Business Models and Organizational Readiness of Digital Health Companies in the context of the European Health Data Space

Helen Marie Schlarb

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Abstract

Title: Business Models and Organizational Readiness of Digital Health Companies in the context of the European Health Data Space

Author: Helen Marie Schlarb

The European Health Data Space (EHDS) Regulation fundamentally sets conditions on how digital health data is used and exchanged across borders in Europe, creating new opportunities for innovation and data-driven business models. This thesis examines how selected organizations in the European healthcare sector are preparing for the EHDS, as well as the emerging business models for monetization through interoperability in primary and secondary use.

Based on interviews and a focus group, this study analyzes governance, strategies, and approaches to monetization. Results show that readiness varies widely and is viewed, by those with awareness, as a cross-functional task involving new structures and responsibilities. Uncertainty regarding implementation and timelines is holding back investments, with a current focus on monitoring and planning.

The thesis discusses data- and AI-based analysis and decision-making services, fee-financed HDABs, and interoperable digital health technologies for primary care. Monetization and scalability plans are just starting to develop, answering RQ1 on business models for interoperability. By proposing an EHDS Maturity Matrix for Companies that illustrates the different degrees of EHDS regulation preparedness displayed by companies and that could complement other maturity model work undergoing in EC-funded projects, the thesis answers RQ2 on the organizational and strategic steps companies are taking. Finally, a set of recommendations for companies, policymakers and associations is outlined.

Keywords: *European Health Data Space, EHDS, Business models, Organizational change, Digital health, EEHRxF*

Sumário

Título: Modelos de negócio e preparação organizacional das empresas de saúde digital no contexto do Espaço Europeu de Dados de Saúde

Autora: Helen Marie Schlarb

O Regulamento relativo ao Espaço Europeu de Dados de Saúde (EEDS) estabelece as condições para a utilização e troca transfronteiriça de dados digitais de saúde, criando oportunidades para a inovação e novos modelos de negócio. Esta tese examina a preparação do setor europeu da saúde para o EHDDS e os modelos de negócio emergentes para a monetização através da interoperabilidade.

Com base em entrevistas e num grupo de discussão, este estudo analisa a governação, as estratégias e as abordagens à monetização. Os resultados mostram que o grau de preparação varia e é visto como uma tarefa multifuncional. A incerteza quanto à implementação e aos prazos está a travar os investimentos, com um foco atual na monitorização e no planeamento.

A tese aborda serviços de análise e tomada de decisões baseados em dados e IA, HDABs financiados por taxas e tecnologias de saúde digitais interoperáveis para cuidados de saúde primários. Os planos de monetização e escalabilidade estão numa fase incipiente. A tese propõe uma Matriz de Maturidade das Empresas para o EEDS. Este estudo poderia complementar outros trabalhos sobre modelos de maturidade em curso em projetos financiados pela CE. Por fim, é delineado um conjunto de recomendações para empresas, decisores políticos e associações.

Palavras-chave: Espaço Europeu de Dados de Saúde, EEDS, Modelos de negócio, Mudança organizacional, Saúde digital, EEHRxF

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List of abbreviations

AI	Artificial Intelligence
APIs	Application Programming Interfaces
B2C	Business-to-Company
B2N	Business-to-Network
CDA	Clinical Document Architecture
CIPL	Centre for Information Policy Leadership
DHTs	Digital Health Technologies
EEHRxF	European Electronic Health Record Exchange Format
EHDS	European Health Data Space
EHR	Electronic Health Record
EU	European Union
FHIR	Fast Healthcare Interoperability Resources
FG	Focus Group
HDABs	Health Data Access Bodies
I	Interview
IT	Information Technology
R&D	Research and Development
RQ	Research Question

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1 Introduction

With the introduction of the European Health Data Space (EHDS) Regulation, the European Union is establishing a common framework for using digital health data across national borders (Ganna et al., 2024; Regulation (EU) 2025/327, 2025). By distinguishing between primary use for patient care and secondary use for research and policy, the regulation aims to enable more data-driven, integrated healthcare while protecting patient rights (Rodríguez-Mejías et al., 2024). The EHDS also aims to promote innovation and new digital health services by establishing interoperable electronic health records and cross-border data exchange (Da Silva Carvalho et al., 2025; Lewerenz et al., 2024). In this context, the question of how healthcare organizations are preparing for the new regulation and what business models relating to interoperable health data could emerge for related companies is becoming relevant.

The EDHS will have far-reaching consequences for companies and organizations in the healthcare sector across the EU, and these consequences will extend beyond technical adjustments (Donia & Marelli, 2025; Svingel et al., 2025). In addition to implementing new standards, such as European Electronic Health Record exchange Format (EEHRxF) and Fast Healthcare Interoperability Resource (FHIR), the main question is how to change interoperability within organizations while delivering strategic benefits (Da Silva Carvalho et al., 2025; Martins et al., 2025). Initial analyses show that interoperable data spaces have the potential to innovate and provide data-based services. However, these analyses often remain at a conceptual level, ignoring the concrete preparations required by companies (Svingel et al., 2025).

The existing literature on digital health systems and interoperability primarily focuses on technical architectures, regulatory conditions, and emerging use cases (Hodapp & Hanelt, 2022; Martins et al., 2025). Moreover, there is limited knowledge about the business models currently being pursued or prepared in the context of the EHDS and how they differ in key areas such as monetization.

Accordingly, this thesis seeks to achieve two objectives. First, emerging EHDS-related business model approaches and monetization logics in the primary and secondary use of health data, describing them within established business model frameworks are analyzed (Dupont et al., 2017; Ojala, 2016; Osterwalder & Pigneur, 2010). Second, the process how selected companies

and organizations in the EU are preparing for the EHDS from an organizational standpoint is examined (Centre for Information Policy Leadership; AvePoint, 2016, 2018; Svingel et al., 2025). As such two main research questions (RQs) are advanced:

RQ1: Which business models could enable companies to monetize their investments in health data interoperability in the European Health Data Space?

RQ2: What concrete organizational and strategic steps are companies already taking to prepare for the European Health Data Space (EHDS)?

2 Background

2.1 The European Health Data Space: Background and Objectives

The European Health Data Space regulation, which came into force on March 26, 2025, establishes a coherent regulatory and technical foundation for the cross-border transfer and use of digital health information within the European Union. The regulatory framework conceptually differentiates between two forms of use: the direct use of patient data for immediate medical care on the one hand, and the secondary use of anonymized data sets for scientific, political, and regulatory purposes on the other. Furthermore, it establishes a single market for EHR systems (Electronic Health Record Systems) that meet specific requirements, such as interoperability, to ensure both primary and secondary use. By standardizing electronic patient records and promoting interoperability, the initiative promises to deliver economic benefits, including cost savings, growth in the digital health sector, and sustainable improvements in the quality of treatment for European citizens (Regulation (EU) 2025/327, 2025). All in all, the EU promises savings of €11 billion over the next 10 years and a 20-30% expansion of digital healthcare (European Commission, 2025a).

2.2 Primary Use of Health Data

The EDHS fundamentally changes the way in which patients control their personal health data. Access to their own data is rendered more straightforward, and patients accrue greater influence over the availability and utilization of their personal information. Patients have the capacity to add entries, adjust authorization according to their preferences, and report errors in the data for correction (Regulation (EU) 2025/327, 2025). Adjustments can then be made online according

to the patient's preferences (European Commission, 2025b). Due to varying degrees of maturity in the standardization of health data, the eHealth Network has identified certain data categories as priorities for the implementation of access and exchange given their relevance among most care situations. This includes patient summaries, digital prescriptions, and dispensing of medicines, which are set to be available across the EU by March 2029. Other types of data such as medical imaging, laboratory results, and discharge reports are scheduled for integration by 2031 due to their complexity (Regulation (EU) 2025/327, 2025). The format serves as the basis for the technical specifications, which are defined and regularly updated by the Commission to incorporate new coding systems or healthcare requirements (Lewerenz et al., 2024). Privacy and data protection are essential in this context. The ability to access relevant health information quickly is especially beneficial for medical professionals, no matter where they are. In the European context, this has the effect of reducing bureaucracy, facilitating interdisciplinary collaboration, and laying the foundation for better treatment processes (Regulation (EU) 2025/327,2025).

MyHealth@EU is being created as a central interoperability platform to implement primary use and ensure the exchange of health data. This will provide healthcare professionals with access to patient data. Each EU country must designate a national contact point connected to MyHealth@EU that is responsible for the technical and organizational aspects of digital health data. All national contact points are connected to each other and to the platform. However, MyHealth@EU will not serve as a central repository for all patient data. Instead, it will act as an interface between different countries, transferring requested data on a point-by-point basis to the respective country. The European Commission will determine and publish the exact technical implementation by March 26, 2027 and will also clarify how personal health data will be protected, what security measures must be taken, and what conditions the contact points must meet (European Commission, 2025; Regulation (EU) 2025/327, 2025).

2.3 The European Electronic Health Record Exchange Format (EEHRxF)

In order to ensure interoperability for electronic health data exchange in the EHDS and via MyHealth@EU, the European Electronic Health Record Exchange Format (EEHRxF) will provide the foundation (Regulation (EU) 2025/327, 2025). Designed to facilitate data transfer between EU countries, this format is particularly detailed and modular (Regulation (EU) 2025/327, 2025). It consists of harmonized data sets, clearly defined data structures, and consistent medical coding systems, allowing variable clinical content and additional

components to be mapped flexibly and consistently (Da Silva Carvalho et al., 2025; Regulation (EU) 2025/327, 2025). The technical specifications cover both structured and unstructured representations, so that image data, texts, and laboratory reports, for example, can be included and transmitted securely (Lewerenz et al., 2024; Regulation (EU) 2025/327, 2025). One special feature of the format is its machine-readable design. Therefore, automatically read and exchanged data is enabled between different software systems, medical devices, and healthcare providers, eliminating the need for user intervention (Da Silva Carvalho et al., 2025; European Commission, 2025b; Regulation (EU) 2025/327, 2025)

2.4 Secondary Use of Health Data

Within the framework of the EHDS, secondary use of health data refers to the use of data originally collected for treatment purposes for research, innovation, policy-making, and regulatory tasks (Regulation (EU) 2025/327, 2025). For healthcare professionals, this implies faster system-independent access to relevant patient data, even across national borders. Scientific research is enhanced by the availability of larger and better-prepared data sets, as well as guaranteed clear access. Authorities are granted superior prospects for the surveillance and development of the healthcare system in a targeted manner, founded on the data collected, thus further reinforcing patient safety. Companies and innovation drivers also benefit, as Europe-wide standardization and the provision of comprehensive, anonymized data sets facilitate market access and promote the development of new solutions. (European Commission, 2025a; Regulation (EU) 2025/327, 2025)

The secondary use of health data offers many advantages. In clinical studies, the control group is often homogeneous and does not represent the general population. Moreover, the secondary use of data in the EHDS can, in the best case, address this issue (Ganna et al., 2024; Pizzamiglio, 2024). Additionally, combining health data from different countries and population groups can generate diverse data sets that facilitate research (Ganna et al., 2024). This should enable the EU to remain competitive at the global level (Svingel et al., 2025). The provision of research data within Europe increases its attractiveness to innovation-oriented companies and researchers (Ganna et al., 2024). This creates favorable conditions for groundbreaking developments such as digital health applications and artificial intelligence and reduces the risk of Europe falling behind other important markets (Baumgart & Kvedar, 2025; Cervera De La Cruz et al., 2025; Ganna et al., 2024). In the European healthcare context, data-based ecosystems are becoming increasingly important as they enable innovation and new service

offerings by connecting different stakeholders (Huettemann et al., 2024; Pizzamiglio, 2024). In contrary to traditional value chains, these ecosystems depend on healthcare data being open, interoperable, and provided within clear governance structures (Firouzi et al., 2022). The current EU study on open data emphasizes that economic and social added value can only be realized if all stakeholders, from public institutions to innovative start-ups, are empowered to share data and develop services through sustainable platforms and partnerships (Pizzamiglio, 2024). Such ecosystems create space for data-driven services, facilitate the development of new digital health offerings, and contribute significantly to exploiting the full innovation potential of using Health Data in Europe.

2.5 Governance: EHDS Board and Health Data Access Bodies (HDABs)

The European Health Data Space (EHDS) Board, established under Article 64 of the regulation, acts as a central body for Member State cooperation on data governance. As per Article 65, it is chaired by the European Commission, it includes representatives from digital health authorities and health data access bodies, focusing on the consistent application of rules and providing technical guidelines. Overall, this board plays an essential role in ensuring consistent implementation of the regulation (Lewerenz, 2026).

The appointment of Health Data Access Bodies (HDABs) by the EU is a key factor in realizing the secondary use of health data (Regulation (EU) 2025/327, 2025). The main function of these institutions is to regulate and manage data. HDABs are public institutions responsible for reviewing applications for the use of health data. It is essential to ensure that access to this data is restricted to legitimate purposes, such as science, innovation, policy-making, or public health (Regulation (EU) 2025/327, 2025; Svingel et al., 2025).

Furthermore, the access bodies are authorized to charge fees for their activities to cover the costs incurred. These fees are determined based on proportionality, transparency, and justification (Regulation (EU) 2025/327, 2025). In addition, differentiation of fees is permitted, for example by granting discounts to small and medium-sized enterprises, researchers, or public institutions. Higher fees are charged for requests that require increased processing effort. The access bodies invoice the collected fees centrally and where applicable, pass on a share to the health data holders. Further, the European Commission is authorized to define guidelines for a common fee policy and harmonization at the European level. Moreover, all EU citizens reserve

the right to object to or approve the secondary use of their health data at any time (Regulation (EU) 2025/327, 2025).

2.6 Interoperability in the EHDS

Interoperability is essential for ensuring successful implementation of the EDHS. The term interoperability refers to the capacity of two or more systems to share and process data with each other (Hodapp & Hanelt, 2022). In the context of the EDHS and in general when considering a care model that goes beyond the conventional inpatient healthcare system, interoperability and rapid access to health data are extremely important (Dupont et al., 2017). Accordingly, there are two types of interoperability. On the one hand, the original concept of syntactic interoperability is defined as the capacity for two systems to transfer data within a specified format. On the other hand, semantic interoperability, is specified as the capacity of systems to not only swap data, but also to interpret and analyze it independently (Reis et al., 2017; Tabari et al., 2024).

2.7 Interoperability as a Driver of Innovation and Business Models

Interoperability promotes innovation by enabling different virtual and analogue systems to interact (Hodapp & Hanelt, 2022). When systems can smoothly exchange and understand information, new opportunities arise to combine and further develop products and services. Especially in digital ecosystems where diverse players work together, interoperability creates the conditions for flexible and modular solutions that can be continuously adapted and expanded. Other points are reduced market entry barriers and lock-in effects, allowing companies to draw on new ideas and complementary offerings, thereby accelerating innovation and making it scalable in many ways (Hodapp & Hanelt, 2022).

Consequently, this connection is particularly evident in data-intensive fields of application in the healthcare sector, such as AI, healthcare communication, studies, and cross-border care (Lehne et al., 2019). Interoperable data infrastructures enable the realization of this potential in the form of improved diagnostics, personalized therapies, and efficient care processes (Lehne et al., 2019). In artificial intelligence and big data, interoperable data infrastructures enable the consolidation of large, high-quality data sets on which reliable models can be developed. Furthermore, in medical communication, interoperability contributes to consistent information exchange between different service providers along treatment pathways (Lehne et al., 2019). Moreover, interoperable access to routine data opens new possibilities for large-scale studies

and real-world evidence in research. Interoperability is also essential for cross-border care and international cooperation because of enabling the sharing of health data across system boundaries (Lehne et al., 2019). At the same time, the literature makes it clear that developing interoperable ecosystems involves areas of tension. For example, there is conflict between standardization and differentiation, as well as between openness and control. This makes governance issues central (Hodapp & Hanelt, 2022).

To sum up, interoperability in the EHDS enables companies to use a variety of new approaches from which they can generate benefits for themselves. A variety of business models emerging in connection with the interoperability of systems are characterized by the monetization of data and data-driven services (Yaraghi, 2015). The following analysis focuses on dividing the models examined in this thesis into categories according to stakeholders and type of value creation.

2.8 Business Models and Digital Health

Business modeling is understood as a central management task in general management literature. Teece describes business models as the conceptual architecture of the mechanisms through which a company creates, provides, and extracts value, emphasizing that innovations cannot be effectively brought to market or commercially exploited without a viable business model (Teece, 2010). Nevertheless, van Limburg et al. argue that many eHealth technologies fail not because of technical shortcomings, but rather due to a lack of implementation strategy, unclear financing and governance structures, and insufficient integration into existing care processes. Business modeling is therefore understood as a value-oriented, participatory process in which stakeholder needs are identified early on and translated into viable implementation and sustainability concepts (Van Limburg et al., 2011). Current work on digital business models in healthcare emphasizes that digital solutions operate in multi-sided, platform-based ecosystems that must capture value (Schiavone et al., 2021; Thanekar & Chaltikyan, 2025). This management and ecosystem perspective clarifies that digital health solutions require new technologies and changed approaches to value creation and stakeholder relationships. In consequence, this may be particularly relevant in the case of the EHDS.

In their 2023 bibliometric analysis and systematic literature review on business models and digital health, Pascarelli et al. examined key components of business models within the digital

health context (Pascarelli et al., 2023). The authors focused on the approaches of Osterwalder and Pigneur, as well as the model developed by Ojala based on these approaches.

As stated by Osterwalder and Pigneur, a business model is a logical structure through which an organization creates and captures value for specific customer groups (Osterwalder & Pigneur, 2010; Pascarelli et al., 2023). To make this logic tangible, many authors use condensed frameworks that break down complex business realities into a few core dimensions. In this context, Ojala distinguishes four main components: First, the value proposition describes an organization's underlying value promise. Second, value capture focuses on revenue. Third, the value network looks at the actors involved and their relationships. Lastly, value delivery encompasses the activities and resources through which the value proposition is implemented (Ojala, 2016; Pascarelli et al., 2023).

The systematic literature review by Pascarelli et al. clearly shows that digital health business models can be structured according to the four components defined by Ojala (Ojala, 2016; Pascarelli et al., 2023). Many digital health solutions aim to improve coordination between stakeholders, increase continuity of care, and improve health outcomes through personalized, data-driven interventions while reducing physical contact at the value proposition level. Regarding value capture, the authors identify subscription, pay-per-use, pay-for-performance, freemium, and data-driven revenue models. Also, the authors refer to the work of Marcos-Pablos et al., who identified four different business models. The value network is characterized by a multilayered stakeholder structure in which insurance companies, technology providers, research institutions, governments, intermediaries, and patients and service providers all play a role. Finally, value delivery encompasses activities throughout the entire life cycle, requirements analysis, co-design with users, clinical validation, integration into existing infrastructures, operation, data management, and training (Pascarelli et al., 2023).

The following section examines possible business models in the context of the EHDS in more detail, based on the framework and the four dimensions proposed by Ojala (2016). As a result, this allows for a systematic consideration of potential data-driven models of secondary use and technology- and service-oriented models of primary use (Pascarelli et al., 2023). Business models that could potentially emerge within the EHDS differ in terms of their value proposition and value capture logic. However, recurring patterns can be identified in the value network and value delivery (Ojala, 2016; Osterwalder & Pigneur, 2010).

To begin with, HDAB-related approaches can be understood as administratively oriented infrastructure models whose revenue logic is primarily based on cost-covering fees to ensure neutral, legally compliant data access (Regulation (EU) 2025/327, 2025). Subsequently, interoperable data sets are used to develop and market analytical value-added services and predictive models (Firouzi et al., 2022; Marcos-Pablos et al., 2019). Moreover, EHDS-related business models include digital health technologies for primary use whose value proposition aligns with traditional digital health objectives, such as increased efficiency, improved outcomes, and novel care methods (Pascarelli et al., 2023). The upcoming analysis addresses these distinctions and classifies the identified potential business model types along four dimensions (Ojala, 2016).

2.9 AI- and Data-Driven Business Models in the EHDS (secondary use)

As stated by Firouzi et al., there are three approaches that companies can take to monetize data. The first approach is sharing data assets, which involves selling raw data that buyers can use for analysis, research, or research and development (Firouzi et al., 2022).

2.9.1 HDABs Fee Model

In the case of the EHDS, the HDABs carry out this monetization. As previously described, the HDABs are the access points to health data for secondary use. These bodies, appointed by member states, receive remuneration to cover costs for processing, anonymization, pseudonymization, and governance. Thus, a form of monetization at the administrative level is created, to ensure a sustainable infrastructure for secure, legally compliant data access (Regulation (EU) 2025/327, 2025). Further economic profit-seeking, such as profiting from the sale of data, is not the intention of HDABs. Instead, the remuneration structure preserves neutrality and public interest and ensures that access to health data is not impeded by unreasonably high costs. The goal of this fee model is to ensure the sustainable financing of the necessary administrative and IT infrastructure without creating excessive barriers to research and innovation (Regulation (EU) 2025/327, 2025). Finally, the mentioned approach generates value through a cost-covering fee structure and is primarily shaped by public actors as infrastructure operators (Ojala, 2016).

2.9.2 Data Analytics Model

As described by Marcos-Pablos et al., various data-based business models in healthcare demonstrate the added value and diversity of monetizing large amounts of data, either through

business-to-network (B2N) models for research networks or business-to-company (B2C) methods to support clinical research and innovation. Building on this, another approach studied by Firouzi et al. is leveraging data analytics, which could be applied in the context of interoperability in the EHDS. One possible monetization method is selling advanced analytics and AI models. Large, interoperable health data collections could be used to develop new insights, predictive models, or AI algorithms, which could then be sold as services or products. This approach creates value for stakeholders and establishes data- and AI-driven business models as forward-looking in the digital health sector (Firouzi et al., 2022).

By accessing comprehensive, harmonized, and semantically interoperable data sets from different sources and countries, health data providers, AI developers, and research institutions can develop models that go beyond traditional forms of use. Advanced analytics products resulting from this process can be used for patient stratification, risk prediction, or diagnostic support. Consequently, these products can be offered as standalone services or embedded in other system landscapes (e.g., via APIs, platforms, or direct licensing models). The insights, analyses, and advanced analytics products can then be sold to a wide range of stakeholders, such as pharmaceutical companies, health insurance companies, public administrations, or healthcare service providers (Firouzi et al., 2022; Marcos-Pablos et al., 2019). Semantic interoperability plays crucial roles in combining heterogeneous data from different member states, making them analyzable and comparable. For this reason, compliance with harmonized coding systems and minimum specifications is essential. Only then can high-quality, meaningful AI services and models be developed and placed on the market (Firouzi et al., 2022; Marcos-Pablos et al., 2019). This means that data sharing approaches in the EHDS can be understood as data-based business models. The core benefit here lies in the provision of comprehensive data sets. Value is created through usage- and project-oriented access concepts supported by a network of research institutions and companies (Ojala, 2016).

2.9.3 Data-Driven Business Model

Another monetization approach promoted by interoperability in the EHDS is the data-driven business model (Firouzi et al., 2022). This model aligns with the European Union's goal of enabling the development of innovative products and services by providing access to large amounts of heterogeneous data (European Commission, 2025a). A key factor in its implementation is the availability of interoperable, standardized infrastructures that comply with data protection regulations and can be used by all relevant stakeholders. These

infrastructures can be created by the EHDS (Firouzi et al., 2022; Regulation (EU) 2025/327, 2025). Based on this newly created infrastructure, potentially entirely new and innovative business approaches can be developed. The data can be used as a basis for developing analytics or AI applications and integrating them as standalone tools into existing systems (European Commission, 2025a; Firouzi et al., 2022). In terms of the four dimensions of Ojala's business model, the EHDS's data-driven model can thus be characterized by a value proposition that focuses on the provision of large, harmonized data sets, value creation through interoperable data infrastructures and analytics capabilities, value capture through usage- and project-based access models, and a value network composed primarily of public data owners, research institutions, and private companies (Ojala, 2016).

2.10 Archetypes of Digital Health Technologies (primary use)

As previously described, the primary use of electronic patient data focuses on the direct healthcare provision for natural persons, EU citizens. Monetization approaches in this area are particularly focused on offering efficiency gains and selling interoperable technologies and services (Regulation (EU) 2025/327, 2025).

In the area of primary use of electronic health data, monetization approaches focus on digital health technologies (DHTs) and interoperable platforms that provide immediate benefits for patients, service providers, and other stakeholders. In addition to the pure distribution of compliant EHR systems and DHTs, whose added value is generated through the market launch and distribution of interoperable, secure systems (Regulation (EU) 2025/327, 2025; Weimar et al., 2025), differentiated archetypes can be identified according to Weimar et al. (2025).

A2 (“Insurer-to-Consumer Digital Therapeutics and Care”) stands for digital applications that are offered by insurance companies to their customers and focus on digital therapies or care services for specific clinical pictures (Weimar et al., 2025). Market approval and monetization of these models require a high level of evidence and recognition as a medical device, so that reimbursement is typically provided by health insurance companies. As a consequence, the primary target group is patients with economic benefits for both service providers and payers in the areas of prevention, therapy, and care management (Weimar et al., 2025).

Alternatively, the A4 (“Professional monitoring platforms“) archetype describes digital platform business models specifically designed to connect patients with healthcare providers for monitoring clinical conditions and tracking progress (Weimar et al., 2025). The central focus

of A4's is structured interaction, the platforms enable continuous digital communication and the exchange of administrative and medical information between patients, doctors, and nursing staff (Huettemann et al., 2024; Weimar et al., 2025). Real-time data exchange is crucial for these business models but is currently limited by the absence of technical standards (Lewerenz et al., 2024). Ideally, uniform standards created by the EHDS, MyHealth@EU and EEHRxF would allow this type of business model to expand even further. Both archetypes demonstrate that sustainable monetization and real innovation in digital health depend fundamentally on standardized, interoperable frameworks. Only then can all healthcare stakeholders fully realize the benefits of DHTs and platforms.

2.11 Organizational Preparedness

The introduction of the EHDS Regulation will present notable and variable challenges for all stakeholders in the healthcare sector, both in Europe and beyond. All companies in the healthcare sector, including vendors, healthcare providers, and networks, will have to undergo internal and external changes. National requirements for stakeholders in this area can vary greatly (Lewerenz et al., 2024; Regulation (EU) 2025/327, 2025). Simply being familiar with technical specifications is not enough; companies also need organizational readiness in terms of governance, resources, skills, and strategies (Kruszyńska-Fischbach et al., 2022; Weiner, 2009).

In order to prepare for the EHDS in a timely manner, companies must do more than be clear about the technical specifications. Organizational readiness and guidance in terms of governance, resources, skills, and strategies is required. Based on Carvalho et al., the entire health data ecosystem must collaborate to ensure timely compliance (Da Silva Carvalho et al., 2025). To understand how companies are adjusting to regulatory changes, it is helpful to examine the implementation of other EU regulations. With regard to the EU General Data Protection Regulation (GDPR), empirical literature sheds light on "compliance preparedness". The 2016/2017 work of the Centre for Information Policy Leadership (CIPL) and AvePoint shows that organizations respond with a combination of governance adjustments. The study aimed to record the approach, implementation status, and benchmarks for internal change and implementation programs for the new regulation (Centre for Information Policy Leadership; AvePoint, 2016, 2018). Key findings regarding systematic preparation were the emergence of change management programs. These programs focused on cross-departmental management, for instance, through steering committees established by third parties within companies. In 58%

of the companies, the initiative mainly came from the legal department, while compliance and IT were cited as the driving forces in 41% of cases (Centre for Information Policy Leadership; AvePoint, 2016).These changes included establishing or expanding data protection programs, appointing data protection officers, creating new processes for data breaches and international data transfers, and allocating additional budgets and personnel for compliance activities (Centre for Information Policy Leadership; AvePoint, 2016, 2018).

Current EU projects are already addressing these considerations for organizational preparation and developing appropriate assessment tools. To give an example, the XpanDH project (https://xpandh-project.iscte-iul.pt) describes a Readiness Model for Organizations and a Readiness Model for Vendors that assess the maturity level of healthcare facilities and providers with regard to the use of the EEHRxF (Sá et al., 2024). The focus is on both technical and organizational aspects, such as understanding the EEHRxF specifications, evaluating market readiness, internal processes, and training and qualification needs. The aim of these approaches is to gradually introduce healthcare organizations, professionals, and technology providers to the format and to systematically identify necessary development needs (Sá et al., 2024).

3 Methodology

3.1 Research Design

This research took a qualitative exploratory approach to examine the organizational preparation and business models of stakeholders in the context of health data interoperability in the European Health Data Space and to assess how ready these stakeholders are for this transformation. Qualitative research offers the opportunity to analyze complex processes, individual perspectives, and organizational cultural dynamics in detail.

Furthermore, qualitative research is particularly well suited in such early phases of major regulatory projects for gaining an in-depth understanding of the interpretative patterns, challenges, and decision-making logic of various stakeholders (Bryman, 2016; Moser & Korstjens, 2018). Semi-structured expert interviews make it possible to capture individual and organization-specific perspectives on processes of preparation, uncertainty management, and strategic orientation in view of the lack of standardization and operational routines (Bryman, 2016; Moser & Korstjens, 2018).

3.2 Sampling

A total of approximately 160 individuals from 60 companies were contacted. They were approached via email, LinkedIn, and a medical trade fair MEDICA (https://www.medica-tradefair.com). In the second step, the companies were categorized as follows: healthcare providers and authorities (n = 8); pharmaceutical and life science companies (n = 7); large MedTech and health IT manufacturers (n = 7); health IT vendors and digital solutions (n = 22); associations and networks (n = 8); and professional services and consulting (n = 9). The companies were from 16 different EU countries and two non-EU countries.

Sixteen people responded, several of whom stated that they had not yet had any contact with the EHDS or were unfamiliar with the regulation. Others pointed out that these matters were confidential and should not be disclosed to external parties. In the end, only two people were willing to participate in the interviews.

Due to the small number of expert interviews conducted, the work design was supplemented with a qualitative research approach using focus group technique. Focus groups provide an opportunity for organized discussions among different participants, often coming from different backgrounds, bringing together various perspectives and experiences (Powell & Single, 1996). They enable effective exchange with a wide range of stakeholders, particularly when dealing with complex issues that require consideration of a variety of variables (Powell & Single, 1996). Unlike interviews, participants can respond to each other's views and engage in a dialogue (Tausch & Menold, 2016). To provide sufficient space for everyone to engage in active discussion, it is recommended that groups consist of six to ten participants (Gibbs, 1997; Powell & Single, 1996).

A variety of EU project networks were leveraged to recruit focus group participants. These projects are developing the EEHRxF, among other objectives, and are actively preparing for the EHDS. This included the email distribution lists of the i2X (www.uphillhealth.com/i2x), xShare (www.xshare-project.eu), and XiA (www.xia-project.iscte-iul.pt). These consortia facilitate collaboration among a diverse group of stakeholders, including health IT vendors, academic partners, healthcare providers from diverse EU member states, and companies based outside the EU that operate within the European healthcare market. Through their active involvement in these projects, all affiliated organizations have practical experience and in-depth knowledge of issues relating to interoperability and regulatory requirements surrounding the

EHDS. This ensured that the focus group participants were not only technically qualified, but also closely involved in current developments in terms of content. A total of approximately 260 people were contacted, of whom ten participated.

ID	Category	Country
Interview		
I_P1	Vendors / digital solution providers	France
I_P2	Vendors / digital solution providers	Germany
Focus Group		
FG_P1	Vendors / digital solution providers	Netherlands
FG_P2	Vendors / digital solution providers	Germany
FG_P3	Vendors / digital solution providers	Greece
FG_P4	Associations / networks	Denmark
FG_P5	Vendors / digital solution providers	Portugal
FG_P6	Vendors / digital solution providers	Spain
FG_P7	Associations / networks	Belgium
FG_P8	Vendors / digital solution providers	Greece
FG_P9	Associations / networks	Spain
FG_P10	Vendors / digital solution providers	Portugal

Table 1: Participant Overview

3.3 Data Collection Interview

Data collection for the interviews is carried out through semi-structured, guided expert interviews with selected stakeholders. The methodological approach provides for continuous development of the interview guide during the work to be able to respond flexibly to new findings, topics, and sub-concepts (Moser & Korstjens, 2018).

Considering the previously analyzed literature on data preparation and business models, four main topics were identified to form the basis of the interview guide (Corbin & Strauss, 2015). For each topic, two subject areas were identified, and open-ended questions were formulated based on them, which allows the interviewees to describe their experiences as freely as possible (Corbin & Strauss, 2015; Tong et al., 2007).

The interviews were conducted remotely via Microsoft Teams (https://teams.live.com/free) and lasted between 20 and 45 minutes. Consent for recording and data collection was obtained verbally at the start of each interview. The language of the interviews was adjusted to the participants' preferences and took place in either English or German. A requested interview guide was provided if needed in advance. Figure 1 summarizes the overall structure of the data collection process, including the derivation of topics and questions. With the participants' consent, the interviews were recorded and transcribed.

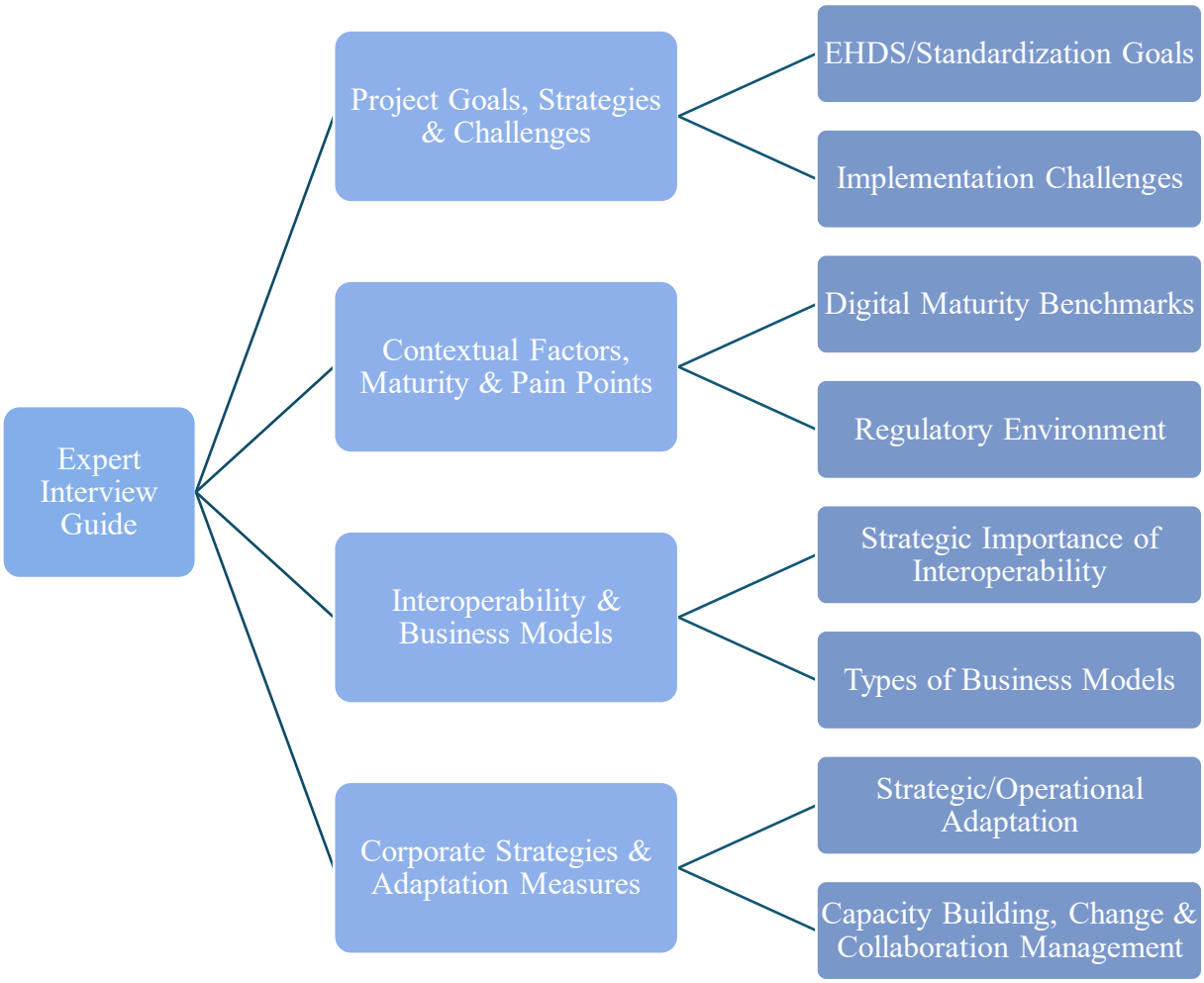

Figure 1: Structure of the Expert Interview Guide

3.4 Data Collection Focus Group

Like the interviews, the focus group was carried out online via Microsoft Teams and was scheduled to last two hours. At the beginning of the meeting, the participants provided their consent for the recording and data collection to be conducted via Microsoft Teams. The session

was audio-recorded, and participants were asked to respond to the questions via the menti.com platform during the initial minutes of each question. Therefore, it was possible to record the answers and perspectives, even in cases where the participant did not express themselves verbally. The answers were only released to participants after they had responded. Moreover, the responses of other participants could only be seen once the discussion round had started (Powell & Single, 1996).

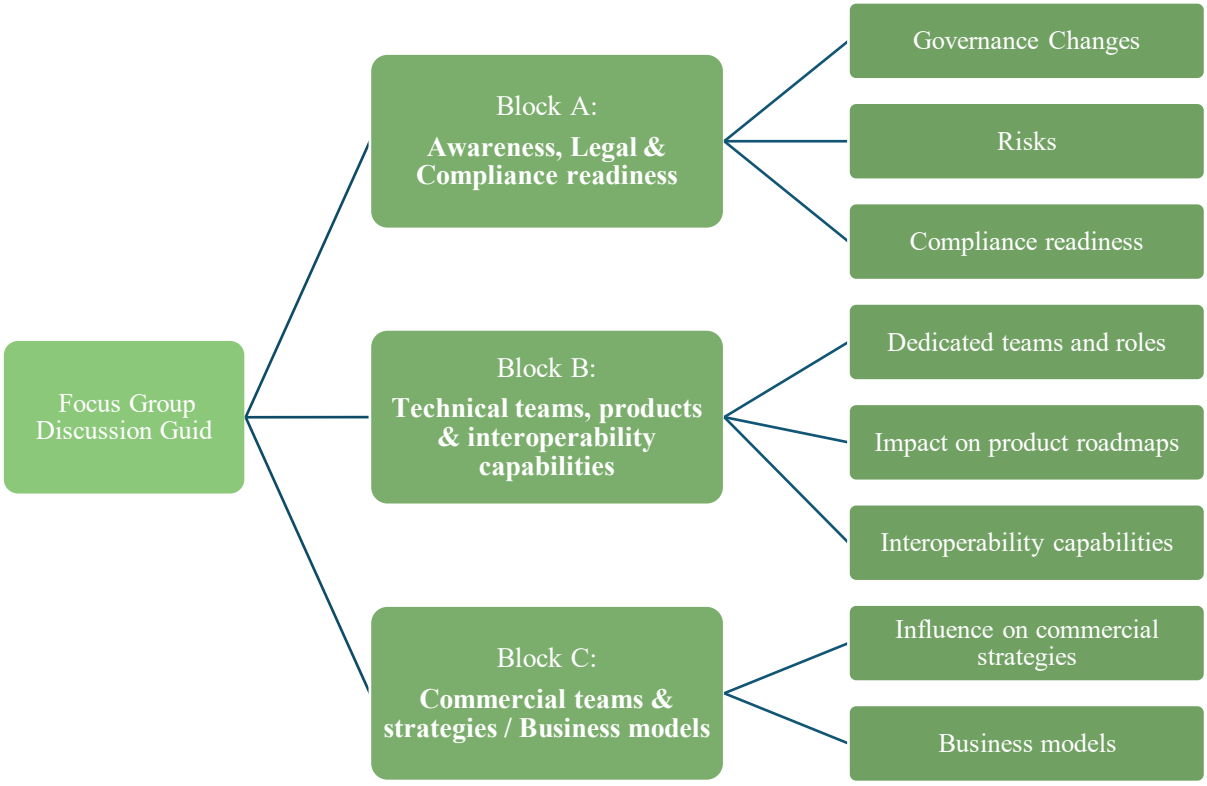

Figure 2: Focus Group Discussion Framework

4 Results

4.1 Governance

In terms of governance structures and the distribution of responsibilities, participants report a clear shift toward more formalized approaches preparing for the EHDS, although the specific arrangements vary between organizations. Some respondents described how specific committees and units had already been created to address the legal and organizational implications of the EHDS. Others mainly adapted their roadmaps and processes and expect structural changes to occur in the coming months. One company stated that an EHDS steering committee was formed about a year ago to serve as a central point of contact for EHDS-related issues. The respondent describes this as follows:

> "*[...] For a year now, we have had a steering committee up and running, and with this steering committee, we keep aligned with developments, such as assigning work to team members to assess the various documents that are released*" (FG_P2).

The interdisciplinary committee reflects different regions and functional areas.

> "*It is chaired by one of the clinical executives of our region, EMEA, and has about 10 people in it, mostly country managers, people from our legal department, people from our compliance department, people from our marketing team. ... We meet every second month on average*" (FG_P2).

Another organization created a new, specialized unit to specifically address EHDS and build capacity by participating in conferences and other exchange formats (FG_P10).

Moreover, a second line of adaptation involves changes to planning and decision-making processes rather than formal structures. Some participants report that corporate and product roadmaps have been aligned with EHDS requirements, and that European requirements are being linked to existing national regimes (FG_P1). Others emphasize that internal procedures will likely change but that this depends largely on the details of the EHDS regulation and how it relates to other regulations, such as the MDR: "*The procedures might change. Depend on the EHDS regulation and how it links to the MDR adjustments*" (FG_P5). At the same time, there is a noticeable reluctance to act as long as specifications are perceived as "*not mature yet*" and further clarification from the European Commission is pending. One person sums up this situation as "*Hesitation and waiting for clarification from EC. We know the task is ahead*" (FG_P4). Overall, this paints a picture in which EHDS-related governance changes are visibly

taking effect but proceeding at different speeds and depths, depending on the maturity of the specifications and the organizations' risk perception.

4.2 Risks

Similar points also emerged among the various participants when it came to risks. A notable factor that contributed to this situation was the ambiguity of the specifications that were available to date. The lack of concrete information and the need for further clarification at the EU and national levels creates uncertainty, which poses an overarching risk to all subsequent implementation steps. This uncertainty and the associated waiting period result in potential risks across various areas. This phenomenon reveals a complex risk landscape that limits the ability of stakeholders to prepare for EHDS compliance.

The barriers in this case are more practical in nature and mostly affect implementation rather than being due to a lack of awareness of the regulatory objectives. This applies to both secondary use and primary use. The participants identified several critical risk categories, with governance risks in the secondary use of data emerging as a concern. The absence of provisions on the part of the EU introduces a degree of flexibility and, consequently, ambiguity regarding infrastructure requirements and the function of national access points in the provision of research data.

> " *[...] our understanding so far is that currently it gives us a good freedom and flexibility how to handle this, but this is on the same time very challenging. [...] How to deal with the infrastructure about the secondary use of data and give access to the research? What will eventually happen with the national authority and bodies that will help with this?*" (FG_P1).

Other participants expressed concerns about the definition of EHR systems. Without specific guidelines on the systems' format (FHIR or CDA), the implementation process will be hindered. As FG_P4 noted, "*that's questions we've been asked by all the vendors*". This results in significant time-related compliance risks for companies, as FG_P7 pointed out. The proposed two-year period (between March 2027 and March 2029) is seen as a significant challenge to ensuring compliance: "*these specifications because compliance will be awfully hard to achieve within two years*" (FG_P7). Additionally, interoperability and payment risks are becoming apparent. For example, national billing systems based on ICD coding are not yet compatible or EHDS-compliant (FG_P1).

Companies are caught between the knowledge that they need to act and the absence of specific technical requirements they can implement. Currently, this is leading to a prioritization of avoiding regulatory noncompliance over proactive technical implementation. Consequently, some organizations are opting to work on pilot projects, build knowledge, or adopt a passive role and wait and see.

4.3 Dedicated Teams

The concept of specialized teams and roles is interpreted differently by each company. Some organizations have established dedicated EHDS structures, while others work with roles and project-based approaches and are still building knowledge and capacity. This shows that dealing with EHDS-related tasks ranges from clearly institutionalized responsibilities to more informally assigned roles.

Several participants reported that their organizations have set up dedicated teams or units to address the EHDS regulation. In another case, the R&D department covers the EHDS topic through various specific projects, and compliance prioritizes these projects on a quarterly basis. This points to a programmatic, cyclical approach to the new requirements.

> "*We run[…] specific projects related to EHDS, unde[r] R&D activities, and the priorities per quarter are defined with that anchor under the compliance area*" (FG_P5)

However, it also became clear that not all organizations have integrated separate teams or are working on a project basis. Some rely on a model in which individuals analyze existing documents from different perspectives and derive consequences for their own organization. "*Teams not yet, but roles yes. Mostly people in charge for analysing existing documents from different perspectives*" (FG_P2).

Another approach for addressing existing skills gaps and gaining expertise within the company is the use of external consultants. One company report collaborating with consultants who help them understand and interpret the new regulatory requirements, enabling them to find ways to "*better comply with the new regulation*" (FG_P3). Thus, external expertise becomes a central building block in reducing uncertainties regarding the interpretation of the regulation and in supplementing internal teams or roles.

Overall, participants statements show that companies are at different stages of organizational preparation, ranging from established specialist teams to initial role models. Despite these differences, all companies have found approaches that aim to make the complex regulatory requirements more manageable and gradually establish sustainable structures for future EHDS compliance.

4.4 Interoperability Teams

When it came to dealing with interoperability requirements, the key question is how organizations can design their internal structures to coordinate EHDS-related interoperability work across different product and technology teams. Overall, interoperability is becoming increasingly formalized while remaining closely embedded in existing product development and governance structures.

Some companies are pursuing a programmatic approach. One company has set up a separate workstream to compile needs, functional requirements, and architectural issues. The product team evaluates and prioritizes the results, which are then transferred to the development teams backlogs. This approach treats interoperability as an integral part of the regular product development process

> "*A specific workstream is created to specify the need, functional needs, architecture; an evaluation is made by the product team and assigned priorities, and it will be assigned to a Dev team to their backlog*" (FG_P5).

Other organizations are guided by existing national interoperability structures and apply this logic to the EHDS: "*We structure the same way as for national interoperability. We identified that some small vendors (primary care) need FHIR skills*" (FG_P4). This approach also reveals skills gaps in wider ecosystem, such as the need for FHIR skills among smaller vendors.

Additionally, in some cases, interoperability work is anchored via central control and coordination bodies. One company refers to the "*stewardship of the Steering Committee*" (FG_P2) an overarching body that channels interoperability activities. Another company has a group within the customer success department responsible for data exchange:

> „*within CS we have a group responsible for data exchange. They are responsible to let the knowledge land within other groups. But not only internally but also externally*“(FG_P1).

This group ensures that EHDS-related knowledge is spread to other internal groups and communicated externally (FG_P1). Clear communication, management, and tracking processes are established between technical departments, product management, and regulatory units to structure interoperability as a cross-departmental task (FG_P3).

4.5 Pricing

Regarding commercial strategies, the focus is clearly shifting from immediate price adjustments to the question of how to embed EHDS-related requirements in existing market and business logic. The EHDS is mainly understood as a legally binding framework with which companies must comply, while they simultaneously consider how to leverage the associated changes strategically to position themselves in the market.

Several participants emphasize that the EHDS does not directly result in a price increase. One participant state succinctly "*If it's law, you can't. You can't hang pricing on it*." (FG_P1) even if the adjustments involve considerable effort and costs, such as new software versions, renewed MDR certification, and other national or AI-related certifications (FG_P1). At the same time, it is pointed out that these adjustments driven by law are by no means cost-neutral and must therefore be indirectly incorporated into commercial considerations. One company describes how it is not currently making any explicit price changes. Instead, the focus is on the long-term potential offered by the EHDS, such as market expansion and new data-based services in the area of clinical decision support systems.

> "*At this stage no, in terms of pricing; at this stage our main driver is the possibilities that EHDS will unlock for a startup in terms of market expansion and better support CDSS*" (FG_P5).

These systems enable individualized treatment paths and recommendations for patients and clinicians (FG_P5).

In terms of market positioning, EHDS is primarily seen as an opportunity for differentiation. One company points out that it is one of the few MDR-certified EHR providers, and EHDS-compliant versions are MDR-relevant once again. This circumstance means "*a lot of work and a lot of money*" but it can also be used to leverage the attraction of new customers (FG_P1). Other participants fundamentally see EHDS as an opportunity and explicitly state "*We see it as an opportunity"* (FG_P2), linking it to the question of which systems will have "*prime time*" among users in the future, especially since interoperability and data use play a central role in

treatment (FG_P2, FG_P1). At the same time, financing issues on the customer side are clear. One participant notes that "*Funding is the question all ask, and this is different for public or privat care providers*" (FG_P4), indicating that the differences between public and private service providers play an important role in the practical implementation and design of offerings. Overall, the EHDS shapes commercial strategies less through explicit pricing logic and more through indirect effects on cost structures, differentiation strategies, and new, data-based value propositions.

4.6 Business Model

Regarding EHDS-related business models for interoperable health data, participants report a pronounced search and orientation phase. The surveyed companies are mainly in a phase in which initial ideas and directions are becoming apparent. However, business models that are explicitly formulated as EHDS-oriented are still rarely identified. One participant summarizes this uncertainty as follows:

> „*[…] I don't really know if we have some kind of EHDS oriented business model. My take however would be on how we could leverage the primary and the secondary use of data and build a business model around that*" (FG_P8).

Instead, the focus is on how the EHDS database can be used to create concrete value propositions, especially in areas where data usage gaps still exist.

One central theme is the innovative use of health data for clinical decision support systems. Companies are outlining business models in which interoperable, structured data is used to provide clinicians and patients with better, more personalized information and recommendations. These models aim to leverage EHDS not only for compliance but also as the foundation for data-driven services that enhance clinical processes and decision-making quality. Emphasis is placed on areas such as prescriptions, dispensing, and laboratory data, which are central to many systems but are insufficiently structured in some countries, e.g., France:

> "*[…] I think everything related to prescriptions, dispensation and lab results will be very influential. These are types of information that many systems need to have structured, and they are currently not structured enough in France*" (I_P1).

Use cases, such as the automated evaluation of laboratory data for chemotherapy planning, demonstrate that the use of structured data results in greater efficiency and improved patient outcomes, creating the basis for sustainable business models:

> *"If we could have these results structured and automatically processed, we could have workflows that inform the patient in advance"* (I_P1).

Overall, this paints a picture of a field in which business models related to the EHDS are perceived as promising. However, they currently exist primarily as spaces for experimentation and exploration, with concrete designs yet to be developed.

5 Discussion

This chapter closely examines the interview results in the context of the research questions and theoretical background. The goal is to identify opportunities for companies to use health data interoperability in the context of the EHDS for monetization. The section also explores how companies are preparing for and implementing the regulation.

5.1 Main Findings

RQ1: *Which business models enable companies to monetize health data interoperability in the European Health Data Space?*

In regard to business models for monetizing interoperability in the EHDS, the interviews clearly show that they are just beginning to emerge. As has been pointed out on several occasions, the current version of the EHDS Regulation and remaining regulatory uncertainties make reliable statements about revenue and pricing strategies difficult. The question of how to systematically monetize these capabilities is seen as a subsequent step. From a business model perspective, these findings suggest that EHDS-related monetization approaches currently remain at the level of technical and organizational preparation and have not yet translated into consistent configurations of value proposition, value capture, value network, and value delivery in Ojala's sense (Ojala, 2016). In terms of this, the challenges identified are similar to those described for other digital health applications, where business modeling is often treated as less important than technical implementation (Van Limburg et al., 2011).

Theoretical literature clearly outlines which business models are possible with interoperable data spaces, such as the EHDS. These include data- and AI-based value-added services based on harmonized data sets, interoperable platform and infrastructure solutions, and digital health

applications whose value proposition is based on efficiency gains, improved outcomes, and new care pathways (Firouzi et al., 2022; Marcos-Pablos et al., 2019). Along the dimensions described by Ojala (2016), these models can be structured as a combination of data-driven value creation and service-oriented revenue (Firouzi et al., 2022; Marcos-Pablos et al., 2019; Weiner, 2009). From a conceptual perspective these models point to a shirt from exclusively digital products to data- and ecosystem business models in which interoperability and governance are not just technical enabler, but become integral components of the value proposition and value network (Ojala, 2016; Teece, 2010). This suggests that the EHDS does not simply fit into digital health archetypes, but requires a new combination of infrastructure services, analytics services and clinical applications to create hybrid business model configuration (Da Silva Carvalho et al., 2025; Weimar et al., 2025).

The results of this work only reflect the initial outlines of these theoretical lines. In individual cases, use cases are described in which structured prescription and laboratory data are used for decision support, risk stratification, or process optimization. These approaches correspond to data-driven analytics services and AI-based value creation models based on harmonized data sets (Firouzi et al., 2022; Marcos-Pablos et al., 2019). Nevertheless, there is a lack of precise information on revenue mechanisms, pricing models, and scaling strategies. Consequently, business model considerations remain largely at the level of ideas and scenarios.

Given this, the research question can only be partially answered. The findings show that interoperability in EHDS regulation could be monetized mostly through data-driven analysis and decision support services (Firouzi et al., 2022). However, these business models have not matured into stable, clearly formulated revenue models. Overall, the combination of a theoretical perspective and limited empirical evidence suggests that the field is in the early stages of business model exploration rather than having an established market for EHDS-based monetization strategies (Ojala, 2016; Pascarelli et al., 2023).

RQ2: *What concrete organizational and strategic steps are companies already taking to prepare for the European Health Data Space (EHDS)?*

Regarding the research question of what specific organizational and strategic steps companies are taking to prepare for the EHDS Regulation, a set of targeted measures has emerged. Particularly among those heavily involved. These companies do not view EHDS readiness as a

purely technical issue, but rather as something that is integrated into the organization through governance structures, planning processes, and competence building.

Above all, establishing specific control and responsibility units is essential. Several companies have formed EDHS-related steering committees or specialized units that systematically monitor regulatory developments (Centre for Information Policy Leadership; AvePoint, 2016, 2018). These committees pool expertise across countries and functions, establishing EHDS as a permanent internal control topic. This aligns with the literature, which cites governance adjustments as a central component of organizational preparation (Da Silva Carvalho et al., 2025).

In consideration of the strategic level, EHDS requirements are integrated into project roadmaps and planning processes by linking European requirements with national regimes and explicitly aligning future developments with EHDS (Da Silva Carvalho et al., 2025; Martins et al., 2025). In addition, companies are investing in EHDS-related knowledge by participating in internal programs, conferences, and EU projects on EEHRxF and interoperability standards (Da Silva Carvalho et al., 2025). Thus, governance structures, roadmap integration, and capacity building can be described as central building blocks of current preparedness (Cervera De La Cruz et al., 2025).

At the same time a lack of clarity on the part of the European Commission limits many companies' options for action (Da Silva Carvalho et al., 2025). The key specifications are perceived as too vague, making preparations immensely difficult. If these uncertainties persist, many activities will focus on observation, scenario planning, and selective adjustments to roadmaps. Larger investments and far-reaching structural reforms will be deliberately postponed (Da Silva Carvalho et al., 2025; Regulation (EU) 2025/327, 2025).

Additionally, this form of preparation is limited to a select group of "early movers." The recruitment process revealed that many companies declined to participate, stating that they had not yet addressed the EHDS regulation or were unfamiliar with it. Overall, RQ2 can be answered by saying that concrete EHDS preparedness is most evident in companies that are aligning their management structures, planning processes, and competencies specifically with the EHDS. Many other companies are still postponing systematic steps due to remaining regulatory and technical uncertainties.

5.2 EHDS Maturity Matrix for Companies

A compact representation in the form of a maturity matrix is proposed as a useful to illustrate the different degrees of EHDS regulation preparedness displayed by Companies. This matrix is based on the three focus group analysis blocks: (A) Awareness, Legal, and Compliance, (B) Technical teams, products, and interoperability capabilities, and (C) Commercial teams, strategies, and business models. Characteristics of companies can be described across several stages. The matrix classifies observed patterns into three maturity levels (1-3) and illustrates how organizations evolve from a reactive stance to strategic EHDS preparedness.

	A: Awareness, Legal & Compliance readiness	**B: Technical teams, products & interoperability capabilities**	**C: Commercial strategies / Business Model**
Level 1	EHDS little known or unknown, no governance adjustments, no clear responsibilities	EHDS barely present in technical teams, no dedicated roles/teams, product roadmaps without explicit EHDS reference	EHDS plays hardly any role in sales/marketing, no explicit EHDS-related business models, interoperability primarily understood as a technical prerequisite
Level 2	EHDS known, internal discussions, but only selective adjustments/monitoring	EHDS known, individuals following specifications, initial roadmap adjustments, interoperability as a cross-cutting issue, but organizationally fragmented	EHDS recognized as a future differentiator, EHDS readiness appears in positioning, initial ideas for data-driven offerings without clear revenue logic
Level 3	Formal steering committee, clear responsibilities, systematic risk analysis	Clearly defined EHDS/interoperability roles or teams, EHDS systematically integrated into product lines and roadmaps, interoperability established as a horizontal capability	EHDS explicitly part of commercial strategy, value propositions geared toward EHDS-based data and service offerings, concrete or piloted business models with defined revenue mechanisms, formal steering committee, clear responsibilities, systematic risk analysis

Table 2: EHDS Maturity Matrix for Companies

Block A

The characteristics identified in Block A are as follows. Category A1 is characterized by the fact that the EHDS regulation is not perceived at all, hardly perceived, or only marginally perceived within the company. Looking at the companies in this group, there are no specific governance adjustments or defined responsibilities for EHDS issues. Legal and compliance aspects have therefore not yet been systematically considered in connection with EHDS, and specific risks remain largely unidentified.

However, companies in group A2 have recognized EHDS as a relevant issue; initial information has been obtained and discussed internally. In addition, individual persons or functions (e.g., legal, compliance, product management) have informally taken on the role of monitoring developments and evaluating them on an ad hoc basis. Risks and compliance requirements are addressed on a case-by-case basis, for example by monitoring documents or participating in exchange formats, without a clearly structured program already in place.

Analyzing the group with the highest level, A3, the EHDS Regulation is already anchored in governance. Formal control structures such as steering committees or clearly defined responsibilities across multiple areas exist. An additional point is that legal, compliance, and risk aspects are systematically prioritized and linked to concrete measures. The organization takes a proactive approach that integrates EHDS-related requirements into decision-making processes at an early stage and understands them as a strategic cross-functional task.

The company from interview 2 is an example of group A1. At the time of the interview request and the interview itself, the company had not yet taken note of the EHDS Regulation and had therefore not yet made any legal adjustments. FG_P4, on the other hand, is an example of group A2. The company is aware of the upcoming changes and is addressing them but is currently waiting for more detailed instructions from the European Commission before taking active measures. Like FG_P1, which has already adapted its product roadmap to the EHDS, clarification on detailed requirements is still needed. A good example of group A3, is FG_P2, which reports that an EHDS steering committee has already been set up within the company. This committee meets regularly to address governance issues, risks and adaptation needs, firmly anchoring the EHDS in corporate management.

Block B

Block B examines how companies are preparing their technical teams, products, and interoperability capabilities. Companies assigned to Block B1 do not yet include the EHDS in their technical teams. They have no dedicated roles or teams for the EHDS or interoperability, and they only sporadically pursue technical specifications. Product roadmaps are mainly driven by national and regulatory factors with no explicit reference to the EHDS.

In B2 organizations, EHDS regulations are present in architecture and development teams, and a few individuals or small groups are pursuing specifications (e.g., EEHRxF, FHIR). Additionally, individual products or modules in roadmaps are linked to EHDS requirements. Interoperability is defined as a cross-cutting issue, though it is not yet consistently structured. Interoperability work is mainly carried out in projects, with coordination between product teams and technology on an ad hoc basis.

The B3 group has clearly defined EHDS and interoperability roles and teams that are linked with architecture, development, and legal teams, where applicable. The EHDS requirements are systematically integrated into product lines and roadmaps, and key products are designed to be EEHRxF compatible. Further, interoperability is organizationally anchored as a horizontal capability through coordinated processes across multiple product teams, with central coordination.

In Block B, the company from Interview 2 represents the lowest level of maturity. In line with the lack of EHDS awareness, no specific EHDS roles have been created, and no roadmaps or technical structures have been adapted to EHDS requirements. FG_P5 can be assigned to level B2. There, EHDS has already been established as an independent topic in development work, for example through clearly named projects and a structured workflow in which requirements are defined. These are then evaluated by product managers and incorporated into the development teams planning. If a company has reached level B3 to some extent, it is FG_P4. Here, national teams have been set up to work on EHDS-related tasks and the use of existing interoperability structures for the EHDS, as well as the targeted development of skills, are seen as prerequisites for further developing technical capabilities.

Block C

Block C focuses on commercial teams and strategies/business models and has the following characteristics. For organizations in Group C1, the EHDS has played virtually no role in sales, marketing, or business development thus far. Commercial strategies, pricing logic, and customer segments are designed without explicit reference to EHDS requirements or interoperable data offerings, and this will continue. Furthermore, potential EHDS-related business models are mentioned only marginally without concrete elaboration.

Group C2 perceives the EHDS as an upcoming competitive and differentiation factor. Commercial teams in this group are beginning to consider the advantages of the EHDS in positioning or partnerships. For example, they view the EHDS as a quality feature rather than a standalone price module. In addition, initial ideas for data-driven services or new offerings are being developed. These remain at the conceptual level, lacking clearly defined revenue mechanisms.

Lastly, group C3 has explicitly integrated the EHDS regulation into its commercial strategy, actively aligning target segments, value propositions, and go-to-market approaches with interoperable data and service offerings. Concrete plans or pilot models for new EHDS-related business models are in place, including tested or planned revenue mechanisms (e.g., analytics/decision support services based on harmonized data). Partnerships with other players, such as research institutions, insurance companies, and platform operators, are being leveraged to develop and scale EHDS-based offerings.

In terms of commercial teams and business models, most companies surveyed can be classified as having a medium level of maturity. They view EHDS as a future opportunity and a way to differentiate themselves, for example by opening markets and developing data-based services. However, pricing and concrete revenue models remain unclear. Initial business model ideas focus on innovative uses of health data, e.g., services that provide decision support and personalized treatment paths for doctors and patients based on the data generated but remain at the conceptual or scenario level. This is because questions about financing and market structure are still unresolved and immature.

5.3 Theoretical and practical implications

This thesis presents several theoretical implications for digital health ecosystems, interoperability, and business models within the framework of the EHDS. The results suggest that organizational preparation for the EHDS is not a one-dimensional state but rather manifests across levels, including governance structures, technical interoperability capabilities, and commercial orientation. The maturity matrix for companies developed in this thesis illustrates companies transition from a reactive, ad hoc regulatory approach to a strategic one, where EHDS requirements are integrated into business operations through formal committees, roadmaps, and targeted competence building (Centre for Information Policy Leadership; AvePoint, 2016, 2018; Da Silva Carvalho et al., 2025; Lewerenz et al., 2024; Regulation (EU) 2025/327, 2025). This can be a useful addition to the work undergoing in i2X about Maturity Models.

At the same time, the results clarify our understanding of interoperability in digital health ecosystems. Although interoperability is frequently described in literature as a technical prerequisite and driver of innovation, this thesis demonstrates that it is increasingly recognized as a horizontal capability embedded in the organizational structure of EHDS-related entities. Interoperability work is shifting from individual, project-related initiatives to recurring structures with clear roles, coordinated processes, and cross-functional responsibility. The specific form of this shift depends heavily on the respective degree of maturity and perceived regulatory uncertainty (Hodapp & Hanelt, 2022; Lehne et al., 2019; Lewerenz et al., 2024). Thus, the thesis contributes to our understanding of interoperability as not only a technical feature but also an integral part of organizational and governance design in regulated data spaces.

Furthermore, this work contributes to the research of business models in digital health. It applies to Ojala's (2016) four-component model, which includes the dimensions of value proposition, value capture, value network, and value delivery, to the context of the European Health Data Space (EHDS). The thesis also links this model to empirical observations (Ojala, 2016; Pascarelli et al., 2023). The results suggest that EHDS-related business models are in an exploratory phase. Companies are outlining the potential for data-driven analysis, decision support services, interoperable platform offerings, and EHDS-compliant solution portfolios, but the underlying revenue logic and network structures are not clearly defined (Firouzi et al., 2022; Marcos-Pablos et al., 2019). In this context the work demonstrates how regulatory uncertainty,

national path dependencies, and the unique role of early adopters influence the design of business models within data-driven health ecosystems, revealing dynamics that have only been partially substantiated in previous conceptual work (Cervera De La Cruz et al., 2025; Ganna et al., 2024).

Moreover, this work presents various practical implications for companies and other stakeholders in the context of the EHDS. From the participating organizations' perspective, EHDS readiness should be understood as an organization-wide task affecting governance, product development, and commercial orientation equally. Therefore, it makes sense to adopt an approach that establishes clear responsibilities and control structures and integrates EHDS issues into existing planning and decision-making processes early on. This involves systematically tracking developments from specific workstreams on interoperability and EEHRxF to gradually adapting product roadmaps and developing FHIR and standardization competencies (Centre for Information Policy Leadership; AvePoint, 2016, 2018; Da Silva Carvalho et al., 2025; Lewerenz et al., 2024).

The results suggest that important preparatory steps can be taken under conditions of regulatory uncertainty, even for companies that have tended to adopt a wait-and-see approach so far. These include setting up internal EHDS contacts, monitoring EU documents and guidelines systematically, exchanging information in relevant networks, and conducting fit-gap analyses to compare existing products and processes with foreseeable requirements. The participants' statements also clarify that investments in interoperability can be viewed as strategic resources, such as when companies use interoperability to differentiate themselves in the market or develop data-based service and decision-support offerings early on (Firouzi et al., 2022; Lewerenz et al., 2024; Pascarelli et al., 2023).

There are also implications for policymakers and funding agencies. The surveys show that many companies perceive unclear definitions, unresolved technical details, and ambitious implementation deadlines as major obstacles, leading to a wait-and-see attitude. From a practical perspective, these findings highlight the importance of secondary legislation, technical guidelines, and coordinated timelines that provide as much specificity as possible. This will increase planning security and stimulate investment beyond the group of early movers who are already heavily involved (Cervera De La Cruz et al., 2025; Regulation (EU) 2025/327, 2025). Finally, support measures targeting organizations with little exposure to the EHDS could reduce

the maturity gap between highly networked partners and cautious market participants, creating a foundation for interoperable, data-driven care models (Ganna et al., 2024; Pizzamiglio, 2024).

5.4 Limitations

The thesis has several limitations that must be considered when interpreting the results. The participants were primarily recruited from an existing network of companies that are active in EU projects or involved in relevant EHDS networks, and thus regularly engage with this topic. Consequently, individuals with prior experience of dealing with regulation or a greater sensitivity to interoperability and data spaces are overrepresented, while companies with no prior contact with the EHDS are largely absent. The perspectives of 'late followers' or completely unprepared actors are therefore insufficiently represented.

Additionally, while different types of companies from various EU countries were interviewed, the sample does not encompass the full range of potential organizational types. Certain stakeholder groups are either not represented at all or only marginally, which is reflected in the patterns identified among the less-represented stakeholders. Overall, this is a qualitative work with a limited number of cases and an exploratory focus. While the results enable a structured classification of preparation patterns and governance approaches, they do not permit statistically reliable conclusions or quantitative generalizations. For example, it is not possible to make statements about the distribution of certain maturity levels in the overall market. Assignment to maturity levels is interpretive and based on the respondents' subjective assessments, so distortions due to social desirability or strategic communication cannot be ruled out.

At the time of data collection, the EHDS regulation was still being developed and implemented, with key technical and governance-related specifications continuing to be refined until 2027. This means that many of the preparatory measures described are being carried out under conditions of regulatory uncertainty, making the interviewees assessments heavily dependent on current expectations and scenario thinking. This means that any statements regarding the long-term design of business models or interoperability strategies are likely to be preliminary. Meanwhile, the thesis focuses on companies operating mainly in the digital health sector or at interoperability and data infrastructure interfaces, while the perspectives of other key stakeholders are only indirectly considered.

Potentially conflicting areas of tension between economic interests, clinical practice and patient protection can therefore only be represented to a limited extent. Finally, it should be noted that the context of data collection, particularly its embedding in EU projects and ongoing funding initiatives, may influence respondents' statements. Companies that are already active in EHDS-related initiatives benefit from specific knowledge and additional resources, which increases their perceived readiness and tends to underestimate the gap between themselves and market participants with less involvement. Future research should address this bias by systematically including actors who are not yet represented in European digital health programs or relevant networks.

5.5 Recommendations

5.5.1 Companies in digital health & EHDS sector

Companies should view EHDS readiness as an organization-wide task and establish governance structures that bring together legal, technical, and commercial perspectives. This can be achieved, for example, through a steering committee or clearly defined responsibilities for EHDS issues (Centre for Information Policy Leadership; AvePoint, 2016, 2018; Da Silva Carvalho et al., 2025).

EHDS-related interoperability requirements should also be systematically incorporated into product and technology roadmaps so that interoperability is not only addressed on a case-by-case basis in individual projects but is anchored as a recurring and company-wide capability (Hodapp & Hanelt, 2022; Regulation (EU) 2025/327, 2025). Parallel to technical implementation, it is advisable to advance business model considerations in a structured manner by specifying possible EHDS offerings along the four dimensions described by Ojala and testing them in the form of pilot projects, for example in the area of data-based analysis and decision support services (Firouzi et al., 2022; Marcos-Pablos et al., 2019; Ojala, 2016; Pascarelli et al., 2023). Companies with little EHDS exposure to date can take advantage of existing network and training offerings, including those related to EEHRxF and readiness initiatives (Sá et al., 2024).

5.5.2 Industry associations

As the EHDS takes shape, it's becoming clear that industry associations and sector networks should play a pivotal role in sharing insights from related projects and bridging the knowledge gap between early adopters and less prepared companies (Da Silva Carvalho et al., 2025;

Huettemann et al., 2024). In this context it is recommended to establish targeted exchange formats on readiness, interoperability organization, and potential business models, as well as compile best practices to make them accessible to a broader range of stakeholders (Pizzamiglio, 2024). Based on existing concepts, such as the XpanDH Readiness Model, associations can develop standardized self-assessment tools. These tools would enable companies to evaluate their maturity level in various areas. Then, they could derive structured development paths (Sá et al., 2024). Additionally, associations should compile feedback from members on open technical questions and contribute it as position papers to national and European consultation processes to help shape the regulatory framework (Da Silva Carvalho et al., 2025; Regulation (EU) 2025/327, 2025).

5.5.3 National policy makers

From the perspective of national policymakers and regulatory authorities, the findings make it clear that many companies view the lack of clarity regarding the definition of technical factors and timeframes as an immense hurdle. This contributes to a wait-and-see attitude (Cervera De La Cruz et al., 2025). A key recommendation is to develop a coherent national EHDS implementation strategy. This should include transparently clarifying responsibilities for MyHealth@EU contact points and HDABs, as well as bundling measures into coordinated timelines (Regulation (EU) 2025/327, 2025).

Furthermore, support measures and practical guidelines should focus on helping smaller enterprises and SMEs establish interoperable infrastructures to achieve the EHDS's large-scale interoperability goals (Pizzamiglio, 2024). When designing the HDABs, it is advisable to ensure that fee and access models are transparent. Additionally, clear information resources should support digital processes for applications (Regulation (EU) 2025/327, 2025).

5.5.4 European Commission

The European Commission should prioritize the development of technical specifications. In particular, this includes the EEHRxF, establishing interoperability standards, and the governance infrastructure. It is also important that timelines be set in a practical manner in consultation with businesses. In the best-case scenario, this will minimize the obstacles arising from regulatory uncertainty. Precise secondary legislation and coordinated implementation deadlines are crucial for the successful implementation of the EHDS and the associated

innovation potential (Da Silva Carvalho et al., 2025; Lewerenz et al., 2024; Regulation (EU) 2025/327, 2025).

In parallel, the Commission can help make the innovation potential described within the framework of interoperable health data spaces practically accessible and reduce differences in maturity levels through pilot programs and targeted support services for Member States with lower digital maturity (Ganna et al., 2024; Huettemann et al., 2024). Systematic monitoring of EHDS implementation, which includes indicators on interoperability, data usage, and process quality of the Health Data Access Bodies, also offers the opportunity to identify areas of tension between standardization and national differentiation at an early stage and to adapt governance instruments accordingly (Hodapp & Hanelt, 2022).

6 Conclusion

This work aimed to examine how various players in the EU healthcare ecosystem are preparing for the EHDS and to identify initial business model approaches within this new system, with a focus on interoperable health data. When it comes to potential business models, three general approaches stand out. First, there is the emergence of data- and AI-driven models, which use harmonized, interoperable data sets as the basis for various applications. Examples include analytical value-added services, decision support, and predictive applications that can be marketed to various stakeholders. In addition, digital health technologies and platforms for primary care are gaining attention. These technologies and platforms can be used to achieve efficiency gains, new forms of care, and expanded service portfolios. Further, Health Data Access Bodies (HDABs) have an infrastructure model oriented toward administration. Their value creation model lies in providing neutral, legally compliant access to research data. Overall, these business models are still largely in the exploratory phase. In most cases, concrete revenue mechanisms, pricing, or mature network structures have not yet been developed.

In the context of organizational preparation, the results indicate that companies increasingly view the EHDS Regulation as a transformation task that affects multiple departments. Many participating companies have already adjusted their governance structures. To give an example, they have established EHDS-related steering committees or specialized units to monitor regulatory developments, coordinate internal activities, and serve as points of contact. Project and technology roadmaps are gradually being adapted to expected interoperability requirements. The evaluation suggests that companies are at different stages of maturity. They

range from a reactive, wait-and-see attitude to a strategic orientation that systematically integrates EHDS issues into decision-making and planning processes.

From a practical point of view, the results highlight that companies can take preparatory measures even when regulatory specifications are incomplete. For example, these steps include establishing clear responsibilities and control structures. These structures are responsible for systematically monitoring EU guidelines and developing interoperability competencies early on. In consideration of policymakers and regulatory authorities, the results indicate that developing precise technical guidelines and realistic timelines is crucial for investment decisions. At the same time, these guidelines and timelines can help reduce the maturity gap between highly networked pioneers and more cautious players.

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Appendices

Appendix 1: Interview Guide

Broad topic	Specific topic	Question
Background & Role Understanding	Role	Could you briefly describe your main responsibilities within your organization?
	Personal Motivation	What personally motivates you to work on health data interoperability?
Project Goals, Strategies & Challenges	EHDS/Standardization Goals	To begin, could you tell me if your organization is already considering, working on, or addressing the European Health Data Space (EHDS) and its requirements, or if this topic is expected to become relevant in the future?
		Are there specific milestones you are striving for, and how do you measure your progress?
		Are there specific milestones you are striving for, and how do you measure your progress?
		Probe: Are there specific milestones, and how do you measure progress?
		Probe: Are these goals aligned with your organization's overall strategy, or do they differ in any way?
	Implementation Challenges	What are currently the biggest challenges (technical, organizational, regulatory) in achieving interoperability in your organization?
		Probe: Are these challenges technical, organizational, or regulatory in nature?
		Probe: Can you share concrete examples of challenges?

Contextual Factors, Maturity & Pain Points	Digital Maturity Benchmarks	How would you describe the level of digital maturity at your organization or site (e.g. compared to national averages or benchmarks)?
		Do you use official metrics (e.g. EMRAM, national indicators)?
	Regulatory Environment	Which local or national regulations most shape your interoperability implementation?
		Probe: Do you see notable differences between EU requirements and national realities?
Interoperability & Business Models	Strategic Importance of Interoperability	What is the long-term importance of interoperability in your organization's digital strategy?
	Types of Business Models	Which business models (e.g. data-as-a-service, platform, open data, secondary data use) are relevant for your organization?
		Can you give concrete examples of innovative approaches emerging through interoperable health data?
		Who are the main internal and external stakeholders involved in data-related business models?
		Probe: How do you coordinate value creation and sharing amongst these stakeholders?
Corporate Strategies & Adaptation Measures	Strategic/Operational Adaptation	What types of internal resources or capabilities does your organization most urgently need to successfully implement the EHDS requirements?
	Capacity Building, Change & Collaboration Management	Are there particular gaps related to personnel, skills, infrastructure, or funding?
		How do you manage change internally? Are external partners or service providers involved?
		How do you monitor and evaluate progress with EHDS readiness?

		What recommendations do you have for policymakers or companies navigating digital health transformation?
Closing & Recommendations	Recommendations & Future Aspects	Are there any further issues or trends you believe are important but haven't yet been discussed?
		Are there other aspects relevant for my research that we haven't covered?

Appendix 2: Focus Group Guide

Block A: **Awareness, Legal & Compliance readiness**		
Question 1	Governance Changes	Have there been any changes in your company's governance structures or allocation of responsibilities because of the EHDS, or are you planning such changes in the next 12 months?
Question 2	Risks	What concrete risks stemming from the EHDS regulation have you identified for your company in the next 12 months, and how are you preparing for them?
Question 3	Compliance readiness	How are you making sure that your company will be compliant with EHDS requirements once the regulation and secondary acts are in force?
Block B: **Technical teams, products & interoperability capabilities**		
Question 4	Dedicated teams and roles	Have you created any specific teams or roles to work on EHDS (for example in legal, architecture, or interoperability), or assigned particular people to follow the technical specifications?
Question 5	Impact on product roadmaps	How are your product lines and roadmaps evolving in response to EHDS, and which key products or modules are being adapted?
Question 6	Interoperability capabilities	How are you structuring interoperability work across your organization in response to EHDS, especially across different product and technical teams?
Block C: **Commercial teams & strategies / Business models**		
Question 7	Influence on commercial strategies	How is EHDS preparation influencing your commercial strategies, for example your pricing approaches, your partnerships with clients or other companies, and your positioning in the market?

Question 8	Business models	Which EHDS-related business models around interoperable health data are you currently considering or implementing in your company?

Appendix 3: Transcript I_P1

Question	Response
Could you briefly describe your main responsibilities within your organization?	My main responsibility is to support all the teams with interoperability aspects, mainly interoperability itself and some medical concepts and knowledge of the ecosystem in France.
You do not work with the government anymore, right?	No, not anymore. I switched three years ago from the government to the private sector, and I actually stayed in government for 17 years.
Was the switch from government to the private sector difficult for you?	Not really. It was interesting because you can see the other side of the story. In government, you always say, "They have to do that; it is in the specifications, it is in the standard, so why do they not do it?" And then you realize why. You have to juggle things and try to make the best of it.
During your time in the government organization, were you already in contact with the European Health Data Space, or is this a new topic for you?	It is mainly a new topic. I was with the government until 2020, no, 2022, sorry, and I also worked on security at one point. We were mainly dealing with the DMP, which is a national PHR in France at first, and then we moved to more specific topics that were closely connected to the French healthcare system. It is not really European-oriented. So the European Health Data Space as we know it now with the EHDS is a new topic. We did work with some apps, but this was a very narrow topic and not our main concern.
At your current organization, are you already considering or working on the EHDS and its requirements, or is this more of a topic for the future?	We are working on it, but not from a technical point of view. Right now, we are working on the requirements for secondary use, mostly from the legal perspective. We are looking at how to open the data, how to finance opening the data, how to finance the structuring of data and similar questions. Basically, like most people, we are waiting for the implementation act to really know what is going on. I have read all the xEHR specifications and made some comments, because they are supposedly what will be in the implementation act, but as long as it is not published, we are not sure. So we are starting to think about what we could do with it, but we are not moving yet because we are waiting for the final texts to be published.
So you are not yet in the implementation process. Apart from the legal work on secondary use, have you already defined milestones for this change, or is it still more of a future topic?	Well, we know that from 2027 onwards we will have to work on it, but 2027 still feels far away for us, and we are still kind of a start-up, even if we are fairly large. So we have many things to do before that. We know it is coming, and we more or less know how it is going to be, but France still has a lot of work to do to translate the European requirements into French regulation. We will not move until we know more about how it will really be implemented. For now, we are only considering use cases, because we know that, for example, the medical summary will be structured and prescriptions will be structured. We can see how this could be used, but we are not moving forward technically yet.
Turning now to more general issues: What are currently the biggest challenges related to interoperability in your organization, for example, technical, organizational or regulatory challenges?	A bit of all three, I guess. Inside my company, we do not have many challenges, because we mostly speak among ourselves. The main challenges are with our clients, because we are what we call an intermediary platform. We take documents from hospitals and send them outside, and we take documents from outside and send them back to the EHR in the hospital, trying to structure things in the middle. So the main challenge is actually with the systems we have to connect to. First, when there is no national specification, we have to confront our understanding of the standards with our partners' understanding. Standards are very broad and can do a lot of things, but sometimes, for a specific use case, it is not easy to quickly find how it can be done, and there may be several possible ways. That is one challenge, and it also reflects a kind of gap: there are some national specifications and localizations of standards, but not for all use cases. So when we end up with a use case that needs something that has not been localized, we cannot easily connect to every EHR. For instance, as I said, we are moving documents, and some documents are exam results, like radiography reports or similar. In France, there is a set of document types derived from law, but it is very generic. Hospitals would like to have the documents organized in folders by exam rather than by document type, because the types are too broad. How to convey the exam information is not specified at the national level, so we have to find a common understanding with each EHR vendor.
In terms of digital maturity, your organization is at a higher level than the national average, right?	Well, I guess, thanks to me, we are pretty advanced. Conceptually, we are quite mature because we understand how it works, but in practice we are basically average, because we have to adapt to all the systems we interact with.

Do you use any official metrics to measure this maturity?	No.
Are there local or national regulations that particularly shape your interoperability implementation?	Yes. The ANS has produced many specifications, which are localizations of international specifications. They are all part of the French national interoperability framework, called CI-SIS, and this shapes our implementation. This is very useful, because when we disagree with another company about something, we can go back to the specification and say, “OK, it is written there.” Even if it is not mandatory, it is still a common reference that everyone can agree on. So it really shapes a lot of what we do.
How is interoperability embedded in your organizational strategy? Is it seen as a long-term priority?	Since we are a SaaS system, we have to communicate with many other systems; otherwise, we would not be useful. I would not say it is the only main topic, but it is one of the main topics: we must be interoperable. This definitely shapes our strategy and will continue to do so, so that we can move data and have access to the data.
You mentioned earlier that you are working on different use cases related to the EHDS. Are there business models or use cases that are particularly relevant for your organization in this context?	I am not entirely sure yet. It is more of a feeling; it depends on the market. But I think everything related to prescriptions, dispensation and lab results will be very influential. These are types of information that many systems need to have structured, and they are currently not structured enough in France. This is definitely something that many business actors require, so it will be taken into account, implemented and, most likely, used most probably.
Could you give a concrete example of an innovation or innovative approach that could emerge from this?	For example, for lab results: when people have cancer, they go to the hospital for chemotherapy every few weeks. Before they go, they need lab tests, and certain blood markers, like white blood cells, must be within specific ranges. Right now, it is a real pain for hospitals to chase lab results and have someone read them to decide whether the patient can receive chemotherapy. It often happens that the patient arrives at the hospital with the lab results and the doctor says, “No, you have to go home; you cannot receive chemotherapy today because of your lab values.” If we could have these results structured and automatically processed, we could have workflows that inform the patient in advance: “We received your lab results; you have a chemotherapy session in two days; you will not be able to receive it, so do not come.” In that case, the hospital would have a slot available for another patient and would not have to prepare chemotherapy unnecessarily. Chemotherapy is prepared one day in advance and is patient-specific, so if the patient cannot receive it, it is wasted. Avoiding this would be a great improvement: the patient does not travel unnecessarily, the drug is not wasted, and the slot can be used for someone else.
Who are the main internal and external stakeholders you work with, for example in relation to new business models?	In my case, I work a lot with project managers, helping them define products from an interoperability perspective, how we interact with other systems to get or send data. I also work closely with developers to ensure that they follow the right standards and implement them correctly. Sometimes I work with the business team, because they have ideas about what might be interesting from a business point of view and ask me to check whether it is possible, not possible, already done or not done. From the client side, I do not interact much with end users. I mostly work with interoperability experts on the client side when something needs to be defined and is not yet covered in the national specifications.
There are many different approaches and requirements for interoperability in different countries, right?	Actually, it is not only the interoperability aspects that differ, although they certainly do, but also the culture and the way of doing things. We have products that are very well adapted to the French context. A medical product that works well for French doctors may not be well adapted for Italian or German doctors, because they do not treat patients in exactly the same way and do not have the same infrastructure. So it is mostly a process issue rather than a purely technical one.
Looking ahead, what types of internal resources or capabilities do you think your organization will need most in order to successfully implement the EHDS once the required work is clearly defined?	I am not entirely sure yet, but I think we will have to strengthen our way of storing data, especially structured data. We currently store some structured data for primary use, but this will increase a lot, so we will definitely need to reinforce that. For secondary use, we already have a lot of social data, but we may not fully follow all international standards yet, so this will have to be aligned at some point. Compared with primary use, where there are many interoperability specifications, the EHDS does not yet go very deep into interoperability for secondary use. There is not much detail on how to structure or technically exchange data for secondary use. You have a lot of legal aspects and process descriptions, but not much on the technical side. Right now, the EHDS is defining a framework for exchanging data for secondary use for example, the obligation to provide data, how contracts can be set up, what can be exchanged, and so on. It does not really say, “You must exchange it in this specific format.” It hints at some directions, but mostly it says that you should choose a format and document it, and that will be acceptable. This will probably change, but we have to wait.
Have you already thought about the European Electronic	Yes, I have looked a lot into prescriptions. I am working with IHE France and HL7 France, and we were localizing the prescription specifications. So we aligned with the

Health Record Exchange Format? Is that something you are aware of or have opinions on, regarding primary use?	standard and added some extensions for French-specific use cases. I am quite familiar with that, although it is still unclear whether it will be based only on APIs or whether document-based exchange will also be used. You have to understand that in France we are currently very document-oriented, not API-oriented, and we do not usually provide data outside of its document context. We have looked into the exchange format, and it is something we would like to implement when it is ready. I have read the other parts as well, so I am aware of them, but apart from laboratories I have not yet seen many concrete use cases. Apart from cross-border exchange, which will be handled at the national level anyway, the national EHR system will take care of it, not each individual hospital.
What recommendations do you have for policymakers or companies to navigate digital health transformation and interoperability, and possibly the EHDS?	For policymakers, I think a use-case-oriented approach is very important; this has already started with the EHDS. We saw 20 years ago that simply saying "Use this standard and you will be fine, everyone will be able to exchange data" is not enough. You need to look at concrete use cases and see how things are actually done. If regulators and stakeholders do that, it becomes easier for everyone, because it provides a reference. People cannot really argue with a well-defined reference. They can say, "It is not ready yet; it will be updated in three months," but they cannot deny it. Another important point for regulation is to acknowledge that new developments take time: time to develop, time to test, and specifications are never perfect the first time. You have to be ready to revise specifications to make them better aligned with what happens in the real world. For implementers, it is crucial to know what is available, what specifications exist. That is a big job, because there are many specifications, and it is not always obvious which one applies to which use case. This requires some training. Sometimes you simply do not know which specification to use.

Appendix 4: Transkript I_P2

Questions	**Responses**
Are you currently only active in the German market, or also in other European countries?	We are mainly active in Germany, but we have had touchpoints in other countries. We are currently involved in a project in Austria, a classic remote patient monitoring project. There is also a larger project with nursing homes that is going to France. In addition, we have had smaller pilot projects from time to time. From this perspective, we do not have a complete overview of all customers using the platform. For example, I believe it has been used in Turkey by a Turkish company. So, primarily Germany, with some individual projects in other countries.
And the specific requirements for such systems in other countries, are these your responsibility, or do you only deal with them to a limited extent?	It depends. If we offer the solution directly to end users, then it is clearly our responsibility, and this will definitely become an issue in France, for example, probably in six to twelve months. We will then start looking into the requirements early on. If we provide the solution as a toolbox, then we are only involved in a secondary role. In that case, we often receive questions such as "Is it MDR-compliant?" "Is it ISO-compliant?" and so on. Then the answer is either yes, no, or "we need to check". We also support our customers in this, but in a more indirect way.
So for you, the basis is that all systems ultimately need to work together. Does interoperability essentially work now that there is a standard like FHIR, or are you still actively working on interoperability issues in your company?	Yes, we are definitely still working on it. Interoperability is always a big topic in discussions with medical users. For example, when we participate in funded projects, we are always very aware of it, because we are part of a consortium. People want to build something new, they have a new use case, and they usually have a highly motivated team of doctors on board, a university hospital or similar. They often want the data to be imported into their practice management systems or hospital information systems. FHIR alone is not always enough, because not all systems are fully FHIR-based. You then have to connect via the existing interfaces of those systems, and this often requires individual work. This is probably still the biggest obstacle for practical use: data flows are not "out of the box" in the way you would like them to be. There is a lot of manual work involved, and you are dependent on the third-party systems into which you want to feed the data. If you wanted to implement everything exactly as the doctors envision, it would often be very difficult or would exceed the scope of the project and no longer be proportionate. That is always a pity, you wish it would work more smoothly. Unfortunately, it does not yet, even though we use FHIR and others do as well. The issue is still far from being solved.
In this context, would you say that the biggest challenge is mainly the technical aspect, that there is still so	Yes, you could say that. From a technical perspective, it is definitely one of the biggest challenges. The biggest challenge in Europe, however, is to make the whole thing financially viable. That is the case everywhere, and it is by far the biggest challenge in the segment we are in. From a technical point of view, interoperability

much variation and the standard is not yet universally implemented?	and the usability of data are always quite difficult, both technically and from a data protection perspective. We can understand the data protection side, of course; we are not complaining and saying that data protection is all bad. But the two are often very intertwined, and you have to see how everything fits together. You cannot clearly separate them anymore; the purely technical aspects and data protection have grown together. That is definitely a major issue.
At the moment, you are not deeply dealing with the regulation itself. Do you have any recommendations for policymakers who are involved in the digital transformation of healthcare? You started digitally from the outset, but are there things you would recommend to those who are now implementing FHIR and similar changes?	I definitely know far too little; I know that I know nothing. But if you look at it purely from a process perspective, it is such a huge, complex topic that I cannot claim to fully understand it – it might make sense to look at existing systems that are already successful and then make changes or deletions in a fairly categorical and sober way. So: what can we keep or adopt 100%? And where do we really need to make specific changes, or not? This is actually common practice in software development; otherwise you end up destroying yourself. The problem is that things are constantly being rethought and rebuilt from scratch. That is a general issue, not only in software: a lot of energy is wasted this way in many areas. So my recommendation would be to approach it with an engineering mindset and see where you can build on what already works. You can still decide to do things 100% differently, but then at least it is an informed decision. I also have the impression that a lot is delegated to lawyers and consultants, who of course earn good money from constantly rethinking everything from scratch.
Is there anything else you think might be relevant for my research in terms of interoperability or what we have discussed that you have not mentioned yet?	Yes, specifically about interoperability. In Germany, the big issue is that KIS vendors are basically the monoliths and the entire market depends on them. I think a lot is possible in theory, but in practice it depends on whether these KIS vendors open up. That is what I have learned so far. They have a lot of market power. Interoperability depends strongly on them, because they are present in all hospitals, or the practice systems are. It is almost a yes-or-no question: either they open up and participate, or they do not, and the 500 other companies around them depend on that. If these smaller companies are interoperable among themselves, that has much less impact than if the five major HIS vendors open up. So in my view, it starts with them. I might be wrong, but that is my impression, and I would probably target them first.

Appendix 5: Transcript Focus Group

Question	Response
Q1: Have there been any changes in your company's governance structure or allocation of responsibilities of the EHDS and or are you planning such changes in the next 12 months?	FG_P1: Well, because of the because the specifications are not mature. But we have adjusted our roadmap with the stuff we are using in the Netherlands and that's the, it's called the Bege set. It's a basis set of data for a patient and that's what we are now building. To see if we can transport it to other hospitals and that should be it's comparable with the IPS and the AUPS. So that's what we are doing now at the moment. For one use case.
And would you say that that you would have done that anyway or the fact that there was this regulation coming up actually increased the interest or the speed to to do something with existing specs?	FG_P1: Oh, in the Netherlands, we were already at that level that we wanted to transport data from a patient to another patient to data from a patient to another hospital or another. Healthcare provider and in the Netherlands we are also using with personal health records. So we are trying to send data to a patient's personal health record.
But my question is, do you think at least for our Company that the fact that the regulation was adopted, the European one actually increased your? Your work at the national level or you were already planning to do it and it is actually something that actually is distracting you from that work. Or on the other hand, you said OK, we don't have the European specs yet, but the more we do at the national, maybe the more ready we are for whatever is coming. I don't want to influence you, I just want to clarify.	Oh, absolutely, yeah. That's the case. If we can transport data on the national level, we are ready to transport data on the international level. And of course it's the NCPs are not ready yet, not fully ready yet. So if we have to transport it to another country, that will be challenging if the NCPs can do that correctly. But that is something we have to find out if we can transport data within between hospitals. I'm not that care. How do you say that? I think we can do it on an international level as well. And besides that, we are also working for the defense ministry and for in that case we in that situation we have to transport the IPS. To another organization, and that can be worldwide.
Q1: Have there been any changes in your company's governance structure or allocation of responsibilities of the EHDS and or are you planning such changes in the next 12 months?	FG_P2: So, we have established an EHDS steering committee. So, as you are talk talking about governance structures, I started with referring our steering committee. We have also a few technical efforts, but probably it will be subject of another of the question. So since a year now we have a steering committee up and running and with this steering committee we keep aligned with developments such as we assign work to team members to assess the various documents that are released by extend DHR. Head us to of our projects soon and to see what we have to do in terms of product alignment and when as the directives have been around since a couple of years now and we have noticed that also the Document the rework document of extend the EHR they are similar to many extent with the directives. We have done a product align fit gap analysis for the for our products against the directives. And we aim to keep repeating this as the documents from extend the EHR and get us to our get an official status
And out of detail, curiosity, the steering committee, how often do you meet and then what is the structure, how does it relate to the existing structures and and whether you have other types of steering committees for other challenges that the company.	FG_P2: I'm not aware of other steering committees, but we do have in US especially this we discussed with we have a company structure that because of historical and geographic regions our European. Area is divided between 3 between 4 now area managers. So we felt that steering committee was the right word and we have we have gathered in this in this steering committee. It is chaired by one of the clinical executive. Of our region, EMEA and has about 10 people into it, mostly country managers, people from our legal department, people from our compliance department, people from our marketing team. So we try to touch more or less all. All divisions of the company and also all geographic areas and we meet every second month on average, so we meet 5-6 times a year.
Q2: What concrete risk as given from the EHDS regulation have you identified for your company in the next 12 months and how are you preparing for them?	FG_P3: So the response from our side, it's actually the one about the secondary use of data. When it comes to research, although there are some very general instruction, nothing more specified, especially national base have been released yet. So our understanding so far is that currently it gives us a good freedom and flexibility how to handle this, but this is on the same time very challenging. So this is the first risk that came up on my mind when it comes to the adoption of the regular behavior data space. How to deal with the infrastructure about the secondary use of data and give access to the research? What will eventually happen with the national authority and bodies that will help with this?
And how would you say that your Company is trying to prepare for this risk?	FG_P3: And to be honest, I'm not the technical person that supervise this activity. So actually from my side, what I'm trying to deal with is have a

	better knowledge and understanding also through my participation in projects such as I flex, for example, so that I can foresee the gaps and make a good use of testing experiments and pilot testings that we are having through project so that I can give back in my colleges a feedback on time. And adopt some good strategies in our products since our platform is also moving towards from MDD certification to MDR. OK, in theory it is already European Health Data Space complied. But we should deal with these in practice as well, so it's more complex.
Q2: What concrete risk as given from the EHDS regulation have you identified for your company in the next 12 months and how are you preparing for them?	FG_P4: I made the last answer because I'm a bit uncertain how we prepare for the risk in Denmark and right now we are concerned about the definition of EHR systems and how to implement them. And is the format going to be only in the FHIR or also in CDA? That's questions we've been asked by all the vendors in Denmark and we are waiting for this clarification from the Commission and I think the whole community of industries hesitating and waiting for some clarifications and that could impact our process of getting prepared for the implementation.
And so far, how are you preparing for this risk? So how are you? What is the organization's behavior? To deal with this uncertainty?	FG_P4: Well, right now we are in a special situation in Denmark because we have a big health reform. So the health authorities and the company where I come from, we are merged into one new organization and some of the regions are merged as well, so everybody is having focus about these big reorganizations in Denmark. So we have only looked into the legal aspects of EHDS and see how that's a sort of technical gap, since
So would I be correct to say that for now you made sure you mitigate any legal risk of falling into any legal misconduct, or let's call it this way, but not for the technical or for the specifications, because you also feel they're not there yet anyway?	FG_P4: Yes, it is a but we have all identified some legislation in Denmark that we can see we have to change to comply with the EHDS. So we will be have a plan for making these changes during 26.
Q2: What concrete risk as given from the EHDS regulation have you identified for your company in the next 12 months and how are you preparing for them?	FG_P5: Just on my side, I think one important topic I was the one that say clarity on the national provisions. I think it is important because most of the EHDS regulation it's not clear what the implications will have in national kind of systems, infrastructure, et cetera. So this connects very well with the FG_P4 kind of components and way of thinking. So in a way it is how systems needs to be changed, not only in terms of the important export kind of feature. It is also how national authorities and healthcare providers will facilitate access to data.
	FG_P1: Well, if you look at the Netherlands for the payment to the care providers, we use ICD in the Netherlands at the moment is that that's ICD 10, but in the future it will be ICD 11 and that's not fulfilled in the in the EHDS yet. So and if you look at the ICD 11 and SNOMED, it's well not comparable, but a lot of same codes in it and we have to find a way to adjust that so that payment can be still on a national level like we do within the Netherlands. That's some of the worries we have besides that getting the care providers register their data also through SNOMED, that's also a challenge. We have to find a way. We have now several projects within Company A how we can help the care providers to put that data in the database in the correct way using SNOMED.
So you mentioned that the company A have initiatives with their clients to prepare in this case data entry efforts. Why are you doing that as a sort of a mitigation for any upcoming needs from the European help at the space regulation, I mean what is the, what was the rationale?	FG_P1: Because we want to be the best EHR vendor and we always work together. We have several groups of care providers where we work together with nurses and doctors. Those are separate, but also the ICT specialists. And that's where we get the information from how we are building our EHR and that's we are also on the market in in Belgium and those groups are different because not the data is different, but the way they work in Belgium or the way they work in in the Netherlands is different and the payment is different.
FG_P2, could I ask you also, in your company, do you also have initiatives with clients either for sort of risk mitigation or others regarding specific preparation for the exchange format or for the European health data space?	FG_P2: No, we have not started yet to engage with the clients. Our clients are aware we have discussed with clients the need of alignment, but in France I know that and in Italy the clients are talking to us, but we have not taken any step yet. So it's not and the risk that I am that I put the first one that the reason that the implementing acts are not approved on time. This is a risk shared from our clients as well which they say will we be on time to dip to actually. Change our solutions and to implement on our solutions the changes that are required to make them compatible with EHDS. But because of there is not, there is nothing finalized yet when it comes to technical documentation. Obviously we haven't started doing some work with any of our clients. But we are aligned for both primary and

	secondary use. In Nordics for example, we are talking to a few partners who are interested on secondary use and as I said in France and Italy for primary use.
Q3: Have you created any specific team or roles to work on EHDS, for example legal architecture or interoperability or assigned particular people to follow the technical specifications?	FG_P6: As vendors we heard about the European health data space, but we asked for the concrete implementation guides for example and it's very difficult to obtain these is answered and I think that it's very theoretic concept, very, very high level theoretical concept and sometimes it's difficult to know exactly what we need to develop.
Have you come across, for example, this website of the exchange format where there's a bunch of resources put together into one website that was organized by X share?	FG_P6: Yeah, we look at it because for example in, we look at them. But I think that sometimes there are a lot of resources, a lot of, I mean sometimes you can look at different models and proposals, Profiles and artifacts and so on, but at least what I need is a link to the implementation guide with the fields is sometimes maybe there are a lot of information that maybe it's not fully useful for developers
	FG_P7: What you guys just said and FG_P6 what you just highlighted of course reminds me very much of our work and our ongoing deliverable and D 3.2 where we're where we actually collected a lot of views on the EHDS, the EHR exchange format and the hub. I think in the hub, in the X bundle registry, there should indeed be links to the relevant information implement. But of course, the implementation guides are not yet available for all of them. There's ongoing work being done by us to complete those. The laboratory report, of course, is a big example. Other work may be ongoing, so we're not quite there yet, but work is going on also in the Xt-EHR project, which of course, in turn requires us to adjust some of the implementation guides to the logical model of the Xt-EHR project. But there again, and this echoes what FG_P4 said earlier, is there's a lot of uncertainty because at this point, we just don't know. And the additional complication is that the Commission has been very assertive just recently to say, hey, what guys, what are you guys talking about in regard to the EHR exchange format? What possessed you? Developing this EHR exchange format website already. Who gave you the permission? It is us who's going to say who's going to determine what the EHR exchange format is. So we're the community HL7 and of course Xshare. We're navigating very carefully here. Around the on the one hand, the prickliness of, if you want, if you will, of the European Commission on the other hand, between on the other hand, the needs of implementers to really know what they need to, what they can use, what they can build on. We need to know these specifications because compliance. Will be awfully hard to achieve within two years. A lot of people are really interested in getting themselves ready and the timeline is very ambitious if you want to publish in March 27 and you require compliance for some categories already by March 2029. Then you're making it very difficult for all sorts of implementers and not just industry to align.
Q3: Have you created any specific team or roles to work on EHDS, for example legal architecture or interoperability or assigned particular people to follow the technical specifications?	FG_P8: So we are working on all three aspects, so legal, architecture and interoperability. So we do have a consultant team. That is helping us with the legal aspects and the regulatory aspects. We also have some technical positions from the system architecture kind of view where we are. Trying to implement those regulations s they become available and we have, we already have some interoperability positions because we're involved in several projects for the past few years, so we are very active on this, on this domain, on this scope.
Q4: How are you structuring interoperability work across the organization and respond to the EHDS, especially across different products and technical teams?	FG_P5: My answer, it was a specific work theme is created to specify the needs. So I'm going to try to elaborate a little bit on that. So basically we have two anchors for this. One, it is the development of agnostic kind of new features, so it is how we tweak the product. So there is a specific team that works in this needs assessment, clinical assessment, functional assessment and architecture changes. That are needed for that feature, then the product will make a priority and how we will implement that feature inside of the product and then we will assign two teams, one that will work on the interoperability and the one that will work on the product itself to be accommodate the ability for example to import or to export kind of information. The other anchor, it is also that we follow up the needs or the national specificities of the national authority and also what are the challenges that the different hospitals and clients that they use our system both in the private and in the public on our side for understand. How diagnostic feature will feed to the market and we don't need let's say

	to specify 10 times for 10 different clients because it's not really sustainable for a scale up situation where we are.
	FG_P1: Yeah, we have a special group. It's called the Exchange Group, which is also responsible for the platform to send and receive data. And we are recent. I'm one of the members of that and … is also one of the members and we are responsible to let the information of the EHDS land within the different groups. You can imagine that the EHR like we have a lot of different groups like medication, laboratory and so on. Appointments. So within those groups we take care that the information lens for the EHDS and also the standards to be used and it's a responsibility then of those groups to make their own group to see if that happens and we are sort of in charge to see if the information is correctly. Besides that, externally we are working for instance together with the Ministry of Health to take care that the information of the EHDS is also sent to other vendors. So we are together with the ministry, we are making webinars. Where other vendors can join and there we share our information as well and also with the Institute of Standardization we work together to see if. There will be things set correctly in the in the information we need from the EHDS and there where possible we try to see if we can use our national knowledge and to get that in the international aspects.
FG_P1, just to understand that, do you have a sort of a team that is called like the interoperability team or do you have interoperability roles in different product teams or service teams?	FG_P1: No, there is a special interoperability team. We call it the SNOMED team, but within that team it's not only SNOMED, it's also LOINC and other standard standards. And that is shattered around the around the organization within other teams. Well, it's a sort of, it's a sort of pyramid. On top is the exchange platform. Those are gathering all the information about the EHDS and there where we need specific information like DICOM or a light lab, we go to the other groups and get the information from there and take care that they get the information for the EHDS implementations.
FG_P3, do you have a team of for interoperability, or everyone does it or you're sort of struggling to create one or you don't think you should have one? How does it work?	FG_P3: So actually, the answer is both, meaning that we also have imported and not very recently, it's more than five years ago that we had imported some interoperability experts. But now things shows that we should focus more on interoperability experts that are also aligned with the new regulations are coming. So both, but not of course the third alternative you suggested that we think we don't need it. No, of course we always should stay updated on this. No, it's needed across all different products and considering that we are delivering both products for end users, I mean a platform that provides interfaces for end users, but also back-end products. It is even more clear to us in in such a way that the capacity is needed horizontally in all these products.
	FG_P4: Yeah, I think the industry market is broad and you have some very big vendors and some small, very small vendors and at the big vendors they have a sort of architect team or who has read the EHDS regulation. But if you take a lot of small vendors, they have heard about EHDS and no further. So in Denmark we try to invite them and try to have some webinars for them to educate them to get some knowledge about EHDS.
	FG_P1: Even in the Netherlands, are still vendors who haven't heard about EHDS.
	FG_P7: I want to second this on my conversations with some vendors. I mean, even those that are at the 4th, even the big vendors that are at the forefront, the people who know about the EHDS cannot always make their voices be heard amongst the product developers. Sometimes these companies are simply too big. So yes, they have the capacity to know about it, but to what extent the product developers and the sales people, how this disseminates within the company is sometimes also a challenge. So even the big vendors, they should be aware, but they may not always be. So that is a that is a universal problem, I think affecting large and small for different reasons.
Q5: How is the EHDS preparation influencing your commercial strategies, for example, your pricing approach, your partnerships with clients or other companies and your positioning in the market?	FG_P9: Especially for our case of my Company and regarding the Catan region because in our case we are not that implied in in this in these activities. But yeah what I would say is that as the EHDS is already a reality for everyone and that we detected already from many a couple of years ago the necessity to adapt to that. It was very important especially in the for example the procurement processes in the in the in the last. Years to include these early adoption early discussions in in the processes

	just to show that in the selection process of companies that would be suppliers of different kind of technologies would already have some experience in this in this context. So yeah this is the some examples that I could give now for the discussion but anyways with the. I think that would be a very interesting partner that could give more details about the yes, this commercial strategy. But yes, in any case to make sure that all the regulation is considered and from the most early stages is one of the most important aspects. So I see that the other comments are let me see. This is different for public or private care providers. That's a real fact, especially because they have different contexts. So yeah, there's some pricing at this stage. The main driver is the possibilities that the EHDS will unlock for a start-up in terms of market expansion and better support to clinical decision support systems, I think. And the last one, it's not only the regulation that's important, also medical device regulation certification. That's for sure. And the EHR regulation is written down in package of requirements of the care providers. So yeah, I think besides.
So for example, on this one, have you been approached as Company H by, for example, healthcare providers to try to understand what they have to do considering this regulation or not yet?	FG_P9: Yeah, well, in our case also we have the data protection office that gives us support especially in the in this legal context. So and this is a consultancy service that all the public system can ask for, and yes also in the in the procurement processes we always have all the aspects that the EHDS will imply. So, yes
Q5: How is the EHDS preparation influencing your commercial strategies, for example, your pricing approach, your partnerships with clients or other companies and your positioning in the market?	FG_P1: Well, it's law. So we have to fulfill this requirement. But besides that, I think we are one of the only EHR vendors who is MDR certified. The EHDS has a complete impact on that MDR certification because if you have a new version which is compliant to the EHDS, it means you also have to do your MDR certification. Again, so everything fits together and it's a lot of work, but it's also a challenge to get new clients.
So would that be right to understand that what you're saying is for companies that have MDR certificate certified products, getting ready for this means extra work not to lose that certification?	FG_P1: Correct. If you have to fulfil the EHDS like the use cases which are asked now, like the IP or a UPS and medication prescription. That means you have a new version of your software. If you have a new version of the software, you need to do your MDR certification again because it's a high impact. And that's also going for the for the AI pact and the other certifications. There are also a lot of national certifications you have to do again because it's a new version. And that means a lot of work and a lot of money.
Q5: How is the EHDS preparation influencing your commercial strategies, for example, your pricing approach, your partnerships with clients or other companies and your positioning in the market?	FG_P3: Yes. Actually I don't have a very strong opinion on this because the pricing approach is a more business oriented perspective. Well, what I know for sure is that usually our approach differs. According to the case, according to the client and the companies, and when you provide software, it depends to many different factors. That's the support we're going to provide the amount of license and stuff like this. So I'm afraid that I cannot contribute very much to this question.
	FG_P5: Now just one comment, because I think this relates with a comment that FG_P10 put on the chat. I think this also depends on the role of each system because in a way the satellite kind of systems, let's call it in this way, that's usually support departments. They are very tied to interoperability and the need of data for EHR. So for that the EHDS it is a kind of an advantage. But if you are an EHR and you have let's say a proprietary kind of database and all information it is in the same system and you want to have prime time of your users to always be. Connected in your user interface, Yeah, this may not be an advantage. The EHDS may be a kind of regulation that will cut some market to your kind of if you think in the end user's kind of perspective. It's not really about pricing. For me it is also about what system we should advocate or in line of the EHDS should have prime time of the physicians that really have impact on the treatment of the patients.
	FG_P1: Agree. If it's law, you can't. You can't hang pricing on it. if you look at the national level, every year some laws change or at least in the financial part there are things change and that's something you have to do as a vendor, because your product needs to fulfill the needs of the law and.
Q6: Are any business models around interoperability health data that you are currently considering implementing in your company?	FG_P8: I'm not sure. I'm not involved in in the business model discovery and exploration. So I'm not really, I don't really know if we have some kind of EHDS oriented business model. My take however would be on how we could leverage the primary and the secondary use of data and build a business model around that. That would be a very interesting business

	direction I think, but apart from my thinking I'm not really sure of how we are exploring this this field.
Who mentioned about the national barrier, the national infrastructures and specifications being a sort of a barrier to the free EHR market?	FG_P4: Yes, yes, it's a concern I have because uh. In the ambition with the EHDS that this should be more easy to open market in the whole European Union to take an EHR system from one country and use it in another country. And it's a brilliant ambition, but I'm concerned whether we end up with having a common exchange format. But we still have a lot of old national infrastructures which make it hard to implement cross-border EHR systems. Um, I don't know what. I think we should make some requirements for the national sharing of data as that add on to the cross-border sharing of data. So we use the exchange format for. Internal in each country we have internal needs of the integrations as well. So wherever you can use the exchange format and the components, we should that that should be mandatory in each member state.
	FG_P1: Either I misunderstand the answer FG_P4 gave, but isn't it so that on the article of the interoperability module, EHR vendors have to build in the format to exchange that data so. If a vendor has that built in his software, it's also able to send that information on a national level. I'm not talking about information exchange within a laboratorium information system in a hospital and the EHR between care providers, and that's one of the articles the EHDS is covering that an EHR should have that interoperability module.
	FG_P4: Yes, but my concern goes that we have to implement this ability to receive or send in the exchange format, but at the same time we have some national standards for uploading medication or lab reports. Which we have been used for the last 20 years. And if we don't change those, if we keep running in these old integrations in each member states, it will still be difficult to move a system from 1 country to another. So we have to make a sort of migration away from the old integrations inside the country. So we use the exchange format for both when we share them cross-border in an SDS use case, but as well as if you have a national database where we upload the data, we should we should mandate people to use the exchange format at these use cases as well.
	FG_P1: Isn't that something what will happen naturally if you have to exchange format built in your software and you have to keep that? How do you say that to get keep that? Always the same. Shouldn't that leave the old stuff out? But if I have to exchange my data and for instance a lab report, that's something we have to do within the EHDS, there's the format for and if we exchange that lab for lab report in the new format of the EHDS. Shouldn't that be easier then then to also send that information in an old way?