the processing of data concerning health for scientific research in the context of the COVID-19 outbreak. These additionally touch upon the essential data protection requirements applicable to this processing, particularly the legality, transparency, necessity and proportionality, and integrity and confidentiality. [23]

2.5.2 FAIR

FAIR (Findable, Accessible, Interoperable, and Reusable) is a principle with an intrinsic connection to the concept of learning health systems. In particular, it is essential to ensure that the health data are findable, accessible, interoperable, and reusable (FAIR).

The FAIR Data Principles, published on Scientific Data in 2016, are a set of guiding principles proposed by a consortium of scientists and organisations to support the reusability of digital assets. These principles have since been adopted by research institutions worldwide. The guidelines are timely, as we see unprecedented volume, complexity, and creation speed of data. [24]

The Commission supports the mapping of existing health data registries to make them more fair. Additionally, other data sources should establish standard data sets for exchanges for health research and policy-making purposes. [12], [11]

3 OpenEHR

OpenEHR is an open standard for e-health data, including open specifications, clinical models, and open-source software components. It is designed to construct an open, vendor-neutral platform for EHRs interoperable clinical and research data. [25]

3.1 Components

The central performance of the openEHR International is divided into four 'programs', which respectively focus on specifications, clinical modelling, software, and education. The first three of these programs correspond to the primary types of output of the openEHR community. Community members perform work on all the programs. A lightweight system of governance, influenced by the governance of Apache Foundation, has been created to encourage efficient and transparent decision-making. [26]

3.1.1 Specification program

The Specification Program delineates the formal models and languages defining the openEHR technical platform. This program includes an information model, the Archetype Language for openEHR content models (archetypes and templates), query language and specifications for openEHR services and APIs. These specifications are published and used for software engineering and underpin the Clinical Modelling Program and Software Program. [26]

3.1.2 Clinical modelling program

The practice of the Clinical Modelling Program is conducted by clinical professionals and health IT experts working in the Clinical Knowledge Manager (CKM) environment. Together, they develop archetypes that act as international standards for clinical data. These archetypes are utilised by national and local e-health programs and form the basis for building openEHR templates. [26]

3.1.3 Software program

The Software Program is responsible for developing open-source implementations of both tools and healthcare information system components. OpenEHR implementers possess unobstructed use of the components to build systems. Many of the software program's projects can be found in the openEHR GitHub project. [26]

3.1.4 Education program

Delivering the technical outcomes of the other programs to the actual environment is the task of the Education Program. This program aims to enable the efficient use of the outcomes of openEHR and make it available in local languages. All of this is possible within diverse healthcare cultures and funding environments. [26]

3.2 The value of OpenEHR use

The value of openEHR deployment can be found in its adaptability. An OpenEHR platform solution can be deployed in a single hospital. However, it can just as easily be deployed across a region, country or continent. In the latter deployments, the capability of health data is presented in a patient-centric rather than institution- or product-centric system. With this, vendor lock-in is avoided. [26]

Additional value is found in separating domain models from the technical layers. This separation allows the platform to be built and deployed independently. The domain models are added at runtime, allowing physicians and professionals to provide input when specifying the semantics of Hospital Information Systems (HISs). [26]

In its most advanced form, the technical advances of openEHR result naturally in a plug-and-play platform economy. Any vendor or developer can produce a solution component, so long as it conforms to the published data and API base standards of openEHR. Additionally, the domain content models are created by the community of clinical professionals. The user is in charge of its own system environment and can procure new components. [26]

3.3 FAIR

OpenEHR is FAIR-Enabling by Design; this is revealed by analysing the intrinsic potential of openEHR to develop a FAIR-compliant Clinical Data Resource. The analysis is performed by applying the openEHR specifications in combination with different ad hoc deployment configurations. Since the initiation of OpenEHR, the native support to FAIR principles is a direct outcome of semantic maintenance and querying in the openEHR philosophy. The native support was present already, long before the FAIR Guiding Principles were formulated. Despite its abstract nature, the analysis reveals how the openEHR approach can be considered a viable choice to have data that is more Findable, Accessible, Interactive, and Reusable in the clinical and biomedical contexts. [25]

4 Methodology

4.1 Aim of study

Given the characteristics of openEHR as a standard used to develop EHR systems, it is important to understand the extent to which the openEHR principles address the requirements mandatory to EHDS. This work aims to study whether and how openEHR addresses the EHDS requirements and contribute to the understanding and development of the EHDS.

. To achieve these aims, four research objectives are established:

- Analyse the requirements for EHDS
- Analyse the OpenEHR principles
- Determine the correspondence of the EHDS requirements with OpenEHR principles.
- Validate the correspondence with an expert.

Moreover, the following research questions are answered:

- What are the requirements for EHDS?
- What are the OpenEHR principles?
- To what extent are the EHDS requirements matched by OpenEHR principles?
- Should OpenEHR be implemented in the development of EHDS?

The hypothesis is as follows:

- It is favourable to employ OpenEHR in the development of EHDS

4.2 Systematic Literature Research

The systematic literature research was considered suitable for addressing the first research objectives for several reasons. The research questions serve to provide an overview of the current development plans and functioning of OpenEHR. The literature research aims to select relevant sources that are representative so that the results portray the entire spectrum of the topic. The complete systematic literature research is internet-based. This can be explained by the fact that the information sources are very recent.

4.3 Analytic approach

The hypothesis of OpenEHR being favourable in the development of EHDS is primarily justified by the possibility of establishing a direct mapping between the openEHR foundational principles and the EHDS requirements.

4.4 Overview of study design

This is a qualitative study. The study is performed throughout four steps:

1) Identify the architecture requirements for cross-border health data sharing in the European Health Data Space (EHDS);

2) Identify the openEHR principles regarding the functionalities of health data exchange;

3) Determine the correspondence of the openEHR principles to the EHDS requirements; and

4) Validate the correspondence with an expert.

4.4.1 European Health Data Space

The publication office of the European Union is the only database that provides information about the EHDS. This can be explained by the fact that the plans of the EHDS have been announced only recently.

Key word	Result
EHDS	1,083
European Health Data Space	535,878

Table 1. Query results based on keyword

It is important to mention that the high results in Table 1 are due to the fact that the publication office of the European Union reveals a correlation each time the keyword is mentioned. The correlation can be found in PDF, Print, HTML, DOC, and XML formats.

The sources were screened and reviewed for their suitability regarding the research question. The aim is to sort the sources gradually. Throughout this process, valuable sources were identified and included in a list for review. The flowchart from PRISMA was used to create the document. PRISMA is an evidence-based mechanism that includes a minimum set of items for reporting systematic reviews and metanalyses. [27]

4.4.2 OpenEHR

The list of openEHR architectural features relevant to EHDS was compiled from the openEHR Architecture Overview [28] by the author of this thesis, aiming to identify its main principles given the functionalities of an openEHR based system. A description is added, and the openEHR features are identified and listed.

4.4.3 Matching EHDS requirements with OpenEHR principles

Each feature can match more than one requirement, and a requirement can be matched by more than one feature. To be considered a match, the openEHR principles should meet the EHDS requirements in a straightforward manner via the simple implementation of its architecture.

4.4.4 Expert validation

To validate the precision of the matching between the EHDS requirements with the OpenEHR principles, validation by an expert is performed. The defined expert is Thomas Beale, the principal architect and tech-lead from OpenEHR.

The expert was discovered through contact with the OpenEHR organisation. The information request on the official website was forwarded to the person with the most expertise.

The validation is performed using a semi-structured method. The matching template is sent empty, motivated by the opportunity for the expert to provide uninfluenced input.

5 Results

This chapter presents the results of the mixed methods review. First, the results from the systematic literature review are presented. Second, the results are matched and validated with an expert review.

5.1 European Health Data Space

The article review on the EHDS in the Publication Office of the European Union resulted in a list of three out of seven articles (Figure 2) relevant for the development of EHDS.

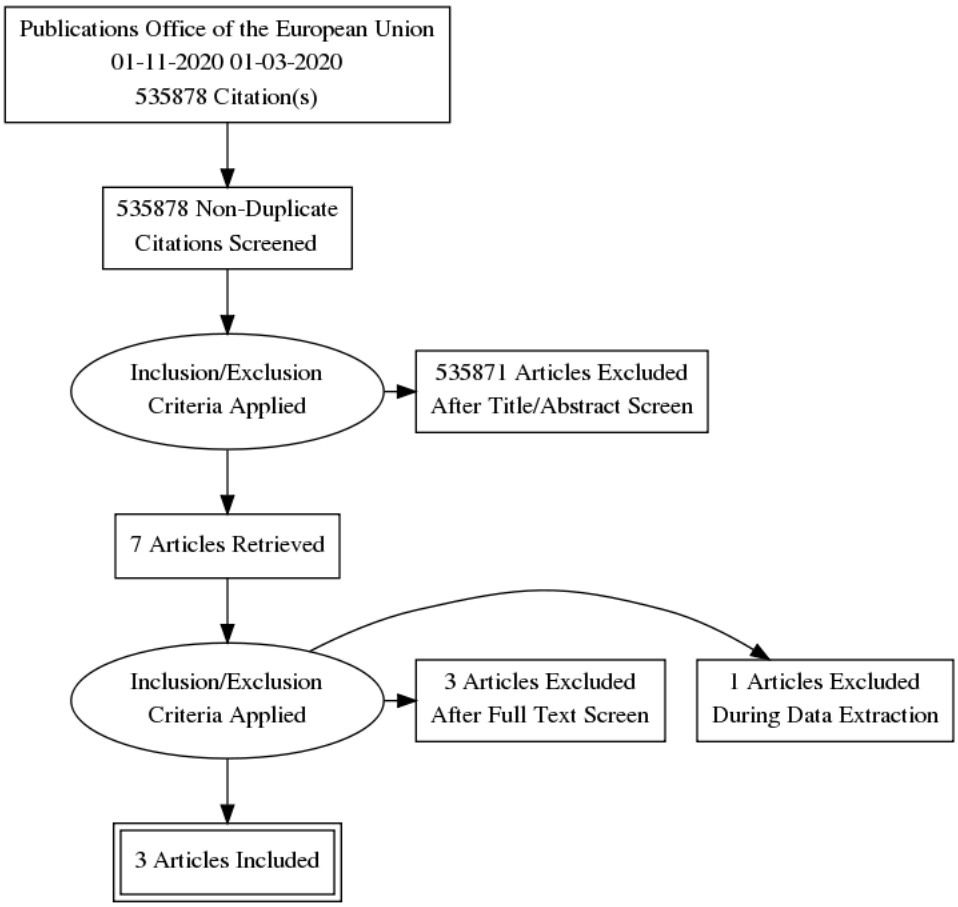

Figure 2. PRISMA Flowchart systematic literature review Publication Office of the European Union [29]

Based on the different articles, an overview is created, with the expectation of a fully functional EHDS. The overview is attached in Appendix 3. From the overview, a list containing the requirements is compiled. These compiled requirements are segmented into five categories:

1) Economic impacts
    a) Legal framework
    b) Governance framework
    c) Data quality framework
    d) Interoperability framework
    e) Facilitate innovations
    f) Improve monitoring
    g) Facilitate epidemiological surveillance

h) Increase secondary use of data

i) Cross-border market

2) Social impacts

a) Preventive strategies

b) Cross-border healthcare

c) Facilitate adoption AI

d) Promote remote (health) care

e) Reduce unnecessary tests

f) Citizens control their data

3) Environmental impacts

a) Efficient use of data

b) Efficient use of resources

4) Fundamental right impacts

a) Safeguards privacy

b) Security health data

c) Full compliance with data protection legislation

5) Simplification impacts

a) Reduction of fragmented and decentralised systems

b) Reduction of administrative burden

5.2 OpenEHR

Analysis of the OpenEHR Architecture overview resulted in the identification of nine principles relevant to the EHDS. [28] The explanation and implications of these principles are substantiated with additional sources. The OpenEHR principles relevant to EHDS are as follows:

Principle 1: Open platform

OpenEHR is based on an open platform ecosystem. An open platform ecosystem is a collaborating combination of entities that grants applications and platform services for health and care organisations and patients, compliant with open platform standards. [30]

The minimum of services for an open platform consists of the following:

- Clinical data repository
- Identity assurance
- Authentication and access control
- Open API interfaces (openEHR, HL7 FHIR, IHE)
- API management
- Audit trail

These services can be expanded with a portfolio consisting of more than thousands of microservices via open standard APIs. [31]

A key aspect of the open platform is the OpenEHR clinical data repository (CDR). A clinical data repository is a centralised database that collects and stores clinical data from heterogeneous data sources and opens access to users. A centralised database supports standardised EHRs, making the data harmonised and consistent. This uniform data allows for effortless data exchange. [32]

Implications (impacts):

- No need for data migration,
- Simplified integrations,
- All data can be accessed by third-party applications,
- Data is compliant for decision support and AI,

- Data is interoperable,
- Provides a tool for integrated care in which data from different levels of health and social care can be integrated,
- Provides a means of adding patient/citizen apps that operate on the same data as professionals: citizens own their respective data

Principle 2: Multi-level modelling

Multi-level modelling is a critical paradigm on which openEHR functions. Under the multi-level approach, there are three levels of models required for a system:

- *Reference model (RM)*: a stable reference information model frames the first level of modelling;
- *Re-usable content element definitions*: formal definitions of clinical content data points in the form of archetypes;
- *Context-specific data set definitions*: formal definitions of use-case-specific data sets, created by combining the required elements of relevant archetypes into openEHR templates.

The separation and independence of the software structure from the content enables interoperable and scalable health systems. [28]

Implications (impacts):

- Maximal data sets; clinical concepts expressed in a context,
- Implementation of terminologies and classifications,
- Established data model to use,
- Applications understand one another's data,
- All stakeholders can access the data model,
- Vendor and technology independence,

- Flexibility in designing applications,
- Faster adaptation to market needs.

Principle 3: International governance of data models

OpenEHR is directed by two bodies, the OpenEHR International (CIC) and the openEHR Foundation. Together with the international community, these bodies execute the governance of the archetypes. Within this governance, Clinical Knowledge Manager (CKM) plays an important role. The openEHR CKM is an online application that supports knowledge governance within and across the health organisation. In practice, it is a system used for collaborative development, management, and publishing of a wide range of clinical knowledge resources, including archetypes, templates, and terminology subsets. As a result, development is co-driven by clinicians. [33], [34]

Implications (impacts):

- International governance,
- Benefits from international collaboration,
- Sharing of resources across different countries,
- International alliance.

Principle 4: Active end-user engagement

Within OpenEHR, clinicians and social care professionals are at the centre of development. The clinicians model the content of the archetypes, which yields data models and care pathways developed by the end-users.

Implications (impacts):

- Tailored for purpose,
- Better end-user satisfaction,
- Stimulation for innovation,

- Engaged stakeholders,
- Agile development.

Principle 5: Archetype Query Language (AQL)

Archetype Query Language (AQL) is a declarative query language explicitly developed to express queries used for searching and retrieving the data found in repositories (e.g. CDR). The query language relates primarily to the openEHR Reference Model and the openEHR clinical archetypes. However, the syntax is independent of the information model, application, programming language, system environment, and storage model. [35]

Implications (impacts):

- Content-based queries,
- Searching in context,
- Population-level analytics and health status,
- Integrated care.

Principle 6: Separation of Clinical and Demographic data

Another openEHR design principle is to enable the complete separation of the EHR from demographic information identification via separated repositories with flexible referencing. In the event of a data breach of the EHR repository, this principle allows the data subject's identity to be preserved. The sensitive data is lost only when the demographic repository is breached. This principle strengthens the data subject's anonymisation regarding the information in the EHR.

Implications (impacts):

- Improved data privacy and security,
- Secondary data analytics.

Principle 7: Process-related specifications

OpenEHR provides specifications for various models and languages to address process- and guideline-driven healthcare. The specifications are defined in OpenEHR Task planning and Guideline Definition Language (GDL). The task planning addresses requirements in the automated clinical process, and GDL is a formal language used for expressing decision support logic. [36], [37], [38]

Implications (impacts):

- Cross-organisational care pathways,
- Cross-sector care pathways,
- Data can be combined for decision support and AI.

Principle 8: Open Modularity

Given the open chrematistics of OpenEHR, the architecture can consist of functional modules from several different vendors. Such vendor neutrality results in replaceable and independent modules. These modules are suitable for rapid and agile development, thus stimulating innovation and adaptation. [39]

Implications (impacts):

- Innovation is preserved by adding new modules,
- Quick adaptation (e.g. COVID-19 crisis),
- Modules can be replaced independently,
- Freedom to choose between vendors,
- No need to migrate when the system parts are changed,
- Stepwise renewal of IT infrastructures.

Principle 9: Separation of the user interface

In openEHR-based ecosystems, there can be multiple modules from different vendors. To facilitate the user, it is possible to create a common unified user experience rather than

offer multiple different user interfaces. In the monolithic environment, the user interface is bundled with the business logic, and so on. OpenEHR enables the separation of the user interface so that a single unified user interface can be built for all modules, even if they come from different vendors.

Implications (impacts):

- Unified user experience in a multivendor environment,
- Improved useability and user satisfaction.

5.3 Matching EHDS requirements with OpenEHR principles

The comparison to EHDS impacts occurs through the openEHR impacts derived from the underlying principles. Implications can overlap in different principles. Moreover, some implications might not match with EHDS, as they may be broader and more ambitious than EHDS. When the requirements do not match with the principles in a straightforward way but do exhibit signs of resemblance, the correlation is marked with a half-circle.

The figure displaying the initial matching between the EHDS requirements with the OpenEHR principles by the author is included in Appendix 4.

5.4 Expert validation

The expert's feedback by the provided empty template from the semi-structured feedback validation method is defined and visualised in Figure 3. Harvey balls are used to differentiate between a *full match*, a *potential match*, and a *no match*.

Extended expert validation feedback is provided in Appendix 5.

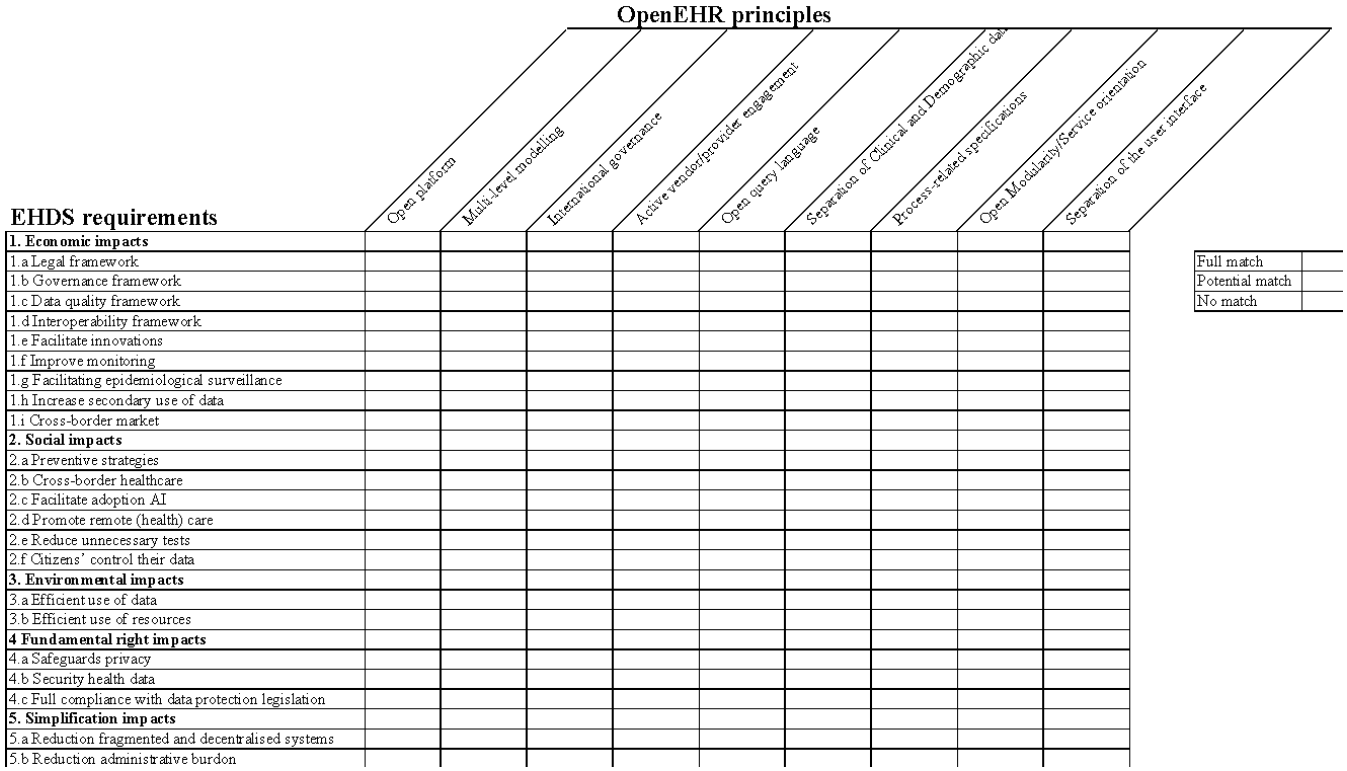

Figure 3. EHDS requirements matched with OpenEHR principles. Source: The author

5.4.1 EHDS requirements matched by OpenEHR principles

Overall, 18 of the 25 EHDS requirements fully match with the selected OpenEHR principles. Of these 18 requirements, 3 match with more than one principle:

1.d Interoperability framework

This EHDS requirement matches with the Multi-level modelling principle, Open query language principle, and Open Modularity/Service orientation principle.

2.b Cross-border healthcare

This EHDS requirement matches with the Active vendor/provider engagement principle and Open query language principle.

5.a Reduction of fragmented and decentralised systems

This EHDS requirement matches with the Open platform principle, Multi-level modelling principle, Open query language principle, Process-related specifications principle, and Separation of the user interface principle.

The remaining 15 EHDS requirements match straightforward and with only one OpenEHR principle.

5.4.2 EHDS requirements not matched by OpenEHR principles

Overall, 4 of the 25 EHDS requirements do not match with the selected OpenEHR principles:

2.c Promote remote healthcare

There is no direct support in openEHR for remote healthcare in the form of a teleconsultation or video call technology. However, it is possible to claim that a shared health record aids remote healthcare because it can accept data from remote devices and make that data available to clinical users in other locations. However, this depends on how the deployment of openEHR is performed;

namely, it must be deployed as a shared record (e.g. on regional servers) to realise this aim.

2.f Citizens control their data

The intention is that openEHR records are citizen-controlled. However, openEHR has not yet codified the technical method of doing this (which is primarily consent + access control + authentication), as the industry has been unable to agree on these subjects. Nevertheless, this will occur in the 'near future'.

3.b Efficient use of resources

A competent data system supports the efficient use of data. However, the efficient use of resources depends greatly on the user.

5.b Reduction of administrative burden

There is a general argument that high-quality, shared health records will reduce administrative burden. However, it does not demonstrate precisely how the administrative work will be reduced.

5.4.3 EHDS requirements potentially matched by OpenEHR principles

Overall, 3 of the 25 EHDS requirements potentially match with the selected OpenEHR principles:

1.a Legal framework

The matching depends entirely on not-yet-defined meaning within EHDS; if it means to have governance (which is not a 'legal' aspect), there is a link. However, if it means that the technology must have some inbuilt legal framework for clinical safety, contract management, quality control, or privacy (GDPR), then there is no direct support (since openEHR publishes no legal frameworks). However, for GDPR, there is sufficient support.

1.f Improve monitoring

The matching depends on the exact meaning of monitoring. If it means that openEHR leads to improved health records (it does, generally) and that better health records enable the improved monitoring of patients (i.e. historical tracking of data, analysis of previous data), then OpenEHR helps to monitor.

1.g Facilitating epidemiological surveillance

This has been classified as partly matching because the principle Open query language has the potential to facilitate epidemiological functions, yet it does not directly facilitate these functions.

5.4.4 Differences author and expert

Between Appendix 4, which describes what is made by the author, and Figure 3, which describes what is made by the author with validation of the expert, some differences are detectable:

Significantly fewer matches

Mutual consensus between the author and the expert resulted in fewer matches. For more understandable results, an agreement was made that a match should be straightforward, not simply based on probability. Harvey balls are implemented to define the difference between exact matches and possible matches.

AI decision support

Both the author and the expert agree that AI decision support connects primarily to *Principle 7: Process-related specifications*. However, additional insights by the expert indicate that the AI connection is one step away. As such, it is not directly 'inside openEHR'; rather, it is encapsulated by decision logic modules (DLMs) and presumably standalone services.

6 Discussion

The primary aim of this work is to study whether and how European Health Data Space requirements address the OpenEHR principles. Additionally, this work aims to contribute to the understanding and development of the EHDS. These aims are motivated by the creation of an EHDS, set to one of the priorities of the European Commission. [12] The EHDS is presented as an essential tool for the prevention, detection, and curing of diseases, providing evidence-based decisions and enhancing the healthcare systems' effectiveness, accessibility, and sustainability. [13] To develop the environment, there will be a preliminary joint action, as predecessor programs have been developed in the same manner. [5], [6], [7] For the Joint Action to be successful and eventually develop a well-functioning EHDS, a significant number of topics require preliminary research. [9]

Recently, the World Health Organization (WHO) recommended OpenEHR, among others, for the development of a digital health platform, as indicated in the 2020-published Digital Health Platform Handbook: Building a Digital Information Infrastructure (Infostructure) for Health. As a result of this publication and given the chrematistics of openEHR as a standard used to build EHR systems [10], this work aims to study whether openEHR principles address the EHDS requirements and to contribute to the understanding and development of the EHDS. To achieve these aims, four research objectives are established:

1) Analyse the requirements for EHDS
2) Analyse the OpenEHR principles
3) Determine the correspondence of the OpenEHR principles with the EHDS
4) Validate the correspondence with an expert

First, a systematic literature review was conducted to answer the research objectives. The review identified 25 requirements of which a completely developed EHDS demands to consist. The 25 requirements were then split into five impact categories, established by the European Commission; namely, these categories are economic impacts, social

impacts, environmental impacts, fundamental impacts, and simplification impacts. Within these categories are different requirements for the EHDS.

Second, the OpenEHR Architecture overview analysis resulted in identifying nine principles relevant to the EHDS. These principles were selected when, at minimum, one EHDS objective was directly connected.

The EHDS objectives were defined, and the OpenEHR principles were identified. The definition and identification create the foundation for understanding whether and how OpenEHR principles address EHDS objectives. To understand the addressing, the EHDS objectives and OpenEHR principles were matched, yielding the following results:

- 18 of the 25 EHDS requirements fully match with the selected OpenEHR principles.
- 4 of the 25 EHDS requirements do not match with the selected OpenEHR principles.
- 3 of the 25 EHDS requirements potentially match with the selected OpenEHR principles.

Overall, 18 of the 25 EHDS requirements fully match the selected OpenEHR principles. Specifically, 15 of the 18 EHDS requirements match straightforward and with only one OpenEHR principle, while the other 3 EHDS requirements match with more than one principle. The latter are as follows:

1.d Interoperability framework

2.b Cross-border healthcare

5.a Reduction of fragmented and decentralised systems

The three EHDS requirements that match with more than one OpenEHR principle indicate that OpenEHR widely covers the requirement. The broad coverage of the 1.d Interoperability framework aligns with one of the three pillars of EHDS, particularly ‘strong infrastructure and interoperability’. [12] Moreover, the multi-matching amidst the

2.b Cross-border healthcare and 5.a Reduction of fragmented and decentralised systems demonstrates that the implementation of OpenEHR is an asset. Furthermore, the other 15 EHDS requirements that match straightforward and with only one OpenEHR principle indicate that the implementation of OpenEHR is advantageous.

However, 4 of the 25 EHDS requirements do not match the selected OpenEHR principles:

2.c Promote remote healthcare

2.f Citizens control their data

3.b Efficient use of resources

5.b Reduction of administrative burden

Presumably, not all EHDS requirements directly match with OpenEHR principles. Sharing healthcare data across borders on such a large scale has not been performed thus far in Europe. SOURCE. Nevertheless, the four EHDS requirements not matched by OpenEHR principles suggest that the EHDS requirements demand more specific criteria and measurable metrics. To match 2.c Promote remote healthcare, it is necessary for more specific criteria to be in place. The criteria must define how remote healthcare would be promoted and what aims are expected. The 3.b Efficient use of resources and 5.b Reduction of administrative burden can be measured only when clear metrics are defined. The need for more specific criteria and measurables reveals that the EHDS requirements have not yet been entirely established.

Additionally, 3 of the 25 EHDS requirements potentially match with the selected OpenEHR principles:

1.a Legal framework

1.f Improve monitoring

1.g Facilitating epidemiological surveillance

The three EHDS requirements that potentially match with OpenEHR principles further indicate the necessity for a more comprehensive definition of the requirements. The

difference between the potentially matching requirements and the non-matching requirements is that the potential matches support OpenEHR principles when the definition is as suggested. Repeatedly, the need for more specific criteria and measurables reveals that the EHDS requirements have not yet been entirely established.

The high level of direct matching (18 of 25) between the requirements and the principles identifies that the initial correlation in OpenEHR is advantageous for realising the EHDS. OpenEHR being advantageous is additionally supported by the potential matches (3 of 25), which have a strong indication of possibly being able to match the EHDS requirements. Discussing the direct matches and possible matches summed with each other would result in a high level of already-matched EHDS requirements. Theoretically, this would suggest that OpenEHR supports a prominent number of the EHDS requirements and that adopting OpenEHR is favourable.

The non-matches between the EHDS requirements and the OpenEHR principles continue to suggest favourability. That is, the non-matches suggest an opportunity rather than a limitation. The requirements that principles do not match are not definite and demand more specific criteria and measurable metrics. Such an opportunity indicates that when better-defined criteria and metrics are established, the non-matches could transform into matches. Theoretically, this means that the adoption of OpenEHR might eventually be advantageous.

Both of these theories support the hypothesis regarding the favourability of adopting OpenEHR in the development of EHDS. Additionally, the theories align with the recent recommendation from the WHO about using OpenEHR, among others, to develop a digital health platform. [10] Such alignments would support the practical implementation of this study.

However, it is not justifiable to make such statements on the favourability of OpenEHR implementation for the EHDS, thus far. Moreover, despite the high level of direct matches between the EHDS requirements and OpenEHR principles, the results of this study reveal the demand for a distinct definition of requirements before the establishment of the EHDS.

Preceding work regarding the EHDS has not been extensive and is insufficient for making factual statements. Therefore, this study has been valuable in analysing the current status of consensus concerning requirements for the EHDS. Additionally, for the analysis of the current situation, this study has noted practical implications.

The first implication is that these outcomes will be topics discussed during the TEHDAS Joint Action for the EHDS. The outline for the discussion is that the implementation of OpenEHR has the potential to be advantageous for the EHDS establishment. However, a distinct definition of requirements is needed before establishing the EHDS.

The second implication of this study is that matching the EHDS requirements with the OpenEHR principles resulted in a framework for matching healthcare infrastructures with EHDS requirements. This framework is helpful for future studies.

The final notable implication is that the study provided new insights and revealed the necessity for refinement in requirements, which will become, after refinement, much more helpful as criteria for judging technologies. Moreover, the study demonstrated the absence of a current definition.

The implications indicate that before the European Commission can begin building the next big step of the European eHealth strategy, the European Health Data Space necessitates more description. Clarification for development will partly arise from the TEHDAS Joint Action and requires focus from all stakeholders. When requirements and needs are better defined, the EHDS can be established. Therefore, enabling exchange and access to different types of health data will be facilitated among member states and improve access for health research and health policy-making purposes. The improvement of health policy-making enables the European Commission to react more quickly to healthcare crises (e.g. the COVID-19 pandemic).

The results from this study should be considered when determining how to establish the EHDS. Greater clarification and definition for the EHDS requirements is a necessity. Nevertheless, the high level of matching and potential matching with OpenEHR principles should not be ignored. This study had a few limitations, yet it demonstrates a strong suggestion that OpenEHR would be profitable for the European Health Data Space.

6.1 Limitations

Although the aim has been achieved, this study has some limitations. First is the novelty of the topic; in particular, the European Health Data Space is a recently developed plan. Therefore, literature research was quite limited given the specific topic. Only a few articles have been published, including relevant information. In addition to the limited number of articles, most have been published very recently, and there is a high probability that supplementary information will be published in the imminent future.

Second, the topic's novelty influenced the definition of EHDS requirements. The reliability of this data is impacted by there not existing a definite list. As such, the requirements list was created based on the best knowledge and the available articles. The plans for EHDS are preliminary and open for modification. The preliminary status of the plans is advantageous for adjustments to achieve better matching with the OpenEHR principles; however, it is disadvantageous for the longevity of the relevance of this work.

The novelty of the topic might have additionally influenced the matching process. As the requirements were not yet clearly defined, this provided the opportunity for interpretation. Interpretation lowers the possibility of achieving the same results after repetitive research. However, the novelty likewise sheds light on the fact that the current definition is lacking.

Finally, the validation and thus the produced results might have bias. The expert who provided validation for this work holds a high position within the OpenEHR foundation and might have additional interests for OpenEHR to be recommended for EHDS development. Such bias might exist, though it would contradict the fact that the validation resulted in fewer matches than pressor work from the author.

With these limitations considered, the results are nevertheless valuable. This work revealed the lack of a current definition of the EHDS requirements. Additionally, it demonstrates the potential of OpenEHR implementation and provides a framework to match healthcare infrastructures with EHDS requirements, which can be used in future studies. This all will be considered for input at the TEHDAS Joint Action.

6.2 Suggestions, further studies, and developments

This research revealed that the current requirements lack clarification and definition. Therefore, the greatest emphasis should be on establishing precise requirements for the EHDS before other research can be conducted.

The methodology adopted in this thesis can be used as a basis for future research, especially the matching framework. It is highly recommended to research the other healthcare standards, such as HL7 FHIR and SNOMED-CT, which the WHO likewise honors in the digital infrastructure recommendation. [10] Healthcare standards could complement one another, as well. [31]

Moreover, further studies should focus on the member states' readiness for a universal platform. Thus far, some studies are related to the GDPR in healthcare readiness from member states. Additional eHealth maturity aspects are expected from the member states than only GDPR compliance in establishing the European Health Data Space.

7 Conclusion

The creation of a European Health Data Space is one of the priorities of the European Commission. This practice analysed whether and how openEHR principles address the EHDS requirements and contributed to the understanding and development of the EHDS. Mixed methodology research resulted in the following findings:

- 18 of the 25 EHDS requirements fully match with the selected OpenEHR principles.
- 4 of the 25 EHDS requirements do not match with the selected OpenEHR principles.
- 3 of the 25 EHDS requirements potentially match with the selected OpenEHR principles.

The high level of matching between EHDS requirements and OpenEHR principles suggests that OpenEHR implementation would be advantageous. However, it is not justifiable to make such a statement on the favourability of OpenEHR implementation for the EHDS, as of yet. Although there is a high level of direct matches between EHDS requirements and the OpenEHR principles, the results of this study reveal the demand for a distinct definition of requirements before the establishment of the EHDS.

Clear statements cannot be made; nevertheless, the results of this study are valuable. This work revealed the lack of a current definition of the EHDS requirements. Additionally, it demonstrated the potential of OpenEHR implementation and provided a framework to match healthcare infrastructures with EHDS requirements, which should be considered in future studies. This all will be considered for input at the TEHDAS Joint Action.

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Appendix 2 – TEHDAS Participation Confirmation

Gmail Rob Schubert [redacted]

Welcome to participate as a stakeholder in TEHDAS Joint Action

1 bericht

TEHDAS Coordination [redacted] 7 april 2021 om 16:28
Aan: TEHDAS Coordinat

Dear applicant in the TEHDAS stakeholder open call,

Congratulations! You have been selected to participate in **the Stakeholder forum** of TEHDAS Joint Action.

There was great interest in the open call with 189 applications from 27 countries.

What happens next?

The first Stakeholder forum event takes place in October 2021. You will receive an invitation to the event by early fall. Until then, we will keep you updated with a TEHDAS newsletter. You can also follow the project on Twitter @tehdas.

Stakeholder forum contact person:

[redacted]

In case you have any questions, please be in touch directly with the contact person.

Welcome aboard!

Best regards,

TEHDAS Coordination Team

www.tehdas.eu

tehdascoordination@sitra.fi

@tehdas

Appendix 3 – EHDS Objectives and impacts

Objective 1: Assuring access, sharing and use of health data for healthcare delivery purposes as well as re-use for research and innovation, policy-making and regulatory activities, in a privacy-preserving, secure, transparent and reliable way:

a) Establishing an appropriate legal and governance framework to cover the access to and exchange of health data for healthcare provision, research, policy-making and regulatory activities.

b) Reducing technical barriers limiting data use and re-use, particularly those related to infrastructure, interoperability, data quality and standards in the health field.

c) Ensuring patients and citizens' access and control over their health data.

Objective 2: Creating a single market in digital health covering digital health services and products, including telehealth, telemonitoring and mobile health.

Objective 3: Magnifying the development, deployment and application of reliable digital health products and services, including artificial intelligence. [21]

Expected Impacts

Economic impacts

- A common legal, governance, data quality and interoperability framework, while requiring some economic investments from the Member States and relevant stakeholders, will benefit patients, healthcare professionals, policymakers, regulators, researchers and innovators in the area of health at large.
- The initiative should facilitate the deployment of innovations that can increase the cost-effectiveness of patients and healthcare systems. Costs can be saved by shortening the time of diagnosis, optimising treatment options, avoiding duplication of tests and efforts, reducing medical errors, reducing inefficiencies in healthcare, facilitating personalised medicine, improving the effectiveness of

prevention programmes, improving the monitoring of medicinal products and medical devices efficacy and safety and facilitating epidemiological surveillance.

- This initiative aims to increase researchers' capability significantly, policymakers and regulators to access health data, both at the national and trans-national level.

- The initiative is expected to boost innovation by reducing barriers and facilitating more accessible access to re-use health data. It will create opportunities for innovation that could better support public health priorities and a more substantial market for EU health technology companies and digital products and services in the EU. The innovation opportunities should increase competitiveness in the health sector. The benefits of increasing coordinated access to health data range from lower technical costs to lower time to develop new health innovations.

- The initiative will improve the achievement of the Single Market by removing barriers to cross-border provision of digital products and services in the area of health, including to the benefit of SMEs. The initiative will support the increase of new AI-based services and products to facilitate treatment and preventive strategies, contributing to growth and investment by relevant stakeholders, resulting in a positive macroeconomic effect.

- The promotion of digital transformation in healthcare is expected to reinforce the sustainability and cost-effectiveness of healthcare systems. The initiative will likely improve the availability and quality of data in the healthcare sector. It leads to fewer errors, less duplication of efforts and better medical outcomes. [21]

Social impacts

- EHDS will support research on new preventive strategies and effective treatments and medical devices, thus contributing to improving citizens' health and their quality of life (e.g., by supporting the implementation of Europe's Beating Cancer Plan and the pharmaceutical strategy);

- It will improve access to innovative healthcare services throughout Europe, enhance the provision of high-quality cross-border healthcare and the protection of patients while travelling abroad;

- It will facilitate the adoption of digital technologies in health, especially AI, which could play a role in helping clinicians and other healthcare personnel work more efficiently and overcome staff shortages (for example, in medical deserts), as well as provide remote care where needed;

- It should also reduce unnecessary tests by supporting patients to share their health data with their healthcare providers; the initiative is likely to support the free movement of people and support patients travelling or living abroad and seeking medical treatment abroad;

- Implementing measures to enhance citizens' control over their health data will increase citizens' trust over digital health services and products. [21]

Environmental impacts

- By enhancing interoperability, re-use of health data, and the portability of patients' data, the initiative will improve the efficient use of resources and data (e.g., reducing unnecessary tests and visits of patients to hospitals). Digitalisation in healthcare increases the sector's environmental footprint. However, by enhancing interoperability, re-use of health data, and the portability of patients' data, this initiative will improve the efficient use of resources and data (e.g., reducing unnecessary tests and visits of patients to hospitals), which will create a positive impact on the environment. [21]

Fundamental right impacts

- The re-use of health data held by the healthcare sector has the inherent risks that require appropriate safeguards regarding individuals' rights to privacy and data protection and security.

- Several elements of this initiative relate to the processing of personal data. In particular special categories of personal data, the measures will need to pay specific attention to ensure full compliance with the data protection legislation GDPR. [21]

Simplification impacts

- The proposed measures are necessary to reduce the administrative burden for researchers, healthcare providers and national authorities. Currently, they are faced with very diverse, fragmented and decentralised systems for accessing health data, which renders complex cross-border scientific research in the health area. At the same time, the possibility of patients having their data transmitted between healthcare providers is likely to reduce unnecessary tests what will have essential impacts on healthcare sustainability.

- It will decrease inconvenience for patients by supporting data transmission and portability, facilitating cross-border healthcare and competition between healthcare services.

- The administrative burden will be assessed with other costs of the policy options considered for different stakeholders, including public bodies, policymakers, healthcare organisations, regulatory bodies and organisations carrying out research (no matter the legal status as public or private organisations). The proposed measures facilitate access to health data will require additional expertise and resources from the public sector.

- That trade-offs between administrative burden for operators and positive health and research benefits exist and will is considered in the analysis.

- The more intensive use of health data and digital workflows through digital health services and products is expected to reduce; duplicated clinical procedures, errors and lengthy procedures for approval of innovative digital health solutions. The reduction is leading to a diminished administrative burden in healthcare systems. [21]

Appendix 4 – Initial matching between EHDS requirements and OpenEHR principles by Author

EHDS requirements	openEHR principles								
	Open platform	Multi-level m	International gove	Active end-user enga	Open quary language	Separation of Clinic	Process-related :	Open Modul	Separation c
1. Economic impacts									
1.a Legal framework		x				x			
1.b Governance framework	x	x	x						
1.c Data quality framework	x	x							x
1.d Interoperability framework	x	x	x				x	x	x
1.e Facilitate innovations	x	x		x				x	
1.f Improve monitoring	x			x					
1.g Facilitating epidemiological surveillance	x		x		x	x			
1.h Increase secondary use of data	x				x	x			
1.i Cross-border market			x				x	x	
2. Social impacts									
2.a Preventive strategies				x	x				
2.b Cross-border healthcare			x						
2.c Facilitate adoption AI	x				x		x		
2.d Promote remote (health) care				x					
2.e Reduce unnecessary tests				x					
2.f citizens' control their data	x								
3. Environmental impacts									
3.a Efficient use of data	x	x		x	x		x	x	x
3.b Efficient use of resources	x	x		x			x	x	x
4 Fundamental right impacts									
4.a Safeguards privacy						x			
4.b Security health data						x			
4.c Full compliance with data protection legislation									
5. Simplification impacts									
5.a Reduction fragmented and decentralised systems	x	x						x	x
5.b Reduction administrative burdon	x	x		x				x	

Appendix 5 – Extended validation feedback form by OpenEHR expert

EHDS requirements	**openEHR principles**								
	Open platform	Multi-level modelling	International governance	Active end-user engagement TB:I would rename this: active vendor/provider engagement	Open query language	Separation of Clinical and Demographic data	Process-related specifications	Open Modularity/ Service orientation	Separation of the user interface

1. Economic impacts									
1.a Legal framework									
1.b Governance framework			has strong governance for specifications; strong gov. for clinical models; limited gov. for software (ATM)						

1.c Data quality framework TB: needs a clear definition									
1.d Interoperability framework		x			x			x	
1.e Facilitate innovations		x							
1.f Improve monitoring									
1.g Facilitating epidemiological surveillance					potential				

1.h Increase secondary use of data					x				
1.i Cross-border market				x					
2. Social impacts									
2.a Preventive strategies							x		
2.b Cross-border healthcare			x	x					

2.c Facilitate adoption AI									
2.d Promote remote (health) care									
2.e Reduce unnecessary tests					x				
2.f citizens' control their data									
3. Environmental impacts									

3.a Efficient use of data					x			x	
3.b Efficient use of resources									
4 Fundamental right impacts									
4.a Safeguards privacy						x			
4.b Security health data						x			
4.c Full compliance with data						x			

protection legislation									
5. Simplification impacts									
5.a Reduction fragmented and decentralised systems	x	x			x		x		x
5.b Reduction administrative burden TB: needs clear definition									

1.a Legal framework

the answer completely depends on what this means in EHDS; if it means having governance (which is not actually a 'legal' thing), yes, there's a link; if it means that the technology has to have some inbuilt legal framework for clinical safety, or contract management, or quality control, or privacy (GDPR), then there isn't a direct support (since openEHR publishes no legal frameworks), but for GDPR, as you already know, there is pretty good support.

1.f Improve monitoring

really depends on what this means; if we say that openEHR leads to better health records (it does, generally) and that better health records enable better monitoring of patients (i.e. historical tracking of data, analysis of previous data etc) then, yes, openEHR helps monitoring.

2.c Promote remote healthcare

well there is no direct support in openEHR for remote healthcare in the sense of there being a tele-consultation or video call technology etc, but again, we can say that a *shared* health record helps remote healthcare, because it can accept data from remote devices and make that available to clinical users in other locations. But really, this depends on how the deployment of openEHR is done - it requires it to be deployed as a shared record, e.g. on regional servers or whatever, to realise this aim.

2.f Citizens' control their data

The intention is that openEHR records are citizen controlled, but in fact openEHR has not yet codified the technical way of doing this (which is primarly consent + access control + authentication) because the industry has not been able to agree on these things. However, this will happen - so it is 'near future'.

5.b Reduction of administrative burden

There is a general argument that a high quality, shared health record will do this, but I would think it needs to be shown exactly how, compared to other technologies: what admin work is reduced exactly?