Aalto University
School of Science

Master's Programme in Life Science Technologies

Interoperability in Centralized and Decentralized Healthcare Systems: How to Integrate a Finnish Digital Health Application into Germany's Telematics Infrastructure

Veera Repka

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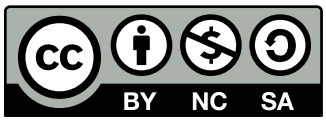

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Abstract

This thesis explores the challenges and opportunities of integrating a Finnish digital health application into Germany's telematics infrastructure (TI) with a particular focus on TI-Messenger as a secure communication platform. Through a comparative analysis of Finland's centralized system based on Kanta Services, and Germany's decentralized TI ecosystem, the study highlights structural, regulatory, and technical differences that impact cross-border interoperability. The research is grounded in qualitative interviews with German professionals involved in TI-Messenger development and implementation within the TI. Findings reveal that while technical integration is feasible, practical barriers such as certification complexity, market saturation, and limited workflow support hinder adoption. The study concludes that strategic partnerships and value-added services may offer the most viable path for foreign providers. These findings contribute to a broader discussion on the harmonization of digital health at the EU level and provide insights into future policy and integration strategies.

Keywords Interoperability, Digital Health, Electronic Health Record, Telematics Infrastructure, TI-Messenger, Healthcare Data Exchange, Integration

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Tekijä Veera Repka

Työn nimi Yhteentoimivuus keskitetyissä ja hajautetuissa terveydenhuollon järjestelmissä: Miten suomalainen terveyssovellus integroidaan Saksan telematiikkainfrastruktuuriin

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Tiivistelmä

Tässä diplomityössä tarkastellaan suomalaisen digitaalisen terveyssovelluksen integrointia Saksan telematiikkainfrastruktuuriin (TI), erityisesti hyödyntäen TI-Messenger-viestintäalustaa. Vertailu Suomen Kanta-palveluihin perustuvan keskitetyn järjestelmän ja Saksan hajautetun TI-ekosysteemin välillä tuo esiin rakenteellisia, sääntelyyn liittyviä ja teknisiä eroja, jotka vaikuttavat kansainväliseen terveydenhuollon yhteentoimivuuteen. Työssä tehtiin haastattelut saksalaisten asiantuntijoiden kanssa, joilla on laaja-alainen tausta liittyen Saksan TI:hin ja TI-Messengeriin. Tulokset osoittavat, että integraatio on teknisesti mahdollista, mutta käytännön haasteet kuten sertifioinnin monimutkaisuus, markkinoiden saturoituneisuus ja rajallinen työnkulun tuki hidastavat käyttöönottoa. Ehdotuksena on, että ulkomaisille toimijoille kannattavin etenemistapa on strategiset kumppanuudet ja lisäarvoa tuottavat palvelut. Tulokset tukevat EU-tason digitaalisen terveydenhuollon harmonisointia ja tarjoavat näkökulmia tuleviin politiikka- ja integraatiostrategioihin.

Avainsanat Yhteentoimivuus, digitaalinen terveydenhuolto, sähköinen potilaskertomus, telematiikkainfrastruktuuri, TI-Messenger, terveysdatan jakaminen, integraatio

Esipuhe

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Otaniemi, 26 September 2025

Veera Repka

Contents

Abbreviations

ABDA	Federal Union of German Associations of Pharmacists
AI	Artificial Intelligence
API	Application Programming Interface
BfArM	Federal Institute for Drugs and Medical Devices (Germany)
BfDI	Federal Commissioner for Data Protection and Freedom of Information
BMG	Federal Ministry of Health (Germany)
BSI	Federal Office for Information Security (Germany)
CDA	Clinical Document Architecture
DICOM	Digital Imaging and Communications in Medicine
DigiG	Digital Act
DKG	German Hospital Federation
DVG	Digital Care Act
DVPMG	Digital Care Modernization Act
DVV	Digital and Population Data Services Agency (Finland)
eGK	Electronic Health Card
eHBA	Electronic Health Professional Card
EHDS	European Health Data Space
EHR	Electronic Health Record
EHRxF	European Electronic Health Record Exchange Format
EIF	European Interoperability Framework
eMP	Electronic Medication Plan
ePA	Electronic Patient Record
eRx	Electronic Prescription
EU	European Union
FHIR	Fast Healthcare Interoperability Resources
G-BA	Federal Joint Committee (Germany)
GDNG	Health Data Utilization Act
GDPR	General Data Protection Regulation
HIMSS	Healthcare Information and Management Systems Society
HL7	Health Level Seven
HTTP	HyperText Transfer Protocol
ICD	International Classification of Diseases
ICT	Information and Communication Technology
IEA	Interoperable Europe Act
IHE	Integrating the Healthcare Enterprise
ISiK	Informationstechnische Systeme in Krankenhäusern
ISO	International Organization for Standardization
IT	Information Technology
JSON	JavaScript Object Notation
KBV	National Association of Statutory Health Insurance Physicians (Germany)
Kela	Social Insurance Institution (Finland)
KIM	Kommunikation im Medizinwesen

KZBV	National Association of Statutory Health Insurance Dentists (Germany)
NFD	Emergency Data Record
NGO	Non-Governmental Organization
PDSG	Patient Data Protection Act
PHI	Private Health Insurance
PHR	Personal Health Record
REST	Representational State Transfer
RIM	Reference Information Model
SDK	Software Development Kit
SHI	Statutory Health Insurance
SMC-B	Security Module Card
SNOMED	Systematized Nomenclature of Medicine
SNOMED CT	Systematized Nomenclature of Medicine Clinical Terms
SOAP	Simple Object Access Protocol
STM	Ministry of Social Affairs and Health (Finland)
THL	Finnish Institute for Health and Welfare
TI	Telematics Infrastructure
TI-M	TI-Messenger
Valvira	National Supervisory Authority for Welfare and Health (Finland)
VSDM	Versichertenstammdatenmanagement
WHO	World Health Organization
XHTML	Extensible HyperText Markup Language
XML	Extensible Markup Language

1 Introduction

1.1 Background and Motivation

Digital transformation is reshaping the landscape of healthcare across the world. While the benefits of information technology in healthcare are undeniable, from electronic health records to AI-assisted diagnostics, the field continues to face complex challenges, particularly when it comes to interoperability. Healthcare remains fundamentally local: every country has its own health infrastructure, regulations, reimbursement models, and care pathways. As a result, sharing data across systems or borders remains difficult, despite increasing technological possibilities. (European Commission 2017)

In recent years, digital health and telemedicine have gained wide adoption. New systems for recording and accessing patient data have emerged, and innovations, such as remote monitoring, AI-driven analysis, and health applications, are becoming integral parts of modern healthcare. While new records are increasingly created digitally, existing data is often unstructured, fragmented, or incompatible between providers or countries. For instance, medical terminology, data formats, and metadata structures often differ even between hospitals, let alone nations, making data exchange a complex technical and policy challenge. (Stoumpos, Kitsios, and Talias 2023)

This complexity becomes more pressing as the number of interconnected medical devices and software applications continues to grow. From fitness trackers and glucose monitors to comprehensive hospital information systems, these technologies generate vast amounts of health data. However, the current fragmentation and lack of harmonized interoperability standards across healthcare systems in the EU pose significant challenges to effectively integrating and sharing this data. While digital health innovation is progressing fast, the full potential of these technologies to enhance care coordination and patient outcomes is constrained by the absence of unified frameworks that enable seamless data exchange and compliance with evolving regulatory requirements. (Rak and Quinn 2024)

Recognizing the importance of health data exchange, the European Union is pushing towards the European Health Data Space (EHDS), a flagship initiative to promote secure, standardized, and interoperable health data sharing across member states (European Union 2025). While national-level systems for interoperability already exist and continue to evolve, harmonizing them across countries remains an open challenge.

This thesis focuses on the national interoperability frameworks of Finland and Germany, two EU countries with highly developed but structurally different healthcare systems. A demonstrative use case explored in this thesis is a Finnish digital health application initially built to work within the Finnish system, which now explores options for integrating into the German healthcare infrastructure. This real-world scenario works as an example for the broader challenges and opportunities of interoperability

in cross-border digital healthcare solutions.

1.2 Scope and Key Concepts

This study focuses on the national-level interoperability infrastructures of Finland and Germany. It covers public sector-driven systems, such as Kanta Services in Finland and the gematik infrastructure in Germany, key technologies and standards used to enable healthcare data exchange and interoperability, regulatory frameworks, including GDPR and national laws governing patient data protection and access, and organizational roles and governance structures involved in maintaining, regulating, and implementing digital health systems in each country. The analysis is grounded in a real-world use case: a Finnish digital health application developed for integration with the Finnish system. The scope includes examining the options for this app to integrate to the German telematics infrastructure.

The following key concepts are central to this thesis:

- **Interoperability**: The ability of different information systems, devices, or applications to connect, exchange, and use data effectively.
- **Digital Health**: The use of information and communication technologies (ICT) in healthcare services, including digital records, health apps, teleconsultations, and other tools that enhance patient care and system efficiency.
- **Telemedicine**: A sub-domain of Digital Health, referring specifically to the provision of medical services remotely via ICT, such as remote diagnosis, consultation, and patient monitoring.
- **Kanta Services**: Finland's national digital health record system, operated by Kela, enabling centralized storage and secure sharing of patient health information.
- **gematik**: The organization responsible for managing Germany's national digital health infrastructure, including electronic health records and related systems.
- **TI-Messenger**: short for Telematics Infrastructure Messenger (TI-M), it is a secure and interoperable messaging system specifically designed for healthcare professionals in Germany. It facilitates secure communication between different healthcare providers, ensuring data protection and compliance with German regulations, including GDPR.
- **EHDS (European Health Data Space)**: An EU-level initiative aiming to establish a common framework for secure and standardized health data exchange across the member states.

1.3 Collaboration and Industry Relevance

This research is conducted in cooperation with two companies, adesso and BeeHealthy. adesso is an IT service provider in Europe actively involved in healthcare digitalization in Germany, and seeks to deepen its understanding of integration pathways for foreign health applications within the German system. BeeHealthy, a Finnish digital health provider, represents the private sector's agile and user-centric approach to healthcare innovation. BeeHealthy's interest in the German market centers on understanding what constitutes a successful integration with the TI and TI-Messenger taking into account technical compatibility and regulatory compliance, practical use cases and certification pathways.

1.4 Research Questions and Objectives

The increasing demand for interoperable e-health solutions across national borders, especially within the European Union, raises questions about how different healthcare systems can support cross-country data exchange and integration of digital health tools. This thesis investigates the structural and functional differences between healthcare data systems of Finland and Germany in terms of interoperability, and how these differences affect the integration of a Finnish digital health application into Germany's telematics infrastructure.

The research is guided by the following questions:

1. **How do the Finnish and German healthcare interoperability systems compare?** This question explores the structural, technical and governance-related aspects of interoperability in both countries.

2. **What are the options for a Finnish digital health application to integrate into the German TI?** This includes an assessment of regulatory, technical and organizational pathways for integration.

3. **What are the use cases and opportunities for using TI-Messenger in the integration?** This question focuses on the role of TI-Messenger within the TI ecosystem and its relevance for cross-border digital health services.

To address these questions, the thesis sets out the following objectives:

1. To compare the healthcare interoperability frameworks of Finland and Germany by identifying key stakeholders, legal structures, governance models, and technical standards that shape data exchange in each country.

2. To assess the feasibility and challenges of integrating a Finnish digital health application into Germany's telematics infrastructure, considering regulatory compliance, technical compatibility, certification requirements, and organizational readiness.

3. To explore the role of TI-Messenger within the TI ecosystem, and evaluate its potential use cases and opportunities for supporting cross-border integration of digital health services.

These questions and objectives are framed around the core constructs of interoperability, governance, technical standards, and digital health system integration. They guide the comparative analysis of the systems and link the theoretical background to the practical case study involving BeeHealthy and adesso, contributing to the broader discourse on digital health interoperability in the EU.

1.5 Structure of the Thesis

This thesis is divided into six main chapters. Chapter 1 introduced the topic by presenting the background and motivation for the research, outlining the main research questions and objectives, defining the scope, and explaining the key concepts. Chapter 2 provides a comprehensive literature review, discussing the concept and importance of interoperability in healthcare, its technological and organizational dimensions, relevant trends in the European context, and a detailed comparison of the healthcare data systems in Finland and Germany.

Chapter 3 outlines the research methodology, explaining the qualitative approach adopted, the methods for data collection, and how the analysis is done. Chapter 4 presents the findings of the research, focusing on the interviews conducted and the insights gained from them. In Chapter 5, the findings are discussed in relation to the research questions and the prior literature. This chapter also considers theoretical and practical implications, outlines the limitations of the study, and offers suggestions for future research. Chapter 6 concludes the key results and contributions of the research. Additional material, such as interview questions, are included in the appendix A.

2 Literature review

Interoperability in healthcare has emerged as a critical field of study within health informatics, public policy, and information systems, driven by the rapid digitalization of health services and the increasing demand for coordinated, data-driven care. Over the past couple of decades, academic research has examined the technical, semantic, legal, and organizational challenges of achieving interoperability, and also the benefits it offers for clinical outcomes, administrative efficiency, and health system integration (Vest and Gamm 2010; Gil-García, Pardo, and Luna-Reyes 2022). Key studies have evaluated how electronic health records (EHRs), health information exchanges (HIEs), and cross-border data-sharing frameworks have evolved, particularly in the European Union context under initiatives like the European Health Data Space (EHDS) and the earlier eHealth Action Plan.

While there is knowledge about interoperability from a technical or architectural point of view, less attention has been paid to comparative analyses of national implementation strategies, or into how real-world applications, such as digital health apps, can be adapted to navigate different infrastructures. This chapter provides a foundation for understanding healthcare interoperability, with a particular focus on developments in the EU and case examples from Finland and Germany. It reviews relevant academic literature, policy initiatives, and technical frameworks to ground the research questions and analysis presented in this thesis.

2.1 Concept of Interoperability

Healthcare Information and Management Systems Society (HIMSS) defines interoperability as "the ability of different information systems, devices and applications (systems) to access, exchange, integrate and cooperatively use data in a coordinated manner, within and across organizational, regional and national boundaries, to provide timely and seamless portability of information and optimize the health of individuals and populations globally" (Healthcare Information and Management Systems Society (HIMSS) 2019). Put simply, interoperability means the ability of two or more different systems to exchange and use information. This requires the adoption of standardized protocols and data formats to make sure that the information exchanged and used is stored and interpreted similarly in all systems involved. Interoperability in a simple form is demonstrated in Figure 1. Person A, working with system A, has some information that needs to be sent to person B working with system B. They have an interoperability system between their systems that enables the information to be stored, moved, saved and used as intended.

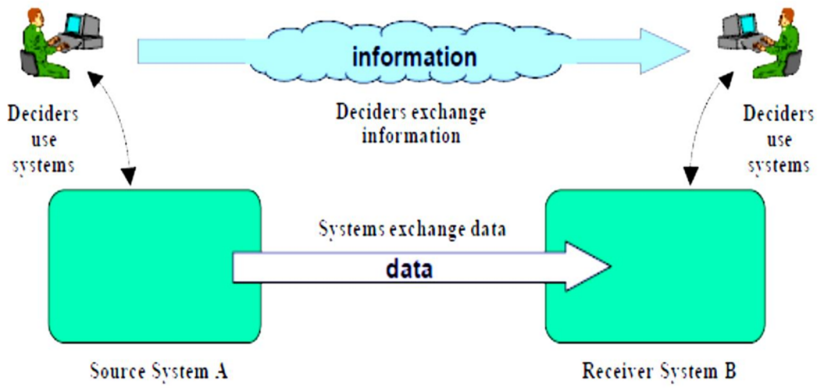

Figure 1: Concept of interoperability (Institute for Alternative Futures (2006), as cited in Olaronke et al. (2013))

The European Interoperability Framework (EIF) (European Union 2017), introduced in 2004 and revised in 2010 and 2017, was developed and has since been used as a guide to develop integrated and interoperable cross-border digital public services (Gil-García, Pardo, and Luna-Reyes 2022). In EIF, interoperability is divided into four main layers:

- **Legal interoperability** means ensuring that organizations operating under different legal frameworks, policies and strategies can work together.
- **Organizational interoperability** is the way public administrations align their business processes, responsibilities and expectations to achieve commonly agreed and mutually beneficial goals.
- **Semantic interoperability** is about making sure that the precise format and meaning of exchanged data is preserved and understood throughout exchange processes between parties.
- **Technical interoperability** refers to the applications and infrastructures which are linking systems and services. This includes interface specifications, interconnection services, data integration services, data presentation and exchange, and secure communication protocols.

In addition to these four core layers, EIF includes two governance-oriented components that support and enable effective implementation. As illustrated in Figure 2, a cross-cutting layer of integrated public service governance spans the main interoperability layers, ensuring that services are designed and delivered consistently and user-friendly. In the background, there is the interoperability governance layer, which provides the strategic oversight, coordination mechanisms, and monitoring tools necessary to sustain and evolve interoperability efforts across different administrative levels and policy sectors (European Union 2017). Introducing this model helps to clarify that interoperability in EU involves more than just technology, and requires coordination

and alignment across all layers. It also emphasizes the role of governance in enabling the public services, such as healthcare, to function across borders.

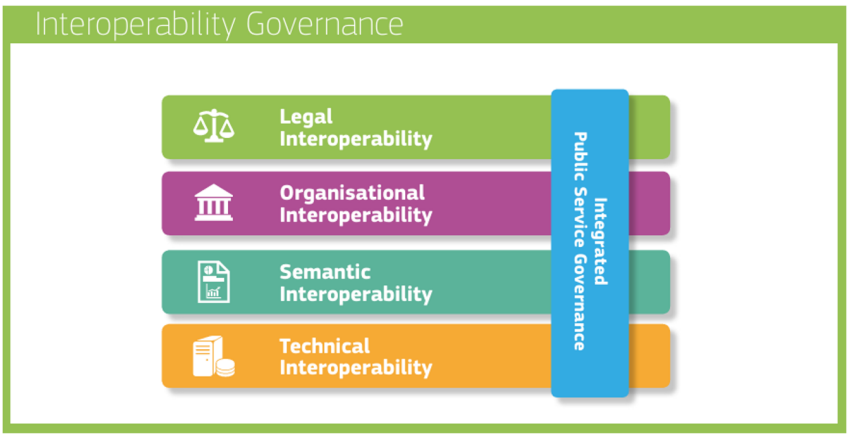

Figure 2: Interoperability layers of EIF. (European Union 2017)

The EU supports interoperability initiatives and frameworks in multiple sectors, including healthcare, justice and security, transport, finance, digital administration, and more. For instance, one of the main six interoperability systems in EU in justice and security is the Schengen Information System (SIS), which includes the information control of persons and objects for judicial authorities and national border control to help maintain public order and security (Duić and Rošić 2022). Although interoperability is a foundational concept in many sectors, its application in healthcare is particularly significant. Health systems involve a wide array of actors, sensitive data types, and critical timing requirements. The increasing digitalization of healthcare delivery, the rise of telemedicine, and the growing demand for patient-centered care have intensified the need for interoperable systems that function seamlessly across institutional and national borders. The next section examines the role of interoperability in healthcare, outlining its impact on care delivery, data governance, and system integration in the EU context. According to European Commission (2021), following the EIF recommendations and establishing interoperability systems in the EU can save time, reduce costs, increase transparency, and improve the quality of services that public authorities provide.

2.2 Interoperability in Healthcare

Interoperability in healthcare refers to the ability of diverse health information systems, devices, and applications to access, exchange, integrate, and use data in a coordinated manner within and across organizational and national boundaries (Healthcare Information and Management Systems Society (HIMSS) 2019). Given the complexity of healthcare, involving a wide range of stakeholders including hospitals, clinics, laboratories, pharmacies, insurers, and regulatory authorities, interoperability is essential for

enabling safe, timely, and effective care delivery.

Efforts such as the European Health Data Space (EHDS) by European Union (2025) aim to promote interoperable health data sharing to enhance cross-border healthcare, patient mobility, and research collaboration. Healthcare-specific interoperability must include not only technical and semantic requirements, but also the legal and organizational layers defined in the European Interoperability Framework (EIF). This highlights that achieving interoperability in healthcare is as much about aligning governance, workflows, and consent management as it is about standardized data formats.

Interoperability plays a crucial role in supporting both clinical and administrative tasks. According to iEHR.eu (2025a), interoperable systems enable a wide range of activities: requests for diagnostic investigations, ePrescriptions, patient transport orders, and coordination of nursing care and medical equipment; the sharing of diagnostic reports (radiology, nuclear medicine), electronic medical records, consultation and discharge summaries; and the exchange of administrative data, including registration, billing and auditing.

From a broader systems perspective, interoperability also enables digital transformation in healthcare. Innovations like electronic health records, telemedicine platforms, wearable health devices, and AI-driven diagnostic tools depend on structured, standardized, and accessible data to function effectively. When implemented in a comprehensive way, interoperability improves care quality, enhances patient safety, and reduces inefficiencies (Stoumpos, Kitsios, and Talias 2023; Rak and Quinn 2024). However, interoperability is not merely a technical solution but a socio-technical challenge requiring cooperation across clinical, regulatory, technical, and institutional domains (Vest and Gamm 2010; Gil-García, Pardo, and Luna-Reyes 2022).

2.2.1 Regulation

Adopted in March 2025, the European Health Data Space (EHDS) Regulation represents a cornerstone of EU-level regulation in healthcare interoperability. It establishes a comprehensive legal and technical framework for the access, sharing, and reuse of electronic health data across the member states, aiming to empower individuals and support innovation, policy, and research across the EU health sector. EHDS has two focus aspects:

- **Primary Use of Data**: This refers to the use of health data by healthcare providers for delivering care. It encompasses activities such as medical treatment, rehabilitation, the prescribing and dispensing of medicines and medical devices, as well as administrative and reimbursement processes (European Commission 2025c).
- **Secondary Use of Data**: This involves reusing health data, which is originally

collected in the context of patient care, for purposes beyond direct treatment. Examples include scientific research, public health policy development, regulatory decision-making and innovation (European Commission 2025c).

The EHDS ensures that individuals have the right to access, control, and share their health data securely, even across borders. For secondary use, the regulation creates a legal and governance framework to guarantee trustworthy and privacy-compliant reuse of health data. It also sets requirements for data governance, standardization, system certification, and individual rights, including data portability and consent management (European Union 2025). Furthermore, the EHDS aligns with the EU's broader European Data Strategy, which aims to make the EU a leader in a data-driven society (European Commission 2020). The strategy envisions a single market for data that spans across sectors, enabling public administrations, businesses, and researchers to access data for innovation and evidence-based decision-making.

The General Data Protection Regulation (GDPR) is the foundational legal structure upon which EHDS is built. GDPR came into effect in May 2018, and it is a core framework for data protection and privacy in the EU. Although EHDS tries to enhance primary and secondary use of health data, it maintains compliance with GDPR (European Commission 2025b) and ensures that data protection and privacy are integral to the interoperability framework.

GDPR has a broader connection to interoperability, because it both enables and constrains interoperability in healthcare. On one hand, it enables interoperability by introducing the right to data portability. This allows individuals to receive their personal data in a structured, commonly used, and machine-readable format and to transmit it to another service provider (European Union 2016). Furthermore, GDPR harmonizes data protection laws across EU member states, reducing legal fragmentation and thus supporting cross-border interoperability (Organisation for Economic Co-operation and Development (OECD) 2021). On the other hand, GDPR also presents barriers to interoperability. The right to data portability is limited to data provided by the user, and does not extend to data processed for legal obligations or public interest, which restricts broader reuse of the data (European Union 2016). Moreover, there is no legal obligation for service providers in GDPR to ensure technical compatibility or real-time interoperability with other platforms, meaning systems can remain closed or siloed despite being compliant with GDPR (Electronic Frontier Foundation 2021). This gap has led to proposals such as the Digital Markets Act, which aims to go further than GDPR by enforcing real-time interoperability and reducing vendor lock-in.

Complementing EHDS and GDPR, the Interoperable Europe Act (IEA) that entered into force on April 2024 aims to reinforce cross-border interoperability among public administrations across all sectors (European Commission 2023b). While not specific to healthcare, the IEA plays a key enabling role in the digital transformation of health systems by promoting the reuse of common interoperability solutions and harmonized technical frameworks. This broader interoperability strategy ensures that

public healthcare providers and national health systems can align with EU-level data infrastructures and exchange mechanisms (European Commission 2023b).

The foundation for current digital health regulation in the EU was laid by the eHealth Action Plan (2012–2020). This initiative aimed to improve healthcare through ICT by promoting cross-border eHealth services, encouraging patient empowerment, and addressing legal and technical barriers to interoperability (European Commission 2012). Although the plan has concluded, it significantly shaped the digital landscape that allowed the emergence of the European Health Data Space. Concepts like patient-controlled data access and digital infrastructure interoperability, first emphasized in the eHealth Action Plan, are now central to EHDS implementation.

Together these regulatory initiatives; GDPR, EHDS, the Interoperable Europe Act, and the eHealth Action Plan, illustrate the evolving commitment of the EU to secure, harmonized, and patient-centric health data ecosystems. They enhance the establishment of a comprehensive framework that balances technological innovation, individual rights, and cross-border cooperation.

2.2.2 Technical Frameworks and Standards

Technical frameworks and standards form the backbone of interoperability in healthcare by ensuring that information systems are able to communicate seamlessly, effectively, securely and consistently. In the EU, the development and adoption of common technical specifications and practices are essential for the goals of EHDS, Interoperable Europe Act and other initiatives. Achieving cross-border healthcare delivery and data exchange requires shared protocols, data models, and semantic vocabularies. To enable data exchange, and semantic and system consistency between different institutions in the EU member states, the EU promotes the use of international and European standards. These standards ensure that health data, such as prescriptions, diagnoses, and laboratory results, can be understood and safely transmitted between providers, systems, and countries regardless of the vendor or platform.

Digital Imaging and Communications in Medicine (DICOM) is the established international standard for exchanging, storing, and managing medical imaging data. Widely used in radiology, cardiology, and increasingly in ophthalmology and dentistry, it ensures interoperability between imaging devices such as X-ray, CT, MRI, and ultrasound machines. Since it was adopted in 1993, DICOM has replaced traditional film with digital workflows, enabling consistent image quality, metadata management, and cross-system compatibility. Standardized as ISO 12052, DICOM supports efficient archiving and sharing of large image files and related patient data. (DICOM Standard Committee 2025)

International Classification of Diseases (ICD), developed by the World Health Organization (WHO), is a global standard for coding diseases and health conditions

and causes of death to support consistent documentation, reporting, analysis and comparison of health data across countries. ICD codes are used in primary to tertiary care, mortality reporting, billing, resource planning, and research. (World Health Organization 2025) The version ICD-10 is still widely in use, and it uses codes from three to seven characters to represent disease categories, severity, etiology, and care episodes (Park 2024). The most recent version ICD-11 was adopted in 2019 and came into effect in 2022. It represents an improved precision, broader clinical coverage, and improved interoperability with different digital systems. ICD-11 expands on the previous standard with a multilingual and digitally integrated structure, making it better suited for electronic health records and analytics applications, such as AI. WHO has also aligned ICD with other terminologies (e.g. LOINC and SNOMED CT) to support semantic interoperability and enable accurate health data exchange worldwide. (World Health Organization 2025)

For clinical terminology, the EU encourages the use of Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT). It is a comprehensive multilingual clinical terminology that standardizes clinical concepts. By ensuring that clinical terms are interpreted consistently across systems and languages, it supports semantic interoperability. SNOMED CT is particularly valuable in electronic health records (EHRs), decision support systems, and health data analytics. The EU promotes its adoption to facilitate cross-border data exchange, especially in the context of EHDS and the European Electronic Health Record Exchange Format (EHRxF) (SNOMED International 2022; European Commission 2016).

Another universal standard used in healthcare is Logical Observation Identifiers Names and Codes (LOINC) that uses standardized codes and names for identifying health measurements, observations, and documents, such as laboratory tests, clinical observations, survey instruments, radiology reports and public health data (HL7 International 2024b). LOINC is important especially in cross-border data sharing (e.g., via EHDS or MyHealth@EU), and EHRs, and it is compatible with other standards such as FHIR and DICOM, enabling interoperability across varying systems.

Health Level 7 (HL7) is a global authority on standards for the exchange, integration, sharing, and retrieval of electronic health information. HL7 group of standards includes HL7 V2, V3, CDA and FHIR that are foundational to healthcare interoperabilty and widely used across clinical, administrative and research domains. HL7 V2 is the oldest one of the group and was introduced in 1980s, and it's one of the most widely implemented healthcare messaging standards globally. It uses a delimited message format that composes of segments and fields for exchanging data between systems. This standard is known for its flexibility and extensibility, but this has also led to variability in implementations, which hinders interoperability. (HL7 International 2018) HL7 V3 was developed to address the limitations of V2 by introducing a more semantically consistent framework. It's based on the HL7 Reference Information Model (RIM) and uses Extensible Markup Language (XML) for message encoding. The complexity and steep learning curve of V3 limited its widespread adoption, however components of it,

such as Clinical Document Architecture (CDA) have been successfully implemented in many national health systems (HL7 International 2018).

HL7 CDA is an XML markup standard, designed to specify the structure and semantics of clinical documents for the purpose of exchange (Dolin, Alschuler, Beebe, et al. 2001). CDA is part of the broader HL7 V3 standard and it is designed to make clinical data both human-readable and machine-processable. Its structure and meaning are based on the HL7 RIM which is a consensus-based object-oriented model of the healthcare domain, and it uses standardized HL7 data types to ensure consistency across different systems (Dolin, Alschuler, Boyer, et al. 2006). One of the main purposes of CDA is to make it easier to extract and share structured information which is often buried in clinical notes that construct of free text. With applying a standardized format, CDA allows different healthcare systems to exchange documents and interpret their content consistently (iEHR.eu 2025b). CDA Release 1.0 was approved in 2000 and Release 2.0 followed in 2005, introducing more capabilities for representing the clinical meaning of documents, such as coded entries and richer metadata (Dolin, Alschuler, Boyer, et al. 2006).

A CDA document is structured into two main parts: a header and a body, all wrapped by the <ClinicalDocument> XML element. The top-level structure of a CDA document is shown in Figure 3. It shows the <ClinicalDocument> element containing both the header and the body, specifically a <structuredBody> (Dolin, Alschuler, Boyer, et al. 2006).

```
<ClinicalDocument>
  ... CDA Header ...
  <structuredBody>
    <section>
      <text>(a.k.a. "narrative block")</text>
      <observation>...</observation>
      <substanceAdministration>
        <supply>...</supply>
      </substanceAdministration>
      <observation>
        <externalObservation>...
        </externalObservation>
      </observation>
    </section>
    <section>
        <section>...</section>
    </section>
  </structuredBody>
</ClinicalDocument>
```

Figure 3: Components of a CDA document.(Dolin, Alschuler, Boyer, et al. 2006)

The header provides metadata that classifies the document and establishes its context. It includes document information, encounter data, service actors and service targets. Document information identifies the document, for example the type, classification

level, language, and creation time, with using standardized elements, usually in LOINC. Encounter data includes information about the time, location and type of care, describing the clinical settings of the document. Service actors is a list of organizations and persons included in the encounter, such as the author of the document, legal authenticator and care providers. Service targets include at least the patient (mandatory) and also possible other persons subject of care, such as family members. (Dolin, Alschuler, Beebe, et al. 2001).

The body contains the clinical content of the document. It can be either unstructured body `NonXMLBody`, that wraps a non-XML format document (e.g., PDF) or a structured body `StructuredBody`, that organizes content into nested `<section>` elements, each with a narrative text block `<text>` for human readability and optional CDA entries (e.g., `<observation>`, `<substanceAdministration>`) for structured, machine-processable data. Additional features of the body include the use of coded entries (e.g. LOINC or SNOMED CT), narrative formatting (paragraphs, lists, tables), and context propagation. (Dolin, Alschuler, Boyer, et al. 2006) To illustrate how the clinical statements are nested within the sections, Figure 4 shows a simple observation, where body temperature of a patient has been measured and documented.

```
<section>
  <code code="8716-3" codeSystem="2.16.840.1.113883.6.1"
   codeSystemName="LOINC"/>
  <title>Vital Signs</title>
  <text>Temperature is 36.9 C</text>
  <entry>
    <observation classCode="OBS" moodCode="EVN">
      <code code="386725007" codeSystem="2.16.840.1.113883.6.96"
       codeSystemName="SNOMED CT" displayName="Body temperature"/>
      <statusCode code="completed"/>
      <effectiveTime value="200004071430"/>
      <value xsi:type="PQ" value="36.9" unit="Cel"/>
    </observation>
  </entry>
</section>
```

Figure 4: An example of simple observation (measured body temperature). (Dolin, Alschuler, Boyer, et al. 2006)

Fast Healthcare Interoperability Resources (FHIR) is the most recent HL7 standard that is designed to combine the best features of HL7 V2, V3 and CDA, while leveraging modern web technologies. It uses RESTful APIs, an application programming interfaces that conforms to the constraints of Representational State Transfer (REST) architecture, JavaScript Object Notation (JSON) and XML to enable modular, scalable and developer-friendly data exchange. At its core, FHIR defines a set of modular components that represent granular clinical and administrative concepts called resources, for example `Patient`, `Observation`, `MedicationRequest`, and `Encounter`. Resources have a defined structure and meaning and they can be extended or combined with others to support complex workflows. These resources are exchanged using

RESTful APIs, allowing systems to perform standard operations like read, create, update and delete over Hypertext Transfer Protocol (HTTP). This allows on-demand access to clinical data in near real time, rather than relying on batch uploads or nightly synchronization, as with HL7 V2 or CDA. Data is formatted in JSON or XML, making it easy to integrate with mobile apps, cloud platforms, and modern web services.

An example of how to use a resource is a patient represented as a FHIR object in JSON, seen in Figure 5. This object contains data about the patient, using key-value pairs that conform to the FHIR `Patient` resource specification. While every resource in FHIR must declare its type (e.g., `"resourceType": "Patient"`), the FHIR standard itself requires that, at a minimum, systems expose a `CapabilityStatement` resource describing the server's overall functionality (HL7 International 2024a). The `identifier` field contains unique identifiers for the patient, such as national ID or medical record number. The `name` field is an array containing the patient's name details. The `gender` and `birthDate` fields provide demographic information, while the `address` field may include details about the street, city, postal code and country. Additional fields can store contact information, like phone numbers or email addresses. The object may also include metadata such as managing organization, communication preferences, and extensions for custom attributes which are not covered by the base specification. This modular and extensible structure allows the resource to be both human-readable and machine-processable, supporting interoperability across diverse systems. (HL7 International 2024a)

```
{
  "resourceType": "Patient",
  "id" : "23434",
  "meta" : {
    "versionId" : "12",
    "lastUpdated" : "2014-08-18T15:43:30Z"
  }
  "text": {
    "status": "generated",
    "div": "<!-- Snipped for Brevity -->"
  },
  "extension": [
    {
      "url": "http://example.org/consent#trials",
      "valueCode": "renal"
    }
  ],
  "identifier": [
    {
      "use": "usual",
      "label": "MRN",
      "system": "http://www.goodhealth.org/identifiers/mrn",
      "value": "123456"
    }
  ],
  "name": [
    {
      "family": "Levin",
      "given": [
        "Henry"
      ],
      "suffix": [
        "The 7th"
      ]
    }
  ],
  "gender": {
    "text": "Male"
  },
  "birthDate": "1932-09-24",
  "active": true
}
```


Figure 5: Patient represented as a FHIR object in JSON. (HL7 International 2024a)

FHIR supports terminology binding, allowing fields within resources to be linked to standardized vocabularies, such as SNOMED CT, LOINC and ICD-10, enhancing semantic interoperability. For example, a blood pressure measurement in an `Observation` resource can be coded using LOINC, ensuring consistent interpretation across systems. In addition, FHIR includes profiles, extensions and implementation guides that allow organizations or countries to tailor the standard to their specific needs while maintaining interoperability. For instance, EHRxF and MyHealth@EU infrastructure rely on FHIR-based specifications to enable cross-border health data exchange in the EU. FHIR's architecture supports real-time data exchange, event-driven workflows, and patient-centered applications, making it ideal for modern digital health ecosystems. It is increasingly adopted in national infrastructures, including Germany's telematics infrastructure and Finland's Kanta PHR, and is endorsed by the WHO as a key enabler of global digital health transformation (World Health Organization 2023)

In addition to these standards, the EU also promotes the use of Integrating the Healthcare Enterprise (IHE) interoperability profiles. Unlike the proper standards as HL7 or DICOM, IHE constructs of profiles that define how existing standards can be implemented together in real-world workflows, such as patient admissions, lab result exchange, or referrals. These profiles are particularly valuable for system vendors and developers, because they offer implementation guides and conformance specifications in practice, not just in theory. (IHE 2023).

A major EU-level initiative that is operationalizing these standards is MyHealth@EU, which is the EU's digital infrastructure for cross-border healthcare services for citizens traveling within the EU needing care. It currently supports patient summaries, ePrescriptions and eDispensations, and is being extended to include medical imaging, laboratory results, and hospital discharge reports, and in the future also the whole health record (European Commission 2025a). MyHealth@EU uses a common European Electronic Health Record Exchange Format (EHRxF) developed to be aligned with the FHIR and vocabularies like SNOMED CT, LOINC, and ICD, and in the near future EU member states will be required to making sure that their national electronic health record (EHR) systems are compatible with this format as part of the implementation of the EHDS, meaning that the first implementing acts are expected to be adopted by mid-2026 (Lewerenz et al. 2024).

Although there is a robust and growing variety of standards, the implementation faces significant challenges. One obstacle to achieving interoperability is vendor lock-in, where proprietary solutions, not compatible with other systems, limit interoperability by discouraging or preventing integration with other systems (Opara-Martins, Sahandi, and Tian 2016). Another barrier is legacy systems, particularly in older hospitals and underresourced regions. They often lack the technical infrastructure or financial capacity to support modern standards such as HL7 FHIR, making full-scale integration costly and technically complex (Dullabh et al. 2020). Furthermore, national variations in how standards are adopted or adapted (e.g., different coding systems and localized extensions of SNOMED CT) can create semantic misalignments that cause barriers for advancing EU-wide interoperability since data cannot always be interpreted uniformly (European Commission 2023a).

Lastly, many of these standards are also internationally recognized by the International Organization for Standardization (ISO). For example, DICOM is standardized as *ISO 12052: Health informatics — Digital imaging and communication in medicine (DICOM)* (2017), and HL7 standards are often referenced in ISO technical reports. The use of ISO-aligned standards ensures that the EU's efforts towards interoperability are not isolated but contribute to global alignment and facilitate data exchange beyond Europe's borders.

2.2.3 API Landscape

An Application Programming Interface (API) is a structured set of protocols and tools that enables software components to communicate and exchange data efficiently. APIs simplify the complexity of underlying systems by abstracting underlying system complexity, which allows developers to access specific functionalities or data without needing to understand the software internals. In healthcare, APIs are increasingly recognized as essential tools for achieving interoperability, enabling secure and standardized data exchange between electronic health records, mobile health applications, and national health infrastructures (Gordon and Rudin 2022).

The adoption of APIs in healthcare has been driven by the need to improve access to patient data, support clinical decision-making, and foster innovation in digital health services. Standards-based APIs, particularly those built on HL7 FHIR, are widely used to facilitate real-time data sharing and integration across diverse systems. Despite their potential, challenges remain in implementing write capabilities, ensuring data provenance, and managing governance across distributed networks. (Dullabh et al. 2020). Nevertheless, APIs are viewed as a transformative technology for enabling patient-centered care, operational efficiency, and scientific discovery (ONC 2021).

Currently, healthcare interoperability across the EU is increasingly shaped by the adoption of HL7 FHIR APIs, which support RESTful communication using JSON and XML formats. FHIR has become the foundation for several EU-level initiatives, most notably MyHealth@EU introduced above (European Union 2025; HL7 International 2024a). Unlike traditional web services based on Simple Object Access Protocol (SOAP) which rely on strict XML message formats, schemas, and envelope structures, RESTful APIs operate over standard HTTP methods (e.g., GET, POST, PUT) and are generally simpler, lighter, and more adaptable to web and mobile environments. Although REST is widely adopted due to its simplicity, flexibility, and alignment with modern web technologies, SOAP still remains relevant in domains where strong security mechanisms, formal contracts, and transactional reliability are essential (Sloane and Hameed 2023).

Despite FHIR's growing adoption, national infrastructures within the EU remain heterogeneous. For example, Finland has integrated FHIR into newer, patient-facing services such as Kanta PHR, while core Kanta systems still operate on SOAP-based HL7 V3 messaging and CDA documents (Jormanainen 2018; Kela / Kanta Services 2024). In Germany, the national telematics infrastructure is pushing the use of FHIR APIs within the electronic patient record (ePA) and other modern services currently developed, but continues still to rely on legacy APIs, such as Kommunikation im Medizinwesen (KIM) for secure provider communication and Versichertenstammdatenmanagement (VSDM) for insurance data validation, and both of them are built on SOAP (gematik GmbH 2023a). Platforms like Redox are gaining attention in the EU for offering a middleware approach that abstracts underlying standards, which enables smoother integration across HL7 V2, FHIR, and proprietary APIs (Redox,

Inc. 2024). This layered API landscape reflects a transitional state where FHIR is becoming central in shaping the future interoperability, while older protocols still remain essential to current operations.

2.3 Finland's Healthcare Data System

The national healthcare and social care system in Finland is a comprehensive digital data system designed for ensuring smooth, secure, and nationwide flow of patient and client data. It is based on a central, nationwide digital system Kanta Services which is operated by Finnish Social Insurance Institution (Kela). Kanta integrates information from various sources to benefit citizens, healthcare providers, social welfare services and policymakers (Jormanainen 2018).

2.3.1 Key Stakeholders and Governance

The development and operation of Kanta Services is a collaborative effort that involves several institutions. The Ministry of Social Affairs and Health (STM) provides the strategic guidance and funding of the Kanta Services, setting the objectives for information management, monitoring results, and preparing relevant legislation (Kela / Kanta Services 2025c). In addition, under STM operates Findata (Finnish Social and Health Data Permit Authority) that grants permits for combining and accessing data for the secondary use of health and social data from multiple public and private sources, including Kanta Services. Findata ensures secure processing, pseudonymization, and privacy protection of the data. (Findata 2025)

Finnish Institute for Health and Welfare (THL) does the operational planning of Kanta Services, and it acts as an expert in social welfare and healthcare content, training of professionals and setting the essential requirements for Kanta systems. THL supports operational changes and approves and publishes national data structures (Kela / Kanta Services 2025c). Kela plans and executes implementation projects, manages communications, and coordinates and supports service deployment. It is responsible of the maintenance and technical development of Kanta Services, including background support, information system support and coordination of joint testing (Kela / Kanta Services 2025c).

All healthcare and social welfare providers in Finland must ensure that their information systems are compatible with Kanta Services and they have to deploy Kanta within their organizations according to THL requirements. System providers design information systems to be compatible with Kanta, aiming to make the new features available simultaneously for all systems. (Kela / Kanta Services 2025a). Digital and Population Data Services Agency (DVV) is responsible for identification and certificate services through its Suomi.fi e-identification service, ensuring reliable identification and

electronic signing for users and documents within Kanta (Kela / Kanta Services 2025b).

National Supervisory Authority for Welfare and Health (Valvira) maintains central registers for national information systems (Kela / Kanta Services 2025a). The verified social welfare and healthcare practitioners are listed in Terhikki and Suosikki registers (Valvira 2025b). The Astori register lists all approved healthcare and social welfare information systems, wellbeing applications linked to Kanta Services, and relevant operating environments. Valvira ensures their compliance with legal interoperability, security, and privacy standards as defined by the Client Data Act and Secondary Use Act (THL 2024).

2.3.2 Architecture and Components of Kanta Services

Kanta Services, seen in Figure 6, includes a wide range of functionalities. The Prescription Center manages electronic prescriptions, dispensations, renewals, and reservations. It is supported by a pharmaceutical database that includes information on medicinal products, pricing, substitution rules, and reimbursement policies. The Patient Data Repository stores structured health records, imaging data, and archived historical patient information, enabling centralized access to clinical data. Citizens can contribute to their own health records through the Personal Health Record (PHR), which allows for the recording of observations, questionnaire responses, and other self-entered data. The Data Repository for Social Services includes information on customer relationships, service items, documents, and legacy data from social welfare services. A Summary Service provides consolidated views of patient health data, including vaccinations, risks, procedures, laboratory results, and physiological findings, as well as summaries for social services clients. Consent and will data, such as organ donation preferences and living wills, are also managed within the system.

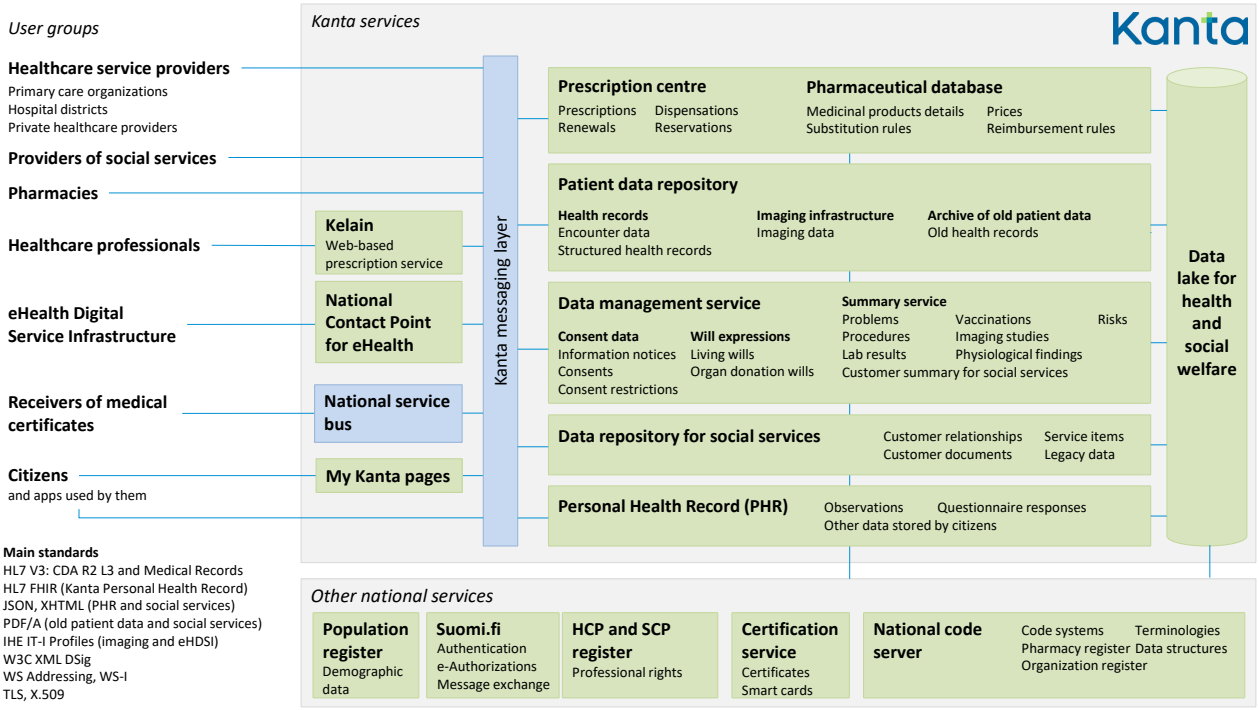

Figure 6: Kanta architecture.

The technical infrastructure of Kanta Services is supported by a secure digital service layer that includes authentication, certification, and messaging services. The system relies on a range of international standards to ensure interoperability and data integrity. These include HL7 V3 (CDA R2), HL7 FHIR for the PHR, JSON and XHTML for social services and PHR data, PDF/A for archived records, and various security and communication protocols, such as W3C XML DSig, WS Addressing, and TLS/X.509. The National Code Server maintains terminologies, code systems, and organizational registers, while the Population Register provides demographic data essential for system integration.

2.3.3 Regulatory Framework and Legal Foundation

Finland's healthcare interoperability is governed by several key legislative acts. The Client Data Act (703/2021) defines the legal basis for processing patient and client data in healthcare and social welfare. It mandates the use of Kanta Services for storing and exchanging health records and outlines the responsibilities of service providers, system vendors, and authorities (STM 2023). The Secondary Use Act (552/2019) regulates the reuse of health and social data for research, statistics, development, and innovation. It established Findata, the Finnish Social and Health Data Permit Authority, which ensures secure and privacy-compliant access to pseudonymized data across sectors (Findata 2019). These laws align with the GDPR and support Finland's participation in EU-wide initiatives like the EHDS. However, while the legal framework is robust,

it has been criticized for being slow to adapt to emerging digital health innovations, especially in the private sector.

Finland is actively participating in the MyHealth@EU infrastructure, which enables secure cross-border exchange of health data such as ePrescriptions and Patient Summaries (European Commission 2025a). The Kanta PHR already uses HL7 FHIR, making it technically compatible with EHDS requirements. However, full-scale cross-border interoperability is still in development, and challenges remain in harmonizing consent management, terminology standards, and patient identification across EU member states (European Commission 2025c).

2.3.4 Role of the Private Sector

Private digital health providers, such as BeeHealthy, play an increasingly important role in Finland's healthcare landscape. These platforms often offer superior usability, faster development cycles, and better integration with everyday care workflows compared to public systems (THL 2024; Kela / Kanta Services 2025b). However, their interoperability with Kanta Services is limited by certification requirements and the lack of standardized APIs for external integration (Valvira 2025a; Kela / Kanta Services 2025c).

This dynamic creates a gap between public infrastructure and private innovation. While BeeHealthy and similar platforms are widely adopted, their ability to exchange data with Kanta or participate in EU-level infrastructures like TI-Messenger remains constrained (European Commission 2025a; THL 2024). Bridging this gap is essential for enabling cross-border digital health solutions and realizing the goals of the EHDS (European Union 2025).

2.4 Germany's Healthcare Data System

Germany's digital health infrastructure is shaped by a series of legislative acts, including the E-Health Act (2015), Digital Care Act (DVG, 2019), Patient Data Protection Act (PDSG, 2020), Digital Care Modernization Act (DVPMG, 2021), Digital Act (DigiG, 2023), and Health Data Utilization Act (GDNG, 2023). These laws define together the technical, organizational, and privacy requirements for systems like the telematics infrastructure, TI-Messenger, and the electronic patient record (ePA), and they are the driving force behind interoperability efforts of Germany.

2.4.1 Key Stakeholders and Governance

Germany's healthcare system has decentralized structure and it's based on a statutory health insurance (SHI) model and a strong emphasis on self-governance. It is compulsory in Germany to have a health insurance and that is provided either through SHI or

substitutive private health insurance (PHI). Around 89 % of the population is covered by SHI, while 11 % opt for the PHI (Blümel et al. 2024).

The GKV-Spitzenverband, the umbrella organization representing SHI funds, plays a key role in negotiating reimbursement models and shaping digital health policy in Germany. It is responsible for setting pricing frameworks for digital health applications (DiGAs) and coordinating their integration into care pathways. Within the framework of the DVG, SHI funds are obliged to cover DiGAs that have passed the fast-track assessment process at the Federal Institute for Drugs and Medical Devices (BfArM). However, the GKV-Spitzenverband has published critical evaluations of their cost-effectiveness and highlighted the need for stronger evidence of clinical benefit. It emphasizes that DiGAs must align with existing care structures and demonstrate measurable improvements in health outcomes in order to be sustainably reimbursed (Gerke, Stern, and Minssen 2020; GKV-Spitzenverband 2021).

The Federal Ministry of Health (Bundesministerium für Gesundheit, BMG) plays the main role in advancing Germany's digital health transformation. It sets the strategic direction, drafts legislation, and oversees implementation (BMG 2025b). In recent years, the BMG has launched key legislative initiatives such as the DigiG and GDNG, which aim to accelerate the adoption of the electronic patient record (ePA) and facilitate the secondary use of health data for research and innovation. The ministry also coordinates the national Digitalization Strategy for Health and Care (BMG 2023), which outlines regulatory frameworks and implementation prerequisites for digital health services.

Gematik GmbH is Germany's national digital health agency and it is the central organization responsible for the design, rollout, and ongoing development of the telematics infrastructure, which forms the backbone of the country's digital healthcare system (gematik GmbH 2023a). Since 2019, the Federal Ministry of Health (BMG) has had a majority stake in 51 %, giving it decisive influence over the strategic direction of gematik and ensuring that national digitalization goals are closely aligned with implementation (BMG 2020).

Gematik's principal role is to guarantee a secure, interoperable, and user-friendly digital health infrastructure. Its responsibilities include defining and enforcing binding interoperability standards, certifying digital health applications and services (such as TI-Messenger, e-prescriptions, and electronic patient records), and managing the continuous improvement of the TI ecosystem. In this role, gematik provides the framework conditions necessary for the nationwide digital transformation of healthcare, while also safeguarding cost efficiency and technical robustness (gematik GmbH 2023a).

Beyond technical implementation, gematik also plays a coordinating and mediating role between diverse stakeholders. It actively engages with health professionals, insurers, industry partners, researchers, and data protection experts, ensuring that digital services meet both regulatory requirements and practical needs. gematik also

maintains close collaboration with developer communities and manufacturers, publishing specifications and guidelines that are binding for system providers. gematik's central role in relation to its stakeholders is illustrated in Figure 7.

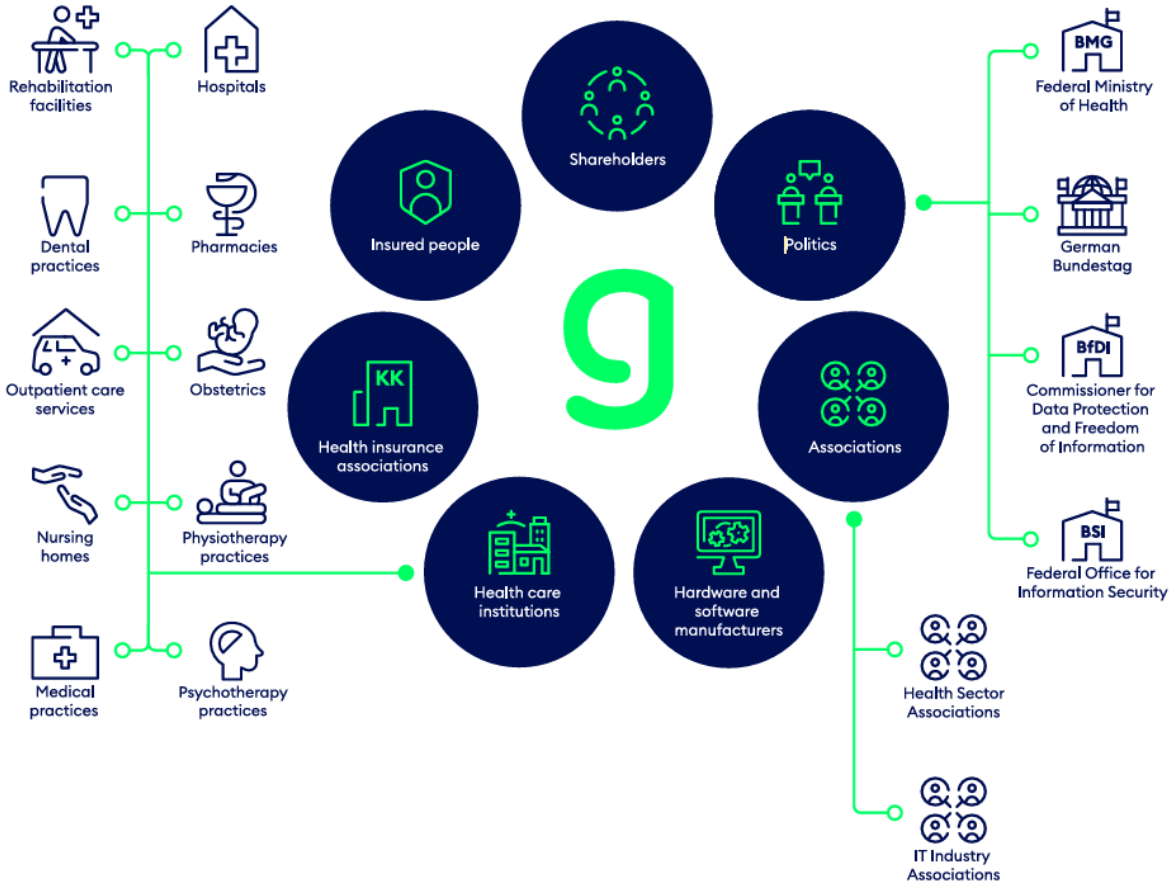

Figure 7: gematik's relation to different stakeholders in Germany. (gematik GmbH 2023a)

The Federal Joint Committee (Gemeinsamer Bundesausschuss, G-BA) is the highest decision-making body in Germany's healthcare self-administration. It defines which treatments and services are covered by the SHI and sets binding quality standards. The G-BA includes representatives from SHI funds, healthcare providers, and patient organizations, and operates under the legal supervision of the BMG. Its decisions are based on scientific assessments and aim to ensure that care remains adequate, appropriate, and cost-effective. (G-BA 2025)

Healthcare professionals and institutions in Germany are represented by different associations, including the National Association of Statutory Health Insurance Physicians (KBV), National Association of Statutory Health Insurance Dentists (KZBV), German Hospital Federation (DKG), and the Federal Union of German Associations of Pharmacists (ABDA). These organizations play a critical role in negotiating

reimbursement terms, shaping digital service implementation, and advocating for the interests of their members. Their involvement in digitalization efforts includes contributing to the rollout of electronic prescriptions, supporting interoperability standards, and participating in policy consultations. However, their differing priorities and levels of digital readiness have also contributed to the fragmented pace of adoption across the healthcare system. (Blümel et al. 2024)

The Federal Institute for Drugs and Medical Devices (BfArM) is responsible for the approval and listing of Digital Health Applications (DiGAs) in Germany. These applications must meet strict criteria for safety, performance, data protection, and interoperability. BfArM conducts a fast-track assessment process, typically completed within three months, to evaluate the evidence of positive healthcare effects and technical compliance before listing a DiGA in the official directory (BfArM 2025). The Robert Koch Institute supports public health surveillance and epidemiological research. Their work includes pandemic preparedness, data analysis, and coordination with international health authorities (Robert Koch Institute 2025).

Data protection and cybersecurity in the context of digital health applications, including TI-Messenger, are supervised by the Federal Commissioner for Data Protection and Freedom of Information (BfDI) and the Federal Office for Information Security (BSI). These institutions are formally represented in the Digital Advisory Board of gematik, where they provide ongoing guidance on privacy, security, and ethical considerations related to digital health infrastructure. (BMG 2025a)

2.4.2 Telematics Infrastructure

The Telematics Infrastructure (TI) is developed and maintained by gematik under the strategic direction of the Federal Ministry of Health (BMG). It connects healthcare providers, insurers, and patients through a secure, federated architecture. The TI is a network of technologies that aims to electronically share healthcare data for all medically insured individuals in Germany securely, requiring comprehensive security measures and authorization structures (gematik GmbH 2021).

The electronic health card (eGK) enables authentication and access to services like the electronic patient record (ePA) and electronic prescriptions (eRx). It ensures secure identification and communication. The electronic health card (eGK) is one of the smartcards that serves a dual function as both an identity carrier and a means of authentication within the TI (gematik GmbH 2021). For instance, ePA registration currently requires the new electronic health card with an NFC interface and a PIN (Rau, Tischendorf, and Mitzscherlich 2024). As of January 2025, ePAs will be automatically generated for all individuals with public health insurance in Germany, with an opt-out option available if they do not wish to have one (Institute for Quality and Efficiency in Health Care (IQWiG) 2024). This is part of a digital law (DigiG) that will change the ePA consent procedure to an opt-out model.

e-prescriptions (eRx) became widely accepted standards in Germany in 2021. More specifically, starting January 1, 2024, the use of eRx became mandatory for all patients with statutory health insurance in Germany, largely replacing traditional paper prescriptions. They are stored securely and encrypted within the TI, making them immune to loss, damage, or falsification, unlike paper prescriptions. (Institute for Quality and Efficiency in Health Care (IQWiG) 2024)

The emergency data record (NFD) and electronic medication plan (eMP) are essential components within the TI that leverage the E-Health-Connector for necessary encryption and signature functionalities (German Medical Association (BÄK)) 2025). NFD provides emergency responders and physicians with access to critical patient information, such as allergies, chronic conditions, and contact details. The eMP offers a structured overview of a patient's current medications, supporting medication reconciliation and reducing the risk of adverse drug interactions.

Since October 1, 2021, doctors' practices have been mandated to use Kommunikation im Medizinwesen (KIM), which is a secure messaging service integrated into practice management systems, enabling encrypted exchange of medical documents and forms. KIM functions as a secure email procedure and is the standardized method for the electronic transmission of medical documents. It enables the secure exchange of sensitive information, such as findings, notices, bills, and X-rays, between various doctors and medical facilities via the telematics infrastructure. (German Medical Association (BÄK)) 2025)

The electronic health professional card (eHBA) is a personalized chip card that healthcare professionals use to identify themselves within the telematics infrastructure (Bundesdruckerei GmbH 2022). Conversely, the electronic ID card for medical practices and institutions (SMC-B) is used by healthcare institutions to authenticate themselves as medical facilities and access TI services. The SMC-B can also be used for encryption when an institution is the recipient (German Medical Association (BÄK)) 2025).

The ISiK regulation requires hospital information systems in Germany to implement standardized, open FHIR-based interfaces, including RESTful APIs and use of FHIR profiles as defined in the gematik GmbH (2023b). It means that vendors must have their ISiK-FHIR interfaces certified via gematik's confirmation procedure.

TI 2.0 is the next-generation upgrade of Germany's telematics infrastructure, with an aim to enable internet-based access, mobile device integration, and digital identities for more flexible and user-friendly healthcare communication. The TI 2.0 itself adopts HL7 FHIR as the interoperability standard for its interfaces (gematik GmbH 2021). This standardization is intended to significantly improve data quality, enable intersectoral and international connectivity, and support structured data for flexible and multi-service integration in the future.

2.4.3 TI-Messenger

TI-Messenger is a secure, interoperable messaging service developed for healthcare professionals within the telematics infrastructure in Germany. TI-Messenger is built on the Matrix protocol, an open standard for decentralized, real-time messaging that supports end-to-end encryption for chat, voice, and video (gematik GmbH 2023c). Communication endpoints are registered and verified via KIM, which ensures identity management and message validation. Gematik's API specifications define the technical and security requirements for TI-compliant communication. These APIs are not publicly accessible in the traditional sense, but they are regulated through trust services and provider roles (gematik GmbH 2023c).

Germany's healthcare system is highly fragmented, with numerous providers using different IT systems. TI-Messenger addresses this challenge by offering a vendor-neutral communication layer that enables interoperability across certified messenger providers (BMG 2023). This aligns with broader European efforts to enhance digital health interoperability, such as the European Interoperability Framework (EIF) and the European Health Data Space (EHDS) (European Commission 2021; European Union 2025). TI-Messenger supports FHIR, eGK and ePA integration and facilitates secure and structured communication between healthcare professionals and, in future phases, between professionals and patients. This supports Germany's Digitalization Strategy for Health and Care, which emphasizes secure data exchange and patient empowerment (BMG 2023).

TI-Messenger's primary users include healthcare professionals, who utilize the service for clinical coordination and patient care, as well as other institutions such as hospitals and clinics that benefit from both internal and external communication capabilities. In future development phases, TI-Messenger is expected to extend its functionality to patients, allowing them to securely interact with healthcare providers and thus enhancing accessibility and continuity of care (gematik GmbH 2023c; Blümel et al. 2024).

Integrating TI-Messenger into healthcare IT systems requires compliance with the strict specifications of gematik. Vendors must obtain a certification to ensure that their solutions meet the security and interoperability standards defined for the TI. This includes implementing identity management protocols, end-to-end encryption mechanisms, and message validation procedures outlined in gematik's API documentation (gematik GmbH 2023c). Access to TI-Messenger's APIs is regulated through trust services and provider roles, meaning that integration is not open in the conventional sense but rather governed by a controlled access model. Compatibility with FHIR resources is also essential, as it enables structured data exchange and supports semantic interoperability across clinical systems (HL7 International 2024a). These requirements collectively ensure that only verified and compliant entities can participate in the TI-Messenger ecosystem, maintaining high standards for data protection and operational integrity.

TI-Messenger has strategic importance, but is still in the early stages of adoption. Integration into existing clinical workflows is limited, and the number of certified providers is still relatively small. Several challenges hinder broader implementation, including the technical complexity of integration, limited awareness among healthcare professionals, and usability issues related to onboarding and interface design (Gerke, Stern, and Minssen 2020; Blümel et al. 2024).

Nevertheless, TI-Messenger is expected to play a pivotal role in Germany's digital health transformation. As certification processes mature and integration pathways become more standardized, the platform is expected to gain traction across healthcare institutions. TI-Messenger's alignment with national and European interoperability frameworks help to reinforce its potential to become a cornerstone of secure, interoperable communication in healthcare (European Commission 2021; European Union 2025).

2.5 Comparison Between Finland and Germany

In the Figure 8, the two structurally distinct approaches to healthcare interoperability of Finland and Germany are summarized as a table. Finland's centralized model, based by Kanta Services and governed by a tightly coordinated public sector, differs with Germany's federated telematics infrastructure that is shaped by self-administration and multiple stakeholder organizations. Although Finland benefits from unified data storage and streamlined governance, Germany's system offers flexibility but deals with fragmentation and slower rollout. Both countries align with EU-level initiatives like EHDS, but differ in implementation maturity, messaging infrastructure, and private sector integration. Understanding these differences is essential for cross-border digital health solutions, especially when considering integration pathways for platforms like BeeHealthy.

Aspect	Finland	Germany
Policy & Regulatory Frameworks	Centralized: Client Data Act, Secondary Use Act, GDPR. Strong alignment with EHDS.	Decentralized: DigiG, DVG, PDSG, DVPMG, GDNG. GDPR-compliant but fragmented.
Technological Approach	Centralized data storage via Kanta Services. Unified national repository for health and social data.	Federated architecture via Telematics Infrastructure (TI). Data stored across certified providers; ePA opt-out model.
Key Stakeholders	STM (policy), Kela (operations), THL (content), Valvira (compliance), Findata (secondary use).	BMG (policy), gematik (infrastructure), GKV-Spitzenverband (insurance), BfArM (DiGA approval), KBV/KZBV/DKG (provider associations).
Messaging & Communication	No national messaging standard. Kanta does not include a secure messaging layer like TI-Messenger.	TI-Messenger built on Matrix protocol. Certified providers only. Secure, decentralized messaging.
Technical Standards	HL7 V3 (CDA), HL7 FHIR (PHR), JSON, XML, PDF/A, IHE profiles.	HL7 FHIR (TI 2.0), Matrix (TI-Messenger), SOAP (legacy systems), strong certification requirements.
API Landscape	SOAP-based APIs dominate legacy systems; FHIR used in newer services. Limited external integration.	Mixed: FHIR APIs for modern solutions, Matrix APIs for TI-Messenger, SOAP for KIM/VSDM. Middleware solutions emerging.
Private Sector Role	BeeHealthy and others offer user-friendly platforms. Integration with Kanta limited by certification and API access.	DiGAs approved by BfArM. Private providers must be certified by gematik. Market is competitive and saturated.
Interoperability Maturity	Technically mature, centralized, but slow innovation in public systems. Active EHDS participation.	Fragmented but evolving. TI 2.0 and TI-Messenger aim to unify communication. Certification and rollout delays persist.

Figure 8: Overview of the Finnish and German systems in a comparative table.

3 Research Methodology

3.1 Qualitative Research

The goal of the research was to get a comprehensive understanding about the landscape and options for integrating a Finnish digital health application to the telematics infrastructure. This involves comprehending the technical, semantic, organizational, and legal aspects of interoperability. Qualitative research was chosen as a method due to its strength in addressing the complex and exploratory nature of this research, since it captures non-numerical information, focusing on people's attitudes, feelings, and behaviors to provide an in-depth and often indicative understanding of the topic (Barclay 2018). Qualitative research methods are also well-suited for addressing questions in areas that evoke many questions and worries, providing practical guidance for conducting high-quality research on phenomena in their "natural context" (Moser and Korstjens 2017).

3.2 Data Collection

A total of six professional interviews were conducted between 18 August and 1 September 2025. The participants were selected purposively for their systemic and technical expertise of the German telematics infrastructure, its interoperability landscape and TI-Messenger. This strategy ensured that the interviews captured in-depth, experience-based insights into the practical challenges and opportunities of cross-border digital health integration.

For academic integrity and confidentiality, the names of the participants and their affiliated organizations are not mentioned. Figure 9 summarizes the professional background and relevance of the participants in relation to TI-Messenger and interoperability. All interviews were organized remotely via Microsoft Teams and lasted approximately 60 minutes each. With the informed consent of participants, the interviews were recorded to enable accurate transcription.

Participant	Current role	Background summary	Relevance to TI Messenger & Interoperability
P1	Software Engineer	Experience in Open-source development and secure communication protocols; contributed to Matrix specifications and implementation of core TI-Messenger components incl. cryptography, identity management, and authentication services	Deep technical insight into TI-Messenger architecture and security implementation
P2	Solution Architect	Background in distributed web technologies and open source; experience with secure email infrastructure; contributor to Matrix-based prototypes and consulting for chat systems	Key contributor to Matrix-based TI-Messenger development and healthcare market adaptation
P3	Chief Product Owner	Early involvement in protocol evaluation and specification drafting; reference implementation and market integration efforts	Strategic role in shaping TI-Messenger's technical and market deployment in Germany
P4	Senior Software Engineer	Specialized in TI infrastructure and security protocols; contributed to reference implementation and supports client-side testing tools	Practical experience in implementing and supporting TI-Messenger infrastructure and test environments
P5	Independent Consultant	20 years of experience in TI specifications and implementation; worked on infrastructure components and application layers including EHR, e-prescription, and secure messaging	Broad expertise across TI infrastructure and applications, with a focus on integration and mobile use cases
P6	Product Manager	Background in industrial and service design; experience in healthcare workflows and stakeholder analysis; managing TI-Messenger product development	Responsible for aligning TI-Messenger with stakeholder needs and ensuring scalable, interoperable messaging across healthcare sectors

Figure 9: Table of the interviewed professionals.

The list of interview questions was developed in collaboration with BeeHealthy and adesso to ensure that the questions were relevant both for the research objectives and for the stakeholders involved. The list consists of open-ended questions, organized under the following thematic categories: TI-Messenger and Integration Landscape, Integration Options for Foreign Providers, Technical Compatibility and Standards, Use Case Exploration for TI-Messenger and Recommendations and Further Thoughts. Semi-structured interviews were chosen to combine consistency across sessions with the flexibility to pursue emerging issues raised by participants.

3.3 Data Analysis

The interview recordings were automatically transcribed by Microsoft Teams, and exported as Word documents. Each transcript was carefully reviewed and questions and answers were manually labelled to ensure accuracy and contextual clarity. To support readability, Microsoft Copilot, an AI-based text assistant integrated with Microsoft services (Microsoft 2025), was used in a data-protected enterprise environment to reformat fragmented responses into coherent sentences while retaining the original meaning and tone of the participants' answers.

After transcription and formatting, all identifying details, such as participant names and company affiliations, were removed to protect confidentiality. The resulting document containing all the answers to all the questions allowed the content of the responses to be analyzed without revealing personal or organizational identifiers. The data were then organized under thematic categories corresponding to the themes in the list of questions, and key insights and recurring patterns were identified manually within each theme. This approach allowed a systematic comparison across participants while preserving the individual perspectives.

4 Findings

The results are presented by theme, as the interviews were conducted by asking questions on different themes. The results consist of the main findings and direct quotes of the interviewees' thoughts related to each theme. The thematic responses serve the purpose of finding answers to the research questions from different perspectives and at different levels. The main objective is to answer the question of what opportunities a non-German digital health provider, such as BeeHealthy, has to integrate into the German TI infrastructure, and what opportunities and use-cases TI-Messenger currently support and could bring in the future. Theme 1: Background & Role has been omitted from the results, as the participants' background was only used to compile the table seen in chapter 3.

4.1 TI-Messenger & Integration Landscape

TI-Messenger is seen as a secure, standardized communication platform within Germany's telematics infrastructure. All six participants discussed its current role, limitations and future potential. There was a general agreement on its importance for replacing outdated communication methods, but participants had varying views on its maturity, adoption, and integration into healthcare workflows.

Key Findings

- **Current use cases are limited**: TI-Messenger is currently used primarly for professional-to-professional communication. Patient-related features, such as messaging between patients and doctors or insurance companies are still under development or in early rollout stages.
- **Rollout is fragmented and delayed**: gematik's original version included three versions of TI-Messenger (for professionals, patients and public use), but delays in implementation have slowed the adoption. Some participants noted that the system is still in a launch phase.
- **Lack of workflow integration**: TI-Messenger is not yet integrated into existing clinical or insurance workflows. It functions as a standalone application, which limits its utility in wider practice.
- **Security and certification are central**: TI-Messenger is built on the Matrix protocol and requires strict certification by gematik and the BSI. This ensures high security but also slows down innovation and future expansion.
- **Perceived as transformational but underutilized**: While some participants compared TI-Messenger to WhatsApp for healthcare, others emphasized that its potential remains largely untapped due to resistance to change and lack of incentives for adoption.

Quotes from Participants

"TI-Messenger is intended to be the healthcare sector's equivalent of WhatsApp, a secure communication platform." (P4)

"Right now, many actors still resist change, seeing TI-Messenger as just another costly technology. But I believe it's transformational." (P3)

"At the moment, the main functionality is basic message exchange and document delivery. There's no deeper integration into daily workflows." (P5)

"Gematik has defined three rollout stages... but it will still take time before TI-Messenger is fully operational and accessible to all user groups." (P1)

4.2 Integration Options for Foreign Providers

The participants explored the possibilities and challenges for non-German digital health providers, such as BeeHealthy, to integrate with the German TI infrastructure via TI-Messenger. All six participants shared insights into technical, legal and strategic conciderations. While integration is technically feasible, the process is complex and requires careful navigation of certification, market dynamics, and cultural expectations.

Key Findings

- **Two main integration models**: Foreign providers can either build their own TI-Messenger product and undergo gematik's certification process (option 1) or partner with an existing certified provider and integrate their services via SDKs or APIs (option 2).
- **Language and regulatory barriers**: The specification for TI-Messenger by gematik is extensive (approximately 2,000 pages) and available only in German, which may pose a barrier for non-German companies. Regulatory complexity and strict privacy laws complicate the entry further.
- **Market saturation and fragmentation**: Around 90 % of the professional market is already covered by existing TI-Messenger providers. Insurance companies and healthacre institutions often rely on established vendors, making it difficult for new entrants to gain traction.
- **Limited interoperability and closed ecosystem**: TI-Messenger does not support bridging with other protocols, and integration with practice management systems is not standardized. Custom integrations are technically possible, but require individual agreements.
- **Strategic entry points**: Participants suggested targeting smaller insurance companies, partnering with existing software vendors, or launching public

awareness campaigns to build demand. However, success depends on offering reimbursement models and clear value to healthcare professionals.

Quotes from Participants

"Most TI-Messenger providers are German companies. For a foreign company, it's quite difficult... the specification is primarily written in German." (P1)

"You can't just copy-paste a solution from another country like Finland and expect it to work here." (P3)

"Currently, TI-Messenger is offered as a standalone messaging service... integration is done on a case-by-case basis and lacks interoperability." (P5)

"A foreign provider could partner with insurers, collaborate with software vendors, or launch a large-scale awareness campaign, but only if the product supports reimbursement." (P2)

4.3 Technical Compatibility & Standards

This theme focused on the technical foundations of TI-Messenger, including its compatibility with standards like Matrix and FHIR, and the challenges foreign providers may face when aligning with German specifications. All six participants provided insights into the architecture, interoperability, and certification requirements. While the Matrix protocol is central and supported, FHIR plays more limited role and bridging between standards is generally discouraged.

Key Findings

- **Matrix is the core protocol**: TI-Messenger is built on the Matrix protocol, which supports secure, decentralized communication. All certified implementations must adhere strictly to Matrix specifications, with no allowance for bridging to other messaging standards.
- **FHIR is present but limited**: FHIR is used primarly for identity management and directory services (e.g. VZD), but not for core messaging functionality. Its role is evolving, and future use cases may involve structured data exchange using FHIR resources.
- **Bridging is technically possible but not permitted**: While Matrix supports bridges to other platforms, like WhatsApp and Signal, TI-Messenger's security requirements prohibit such implementations. End-to-end encryption must be preserved, and intermediary systems cannot access message content.
- **Integration requires full compliance**: Foreign apps must fully implement the Matrix protocol and meet gematik's specifications. Partial compliance or use

of adapters is not allowed. Most vendors rely on open-source components like Synapse and Element, adapting them to meet German requirements.

- **Middleware and SDKs exist but are limited**: Some frameworks and software decelopment kits (SDKs) are available to help with development, but vendors must still handle complex cryptographic and certification requirements. Gematik provides test suites to validate compliance.

Quotes from Participants

"TI-Messenger is essentially a Matrix-based messenger... you must fully implement the required specifications to gain access." (P4)

"FHIR compatibility doesn't play a significant role in TI-Messenger. The system is still focused on plain text, HTML messages, and document exchange." (P5)

"Bridging between protocols isn't allowed... the product must use the Matrix protocol directly, without any bridging." (P5)

"Gematik provides a test suite that vendors must connect to, allowing them to test the product independently." (P5)

4.4 Use Case Exploration for TI-Messenger

In this theme, participants explored realistic and potential use cases for TI-Messenger, particularly from the perspective of foreign digital health providers like BeeHealthy. All six participants shared examples of current implementations, envisioned future applocations and limitations of the system. While TI-Messenger is still in early stages of adoption, participants identified several promising use cases that could support both professional and patient-facing communication.

Key Findings

- **Professional-to-professional communication is most mature**: Peer consultations, coordination between doctors and nurses, and communication in caregiving environments were frequently mentioned as realistic use cases and already in use.

- **Patient-to-professional communication is emerging**: While not yet fully implemented, participants expect future use cases to include short consultations, follow-ups, and document exchange between patients and doctors or insurance companies.

- **Workflow support is limited**: TI-Messenger currently lacks automation and integration with clinical workflows. Participants noted that existing solutions

like Teamwire or NetSfere offer more comprehensive support for internal communication.

- **Potential for enhanced user experience**: Some participants suggested that foreign providers could offer alternative TI-Messenger clients with better usability, layered services with appointment booking, or multilingual support.
- **Future use cases include video, bots, and patient journeys**: Participants envisioned TI-Messenger evolving into a platform that supports video consultations, automated workflows and guided patient experiences across healthcare institutions.

Quotes from Participants

"A group of five cancer specialists... started using TI-Messenger to consult with each other in real time. This kind of peer-to-peer collaboration is a realistic and valuable use case." (P1)

"TI-Messenger could be used for short consultations and second opinions... sharing images and opinions directly would save time for both patients and practitioners." (P2)

"TI-Messenger is essentially a secure version of WhatsApp... but it doesn't support digitized processes or automation." (P5)

"I see its future as a tool to guide patients through their healthcare journey... from symptom check to follow-up communication." (P6)

4.5 Recommendations and Further Thoughts

This theme covered participants' strategic advice and reflections on the broader implications of TI-Messenger integration, especially for foreign providers like BeeHealthy. All six participants offered recommendations, ranging from technical and market strategies to political and cultural conciderations. While some were optimistic about the future opportunities, others emphasized the challenges of entering a saturated and complex market.

Key Findings

- **Market saturation and entry barriers**: Most participants advised against developing a new TI-Messenger product due to the high number of certified providers and limited differentiation. The market is dominated by a few large players, making entry difficult without strong partnerships.
- **Strategic positioning is crucial**: Foreign providers must decide whether to compete or cooperate. Cooperation through partnerships with insurers or existing

vendors is seen more viable option. Competition entry requires a strong product, marketing and lobbying efforts.

- **Certification is complex but achievable**: While the certification process is demanding both technically and financially, it is open to any company, including foreign ones. Success depends on understanding gematik's specifications and navigating the regulatory landscape.
- **Networking and local expertise matter**: Participants emphasized the importance of building connections with local stakeholders, hiring regulatory experts, and engaging with gematik early to clarify roles and expectations.
- **Future opportunities lie beyond messaging**: Several participants suggested that foreign providers should look beyond TI-Messenger and explore other areas of the telematics infrastructure, such as automation, video communication or patient journey support.

Quotes from Participants

"My recommendation... is that it's probably not worth developing a new TI-Messenger. The market is quite saturated." (P1)

"Unless there's a clear automation benefit, I wouldn't recommend using TI-Messenger." (P5)

"A foreign provider needs to decide whether they want to pursue competition or cooperation." (P2)

"Start by talking and building connections. That's where it begins." (P6)

5 Discussion

The interviews revealed that the landscape for integrating into Germany's telematics infrastructure (TI), particularly via TI-Messenger, is complex but navigable. Across all themes, there emerged a recurred tension between the technical feasibility of integration and the practical barriers posed by regulation, market saturation, and cultural resistance. While TI-Messenger is technically robust and built on open standards like Matrix, its adoption and integration are slowed by fragmented rollout, limited workflow support, and a closed ecosystem.

5.1 Theoretical Implications

This thesis contributes to the limited but growing amount of literature on interoperability in centralized and decentralized healthcare systems, particularly in the context of EU-level initiatives, like the European Health Data Space (EHDS) and the European Interoperability Framework (EIF). The findings support the notion that interoperability is not just a technical challenge but a socio-technical construct that involves governance, certification, and stakeholder alignment (Vest and Gamm 2010; Gil-García, Pardo, and Luna-Reyes 2022).

The interviews validate the layered model of interoperability (legal, organizational, semantic, technical) and highlight the governance gap between specification and implementation. The role of gematik as both a certifier and gatekeeper reinforces the importance of institutional interoperability in national systems.

5.2 Practical Implications for BeeHealthy

For BeeHealthy, the findings of the interviews suggest that direct entry into the TI-Messenger market is not strategically viable due to saturation and certification complexity. Instead, the most promising path is partnering with some existing certified providers and offering services that have added value, such as multilingual support, appointment booking, or patient journey coordination.

BeeHealthy's strengths in usability and integration could be leveraged to improve the user experience of TI-Messenger clients, especially if the system evolves to support modular extensions. Furthermore, success depends on navigating gematik's certification process, aligning with German data protection laws, and identifying reimbursement models for healthcare professionals.

5.3 Implications for European Policy Landscape

Integration of foreign digital health providers into national infrastructures like Germany's TI must be viewed in the context of broader EU-level policy developments. While there are initiatives that aim to harmonize health data exchange across member states like EHDS and Interoperable Europe Act, the implementation still remains uneven. EU promotes open standards and cross-border interoperabilty, but national systems like Germany's TI continue to operate under distinct regulatory and institutional frameworks. This creates a gap between the political ambition and the practical execution. The findings suggest that successfull integration will require not only technical alignment but also political and institutional cooperation across borders.

5.4 Limitations of the Research

While this research provides valuable insights into the integration landscape of TI-Messenger from the perspective of German professionals, several limitations must be acknowledged. Firstly, the sample size was relatively small with only six participants interviewed. Although they were selected for their expertise and relevance to the topic, the small number limits the generalization of the findings. Each participant also brought their own professional agenda and personal viewpoints, which are shaped by their role in the healthcare ecosystem. This may cause potential bias, as their perspectives may reflect organizational interests or individual experiences rather than a neutral overview of the system.

Additionally, the geographic scope of the study was confined to Germany. Finnish stakeholders, EU-level regulators, and patient perspectives were not included, which narrows the cross-border dimension of the analysis. The study also did not involve technical prototyping or hands-on testing of integration pathways, which means that technical feasibility assessments remain theoretical. In addition, the timing of the research coincides with an ongoing rollout of TI-Messenger, and future developments may significantly change the landscape, potentially causing some findings to be outdated.

5.5 Recommendations for Future Research

Building on the findings of this research, there are several possibilities for future research. There is a clear need for cross-border pilot projects, that test the real-world integration of non-German digital health applications, like BeeHealthy, into the German telematics infrastructure. These pilots could explore both technical feasibility and user experience in controlled environments. In the future, studies should incorporate patient perspectives, especially regarding usability, trust, and expectations around secure digital communication. Understanding how patients perceive TI-Messenger

could inform design improvements and adoption strategies.

Additionally, a comparative analysis of certification processes across EU countries would be valuable, particularly as more member states begin to adopt Matrix-based messaging systems. Such research could identify best practices and harmonization opportunities. Further investigation is also needed into automation and workflow integration within TI-Messenger. Exploring how bots, structured data exchange, and clinical decision support tools could be embedded into the messaging infrastructure would help unlock its full potential and increase its relevance for daily healthcare operations.

6 Conclusion

This thesis demonstrates that integrating a Finnish digital health application into Germany's telematics infrastructure is technically feasible but practically challenging due to certification complexity, limited workflow support, and a saturated vendor landscape. The comparison between Finland's centralized Kanta Services and Germany's decentralized TI ecosystem reveals how governance structures and implementation models significantly influence interoperability. While Finland benefits from unified architecture and regulatory clarity, Germany's fragmented system offers flexibility but slows adoption. For foreign providers, strategic partnerships, alignment with local standards and having a value-added service present the most realistic opportunities. These findings underline the need for more harmonized EU-level frameworks that support both technical and institutional interoperability.

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A Interview Questions

Background & Role
1. Can you describe your background and current role with the telematics infrastructure, TI-Messenger, and healthcare interoperability?

TI-Messenger & Integration Landscape
2. Within the telematics infrastructure, what is TI-Messenger's current role and the main use cases that it is designed to support (e.g. professional-to-professional, patient-to-professional or other)?
3. What are the different parties involved in a TI-Messenger integration, and what responsibilities do these different parties have?

Integration Options for Foreign Providers
4. What are the available integration options for a non-German digital health provider (e.g. full-stack implementation vs. partner integration)?
5. Are there technical or legal barriers for foreign applications to act as TI-Messenger endpoints?
6. What are the certification or onboarding requirements (e.g. gematik approval, connector setup)?
7. How does identity management work for patients and professionals, especially in cross-border scenarios?

Technical Compatibility & Standards
8. How important is FHIR compatibility in TI-Messenger?
9. If a foreign application uses different APIs or standards, how difficult is it to bridge that gap?
10. Are there existing adapters or middleware that help with integration?

Use Case Exploration for TI-Messenger
11. In your view, what would be a realistic use case for a foreign digital health application using TI-Messenger in Germany?
12. What kind of data flows are involved (e.g. messaging, event logging, clinical data exchange) when using TI-Messenger?
13. What kind of audit trails or logs are generated in TI-Messenger interactions?
14. How does data governance change depending on the use case, for example if the communication is patient-initiated vs. provider-initiated?

Recommendations and Further Thoughts
15. What would be your top recommendations for a foreign digital health provider exploring TI integration?
16. Are there any ongoing initiatives or pilots concerning the cross-border integration that I should be aware of?
17. How do you see the TI-Messenger architecture evolving in the next few years?
18. Is there anything else you think is important that we haven't covered?