tise transition, innovation and sustainability environments

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Exploring Key actors and their Interests in the Potential Enforcement of the European Health Data Space. the Austrian landscape

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ABSTRACT

This thesis explores the challenges and implications surrounding the establishment of a European Health Data Space (EHDS) within the context of the Austrian healthcare system. The research initially highlights the importance of data access for SMEs in the MedTech industry, as demonstrated through a transdisciplinary project. However, the issue of data access extends beyond SMEs and affects multiple stakeholders. In response, the concept of data spaces, particularly the creation of a European Health Data Space (EHDS), emerges as a potential solution to promote data-driven innovation and enhance the effective utilization of EU data resources. The secondary use of data allowed by the EHDS offers improved data access and real standardization, aligning with the principles of data sovereignty and supporting the digital agenda of the EU.

The research aims to understand the EHDS proposal and analyzes the key actors involved, with their interests, interactions, and potential roles in implementing the EHDS in Austria. With a literature and document review and the use of a causal loop diagram, the research provides valuable insights into the interdependencies among actors and their instances, facilitating effective coordination and communication. The findings from this research contribute to a comprehensive understanding of the EHDS and its potential impact in the healthcare sector and in its actors. This knowledge can inform decision-making and guide future implementation efforts not only in Austria but also in other countries facing similar challenges.

By addressing the complexities of stakeholder dynamics, this research seeks to contribute to the realization of a federated health system that promotes data-driven innovation while upholding privacy and data protection principles, the right of citizens and the values of the EU.

Keywords:

SMEs, Big Data, Data Analysis, Data Spaces, European Health Data Space (EHDS)

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1
INTRODUCTION

In 2014, the European Union (EU) initiated the Horizon 2020 program, which allocated a substantial budget of approximately 80 million euros to support research and innovation endeavours. The program's emphasis on funding projects related to data-driven innovation, big data, and data science underscores the significance accorded by governmental institutions to this path of innovation. More specifically, the EU sought to empower Small and Medium Enterprises (SMEs) to actively participate in the digital revolution and effectively capitalize on their data resources (*EU-Funded R&I Projects on Data | Shaping Europe's Digital Future*, n.d.; Mohamed & Weber, 2020). Consequently, the convergence of two key factors emerged: SMEs and big data (or data analysis in a broader sense).

Concerning Small and Medium Enterprises, the decision of the European Parliament to prioritize their participation in Horizon 2020 through dedicated instruments and budgets (Sen et al., 2016; Temel et al., 2016) stems from the crucial role played by SMEs in the European market. Often hailed as the backbone of Europe, SMEs constitute 99% of all businesses in the EU, contributing more than half of the total GDP and employing approximately 100 million individuals (*SMEs*, n.d.). However, the unique characteristics of these businesses, such as their small size and limited business volume, introduce both advantages and disadvantages that necessitate careful consideration for those seeking to transition their businesses towards a more technology-driven approach.

Moving to the second factor, big data and data analytics have emerged as critical pillars of success for organizations across various sectors (Song & Zhu, 2016). The proliferation of digital technologies, along with the exponential growth of data generation, has created unprecedented opportunities for businesses to extract valuable insights and make data-driven decisions (Iqbal et al., 2018). The use of big data allows organizations to reveal patterns, trends and correlations that were previously inaccessible. Sophisticated data analytics techniques facilitate the optimization of business operations, predict consumer behaviour, and identify new

market opportunities (Iqbal et al., 2018). Moreover, big data and data analytics play a crucial role in addressing complex societal challenges. All these aspects contributed to the metaphor of data as the notorious "new oil", that, as much as the original one, has to be refined, carefully handled and consciously used. Now, in 2023, the challenge of data is still one of the biggest ones that Europe has to face while respecting the laws and values of the EU of the present and of the future.

Given the immense potential of these capabilities, it is crucial for organizations, including small and medium enterprises (SMEs), to embrace and utilize big data analytics (BDA) in order to thrive in today's data-centric world (Falahat et al., 2023). However, SMEs face various challenges in effectively implementing the use of big data, both internally and externally within their organizations.

These challenges were thoroughly explored and ranked based on their significance during a transdisciplinary research project[1] with scientists and practitioners with expertise connected with Austrian SMEs Medical Technologies (MedTech) (Issaliyeva, K. et al., 2023). The Transdisciplinary (TD) research serves as a preparatory step to gather insights from Austrian MedTech SMEs regarding the importance they place on these factors within their community. The study highlighted that one of the major issues faced by these SMEs is data access. In particular, the aspect of *data access* was operationalized by the availability of extensive data lakes (systems or repositories of data stored in its natural/raw format) containing relevant training data. The interest is towards anonymized, cleaned, and/or aggregated cohort data that are continuously expanding and regularly updated. Importantly, these data lakes are easily accessible, allowing for convenient and cost-effective retrieval of the desired data (Issaliyeva, K. et al., 2023).

In fact, currently, EU medtech SMEs often rely on acquiring personal and non-personal data from US *data lakes*. However, this approach leads to treatments that are not specifically tailored to the European population, and it compromises data sovereignty by relying on non-European providers (European Digital SME Alliance, 2019; Issaliyeva, K. et al., 2023). In the absence of comprehensive repositories, both

[1] A project performed as part of the Transdisciplinary Field Research Training under the *TISE Program*. Authors: Issaliyeva Kamilya, Miozzo Chiara, Pham Ngan, Ruiz Diana, Schranz Franziska. Supervision: Liliya Satalkina, Roland Scholz, Christiane Ulbrich. Conducted from March to April 2023

governments and companies need to individually contact who they assume to be the data owners to gather the required data. However, the lack of common *standards* that all nations, and sometimes even regional entities, adhere to, creates additional challenges in interoperability and therefore on data exchange (*Interoperability Requirements*, n.d.; Pauer et al., 2018).

This thesis is trying to explore this complexity, introducing the concept of *data spaces*, particularly of the European Health Data space as a possible solution favoured by the European Commission, with its proposal of regulation.
Considering the significance given to data sovereignty by the EU itself and by the *European Digital SMEs Alliance* in their manifesto for Europe's digital future (European Digital SME Alliance, 2019), data spaces seem to be a very bright option for the future to address the lack of *data access* and inadequate *data standardization*. By starting with the concerns and requirements of the MedTech industry, this research will analyse the characteristics of what the EU Commission has presented as a regulation for the creation of a European Health Data Space (EHDS) (*Proposal for a Regulation on the European Health Data Space | Legislative Train Schedule*, 2022), which stems from the European Data Strategy[2] and health strategy (*European Data Strategy*, 2019).

This research aims to address the various challenges and implications arising from this proposal, particularly within the Austrian context. It is a problem that not only affects the MedTech field but also extends more generally to healthcare SMEs and relies in fact on a complex system, with multiple actors with different instances. As the perspectives and interests of SMEs often overlap with those of larger companies, governments, and civil society, focusing only on small and medium enterprises would not allow a deeper understanding of the different layers and their correlation. It is then essential to structure and examine the different issues associated with this proposal in order to gain a comprehensive understanding. It is particularly crucial to identify the relevant actors and their instances and potential roles in implementing the Health European Data Space in Austria. By pinpointing the focal challenges, these stakeholders can make informed decisions about where to direct their efforts

[2] that, in short, aims to make "the EU a leader in a data-driven society by creating a single market for data. This will benefit businesses, researchers and public administrations" (European Data Strategy, 2019)

effectively and identify decisive affairs which are not yet addressed. Furthermore, understanding the potential limitations or barriers specific to the Austrian landscape can provide valuable insights for other countries with similar characteristics, enabling them to navigate similar implementation challenges.

The research is going to define the issue of data access and its relevance, understood thanks to the preparatory Transdisciplinary research (*Chapter 3*). With the premises of what was discussed by Austrian MedTech SMEs and what was considered central for them and for similar companies, the research path is formulated to understand how implementing data spaces, and particularly the European Health Data Space, is a resolute approach to the challenge of data access, and how the problems and reasons that this arises are structured. The research question will be the following

Research Question:

> Who are the key actors, and what are their interests and their interactions in the potential enforcement of the European Health Data Space?

It is structured in two sub-questions:

.1 What is the European Health Data Space (EHDS), and how can it be a viable solution to address the healthcare challenges of data access? (*Chapter 4*)

> Understanding the fundamental concepts of data spaces, specifically the European Health Data Space (EHDS) proposal, is essential to answer the main research question. This involves examining the current state of data spaces, with a focus on the EHDS proposal and the progress made in establishing it, from a perspective which is not strictly related to the policy. The secondary use of electronic health data will be the center of the attention, since is the instument that will facilitate data access fostering research and innovation for all the actors involved.

.2 How does the potential enforcement of the European Health Data Space (EHDS) relate to the Austrian context, and what are the specific interests of the key actors involved? (*Chapter 5*)

This part focuses specifically on the Austrian landscape, aiming to map the interdependencies among the instances of the actors and examine how they influence each other. Successful implementation of this proposal necessitates effective coordination and communication across relevant sectors. In the Austrian ecosystem, there is a notable level of awareness, as evidenced by statements from industry insiders and the Chamber of Labour (AK ÖGB Europa, 2023). However, insiders also acknowledge the variety of perspectives that need to be addressed, which will be facilitated and explored through the use of a system model. The result will be a depiction of how the actors interact through their instances, within the national landscape.

2
RESEARCH DESIGN AND METHODOLOGY

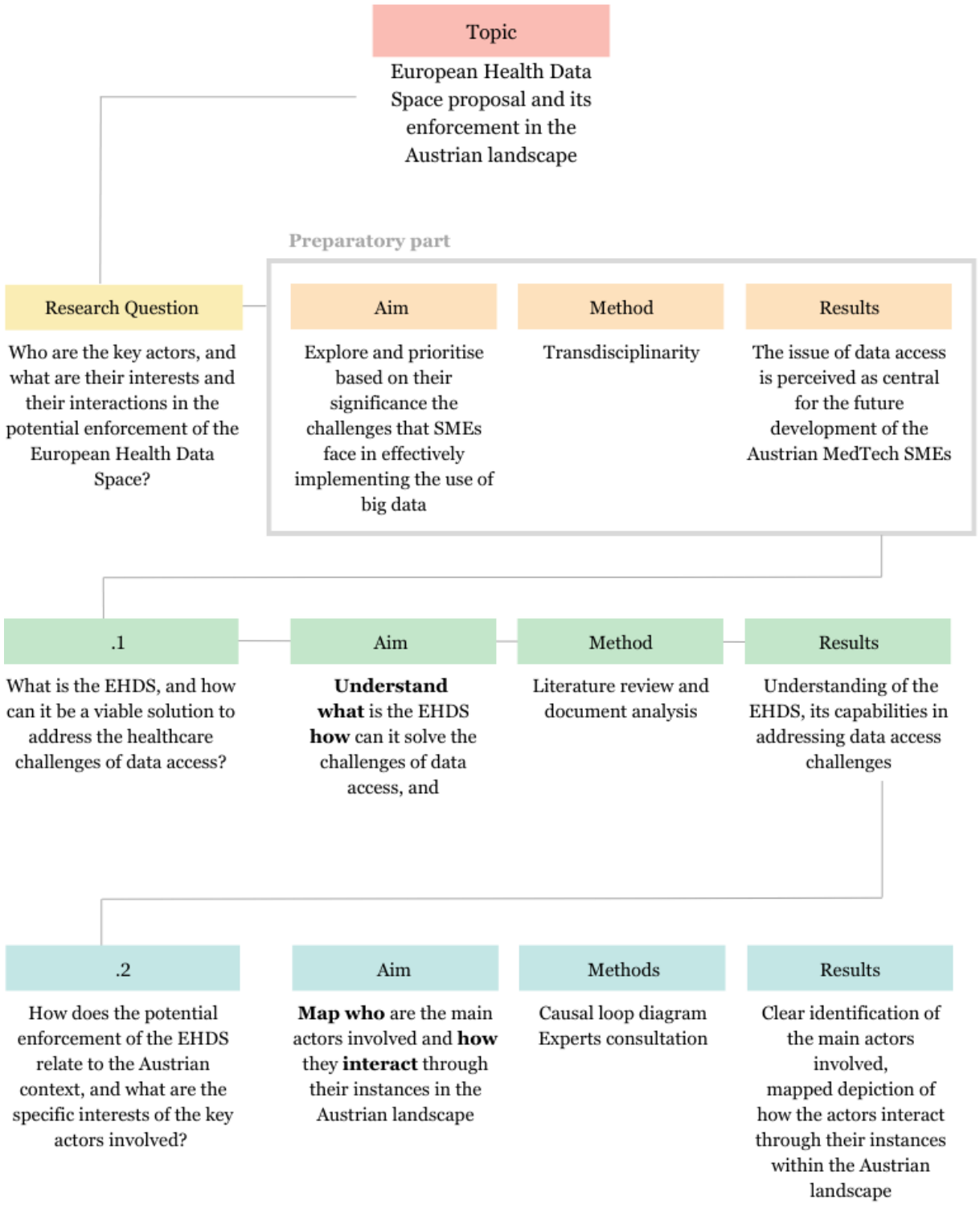

Figure 1: Research design

The methodologies throughout the thesis will be three, selected based on their suitability for answering the research question posed earlier:

1. analysis of the issues encountered by SMEs in effectively working with Big Data identified during the Transdisciplinary (TD) research merging literature review and experts' contribution (*Chapter 3*),
2. literature review and document review on the European Health Data Space (*Chapter 4*),
3. Causal Loop Diagram, incorporating in the process expert perspectives through targeted consultations (*Chapter 5*).

2.1 Transdisciplinarity

Firstly, analysing focal points allowed us to examine the current state of knowledge related to SMEs' ability to deal with Big Data and identify the main issue requiring further investigation: data access. This primary research project provides an excellent foundation upon which to build subsequent analyses, helping ensure that the conclusions are well-informed and evidence-based. It is based on a first-hand study as part of the Transdisciplinary Field Research Training on "The role of data analytics and big data for Austrian MedTech SMEs" (Issaliyeva, K. et al., 2023).

The approach of TD integrates different epistemics of science and practice in complex systems and is used to respond to continuous societal changes, crises, and transformations (Scholz & Steiner, 2015b). TD functions as a means for examining intricate contemporary issues in a joint and imaginative manner, while pinpointing the present situation and envisioning alternative prospects within a specified set of parameters. It aims to foster sustainable transformations by engaging stakeholders in conferences and preparatory work to allow knowledge integration. This approach allows for a better understanding of the multifaceted factors that influence scenarios, particularly in areas such as innovation trends (Scholz & Steiner, 2015a).

To apply transdisciplinarity in practice, two workshops were conducted, bringing together scientists and practitioners and discussing a problem formulated as a guiding question (GQ). The GQ itself was rephrased and discussed with consultations

to make sure it incorporated a relevant issue according to the experts, and after all the revision processes, it was:

> What specific factors are relevant for Austrian Medtech SMEs to effectively work with (Big) Data, to foster competitiveness in the EU Area over the next decade? (Issaliyeva, K. et al., 2023)

The transdisciplinary process structure is briefly presented as follows:

I. Building of guiding question:

1. Identifying relevant societal problems: Exploring potential factors for enhancing the competitiveness of SMEs in Austria.
2. Conducting secondary research: Information was gathered on the potential field of applications to establish system boundaries.
3. Defining system boundaries: The literature review guided the framing of the GQ, clustering relevant actors who needed to participate in the analysis and evaluation: Tech Industry, Medical Industry, and Medical Academia.

II. Stakeholder engagement:

1. Contacts database: Contacts were collected for each actor group from professional platforms and institutional websites. Existing contacts from the medical industry/academia were also approached.
2. Engaging stakeholders: Up to 15 stakeholders were selected and introduced to the research project via email, requesting
    - Feedback on the GQ: Requesting their feedback on the relevance and applicability within their areas of expertise.
    - Evaluation criteria: Preliminary evaluation criteria (proposal of key performance indicators) to measure the system

III. 1st Stakeholder Conference:

The first conference aimed to evaluate the validity of the GQ. Through a facilitated brainstorming technique, six experts discussed their feedback from the engagement emails, focusing on arguments within the defined system boundaries. The main outcomes of the conference included:

- Finalized guiding question
- Validated evaluation criteria and system description
- Construction of intuitive scenarios[3]

IV. 2nd Stakeholder Conference:

1. Definition of the impact factors: After describing evaluation criteria, discussing potential threat scenarios, and identifying impact factors, the second conference utilized brainstorming techniques to collect information from the six experts. The focus was on 10 impact factors, three threat variables, one development scenario, and three threat scenarios, in addition to the status quo scenario (Issaliyeva, K. et al., 2023).
2. Discussion of impact factors, status quo and development scenarios: Overall, the application of transdisciplinarity, as described in the outlined process, facilitated a comprehensive exploration of the research problem, engagement of relevant stakeholders, and the identification of potential impact factors and scenarios for further analysis.

Based on this transdisciplinary research, the primary goal of this thesis is to utilize both the key findings and the expert discussions to gain a comprehensive understanding of the core values, issues, and challenges faced by SMEs as stakeholders, particularly in the healthcare sector. This research will focus on factors identified by experts as essential for effectively working with Big Data, providing valuable insights for the study.

2.2 Literature review and document analysis

Secondly, conducting an extensive literature review brought from the issue of data access throw through the data sharing mechanism to arrive at data spaces and their potential applications in healthcare settings and especially in fostering access to data. The proposal of the EHDS analysed in this thesis is seem to be the most central for this industry, along with Data Space 4.0, which brings together initiatives for Industry 4.0 (*Manufacturing DataSpace CSA*, n.d.). The reason why EHDS was chosen instead of the latter mentioned is that this is a proposal at the primordial

[3] Worst and best-case scenarios that they could imagine for the development of the field toward the RQ

stage, brought forward mainly by industry and supported by the Digital Factory Alliance, but it still has no literature and no European proposal to back it up.

Through a careful evaluation of academic publications, documents and grey literature (Cooper et al., 2009; Pappas & Williams, 2011), the topic will be explored to understand its essential aspects. In particular, the review of academic literature will give an initial understanding of the existing scholarly knowledge on the topic up to the present date. The chosen platform to achieve this will be mainly the Web of Science (WoS) for its rigorous evaluation system. The document analysis of the proposal itself and of the relevant related documents of the European Commission will inform on the current state of the legal proposal (not sticking to the policy), the reasons considered by the commission in its creation and the data that are validating it. Since the proposal itself is still in the process of discussion, to grasp all the aspects of it and the relevant actors involved, the academic literature will be enriched by the position papers of various stakeholders, panels on the topic and similar documents. This process will allow an answer to the .1 RQ, and lay the foundations for understanding the relationships among them, with a focus on the Austrian context. Apart from the general analysis of the proposal, the actors and instances considered will preferably be taken from the Austrian context to better answer the .2 RQ. The standpoint EU-wise will be considered if there is not a specific representation in the Austrian landscape of that actor and its instances. The research for this thesis is conducted entirely in English, with specific actors' information being researched in German and relying on machine translations for comprehension. The insights provided by the experts contacted for the research are invaluable in gaining an internal perspective and enhancing the overall understanding of the phenomenon, particularly within the Austrian context as a case study.

2.3 Causal Loop Diagram

Thirdly, a Causal Loop Diagram (CLD) will be used to structure the complexity of this topic thanks to the information gained in the previous steps, concentrating particularly on the Austrian Landscape. The literature and document review is central for the construction of the CLD but additional input from subject matter experts through targeted consultations enhances the validity and reliability of the work.

Engaging professionals with practical experience in areas closely related to data spaces and healthcare systems increases the likelihood that the recommendations the actors and their instances reported will resonate with practitioners and decision-makers. A CLD allows system modelling, creating a graphical representation used to understand the *dynamics* and *interrelationships* within *complex systems* (Haraldsson, 2004). It illustrates the cause-and-effect relationships between various factors, allowing for the analysis of the system behaviour and the identification of feedback loops, whose utility will be discussed later.

Causal Loop Diagrams emphasize feedback mechanisms, providing a structured framework that outlines the interactions within complex systems. They offer both conciseness and comprehensiveness, allowing the creation of detailed yet expansive diagrams that capture the inherent dynamics and interdependencies within various configurations (Barbrook-Johnson & Penn, 2022). Given the complexity of the topic and the multiplicity of the actors confirmed by experts and literature (Iqbal et al., 2018), this appears to be a meaningful and yet not overcomplicated way to understand the correlations among the actor's instances. By integrating expert opinions and feedback into the final products, we aim to create actionable guidance that addresses the issues of the Austrian scenario.

The creation of the causal loop diagram will involve the following steps:

1. *System definition*: Defining the system under study. Identify the key actors and components that play a significant role in the system's dynamics of the Austrian framework, with a clear understanding of the boundaries and scope of the system being analysed.
2. *Identify Variables*: Identify the variables that are relevant to the system, which are the instances of the actors and the elements that have an influence on the system or are influenced by it.
3. *Determine Cause-and-Effect Relationships*: Analyze the relationships between the identified variables considering thanks to what emerges in the study. Determine how changes in one variable impact other variables in the system. These cause-effect relationships can be positive (reinforcing) or negative (balancing). Positive relationships indicate that an increase in one variable

leads to an increase in another, while negative relationships suggest that an increase in one variable leads to a decrease in another.

4. *Represent Variables and Relationship*s: Represent the identified variables as nodes in the CLD and label each node with the variable it represents. Connect the nodes with arrows to indicate the cause-and-effect relationships. Label each arrow to describe the nature of the relationship. The signs + and - on the arrows indicate positive and negative relationships, respectively.
5. *Identify Feedback Loop*s: Analyse the connections between variables to identify feedback loops, which occur when the output of a system feeds back into itself, influencing its own behaviour. They can be *reinforcing* (positive) or *balancing* (negative). Reinforcing feedback loops amplify changes within the system while balancing loops counteract and stabilize the system, therefore detecting them is central for the understanding of the system.
6. *Refine and Validate*: Review it to ensure that the relationships and connections accurately represent the dynamics of the system. Checking expert opinions, relevant literature, and discussions with stakeholders is central validate its accuracy.
7. *Analyze System Behavior*: Once the CLD is constructed and validated, it can be used to analyze the behaviour of the system. By simulating changes in variables and understanding how they propagate through causal relationships, insights into the system's behaviour can be gained, identify potential leverage points for intervention, and understand their potential consequences.

Causal loop diagrams depicting complex systems provide a powerful visual tool for understanding and analysing them. They allow for a holistic view of system dynamics, highlighting the interconnectedness and feedback mechanisms that shape system behaviour. By capturing the cause-and-effect relationships and feedback loops, CLDs enable to gain insights into system behaviour and make informed decisions for system improvement and intervention. Overall, this process aims to provide a proper answer to the main research question, of the key actors and interests, touching on its dynamic of power. By using the literature review and the causal loop diagrams technique, this research can gain a deeper understanding of the enforcement of the

EHDS in the context of the country. Given the high number of variables considered the causal loop diagram will have a low level of detail (Haraldsson, 2004, p.17)

3
TRANSDISCIPLINARITY APPROACH FOR PROBLEM IDENTIFICATION

As anticipated in the methodology section, the transdisciplinary (TD) process serves as a collaborative approach that seeks to integrate the knowledge of science and of practice to collectively comprehend complex systems and exchange insights and visions with the aim of achieving sustainable transformations (Scholz & Steiner, 2015b). Essentially, the process tries to structure complex problems, with the help of the expertise of professionals in that area. By initiating the process with an in-depth understanding of the problem at hand and conducting a comprehensive assessment of the current state of knowledge, the TD process, facilitated by individuals knowledgeable in the subject, enables the identification of the key issues while also fostering the exploration of alternative solutions (Scholz & Steiner, 2015a). The ultimate goal of this collaborative tool is to develop a socially robust orientation that can be used by all the actors in the field to take more informed decisions.

A brief introduction to the issue analysed, and privileged access to the transcript of the stakeholder conferences allowed the understanding of the state of the art regarding the issues encountered by Austrian SMEs in the field of Medical Technologies and facilitate the precise identification of the problem at hand. This chapter will connect what emerged in the literature with what emerged in the TD process, with some peculiarities due to the field in which they are rooted. Additionally, apart from offering foresight, a broader examination of the interconnections perceived by industry professionals among various issues enhanced the comprehension of their hopes and fears for the future of the field. Consequently, a clearer understanding of the challenges specific to SME stakeholders in the Austrian context will be obtained, setting the stage for the subsequent chapters of this dissertation. In the subsequent chapters of the research, the scope will expand beyond MedTech SMEs to encompass the broader *healthcare* sector, with includes MedTech, eHealth, and other related subfields. The input from experts suggests that the challenges faced by healthcare SMEs regarding data access share enough similarities to be generalised.

3.1 The Background of the transdisciplinary research

3.1.1 Aim of the research

In the introduction, it has been mentioned that Small and medium-sized enterprises, SMEs[4], represent the backbone of Europe, consisting of almost the total number of enterprises (99%). Narrowing down to the country focus of this research, Small and Medium Enterprises constitute almost 99.6% of all national companies in 2021, with an added value of 116.9 billion euros, a 56.2% share percentage (European Commission, 2022; 'SME DATA', n.d.). Furthermore, SMEs employ the majority of Austrian workers, 64.5% (European Commission, 2022; 'SME DATA', n.d.).
However, in relation to digital technologies, Austrian SMEs are overall less advanced than the European average, using Big Data comparatively less than their European counterparts, 8% compared to 14% of SMEs EU-wide (*KMU Im Fokus 2021*, 2022). Nevertheless, the level of digital intensity of this kind of business in the county is 60%, slightly above the EU average and the country is ranked in the 11th position on integration of digital technologies (European Commission, 2022).

For the TD research, it was chosen to work on the SMEs in the field of *medical technologies (Medtech)*, described by Statista as hospital technology and medical equipment, such as computer tomographs, dialysis machines and pacemakers (Statista, 2022b). More specifically, they are products, services or solutions that help with prevention, diagnosis or cure, attributable to three main categories (MedTech Europe, 2022):
• Medical devices (MDs), the pivot of this research
• In vitro diagnostics (IVDs)
• Digital health, using information and communication technologies (ICTs)
To give some numbers, in 2020 the Austrian Medical Technology Sector recorded 577 registered Businesses (Statista, 2022b) and a revenue of 9 Billion Euros (Statista, 2022a). Austria, due to its high demand, relies on imports for half of its medical technology products, with Germany being a prominent source (Bundesministerium

[4] Defined as employing less than 250 people, and, with an annual turnover of up to EUR 50 million or a balance sheet total of no more than EUR 43 million (Small and Medium-Sized Enterprises (SMEs) - Structural Business Statistics - Eurostat, n.d.). The European Union put in place different policies for assure fair completion among these enterprises and between them and the large ones

für Wirtschaft und Klimaschutz, o. J.). Notably, Germany is home to several large technology companies by revenue such as Siemens Helthineers, Fresenius Medical Care, Roche Diagnostics and B. Braun (Gilbert, 2021). The Austrian landscape is characterised by big players too, such as MED-EL Medical Electronics, Ottobock and GE Healthcare (*The Big Players- LISA*, n.d.). These players are surrounded by a universe of SMEs since 90% of the medical devices companies are in fact SMEs working in different technological fields (Auer & Jarmai, 2018; aws Life Science Austria, 2021).

Focusing on these businesses and their approach to big data analysis is particularly interesting for two reasons: the potential positive impact on healthcare resulting from the advancements in the Medtech sector, and the adaptability of companies of this size. Medtechs are already familiar with the technology which is a great part of their development but, at the same time, they have to deal with medical data, *personal* and *non-personal*, which are difficult to be treated due to privacy protection rules. Big data can and have a significant impact on the medical technology industry: they have the potential to remarkably improve the quality of patient care, optimise operations and accelerate research and innovations (Iqbal et al., 2018; Issaliyeva, K. et al., 2023). Secondly, "due to their ability to quickly adapt to changing contexts and high levels of internal flexibility, SMEs are considered a driving force of innovation", having a more agile approach to changes compared to big enterprises (Auer & Jarmai, 2018). The last was also confirmed by the participant in the research.

In parallel with these positive aspects, these advancements have also given rise to concerns regarding data privacy, transparency, and the fight against potential monopolistic practices of large technology companies. Existing data regulations, such as the EU's General Data Protection Regulation (GDPR)[5] and its counterpart, the Austrian Datenschutz-Anpassungsgesetz[6], offer some guidance, but they exhibit certain limitations when it comes to addressing the intricacies of technology and market regulation. Moreover, the peculiarities that make SMEs flexible, have a downside in the low possibilities of allocating resources, especially specialised, to this transition, and in general on the low monetary power and the high number of

[5] https://gdpr-info.eu/
[6] https://www.parlament.gv.at/gegenstand/XXVI/I/68

constraints of the small and medium enterprises such as the difficulties in exercising a cohesive and decisive lobbying power.

The objective of this study was to identify key factors that are pertinent to Austrian Medtech SMEs in effectively utilizing (Big) Data to enhance their competitiveness within the European Union in the next 10 years. The research was driven by the recognition that although small and medium enterprises are crucial for the Austrian economy, the MedTech SMEs encounter obstacles in harnessing the potential of big data as mentioned earlier. Shedding light on the impact of big data accessibility on Austrian SMEs operating in the MedTech sector the study explored how they can leverage big data to make better-informed business decisions.

3.1.2 Theoretical background

As beforehand mentioned, in today's world, data production is increasing exponentially and so is the use (or the attempt to use) by companies (European Commission, 2020). While data is manageable by humans and machines under a certain quantity, once the size becomes enormous the problems begin. The term big data (BD) is frequently used to refer to a generally wide amount of data but, this study confirms it, sometimes not even companies, especially if they are small, are aware of the data that they produce, collect, store or elaborate, can be considered big data (Iqbal et al., 2018). Moreover, data can come from past performances of the company or even external data, acquired in different forms by companies (Sen et al., 2016). As a general definition, we refer to BD in the presence of a "massive volume of both structured and unstructured data" (Iqbal et al., 2018). More precisely, BD is usually defined as characterised by 3V: Volume, Variety and Velocity, and these features can become 5 summing low Veracity and high Value (Shah et al., 2017; Mattera, 2018). In many cases the first approach to data analysis of SMEs is via the use of software that automatically analyses their data such as enterprise resource planning (ERP), customer relationship management (CRM), supply chain management (SCM), or cloud-related technologies that can be used on-demand, allowing scalability and pay per use/capacity (OECD, 2019, pp.10-22). However, in many cases, these softwares are either not sufficiently useful or have a long learning curve (Iqbal et al., 2018).

Big data, data science and data analysis would play a big role in fostering the competitiveness of SMEs. To understand the high value of data-based decision making we have to consider that companies are used to making decisions based on *anecdotal evidence*, considering their intuition, experience and feelings or based on *empirical evidence*, through quantifiable and measurable information or events (Kessler, 2019). Data analysis provides objective and high-quantity data-driven decisions and, consequently, optimises products and processes (Kessler, 2019; Rautenbach et al., 2022). Certainly, it has to be kept in mind that companies utilizing big data must have a clear understanding of their objectives, recognizing that big data is merely a tool to be incorporated into a broader strategy (Rautenbach et al., 2022).

Overall, OECD considers the five channels of the impact of data analytics and data-driven decision on companies (OECD, 2019):

1. *data-driven R&D*: "enhancing research and development"
2. *data products and data-intensive products*: "developing new goods and services by using data either as a product or as a major input" which can help a major understanding of clients and the market, and a better selling point (Rautenbach et al., 2022)
3. *data-driven processes*: "optimising production or delivery processes" with demanding forecasting and predictive inventory planning (Sen et al., 2016)
4. *data-driven marketing*: "improving marketing through targeted advertisement"
5. *data-driven organisation*: "developing new organisational and management approaches or significantly improving existing practices", help in workload reduction and more broadly decision-making (Rautenbach et al., 2022).

But not all the sectors are equally impacted, since some have higher data intensity[7] such as the one of discrete manufacturing, that can comprehend Medtech machinery (OECD, 2019). More precisely, following this flow of data and how it has to be heald, at the initial stage of product design, MedTech SMEs gather requirements and establish product specifications based on customer input. Subsequently, the R&D team develops the product, and the data generated during this phase is securely stored. Once the product is released, data is collected from the devices and analyzed

[7] it is defined by the "average amount of data per organisation" (Data Analytics in SMEs, 2019)

to enhance its quality. Utilizing big data analytics, the data is processed, and predictive algorithms are optimized to deliver accurate and timely medical diagnoses. Good data analysis allows predictive maintenance, that allows both provider and client to save time and money from unexpected breaks, ensuring service continuity, especially in a sensitive field such as healthcare (Sen et al., 2016).

Throughout the product development process, MedTech SMEs must adhere to data privacy regulations imposed by external entities such as the EU MDR (Medical Device Regulation) and medical technology regulatory agencies. Additionally, they prioritize meeting the needs and expectations of their clients/patients, ensuring data security and delivering high-quality services. Consequently, the flow of data across different stages begins with customer information input, followed by product development, data storage, analysis, and processing. The processed data is then employed to enhance product and service quality, offering predictive analytics, personalized medicine, operational efficiency, and clinical decision support.

To summarize, MedTech SMEs that harness big data operate within a systemic framework influenced by various external entities, including regulatory bodies overseeing data privacy (both domestically and internationally), medical regulatory agencies, and clients/patients. The boundaries of this system define the types of data, company characteristics, timeframes, locations, and applications that dictate the flow of data through different stages. This flow enables SMEs to design and develop products (and related services) that meet the needs of clients, comply with regulations, and deliver high-quality services.

While the utilization of big data can offer numerous benefits to SMEs, it is evident that a significant number of businesses struggle to keep up with the digital transition. Financial and human resource limitations emerge as the primary obstacles for small and medium-sized enterprises. In addition, according to a 2019 report by the OECD, other challenges related to privacy concerns, digital security, and restricted access to data arise from the rapid technological changes (OECD, 2019).

Getting into the fundamental difficulties encountered by generic SMEs[8], an extensive and recent literature review highlights the barriers to data science implementation in SMEs from so-called developed countries, which can be condensed into five core issues (Rautenbach et al., 2022; Falahat et al., 2023). From the least to the most mentioned in this paper:

1. *Regulatory challenges and difficulties complying with policies due to their size*: the lack of knowledge in SMEs is an issue for their compliance with the regulation. Moreover, the increasing use of software and clouds exposes them to privacy and security concerns;
2. *Economic challenges due to lack of capital*: seen as the first obstacle to the use of data science, often just indirectly mentioned in papers, probably for its obviousness and the impact that it has on the quantity and quality of the resources obtainable. This issue trickles down to the necessity to have "cross-functional experts" to employ them in more areas, which translates into either more expensive or less specialised workers (Iqbal et al., 2018);
3. *Technical challenges, including the shortage of specialized workers*: concerning the data acquisition storage and analysis. The implementation of algorithms and their supervision interests SMEs. Their limited knowledge of cybersecurity makes them feel and be more prone to cyber-attacks.
4. *Organisational challenges*: considered very central in the literature, is based on the idea that, contrary to the common manager's behaviour, data science would require a permanent transformation of the company structure, rather than a project limited in time, to avoid discontinuity and fail to meet an adequate ROI. This point is critical since it also involves human-related transformations and the resistances at every level
5. *Lack of skills*: presented as the barrier most frequently met, is, in fact, present in the vast majority of the publication related to the field. It seems to be a transversal problem between developing and developed countries since the data literacy shortage is global. However, the developed countries' shortage mostly concerns specialised positions related to AI.

[8] without a specific focus on Austrian Medtech, since it is the Transdisciplinary research that focuses on that with first-hand consideration

3.2 Transdisciplinary project results

Based on the aforementioned topic issue, research questions, and research boundaries, two stakeholder conferences were held. Concentrating on the issues that rose, at the end of the *first conference* it was asked to build an intuitive scenario of the worst and best case for the future of the use of big data and data analytics by Austrian MedTech SMEs. This procedure was made to unlock the imagination of the participants on the future possibilities of the field and, at the same time, understand what could be considered the key aspects according to their study and experience.

These inputs were afterwards clustered in topics by the facilitators, according to the connections among them appearing both in the literature and in the conference debate. At that moment data accessibility has just two inputs, on the fact that the situation as it is in this regard is already the worst-case scenario and making easier the way to access the data. Connected to this problem it was reported the issue of monopolies, which seemed to the participants the only one with the right to centralise data.

At the beginning of the second conference, it was asked the parties to agree on the ten topics clustered from their input and choose three topics they would have preferred to discuss, with a subsequent discussion on what they rephrased as:
1. Research, innovation grants and institutions
2. European legislation on licensing and certification processes
3. Data accessibility

All the points were somehow related to innovation and the perceived obstacles to it. They appear to be related but slightly different from what emerged in the literature, due to the specificity of the field and of the European and Austrian landscape. The grants and partnerships with institutions (1) create problems when companies need big investments for bigger developments. The second (2) obliges the companies to fulfil requirements that sometimes are critically too expensive, as for instance the "demand for randomised trials to prove the effectiveness (clinical effectiveness) of products can require 15-20 million euros, an unsustainable cost for most SMEs" (Issaliyeva, K. et al., 2023) and without providing sufficient knowledge or support. The last one (3) seemed especially concerning for MedTech SMEs as they recognize

its significant connection to excessive regulations and the centrality of data access to drive innovation, associated with a proper dose of data standardisation and interoperability.

As emerged in the discussion, hospitals are generally hesitant to share any data with research teams due to GDPR regulations, and, even within the public sector, the absence of a unified database is prevalent. It also emerged from further comments, that sometimes the GDPR would not legally forbid certain kinds of data sharing, but that those who should give the final permission are rather hesitant and prefer to be safe than sorry. This can be dependent on reasons such as insufficient up-to-date knowledge, which would explain why the same project receives refusal from the different regional offices of the same country referring to different motivations.
Consequently, data collectors hold significant discretion in terms of data processing, and a lack of data standardization persists.

When it comes to data access, the economic dimensions of *excludability* and *rivalry* play a major role, in the status quo which the actors in the conference predominantly seek to maintain. This means that there is limited power to compel large data providers to share raw data, and open access is often not a viable option. Additionally, the challenges associated with data usage are closely linked to the concept of data libraries, which currently do not exist at the Austrian or European level. While stakeholders primarily focused on discussing the problems faced in the field, there was an effort to explore potential intervention strategies to address potential threats. The only common agreement of a possible betterment of the field envisions a situation in which "data registries that are reliable, publicly available, and affordable for small and medium enterprises" (Issaliyeva, K. et al., 2023)

According to the stakeholders, addressing data accessibility requires a discussion on *data ownership*. It is important to determine whether data collectors should be the sole beneficiaries of the data they collect[9] or if customers should have the ability to decide who can access their collected data. This approach would foster competition and innovation. The stakeholders considered the German Deutsches Krebsregister[10]

[9] as at the moment is happening with big providers like Siemens
[10] a cancer register that allows studies on pseudonymized population data (Abele et al., 2022)

as a possible model in this regard. However, the need for increased trust in the system requires introducing transparency, secure use of data and anonymisation. Public campaigns, tailored to specific target audiences and desired outcomes, can effectively raise awareness about the benefits of data and the value of sharing anonymized data for the greater public good.

Moreover, policymakers and other stakeholders need to collaborate in defining certifications that meet expectations but are executable. This requires policymakers to work hand-in-hand with industry experts to bridge gaps in the system and streamline bureaucratic processes, making the certification process more efficient. Additionally, there is a need for well-informed experts to audit these rules. Currently, the Chamber of Commerce appears to be the most suitable entity for addressing this issue, but negotiations at the European level require compromises.

Furthermore, clear incentives should be provided to companies to encourage data sharing, a solution to slightly compensate companies that are data collectors for the partial loss of their competitive advantage. Standardization is another essential requirement in this direction, and the IHE consortium[11] serves as a good example of an approach to standardization. Experts often find that top-down approaches to standardization, as well as other aspects discussed, frequently fall short because legislators often lack industry knowledge. Therefore, involving industry actors in the process is crucial.

In general, experts acknowledged the need for a white paper that outlines the state-of-the-art and potential developments in the field. However, as in many other discussions, personal and professional perceptions of the experts, such as preferences for centralization or decentralization, are deeply embedded in the reported concepts and desired solutions.

3.3 Outlook for research direction

The inputs shared during the discussion sparked curiosity about the resolution of the prominent issue at hand: data access. SMEs were hoping and proposing as a solution the implementation in the EU of nationals or even European data lakes, inspired by

[11] https://www.ihe-austria.at/

the data lakes found in the USA, which serve as significant sources of data for the MedTech industry. Moreover, even though data partnerships, data sharing, and in general collaborative mechanisms seemed to be very promising and already used solutions, there is no significant literature regarding that (see 3.1).

A closer examination was conducted to gain a better understanding of how the European Data Strategy (*European Data Strategy*, 2019) was addressing and aiming to solve issues like data access. Accessing data for research purposes is in fact not just an issue for SMEs but also of bigger enterprises and even for governments and public bodies. This inquiry led to the identification of the concept of *data spaces*, which is strongly advocated by the European Union. The EU plans to establish several European data spaces in the upcoming years, one for each specific field. For a general understanding, data spaces serve as environments where data specific to a particular domain can be easily shared. Given the significant generation of data within the Union, the Commission aims to harmonize and facilitate the use of this data by connecting national data flows, with the ultimate goal of creating a revolutionary system similar to the Single European Market of 1993. This envisioned system would be a common market for data from both the private and public sectors. Achieving this solution requires both a policy strategy and technical implementation. While the initial focus is on creating data spaces with homogeneous types of data (e.g., energy data within the energy domain, public administration data within the public administration domain), the long-term objective is to establish a (single) European Data Space. This would enable data sharing across different domains, as many potential use cases for data inherently involve interdomain interactions (Publications Office of the European Union, 2023).

The initial step in this trajectory involves the establishment of a European Health Data Space, which is currently the only data space in this series that has a concrete proposal backing it. This proposal offers an ideal opportunity to assess its applicability in addressing the pressing issue of data accessibility, especially considering that it operates within the same domain, the health one.

A detailed exploration of data spaces will be undertaken, encompassing their fundamental principles, the current state of the field, and the latest advancements in

existing data spaces. This exploration will prepare the way for a focused analysis of the European Health Data Space (EHDS), examining its characteristics and its potential as a viable solution to address data access issues in the healthcare domain. Lastly, in order to gain further insights into how the EHDS project can be integrated within the Austrian context, stakeholders will be identified and their perspectives analysed, connecting them in a Causal Loop Diagram to better map the system and understand the focal points to be considered when implementing the EHDS.

4
THE EUROPEAN HEALTH DATA SPACE

4.1 Data spaces and the European data space(s)

A commonly used metaphor, which provides a gentle approach to this topic, compares data lakes to fishing ponds and data spaces to fish markets. Both structures enable the collection and subsequent use of fish (representing data), but they differ in certain aspects (Publications Office of the European Union, 2023). The data, fish in this metaphor, has to be fished in a lake but is in fact well organised in the fish market. In fact, while accessing a data lake gives access to all the data contained in it, in a data space data holders[12] control who has access to their data, with which purpose and under which conditions (Publications Office of the European Union, 2023).

To be more specific, according to the definition of the Data Space Support Centre (DSSC), data spaces are

> "[a]n infrastructure that enables data transactions between different data ecosystem parties based on the governance framework of that data space. Data space should be generic enough to support the implementation of multiple use cases" (*DSSC Glossary*, 2023)

According to the same document, data ecosystem parties are individuals or organizations involved in a data ecosystem. A data ecosystem consists of independent parties that collaborate to provide data access to others, following specific technical, financial, legal, or organizational requirements. The term encompasses a wide range of practices related to sharing various types of data, including both open-data and non-open-data sharing methods (DSSC Glossary, 2023). At this stage, the significance of data spaces in addressing data access challenges becomes evident.

[12] a *data holder* is defined in the proposal for a European Data Governance, as "a legal person or data subject who, in accordance with applicable Union or national law, has the right to grant access to or to share certain personal or non-personal data under its control" (*Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on European Data Governance (Data Governance Act)*, 2022). However, this definition is often considered too vague by the stakeholders.

There are five central aspects to consider in the creation of data spaces, according to the kit made by the Data Spaces Support Centre, which follow the BLOFT framework: business, legal, operational, functional, and technical (*Starter Kit for Data Space Designers*, 2023). Given the importance of facilitating efficient and trustworthy data sharing among participants, it is essential to look closer into the aspect of *functionality*.

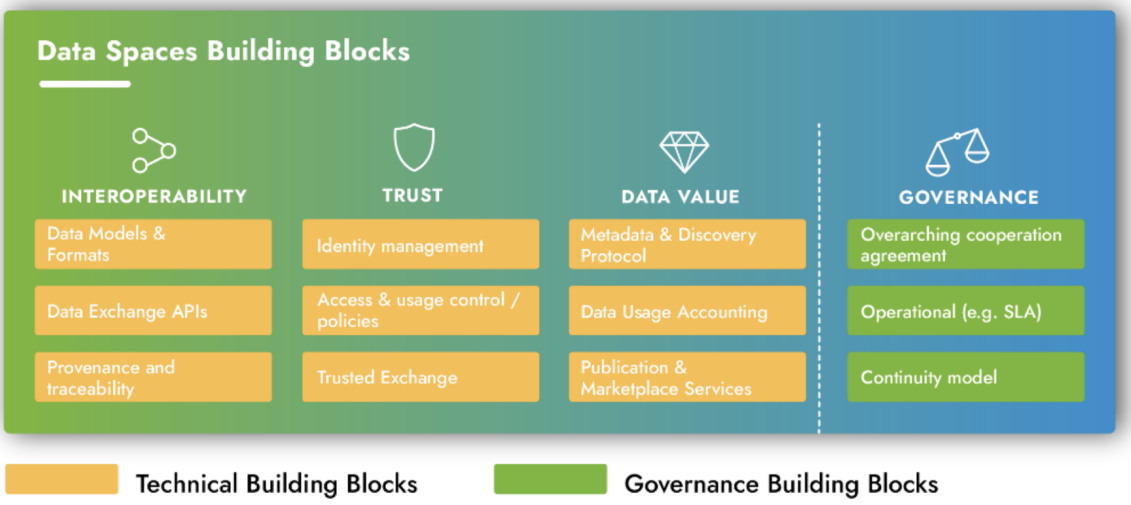

Figure 2: Building blocks (*Starter Kit for Data Space Designers*, 2023)

These building blocks, along with the needed guidelines and architectures, form the foundation of the Data Sharing and Governance (DSSC) blueprint. The data spaces technological foundation encompasses, apart from the governance one, three major pillars (Starter Kit for Data Space Designers, 2023):

1. *Interoperability*: to establish a robust framework for seamless data exchange among participants. This ensures that data services are Findable, Accessible, Interoperable, and Reusable (*FAIR*)(*FAIR Principles*, n.d.). Interoperability between domain-specific data spaces is crucial for two reasons. Firstly, it reduces integration and adaptation costs while providing users with more value. Secondly, prevents fragmentation in the data economy to maximize value. This requires the adoption of interoperable APIs, compatible data models, and mechanisms for tracking data exchange transactions and origin.
2. *Trust*: incorporating technical mechanisms that establish trust among participants and enable them to maintain control over the data they share

through user-controlled consent. This requires the adoption of interoperable standards for managing participant identities, verifying trustworthiness, and enforcing agreed-upon policies for data access and usage control.

3. *Data value*: opportunities should be provided for participants to derive value from data sharing, going beyond FAIRness and delving into data quality and the creation of data value chains. This often involves the inclusion of multi-sided markets within data spaces, where participants engage in trading, buying, and selling data services as part of their business models. To facilitate this, interoperable mechanisms are needed to describe terms and conditions, including pricing, associated with data service offerings. Furthermore, the publication and discovery of these offerings and the provision of data value chains are integral components.

A more concise definition of data spaces is the one offered by Open DEI of

> "a decentralised infrastructure for trustworthy data sharing and exchange in data ecosystems, based on commonly agreed principles" (Nagel & Lycklama, 2021)

Decentralisation plays a crucial role in data spaces, as they are designed to operate without depending on a centralised database schema or physical data integration. Instead, utilising distributed stores allows a more flexible and scalable approach to data sharing, permitting data to remain stored at its original sources (Otto, 2022). Unlike traditional one-to-one or group-sharing mechanisms, the data space serves as a framework within which data is shared. This distributed model offers several advantages, such as scalability and resilience against single points of failure. At the same time, the framework provides the necessary infrastructure and protocols for secure and efficient data sharing within a trusted environment (Nagel & Lycklama, 2021).

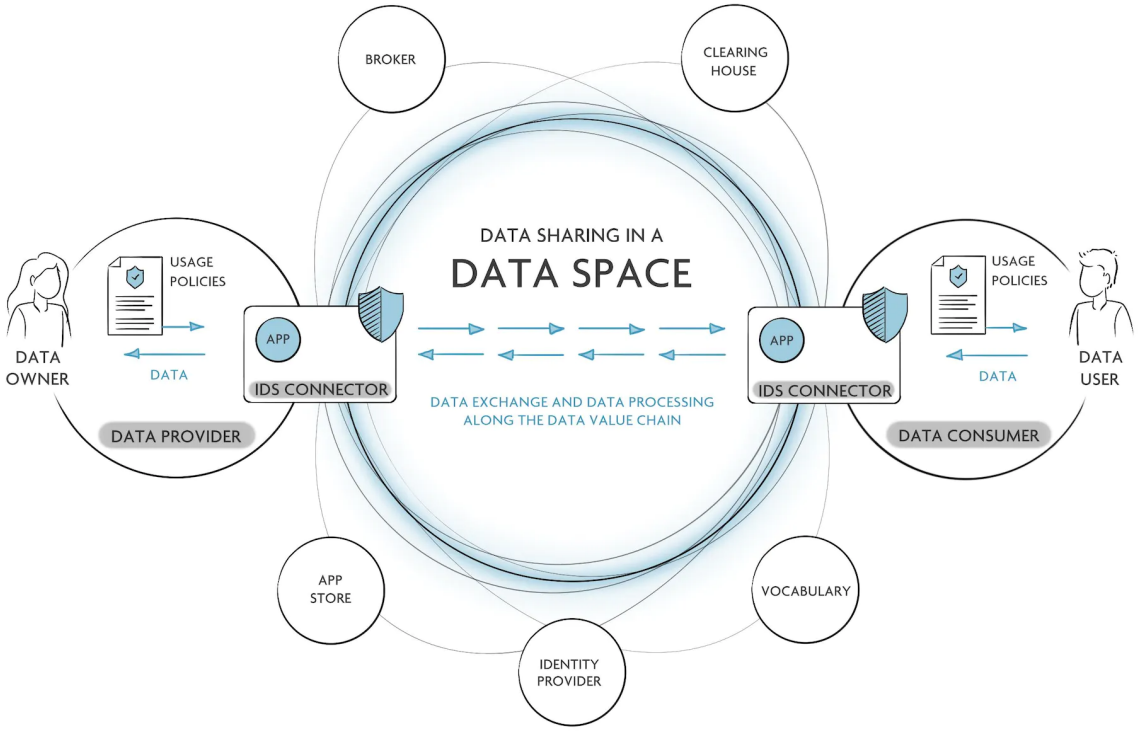

Figure 3: What is a data space (*Wat zijn data spaces?*, 2023)

Nevertheless, in order to fulfil the essential prerequisites of data spaces regarding participant trust, data security, and interoperability, the involvement of intermediary services becomes necessary. The federation, therefore, assumes the responsibility of providing these intermediary services, which encompass tasks such as cataloguing and brokering data sources, establishing trust between participants, and offering data sovereignty services. It mediates the roles of the data provider and data consumer (Otto, 2022).

This safeguard ensures that data can be accessed and exchanged among participants easily and without compromising data ownership or control. Data spaces are the sum of the data infrastructure and the governance framework (Publications Office of the European Union, 2023). In fact, participants in a data space can define their own data governance rules, specifying who has access to what data and under what conditions, complying with the policy framework decided for the data space. The ability of individuals or organizations to have complete autonomy and control over their economic data assets is *data sovereignty*. Within data spaces, participants

experience data sovereignty in two key aspects: firstly, being able to view, process, manage, and secure their data, and secondly, retaining full control over their data when granting access to other parties (Nagel & Lycklama, 2021).

Nonetheless, part of data sovereignty is to understand when the data is physically located[13] (Hummel et al., 2021) and that is why Europe's strategy for achieving digital sovereignty revolves around two primary pillars: cloud sovereignty and data sovereignty. The first pillar focuses on cloud sovereignty, aiming to establish cloud services that align with European regulations. The resolution to establish a sovereign cloud infrastructure relies on the integration of European cloud services through the GAIA-X association. The second aspect centres around data sovereignty, aiming to facilitate secure data sharing among consortium participants, with the International Data Spaces Association's reference architecture model forming the basis for this endeavour, and in general with the creation of data space (Braud et al., 2021).

By providing a robust and scalable solution the European Union (EU) has strategically embraced data spaces as a central measure to establish data sovereignty. The EU's decision to prioritize data spaces stems from its recognition of the need to ensure data sovereignty, not only at the individual party level but also for the Union as a whole, currently in an uneven competition on data with the US and China. The creation of different European data spaces has the ultimate goal of interconnecting all the data spaces and setting among them similar rules and criteria to support interoperability. This mission is followed by the Data Spaces Support Centre (DSCC.eu). Generally, this would allow the creation of more synergies and improve the economy of scale at the European level. In order to achieve that, the intermediary steps needed are the establishing sector-specific data spaces, since every sector has unique characteristics in terms of data types, data flows, business models, and stakeholders instances. These data spaces serve to introduce participants to the rules of data spaces and to agree upon common international data standards for that specific domain (Publications Office of the European Union, 2023). The European Commission individuates the following as the needed features of a common:

[13] since it can affect the actual enforcement of law and data protection. The US government, for instance, could access the data of EU citizens if stored in US territory or by US companies (Murphy, 2022)

- "A secure and privacy-preserving IT infrastructure to pool, access, process, use and share data.
- A data governance mechanism, comprising a set of rules of legislative, administrative and contractual nature that determine the rights to access, process, use and share data in a trustful and transparent manner (policies and rules).
- Data holders are in control of who can have access to their data, for which purpose and under which conditions it can be used.
- Presence of vast amounts of data that can be reused under certain conditions against remuneration or for free, depending on the data holder's decision.
- Participation by an open number of organisations/individuals."
  (Staff Working Document on Data Spaces | Shaping Europe's Digital Future, 2022)

This vision aims to overcome legal and technical barriers to data sharing by combining the necessary tools, and infrastructures, and addressing trust-related issues through common rules.

More specifically data spaces are central to the European Data Strategy, which was adopted in February 2020 with the objective of establishing an internal data market adhering to EU values and rules. The realization of this vision relies on a legislative framework comprising three bills.

- Data Governance Act (in force from July 2022)
- Data Act (proposal made in February 2022)
- Implementation Act on High-value datasets (Open Data Directive) (draft May 2022)

According to the European strategy for data, the data spaces will encompass three main elements (*Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on European Data Governance (Data Governance Act)*, 2022):

1. Formation of data sharing tools and services that enable organizations to pool, process, and share data. This includes the federation of energy-efficient and trustworthy cloud capacities and related services.

2. Implementation of data governance structures compatible with relevant EU legislation. These structures ensure transparent and fair determination of rights regarding access to and processing of the data.
3. Improvement of data availability, quality, and interoperability. This applies to both domain-specific settings and cross-sector scenarios.

Similarly to the enforcement of the GDPR and the organs to safeguard it, such as the EDPR (European Data Protection Board) and the EDPS (European Data Protection Supervisor), the enforcement of European data spaces will require some common actors (Publications Office of the European Union, 2023):

- Data Spaces Support Centre (DSSC), aforementioned
    - Coordinates actions for sectoral data spaces in Europe, including blueprints, best practices, standards, support, and knowledge transfer.
    - "funded by the DIGITAL Europe Programme" (Publications Office of the European Union, 2023)
- Data Space Coordination and Support Actions (CSAs), which not working yet but probably is going to be in place from September 2023
    - "for sectoral/domain-specific data spaces
    - community of practice, priority datasets, stakeholder engagement, governance/business models, roadmap
    - funded by the DIGITAL Europe Programme" (Publications Office of the European Union, 2023)
- European Data Innovation Board (EDIB), which is going to be created by the Data Governance Act and will contain people from SMEs
    - "Consultative and advisory body established by the Data Governance Act, to be set up in September 2023 guidelines for interoperability of common European data spaces
    - guidelines for interoperability of common European data spaces" (Publications Office of the European Union, 2023)

To sum up, data spaces provide benefits such as enhanced data access, increased data standardization, facilitated collaboration, data sovereignty and control, scalability and flexibility, improved data governance and compliance, and accelerated

data-driven insights. For these reasons they are considered a very valutabe for public and private organisations, and can particularly be considered a viable seolution to address the challenges of data access. Indeed, these advantages empower organizations to efficiently utilize data, foster collaboration, ensure privacy and security, adapt to changing needs, and make informed decisions based on valuable insights.

4.2 A European Health Data Space

As discussed in *Chapter 3.3*, the European Commission formulated the European Data Strategy in 2020 with the objective of establishing domain-specific data spaces in strategic sectors such as manufacturing, agriculture, public administration, and tourism. The Health European Data Space (EHDS) is the first data space with a concrete proposal, assessments, and previous public consultations, aiming to address challenges related to health data access and sharing for the integration of a European Health Union.

The EHDS focuses on two key aspects:

1. *primary data*, enabling individuals to control their electronic health data and share them with cross-border healthcare providers, and
2. *secondary data*, which pertains to the availability of health data for research, innovation, and policymaking purposes.

For secondary data, the implementation of the EHDS establishes a new regulatory framework that mandates *data holders* to provide access to various types of *electronic health data (EHD)* to *data users* for specific purposes. The purposes encompass scientific research, development and innovation activities, and algorithm training. This is particularly promising for developers, especially those in the field of artificial intelligence, as gives them access to extensive data sets necessary for training and validating their models, contributing significantly to the advancements in their work (Takhar, n.d.). This thesis decides for this reason to concentrate primarily on the secondary data, emphasising the conditions under which the data is made accessible to researchers, innovators, and policymakers. This allows the support of healthcare delivery and facilitates research and policy-making activities.

Following this very brief overview of the EHDS, this chapter aims to delve into the proposal and analyse the literature related to it, to better understand which topics are majorly discussed.

4.2.1 The proposal

The proposal elaborated by the European Commission and presented in May 2022, aligns with the EU's digital transformation goals and principles and states explicitly the reasons that drove the creation of the European Health Data Space (EHDS) (*Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space*, 2022). Firstly, natural persons faced challenges in exercising their rights guaranteed by the GDPR regarding their electronic health data, including accessing and transmitting the data both within their own country and across borders. Secondly, the uneven implementation and interpretation of the GDPR[14] by the Member States created legal uncertainties and barriers to the secondary use of electronic health data. This is blocking innovation, research, and effective policy-making in healthcare. Moreover, the COVID-19 pandemic highlighted the importance of electronic health data for policy development and emphasized the need for prompt access to personal health data.

The EHDS wants to give individuals increased control over their electronic health data and establish a trusted legal framework for data governance. It aims to facilitate access to relevant health data for researchers, innovators, policy-makers, and regulators to improve diagnosis, treatment, and well-being. In order to achieve so, it also aims to harmonize rules, promote interoperability, and contribute to a genuine single market for digital health products and services.

Additionally, previous EU legislation[15] had voluntary provisions and limited effectiveness in supporting individuals' control over their health data. The evaluation of digital aspects in healthcare during the COVID-19 pandemic highlighted the need for interoperability, harmonization, and a common EU approach to utilizing electronic health data. The EHDS will promote better exchange and access to various

[14] General Data Protection Regulation
[15] such as the directive about the application of the rights of patients' in cross-border healthcare with reference to eHealth

types of health data and establish mechanisms for data altruism[16] in the health, considering the specificities of the health sector and the different stakeholders involved.

The proposal relies on ensuring that “electronic health data are as open as possible and as closed as necessary” (*Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space*, 2022) to enhance the functioning of the internal market in respect of the Union values, specifically for the development, marketing, and utilization of electronic health record systems (EHR). This data space will have to work in close synergy with the European Open Science Cloud (EOSC) and the European Research Infrastructures (ERI), for their mutual benefit.

Moving to the actual proposal, the core of it is the following, summarisable as “support[ing] healthcare delivery (known as the "primary use of data") and facilitat[ing] access to health data for research and policy-making purposes (known as the "secondary use of data"” (Hussein et al., 2023).

While ensuring the enforcement of primary use is essential for healthcare and serves as a premise for secondary use, this research focuses on the secondary use of data. The secondary use presents a favourable opportunity to utilize the data that is already being collected for research purposes while safeguarding the rights and freedoms of individuals. This includes both personal electronic health data collected during primary use and electronic health data specifically gathered for secondary purposes.

The regulation establishes the legal basis and mechanisms for accessing and processing health data, while also defining the responsibilities of health data access bodies. It encourages data holders[17] to make different categories of health data available for secondary use, promoting collaboration among healthcare providers, organizations, associations, and researchers. The proposal leaves the categories of electronic health utilisable for secondary purposes broad and adaptable enough to

[16] it refers to the voluntary sharing of personal and non-personal data, with the consent of data subjects or the permission of natural and legal persons, without expecting any form of compensation, and with the aim of serving the common good (Lalova-Spinks et al., 2023)
[17] “defined widely to include most hospitals, public health bodies, pharma and medtech” (Takhar, n.d.)

meet the changing requirements of data users but still focuses on data that is relevant to health or has an impact on health. The scope of data is broad and encompasses

- *data from the health system*, such as disease registries, electronic health records, genomic data, claims data, etc.
- *data influencing health*, for instance, consumption of various substances, homelessness, health insurance information, minimum income levels, professional status, behavioural patterns, and environmental factors like pollution, radiation, or the use of specific chemical substances, and
- *person-generated data* such as data from wellness applications, medical devices, wearables or digital health applications.

The regulation supports the improvement and enrichment of datasets, with the requirement for data holders to share the enriched dataset with the original data holder. The data user who benefits from access can enrich the data with various corrections, annotations and other improvements, supplementing missing or incomplete data, and managing to improve the accuracy, completeness or quality of data in the dataset. The dataset with such improvements and a description of the changes should be made available free of charge to the original data holder. The data holder should make available the new dataset unless it provides a justified notification against it for instance in cases of low quality of the enrichment. This should support the improvement of the original database and further use of the enriched dataset.

Moreover, the regulation covers various types of data holders, including public, non-profit, and private entities involved in healthcare, research, and statistics[18]. In this regard public or private entities often receive public funding, from national or Union funds, to collect and process electronic health data for various purposes such as research, statistics (official or unofficial), or similar endeavours. This is particularly crucial in areas where data collection is challenging or fragmented, such as rare diseases or cancer. When such data is collected and processed with the support of public funding, it should be made available by the data holders to health data access bodies. This ensures that public investment has a full impact on research,

[18] Micro-enterprises (<10 employees) are the only actor exempted from the obligation to provide data for secondary for the public

innovation, patient safety, and policy-making for the benefit of society. Moreover, in some Member States, private entities play a significant role in the healthcare sector. Therefore, the health data held by these providers should also be made accessible for secondary use. However, certain types of data, such as those protected by intellectual property (IP) rights of medical devices or pharmaceutical companies, may have legal protections, including copyright. Nevertheless, public authorities and regulators should have access to such data, particularly in critical situations like pandemics, to verify the safety of devices and protect public health[19], making sure to safeguard IP and trade secrets.

It is highlighted, finally, the value of pathogen genomic data for public health and emphasised the need for timely access and sharing of such data after the COVID-19 pandemic. The pandemic has also highlighted the difficulties policymakers face in accessing health data and other related information. Public bodies and institutions may require regular access to health data for fulfilling their legal mandates. Specific rules should be established regarding the secondary use of health data, taking into account the unique aspects of the healthcare sector, and prohibiting the misuse of data for purposes detrimental to individuals, such as increasing insurance premiums or developing harmful products.

The presented overview of the EHDS proposal has emphasized key aspects of the initiative, and the ways in which it can be a solution to the issues of data access speficically related to the healthcare sector. Hereunder, the literature analysis will delve into the identified topics that have been extensively discussed in the field.

4.2.2 Literature review

In order to examine the literature covering the EHDS proposal, a search was conducted on the Web of Science (WoS). Initially, the themes and years of publication were clustered according to WoS to obtain an overview of the academic discourse. Subsequently, a deeper analysis of all the papers allowed a more accurate identification of the key topics. Google Scholar was also utilized for a preliminary

[19] the text mentions the *PIP breast implants fraud* as an example of such situations of need, where it has been challenging in the past to understand what was the knowledge held by manufacturers regarding defects in certain devices

understanding, but the collected papers were not included in the literature review due to the absence of effective filters on the platform, which could compromise the quality of the paper sample.

The literature on the topic is rather small. WoS shows a total of 30 results with the research key *"European Health Data Spaces"*[20]. The research engine clusters 25 out of the 30 results giving as central the topics as follows, with 7 covering *Public Environmental Occupational Health*, the major topic covered, and 5 on *Health Care Sciences Services*, the second most relevant cluster[21]. Looking for *"European Health Data Spaces"* just in the title gives 16 results, with again *Public Environmental Occupational Health* as the first topic, C*omputer Science and Information Systems* as the second one, and third in the previous research.

Figure 4: Web of Science Categories for *"European Health Data Space"* in all fields

[20] results obtained including the inverted commas. The research of "EHDS" for soon excluded indicating *electrohydrodynamic spraying*
[21] data last collected 1/07/23

Figure 5: Web of Science Categories with *European Health Data Space* in the title

The papers, according to the data of WoS were mostly published in 2022, the year of publication of the EHDS proposal itself. They are more than twice as many as the ones published in 2023 on the topic, probably influenced by the fact that there is still half of the year remaining. In 2021 the public consultation for the proposal was open so most of the articles of that year were around this topic.

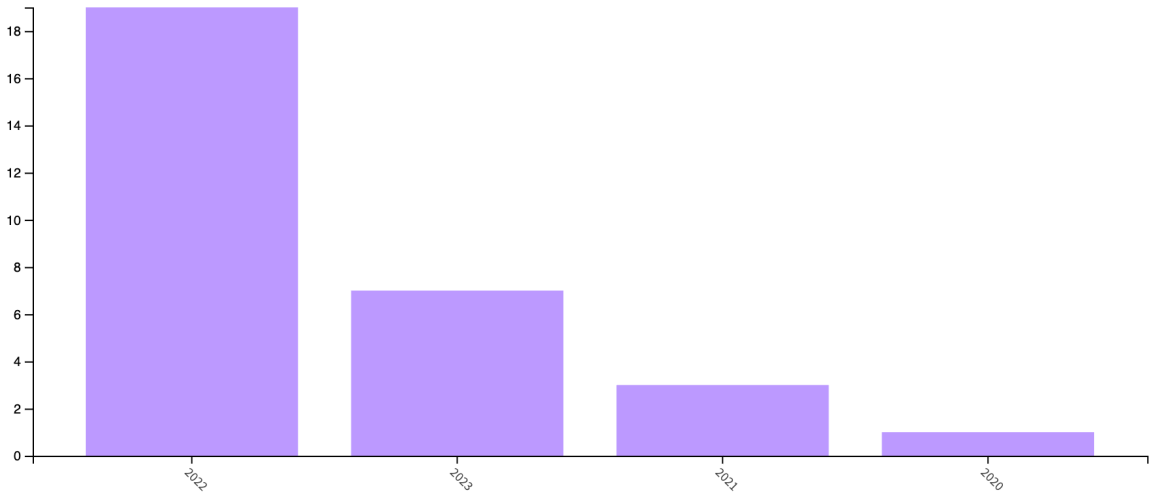

Figure 6: Bar chart of the Publication Years WoS

Google Scholar confirms that 2022 was the year of major publication of articles with these criteria, scientific articles are 444 in 2022, while just 292 in 2023. Some of the

papes found by it will be considered in the dissertation but other data are not considered to be relevant as per its lack of criteria and precision in the research (Boeker et al., 2013).

The discussion of the previous chapters brought us to the relevance of the topic of data access for SMEs in general and for Austrian MedTech SMEs in particular. Therefore the literature was explored to check for any relevant connection. For what concerns the couple *"European Health Data Space" AND "SMEs"*, WoS gives no result[22], while Google Scholar gives 16. No article is focusing on this connection as a centre of the research itself, some are considering the connection between the two topics, while others are just articles in which both of the concepts are mentioned without any interrelation. The exploration of topics related to SMEs and data sharing in the literature is relatively limited too, therefore this search would be a dead end.

Given the limitation in accessing certain papers, several key topics were identified emerge in the discussion of the European Health Data Space (EHDS) in the literature, here are the main ones:

- Relevance of the measure for public health: overall importance, digitalisation of the health systems and advancement of integrated care ('2.G. Workshop', 2021; Genovese et al., 2022);
- Legal considerations and ethical considerations: including GDPR, data privacy, and data anonymization, with some discussion on genetics (Machado & Polonia, 2022; Molnar-Gabor et al., 2022);
- Validation of European Union assessments and utilization of existing health records for secondary purposes (Bernal-Delgado et al., 2022; Machado & Polonia, 2022; Tavazzi, 2023);
- Technical perspective: data governance and the impact of data quality on achieving the desired Data Space, necessary investments in technical equipment for proper enforcement ('2.G. Workshop', 2021; Bernal-Delgado et al., 2022; Hussein et al., 2023);
- Possible introduction of mechanisms for individual control over health data access and reuse for secondary objectives (Machado & Polonia, 2022);

[22] simal research keys as small and medium enterprises were tried with no results as well

- Challenges and opportunities in digital health literacy of the general public and professionals, with a focus on stakeholder involvement (Genovese et al., 2022; Hussein et al., 2023; Pfoerringer & Back, 2023).

To address the complex framework surrounding the implementation of the European Health Data Space (EHDS) and its associated topics, it was crucial to comprehend the proposal itself, its purpose, and the underlying premises on which it was formulated, without diving deep into the legislative text itself. This literature review builds up on this identifying some of the topics that will be discussed in the next chapter to better understand the multiple layers of discussion the actors involved and their instances concerning the secondary use of data. Hence, the following chapter will bring together position papers, grey literature, academic literature, comments and annexes to the proposal itself, to understand the core issues and who is bringing them up in the European and Austrian context.

5
THE AUSTRIAN SYSTEM

To better comprehend the intricacies of this issue, an examination of the Austrian context will be undertaken as a means to provide structure. The analysis will focus on the main stakeholders and their positions, drawing insights from position papers, interviews, and public discourse within Austria.

The chapter will start by proposing some of the themes that make the introduction of the EHDS a complex topic (5.1). The preferred source will be the Austrian ones, but in cases where a specific actor is not present or their stance is unclear within the country, the European representative will serve as an example representing the respective category. Secondly, some relevant documents will be examined to gain a thorough understanding of the state of the art in the digitalization of public health, and related aspects within the country (5.2). The assessment will concentrate on the peculiarities of Austria, without stressing the comparison of what other nations are doing. However, for a general understanding of the position of Austria with respect to other EU countries, it is fair to say that in most of the statistics to be mentioned, Austria is in the middle half of virtuous states. A brief understanding of the cultural context and the regulations in place will help depict the implications of the enforcement of the EHDS. Thirdly, the actors and their instances will be listed, merging all the information collected in the research (5.3). Finally, the aforementioned instances will serve as factors of a causal loop diagram, to understand the connection and the causal relations (5.4). The creation of the diagram helps visually to identify the central pivots of this network, which are the fundamental interaction involved in the potential enforcement of the EHDS.

5.1 A complex topic

The rapid advancement of digitalisation that is encompassing various sectors including healthcare, wants to bring the prospect of simplification and enhancements. However, this proposal has sparked significant concerns among numerous stakeholders regarding the protection of fundamental rights, patient privacy, autonomy, and feasibility.

After the explanation of the proposal itself, this section delves into the enforcement of the EHDS, aiming to grasp the complex nature of the topic and some of the various layers involved. Exploring this multifaceted reality will facilitate the identification of stakeholders and their roles while bringing to light crucial issues concerning the implementation of the EHDS in the EU, with a special focus on Austria. While some examples necessitate detailed explanations based on case studies, others will be just briefly outlined.

Weak Stakeholders Involvement

The Austrian Federal Chamber of Labour AK Europa laments the lack of adequate stakeholder involvement in the Commission's proposal, despite attempts to address this in the annexes (AK ÖGB Europa, 2023; *COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the Document PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space*, 2022). The absence of proper representation for healthcare staff, trade unions, and employers is highlighted. It is emphasized that patient groups and health professionals should be included in the decision-making process at both national and European levels. Additionally, workers emphasize the importance of effective communication to prevent a perception of unilateral decision-making and ensure a collaborative approach in the effective implementation. The involvement of the stakeholders should not be implemented as a token but throughout the entire process (Collen, 2022).

Patents and Intellectual Property

The issue of intellectual property (IP) rights and patent ownership within the context of the European Health Data Space (EHDS) poses a significant challenge. There are some doubts among experts regarding the appropriate reference in the possible patent share to data collectors, but most of the position papers' concerns are related to the safeguarding of trade secrets and intellectual property (DIGITALEUROPE, 2021). It is crucial to address the inclusion of electronic health data that may contain protected IP and trade secrets from private enterprises for secondary use as stated by the proposal, but stringent measures must be implemented to ensure the confidentiality and protection of intellectual property rights and trade secrets.

Balancing the need for data sharing while respecting the rights and interests of private entities is a complex task in the development of the EHDS.

Opt-in, opt-out

To understand this issue a refresh is needed on the meaning of the expression opt-in, which refers to a type of consent provided by users on taking part in a specific activity, or arrangement. The cookies wall, for instance, with a request of explicit consent (opt-in), is needed to comply with the GDPR which asks the controller to obtain the *explicit consent* of the user to specific data treatments. In the Proposal for the EHDS, this request is not present and the term consent is mentioned only 4 times related to other issues. Shortly, the proposal itself does not contain any opt-in system that could give explicit consent, but it does not even consider an opt-out option, to withdraw partially or totally the consent to data treatment.

For this reason, "32 European patient organisations, medical associations, research organisations, data collaborations and industry associations [published a joint paper to share] their common views on specific recommendations for a potential opt-out mechanism in the EHDS" (EPIC, 2023). Experts interviewed, associations, trade unions, and other actors presented a similar request (AK ÖGB Europa, 2023). Some lawmakers emphasize the need for this option to possess certain distinct attributes. These include its universal applicability by Health Data Access Bodies in all EU Member States, a well-defined and limited scope, consistency, transparency, and the provision of accurate information to citizens (Collen, 2022). AK, the Austrian Federal Chamber of Labour, emphasizes the need to ensure patient rights and prevent the commercial misuse of sensitive data, and the creation of independent data protection authorities (AK Europa, 2022).

In the case of other health databases, if an individual does not actively choose to opt out of the database, their participation is deemed to be consensual, thereby potentially compromising their right to provide explicit consent (V. Árnason, 2004; BioNews, 2004). For this reason, some would state the need for an opt-out system for primary use and an opt-in for reuse (secondary use) (EHDS, n.d.; Penfrat, 2023). However, the insertion of an opt-in one is unfeasible and would decrypt the death of the EHDS itself. Intuitively comparing the data donation to the blood one it is clear

that, even if the importance of the gesture is unanimously recognised, the economic effort of donation campaigns is massive and the results only partly repay it. Therefore, the hoped, GDPR-compliant, opt-in option, is out of the discussion for its very high costs (Boom et al., 2010), not being able to pay back the effort of the construction of such a complex structure and not gaining a representative sample.

The actors' instances were heard, and in the Draft Report of February 2023, the parliamentary rapporteurs have incorporated the suggestion of the provision of an opt-out right. They highlight the importance of ensuring the participation of data subjects in accordance with Article 9(2) of the GDPR and emphasize that this opt-out right is crucial for maintaining trust between patients and healthcare providers. Consequently, in the amended proposal, patients would have the right to choose not to have their personal electronic health data (EHD) used for secondary purposes. However, the wording proposed by the rapporteurs might lead to some confusion in interpretation[23], asking for a more specified and structured mechanism in the final bill (*DRAFT OPINION on the Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space*, 2023; Kogut-Czarkowska & Fiers, 2023).

To conclude, rules for consent change from country to country, for example, “some Member States require specific consent of patients for secondary use for research, others apply the principle of broad consent, and several refer to the derogation for public interest or research” (Vettorazzi, 2023). Austria at the moment has a rule that does not allow the use of this data for research[24] that will have to be changed in order to implement the EHDS. This emphasises the need for a proper check, at the country level as much as at the EU to avoid overlaps and contradictions.

Broad terms

Some stakeholders highlight the importance of better definitions, of the terms used and of the services (DIGITALEUROPE, 2022) that the EHDS included. More specifically, AK asks for a narrower definition of "health data"(AK Europa, 2022). The

[23] as it permits individuals subject to secondary use to "decline the processing of their health data" and this right to opt-out is granted what qualifies as personal data
[24] see 5.2

European Data Protection Board (EDPB) and the European Data Protection Supervisor (EDPS), ask for a narrower definition of "health data" in the proposed regulations too (EDPB-EDPS, 2022). They recommend excluding wellness applications and other digital applications, as well as wellness and behaviour data relevant to health, from the scope of the proposal. The processing of personal data derived from these applications for secondary use should require prior consent within the meaning of the General Data Protection Regulation. The EDPB and the EDPS highlight that health data generated by wellness applications and digital health applications have different characteristics and pose potential privacy risks due to their invasive nature (EDPB-EDPS, 2022; Sadare et al., 2023).

Furthermore, EDPB and EDPS express concerns about the purposes for secondary use of health data listed in the proposal, which encompass various development, innovation, training, and evaluation activities (EDPB-EDPS, 2022). They emphasize the need for a clearer delineation of these purposes to ensure a sufficient connection with public health and social security. The EDPB and the EDPS also point out that the criteria for assessing and deciding on data applications, as stated in the proposal, should align with the provisions and principles of the GDPR, particularly Article 9(2) (EDPB-EDPS, 2022).

These recommendations highlight the need for a more precise definition of health data, as well as clearer delineation and alignment of purposes and criteria for secondary use. This approach is essential to strike a balance between achieving the objectives of the proposal and safeguarding the protection of the personal data of the individuals affected by the processing (EDPB-EDPS, 2022). By addressing these concerns, the proposed regulations can enhance data protection and ensure the responsible and ethical use of health data in the European Health Data Space.

Undermine public health

The implementation of the EHDS has raised concerns about potential negative effects on public health and the increment of health inequalities. The development of the EHDS with the involvement of individuals but not of patient groups has led to worries that important needs may be overlooked, particularly for individuals with sensory or cognitive impairments and those with low digital literacy. Failure to

address these concerns could result in the underrepresentation of healthcare data, the introduction of biases and more simple difficulties to access healthcare. To ensure equitable access to digital health technologies, it is essential to prioritize diverse patient and population groups in the development of the EHDS (Kessel et al., 2022). Despite the EU's substantial progress in incorporating digital health into the European health ecosystem and future health union, it is imperative to prioritize universal access to digital technologies, irrespective of income, age, or ability. Active involvement of diverse patient and population groups is essential for transforming the EHDS into a means of addressing, rather than aggravating, structural health disparities in the digital era (Kessel et al., 2022).

In addition, there are concerns about the potential creation of health inequalities and the neglect of digitally vulnerable groups. The EHDS obliges public and private health authorities to share health data with private commercial firms for secondary use, but the fair need to safeguard the IP and the trade secrets could jeopardise this duty. This possible imbalance could further exacerbate health inequalities between countries and within populations. There are also general concerns about the creation of a telemedicine market and the feasibility of the proposal considering the already overburdened health systems in many Member States (*Guidance on Private Sector Data Sharing | Shaping Europe's Digital Future*, 2023; Kessel et al., 2022).

Moreover, the involvement of healthcare workers and the allocation of resources for training and staff incrementation are important considerations in the implementation of the EHDS. Experts from the Standing Committee of European Doctors (CPME) have emphasised the need to enhance healthcare access without burdening doctors and small practices. The European Economic and Social Committee has highlighted that funding remains a fundamental problem in public health and that the issue of exhausted healthcare professionals due to excessive workloads and inadequate compensation is not adequately addressed (AK ÖGB Europa, 2023). Moreover, public entities will be targeted with requests to access their data sets as much as private ones. This implies that adequate measures to answer these inquiries should be put in place and financed (Takhar, n.d.).

Despite these concerns, studies emphasize the importance of global collective responsibility and sustainable financing in healthcare, including the EHDS as a transformative system. Initiatives like the European Health Emergency Preparedness and Response Authority (HERA) and the establishment of a unified digital EHDS can contribute to stable recovery, continuous improvement, and efficient response to emergencies. Building the necessary infrastructure and promoting digital education today can pave the way for better policies and effective healthcare planning (Tulai et al., 2022). The potential benefits in this regard are numerous, yet particularly in the long term.

Overall, addressing the concerns regarding health inequalities, digital literacy, workforce involvement, and sustainable financing is crucial for the successful implementation of the EHDS and to ensure equitable and inclusive access to digital health technologies and services.

Data protection

In the context of the European Health Data Space (EHDS), it is crucial to enforce robust data protection measures to ensure consumer protection in the digital landscape (AK ÖGB Europa, 2023). However, the current implementation of data altruism in clinical research raises uncertainties and requires a clear and harmonious interaction between the Data Governance Act (DGA), General Data Protection Regulation (GDPR), and the EHDS to uphold patient-centric healthcare and protect fundamental rights (Lalova-Spinks et al., 2023). This necessitates additional efforts from lawmakers to develop an operational system that safeguards patients' interests, promotes data altruism, and prevents the commercial exploitation of sensitive data (AK ÖGB Europa, 2023).

A comprehensive analysis of the legal and technological aspects surrounding the EHDS reveals critical considerations (Machado & Polonia, 2022). From a legal standpoint, the limitations imposed by the GDPR, particularly regarding privacy, anonymization, and the secondary use of health records, need careful examination (Machado & Polonia, 2022). Technologically, effective governance mechanisms and data quality management must be established to ensure the intended realization of the Data Space (Machado & Polonia, 2022). It is suggested that individuals should

have the ability to define terms and conditions for accessing and reusing their health data, granting them greater control and consent (Machado & Polonia, 2022). However, according to some actors, this proposal is particularly needed to create a more permission framework for data access for researchers, addressing the limitations acted by the General Data Protection Regulation (Takhar, n.d.).

Addressing the necessity of a research exemption from consent for the use of sensitive personal data in medical research is essential within the EHDS proposal (AK ÖGB Europa, 2023). Striking a balance between privacy concerns and research advancements becomes paramount, particularly in protecting highly sensitive data encompassing mental health, genetic information, chronic illnesses, and socio-economic factors to prevent commercial exploitation (Mostert et al., 2016). Strong and independent data protection authorities play a central role in overseeing the EHDS and ensuring compliance with data protection regulations, upholding transparent processes, informed consent, and privacy regulations to foster consumer trust (EDPB-EDPS, 2022; Penfrat, 2023). The direct connection between the active participation and consent of data subjects and the opt-out option is evident.

The vision behind the EHDS proposal raises concerns about data security, competition in the data economy, and the protection of fundamental rights (AK ÖGB Europa, 2023). The exploitation interests of the data economy, dominated by North America and growing rapidly in Asia, including China, present challenges regarding data protection and privacy (AK ÖGB Europa, 2023). It is important to question whether competing with the USA and China in terms of fundamental rights is desirable, given the disparities in data protection levels (AK ÖGB Europa, 2023). The EDPB and the EDPS emphasize the need to store personal electronic health data within the EU/EEA to ensure effective supervision, mitigate risks of unlawful access, and protect highly sensitive data (EDPB-EDPS, 2022).

Consumer protection and the right to privacy, with a focus on ethical considerations, are crucial aspects that need attention (AK ÖGB Europa, 2023). Granting explicit consent to individuals affected by electronic health records and patient data is essential, and relying solely on data anonymization is inadequate due to the possibility of re-identification (AK ÖGB Europa, 2023; Penfrat, 2023).

Genetic privacy

Latter, concerning again the secondary use of data there are issues related to health data that appeared in cases such as the notorious Iceland one, a moral major problem that rose from the project of the *deCODE genetics database*, not stressed in the EHDS but relevant for some eventual issues. Briefly introducing the story, in the year 1998, the Icelandic government authorized the biotech company *deCODE Genetics* the exclusive access for commercial development to the medical records, family lineages, and genetic data of all 270,000 inhabitants of the country. The Icelandic genetic peculiarity lies in extreme homogeneity due to the low immigration since the Vikings and extensive genealogical records, making the island's population a perfect sample for genetic research on diseases. This initiative, known as the 'Health Sector Database', was controversial due to its reliance on assumed patient consent, similarly, at the moment, to the EHDS proposal that contains neither an opt-out nor an opt-in option (AK Europa, 2022).

Some concerned academics and medical professionals fought against this decision establishing an organization called *Mannvernd* (which means *human protection* in Icelandic), known as the Association of Icelanders for Ethics in Science, self-positioned as the organised opposition to the Icelandic government's Act on a Health Sector Database (HSD). Mannvernd was stating that this measure was against human rights, infringing on both personal privacy and "accepted medical, scientific and commercial standards" (Winickoff, 2006). The answer of the government that managed to make the act pass was peculiar:

> "[it] asserted that because the state paid for the medical care giving rise to the data, the state could control and "exploit" those data for the benefit of Iceland. Rhetorically, the act denies that medical data can be owned, but this language is a mere formality—access, use, and control are nothing if not the traditional components of property. In effect, the state reduced the complex web of legal interests around the medical data by cutting off the doctors and asserting the power to license, which is a property interest" (Winickoff, 2006)

In addition, there were parallel concerns related to unfair market practices, such as the Genetics company's sale of shares to the public in the grey market prior to its

official public offering (E. Árnason & Andersen, 2013). Furthermore, there was a lack of ethical committee review in this decision, resulting in a subsequent declaration of unconstitutionality. In fact, the public database on which deCODE Genetics based its initial public offering was never constructed but the company benefited from its database from a number of relevant scientific papers (E. Árnason & Andersen, 2013).

This case arose over the world and especially in the biotechnology community a debate regarding the appropriate methods for acquiring data and conducting research advancements. Despite efforts over a five-year period, during which campaigns were conducted on the issue, only 7% of the population opted out. It is important to acknowledge that when dealing with a vast amount of data from a specific population, the effectiveness of the opt-out option is often limited since the collective nature of genetics highlights that genetic information is inherent "involuntarily" shared. Consequently, it is possible to obtain significant insights into an individual's genetics even without their explicit consent to share such information. The voluntary disclosure of data or *data altruism* can have severe consequences for the relatives of the individuals who disclose the information. Some scholars, therefore, suggest that any processing of genetic data should involve a careful consideration of interests, extended to other parties than the donor (De Miguel Beriain, 2021), and others formulate implementations of genomic medicine in healthcare considering multiple stakeholders (Tommel et al., 2023). Some of the options simply include the possibility to ask the major number of family members "their willingness to (partly) forfeit their privacy rights, through required entrance tests and signing open consent, respectively" (Shabani, 2022). However, these measures create difficulties in the obtainment of a wide population agreement and risk causing a drastic shrink of the sample.

While technical interoperability is advancing, the legal framework, particularly regarding data protection law, is not yet clearly defined. Some scholars highlight the barriers and compliance burdens associated with international data transfers (Molnar-Gabor et al., 2022), the need to carefully consider privacy concerns and the rights of data subjects (De Miguel Beriain, 2021), and the importance of harmonizing data protection rules across European member states (Tommel et al., 2023). It is indisputable that this amount of data can have and in fact, had a huge impact on

scientific research but it has to be find a common ground between this necessity and the protection of citizen's personal health data, especially considering the difficulties of anonymization and the real possibility of de-anonymise data. Moreover, the citizens have to benefit from this data sharing, making it easier and economically sustainable to access the better treatment this innovation would eventually bring.

5.2 The Austrian Framework

In light of some of the current discussions and concerns raised by stakeholders in Austria and the EU, it is important to provide a general overview of the country's technical and legal landscape, as well as its general approach to such changes and the implementation of the European Health Data Space (EHDS). Austria has demonstrated notable advancements in the realm of digitalization, particularly in the development of Electronic Health Records (EHR)[25], surpassing many other EU countries in this regard (Boyd et al., 2021).

More specifically, according to the Assessment Report to the EHDS (*COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the Document PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space*, 2022), the one that regulated health data exchange via EHRs, both internal and cross-border, seems the only piece of legislation in Austria relatively against the implementation of the proposal (Abboud et al., 2022). However, eHealth and digital health policies are built upon and integrated with the outcomes of EU initiatives aimed at promoting interoperability both inside and outside the country. Individuals can easily access their EHR and Austria has a national institutionalised competent authority. Like many EU countries, the healthcare personnel who work with the national EHR systems did not receive adequate training and possess awareness about the risks associated with cybersecurity. Overall the readiness for the use of EHR itself is high, a good premise for effective implementation for secondary use too, especially since the technical requirements are met and the missing of sharing is due to policy decisions and laws. To work on interoperability many levels have to be considered, but Austria has already a good pace in it. The future implementation is going to be

[25] which adherence to SNOMED health data standards, contributing to a robust and standardised health data ecosystem.

put on top of "existing health data infrastructures must be leveraged to allow continuity and build on existing expertise" (DIGITALEUROPE, 2022).

Moving to secondary use, the report "Secondary use of health data in Europe" by the Open Data Institute (Boyd et al., 2021) identifies Austria as one of the leading countries[26] with strong policy quality and advanced implementation. Austria acknowledges the significance of leveraging health data for innovation, personalized healthcare, and improved diagnostics. The country is also actively working towards implementing health data infrastructure and ecosystems to enable data reuse, as well as integrating real-world data and evidence into healthcare systems. Although the report does not specifically mention the enforcement of the EHDS, it highlights Austria's favourable position on secondary data use. However, the country faces certain obstacles despite its high readiness to comply with secondary use, as outlined in the comprehensive profile provided in the appendix:

> "While the Austrian Data Protection Act states that the citizen must give explicit consent for the use of their health data, unless it is a public health emergency or the patient is incapacitated, the government recognises the interpretation of Recital 157 of the [GDPR] which states 'personal data can therefore be processed for scientific research purposes, subject to reasonable conditions and guarantees set out in Union law or in the law of the Member States'. The Research Organisation Act was amended in 2018 to allow scientific research using personal data, however, other acts differ. The Gentechnikgesetz Act on genetic engineering sees genomic information as personally identifiable, and therefore limits its use in research without individual consent. Further, in Austria the Forschungsorganisationsgesetz (FOG) defines the basic legal framework for research with registers. However, no registers are actually released by the law. Specific registers must be released for research purposes via regulation from the responsible ministries.
>
> Challenges: policy barriers
>
> - Emerging innovation: The government has set strategic goals to encourage secondary use of health data in research, but has not yet had time to create or implement processes, new legislation, and institutions.

[26] for reference, the other leaders are Austria, Belgium, Czech Republic, Denmark, Estonia, European Commission (included in the count), Finland, France, Israel, Italy, Luxembourg, Norway, Portugal, Spain, Sweden, UK

- Lack of quality: Registry datasets are being collected but vary in quality, with some data registries poorly resourced by the government. This is further exacerbated by poor quality electronic-health-records [...] systems management, which locks the value of patient care behind PDFs.
- Complexity: Health registry datasets are not easily searchable and do not use common data models. Health institutions also lack coordination and the links between them can be unclear.

Opportunities: policy achievements

- Austria's recognition of Recital 157 of the GDPR, which acknowledges the role of personal data in health research, stimulated new research organisation legislation to better balance the privacy of personal data with opportunities for research for social good.
- Austria's Biobank initiative is ranked world-first, and includes citizen/patient education to build trust in healthcare.
- This Covid-19 data platform has been developed by the Federal Ministry for Social Affairs, Health, Care and Consumer Protection and Health Austria, and makes data available relying on FAIR Framework principles. An advisory board has been established to oversee guidance and research teams must apply for access. Researchers are already publishing papers based on data published in the portal.
- Two models that demonstrate how data can be managed within ethical and legal structures for secondary use are: Austria's Platform Register for Research (a platform for research based on registry data) and the emerging initiatives to create an 'Austrian Micro Data Center'.
- Digital Health Wien initiative is a cooperative network that involves researchers, government, and patients to build a knowledge network on secondary use of health data." (Boyd et al., 2021)

This work should not be underestimated, as it is the result of many years of dedicated efforts by the country in this direction. The transition was initiated and fostered by Clemens Martin Auer, politician, former Vice-Chair of the Executive Board of the World Health Organization in Geneva and head of a section at the Federal Ministry of Labour, Social Affairs, Health and Consumer Protection since 2005. Auer played a pivotal role in the country's health system, managing care planning, financing, quality, and digitization. One of his focuses has been on eHealth, leading the

introduction of the Electronic Health Act (ELGA) in Austria and serving as the chairman of ELGA. Auer also holds the position of co-chairman of the eHealth Network of the head authorities within the EU. Furthermore, he serves as the coordinator of various collaborative initiatives within the EU, guiding the strategic direction of the common eHealth policy among member states (*Clemens Martin Auer*, n.d.; *EHFG — Clemens Martin Auer*, n.d.).

ELGA GmbH, a legal entity jointly owned ⅓ by the federal administration, ⅓ *by* federal states, and ⅓ social insurance, is responsible for the development, management, and sharing of electronic health records in Austria. Its primary task is to handle, exchange, and provide access to electronic health records, responsible for the primary use of data. Therefore it is responsible for the primary use of data. Gesundheit Österreich GmbH (GÖG), the National Institute for Health Research, created in 2006 by the Federal Health Act (GÖGG), is instead responsible for the secondary use, as the national "research and planning institute for the health care system" (*Gesundheit Österreich GmbH*, n.d.); (Abboud et al., 2022). It is completely publicly owned.

As remarked by one of the experts interviewed, Helene Prenner, Project and Innovation Manager at ELGA GmbH and Board-Memeber of Data Intelligence Offensive, one of the crucial steps to implement secondary data use in Austria is the deletion of the law that forbids the use of health records for research[27] (without explicit and punctual consent) (Abboud et al., 2022; Hebenstreit, 2023; Milieu Ltd & Time.lex, 2014) (Abboud et al., 2022). The explanation for this binding legislation is historically related to a public pervasive campaign[28] in one of the most widely read national newspapers that was carried out by the Austrian Medical Chamber, and in general, of a very long debate among politicians, organisations and civil society, which clearly shows the cultural and personal aspects related to the secondary use of data (Bogumil-Uçan & Klenk, 2021; Schmitt, 2023). However, is the GÖG the competent authority for the enforcement of the EHDS of secondary use of data, before sharing anonymised patients' data (ELGA's ones), there are actually other

[27] in particular: "medical treatment or care, nursing care, invoicing of health services, insurance of health risks or exercise of patient rights" (Hebenstreit, 2023)

[28] the campaign featured two individuals without clothing, conveying the message that the introduction of ELGA would result in "glass patients." This imagery created fear and hesitation among many people regarding the effectiveness of the measure

steps that involve the data gathered during Covid and the administrative ones, that are not personal data, therefore can be used.

The lack of harmonised answers to requests for data for research by specific legal frameworks has been a subject of complaint among many members of SMEs. This suggests that the absence of specific and up-to-date laws on the relevant topics, or the limited knowledge of these laws by legal authorities, is currently an issue faced by the country. Ideally, the enforcement of the European Health Data Space (EHDS) could help improve this situation.

5.3 Mapping the actors and their instances

Based on the information collected and the experts' evaluations, the actors are summarised and some of their major instances are used to construct the causal loop diagram (CLD) as a representation of the key actors involved and their significance within the system. This approach is necessary due to the multiple layers and complexities involved, to understand the interactions among these actors. This list is intended to be broad but not all-encompassing and will be further refined by the creation of the CLD considering the autonomous nature of certain factors. Other factors are added to bridging logically two instances. In the list, some actors, the *individuals* in particular, that embed instances related to the primary use of data will be mentioned. This has the same role in the discussion of the discourse on the opt-in and opt-out options since primary use is, to all intents and purposes, a preparatory stage for the secondary use of the data because it enables the collection of data.

SMEs [29]	• legal and technical interoperability profits • data sovereignty (European Digital SME Alliance) • fight the monopoly/ higher competition • avoid overregulation • easy compliance • easy and efficient data access • law harmonisation (within and among) Austrian/EU market rules • understanding by the authorised officer of the legal options for obtaining data

[29] they are typically data producers and providers of relatively to their niche. They are consumers of public datasets, and normally buy data in other countries so they are potential consumers of Big companies's data (Nagel & Lycklama, 2021)

Big companies [30]	• legal and technical interoperability • profits • data sovereignty • no imposition for them to share • law harmonisation (within and among) Austrian/EU market rules • protection of competitive advantage • protection of intellectual property rights and trade secrets • effect on the patents of things created with their data/ patent share
Individuals [31]	• safeguard public health • receive the benefit from the research • convenient medical care • protection over their data • opt-in/out option • data protection • cyber security • data subject's rights • data control • access to their EHR • privacy safeguards (organizational and technical)[32]
Researchers	• easy access to every kind of data • easy compliance
Health professionals	• no additional boredom • high usability of health records as a clinical tool • sufficient assistance[33]
Austrian authorities [34]	• enforcement of the EU regulation • compliance to the DSGVO (GDPR) • boost research

[30] they are typically data producers and data providers of big quantities of data, especially if they have a strong competitive advantage in a certain field. They are also data consumers of, for instance, public datasets. (Nagel & Lycklama, 2021)
It has to be considered that health data access bodies and data controllers, whether public or private, may charge fees as provided for in the Data Governance Act, taking into account the circumstances and interests of SMEs, researchers and public bodies. Charges for access to data and services must be reasonable and reflect the associated costs.
[31] individuals cannot be considered a "solid" stakeholders
[32] typically data owners, therefore they the authority to grant or revoke terms and conditions for data access and usage. (Nagel & Lycklama, 2021)
Suggestion for oversight by a data access committee and an ethical board, to ensure that the reuse of data serves the public interest and follows ethical standards (Shabani, 2022). However, if this would be mandatory just for researchers, it is not clear what option would be for for-profit
[33] in terms of help and professional updates
[34] Ministry of Health as the most important authority, GÖG-Gesundheit Österreich, ELGA-Electronic Health Record, DSB-Datenschutz Behörde data protection

	• better policy creation • help the industrial sector • safeguard the citizens' data • safeguard the right to public health
EU authorities [35]	• Union's data sovereignty • shape a single market for digital health products and services • foster innovation • easy access to data • better decision-making • crisis management (eg. Covid)

5.4 The interaction picture and its discussion

A Causal Loop Diagram was developed to capture the significant instances of each actor and their potential impact on other factors within the system. This CLD, far from offering a panoptic view of the instances related to the EHDS, seeks to show the intricate net of connection present in the field incorporating more than 30 instances. Some topics are not included in the diagram because they are the obvious result of enforcement (e.g. the Austrin's authority one "enforcement of the EU legislation"), others because they have no deep implications for other stakeholders (e.g. patent share). Even acknowledging this, the CLD still aims to showcase the interdependencies and relationships among the included factors.

[35] Commission, Parliament, DG SANTE (Directorate-General for Health and Food Safety), European Data Protection Board, European Data Protection Supervisor

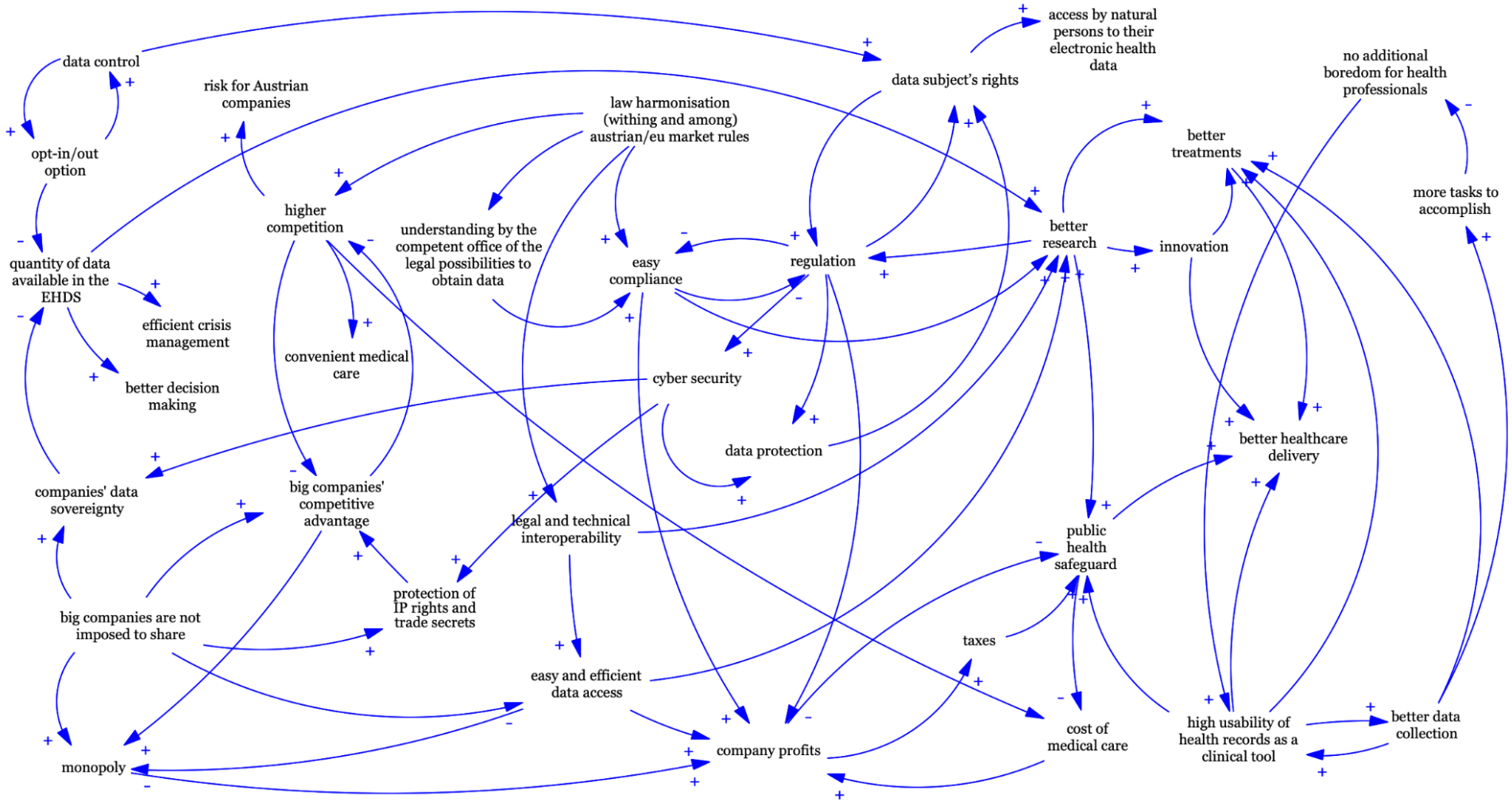

Figure 7: Causal loop diagram

In order to address the research question, it is essential to identify the complex issue and the areas where multiple stakeholders converge. This analysis will provide a deeper understanding of their significance and help determine the priority for resolving these issues. Taking a closer look at the diagram, two main topics can be highlighted, and they are in fact the factors related to the competitive advantage of big companies (1) and the factors that surround the decisions made by the population itself (2).

(1) The topic of competition brings together various stakeholders such as Big Companies, SMEs, and government bodies. While some stakeholders anticipate that the European Health Data Space will enhance healthcare and boost competitiveness and productivity, there are concerns and doubts surrounding the project.

The EHDS involves data sharing benefits both governmental and private entities in terms of research. While it requires effort from all participants, the deal appears favourable for everyone. However, for big companies, sharing already processed data may seem unfair given the volume of data they collect. In particular, it should be acknowledged that despite data being non-rival, the collection and processing of data impose significant resource burdens on companies (Guidance on Private Sector Data Sharing | Shaping Europe's Digital Future, 2023). This likely explains the lack of extensive discourse on data sharing within both academic and practitioner communities. Another factor to consider is that data holders, particularly large companies, already possess a competitive advantage in research, which complicates the notion of mandatory data sharing.

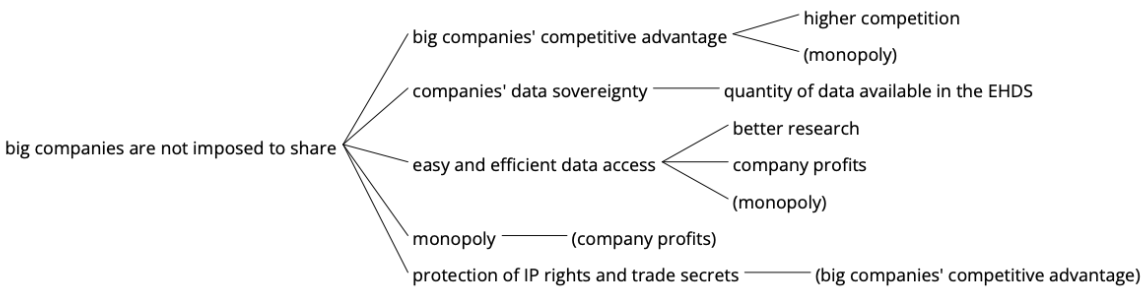

Figure 8: Uses tree of the imposition to share for big companies

Enforcing mandatory data sharing for companies, even beyond emergency scenarios, presents opportunities for smaller players such as SMEs and start-ups to gain awareness of available data and the conditions for accessing it. The requirement for proportional fees to obtain data, even when charged to private entities, creates a favourable environment for SMEs and start-ups. For big companies, their obligation to share data and their perception of its value depends on their trust in the system's protection of intellectual property and trade secrets. Nevertheless, these companies recognize the value of obtaining data from governmental sources like ELGA and possess the processing capabilities to leverage its use. Moreover, they recognise the importance of the research to obtain better and fairer regulations, for them too. This is the reason one of the feedback loops identifiable in the CLD, which connects the instances of regulators, in a feedback loop that reinforces the data sovereignty of companies. However, a discussion regarding the lobbying power and potential influence of these companies in shaping policies related to data utilization and access would suggest that this connection is not of central importance to them.

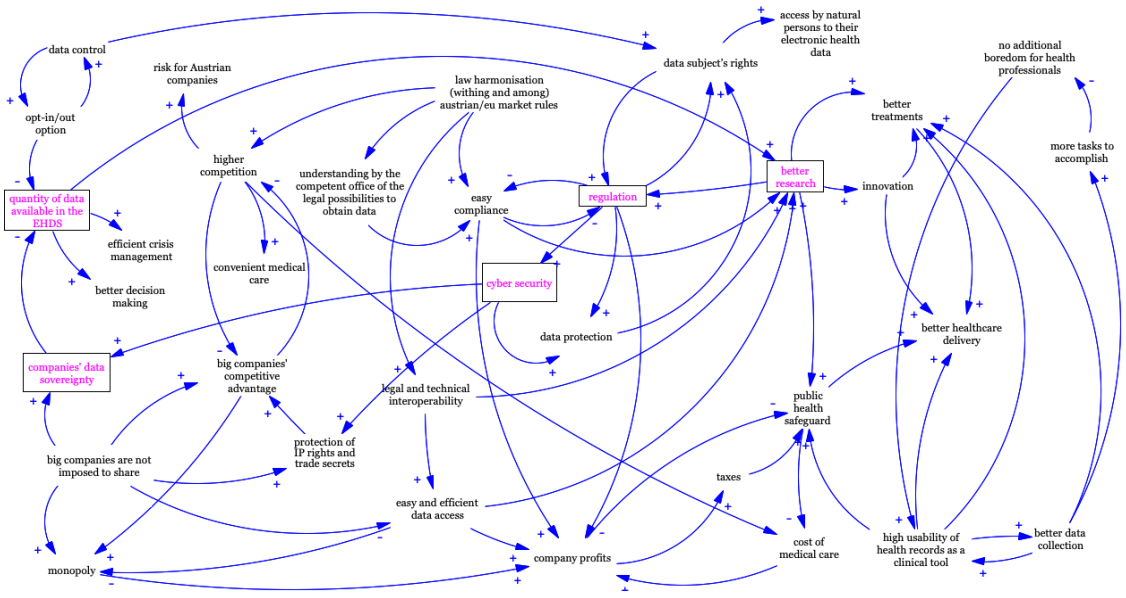

Figure 9: Feedback loop regulators-big companies

While private actors contribute to research and advancements in treatment, the data obtained from citizens and public health should generate additional positive impacts on public health beyond increased taxation and improvements in private research and healthcare (which are the only

connections among these factors). It is anyway important to note that the benefits derived from their activities are considerable, such as innovation, better treatment and better healthcare delivery. Therefore, incentivising their efforts and fostering their research with data can be very beneficial (Jetzek et al., 2014)

(2) Individuals play a unique and significant role in the implementation of these measures as they are both highly influential and greatly impacted. Their involvement not only affects the various instances but also has implications for research, both public and private, with a direct causality between the quantity of data collected (*4th cause in Figure 10*) and the public health safeguard.

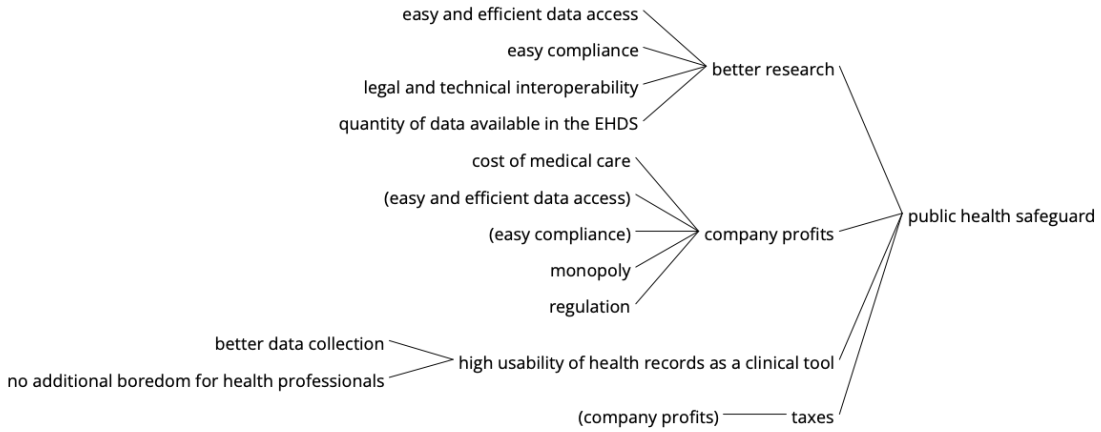

Figure 10: Causes tree of public health safeguard

The utilization of secondary data, particularly for enhancing data access, requires indeed not only interoperability but also an adequate volume of data and representativeness of the population (Schmitt et al., 2023).

Understanding individual motivations to share data or not is challenging, as different individuals may assign varying levels of importance to certain objectives, and the interpretation of fairness can differ. While there is no definitive explanation of what constitutes *fair* data sharing from citizens' perspectives, ethical and personal variations in perception exist. For instance, some individuals may associate fairness with the level of control they have over their data, while others may also seek clear models for benefit sharing and equitable distribution of research outcomes (*Engaged Genomic Science Produces Better and Fairer Outcomes*, 2021; Shabani, 2022). This topic refers

to what was said above about the positive impact of public data used by big companies.

Private entities are exploring models that offer financial incentives for data sharing, while the public sector is more cautious about adopting such approaches (Shabani, 2022). If the benefit for the population should be considered in the studies using this data, this concept is also very vague and the importance to obtain this data for research and to foster EU sovereignty in the global market is crucial. Researchers say that "[t]he drafters of the EHDS regulation have a difficult task ahead, navigating the existing legal complexities related to consent requirements and uncertainties regarding the concept of scientific research for the public interest"(Shabani, 2022).

Overall, based on the data collected, every actor in this system, seem to have a huge reason to be interested in the creation and enforcement of the European Health Data Space. The secondary use of health data would significantly "improve health policies, research and innovation in Europe" (Schmitt et al., 2023), bringing a betterment of the national healthcare and of the EU one, possibly on the way to federated healthcare. It is crucial for making advancements in disease prevention, detection, and treatment, as well as for making informed decisions based on evidence to enhance healthcare systems. In cases of crises, systems like this are extremely helpful, but they should not be forgotten their usefulness in routine administration, such as the ageing population and the cure of cancers or rare deceased patients[36]. With the Austrian population, and more generally the European one, growing old, the need to create a proper data-driven plan to safeguard public health is high. For what concerns individuals with rare diseases data aggregation would be essential to better understand the disease itself and develop a proper treatment (Wessel et al., 2022). However, it is the Proposal itself explains that these cases are exactly the ones in which data aggregation (and anonymisation) is less efficient since the scarce number reduced the possibility to preserve the privacy of the patients while maintaining the meaningfulness of data (p.41) (*Proposal for a REGULATION OF THE EUROPEAN*

[36]On the other hand, their risks have to be acknowledged and prevented since the government access to data, even anonymised, can present dystopic scenarios related for example to the recent laws against abortion in some European countries and the previous use of private data to enforce them in the US

PARLIAMENT AND OF THE COUNCIL on the European Health Data Space, 2022). Despite these problems, associations both on the medical and on the patient side are pushing towards the adoption of these measures (Das, 2022), on the example of a German cancer database.

The establishment of the European Health Data Space (EHDS) brings about complex interactions with existing and future EU laws such as the Data Act, GDPR, and DGA. While the EHDS proposal addresses some overlaps, there remains a substantial risk of unintended overlaps and incoherence (Vettorazzi, 2023). The establishment of a proper, coherent, policy framework, without overlaps or discrepancies among the norms, is an essential precondition to the enforcement of this useful tool. For the effective implementation of the EHDS, collaboration between national governments and the EU is crucial. This requires the involvement of various bodies, including national governance mechanisms and support functions, national sectoral bodies for interoperability, and national sectoral bodies on data authorization. Last, at the EU level, the establishment of a body on secondary health data, represented by the EDIB (mentioned in Chapter 4.1), is necessary (*COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the Document PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space*, 2022).

Central in the enforcement of the EHDS is also the creation of adequate safeguarded measures. However, this alone is insufficient without comprehensive and up-to-date digital literacy campaigns, specifically targeting the EHDS. Building trust in the infrastructure and clarifying its objectives will encourage individuals to willingly share their aggregated and anonymized data securely. Trust-building processes take time, and therefore the EU should not delay (Schmitt et al., 2023). Some patient associations propose to introduce the possibility to see who is accessing data too (Karacic, 2022). The right to choose must be clearly explained and effectively enforced. The opt-out mechanism, proposed in the revised draft of February 2023[37] should be properly implemented to enable individuals to exercise their data sovereignty appropriately. An exemplary model in this regard is ELGA, which offers three opt-out options.: “

[37] see 5.1, Opt-in, opt-out

- *General opt-out*: No participation in ELGA
- *Partial opt-out*: No participation in a particular ELGA application, e.g. eMedication
- *Case-specific opt-out*: No participation in ELGA only regarding a particular case/treatment." (Milieu Ltd & Time.lex, 2014).

In conclusion, the European Health Data Space (EHDS) is a healthcare-specific ecosystem that encompasses regulations, standardized practices, infrastructures, and a regulatory framework. It provides a secure and trusted environment for the exchange, use, and reuse of electronic health data, addressing the challenges associated with data access. By facilitating secure access to high-quality data at reduced costs, the EHDS promotes data-driven advancements in healthcare. It serves as a viable solution to enhance data access and utilization, fostering collaborative research, innovation, and evidence-based decision-making in both the private and public healthcare sectors.

In the Austrian context, the potential enforcement of the European Health Data Space (EHDS) aligns with existing infrastructure and practices. Austria maintains good practices in data management, including data registries on medicinal products and healthcare devices, a secure research data access platform, and adherence to health data standards. Key actors in Austria, such as governmental bodies, healthcare providers, and researchers, have specific interests in ensuring data security, privacy, and interoperability. They also seek to leverage the EHDS to advance research, improve healthcare outcomes, and facilitate cross-sector collaboration for the benefit of the Austrian healthcare system and its stakeholders.

The key actors involved in the potential enforcement of the European Health Data Space (EHDS) include national governments and the European Union, which form the foundation for the success of the initiative. Assuring in particular, according to the group of action *Towards the European Health Data Space*, 4 points:

> "i) data governance should ensure trustworthy health data exchange;
> ii) data must be of high-quality and interoperable;
> iii) technical infrastructures should allow safe data exchange; and finally
> iv) there should be mechanisms in place to involve and inform citizens about to the benefits of health data re-use" (Schmitt et al., 2023).

Additionally, individuals and companies hold significant importance within the EHDS framework. Individuals are directly impacted by the system and should be actively involved in its understanding and implementation. Companies, on the other hand, need to navigate the sharing mechanisms to create a fair market, safeguard intellectual properties, protect trade secrets, and simultaneously contribute to advancements in public health and their own profitability. These actors have interconnected interests that revolve around effective governance, support mechanisms, interoperability, and facilitating data access and sharing for research, innovation, and public health purposes. Due to their respective interests, all of these actors have in common the investment in the enforcement of the EHDS. Therefore it is essential to foster collaboration and alignment among them to ensure a unified effort towards achieving the goals of the initiative.

6
LIMITATIONS AND FUTURE RESEARCH

The research will have limitations that should be acknowledged in terms of its scope and focus. It will primarily concentrate on the Austrian landscape and may not encompass all aspects of the EHDS, especially the exquisitely legal and technical frameworks. Additionally, the legislative process regarding the EHDS was not deeply dissected, as the main focus is on understanding the actors, instances and implications within the Austrian context.

The focus of the research stays on SMEs just for what concerns the problem identification (*Chapter 3*). The potential of data spaces as a promising solution for SMEs to leverage big data is evident, yet the current state of the literature lacks exploration of this connection, and the references are limited in the grey literature too. This connection seems to be stated in the documents of the European Union[38] suggesting some facilitation to data access such as proportionate fees (Art. 42 (4)) but does not have adequate feedback on the quantity and quality of papers produced. However, the problem of data access is shared by SMEs with researchers, policymakers and bigger enterprises. Given the strong interconnections between the actors, mapping the field involves identifying and understanding the perspectives and experiences of various stakeholders, including larger companies, government bodies, and civil society. These stakeholders often have overlapping or conflicting issues and interests within the medical sector. By mapping them, this research aims to facilitate the progress and development of the healthcare sector, taking into account the challenges and opportunities experienced by different stakeholders, as well as some issues of, for instance, ethics and bureaucracy.

Even acknowledging the existence of some data spaces, whose material was used to define crucial terms of the field of data spaces, the EHDS stays the primary interest of this research, and the analysis of its development and importance was prioritized. Examining the EHDS proposal and its annexes gave comprehensive insights into the

[38] Considering the 3rd policy option as the one they would benefit from the most but the least likely to happen, given the high of regulatory intervention (Impact Assessment) (Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space, 2022)

specificities of the health sector and understand some of the challenges and opportunities associated with implementing a data space in this context. Although official documents and publications are limited, other sources of information that shed light on data spaces and their applications were explored. White papers, research reports, and case studies from organizations, industry associations, and academic institutions that focus on data spaces or similar concepts were considered, along with relevant conferences, webinars, or panel discussions where experts discussed the EHDS and related topics. These alternative sources supplemented the information available in official documents and provided additional perspectives on data spaces. To overcome the lack of comprehensive information, experts and stakeholders of connected fields evaluated the different steps of the research. Their insights and practical knowledge filled gaps in the existing literature and provided more nuanced guidance on the issues related to the EHDS in their fields.

The study focuses on the Austrian landscape and its actors, in order to have a concrete and grounded understanding of the issues of enforcement. This may not fully capture the nuances and challenges that exist in other countries or regions. The findings and conclusions drawn from this research may not be directly applicable or generalizable to different contexts but are always considered as related to the actors of the country, which can be more or less knowledgeable on this topic than ones of the other places.

Additionally, the research primarily focuses on the issue of data access, relating this to aspects of data privacy, security, and governance as crucial to consider in the implementation of data spaces, this research does not extensively explore these topics extensively, but to understand how can they interrelate and have an effect on each other. The legislative process regarding the EHDS is only briefly touched upon, and the research does not provide an in-depth analysis of the current level of legislative development or potential legal barriers to implementation. Therefore, the legal and regulatory aspects of implementing the EHDS may require further investigation beyond the scope of this research.

Lastly, the methodologies employed, such as the analysis of the transdisciplinary research project, literature review, and the development of a Causal Loop Diagram,

have their inherent limitations. The findings and insights derived from these methodologies rely on the available literature, the quality of the sources reviewed, and the expertise and perspectives of the subject matter experts consulted. The results may be subject to biases, limitations in data availability, and the interpretive nature of qualitative analyses. It is essential to recognize these limitations when interpreting the findings of this research and consider them as opportunities for future studies to address and explore in more detail.

For future research, it is suggested the incorporation of parallel methodologies in the study of EHDS. Popular surveys and expert semi-structured interviews appear as compelling strategies that could enrich the qualitative research initiated in this paper, to have first-hand data, and more ground to the practitioners instead of the associations they are related to. Understanding better the popular perspectives and opinions is key in such a delicate topic as public health. For this reason, it would be interesting to consider double-checking with the population the important parts of this proposal that should be conveyed to increase digital data literacy and help citizens to exercise their rights while fostering healthcare. Regarding quantitative analysis, further studies with big data analysis and statistical investigation are needed to be applied to better control all the technicalities EHDS offer. Under a fast-paced technological development scenario the Internet of Things and artificial intelligence unleash potential capacities that need accountability, measurement and constant evaluation. These numerical investigations could shed light on improving the understanding that can be grasped from this tool. Social, economic and political advantages are directly pending from the proper understanding of the capabilities the 4th industrial revolution is yet to unleash.

Second, this paper encourages subsequent cross-country analysis of this phenomenon. Different countries, contexts and socioeconomic backgrounds are likely to construct a different performance than the one observed on these pages. Addressing the cultural factor and the hidden mechanisms societies utilised can create valuable anthropological knowledge. Different areas of the world recognise health and public health in different ways and this can highlight challenges and best practices to be shared.

Finally, this paper invites peer scholars and researchers to perform updates on this very research. Increasing the scope, the dimension and the time period in which this investigation takes place can build trends, patterns and strategic lines creating a movie, where now we have just a picture, or even taking counties that are further in this development as an example. Further research is especially required due to the mutable nature of the proposal, which is currently in the process of revision and creation of compromise texts, especially related to secondary use (*Proposal for a Regulation on the European Health Data Space | Legislative Train Schedule*, 2022).

7
CONCLUSION

In the field of healthcare, small and medium-sized enterprises (SMEs) in the medtech industry face challenges in accessing data. However, this issue extends beyond SMEs and affects various stakeholders in the healthcare sector. The European Union (EU) aims to address these challenges by implementing data spaces, which can potentially offer better solutions than traditional data lakes. The EU's focus on establishing a data space specifically for health is a significant step forward. This should be able to facilitate affordable data sharing not just for SMEs but for research in the private as much as in the public sector. The sharing of data itself in this context involves not only the public but also the private sector, asking all the actors to provide the health data in an interoperable and with *FAIR* principles[39]. However, the generic attention on the actors involved, their specific roles and the connections between them is translated into a vague understanding of the pivots that connect most of them.

Pandemics, health crises and biological risks, consequences of escalated disequilibrium suffered by the ecosystem we live in, shape a threat scenario that makes health the most relevant aspect of current events. Under these risks and menaces, it is crucial to recognize the opportunities that arise within this context, particularly in harnessing the potential of big data to tackle public issues. This will be clearly facilitated with the utilization of data spaces as intermediaries. Aligning with the aspirations of the European Union, experts, and a portion of the population, the establishment of a European Health Data Space represents a significant stride towards the realization of a federated health system. Data spaces are in fact an elaborated version of databases, more horizontal and with specific rules to facilitate data interoperability within and outside the sector. In there both data holders and data users are present, with interchangeable roles depending on the specific data involved. However, their creation, exempting the technical part, brings up some of the issues that every process of digitalisation and data aggregation could rise which collides with the incredible leverage brought to innovation by big data.

[39] Findability, Accessibility, Interoperability, and Reuse of digital assets (*FAIR Principles*, n.d.)

To carry on the analysis of the use of data for public health reasons, a holistic approach is presented covering three complementing methodologies. Transdisciplinarity concepts, a detailed literature and document review and a causal loop diagram are combined to make a clear understanding of the current situation. All the stakeholders' interests are taken into account to understand their thoughts and hope regarding the proposal for the EHDS. While doing so, a varied range of interests, lines of conflict and ethical dilemmas appeared crucial to be discussed during the pages covered. The main issues that rose from the documents and grey literature analysis match related to its implementation match with what was investigated (Schmitt et al., 2023).

As a result of this process, this thesis proposes the concept of EHDS as the next fundamental tool to tackle future challenges in the field. Incorporating the Austrian experience as a case study, the two crucial aspects of the implementation of this measure revolve around companies on one side and individuals on the other.
The former focuses on the relationship between SMEs and big enterprises in terms of the creation and use of data. Both actors consider necessary the possibility to comply easily with the laws, a thing that is at risk due to the overlapping with other EU legislation relevant to the field. Many actors have hopes for a stop to the over-regulation of the field. The EHDS is highly likely not the resolutive tool for this issue, but it will hopefully make rules and standards more clear and uniform. Data access, mentioned as central throughout the thesis for SMEs, seems on the good track to be solved, with better and easier access to the European data, specifically focusing on this very population.
The latter shows the connection between primary and secondary use, demonstrating that the key to success with secondary use is getting individuals all the information needed, and creating a secure environment in which they can trust. To achieve it, digital literacy is fundamental, and a work of education on this theme must be put in place as soon as possible by the EU and by the member states, possibly with the involvement of a sample of the target audience.

In conclusion, the establishment of a European Health Data Space (EHDS) holds great promise for addressing data access challenges in the healthcare sector. By implementing data spaces and fostering interoperability, the EHDS aims to facilitate

affordable data sharing, research collaboration, and innovation. To fully harness the potential of the EHDS, it is essential to address concerns, ensure compliance with data protection regulations, and prioritize individuals' rights and digital literacy. With careful implementation and effective data governance, the EHDS has the potential to drive transformative advancements in healthcare and enhance patient-centric care in the digital era.

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