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Managing Interoperability of Digital Health Platform Ecosystems

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Prolog

Liebe Leserinnen und Leser,

in den letzten Jahren hatte ich das Privileg mich intensiv mit spannenden Digitalisierungsthemen im Gesundheitswesen zu beschäftigen, immer mit dem Fokus auf Interoperabilität. Interoperabilität ist "die Fähigkeit zweier oder mehrerer Systeme oder Komponenten, Daten/Informationen auszutauschen und die ausgetauschten Daten/Informationen zu nutzen" IEEE (2002) und damit die Grundvoraussetzung, um gespeicherte Daten und Informationen zu verarbeiten und Potenziale zu heben. Erste Berührungspunkte mit dem Konzept der Interoperabilität ergaben sich bei der Bearbeitung einer Fallstudienlösung für ein integriertes Versorgungskonzept mit Hilfe einer elektronischen/digitalen Aktenlösung, die im Rahmen des Mastermoduls E-Business behandelt wurde. Zum Zeitpunkt des Promotionsbeginns im Jahr 2018 waren die Potenziale einer flächendeckenden und integrierten elektronischen Patientenakte (ePA) für die Versorgung im Gesundheitswesen unbestritten. Mehrere Länder hatten es bereits vorgemacht und weit-reichende Lösungen im Einsatz, z.B. Estland, Finnland, Dänemark (u.a. Aanestad & Jensen, 2011). In Deutschland hingegen gab es zwar verschiedene Initiativen einzelner gesetzlicher Krankenkassen und IT-Dienstleister, u.a. des IT-Dienstleisters der gesetzlichen Krankenkassen, eine elektronische/digitale Akte einzuführen, eine flächendeckende Anwendung ist jedoch bis dato nicht gelungen. Interoperabilität wurde in diesem Zusammenhang häufig als eine Ursache für die Stagnation der digitalen Transformation und den mangelnden Datenaustausch von versorgungsrelevanten Gesundheitsinformationen diskutiert. Mit der Ernennung von Jens Spahn zum Bundesminister für Gesundheit (2018 - 2021) hat die Digitalisierung im Gesundheitswesen deutlich an Fahrt aufgenommen. Dazu zählen unter anderem die Einführung der elektronischen Patientenakte, die Einführung von digitalen Gesundheitsanwendungen (DiGAS), auch Apps auf Rezept genannt, sowie der Fokus auf Interoperabilität bei der Nutzbarmachung von Gesundheitsdaten. Dies bot eine spannende und zugleich einmalige empirische Gelegenheit, die einzelnen Initiativen und Veränderungen in diesem Zeitraum zu analysieren.

Im Rahmen dieser Arbeit sind vier Forschungsbeiträge entstanden. Der erste Beitrag konzentrierte sich auf die ökonomischen Zusammenhänge von Interoperabilität und die daraus resultierenden Herausforderungen. Im zweiten Beitrag wurden einzelne Episoden der Einführung einer elektronischen Gesundheitsakte sowie elektronische Patientenakten und entstehende Plattformökosysteme aus ökonomischer und sozio-technischer Sicht der Interoperabilität analysiert und Herausforderungen identifiziert. Der dritte Beitrag vertieft einige dieser Herausforderungen der elektronischen Patientenakte sowie komplementärer Anwendungen, u.a. DiGAs und Geräte, um diese als integrierte Versorgungsangebote zu gestalten. Das Ergebnis ist eine Schnittstellenlandkarte für DiGAs, die gleichzeitig Schwachstellen in den damaligen Regularien aufzeigt. Die Beiträge eins bis drei bildeten die Grundlage für das Problemverständnis und die Motivation für den vierten Beitrag, ein nutzenstiftendes Artefakt zu gestalten. Hierbei wurde ein Interoperabilitäts-Reifegradmodell entwickelt, das Plattformbetreiber und -orchestratoren unterstützt, ein integriertes Ökosystem auf Basis des Reifegradmodells und damit verbundener transparenter Anforderungen aufzubauen.

Ohne die nötige Inspiration, Motivation, Unterstützung und Vertrauen sowie Verständnis wäre diese Arbeit nicht möglich gewesen und so möchte ich mich bei allen, die mich auf diesem Weg in irgendeiner Weise begleitet haben, von ganzem Herzen bedanken. Ein großer Dank ...

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Zusammenfassung (Deutsch)

Das Thema Interoperabilität im Gesundheitswesen ist Gegenstand langjähriger Diskussionen und wird in dieser kumulativen Dissertation eingehend untersucht. Eine fragmentierte Systemlandschaft und entstandene Datensilos sind u.a. Gründe für eine mangelnde Interoperabilität. Dabei zeigt sich, dass Interoperabilitätsentscheidungen sowohl von ökonomischen Herausforderungen, wie hohen Kosten und Pfadabhängigkeiten als auch von soziotechnischen Herausforderungen begleitet werden. Die Harmonisierung der Daten und deren Nutzbarmachung für die Gesundheitsversorgung werden den elektronischen Patientenakten sowie den darauf basierenden Plattformökosystemen zugeschrieben. Zusammen mit komplementären Diensten, wie digitalen Therapeutika, entstehen neue Versorgungsformen, die die Orchestratoren der Plattformen vor große Herausforderungen beim Schnittstellenmanagement stellen. Die Komplexität für die Plattformorchestratoren erhöht sich zusätzlich dadurch, dass die ergänzenden Dienste unterschiedliche Anforderungen an die Datenqualität haben. Es gilt, klare Anforderungen zu definieren, um die entstehenden Leistungsbündel digitaler Dienste bei der Plattformintegration zu unterstützen. Um den vielschichtigen Anforderungen gerecht zu werden, wurde im Rahmen dieser Arbeit nach einem gestaltungsorientierten Ansatz ein Interoperabilitäts-Reifegradmodell entwickelt, das gezieltes Management von Interoperabilitätsentscheidungen von Plattformorchestratoren unterstützt. Das Modell besteht aus fünf Stufen und umfasst sieben Dimensionen der Charakterisierung von Interoperabilität. Das Reifegradmodell dient der Bewertung von komplementären Services bei der Integration, der Definierung von Anforderungen an die komplementären Services sowie der Definierung von Integrationsprofilen für das Plattformökosystem. Zugleich liefert das Reifegradmodell wichtige Impulse für die zukünftige Entwicklung des Plattformökosystems und unterstützt die Forschung zu diesem Thema.

Die kumulative Dissertation besteht aus vier veröffentlichten Forschungsaufsätzen, die das Thema Interoperabilität mit unterschiedlichen Fragestellungen und Forschungsmethoden untersuchen. Aus Sicht des Interoperabilitätsmanagements von Plattformökosystemen ergeben sich aus der Arbeit drei Kernergebnisse: Erstens, Interoperabilitätsentscheidungen sind von starken ökonomischen Mechanismen geprägt, welche näher charakterisiert und diskutiert werden. Zweitens, wurde das Konzept der patientenzentrierten Interoperabilität vorgeschlagen. Hierdurch werden Interoperabilitätsentscheidungen stärker prozessual, entlang von Versorgungspfaden, betrachtet, um integrierte digitale Leistungsbündel auf Plattformen für eine bessere Versorgung zu bieten. Drittens, das entwickelte Reifegradmodell unterstützt Plattformbetreibern bei der Gestaltung der Schnittstellenanforderungen des Plattformökosystems. Mit dem Wissen aus dieser Arbeit können die diskutierten Aspekte von Interoperabilität aus Forschungssicht als auch Praxissicht z.B. Plattformorchestratoren besser antizipiert und adressiert werden.

Abstract (English)

The topic of interoperability in healthcare has long been a topic of discussion and is examined in detail in this dissertation. A fragmented system landscape and the resulting data silos are among the reasons for the lack of interoperability. This shows that interoperability decisions are accompanied by economic challenges such as high costs and path dependencies as well as socio-technical challenges. The harmonization of data and its use for healthcare is attributed to electronic patient records and the platform ecosystems based on them. In combination with complementary services such as digital therapeutics, new forms of healthcare are emerging that present platform orchestrators with major challenges in interface management. Clear requirements must be defined to support the resulting service bundles of innovative healthcare services on the platform. These challenges are further complicated by the different data quality requirements of the complementary value-added services. To address these complex requirements, this dissertation develops an interoperability maturity model based on a design-oriented approach that supports the targeted management of interoperability decisions by platform orchestrators. The model consists of five levels and includes seven dimensions of interoperability characterization. The maturity model is used to evaluate complementary services during integration and define requirements for the complementary services and integration profiles for the platform ecosystem. At the same time, the maturity model provides important impetus for the future development of the platform ecosystem and supports research in this area.

This cumulative dissertation consists of four published research articles that explore the topic of interoperability with different questions and research methods. From the perspective of interoperability management of platform ecosystems, three key findings emerge from the summary of the cumulative dissertation: First, this work shows that interoperability decisions are shaped by strong economic mechanisms, which are characterized and discussed in more detail in the thesis. Second, this thesis proposes the concept of patient-centered interoperability. This means that interoperability decisions are viewed more processually along care pathways to offer integrated digital service bundles on platforms for better care. The third core contribution is the developed maturity model, which supports platform operators in designing the interface requirements of the platform ecosystem. With the knowledge gained from the cumulative dissertation, the discussed aspects of interoperability can be better anticipated and addressed from both a research and a practical perspective, e.g., by platform orchestrators.

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List of Abbreviations

AI	Artificial Intelligence
App	Application
BSR	Behavioral Science Research
CDA	Clinical Document Architecture
DICOM	Digital Imaging and Communications in Medicine
DRG	Diagnosis Related Groups
DSR	Design Science Research
DTx	Digital Therapeutics
EHR	Electronic Health Record
EIF	European Interoperability Framework
FHIR	Fast Healthcare Interoperability Resources
GDPR	General Data Protection Regulation
GECCO	German Corona Consensus Dataset
HIMSS	Healthcare Information and Management Systems Society
HIS	Health Information Systems
HL7	Health Level 7
ICD	International Statistical Classification of Diseases
IEEE	Institute of Electrical and Electronics Engineers
IHE	Integrating the Healthcare Enterprise
IS	Information Systems
IT	Information Technology
ITIL	Information Technology Infrastructure Library
ISO	International Organization for Standardization

JSON	Java Script Object Notation
LOINC	Logical Observation Identifiers Names and Codes
MIO	Medical Information Objects
MM	Maturity Model
PHR	Personal Health Record
RG	Research Goal
RIM	Reference Information Model
RQ	Research Question
SLR	Systematic Literature Review
SSO	Standard-Setting Organizations
SNOMED CT	Systematized Nomenclature of Medicine Clinical Terms
TI	Telematics Infrastructure
TK	Techniker Krankenkasse
VPN	Virtual Private Network

Part I.

Synopsis of the Doctoral Thesis

1. Introduction

1.1. Research Motivation

"Make everything as simple as possible, but not simpler." (Albert Einstein)

Understanding the slowly emerging digitalization in healthcare (e.g., Agarwal et al., 2010; Sun et al., 2021), especially for digital innovations (e.g., Hobeck et al., 2021), is one of the main motivators of the research of this cumulative doctoral thesis. Although, the opportunities for better healthcare offered by digitalization are well known, including rapid accessibility through platforms, telemedicine, and patient portals (e.g., Sun et al., 2021; Barrett et al., 2016). It can reduce healthcare costs by eliminating redundancy in tasks such as data collection and diagnostic testing (Han et al., 2020). More complete health data also improves the quality of care, as further decisions are made based on it, leading to fewer clinical errors (e.g., Sun et al., 2021; Yaraghi et al., 2015; Han et al., 2020; Caldwell, 2015). Digitized healthcare data and information can also be more easily shared for research purposes, and with more data, better research can be conducted (e.g., Dainton & Chu, 2017).

A key issue in this regard is interoperability, which has been widely discussed in information systems research for several decades (e.g., Hodapp & Hanelt, 2022). Interoperability can be described as *"[t]he ability of two or more systems or components to exchange [data/] information and to use the [data/] information that has been exchanged"* (IEEE Standards Board, 1990). In digitally-enhanced care approaches, using digital data-based innovations, e.g., Digital Therapeutics (DTx) (Fürstenau, Gersch, & Schreiter, 2023) or digital health ecosystems such as Electronic Health Record (EHR)-based platform ecosystems, interoperability is a prerequisite for generative value creation (e.g., Hodapp & Hanelt, 2022; Yoo et al., 2012; Sun et al., 2021; Kohli & Tan, 2016). Compared to early discussions on interoperability regarding interorganizational data and information[1]

[1]Depending on the nature of the data to be exchanged, in terms of syntax, semantics and a distinction can be made between data, information, and knowledge (e.g., Rehäuser & Krcmar, 1996). This aspect is discussed in more detail in subsection 2.2.1.

exchange in healthcare, the design and management of digital platform ecosystems have become increasingly complex due to the large number of actors, such as physicians (e.g., Kohli & Tan, 2016), heterogeneous systems, e.g., Health Information Systems (HIS), mobile applications like health apps and DTx (Fürstenau, Gersch, & Schreiter, 2023; Schlieter et al., 2023), as well as devices (e.g., for blood glucose and blood pressure monitors (see part II paper P3).

Interoperability issues in digitized healthcare are not purely technical in nature. Instead, they are socio-technical issues that require consensus on usage and implementation (Scheplitz & Neubauer, 2022; Hanseth & Bygstad, 2015; Hanseth et al., 2012; Markus et al., 2006). Recent framework approaches, such as that of the European Commission (2017), also emphasize the socio-technical character of interoperability, including dimensions such as regulatory, policy, organizational, legal, and business processes (Scheplitz & Neubauer, 2022), thus going beyond the traditional technical views, such as technical, structural, syntactic, semantic dimensions (e.g., Oemig & Snelick, 2016). In the realm of digital innovation and ecosystems, there is a pressing need for novel approaches to design and manage interoperable platform ecosystems. This doctoral thesis explores previous research on interoperability and management within digital platform ecosystems and proposes actionable solutions to address these challenges.

Most of the studies in this doctoral thesis focus on the digital transformation of the German healthcare system. Returning to Einstein's quote, the German governmental specification institutions, especially gematik[2], have not always chosen the "simplest possible" approach when setting the framework for designing a well-integrated digital healthcare ecosystem involving many stakeholders. Instead, by following international standards (see part II paper P2 and P3), they have repeatedly opted for idiosyncratic approaches that limit the options for data use by other stakeholders and make the system "simpler" in terms of limited possibilities for full utilization. This has far-reaching consequences for those aiming to build digital ecosystems based on these specifications, such as health insurance companies and IT service providers of EHR-based platform ecosystems and their complementary services. The implications of this situation and how a maturity model for interoperability can provide support are discussed in detail in this doctoral thesis.

[2]The German national healthcare institution responsible for specifying and approving infrastructure components and applications for the Telematics Infrastructure (TI), such as the EHR.

1.2. Overview of the Research Goals

The doctoral thesis contains four published research papers, P1-P4 (see part II). Table 1.1 provides an overview of the papers with their contribution and methodological approaches[3]. The contributions of the doctoral thesis can be summarized in two overarching Research Goals (RGs).

Table 1.1.: Overview of the contributions

Paper	**Title, Outlet (Rating$^{\alpha}$), Points$^{\beta}$**	**Outcome**	**Method**	**Research goal$^{\gamma}$**
P1	Title: Interoperability – Technical or economic challenge? Outlet: it - Information Technology, journal paper *(VHB: D)* Points: 0.5	Overview of the economic challenges discussed in the literature that impede interoperability.	Systematic Literature Review (SLR) according to vom Brocke et al. (2009)	RGI
P2	Title: The Emergence and Dynamics of Electronic Health Records – A Longitudinal Case Analysis of Multi-Sided Platforms from an Interoperability Perspective Outlet: Proceedings of the 54th Hawaii International Conference on System Sciences (HICSS), full conference paper, *(VHB: B)* Points: 0.5	Seven challenges related to interoperability issues were identified by analyzing three emerging EHR-based platform ecosystems for economic and socio-technical perspectives.	Case study by Yin (2018) and Eisenhardt (1989b)	RGI
P3	Title: Future-oriented and patient-centric? A qualitative analysis of Digital Therapeutics and their interoperability Outlet: Proceedings of the European Conference on Information Systems (ECIS), full conference paper, *(VHB: A)* Points: 0.14	Focus on key interfaces of DTx, Electronic Health Record, devices, and other digital health innovations such as telemedicine, and highlight current challenges and potentials for future development, e.g., unresolved issues of care coordination, the optional role of the EHR as regulated platforms for care, and the importance of integrating DTx data into public data spaces for research.	Exploratory qualitative study (Sarker et al., 2018)	RGI
P4	Title: Interoperability Maturity Model: Orchestrator Tool for Platform Ecosystems Outlet: Proceedings of the 18th International Conference on Wirtschaftsinformatik (WI), full conference paper, *(VHB: B)* Points: 1.0	An interoperability maturity model to measure the degree of interoperability of platform complementors for achieving and sustaining integrated value chains with multiple players and diverse technology	Design Science Research by Hevner et al. (2004)	RGII
	Points: Total 2.14			

$^{\alpha}$ According to the VHB Publication Rating 2024 for Information Systems
$^{\beta}$ Points included in the comulative disertations, according to the FU regulation for cumulative disertations
$^{\gamma}$ Contribution to the overarching research goal

[3] A list of the publications with the names of the co-authors and all articles written during the Phd period can be found in part II.

The first overarching goal, RGI, focuses on identifying and expanding the understanding of interoperability challenges in digital health ecosystems. Besides the different dimensions, the economic reasons for the lack of interoperability of closed and proprietary solutions of digital artifacts, have rarely been considered; this gap will be addressed in the first paper (see part II, paper P1). Paper P1 examines the challenges of ensuring interoperability from an economic perspective. The results of the systematic literature search according to vom Brocke et al. (2009) have shown different cost-benefit considerations as well as mechanisms (Sydow et al., 2009) that lead to path dependencies, which can be attributed, inter alia, to the lack of interoperability as part of the business model. The development of platforms in the highly regulated healthcare market, especially in uncertain times, is subject to significant implementation risks. These risks are contingent upon government decisions and the timeliness of their implementation. In the second paper (see part II paper P2), a case study by Yin (2018) and Eisenhardt (1989b) examines the interoperability challenges of EHR platform ecosystems for platform owners/orchestrators, complementors (such as DTx providers), and insurants. In the third paper (see part II, paper P3), workshops and problem-centered interviews proposed by Witzel & Reiter (2012) were conducted to analyze the interface landscape of DTx and discuss future-oriented scenarios of DTx (e.g., Rassi-Cruz et al., 2022) and corresponding interface requirements in the healthcare ecosystem from a patient-centric interoperability perspective, focusing on the interrelationships of digital innovations, e.g., DTx along individual care pathways. In summary, the first overarching research goal is guided by the following Research Question (RQ):

RQI: What are the economic and socio-technical interoperability challenges of emerging EHR-based platform ecosystems?

The second overarching goal, RGII, focuses on the increasing importance of interoperability from a care pathway perspective for the management of EHR-based platform ecosystems. With a process-oriented view of the interoperability of digital solutions along care pathways, the fourth paper (see part II, paper P4) followed a Design Science Research (DSR) approach (Hevner et al., 2004) to provide a solution for assessing interoperability through a maturity model for platform owners with respect to the platform orchestrators.

The orchestration of EHR platform ecosystems and their complementary services has become increasingly challenging due to the complexity of interconnected systems and potential value chains (e.g., P. C. Tang et al., 2006). At the same time, achieving interoperability is crucial for fully utilizing the benefits of interconnectivity. Platform orchestrators and managers must ensure compliance with the requirements when integrating complementors into the platforms. Motivated by Hodapp & Hanelt's (2022) research agenda, a maturity model is a contributor to measuring interoperability, providing more transparency and clarity to different requirements, both in definition and verification. In addition, a maturity model for platform orchestrators should help them assess the interoperability maturity of a solution already integrated or to be integrated. The Interoperability maturity model aims to aid orchestrators and platform ecosystem managers in analyzing and implementing integrated care solutions within digital ecosystems along care pathways. In summary, the second overarching research goal is guided by the following RQ:

RQII: How can platform orchestrators be supported in managing the interoperability of platform ecosystems?

1.3. Structure of the Doctoral Thesis

The above-mentioned research threads and corresponding studies will be compiled in a synopsis in which the conceptual background of the studies, the method, and the results of the studies and research branches will be summarized and discussed. Figure 1.1 visualizes the structure of the doctoral thesis. The work is structured in three parts: part I, the synopsis of this doctoral thesis; part II, with the four published papers (P1-P4) and part III, with the appendix of additional tables and figures.

Part I contains the synopsis of the thesis and represents the main body of the thesis. Essentially, it consists of four studies on the topic of interoperability and interoperability management of EHR-based platform ecosystems. After this introductory chapter (see chapter 1), which gives a rough overview of the topic, the problem, and the research approaches, chapter 2 explains the conceptual background. This includes the research objects that have been investigated in the context of interoperability, a comprehensive overview of the spectrum of interoperability, and the management of interoperability, in particular of platform ecosystems. Chapter 3 provides an overview of the research designs and methods used in the studies to investigate and address the research questions posed. A brief overview of the resulting findings of the four studies is provided in chapter 4. The results are discussed in more detail in chapter 5, where the different findings are consolidated and discussed according to the two research threads – on the one hand, according to economic factors in connection with interoperability and on the other hand, from a care perspective, which needs to be considered when realizing interoperable care scenarios on platform ecosystems and how the designed maturity model can contribute to this. Finally, chapter 6 summarizes the core results of the research, as well as limitations and an outlook for further research.

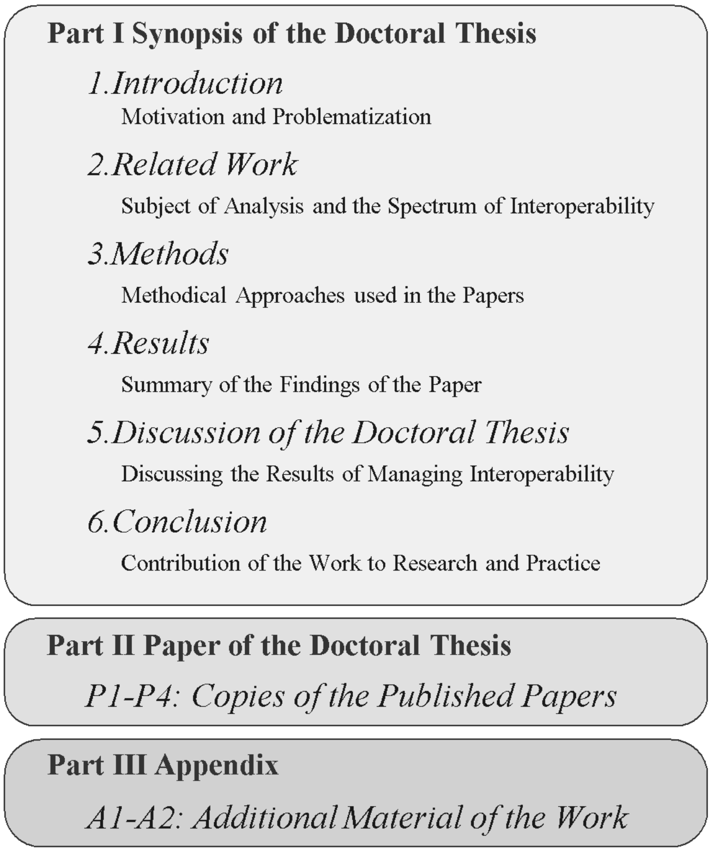

Figure 1.1.: Structure of the doctoral thesis

2. Related Work

2.1. Subjects of Analysis

2.1.1. Digitalization of the German Healthcare System

Three of the four studies in this doctoral thesis took the German healthcare system as their empirical base. This subsection is intended to provide a brief overview of certain characteristics of the digital transformation of the German healthcare system, including central constructs such as the EHR, emerging platform ecosystems of the EHR, Digital Therapeutics (DTx), digital health devices, and other healthcare innovations, which are introduced and differentiated below.

The German healthcare system is founded upon the principles of solidarity insurance and self-administered healthcare, which were initiated by Otto von Bismarck in 1883 (Busse et al., 2017). In essence, all citizens are covered by health insurance, with the majority enrolled in statutory health insurance and only specific occupational groups and income brackets having private health insurance (e.g., Busse et al., 2017). The main focus of the doctoral thesis lies on the first healthcare market. The first healthcare market is the primary, highly regulated, and regimented part of the healthcare system. Services in the first healthcare market are predominantly paid by the statutory insurance companies (e.g., Müller-Mielitz & Lux, 2017; Busse et al., 2017). In contrast, the second healthcare market is less regulated and services are usually paid by consumers directly (e.g., Herrmann et al., 2014).

For a nuanced understanding of the digital transformation in the healthcare system, relevant topics and actions would be divided into three levels of analysis. The *macro level* represents decisions and changes that are made through policies or laws at international and national stages. The lowest level, the *micro level*, looks at individual actors or organizations with little influence, such as hospitals or software vendors. In between, the *meso level* includes institutions and organizations with influence on the regional or extended community stage, such as health insurance companies or certain associations.

Initial digitization initiatives in the healthcare sector were observed rather at the micro and meso levels. Healthcare providers such as hospitals or general practitioners were using Health Information Systems (HIS) to document and optimize the treatment processes (Holmgren & Adler-Milstein, 2017; Agarwal et al., 2010; Schweiger et al., 2007; Kohli & Kettinger, 2004) as well as for the billing of cases, e.g., with the health insurance company (e.g., Kim et al., 2011; Menon et al., 2000). In 2004, with the enactment of the Act to Modernize the Statutory Health Insurance (GKV-Modernisierungsgesetz; see part III Appendix A1), the national digitization initiatives (in Germany) came up with the idea of establishing a secure network to connect all care-relevant actors in the healthcare system and make information universally available. The network is called Telematics Infrastructure (TI) and consists of an electronic health card system and an encrypted Virtual Private Network (VPN) solution with specific hardware components (e.g., Wessel et al., 2017; Elmer, 2016; Wirtz et al., 2012; Schweiger et al., 2007, or see paper P2). Wessel et al. (2017) examined the German digitization initiatives from 2007 to 2011 with a focus on information pathologies; for example, the authors uncovered avoidable shortcomings and inconsistencies in the development process of the German electronic health card for the TI. With the introduction of the TI in Germany, the government is building an inter-organizational network for data exchange in the health sector and offering digital services in a highly regulated digital ecosystem. The TI can be understood as an installed base (Hanseth & Lyytinen, 2004) on which actors, such as IT service providers, government organizations, or health insurers, offer digital services, such as a nationally mandated EHR, E-prescriptions, and communication services for medical stakeholders. As with most applications of the TI, the EHR is highly specified, e.g., security requirements, interfaces, and the way stakeholders co-create value are subject to explicit governance rules.

Interoperability is a basic requirement for data exchange on EHR/Personal Health Record (PHR) platforms (e.g., Essén et al., 2018; Blechman et al., 2012). Part III Appendix A1 shows an example of 16 laws on health digitization in Germany (from 2004 - 2023) in which interoperability is mentioned 425 times, setting the course for the specifications (on the macro level). There are also initiatives at the European Union level to conceptualize interoperability and set the course for an international interoperable design, starting with the European Interoperability Framework (EIF) for certain priority sectors, including health, in 2004 (European Commission, 2004), which was revised in 2015 (eHealth Network, 2015), with an updated version in 2017, as the new

EIF was published (European Commission, 2017). All initiatives are summarized in the National Interoperability Framework Observatory (European Commission, 2023). This illustrates that interoperability is a relevant topic, but also a complex design feature (e.g., Kobusinge, 2020) to be defined along multiple legislative initiatives, both in national and international contexts.

2.1.2. The Electronic Health Record

The International Standard Organization (ISO) defines EHR[4] as *"a repository of patient data in digital form, stored and exchanged securely, and accessible by multiple authorized users. It contains retrospective, concurrent, and prospective information, and its primary purpose is to support continuing, efficient, and quality integrated health care"* (ISO, 2005). In addition, the Healthcare Information and Management Systems Society (HIMSS) emphasizes the longitudinal storage of data in its definitional approach (e.g., Kohli & Tan, 2016); after all, the data should be stored and usable for a lifetime. In addition to the EHR, there are other forms of records in the literature, which are briefly defined below for a differentiated understanding.

- The Electronic Case Record provides a medium for the exchange of medical documentation of a case between directly involved actors, e.g., in the context of integrated care solutions (vesta Standards, 2023).
- Electronic Medical Records or Electronic Patient Records focus on medical documentation, usually within a health information system in an organization such as a hospital or doctor or therapist's practice (Häyrinen et al., 2008).
- The Personal Health Record (PHR) is controlled by the insurant and contains information that is at least partially entered by the patient and selected doctors (e.g., Hanseth et al., 2006; Q. Tang & Cheng, 2006).

The descriptions cannot be precisely differentiated from the EHR because the EHR also covers functions of the other records solutions. Two main objectives of the EHR can be observed. On the one hand, it serves as a repository for health and medical data that can be stored and used over a lifetime, e.g., medical reports, vaccination records, medication schedules (e.g., Reza et al., 2020; Dixon & Grannis, 2020; Hess et al., 2014).

[4]The prefix 'electronic' is commonly used in the term 'electronic health record', but it implies that information is only exchanged electronically. For this reason, the prefix digital is increasingly used in the primary and secondary literature; for the sake of simplicity, the traditional form is used in this paper as a prefix for various health record solutions.

On the other hand, the EHR as data hub should bundle all health information in order to bypass existing data silos (e.g., Miller & Tucker, 2014; P. C. Tang et al., 2006) so that the data can be used by relevant stakeholders (Kohli & Tan, 2016). The interoperability of data is critical to its full use, especially in an interorganizational context (e.g., Marwaha et al., 2022; Aanestad et al., 2017b; Bowden & Coiera, 2017; Kohli & Tan, 2016; Blechman et al., 2012).

The introduction of a record solution in Germany was intensively examined in paper P2 and can be divided into three phases: I, the Experimental Phase of the PHR; II, the Transition Phase from PHR to EHR; and III, the Phase EHR Becomes Mandatory. *Phase I: Experimental Phase of the PHR:* The first legislative initiatives were taken in 2004, allowing statutory health insurance companies to develop PHRs and can use financial resources for their development. Over a long period, no significant progress was made, causing considerable tensions, particularly in cross-sectoral and interdisciplinary care (see paper P2). *Phase II: Transition from PHR to EHR*: In this phase, initial solutions came to market to offer a record solution as PHRs. Health insurance companies and their IT service providers faced numerous challenges in the development and implementation of these records, which were examined in detail from an interoperability perspective in paper P2. *Phase III: EHR Becomes Mandatory*: Since January 1, 2021, all statutory health insurers must offer their insurants an EHR upon request in accordance with §325 (1) (SGB V). In Germany, three EHR versions have been approved (as of 2024) by different providers or IT service providers. One was developed on behalf of a health insurance company, one in close cooperation between the insurance company and an IT service provider, and a white label version, i.e., for comparatively smaller insurance companies as well as some private insurance companies. From January 15, 2025, all statutory insurants will automatically have an EHR unless they waive it (§342 SGB V). The EHR is defined in §341 and §342 SGB V, which particularly emphasizes the sovereignty of the insured person, meaning that the record is controlled by the insured person.

The data and information provided by the EHR offer a wide range of opportunities to improve health and health care by giving individuals and health care providers better access to a wide range of credible health information. This enables individuals to maintain and improve their health. But the information has a great potential, especially in medical care and treatment, to shape the treatment precisely on the basis of the intended information (e.g., P. C. Tang et al., 2006; E. J. Davidson et al., 2015).

From an interoperability perspective, the EHR serves two primary functions: to store data/information in an interoperable manner and to utilize the data/information without loss of information. A significant aspect of these functionalities relies on interfaces, syntactic and semantic standards, and workflows for exchanging and utilizing the data/information in an interoperable format. Therefore, a core function of the EHR as a data hub is to provide (interoperable) interfaces for data/information exchange. In the literature, the benefits of digital solutions in the healthcare sector, such as EHR, are seen from a care perspective, including the improvement of medical care and the quality of care, and from an economic perspective, with factors such as efficiency and financial performance (Bowden & Coiera, 2017; Agarwal et al., 2010). In particular, the primary use of the data will be considered. However, the data opens up many opportunities for secondary use, especially for research and new, innovative business models based on digital innovation, e.g., in connection with big data or self-learning algorithms (Angst et al., 2017; Lumor et al., 2021; Sahay et al., 2013; Kendziorra et al., 2023; Lumor et al., 2021). Besides the nature of health data, metadata in an interoperable format, e.g., for Big Data systems, are also crucial for the secondary use of data (e.g., Lumor et al., 2021; Sinaci & Erturkmen, 2013). Long-term health data facilitates precise diagnoses through comprehensive patient profiling, for example, disease risks that can be addressed by targeted preventive measures (Kohli & Tan, 2016). Anticipating the composition of data for subsequent and secondary use poses challenges (e.g., Zhao & Xia, 2014). However, data interoperability significantly enhances the agility in utilizing stored data for secondary purposes (Kendziorra et al., 2023). In the literature within the field of Artificial Intelligence (AI), for instance, it is recommended that data be stored in as granular a semantic coding as possible (see section 2.2.1) to enable algorithms to operate more precisely (e.g., Lehne et al., 2019).

2.1.3. Germany's Digital Healthcare Ecosystem and Emerging Platforms

In recent years, various types of platforms have become established in both the first and second healthcare markets. In the first healthcare market, platform approaches for cross-sector data exchange are related to EHR (see paper P2 as well as Fürstenau et al., 2019; Holmgren & Adler-Milstein, 2017; Yaraghi et al., 2015) for health preservation and care management, such as those offered by insurance companies (see paper P2), or platforms for specialized indication areas that focus on supporting better care, including coordination and procurement (Fürstenau et al., 2021). In the second healthcare market, platforms are offered by dominating players (e.g., Gleiss et al., 2021; Hermes, Riasanow, et al., 2020) or online communities (Barrett et al., 2016). This work focuses in particular on emerging platform solutions of statutory health insurances that build an ecosystem around the EHR. The EHR serves as the data hub for both the health insurers' platform ecosystems and other initiatives and innovations. Currently, health insurance companies are the predominant players in Germany in building platform ecosystems. In particular, the Techniker Krankenkasse (TK) is pursuing a broader offering compared to many others. Hein, Schreieck, et al. (2019) offer a suitable approach for defining platform ecosystems as *"a digital platform ecosystem comprises a platform owner that implements governance mechanisms to facilitate value creating mechanisms on a digital platform between the platform owner and an ecosystem of autonomous complementors and consumers"*(Hein, Schreieck, et al., 2019, p. 4). These roles are explained below:

Customers: The primary focus of value creation is the insured individual, who should be provided with additional services beyond those provided by the service around the EHR in order to enhance both customer satisfaction and health literacy. Health insurance companies are actively pursuing various strategies to provide incentives that can enhance quality, drive economic improvements, and gain competitive advantages. Access to services and management of the EHR is primarily through a mobile health insurance Application (App), which provides users with direct control of their healthcare information and services.

Ecosystem: From the customer's perspective, the health insurance App is designed to present a seamless and unified experience, seemingly molded from a singular entity. However, in the background, it functions as a bridge connecting two distinct ecosystems. On one side, it integrates with the highly regulated TI and associated services, encompassing EHR, E-prescriptions, and similar offerings. On the other side, it interfaces with the insurance ecosystem, which encompasses the diverse array of services provided by the insurance company.

Platform owner/orchestrator: Ownership of the platform stands as a pivotal factor influencing the design and governance of digital platform ecosystems (Hein, Weking, et al., 2019; Tiwana et al., 2010). In terms of EHR-based platforms in Germany, platform owners would be the insurance companies, whereas the platform orchestrator is considered as a dedicated role to manage the platform ecosystem (e.g., Jacobides et al., 2024). This role is the focus of this work for the management of interoperability. However, the levels of flexibility in designing these ecosystems vary considerably. A nuanced consideration is required between the TI ecosystem, which is particularly regulated by the Government especially the gematik. In contrast, the insurance ecosystem faces fewer regulations in terms of complementary service offerings and governance, presenting more opportunities.

Complementors: Complementors add value to the platform by offering complementary products and services (Hein, Weking, et al., 2019) and exchange knowledge, e.g., by promoting the generativity of the ecosystem (Fürstenau, Baiyere, et al., 2023; Autio, 2022). In the context of traditional medical care, these are primarily care providers who also benefit from the information and services available on the platform, such as the EHR, which can improve patient outcomes. However, there is a growing range of digitally supported care services, such as DTx (Fürstenau, Gersch, & Schreiter, 2023).

The degree of integration can be divided into loosely coupled and tightly coupled (Hein, Weking, et al., 2019), which can also represent a difference in terms of interoperability requirements, especially for the connection and use of data by additional value-added applications. The adoption and use of recognized interfaces is an essential part of expanding the platform ecosystem (Fürstenau et al., 2019; Abdelkafi et al., 2019) whereby the TI ecosystem has stricter regulatory constraints than the individual health insurance companies' ecosystem. Orchestrating the various complementary services with their individual policies, resources, and requirements, including data quality and interoperability, is the task of the responsible platform orchestrator (e.g., Teece et al., 2022; Tiwana, 2014). This is where orchestration of partnership assets and resources has a huge impact on increasing the overall value of the platform (van Alstyne & Parker, 2017) as well as ecosystems in general (Autio, 2022).

2.1.4. Digital Therapeutics

According to Fürstenau, Gersch, & Schreiter (2023), DTx can be defined as *"therapeutic interventions through a clinically evaluated, patient-directed software application intended to improve the process of diagnosing, treating, managing, and/or preventing diseases"* (p. 1). This applies in particular to the complementary services offered in Germany's first healthcare market, e.g., the so-called apps for prescriptions (e.g., Ludewig et al., 2021; Gerke et al., 2020; Schlieter et al., 2023) as well as services offered by individual health insurance companies. Interoperability-relevant issues of DTx with regard to data connectivity, platform integration, and the design of regulatory approaches were part of papers P2, P3, P4 and will be discussed deeply in chapter 5.

2.2. Spectrum of Interoperability

2.2.1. The Evolution of Interoperability

One of the earliest definitions was established by the U.S. Department of Defense and defines interoperability as *"the ability to exchange and process information between (among) systems. Information exchange is usually realized through the use of digital communication channels configured into a network. Processing of the exchanged information is performed through functions of the System under test which may be termed interoperability functions"* (Jacques, 1984, p. 3). Building on Jacques (1984) definition approach, the Institute of Electrical and Electronics Engineers (IEEE) presented a widely cited definition of interoperability first in 1990. According to the IEEE, interoperability is *"the ability of two or more systems or components to exchange information and to use the information that has been exchanged"* (IEEE Standards Board, 2002, p. 42). A distinction must be made between interoperability and the term compatibility, which is defined as *"the ability of two or more systems or components to perform their required functions while sharing the same hardware or software environment"* (IEEE Standards Board, 1990, p. 18). Compatibility is, therefore, a prerequisite of interoperability in order to transfer information between two or more systems. This requires hardware interfaces and communication protocols that allow the bits to be transmitted by one or more systems. Interoperability considers not only the transmission of data but also whether the data can be processed by the receiving system.

2.2.2. Interoperability Conceptualization from a Technical Perspective

The definition of the IEEE focuses on interoperability from a rather technical perspective, but most studies in the literature also adopt this approach. This is reflected in particular in early conceptualization approaches and frameworks of interoperability, which addresses interoperability-related issues (e.g., Jardim-Goncalves et al., 2013; Berre et al., 2007; Chen, 2006). A very basic and widely used model in the literature is based on the OSI seven-layer network model (ISO/IEC, 1994). Figure 2.1 shows the interoperability layer model, which is structured from bottom to top, whereby the upper layer is built on the lower layer. *The technical level* states that two systems can communicate by using the same communication standards and protocols; in other words, they are compatible high — Interoperability — low

automatic — Potential for automatization — manual

Level	Description	Examples of typical standards
Organizational/ pragmatic interoperability	Cross-system processes, roles, Authorizations (knowledge exchange on business concept level)	Medical guidelines, ITIL (ISO 20.000), ISO 9001, ISO 27000
Semantic interoperability	Achieving a uniform understanding of the information units (knowledge exchange on IT concept level in computer analyzable format	*Terminologies*: SNOMED CT, LOINC *Classification Systems*: ICD 9/10, DRG *Reference models*: HL7/FHIR (RIM, CDA), IHE, MIO
Syntactic interoperability	Recognizing information units in the data (information exchange	e.g., HL7, FHIR, XML, CSV, DICOM
Technical interoperability	Bit transmission, technical plug and play	Technical Interfaces and Standards

Figure 2.1.: Level conceptualization of interoperability adapted from Blobel & Pharow (2008), Benson & Grieve (2016) and Oemig & Snelick (2016)

with each other (e.g., Blobel & Pharow, 2008; Benson & Grieve, 2016). *The syntactic level* describes the exchange of data based on the basis of structured standards or formats for extracting information units. In medicine, Health Level 7 (HL7) and Fast Healthcare Interoperability Resources (FHIR) are common for structured, mostly text-based data exchange, while Digital Imaging and Communications in Medicine (DICOM) is common for image-based data (e.g., Benson & Grieve, 2016; Blobel & Pharow, 2008). *The semantic level* refers to the understanding and distinct interpretation of exchanged information units. Knowledge can be abstracted through granular structuring and coding, such as terminologies (e.g., Benson & Grieve, 2016; Blobel & Pharow, 2008). *The organizational/pragmatic level* refers to the aspect of the practical realization of joint business processes and how different systems (organizations, individuals, and machines) work together on specific tasks based on the abstracted knowledge. Representatives of standards for uniform processes, roles, and tasks specify clinical guidelines (e.g., Benson & Grieve, 2016; Asuncion & van Sinderen, 2010; Blobel & Pharow, 2008).

Figure 2.1 also illustrates that interoperability increases the potential for automation (Oemig & Snelick, 2016), e.g., for business processes and for self-learning algorithms (Lehne et al., 2019) that recognize new patterns based on structured and coded information units and can be trained with high interoperability in shorter learning cycles (e.g., Hu et al., 2022). With growing connectivity and digitization, interoperability issues and decisions have become more complex and are no longer a purely technical topic that can be explained by the layer model (see figure 2.1. Data are a crucial asset, particularly for data-driven systems. Therefore, data provision and exchange and the formats and interfaces used with partners have become a management issue.

2.2.3. Conceptualization of Interoperability from a Socio-Technical Perspective

In the literature, interoperability has mainly been considered from a technical perspective, (e.g., Blobel & Pharow, 2008; Benson & Grieve, 2016; Oemig & Snelick, 2016). In more recent studies, especially in the field of information systems, interoperability is considered as a socio-technical phenomenon (e.g., Scheplitz, 2022; Hodapp & Hanelt, 2022). This was also due to the frequently cited framework approaches, such as the (New) EIF, which extended the views by, for example, including dimensions such as legal and regulatory aspects, as well as organizational, policy, and process aspects on interoperability (European Commission, 2017).

In their work, Hodapp & Hanelt (2022) employ a morphological box to conceptualize the primary mechanisms of interoperability issues from a socio-technical perspective. Figure 2.2 depicts the box, which is based on three dimensions and includes inquiries for each

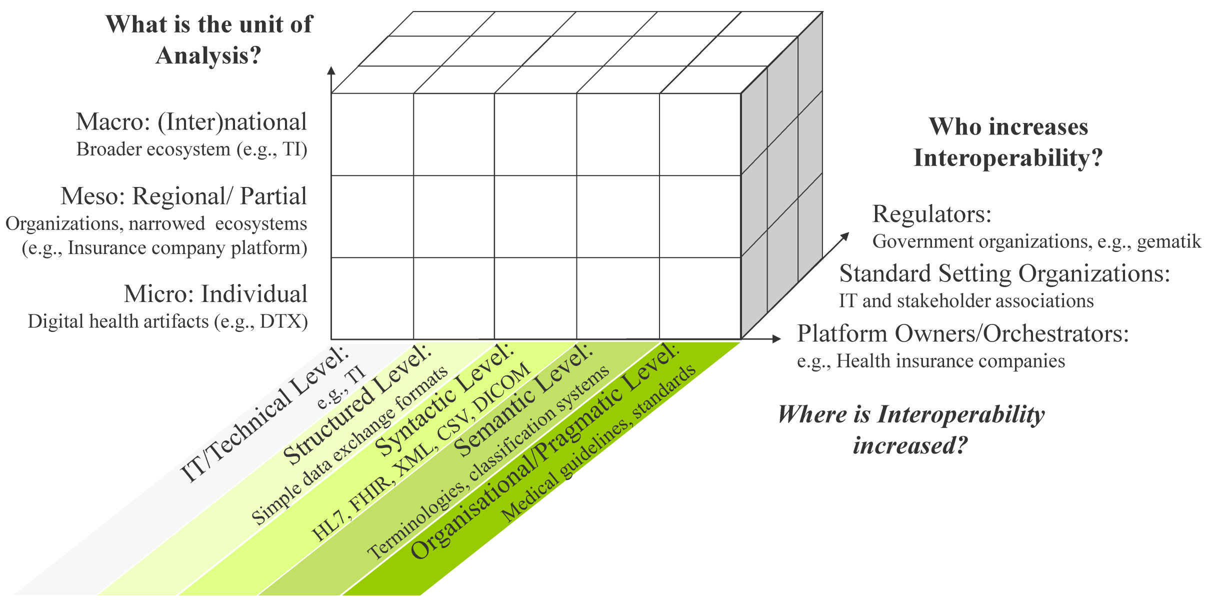

Figure 2.2.: Morphological Box of Interoperability Mechanism adapted from Hodapp & Hanelt (2022)

dimension.
The question *what is the unit of analysis?* delineates the scope of the analysis, indicating whether it is conducted from a rather macro perspective, e.g., national level, or a rather micro perspective, e.g., healthcare provider or software manufacturer (Hodapp & Hanelt, 2022). The question *where is interoperability increased?* focuses more on the technical design of IT, data and application (Hodapp & Hanelt, 2022). Adapted from this approach, there are further dimensions in the literature where interoperability can increase, especially from a more socio-technical point of view such as pragmatic interoperability by procedural standards (European Commission, 2017). The third dimension shows also the socio-technical aspects of interoperability issues with the question of *who increases interoperability?* – whether through the governance, (independent) standard-setting organization, e.g., Integrating the Healthcare Enterprise (IHE), HL7, or platform owners/orchestrators, e.g., the health insurance companies (adapted from Hodapp & Hanelt, 2022).

2.2.4. Scheme of Mechanisms to Achieve Interoperability

In order to understand the control tasks in terms of managing interoperability, this section briefly examines how interoperability can be achieved with a focus on socio-technical aspects.

Achieving interoperability is an extensive process, particularly within inter-organizational contexts. Interoperability of IT artifacts can be planned or unplanned in order of successive emergence or convergence (Hodapp & Hanelt, 2022). This is preceded by the discussion about the diffusion of standards, e.g., in Weitzel et al. (2006), Arthur (1989) or Hanseth et al. (2006). Based on de Vries (1999) and Oemig & Snelick (2016), figure 2.3 provides an overview of the process by which interoperability is achieved or developed by standards. With the advent of new technologies, there is a growing requirement for transmission standards to tackle emerging problems around data exchange. This is commonly done retrospectively, after initial problems have emerged, and less frequently ex ante, prior to the introduction of new technologies to the market (de Vries, 1999).
If no suitable standard exists, a new one must be developed or adapted based on existing approaches. A distinction can be made between closed (proprietary) standards, de facto standards resulting from multilateral firm agreements, de jure standards imposed by governments, and open (independent) standards (Deishin Lee & Mendelson, 2007; de Vries, 1999). Acceptance and coverage of interface requirements are basic prerequisites

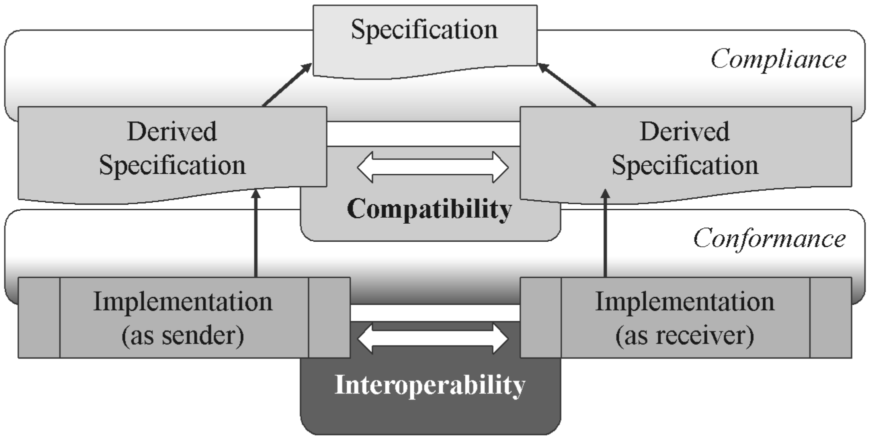

Figure 2.3.: Derivation scheme for achieving interoperability de Vries (1999) and Oemig & Snelick (2016)

for selecting and implementing a standard specification.

In the realm of medical informatics, there are comprehensive transmission standards for health data at the lower levels of interoperability, namely the technical and syntactic levels. This encompasses exchange formats such as HL7 and FHIR, as well as DICOM, which is extensively utilized for transmitting medical images. Nevertheless, the prevailing challenges associated with standardization predominantly reside at the higher levels of interoperability, specifically the semantic and pragmatic levels. A decisive role in initiating and moderating this phase is played by Standard-Setting Organizations (SSO) operating on a regional, national or international level (de Vries, 1999).

There are deviations in compliance and conformance in interoperability contexts. *Compliance* indicates how closely a standard aligns with its own specifications and requirements (Oemig & Snelick, 2016). On the other hand, *conformance* indicates the degree to which the standard has been implemented in practice, specifically how closely the implementation adheres to the standard's requirements for data exchange between sender and receiver (Oemig & Snelick, 2016). Technical and organizational implementation are carried out by the stakeholders involved in the data exchange process. Achieving interoperability between these stakeholders (sender and receiver) entails more than merely adopting an established standard; it necessitates a conformant implementation both technically, such as in FHIR through adherence to implementation guidelines or profiles, and organizationally, ensuring that processes align with it, such as filling data fields with the correct information. In the initiation of digital ecosystems, decisions related to interoperability are made to ensure optimal connectivity and participation (e.g., Autio, 2022).

2.3. Interoperability Management

Even interoperability is primarily discussed from a technical and socio-technical perspective, but decisions about interoperability are taken by management from a more economic perspective. Management should continuously evaluate the benefits and risks of the platform (e.g., Aggarwal et al., 2012), including the interface management, e.g., to expand the service offering of the platform by innovative services (e.g., Ondrus et al., 2015; Eisenmann et al., 2008). But with larger ecosystems of complementary services, it becomes more difficult to handle, e.g., when making adjustments to the platform (Tiwana, 2014). Here, interoperability criteria in terms of syntax and semantics are essential design parameters for interorganizational and sustainable collaboration (Legner & Wende, 2006; Noran & Panetto, 2013). So far, little is known about the strategic and organizational contexts of interoperability and healthcare information exchange (Langabeer & Champagne, 2016). From a management perspective, Legner & Wende (2006) introduced the term business interoperability in their article, which the authors defined *"as the organizational and operational ability of an enterprise to cooperate with its business partners and to efficiently establish, conduct and develop IT-supported business relationships with the objective to create value"* (p. 3). The following management issues—where interoperability is relevant—can be identified. These issues must be orchestrated by the platform orchestrator:

- Data management: This involves storing and linking data and information in a well-structured format for use by other systems. A fundamental architecture decision in this regard is where the data is stored— centralized, decentralized/federated, or on a mobile device (edged) (e.g., Sun et al., 2021; Shim et al., 2022). In case of the EHR platforms in Germany, the health data of the insured persons is stored centrally at a few certified cloud providers located in Germany.

- Interface management: In the development of platform ecosystems, one of the core tasks is the definition of interfaces to the ecosystem (e.g., Fürstenau et al., 2019; Tiwana, 2014; Baldwin & Woodard, 2009), which minimizes the complexity of integrating complementary systems (Hein, Weking, et al., 2019). The term boundary resources is widely used in the platform literature because, in addition to the exchange of data and information, functions are provided to enable complementary parties to contribute to the value chain (e.g., Ghazawneh & Henfridsson, 2013).

- Governance management: This is concerned with determining the fit of openness to the platform ecosystem (e.g., Eisenmann et al., 2008; Ondrus et al., 2015; Boudreau, 2010). Depending on the objectives of the platform, specific governance modes of engaging with the ecosystem are required (e.g., O'Mahony & Karp, 2020) to balance the autonomy and integration (Tiwana, 2014). So far, the core focus has been on facilitating the information flow via the EHR, but in order to promote innovation by opening up the platform (Boudreau, 2010), some EHR platforms are striving to become more conducive to innovation than other health insurance platforms.

Third parties (complementors) and platform owners are usually different organizations that primarily pursue their own interests, even if this is at the expense of the other (Eisenhardt, 1989a), e.g., with regard to the effort of platform integration and balancing binding mechanisms (Tiwana, 2014). Complementary applications must work together seamlessly and integrate with the platform to ensure a coherent platform ecosystem. Due to continuous development, this is an ongoing process and requires control mechanisms to ensure, e.g., that both-interfaces are implemented correctly, and data flows are bidirectional in line with the platform goals (e.g., Tiwana, 2014). When designing and managing interoperability-relevant components, such as those on a digital platform, additional questions arise beyond what is considered by Hodapp and Hanelt's 2022 conceptualization:

- How should the interoperability of collaborative systems be designed in order to implement the business platform strategy?
- What are the economic aspects of interoperability that need to be considered?
- What is hidden interoperability and how can it be improved?
- What measures can be taken to ensure interoperability?

Until the early 2000s, there was a great appeal in the literature for the development of syntactic and semantic standards (e.g., Detmer et al., 2008; Kobusinge, 2020; Hodapp & Hanelt, 2022) to improve interoperability, particularly on the technical, data, and information dimensions (see figure 2.2). Many international standards have since been established, including those in the healthcare sector such as HL7, FHIR, Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT) as well as standards of implementation profiles like IHE. The focus has shifted towards the semantic, pragmatic, business, and organizational dimensions (e.g., Noran & Panetto, 2013). The mentioned points are considered and conceptualized in more detail in this doctoral thesis with the goal of expanding the view of the conceptualization of Hodapp & Hanelt (2022).

3. Research Methodology and Design

3.1. Overview of the Research Design

This chapter aims to convey the epistemological and conceptual understanding with which the work was created and the perspective that was fundamental to the processing and identification of the results. According to Becker et al. (2003), the research design comprises three fundamental decision parameters: the epistemological and ontological positioning[5] (discussed in section 3.2), the research goals (discussed in section 3.3), and the selection of appropriate research methods (discussed in section 3.4).

3.2. Basic Epistemological and Ontological Positions of the Work

The interplay between ontology and epistemology is intricate and often challenging to disentangle due to their interconnectedness (Crotty, 1998). *Ontology*, centered on the study of being, grapples with questions such as *"what is being?"* and *"what is theory?"*, while *epistemology* delves into inquiries about the nature of knowledge, asking *"how do we know?"* (Crotty, 1998; Gregor, 2006; Devinder & Haj-Bolouri, 2023). The philosophy of science serves as a rational inquiry into fundamental questions concerning human existence, the universe, and our existential context, aiming to provide justifiable responses to these inquiries (Rescher, 2001). In the context of Information Systems (IS), philosophical questions take on a pragmatic significance. Hassan et al. (2018) propose inquiries across various layers, including metaphysics, epistemology, rationality, and axiology, highlighting their implications for IS. For instance, they pose questions such as *"information – does it exist and what is its nature?"* (Hassan et al., 2018, p. 265), which bear relevance to interoperability considerations. Scholars like (Orlikowski & Iacono, 2001, p. 122) delve into fundamental philosophical questions within IS research, particularly concern-

[5]Furthermore, the authors address the topic of linguistic position, where the importance of language is also considered and reflected upon. Language and the meaning of words in the description of real phenomena is important and a point that was reflected upon in the research process, but is not discussed further here.

ing IT artifacts, pondering what technology is, how it affects things, and how and why it is implicated in social change. Within the scope of this doctoral thesis, the exploration of existence and knowledge intertwines with the analysis of IT artifacts, notably EHR platform ecosystems and DTx initiatives and their interrelationships. This examination extends to the realm of interoperability, a critical factor influenced by decisions made at multiple levels, spanning from the micro to the macro.

The comprehension of the findings in the doctoral thesis can be enhanced by elucidating the fundamental assumptions underlying knowledge acquisition, thereby shedding light on the diverse perspectives and scientific schools of thought involved (Becker et al., 2003). In articulating the fundamental epistemological position, Becker et al. (2003, pp. 6-7) has posed questions aimed at defining this position:

- How does cognitive content arise? (Exploring the role of the cognitive faculty, experience, and mind)
- How do we arrive at knowledge? (Examining deduction and induction)
- What is the relationship between cognition and object? (Investigating the possibility of objectively evaluating and recognizing reality)

This section aims to briefly outline the philosophical perspective on the phenomenon of interoperability and discuss the perspective through which the studies were examined. The motivation for the four papers is strongly phenomenon-focused and problem-driven (Monteiro et al., 2022; Gkeredakis & Constantinides, 2019), with a focus on the latest developments and changes in the German healthcare sector, particularly regarding regulatory changes and related dynamics in the market of digital EHR platforms and new healthcare concepts such as DTx. According to Alvesson & Sandberg (2013), the research intention for the studies in this doctoral thesis can be categorized as neglect spotting, a specific form of gap spotting. From a normative perspective, the fundamental notion of the importance of interoperability is widely accepted due to its numerous advantages, particularly in terms of patient welfare and improved care (see Chapters 1 and 2). Interoperable design has the potential to reduce healthcare costs by eliminating redundancy in tasks such as data collection and diagnostic testing (e.g., Han et al., 2020). Moreover, the availability of more comprehensive health data can enhance the quality of care by facilitating informed decision-making, thereby reducing clinical errors (e.g., Sun et al., 2021; Yaraghi et al., 2015; Han et al., 2020; Caldwell, 2015). The real phenomenon in this context is the existence of unresolved problems or barriers that impede the process of interoperable design of applications or platform ecosystems, necessitating further exploration. While the fundamental purposes of interoperability are well-established, there remain overlooked or under-researched areas that will be addressed in this work from both economic and socio-technical perspectives.

The ontological foundation established for this work prompts inquiry into whether the phenomenon under investigation exists independently of our knowledge of it. In the case of the described phenomenon, this assumption is deemed intrinsic to its investigation. From an epistemological standpoint, the primary focus of the study is to comprehend presumed problems in relation to the real phenomenon and critically evaluate these issues, aiming to propose solutions to specific problems. The underlying assumptions for each paper, which guide this doctoral thesis, are the following:

- Paper P1: Barriers and challenges of achieving interoperability are much more economic than technical.
- Paper P2: The regulatory framework for the EHR is incomplete for interoperability reasons, with individual stakeholders advocating for unique elements/components, digital health platforms face multiple challenges that need to be addressed.
- Paper P3: The regulatory design of the interoperability platform poses significant barriers and resistance to the delivery and successful integration of DTx into the healthcare system.
- Paper P4: An artifact can help platform orchestrators formulate and manage interoperability decisions.

Based on the results of the studies in papers P1-P3, identified issues set the foundation for paper P4, by designing a beneficial artifact (see figure 3.1 in section 3.4). In order to test the basic assumptions and to investigate the research goals (see subsection 3.3), the studies use deductive and inductive approaches to gain new knowledge. Papers P1-P3 use qualitative research methods, while paper P4 adopts a design-oriented approach, where both the requirements analysis and the evaluation are basically carried out using qualitative research methods, e.g., literature research, interviews and workshops, by analyzing according to an interpretative approach. Qualitative research is recognized as a multi-method approach (Rynes & Gephart, 2004) rooted in an interpretive and naturalistic perspective (Denzin & Lincoln, 2017). Papers P1-P3, in particular, aim to describe and understand the observable real phenomenon and identify explanations or mechanisms, aligning with an interpretative research approach, also known as part of the hermeneutic school (Bernstein, 1984; Crotty, 1998; Devinder & Haj-Bolouri, 2023). In contrast, a positivist approach, which seeks to discover a singular truth, is exemplified by Rynes and Gephart (2004). However, given the complexity and dynamism of the real phenomenon, claiming to uncover an absolute truth would be naive.

3.3. Research Goals and Methodological Overview of the Papers

According to Becker et al. (2003), research goals can be differentiated in terms of their knowledge objectives or design objectives, as well as in their methodological mission or content-related functional mission. In essence, this work pursues two Research Goals (RGs), addressing the two research questions, as briefly described in the introduction (see chapter 1).

- RGI: Identify economic and socio-technical interoperability challenges of digital health platforms (addressing RQI)
- RGII: Exploring of design approaches to manage interoperability in digital platform ecosystems along care pathways (addressing RQII)

Table 3.1 illustrates the classification of the research goals according to Becker et al. (2003). Therefore, RGI follows a knowledge objective with a content-related functional

Table 3.1.: Definition of research goals according to Becker et al. (2003)

	Knowledge objective	**Design objective**
Methodological mission	Understanding of methods and techniques of information system design	Development of methods and techniques of information system design *RGII: Exploring of design approaches to manage interoperability in digital platform ecosystems along care pathways*
Content-related functional mission	Provision of IS reference models for individual companies or sectors *RGI: Identify economic and socio-technical interoperability challenges of digital health platforms*	Understanding of business information systems and their areas of application

mission to address the corresponding RQI: *What are the economic and socio-technical interoperability challenges of emerging EHR-based platform ecosystems?* RGII, on the other hand, pursues a design objective, with a methodological mission, to answer RQII: *How can platform orchestrators be supported in managing the interoperability of platform ecosystems?*

3.4. Methodological Overview of the Papers

The essence of the doctoral thesis lies in delving into various facets of this issue in greater detail and developing an appropriate solution. This chapter will explain the research design and briefly introduce each paper according to its research approach. This includes a classification of the research goals, research context, research method, data collection, data analysis, and evaluation of the data. Table 3.2 presents a summary of the papers and their contributions and the concepts and methods used to examine the overall research goals of this thesis. RGII builds upon the findings of RGI, as illustrated in figure 3.1.

Table 3.2.: Overview of the contributions

Paper	Research method	Data collection method	Concepts	Contribution to the research goal
P1	Qualitative content analysis, grouping of identified economic challenges	Systematic Literature Review according to vom Brocke et al. (2009)	Economic view of interoperability, including path dependencies, cost-benefit effects	RGI
P2	Case study according to Yin (2018) and Eisenhardt (1989a) using a longitudinal approach. Structuring of events according to Fürstenau et al.'s 2019 framework and temporal bracketing by Langley (1999)	Primary/secondary literature, field notes, legislative changes, interviews	Socio-technical view of interoperability and digital platform ecosystems of EHRs	RGI
P3	Phenomenon- and problem-oriented (Monteiro et al., 2022; Gkeredakis & Constantinides, 2019) explorative qualitative study (Sarker et al., 2018), with an open and selective coding procedure (Saldaña, 2009; Witzel & Reiter, 2012)	Series of workshops and additional problem-centered interviews (Witzel & Reiter, 2012)	Interoperability of digital innovations, including DTx from a patient-centric perspective, digital depts	RGI
P4	Development of a maturity model according to Becker et al. (2009) and DSR according to Hevner et al. (2004), with several evaluation iterations (Sonnenberg & vom Brocke, 2012)	Systematic Literature Review (SLR) according to vom Brocke et al. (2009), workshops and several interviews	Frameworks and maturity approaches to conceptualize and manage interoperability	RGII

The results of paper P1-P3 provide the empirical basis for the motivation and problem identification for the artifact in paper P4. The intention of designing an artifact led to an increase in the understanding of the problem and the motivation for the maturity model, as observed in studies in the papers P1-P3. In particular, the interviews in paper P2 and P3 provided valuable insights. To investigate the research goals, this work adopts a multi-method research approach, integrating methodologies from both research paradigms, Behavioral Science Research (BSR) and Design Science Research (DSR) (e.g., Wilde & Hess, 2007; Friedrich et al., 2017). This blended approach fosters a comprehensive understanding of the research problems and enables the development of actionable solutions. While the BSR and DSR paradigms employ different approaches, they effectively complement each other. Which is also shown in the process of developing the artifact in paper P4 on the basis of prior knowledge from papers P1-P3.

- BSR: Aims to understand reality and find the truth (e.g., March & Smith, 1995), and is concerned with developing, testing, or justifying theories that explain, for instance, human or organizational behavior (Friedrich et al., 2017).
- DSR: Seeks to create novel IT artifacts to solve a specific problem (Hevner et al., 2004).

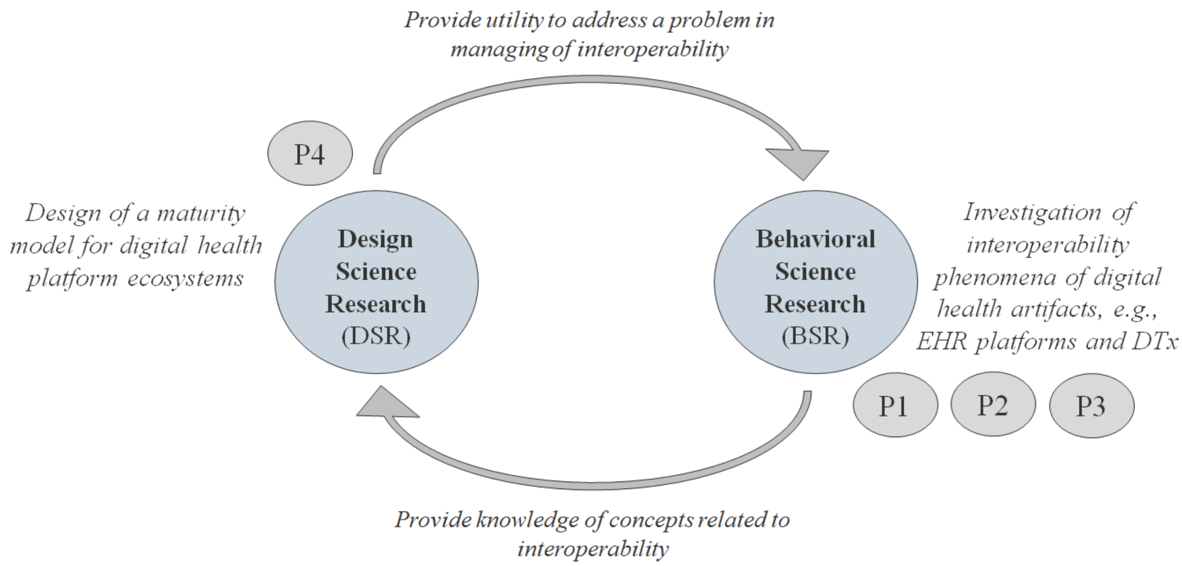

Figure 3.1.: Characterization of the papers in line with the research paradigm, adapted from Hevner & Chatterjee (2010)

The papers attempt to comprehensively understand the identified grievances related to digital health, particularly interoperability challenges and barriers, and to formulate viable solutions. Figure 3.1 illustrates the characterization of the papers into one of the research paradigms (BSR or DSR).

Following a BSR approach, qualitative empirical methods were used in papers P1, P2 and P3 to elaborate and understand the existing problems related to the interoperability of EHR platform ecosystems and their complements, such as DTx. The studies in this doctoral thesis have elucidated the perspective on interoperability, highlighting the added values that can be achieved by interoperability, e.g., improving health and medical care. Paper P1 represents a literature review according to the SLR framework by vom Brocke et al. (2009). Paper P2 follows a case study approach by Yin (2018) and Eisenhardt (1989a). In essence, paper P3 pursues an explorative qualitative study (Sarker et al., 2018). The following decision to pursue a qualitative research approach in investigating the research questions outlined in papers P2 and P3 is justified by the nuanced and often ambiguous boundaries between the phenomenon of non-interoperable design of IT artifacts (such as digital platform ecosystems and DTx) and their respective contexts. These boundaries are frequently shaped by idiosyncratic design decisions (e.g., Recker, 2021). Papers P1 through P3 laid the groundwork and provided the motivation to design an artifact aimed at addressing a specific problem. This artifact was subsequently developed and evaluated in paper P4 utilizing a DSR approach, as proposed by Hevner et al. (2004). The discussion will delve into both the BSR approach and the DSR approach in greater detail.

3.5. Papers According to a Behavioral Science Research Approach

3.5.1. Methodological Approach of Paper P1

It can be reasonably assumed that almost every research paper is based on knowledge derived from the existing literature (Webster & Watson, 2002). This is also true of the papers included in this doctoral thesis. Each of the papers was developed on the basis of an extensive literature review. In this context, basic literature searches follow a rather deductive approach (Kraus et al., 2022). Conversely, SLR according to a systematic framework, as proposed by, e.g., vom Brocke et al. (2009), Webster & Watson (2002), or Kraus et al. (2022), can be assigned to the inductive reasoning approach (Kraus et al., 2022). This is also the case in this study. The findings were subjected to rigorous analysis and were categorized based on their relevance to economic decisions concerning interoperability. This approach was informed by a predominantly inductive reasoning approach, as outlined in (Kraus et al., 2022). However, paper P1 is explicitly prepared as SLR, according to the framework by vom Brocke et al. (2009). The literature cites specific instances that offer overarching descriptions of the economic challenges associated with interoperability decisions. This involved defining the scope of the research, conceptualizing the relevant subjects, searching several scientific databases, and finally filtering and analyzing the hits. The analysis follows an in-depth qualitative analysis of the findings, which were elaborated, structured, and discussed to answer the research question of paper P1: *what are relevant economic interoperability challenges in healthcare, and how can they be characterized?* The concept matrix has been used for the characterization and categorization of the identified economic issues of interoperability that are discussed in the literature. The SLR was chosen to get an overview of the state of the literature on the topic and to see what economic challenges of interoperability have been discussed in recent years.

3.5.2. Methodological Approach of Paper P2

Starting in 2016, interesting dynamics began to emerge in the German healthcare market. Two insurance companies and an IT service provider with a white label solution for insurance companies started to establish a platform ecosystem with a patient health repository. Meanwhile, the government planned to publish an official specification. This sparked competition among the platform owners to establish design and interface leadership for the EHR in order to gain a competitive advantage if the official specification adopted the architecture and design features of the respective platform.

To observe and analyze these events in more detail, a case study according to Yin (2002) and Eisenhardt (1989a) was conducted in paper P2. The data was based on field notes from various events, interviews with health insurance companies, potential complements, especially start-ups and experts in the field, press articles, professional articles, legal reforms and specifications. This data was analyzed and structured. For the in-depth analysis of the data, the observed activities and events were structured both in terms of time and content. The temporal bracketing approach of Langley (1999) was used for the chronological structuring of the longitudinal data from approximately 2016 - 2022 by dividing the results into three phases, the experimental phase of PHR, the transition phase from PHR to EHR, and the phase where EHR becomes mandatory in Germany. In terms of content, the activities were structured based on the design and management framework of Fürstenau et al. (2019) in order to categorize the observed events.

The case study method combined with the structuring approaches supported the preparation of the many different data sources in a structured way to answer the research questions of paper P2. RQI: *How do PHRs and their respective ecosystems evolve differently over time in a highly regulated market?* RQII: *What specific interoperability challenges can be observed prior to the official implementation of EHRs in Germany?*

3.5.3. Methodological Approach of Paper P3

The empirical basis for paper P3 is derived from the DiGIOP[6] research project. The research project was carried out in close cooperation with the German Federal Ministry of Health in order to understand where and what weaknesses exist in the interface regulation and specific implementation of the interface specifications of DTx from the perspective of different stakeholders and how this can be improved. The focus of the study is to explore the regulatory design of prescribable DTx, medical devices, and EHR in a future-oriented way. For this purpose, the discussions on the design of the DTx, in particular the interface design to the EHR and other devices, were examined.

The basic motivation for the study had a strong phenomenon-focused and problem-driven character (Monteiro et al., 2022; Gkeredakis & Constantinides, 2019). The intensive discussions were accompanied by an exploratory study (Sarker et al., 2018) of high relevance and uncertain nature (Patel & Butte, 2020). Specifications, transcripts, and field notes from six workshops and interviews were used as the empirical data for paper P2. The workshops were held between October 2021 and April 2022. A total of 51 problem-centered interviews were conducted with various experts (e.g., Meuser & Nagel, 2009; Witzel & Reiter, 2012) in preparation for and follow-up to the workshops. According to the quality criteria of qualitative research, the emergent material was analyzed together with co-authors in the style of open and selective coding (Saldaña, 2009; Witzel & Reiter, 2012) and categorized into topic areas (Grodal et al., 2021).

3.6. Paper According to a Design Science Research Approach

3.6.1. Introduction to Design Science Research Approach

The scientific design of IT artifacts aimed at solving concrete problems and often motivated by practical experience has sparked extensive discussion regarding its recognition as a legitimate scientific paradigm. Contrary to opinions suggesting that DSR is purely practical, its early stages involved rigorous debates on its scientific validity (e.g., Winter, 2008; Nunamaker et al., 1990; Gregor & Hevner, 2013a; Bayazit, 2004). In this regard, Baskerville (2008) clearly differentiated in his contribution "What Design Science is not" to address the need to clarify the distinction between DSR and practical application, aiming to legitimize research within the DSR framework. This differentiation is

[6] Acronym for making digitally supported care processes feasible and implementing interoperability between prescribable DTxs, medical aids, and EHR.

crucial for ensuring that DSR projects are recognized as legitimate research endeavors rather than mere practical applications. One aspect of this involves leveraging generalized design knowledge within DSR projects, as highlighted by Johannesson & Perjons (2021). Moreover, the design process within the DSR cycle involves various cognitive phases, including deductive, inductive, and sometimes abductive approaches (Kuechler & Vaishnavi, 2012). DSR can be understood here as a generic term, encompassing two forms according to Cross (2001): research into the design of an IT artifact (design research) and research into the creation process and generalization approaches (design science).

As the placement of RGII (see section 3.3) under the heading design goal already suggests, paper P4 pursues a design-oriented research approach to develop an artifact for platform orchestrators. The approach in paper P4 in accordance with recognized DSR frameworks is presented in more detail in the next subsection (subsection 3.6.2).

3.6.2. Methodological Approach of Paper P4

The findings from paper P1, P2, and P3 yielded valuable insights into the challenges of managing the interoperability-related design of digital platform ecosystems. In preparatory meetings with platform orchestrators from statutory health insurance companies, interoperability experts, and other industry and association representatives, two specific problem areas were identified: management and uniformity of interoperability, particularly regarding requirements. This includes addressing the uniformity in the definition and interpretation of interoperability requirements among complementary parties in the ecosystem. *"For us, this is where we are in control and can deciding whether we cooperate, e.g., in terms of connecting partners to our ecosystem. Partner services should have minimum requirements; a maturity model would help to grant approval"* (responsible platform ecosystem orchestrator of health insurance company B, see paper P4).

The spectrum of interoperability can be defined quite broadly. The interpretation of certain standards leaves room for interpretation (see subsection 2.2). For example, criteria such as machine-readable or syntactic and semantic interoperability are sometimes minimally accounted for in implementation. As the size of a platform ecosystem grows, the complexity of managing information processes among the numerous subsystems and devices within it increases. Failure to meet interoperability criteria or requirements can result in difficulties in presenting exchanged information and its utilization along care

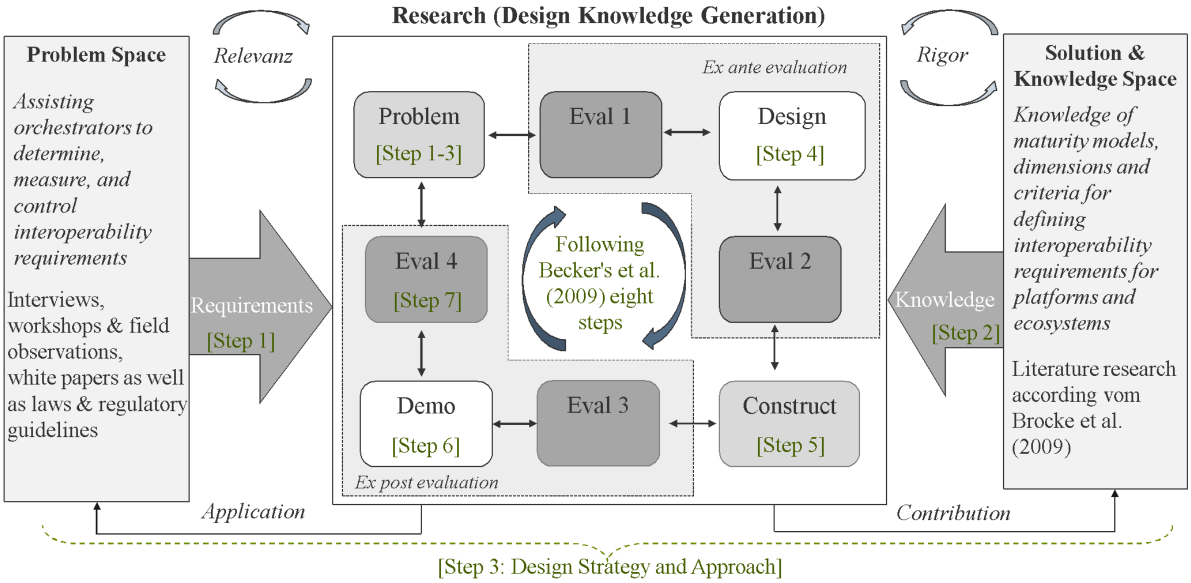

Figure 3.2.: Design science research approach

paths. This necessitates clear and standardized gradations, which also enhance transparency for all stakeholders involved. Additionally, Hodapp & Hanelt (2022) highlights in their research agenda that the measurement of interoperability has been a research gap thus far. These circumstances motivated the study to address them using a design-oriented research approach. The aim of the paper P4 is to design a maturity model to address the following research question: *How should a maturity model be designed to support orchestrators of platform ecosystems in evaluating the interoperability of service offerings?* As an overarching research paradigm, the study is based on the DSR methodology by Hevner et al. (2004). At the core of the artifact development, a maturity model according to the eight steps by Becker et al. (2009) was developed, including several evaluation cycles according to Sonnenberg & vom Brocke (2012). Figure 3.2 visualizes the methodical approach. Hevner et al. (2004) differentiate the types of domains into problem spaces and solution & knowledge spaces.

The problem space in paper P4 represents the requirements for the artifact. Empirically, the problem was initially understood and evaluated through several iterations, during which new requirements were added. The empirical basis was formed by data collected from 2021 to 2023, derived from a total of six workshops conducted as part of a study with the German Federal Ministry of Health, as well as two evaluation workshops and 23 semi-structured interviews conducted according to the guidelines outlined by Miles et al. (2014). Out of these, 12 interviews were conducted with orchestrators of the EHR-based platform ecosystem from five health insurance companies, collectively covering approximately 40% of all insured persons in Germany.

The solution & knowledge spaces (see figure 3.2) serves as the primary source of descriptive knowledge for the study. Initially, an SLR was conducted following the procedure proposed by vom Brocke et al. (2009). From an initial pool of 536 database hits, 21 articles were filtered, providing an overview of the dimensions of interoperability. These articles also served as inspiration and a foundation for the development of the maturity level scale. The maturity model comprises dimensions that provide further detail on interoperability and levels that represent maturity. The dimensions, which were developed through a process of literature research and qualitative summarization, form the basis for the evaluation cycles. Seven dimensions were developed to provide greater detail on interoperability. The levels of the maturity model are intended to contain predictable patterns of development and change, forming a sequence of levels from an initial level to maturity (Becker et al., 2009; Gottschalk, 2009; Kazanjian & Drazin, 1989). The literature indicates that a five-level gradation is common for maturity models, and the levels were derived from literature, including general classification (see e.g., figure 2.1) and further evaluation levels. Level one represents the initial level at which interoperability can be considered.Levels 2 and 3 represent the minimum level that can be considered a basic requirement for connected solutions. Levels four and five illustrate the potential and development goals associated with achieving the highest level of maturity. In these higher levels, the literature base is significantly more limited and has been developed through empirical data gathered through workshops and interviews.

3.7. Reflection of the Methods used in the Research Projects

"Many scholars argue that research methodology is the most critical design choice in the research process" (Recker, 2021, p. 48). The choice of research design and method depends on various factors, including sampling, data collection (where, when, who, what), analysis, and questions about validity. The qualitative inductive research approach is particularly suitable for investigating one or more real-life phenomena (Recker, 2021), such as the contextual relationships of IT artifacts and their design concerning interoperability, as explored in this doctoral thesis.

The SLR in paper P1 presents an opportunity to provide an overview of the literature concerning economic factors of interoperability, allowing for the classification and characterization of existing results and offering new insights for research. However, it is important to note that recent events and new technologies may be neglected or not fully taken into account in the literature due to time-delayed impressions of real phenomena that are partly attributable to publication processes. Furthermore, the result depends very much on the previously defined scope and the determination and filtering based on the corresponding keywords.

The problem areas to be investigated in papers P2 and P3 are quite new and more complex than the questions could be determined and standardized, for example, by a questionnaire. In addition, the empirical approach is very limited to investigate just the defined research objectives; only a comparatively exclusive circle of experts in industry, associations, health insurance companies, and government organizations is sufficiently deeply involved with the topic in the context of interoperability in healthcare. The empirical study group was not the only exclusive entity; the time windows of the investigations of papers P2 and P3 were also exclusive. A number of legal digitization initiatives within the German healthcare system offered insights that were both relevant and informative, both before and after the introduction of the EHR in Germany (see P2), as well as the introduction of prescription-enabled DTx, which was a novel concept internationally, with the vision of integrating it into care scenarios.

The decision to employ a qualitative research approach in investigating the research questions in papers P2 and P3 is justified by the complex and non-obvious nature of the boundaries between the phenomenon of non-interoperable design of IT artifacts, such as digital platform ecosystems and DTx, and the contexts, which are not obvious and are often subject to idiosyncratic design decisions (e.g., Recker, 2021). Qualitative research methods offer a suitable means to explore and understand such complexities, allowing researchers to delve deeply into the nuances of the phenomenon and its contextual factors. Through qualitative analysis, researchers can capture the richness and depth of the subject matter, including the intricacies of design decisions and their implications for interoperability. Moreover, it is important to highlight that the results of papers P1-P3, are inductive in nature. This means that they are derived from observations and interpretations of interoperability events, with individual aspects linked together to generate generalized findings. The applicability of these findings to individual cases may vary depending on the specific circumstances, underscoring the nuanced and context-dependent nature of the research outcomes. In particular, paper P2 and P3 examine challenges and aspects of interoperable design, focusing on the platform ecosystems of EHR and DTx. The studies are characteristically phenomenon- and problem-driven, where paper P4 presents a concrete solution approach. Both papers P2 and P3 are initially grounded in the assumptions described (see section 3.2) for the studies. However, the true issues at hand only became evident when the first empirical data became available. The focus of paper P2 is somewhat narrower than in comparison to paper P3. In P2, the focus of interoperability barriers is closely aligned with the case of the EHR platforms of three providers in the German healthcare market. In contrast, the procedure of paper P3 is somewhat more exploratory, investigating and understanding the difficulties of interoperability issues of the DTx.

The studies utilized a passive, uncontrolled setting of semi-structured interviews (e.g., Flick, 2009). In these interviews, certain topics were framed without being overly specific in order to avoid influencing or directing the participants' statements. Furthermore, the interview guidelines are subject to an iterative process (Bryman & Bell, 2015), which includes the formulation of interview questions according to the research question, the revision of the questions after the first pilot interviews and, if necessary, the readjustment of individual focal points as well as the principles of question formulation (e.g., Flick et al., 2007). In comparison to quantitative research, for example, the advantage of qualitative research is that the initial assumptions could be readjusted more quickly. But due to the greater explorability of the studies, it is more difficult to maintain the focus with the help of the questions asked in the semi-structured interviews without excluding any interesting aspects; a good balance of exploration and guidance with regard to the assumptions is a trade-off that applies in this work. Another crucial point after the data collection is the analysis of the data. Validity of the data is achieved by coding the same impressions from different sources or, as in paper P3, by coding in the author team to ensure the objectivity of the results. Conversely, triangulation with the literature or secondary literature was also a method of quality assurance in the studies. However, a major issue is also the restriction of the number of data sources with respect to interview participants for these very specific topics of the studies. The key interviewees for the studies were acquired in Germany. Due to the reference to real-life phenomena in the German healthcare system, experts at an international level were not considered in detail.

Validity is an important consideration for DSR artifacts. In addition to the existing evaluation step according to Becker's et al. (2009) approach, the study in paper P4 adopted the evaluation framework from Sonnenberg & vom Brocke (2012). Through several iterative cycles, the problem was initially understood in detail, and a solution was developed and evaluated incrementally. Detailed steps are explained in paper P4. Another critical aspect of DSR studies is ensuring scientific rigor and practical relevance (e.g., Winter, 2008; Gregor & Hevner, 2013b; Hevner et al., 2004). In the developed maturity model (in paper P4), this trade-off is particularly evident in the gradation of the degree of generalization. This involves balancing projectability, enabling the artifact to be applicable across different domains (e.g., non-healthcare) with fitness, ensuring direct applicability to specific problems, such as assisting platform orchestrators in integrating complementary applications (vom Brocke et al., 2020).

4. Results of the four Research Papers

4.1. Brief Overview of the Chapter

This chapter provides a concise overview of the key findings from papers P1-P4 (The entire results of the papers can be found in part II). A comprehensive analysis of these core results is presented in chapter 5, which delves into specific perspectives on overarching relationships and discusses the significance and implications for interoperability management in the healthcare sector.

4.2. Results of Paper P1

The first study, paper P1, examined the dependence of interoperability decisions on various economic factors. From an economic perspective, two key challenges are discussed in the literature: decisions involving *(1) cost-benefit considerations* and the peculiarity of *(2) path dependencies.*

Looking for cost-benefit trade-offs resulted in three subcategories that were identified during the analysis. *(1.1) Simple cost-benefit considerations*, *(1.2) cost-benefit-cost-benefit considerations over time* and *(1.3) cost-benefit considerations in terms of business relationship management.*

(1.1) Simple cost-benefit considerations: interoperable realization or implementation of digital IT artifacts can result in direct and indirect costs. Direct costs may arise during the implementation process, while indirect costs may arise due to process changes or training (e.g., Zhang et al., 2007; Dewenter & Thun, 2017). The second identified aspect of differentiating costs and benefits includes a time-related component where *(1.2) cost-benefit-cost-benefit considerations shift over time*, for example, if interfaces must be maintained or the benefit for one may only be relevant in the future, which must be taken into account (e.g., Moumtzoglou & Kastania, 2011). The third identified aspect examines *(1.3) cost-benefit considerations in terms of business relationship management.* Both service providers and IT system vendors could face threats from an interoperable

design where the benefits outweigh the costs and risks. For IT providers, interfaces can serve as a revenue source, but they also facilitate easier provider switching. Similarly, from the service provider's perspective, patients can more easily switch providers, for example, with the assistance of the EHR. This example is closely related to path dependency considerations.

Three sub-characteristics of path dependence were also identified: *(2.1) general or unspecified*, *(2.2) learning effects*, and *(2.3) network effects*. *(2.1) General or unspecified path dependencies* in the literature discussing path dependencies in the context of interoperability usually refer to the lock-in state of path dependency, which corresponds to the third phase of path dependency according to Sydow et al. (2009). For example, changing a system such as the physician's health information system, which is associated with excessive switching costs. A more differentiated approach showed the consideration of *(2.2) learning effects* associated with the change of existing routines (e.g., Alkraiji et al., 2013). Another example could be observed in connection with *(2.3) network effects*. The benefits and their self-reinforcing effects, both direct and indirect, are associated with interoperability decisions. Direct network effects can be observed where the benefit of a standard increases with the number of participants using the same standard. For example, Apple's decision to adopt the FHIR standard in its Apple Health Kit had a direct impact on their ecosystem respectively its complementary services (e.g., Braunstein, 2018). This decision also had indirect network effects by increasing dissemination and recognition of the FHIR standard.

Another example can be observed in connection with the topic of *(2.3) network effects*. The benefits and their self-reinforcing effects, both direct and indirect, are associated with interoperability decisions. Direct network effects can be observed where the benefit of a standard increases with the number of participants using the same standard. For instance, Apple's decision to adopt the FHIR standard in its Apple Health Kit had a direct impact on its complementors, as evidenced by Braunstein (2018). This decision also had indirect network effects as it increased complementary services and the acceptance of the standard. From a research perspective, the study addresses the gap in the literature that, in addition to the widely discussed technical areas of interoperability (e.g., Blobel & Pharow, 2008; Benson & Grieve, 2016; Oemig & Snelick, 2016) and socio-technical issues (e.g., Hodapp & Hanelt, 2022; European Commission, 2017; Scheplitz & Neubauer, 2022), economic factors have a significant influence on interoperability decisions in the design of digital systems and services. With a differentiated view of cost-benefit decisions and path dependencies, practitioners can also benefit from the knowledge to anticipate, e.g., the balancing of incentives and requirements.

4.3. Results of Paper P2

Paper P2 conducts a longitudinal investigation to identify interoperability-related challenges that emerging platform ecosystems must overcome, particularly during periods of uncertainty. Seven challenges were identified from the perspectives of *platform owners*, *complementors*, and *insurers*. The study underscores the importance of interoperability as a design parameter for emerging multi-sided platforms and contributes to the ongoing discussion on this topic.

From the point of view of *platform owners* as well as platform orchestrators, three challenges could be identified. The *(1) timing of the design of the technical architecture and the choice of standards.* Leading providers have used the early phase to demonstrate a possible design of architecture and standards in order to gain a competitive advantage. However, this comes with the *(2) development risks* of later adjustments, e.g., of interfaces or architectures. Another identified point is the *(3) choice of a suitable governance mode* to strike a balance between opening interfaces, such as with competitors and complementary players. It was observed that established players, which are also in competition, have developed reference solutions with jointly developed interfaces, forming alliances against new competitors. Additionally, efforts were made to offer complementary services exclusively on the platform to differentiate themselves from competitors. For *complementors*, especially in the case of DTx, achieving a minimum level of interoperability *(4) is a criterion for market entry for reimbursement* purposes. Additionally, *(5) choosing the appropriate platform* involves considerations of interoperability and the nature of the data. Depending on the business model and the requirement of accessing existing health data, such as the EHR, the transfer of data in an interoperable manner is necessary for the service to function effectively. In cases where significant interface adaptations are required, such as for platform integration, *(6) binding effects* may occur. The interoperable design of the EHR platform ecosystem of health insurance companies also affects their *insurants*. The stored health data on a platform can lead to *(7) lock-in effects*, increasing switching costs if transferring healthcare data becomes more difficult.

The challenges identified in the study have practical implications for stakeholders of

EHR-based platform ecosystems, especially in highly regulated environments. While they present opportunities for participation in shaping regulations during uncertain times, they also entail significant risks. From a research perspective, the strategic approaches of these platforms shed light on the importance of interface designs in competitive settings. Additionally, the study contributes to discussions surrounding interface design in EHR platform ecosystems and lays the groundwork for further research, as well as for the development of business models or frameworks to manage these challenges.

4.4. Results of Paper P3

The paper P3 focused on DTx and the interfaces needed to integrate DTx as a full-fledged component of comprehensive care solutions, such as care management, treatment, and prevention processes. In addition, the potential of using the data generated by DTx for data-driven research, including real-world evidence, was explored. To achieve this goal, the concept of patient-centric interoperability was introduced to analyze interface design across care pathways. The objective of patient-centricity is to achieve high-quality, cost-effective, accessible, and connected healthcare services while promoting principles such as data sovereignty, empowerment, and data protection (see paper P3 as well as de Hert et al., 2018; Berwick et al., 2008; Gohar et al., 2021). To this end, the process of data flow along the patient journey is considered when analyzing and designing interoperability in order to ensure interoperability within an ecosystem. Three topic areas, *(1)* DTx and EHR, *(2) DTx and devices*, and *(3) DTx and innovations* were identified to map the interfaces of DTx within the existing infrastructure of the German healthcare system. The interface mapping exercise identified a total of 10 issues and discussed implications as a solution approach across the three topic areas relevant to practice, regulation, and research. Addressing these issues is critical to the development of innovative care solutions and the use of data in medical research.

The first topic area addresses the interfaces between *(1) DTx and EHR.* Five issues were identified along with their implications for various stakeholder groups such as regulators, standards-setting organizations, and IT manufacturers. These issues included outdated infrastructure design hindering the full potential of new technologies, unclear responsibilities for presenting DTx data in doctors' systems, and limited incentives for DTx to develop innovative solutions due to restrictive access rights.

Three issues are discussed from the perspective of the topic area *(2) DTx and devices*, including a lack of examples for adapting new direct interfaces between DTx and devices.

For the topic area *(3) DTx and innovations*, three issues could be identified, including the inability to directly integrate DTx with each other, for example, in cases of multimorbidity.

Given that DTx will be first introduced in Germany in 2021, there is significant potential for further research and development of additional scenarios. The study presents a patient-centric design perspective on IT artifacts to strengthen a process-oriented approach to care management. This perspective also has implications for research and practice, guiding the design of innovative care concepts to address existing deficits and discuss coordination challenges. From a practical perspective, the interface map provides an overview of the regulatory implications and development deficits associated with the integration of DTx into care management.

4.5. Results of Paper P4

In the fourth study, outlined in paper P4, a maturity model was developed to aid platform orchestrators of platform ecosystems in defining and monitoring interoperability requirements based on different levels. The model comprises two main components: seven dimensions characterizing interoperability and five levels describing the degree of interoperability. The dimensions and interoperability levels are illustrated in figure 4.1. The dimensions encompass various aspects of interoperability considerations, ranging from technical (Technical, Data & Information) to socio-technical (Application & Service, Legal & Regulatory, Care Process, and Individual), as well as a blend of economic and socio-technical perspectives (Organizational & Business). The five levels directly correspond to these dimensions and articulate the degree of each dimension from an interoperability standpoint.

The five levels of the maturity model range from initial interface characteristics (Initial Level) to a defined minimum level (Integrated Level) to the potential for automation and decision support (Optimized Level). It extends to international interoperable design (Universal Level) and potential across domains (Pioneer Level) as a development goal.

From a research perspective, the developed maturity model serves as a proposal for measuring interoperability, responding to the call for contributions by Hodapp & Hanelt

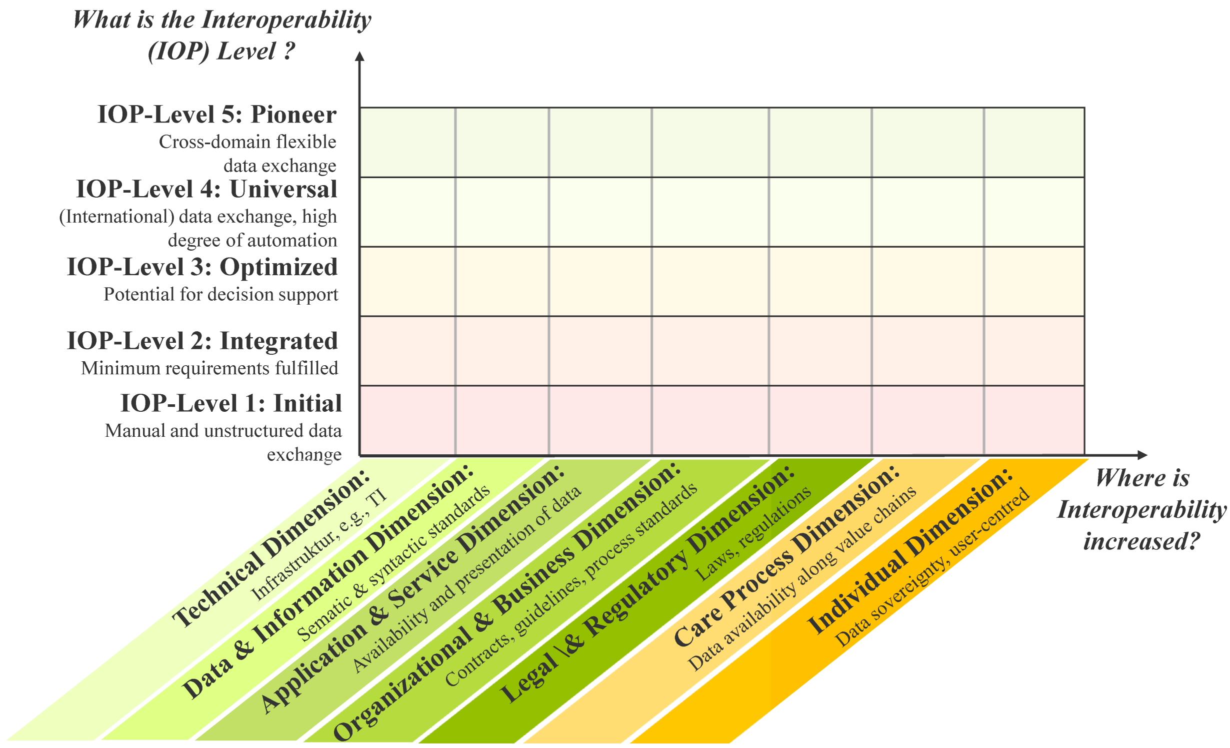

Figure 4.1.: Dimensions and levels of the interoperability maturity model

(2022). Additionally, the maturity model offers a compilation of pertinent dimensions related to interoperability, encompassing technical, socio-technical, and economic attributes. Moreover, the level gradations, particularly at the higher levels, offer inspiration for future advancements, such as envisaging future scenarios and (interface) solutions.

From a practical standpoint, the artifact was evaluated using two applications. As depicted in paper P4, the artifact aids platform owners and orchestrators in delineating requirements for a supply care path-oriented design of the platform and ecosystem. This is accomplished by enabling seamless data/information flow between participating services and devices while maintaining consistent quality and integrity. The maturity model allows orchestrators to define requirements and check which different dimensions need to be considered along care pathways to provide integrated digital tools for care scenarios. In addition, the maturity model provides increased transparency of complementarities to articulate the goals set.

4.6. Summary of the Paper Results

Figure 4.2 visualizes the various topics covered in the doctoral thesis. On the left side, topics related to obstacles for interoperable design of IT artifacts, especially within the EHR platform ecosystem, are discussed. These include economic aspects such as path dependencies, cost-benefit decisions (see paper P1), and the necessity for interoperable interface design, which is a fundamental requirement for refinancing (see paper P2). Additionally, socio-technical aspects are addressed, such as the timing of standard selection, which presents both opportunities and risks. These risks may include the need for extensive adjustments to interfaces or architecture despite potential advantages such as regulatory showcase demonstration or gaining a competitive edge over rivals (see paper P2). On the right-hand side of figure 4.2, the envisioned goals of interoperable design were discussed, including from a care perspective and the potential of integrated services within EHR-based platform ecosystems. Paper P3 introduces the concept of patient-centric interoperability, which considers interface design from a process-oriented perspective along care pathways, taking into consideration various components such as EHR platforms, DTx, devices, and other innovations. The data, including real-world data from DTx, represents a substantial and valuable resource for research, particularly in the domain of real-world evidence. Platform ecosystems serve as the conduits that aggregate, store, and facilitate access to this data for further utilization, including secondary analysis. Orchestrators of platform ecosystems are tasked with managing the increasing complexity of the ecosystem's components and interfaces.

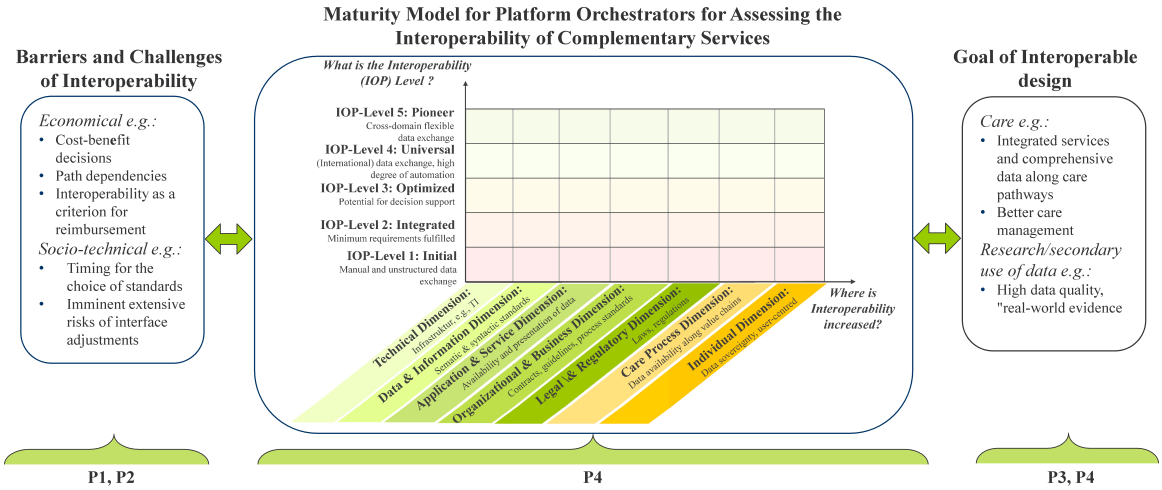

Figure 4.2.: Summary of the paper results (in large, see part III A2)

The developed maturity model (in the center of the figure 4.2) aims to help platform orchestrators to verify, identify requirements, anticipate challenges, and develop a vision for the interoperable design of platform ecosystems that enable the realization of integrated digital care models. The model serves as a tool to provide clear guidelines for defining requirements. In fact, the five levels along the seven dimensions of interoperability provide guidance on which of these dimensions should be prioritized during integration efforts and which target level should be sought. In addition, a future vision can be developed to improve interoperability in the medium to long term, thereby unlocking additional potential and fostering innovative value creation.

5. Discussion of the Doctoral Thesis

5.1. Challenges of Managing Interoperability

The opportunities presented by digitalization in healthcare are often discussed from a pluralistic perspective. On the one hand, there are economic benefits, such as process optimization and cost reduction. On the other hand, from a medical care perspective, digitalization can lead to improved treatment procedures and faster responses based on available information (e.g., Gersch & Wessel, 2023). However, the debate surrounding IT systems and the use of data for medical purposes versus management interests is challenging (Gersch & Wessel, 2023) and can lead to tensions and dilemmas (Haring et al., 2022).

From both an economic and healthcare perspective, decisions within EHR-based platform ecosystems regarding standards and interoperability are fraught with conflicting tensions, requiring deft management by platform orchestrators (e.g., Mini & Widjaja, 2019; Haring et al., 2022). In papers P1-P3, interoperability issues emerged due to unclear specifications and gradations of interoperability requirements.

From the perspective of managing the interoperability of platform ecosystems, several socio-technical and economic issues have to be overcome. Platform orchestrators of EHR-based platform ecosystems pursue specific strategic goals through interoperability decisions, which can be driven by intrinsic or extrinsic motivations. For example, they may aim to enhance the value of EHRs for healthcare, research, and secondary use of health data (Stellmach et al., 2022, e.g.,). The value of EHRs can be augmented through the adoption of new technologies or a higher level of interoperability, such as through cross-sector services. However, there are various socio-technical and economic barriers or challenges that must be addressed in the decision-making processes related to platform architecture and interface design, particularly during the design and development phase of platform ecosystems (e.g., Fürstenau et al., 2019).

By answering RQI, *"What are the economic and socio-technical interoperability chal-*

lenges of emerging EHR-based platform ecosystems?" (see subsection 1.2), the benefits and challenges are determined (see subsection 5.1.1). RQII, *"How can platform orchestrators be supported in managing the interoperability of platform ecosystems?"*, will be discussed in the following subsection (see subsection 5.2), in which some of the identified issues with the help of the maturity model will be addressed to show how to manage interoperability of platform ecosystems.

5.1.1. Interoperability Challenges from an Economic Perspective

5.1.1.1. Cost-Benefit Considerations Regarding Interoperability

Historically, the legitimacy of leveraging digitization in healthcare to optimize business processes and reduce costs has long been debated (e.g., E. J. Davidson et al., 2015; Kohli & Kettinger, 2004). These can also be observed with regard to standardization processes on the technical, structural, and semantic level (e.g., Hanseth et al., 2006; Hanseth & Bygstad, 2015; Benson & Grieve, 2016), as well as on the pragmatic and organizational level of interoperability (see paper P1 and P2 as well as Haring et al., 2022; Kuziemsky & Peyton, 2016). *"You have to be able to afford interoperability"*[7] (health startup A, interview in paper P2) underscores the fact that the ability to implement interoperable IT systems depends on the size and financial resources of the organization (Pylypchuk et al., 2019).

However, this was also evident in interviews with the founders or technical directors of health startups in papers P2 and P3, where the focus is on the functionality of the application and less on interoperability. They often mentioned that interoperability was perceived as less of an obstacle because they often used freely programmable interfaces such as Java Script Object Notation (JSON) or FHIR. *"It's all possible, in principle, we have the option of creating a structure later that we can work with. But the structure we are currently using is simple JSON"* (health startup B, interview in paper P2). The distinction between compliance and conformance in standard implementation, as discussed in subsection 2.2.4, emphasizes that merely implementing a standard does not guarantee alignment with the specification or with other systems or ecosystems in terms of interoperability. Late decisions regarding interface adaptations can incur significant costs, particularly if recertification is required, as is the case for health and medical services such as DTx or medical devices in Germany (see paper P3, *high possible costs for*

[7] This and the following quotes have been translated from German using translation tools and professional editing.

recertification). The cost balance is also affected by the risk classification of the medical device or service in relation to the benefits associated with accessing data and participating in the ecosystem (see paper P3, *risk class-related considerations*). In particular, certification is intended to ensure a minimum degree of interoperability, which may also be a criterion for reimbursement (see paper P2, *interoperability as a financing criterion for digital health services*). The maturity model can effectively address this distinction by aligning with the identified dimensions, facilitating the description of requirements for complementors, and aiding platform orchestrators in reviewing and designing these requirements. From the perspective of managing interoperability, the maturity model is discussed in detail in subsection 5.2.

Interface implementations require balancing costs and benefits, encompassing both direct and indirect costs. Direct costs stem from integration, software, and interface adaptation, while indirect costs arise from long-term effects and process restructuring across technical, structural, semantic, organizational, and pragmatic dimensions (see paper P1, *cost-benefit analysis*). The authors van Offenbeek et al. (2024) distinguish between design costs of implementation and compromise costs in the adaptation of EHR. Compromise costs refer to organizational and pragmatic issues that may arise due to inflexibilities. Cost-benefit decisions may have a temporal component, where the balance may shift over time, either positively or negatively (see paper P1, *cost benefit over time*). Interface costs and maintenance are typically regarded as fixed costs in the long term due to ongoing application and platform development. However, the benefits derived from these investments may not always align with expectations, leading to issues such as avoidance of responsibilities due to unclear assignments or the passing of responsibilities between manufacturers (see paper P3, *unclear responsibilities*). For instance, this challenge may arise in scenarios involving the display of exchanged data between DTx manufacturers and the presentation of these values from the EHR in the health information system (see paper P3, *frontend display of DTx data*).

Timing is also a critical factor in the implementation and selection of standards, presenting both opportunities and risks (see paper P2, *timing of designing technical architecture and selecting standards*). For instance, in the context of EHR platforms in Germany, two major statutory health insurers and an entrant IT service provider have introduced platform solutions for their clients and insurants, aiming to serve as early adopters and showcasing their architecture and interface design for the regulation (see paper P2). They hope that their architecture and design will set the standard for future developments. To illustrate how data exchange between various institutions and insurance companies can occur, the two competing health insurers have formed strategic partnerships with complementary services. This collaboration aims to showcase how data exchange with hospitals can adhere to international standards. However, a side effect of this collaboration is the exclusion of the new market participants. Therefore, an *appropriate governance mode* of interface orchestration with competing partners is necessary (see paper P2). In the end, the regulators in Germany opted for a unique design that deviated from international models and standards, which was accompanied by extensive adjustments and thus the effort and cost for the three, which is one reason why the entrant IT service provider was unable to overcome it (see paper P2).

Balancing the costs and benefits of platform ecosystems' interoperability is a task of the platform owner/orchestrator especially during the design phase of the platform (e.g., Fürstenau et al., 2019). According to Hodapp & Hanelt (2022), increasing or expanding interoperability falls under the purview of platform owners/orchestrators, standards-setting organizations, or regulators. Regulators can specify standards and determine consequences, such as sanctions. Standard-setting organizations may propose or develop binding recommendations for regulators, as seen in the case of the German Interop Council[8], which includes, inter alia, representatives from industry and associations. Expanding or increasing interoperability within the platform ecosystem involves a trade-off between costs and benefits, a responsibility that must be managed by the platform owner/orchestrator. Interoperable standards are crucial for the functioning of data-based service platforms (e.g., Tiwana, 2014), as they help minimize the complexity of the platform ecosystem (Evans et al., 2008). Depending on the variety of complementary innovative services available on the market, platform orchestrators may initially be willing to accept compromises in terms of interoperability. *"In practice, you want to realize a goal with use cases that exist on the market and develop interoperability together with the company, we have to start with existing solutions and then develop interoperability together"*[9] (platform orchestrator of health insurance company A, interview as part of paper P4). Three directions of action can therefore be derived as modes of interoperability management:

a) Interface requirements are legitimized by regulation and must be implemented.

[8] The Interop Council is concerned with coordinating the needs and requirements of interoperability between the various players in the German healthcare system and develops binding guidelines (INA, 2024).

[9] Translated from German using translation tools and professional editing.

b) Platform orchestrators design interoperability requirements as contractual conditions with partners without compromise.

c) Platform orchestrators try to find compromises with compliant partners, for example, by offering integration/adaptation profiles.

The maturity model can be used by platform orchestrators as a guide for defining interoperability requirements as well as for defining common goals or future goals with complementors (see subsection 5.2), for example, by defining platform adaptation and interoperability profiles (inspired by van Offenbeek et al., 2024). The profiles can be aligned with the interoperability levels defined in the maturity model, ranging from the *integrated level* with minimum interoperability requirements, an intermediate version at *optimized level*, up to the *universal level* with advanced interoperability requirements (see paper P4). This also addresses the problem identified in paper P2, *finding an appropriate governance mode.*

5.1.1.2. Path Dependency Considerations Regarding Interoperability

"Insufficient interoperability destroys the market and hinders the ability to innovate, e.g., through lock-in effects to a outpatient and inpatient healthcare information system"[10] (platform orchestrator of health insurance company E, interview as part of paper P4). This statement also relates to the second economic discussion thread, the characteristics and examples of path dependencies in managing interoperability. In terms of interoperability, the issue of path dependencies and self-reinforcing mechanisms (e.g., Sydow et al., 2009; Arthur, 1989) can be considered from two perspectives, from the point of view of the diffusion of standards and from the point of view of the discussion of path dependencies leading to lock-in effects (e.g., Hanseth & Lyytinen, 2010; Wessel et al., 2017).

When examining the evolution of interfaces and standards, the analysis of the diffusion of standards can be approached by Arthur (1989), which standard finally becomes established may also be influenced by random small events (Buxmann et al., 2011; Arthur, 1989). The path dependencies perspective provides insights into how historical decisions shape current outcomes and future possibilities within a particular context (Arthur, 1989, 1994; David, 1985). Self-reinforcing mechanisms and network effects can establish a solid and widely accepted standard (e.g., van den Ende et al., 2012). This minimizes

[10]Translated from German using translation tools and professional editing.

the risk for those who have to make decisions about interface design and standard selection (see paper P1 as well as Schwarze et al., 2005).

Path dependencies, especially the phase of lock-in (e.g., Sydow et al., 2009; Arthur, 1989), are a widespread phenomenon in the literature related to Information Technology (IT)-artifacts such as IT-infrastructures (e.g., Hanseth & Bygstad, 2015; Hanseth & Lyytinen, 2010; Henfridsson & Bygstad, 2013), software application as well as digital platforms (e.g., Shapiro & Varian, 1999; Parker & van Alstyne, 2018). To distinguish non-path dependent processes from path dependent processes, Sydow et al. (2009, p. 690) formulates the following characterization of path dependent processes:

- Nonpredictability—There is an indeterminacy of outcome.
- Nonergodicity—Several outcomes are possible (multiple equilibria), and history selects among the possible alternatives.
- Inflexibility—The actors are entrapped, so a shift to another option is impossible.
- Inefficiency—Actions resulting from the path lock the market into an inferior solution.

Path dependencies regarding interoperability can also be observed in relation to the healthcare market (e.g., Hodapp & Hanelt, 2022), such as on the first healthcare market[11] with health information systems (e.g., Peng et al., 2014), healthcare infrastructures (e.g., Braa et al., 2007; Aanestad & Jensen, 2011; Aanestad et al., 2017a), EHR as well as EHR-based platforms (e.g., Demirezen et al., 2016; Aanestad et al., 2017a; Aanestad & Jensen, 2011; Gray et al., 2011), DTx (see paper P3 as well as Schlieter et al., 2023) or telemedicine services (Singh et al., 2015), as well as in the second healthcare market with trackers, health platforms, or simple health apps (e.g., Gleiss et al., 2021; Hobeck et al., 2021; Hermes, Hein, Böhm, Markus, et al., 2020).

The lock-in phase–as described by Sydow et al. (2009)–marks the state at which a process of path dependencies become deeply entrenched. It occurs when self-reinforcing dynamics lead to a state of inflexibility and dependency, making it challenging or economically unattractive to transition to alternative options despite the existence of constraints (Shapiro & Varian, 1999). The process of breaking free from lock-in typically

[11] Distinction between the first healthcare market and the second healthcare market in Germany would be explained in subsection 2.1.3.

requires a significant investment of both time and resources. This is due to the necessity of overcoming technical barriers as well as addressing economic considerations (e.g., Kunow et al., 2013). In the literature, path-dependent processes are mentioned as a reason why data silos arise. This can be observed in particular in connection with the major systems at the healthcare service providers. In the field of health IT, studies have demonstrated that systems characterized by strong vendor lock-ins, such as health information systems, tend to be inflexible when it comes to integrating with other systems or require significant investments for interfaces (see paper P2 as well as Alkraiji et al., 2011; Hammond, 2005; Aanestad & Jensen, 2011; Hobeck et al., 2021; World Health Organisation, 2016; Hermes, Hein, Böhm, Markus, et al., 2020; Lin et al., 2012).

The proximity of such systems, whether deliberate or unconscious, and the lack of interoperability present challenges for innovations to work with existing data and gain traction in the market. This has implications for the broader healthcare market and manufacturers of these systems in the long term, particularly in light of the increasing trend towards platformization, including the advent of the EHR, which could potentially lead to competitive disadvantages (see paper P2 as well as Agarwal & Tiwana, 2015). Differentiating the identified examples of path dependencies, e.g., lock-ins of large platform ecosystems due to their self-reinforcing mechanisms and high switching costs related to interoperability, can be examined at the macro, meso, and micro levels (see subsection 2.1.1).

Macro:
In the first healthcare market in Germany, applications are required to use the specified Telematics Infrastructure (TI) for data traffic within the healthcare system. This infrastructure constitutes a closed network ecosystem that encompasses various applications including E-Prescription, EHR, and communication services for healthcare providers, among other services. Both IT service providers and platform owners/orchestrators as well as manufacturers of DTx must comply with these requirements if they want to operate in the first healthcare market (see subsection 2.1.3). The TI is an established infrastructure (see subsection 2.1.1), in a highly regulated governance structure. The TI can be understood as an installed base that cannot be easily changed or replaced (e.g., Han et al., 2020; Aanestad & Jensen, 2011; Aanestad et al., 2017a). This infrastructure serves as the foundation upon which the EHR platform can be further developed and expanded. From the perspective of complementors, manufacturers, and providers of specialized applications within the TI, these are technically locked-in to the TI envi-

ronment (e.g., Eriksson & Ågerfalk, 2010) as well as from the perspective of distribution channels, e.g., in case of international expansion. From the business point of view of the manufacturers, a departure from the TI and its associated technical requirements would require a fundamental reorganization of the business model and the distribution channels.

The basis of the TI is the underlying VPN network with the specified interfaces and many certificates for the respective specialized applications. To make matters worse, the outdated technical design is less flexible and significantly restricts integration due to the certificate solution, which has a significant impact on interoperability and data usage (see paper P3, *technical exchange infrastructure outdated* as well as *problems with data reuse and analysis*). Some of the issues related to interfaces and the cumbersome authentication mechanisms for access control, among others, could have been anticipated Wessel et al. (2017).

Meso:
Examples of path dependency regarding interfaces and interoperable standards at the meso level can be observed especially from the perspective of platform orchestrators of platform ecosystems. After the introduction of EHRs in Sweden and Denmark, a small number of technical providers of EHRs solutions eventually dominated the market over the years. In Denmark, three out of 23 EHRs providers (Aanestad & Jensen, 2011) and in Sweden, four out of 27 (Gray et al., 2011) gained prominence, leading to varying degrees of risk for collaborating stakeholders and insured parties. Paper P2 examined the development of EHR-based platform ecosystems in the German healthcare market. Three providers initially offered individual versions of the EHR as Personal Health Record (PHR) and made them available to their policyholders or customers. These PHRs were intended to serve as a showcase for the official EHR and to generate initial network effects (Katz & Shapiro, 1994) for the platform. Following the release of the official EHR specification, one vendor exited the market and another entered, offering a EHR solution in Germany. While the German market experienced less intense dynamics during the formation phase of path dependencies (Sydow et al., 2009) compared to Sweden and Denmark due to high initial hurdles, providers of EHR-based platforms still faced a phase of uncertainty. This is in line with the findings of paper P2, which highlights the importance of timing in *designing technical architectures and selecting standards* as well as the importance of *avoiding development risks associated with interfaces and subsequent adaptations* (see paper P2). From the perspective of the platform

orchestrators of EHRs and health insurance companies, lock-in effects are caused by the IT service providers or cloud service providers who are responsible for the backend infrastructure of the EHRs platforms. German health insurance companies deal differently with the risk of path dependencies and possibly resulting switching costs, with one primarily developing the EHR platform internally and thus retaining greater flexibility and others collaborating closely with IT service providers. Still, others predominantly acquire white-label solutions for their EHR (see paper P2).

An illustrative example from the second healthcare market can be observed in the case of Apple's and Google's decisions to utilize the FHIR standard for their health kits, which has an impact on the meso level (see paper P2). Due to its dominant market position, network effects (Katz & Shapiro, 1994) have an influence on the choice of interfaces and complementary services participating in the healthcare market. This development has also impacted the recommendations of standard-setting organizations (see paper P2).

From the perspective of healthcare service providers, path dependencies, particularly lock-in effects with high switching costs, emerge from software manufacturers with a dominant market position. This phenomenon is evident in the health information systems sector, where manufacturers have integrated a lack of interoperability and closed software design into their business models to generate revenue through adaptations or interface unlocking (see paper P1 as well as Kadry et al., 2010; Hermes, Hein, Böhm, Markus, et al., 2020).

"We are still in the dilemma that outpatient and inpatient healthcare information systems cannot talk to each other, there is still no structured data in the EHR"[12] (Ozegowski, responsible for digital affairs at the German Federal Ministry of Health, in Grätzel von Grätz, 2023). This is one of the reasons why the EHR is hardly used in Germany so far, and why there are no network effects towards a broad standardization and use.

Micro:
Other examples of path dependencies of interoperability can also be observed at the micro level, individual actors such as healthcare providers, digital health service providers such as DTx, and the customers as well as insurants.

From the perspective of healthcare service providers, learning effects (Sydow et al., 2009)

[12]Translated from German using translation tools and professional editing.

play a significant role in the adoption of new standards and procedures. Physicians are often reluctant to adapt or change their established practices to meet newer standards, especially without adequate incentives (Alkraiji et al., 2013). This reluctance stems from the potential initial inefficiencies that may accompany changes in workflow or procedures (see paper P1). A notable example in Germany is the transition from traditional FAX communication to digital communication methods. *"The costs are one thing, but there is also a need for stronger incentives, e.g., to ban outdated solutions that essentially do the same thing, e.g., FAX"*[13] (Product-Owner of a leading healthcare information system, interview as part of paper P2). It can be observed that routines have become firmly established among service providers. In some cases, the advantages of digital communication and processing for the entire healthcare system were only made possible following a changeover that was made possible through sanctions.

Removing such media discontinuities is essential for interoperable communication, e.g., between service providers; according to the maturity model, this would correspond to the first level (integrated) according to the maturity model (see paper P4). Indeed, path dependencies can manifest at the socio-technical level by means of learning effects (Sydow et al., 2009) through the entrenched processes of healthcare providers. These processes, often well-established over time, may resist alignment or adaptation to newer standards or technologies, leading to significant switching costs (e.g., Fichman et al., 2011; Alkraiji et al., 2013). For instance, changes in disease documentation practices, such as coding according to semantic interoperability standards or adjustments to workflow procedures at the pragmatic and organizational level, can face resistance and incur switching costs (see paper P1 as well as Fichman et al., 2011; Alkraiji et al., 2013). This phenomenon serves to illustrate the intricate interrelationship between technical standards and organizational practice standards within the healthcare domain. Since 2000, healthcare providers in Germany must code diagnoses according to the semantic standard International Statistical Classification of Diseases (ICD) as part of the reimbursement process. In 2020, a diagnosis coding system was introduced to make this easier (Deutsches Ärzteblatt, 2020). However, this only refers to the diagnoses made and does not reflect the patient's health status; there is a request to move away from billing documentation towards documentation of the health status. An example of this would be the documentation of the health status according to the semantic standard SNOMED CT, but this is not binding in Germany yet and will be used primarily in the

[13]Translated from German using translation tools and professional editing.

context of medical research, as it would initially mean additional work and a learning curve for service providers without any direct benefit. One illustrative example of the initial widespread deployment of SNOMED CT in Germany is the joint data set utilized in the German Corona Consensus Dataset (GECCO) project for the investigation of the coronavirus pandemic (Sass et al., 2020). However, *"SNOMED CT is significantly more comprehensive than ICD-10, and there is still work to be done to convince people that there is a benefit behind it. This is primarily up to the physician"*[14] (Digital health and interoperability expert, interview as part of paper P2). In the long term, the advantages of less free text in the documentation, e.g., with the help of semantic coding, can result in a higher degree of interoperability according to the maturity model (see paper P4), and also increases the opportunities for self-learning algorithms and decision support systems, which can process semantic coded information more precisely (see paper P4, section 2.2 as well as Lehne et al., 2019).

From the perspective of the insurants, providers also have no incentive to share the data collected from their patients, as patients are dependent on the stored health data (Ozdemir et al., 2011). Sharing the data, for example, reduces the patient's switching costs, e.g., in the case of a change of provider, which can lead to a reduction in revenue for the provider (see paper P1 as well as Schwarze et al., 2005; Miller & Tucker, 2014). This can result in path dependencies and lock-in effects, also from the perspective of the insurants. In Europe, the General Data Protection Regulation (GDPR) requires that individuals must be able to export their data in a structured, commonly used, and machine-readable format with the option of transferring the data directly to another provider (General Data Protection Regulation[15]). In a more stringent version, the SGB V regulates the transfer of data in the EHR, in particular for statutorily insured persons. In the event of a change of health insurance company, they can take their data to another the insurance company and thus another IT service provider in a machine-readable format. However, other health insurance companies can only process interoperable data. This only concerns data in the EHR, but not other data, e.g., from additional services stored by the health insurance company (see paper P2 *lock-in effects to the initial PHR platform*). Additional services also include data from DTx which are offered exclusively via the health insurance company as part of selective contracts. Lock-ins with regard to interoperability can also occur when changing the provider of DTx if the stored data cannot be transferred to the new provider in an interoperable format due to a change of

[14] Translated from German using translation tools and professional editing
[15] Article 20 General Data Protection Regulation (GDPR), right to data portability, https://gdpr-info.eu/

provider, which is also equivalent to losing the data or having to collect it again (P3, *to be observed when changing the DTx provider*).

Path dependencies resulting from interoperability obstacles at the micro level for complementors of EHR-based platform ecosystems can be analyzed. Platform orchestrators of EHR platforms aim to offer innovative health services as a unique selling point for their clients. This strategic decision can create dependencies among complementors of health services, as they may seek to avoid multihoming (e.g., Tiwana, 2014; Gawer, 2022) and commit to a single platform (see paper P2, *binding effects*). Complementors should carefully evaluate which platforms are suitable for cooperation based on their interface requirements and facilitation of interoperability properties (see paper P2, *choose the appropriate platform in terms of interoperability*). Depending on the underlying technology and data quality/condition, complementary services, particularly those involving AI services or interaction with medical devices, may necessitate a certain level of interoperability to function effectively (see paper P3). This underscores the importance of interoperable design in platform ecosystems to ensure seamless collaboration among complementors and maximize the value of integrated digital health solutions.

In each levels of analysis (macro, meso, and micro), lock-in can perpetuate itself through network effects, economies of scale, and institutional inertia, further entrenching the dominance of existing platforms and standards. Overcoming lock-in requires concerted efforts to promote interoperability, foster competition, and encourage innovation within the ecosystem.

5.1.2. Interoperability Challenges from a Healthcare Perspective

This subsection focuses on the care perspective of digital platform ecosystems and interoperability considerations. The question arises: what is the vision of operators of digital platform ecosystems, and what contribution for care can interfaces make to this? To clarify the question, suggestions and examples collected in studies on how a digital and interoperable design of services or service bundles within the platform ecosystem are discussed in the following.

The economic barriers and challenges are balanced by the social goals of enhancing medical care through interoperable designs. Platform ecosystems like EHR-based platforms, such as those managed by health insurance companies in Germany, aim not only to minimize processes and coordination costs but also to keep their insured individuals healthy for extended periods. Intelligent data utilization plays a crucial role in achieving these objectives. Two quotes collected as part of the study in paper P2 emphasize platform orchestrators' vision. First quote: *"The idea of the [platform] ecosystem is that we can access the data all at one place. That's the goal we want to achieve in order to generate added value by linking different data"*[16] (platform orchestrator of a leading health insurance company, interview in paper P2). The second vision quote: *"Providing insured persons with care content and bringing transparency and support to the treatment process"* (platform orchestrator of a health insurance company, interview in paper P2), underlines the endeavor to involve patients more closely in their health maintenance and treatment. However, this raises new issues and problem areas that have been relatively under-studied thus far. Key topics from the interoperability point of view include the self-determined management of patient data and the integration of self-collected data into the treatment process. Due to the increasing use of health applications Statista (2023a) as well as wearables and health devices Statista (2023b), more and more health-related information is being generated and stored by people themselves in their everyday lives (e.g., Hussein et al., 2021).

Health applications can be divided into simple health apps, software-as-a-medical device, and DTx (Fürstenau, Gersch, & Schreiter, 2023). In the area of hardware, a rough distinction can be made between medical devices and consumer devices. The distinction depends on the risk class, e.g., invasive non-invasive as well as accuracy, confidence, or effectiveness. Consumer devices, such as Apple's watch with a 1-channel ECG, are becoming increasingly precise, instilling confidence in their measured values (Isakadze & Martin, 2020). Due to the increase in various wearables, trackers, and vital sign measuring devices, e.g., for pulse, blood sugar, and blood pressure, more and more data is being stored in everyday life, which can also be used for care related purposes, e.g., doctors consultations and studies (see paper P3 as well as Hussein et al., 2021; Ciortuz et al., 2024; Chromik et al., 2022). This increased accuracy means that consumer-grade devices' data can now be considered in medical consultations, expanding the scope of care possibilities. Access to vital data and the ability to retrieve measurements via the network, open up new avenues for innovative care services. For instance, telemedicine becomes more accessible for individuals with limited mobility or those residing in rural areas, where long distances hinder traditional healthcare access. Additionally, these

[16] This and the following quotes have been translated from German using translation tools and professional editing.

data provide valuable resources for research purposes, contributing to advancements in healthcare knowledge and practice (see paper P3 as well as Deutsches Ärzteblatt, 2022). Health platforms in particular have a great interest because the availability of more data on the platform, e.g., the EHR, allows more innovation and thus self-reinforcing mechanisms such as network effects (Katz & Shapiro, 1985) can take effect. This also includes better and more efficient patient, treatment, and procurement management (e.g., Fürstenau et al., 2021; Fürstenau, Gersch, & Schreiter, 2023). With more data and a combination of innovative services for self-assessment, patients can get to the relevant healthcare service provider faster in the event of complaints (see paper P3, *coordination vacuum*). However, *"interoperability is crucial when it comes to customer experience. Use of multiple products and services must be interoperable"* (platform orchestrator of a leading health insurance company, interview in paper P3). If data transport is too cumbersome or there are no solutions, users strive to find workarounds (Wiesche et al., 2024) that are both insecure and unsustainable in terms of data reuse due to media breaks, such as the FAX example. The prerequisite for such care scenarios is an interoperable data exchange along the use cases, beginning from the collection of values, e.g., vital tracker, wearable, or measuring devices for blood pressure or blood sugar, to the further processing of the values, e.g., in combination with a DTx, and finally to the doctor or therapist (see paper P3). Here, interoperability contributes to the realization of innovative digitally supported service bundles, e.g., telemedicine, prevention, triage, etc. (see paper P3, *integration with other care-related or medical apps, such as triage, prevention*). For this purpose, for such service bundles different solutions must be orchestrated, in particular the interfaces, so that an interoperable data exchange is given and thus the function is guaranteed (see paper P3, *heterogeneity of telemedicine programs*).

Papers P3 and P4 provide valuable insights into the use cases and strategies for achieving interoperable data exchange in the context of DTx and health innovations. In paper P3, the patient-centric perspective on data exchange, from the collection of the data to the processing of data and its usage, is emphasized. Standardized interfaces and data models play a crucial role in enabling this seamless exchange of data along care pathways. This patient-centric approach of interoperability design, as discussed in paper P3, is further developed in the maturity model presented in paper P4, particularly within the dimensions of *Individual* and *Care Process* (see paper P4). By considering the interface requirements for the services involved, beneficial use cases and service bundles can be realized. Moreover, ensuring user-friendliness through seamless interoperable data transfer is essential. Cumbersome data transfers and multiple entries can lead to user frustration but can be mitigated by automating data transfers from medical devices, such as blood glucose or blood pressure monitors, to applications like the EHR (see paper P3). This automation not only reduces user burden but also promotes adherence to treatment regimens, particularly in the context of DTx.

5.2. Managing Interoperability of EHR-based Platform Ecosystems by the Maturity Model

In the realm of interoperability management, papers P2 and P3 illustrate that the design of an interoperable interface should be approached from a process-oriented perspective. This involves considerations of both data flow and timeframe. Concerning data flow, an interoperable, patient-centric interface design ensures interoperable data flows along care pathways (see paper P3). In terms of timeframe, an interoperable interface design must account for ongoing technical changes and dependencies within the ecosystem, as well as regulatory considerations (see paper P2 and P3).

From the perspective of platform orchestrators, EHR-based platform ecosystems necessitate an interoperable interface design, which serves as a fundamental prerequisite for delivering valuable bundles of digital or digitally supportive services. The delineation of interfaces and standards constitutes a central task in platform development (Fürstenau et al., 2019), as well as in ecosystem development in general (Autio, 2022). One goal of targeted ecosystem orchestration is to furnish digital tools that support the inherent dynamics of complementors, facilitating the generation of innovations and generative solutions (e.g., Lehne et al., 2019; Thomas & Tee, 2022). Thomas & Tee (2022) suggests that a loosely coupled architecture design promotes the emergence of generative services. Interoperable interfaces and standards stand as prerequisites for fostering innovation, particularly for digital or data-driven services (Hodapp & Hanelt, 2022). From an interoperability perspective, this concerns data quality and interoperability, which can lead to new innovations that the orchestrators did not directly anticipate (Autio, 2022).

Interoperability challenges, such as development risks, increasing complexity, path dependencies, and the design of integral care processes, as discussed in the previous section (see section 5.1), can be more effectively addressed through targeted management of interoperable interface design. This approach facilitates the achievement of the platform ecosystem's objectives and harnesses the benefits of an interoperable ecosystem[17]. Moreover, there is considerable variation in the interoperability requirements for the services or service bundles necessary to achieve the aforementioned objectives on the platform. This is particularly evident when considering the case of multiple health services, as well as solutions that combine services and devices (see paper P3).

In subsection 5.1.1.1, it was proposed that interoperability challenges can be mitigated through the use of integration profiles. Depending on this, complementors exhibit varying requirements regarding the degree of interoperability during integration. Furthermore, the maturity model can be leveraged to establish developmental objectives for the platform's evolution. These profiles can be harmonized with the maturity model levels (see paper P4), which may vary depending on the service and use case. Drawing on the maturity model, there are diverse implications contingent upon the dimensions and interoperability level under consideration. The subsequent paragraphs outline implications from the standpoint of platform orchestrators concerning interoperability decisions, as addressed by the interoperability maturity model. This model delineates five levels of interoperability maturity, each characterized by a distinct set of interoperability attributes and characteristics across seven dimensions. The definitions of these five levels are expounded upon in paper P4. The utilization of the maturity model from the perspective of platform orchestrators in the integration process of a DTx for diabetes is exemplified and deliberated below.

Technical Dimension: *Is the compatibility with the necessary infrastructure given?* (see paper P4). This question assesses fundamental prerequisites for stakeholders within the platform ecosystem to ensure that data can be transmitted using transmission and network protocols within an infrastructure such as the TI. In the context of diabetes, as exemplified in the scenario of the measuring device and app (see paper P3 as well as P4), this entails, for instance, the basic transmission of data from the measuring device to the app and subsequently to the EHR.

Data & Information Dimension: Platform orchestrators ask in these dimension: *How are the data structured and coded?* (see paper P4). In particular, the data structures

[17]Detailed discussions on the correlations between data quality and interoperability in healthcare were provided in the previous chapter (see subsection 2.1.1).

are considered according to syntactic and semantic standards and whether the underlying data models conform to each other (see subsection 2.2.4), e.g., on the basis of implementation guidelines.

Application & Service Dimension: In this dimension, platform orchestrators contemplate the following question: *Are the required data and information findable, accessible, and reliable?* (see paper P4). The definition of interoperability by IEEE Standards Board (1990) encompasses not only the exchange but also the utilization of the exchanged data and information. This includes data availability and reliability, which are essential for the treatment and monitoring of vital data. Without these assurances, practitioners and patients cannot depend on the data.

Organizational & Business Dimension: Beyond fulfilling legal and regulatory prerequisites for ensuring interoperability, agreements within the platform ecosystem are executed through contracts, policies, or disciplinary guidelines. The question arises: *Does the exchanged data support and adhere to the relevant agreements, contracts, and guidelines?* (see paper P4). For instance, throughout the integration process, complementors are assessed against criteria established by the platform orchestrator to ascertain compliance with contractual and guideline requirements.

Legal & Regulatory Dimension: With the question: *Are regulatory and legal requirements considered and adhered to?* (see paper P4), regulatory and legal basic requirements for interoperability are defined at macro level, both within the ecosystem and through interfaces third parties that are not within the control of the platform orchestrators.

Care Process Dimension: The question: *Will the assessment be conducted from a care scenario or process perspective?* (see paper P4) ensures that data availability and usability along the care pathway are maintained, even with multiple service providers, without interruptions in data flow or degradation in data quality or interoperability levels due to non-conformant data models (see section 2.3).

Individual Dimension: Pose the question: *Can users exchange and share data in a self-determined manner?* (see paper P4). As elucidated in chapter 5.2, an interface design that prioritizes end-users enhances user-friendliness and reduces the risk of unintended consequences, such as workarounds Wiesche et al. (2024). Additionally, with the proliferation of diverse health-related services and devices gathering patient-generated health data (e.g., Sayeed et al., 2020), there is a growing necessity to empower patients to govern their own data. In paper P3, the concept of patient-centric interoperability is introduced to address these needs, facilitating the exchange and processing of data and information throughout the patient or user journey.

Level of Interoperability Maturity: The gradations of the five levels must be considered for each individual dimension (see paper P4). The levels are explained below with reference to the "Data & Information" dimension. For example, the exchange of a report as a PDF document, which is manually transmitted from the app to the doctor via email, falls under Level 1 of the maturity model (see paper P4). If this is automatically stored according to a structured data model after creation, e.g., in the EHR where the doctor can retrieve it, this would be considered Level 2. If the information is semantically coded, this would correspond to Level 3, with the effect that decision support systems can process it well. Level 4 would be given if the data and information can also be processed internationally, and Level 5 if the data model basis can be processed for cross-domain use cases (see paper P4).

5.3. Resumption of the Discussion on Managing Interoperability

The balancing of costs and benefits in health economics is a major topic whereby services are measured according to various scales, including the effectiveness of a treatment, for which input and output are measured in direct realization (e.g., Nord, 1999). This also applies to the topic of prevention, where many offers have not been profitable for insurance companies to date or have been unprofitable. If a critical mass of qualitative health data is exceeded, this can be used with the help of innovative solutions to personalize care management and thus offer both medical and preventive services (Baas, 2021). The key to personalized medicine is high-quality data and decision-support solutions for the assessment of services. In the future, large language models will support the processing and coding of data collected by humans, e.g., the service provider, into semantic information (e.g., Daumke et al., 2024; Deutsches Ärzteblatt, 2020), so that machines or other services can process it better and more efficiently (e.g., Lehne et al., 2019). The maturity model (see paper P4) can help to define parameters for such systems to determine which level should be reached.

By understanding the discussed stakeholder perspectives and the economic and socio-technical contexts of the interoperability decisions of platform ecosystems, platform orchestrators can better consider and anticipate risks and imbalances in distribution. The results of papers P1-P3 contribute to this. With the maturity model in paper P4, entire treatment pathways can be realized from a care perspective, services, and service bundles with the support of digital artifacts in order to make a positive contribution to care. When defining or specifying interoperability criteria for the objectives, the maturity model can help to define clear specifications as to what level of interoperability is required for realization.

The interoperability challenges identified here can be used to derive four core lessons that need to be considered when managing the interoperability of EHR-based platform ecosystems:
(1) Assessment and verification during the onboarding of complementary services: Designing specific service bundles to ensure seamless integration. (2) Definition of interoperability profiles (for platform integration) based on the requirements of respective use cases and the data needs of services: Managing high complexity with diverse requirements for each use case. For instance, AI services may necessitate a higher quality of data at a semantic level to provide more precise decision support, whereas services combined with vital signs devices may require data accessibility for medical consultations. Implementation strategies are essential. (3) Anticipating potential interoperability-related risks and challenges: The discussed economic and socio-technical challenges provide input to platform orchestrators, standard-setting organizations, and government agencies for shaping healthcare ecosystems, platform ecosystems, and infrastructure such as healthcare IT. (4) Medium to long-term planning of interface and data management within the platform ecosystem: Following an assessment of maturity, target images of interface management can be established.

6. Conclusion

6.1. Contribution of the Doctoral Thesis

The topic of interoperability is of significant importance and, despite a decade-long discussion, is one of the identified grand challenges (E. Davidson et al., 2023). This is not least because interoperability is a basic prerequisite for a smooth exchange of information and data. Despite the history of discussion on interoperability, there is a need for research to investigate barriers or challenges in different contexts and to further develop the concept of interoperability. This thesis focuses on the management of interoperability in emerging EHR platform ecosystems. In essence, this doctoral thesis is an empirical work (Díaz Andrade et al., 2023) in which concepts related to interoperability were examined and further developed, including the economic view of interoperability, particularly from the perspective of managing interoperability. Chapter 1.2 presents two research objectives, each with a research question, which were investigated and answered in the four papers as well as in the synopsis of the doctoral thesis.

RQI asks: *What are the economic and socio-technical interoperability challenges of emerging EHR-based platform ecosystems?* From a multi-dimensional perspective of interoperability considerations, the framework of Hodapp & Hanelt (2022) provides a basis for understanding how, where, and by whom interoperability can be increased. With the help of their morphological box, snapshots of interoperability can be described and understood from a socio-technical perspective. This doctoral thesis builds on the conceptual knowledge base by considering not only socio-technical aspects but also economic aspects of interoperability. In recent years, many technical standards for data exchange in the healthcare sector have become established, but interoperability problems still do not seem to have been solved. Paper P1, therefore, dealt with the assumption that interoperability decisions are determined less by technical and more by economic factors. Using a systematic literature search according to vom Brocke et al. (2009), economic correlations and characteristics of cost-benefit decisions as well as forms and examples of resulting path dependencies were identified and discussed from various stakeholder perspectives. Paper P2 examines the emerging EHR-based platform ecosystems empirically as a longitudinal case study (Yin, 2018; Eisenhardt, 1989b). Challenges for platform orchestrators, complementors, and users, i.e., insurants, are identified from a socio-technical perspective, e.g., the importance of the temporal reference in the development of the interface concept of the platform, as well as from an economic perspective, e.g., with binding effects and other path dependencies due to the interface design for complementors and users.

The complexity of new forms of healthcare, which arise primarily through DTx in connection with devices and sensors in networked healthcare ecosystems (Sunyaev et al., 2024, e.g.,), was examined in paper P3 using a problem-driven (Monteiro et al., 2022) approach in a qualitative explorative study (Sarker et al., 2018). With the proposed perspective of patient-centric interoperability, a process view for analysis and design of the interfaces is taken. In paper P3, the consideration of the various interfaces along the treatment pathway is helpful in identifying interoperability issues in order to ensure an integrated and interoperable ecosystem. Paper P3 thus ties in with the fairly recent discussion on DTx and provides a contribution to the interface design of ecosystems and treatment concepts of DTx (Fürstenau, Gersch, & Schreiter, 2023) in interaction with EHR, devices, and other innovative services such as telemedicine solutions.

RQII asks: *How can platform orchestrators be supported in managing the interoperability of platform ecosystems?* For both analysis and planning, a patient-centric interoperability view is helpful for managing interfaces in the healthcare ecosystem, e.g., to offer integrated service bundles complementary services on the platform (see paper P3). This view is also taken up in the maturity model developed in paper P4, as it can be used to assess the interoperability maturity. Previous maturity models are less process-oriented and less sensitive to cross-stakeholder concerns. In addition, these are outdated (e.g., Clark & Jones, 1999), with a focus on non-platform architectures and governance structures (Campos et al., 2013; Wasala et al., 2015), such as enterprise interoperability (Weichhart et al., 2016; Carvalho et al., 2017) or domains (Lopes & Oliveira, 2015; Gottschalk, 2009). The developed maturity model in paper P4 consists of five interoperability levels and seven dimensions that characterize interoperability properties. The artifact was evaluated in the healthcare domain. The domain is characterized by the fact that both the regulatory and structural conditions are subject to an increased level of difficulty for operators of portal ecosystems, including when establishing themselves on the market. In addition, health data has a high social as well as ethical value, both to positively influence the course of treatment and to be used by research (e.g., Maguire et al., 2015; Gunasekeran et al., 2021; Sunyaev et al., 2024). This requires high standards of data quality. This is where the maturity model comes in and supports platform orchestrators in assessing the interoperability of the platform ecosystem and, in particular, of complementary systems in platform integration. Additionally, the maturity model serves as a framework for defining an interface concept for the platform. This can be done by defining use-case-related or technology-related interoperability profiles for platform integration. Furthermore, the maturity model provides incentives for the further development of the platform or targets for the interface concept. The storage of data without a conceptual framework and without consideration of interoperability requires significant effort in platform ecosystems, and its usability is often limited. To utilize the potential and anticipate possible further use, e.g., for research or secondary use, the maturity model provides an orientation to consider the different dimensions of interoperability and provide inspiration for further development of the interface concept for new technologies, e.g., AI-based services, other use cases, or cross domain scenarios.

In summary, this doctoral thesis about managing interoperability contributes to the following three key points: First, stakeholders must more strongly consider economic contexts of interoperability and anticipate consequences of interfacing decisions. Second, the design of interfaces should be considered in the context of care pathways. This should be done from a patient-centric interoperability perspective, which considers different data sources along care pathways. The use of future technologies or services can facilitate the extraction of values from interoperable data, which can generate benefits in the future. However, not all those involved will benefit equally from this investment. Instead, it can be seen as an investment in the common good of society, including research. Third, with the interoperability maturity model, platform orchestrators can manage the interface landscape of the platform ecosystem. With the maturity level presented here, seven interoperability dimensions (questioning what is the interoperability level and where is interoperability increased) can be defined. The maturity model provides support for the interface design, integration, monitoring, and planning of the interface concept for future use cases and technologies.

With the help of propositions, the key points and constructs are summarized and linked in a concise way Recker (2021). For this purpose, the three core points of the work summarized above are formulated into three propositions for further research inspired by Chalmers (1999).

1. Interoperability decisions are strongly determined by economic factors that need to be balanced.

2. Interoperable interface concepts should be considered from a process perspective in order to design integrated value chains for future innovations.

3. An interoperability maturity model supports the realization of interoperable platform ecosystems.

6.1.1. Implications for Research

As a complement to the morphological box of Hodapp & Hanelt (2022), this doctoral thesis provides a contribution to the conceptual extensions of interoperability, focusing on the evaluation of interoperability decisions such as interface concept as well as considerations of integration decisions from a socio-technical and economic perspective. The empirically identified patterns, particularly causal explanations of interoperability and prescriptive statements (Gregor, 2006), represent a contribution to the conceptual extension of interoperability, which can also serve as a basis for further theorizing (e.g., Gregor, 2006; Miranda et al., 2022; Baskerville & Pries-Heje, 2010), such as contextual theory (Avgerou, 2019). Theories can emerge through the recognition of relationship patterns between constructs within a specific case as well as across cases (Eisenhardt & Graebner, 2007), such as on the basis of the relationships between the constructs of interoperability and path dependencies presented in papers P1, P2, and P3. The identified propositions also provide a basis for the theory development process for the development and verification of a developed theory (Eisenhardt & Graebner, 2007). From a design-oriented point of view, the artifact from paper 4 also offers characteristics for the development of design theory (Eisenhardt & Graebner, 2007).

The work provides data on the emerging platform ecosystems of EHR in a highly regulated environment. This environment is characterized by extensive debates on digitization issues at the macro level, involving politics, associations, and government organizations, which lead to uncertainties and reluctance at the meso and micro levels, such as in the development of digital solutions like a digital record system for insurants or patients. Following a longitudinal approach (Langley, 1999), episodes related to the electronic file were reconstructed, analyzed, and discussed. The construct of DTx (Fürstenau, Gersch, & Schreiter, 2023) as a new form of healthcare is still quite new and therefore under-researched. This work also contributes to the discussion on DTx, examining how DTx is establishing itself as a new form of care in a highly regulated environment, and highlights the challenges that arise from an interoperability perspective, particularly regarding integration with the EHR. The implications for platforms, standardization organizations, and governments are also considered in light of the identified problems.

The developed maturity model was evaluated in a highly regulated environment where both government and platform orchestrators have a significant influence on the design of the ecosystem. In other ecosystems that are less regulated, the maturity model provides guidance for a more precise description of the data. This would be the case, for example, with data spaces, which are increasingly being discussed on government level, e.g., the European Health Data Space and the European Union's Gaia-X initiative (e.g., European Commission, 2020), as well as in the research literature (e.g., Jarke et al., 2018, 2019; Beverungen et al., 2022). The data architecture of data spaces follows a decentralized approach, whereby the data condition is largely unknown to the data user. In order for innovative services to be able to utilize the data spaces, it is necessary that the minimum interoperability requirements are met. The maturity model provides a basis for such adaptations, for instance, to describe the available data in the data space through fields of interoperability characterization on the basis of the maturity model, either by self-assessment or automatically using an analysis tool.

The evaluation of the maturity model in a highly regulated environment highlights its applicability in contexts where government regulations and platform orchestrators play significant roles in ecosystem design. However, the utility of the maturity model extends beyond such environments, particularly to ecosystems with lower regulatory constraints, like data spaces. Data spaces, such as the European Health Data Space and the Gaia-X initiative, are gaining traction both at governmental levels (e.g., European Commission, 2020) and in research discussions, such as the discussion on the architecture of data spaces (Otto et al., 2019; Jarke et al., 2019), realization of services Beverungen et al. (2022), as well as with questions of the further use of data as secondary use of data (Hussein et al., 2024). Data spaces can be understood as a kind of public platform with less top-down (one-sided) governance approaches that strengthen user data sovereignty to promote innovation and easier access to data (Braud et al., 2021; Beverungen et al., 2022; Shabani, 2022). In these contexts, data is often decentralized, and its characteristics may be obscure to data users. To enable the deployment of innovative services meeting minimum interoperability requirements is crucial. In this scenario, the maturity model offers valuable guidance for providing precise descriptions, e.g., in the meta-data, of available data within data spaces. This involves categorizing data based on interoperability characteristics, either through self-assessment or automated analysis tools. By employing the maturity model, data within data spaces can be structured and described in a manner that facilitates its utilization for innovative services, thereby promoting interoperability and enabling the realization of data-driven initiatives within these ecosystems. The artifact facilitates the planning of interoperability design for platform ecosystems, defining requirements, assessing, anticipating challenges and risks, and conveying a strategic vision for future interface design.

6.1.2. Implications for Practice

The findings expounded upon in this doctoral thesis bear practical relevance for managing interoperability across various domains, including platform orchestrators, standard-setting organizations, governmental institutions, and complementary service providers. With a focus on economic underpinnings, the insights gleaned from this research serve to elucidate the rationale behind interoperability decisions and the hurdles encountered by diverse stakeholders. For instance, the recognition that incentives for interoperability design are perceived disparately underscores the need to navigate risks and obstacles without necessarily expecting immediate reciprocation. Balancing this tension is essential in practice. Furthermore, at a socio-technical level, the findings underscore the importance of designing interface concepts in a holistic rather than selective manner. This approach not only enhances user experience for customers or patients but also fosters stakeholder engagement, enabling them to derive benefits from enhanced interoperability, such as improved data transfer, storage, and subsequent utilization. Thus, the practical implications extend beyond economic considerations to encompass socio-technical dimensions, emphasizing the need for a balanced and inclusive approach to interoperability management.

The central message of this doctoral thesis is that the design and orchestration of interoperable interfaces along care pathways that include multiple data sources is essential for the realization of service bundles that will improve healthcare. As a supportive tool, the maturity model proposed for measuring interoperability serves multiple purposes, i.e., facilitating the alignment of complementary services, guiding the development of the platform, and monitoring integration processes of the platform ecosystem. The interoperability maturity model's implications for practice were also a criterion in the evaluation process, particularly in the context of platform orchestrators of EHR-based platform ecosystems. The maturity model provides a framework contingent upon widespread adoption by stakeholders, including the transparency effect in evaluation processes. Further dissemination and support of the maturity model, for example, by standardizing organizations such as the German Interop Council at the macro level, could significantly increase its reach and acceptance.

6.2. Limitations of the Doctoral Thesis

The insights derived from this doctoral thesis are subject to a number of limitations that need to be considered when evaluating the findings. In the literature, the benefits of interoperable IT systems through open standards are often positively normatively portrayed (e.g., Han et al., 2020; Aggarwal et al., 2012; Deishin Lee & Mendelson, 2007). Interoperability between two or more systems in healthcare has societal and ethical implications, as the collection of well-structured data, sharing of data, and its utilization through innovative solutions can improve medical care and promote health maintenance, for example, through targeted prevention efforts. However, there is also a highly critical discussion, mostly concerning ethical and data protection concerns, which has not been further examined in this work. Therefore, depictions of the positives or opportunities arising from digitization and interoperability, especially from a healthcare perspective, focus on the positive effects that can be achieved through these means. The studies conducted in this work are strongly driven by problem and phenomenon, with a focus on developments in the digitization of the German healthcare system (e.g., TI, EHR, DTx). Specifically, the studies in papers P2 and P4 examine and evaluate platforms in the developmental phase, with further investigations in later phases, including the scaling phase. The discussions in the studies in this work predominantly consider interoperability considerations at the structural and semantic interoperability levels, with less focus on the pragmatic interoperability level, especially in empirical discourses.

Another point addresses the importance of scientific rigor and practical relevance in DSR studies, which is widely acknowledged (e.g., Winter, 2008; Gregor & Hevner, 2013b; Hevner et al., 2004). In the developed maturity model (see paper P4), this inherent trade-off is particularly apparent in the calibration of the degree of generalization. This calibration entails striking a balance between projectability, which enables the artifact to be extrapolated across various domains (e.g., beyond healthcare), and fitness, ensuring direct applicability to specific contexts, such as aiding platform orchestrators in integrating complementary applications (vom Brocke et al., 2020).

6.3. Outlook

The results of the work offer several implications for further research. Firstly, the identified patterns of interoperability, such as economic and socio-technical challenges, as well as construct extensions through a stronger process perspective, such as patient-centric interoperability, in the design of IT artifacts provide a foundation for future research endeavors. For instance, frameworks, explanatory mechanisms, and the design of artifacts such as design principles and design knowledge could be developed. Consequently, the results can be utilized as a framework or toolbox to facilitate the systematic balancing of interoperability-related decisions and the management of associated tensions among stakeholders. Secondly, the maturity model was developed and evaluated from the perspective of platform orchestrators. Further investigations of the maturity model in different contexts, such as orchestrators of platforms with different governance and regulatory structures (e.g., data spaces), can explore its applicability to other domains and stakeholder perspectives. This exploration could lead to the generation of additional design knowledge, such as principles for interoperable integration processes. Thirdly, there is a lack of real-world examples and conceptual evaluation for the investigations of maturity levels 4 and 5. The feasibility of these levels could be examined through future studies.

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Part II.

Paper of the Doctoral Thesis

Paper Overview

Overview of the Publications Made in the PhD Period

Paper[18]	Title	Authors	Year	Outlet & Publication type	Ranking[19]	Points[20]
–	Interoperabilität – technische oder doch vielmehr ökonomische Herausforderung?!	Stegemann, Lars and Gersch, Martin	2019	Digitale Innovationen im Gesundheitsmarkt: Märkte – Geschäftsmodelle – Technologien, GITO Publisher, p. 41–47, short paper	–	–
P1	Interoperability – Technical or economic challenge?	Stegemann, Lars and Gersch, Martin	2019	it - Information Technology, journal paper	D	0,5
P2	The Emergence and Dynamics of Electronic Health Records – A Longitudinal Case Analysis of Multi-Sided Platforms from an Interoperability Perspective	Stegemann, Lars and Gersch, Martin	2021	Proceedings of the 54th Hawaii International Conference on System Sciences (HICSS), full conference paper	B	0,5
–	How to turn the Fast-Track into a Fast-Track: Process integration for evaluation of the quality of Digital Health Applications (DiGAs) on the example of the German Fast-Track Process	Karagülle, Muhammed-Ugur; Lehmann, Nicolas J.; Muth, Lea R.; Hintze, Cora; Juritz, Marc-Andr´e; Stegemann, Lars; Gersch, Martin	2022	Proceedings of the 55th Hawaii International Conference on System Sciences (HICSS), full conference paper	B	–
–	Enabling Data-Driven Mobility Research: Design Principles and Design Features for an Open Platform Approach	Sivizaca Conde, Daniel; Kliewer, Natalia; Rößler, David; Stegemann, Lars	2023	Proceedings of the 56th Hawaii International Conference on System Sciences (HICSS), full conference paper	B	–

[18] Papers which are part of the cumulative dissertation
[19] According to the VHB Publication Rating 2024 for Information Systems
[20] Points included in the comulative disertations, according to the FU regulation for cumulative disertations

P3	Future-oriented and patient-centric? A qualitative analysis of DTX and their interoperability	Stegemann, Lars; Gubser, Rahel; Gersch, Martin; Bartschke, Alexander; Hoffmann, Andreas; Wagner, Michael; Fürstenau, Daniel	2023	Proceedings of the European Conference on Information Systems (ECIS), full conference paper	A	0,14
P4	Interoperability Maturity Model: Orchestrator Tool for Platform Ecosystems	Stegemann, Lars	2023	Proceedings of the 18th International Conference on Wirtschaftsinformatik (WI),	B	1
						Total Points: 2,14 (Required: 2.0)

P1 – Interoperability – Technical or economic challenge?

Author Contribution Statement

The purpose of this statement is to give appropriate credit to each author for his or her role in the preparation and writing of the paper listed below. I would like to take this opportunity to thank all co-authors for their contributions. By signing this form, each person listed as an author acknowledges the contributions made to the specified work in terms of their role and share of the total amount of work (see below).

Article Information

Manuscript title:	Interoperability – Technical or economic challenge?
Year of publication:	2019
Outlet & ranking:	it - Information Technology *(VHB: D)*
Type:	Journal-Paper
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Contributions

Ideation:	equal	equal
Conceptualization:	equal	equal
Research design:	equal	equal
Data collection:	lead	support
Data investigation:	lead	support
Writing:	lead	support
Review & editing:	equal	equal

Signatures

Place & date: Signature:		

Background on the origins of the paper: MG played a key role in developing the idea of looking at interoperability from an economic perspective. Initially, a short paper was prepared and discussed at a workshop of the German Informatics Society (Health subgroup). The results were further developed into the journal article.

P2 – The Emergence and Dynamics of Electronic Health Records – A Longitudinal Case Analysis of Multi-Sided Platforms from an Interoperability Perspective

Author Contribution Statement

The purpose of this statement is to give appropriate credit to each author for his or her role in the preparation and writing of the paper listed below. I would like to take this opportunity to thank all co-authors for their contributions. By signing this form, each person listed as an author acknowledges the contributions made to the specified work in terms of their role and share of the total amount of work (see below).

Article Information

Manuscript title:	The Emergence and Dynamics of Electronic Health Records – A Longitudinal Case Analysis of Multi-Sided Platforms from an Interoperability Perspective
Year of publication:	2021
Outlet & ranking:	Proceedings of the 54th Hawaii International Conference on System Sciences *(VHB: B)*
Type:	Conference-Paper (Full-Paper)
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Contributions

Ideation:	equal	equal
Conceptualization:	equal	equal
Research design:	equal	equal
Data collection:	lead	support
Data investigation:	lead	support
Writing:	lead	support
Review & editing:	equal	equal

Signatures

Place & date: Signature:		

Background on the origins of the paper: When considering the methodological approach for the second paper, MG came up with the idea of structuring the collected data since the beginning of the PhD on electronic health record and similar health platforms as a longitudinal case study, which has significantly advanced the paper. Furthermore, MG has been particularly helpful in providing very valuable and rare contacts in the field of digital health platforms, especially insurance companies and governmental organizations.

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The Emergence and Dynamics of Electronic Health Records – A Longitudinal Case Analysis of Multi-Sided Platforms from an Interoperability Perspective

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Abstract

Emerging health record platforms are interesting examples of the ongoing process of digitalization and the great opportunities they provide for innovation and additional services. Incumbent players are under increasing pressure from new entrants to offer their customers a user experience they have become familiar with through platforms such as Apple and Google. The emergence of the digital German health record is shown as a case-study, harnessing a longitudinal database and adopting a process-sensitive perspective. Important events are structured into individual episodes and phases and discussed in-depth. The study shows how platform owners of health records respond to changes in the highly regulated healthcare system and its digitalization in Germany. Contrasting with extant knowledge about interoperability as a relevant precondition for platforms, our study shows the important role played by interoperability as a design parameter for emerging platforms, which results in seven interoperability challenges for respective stakeholders.

1. Introduction

Compared to other industries, the progress of digitalization is much slower in the healthcare sector [16]. Reasons include the necessary regulation within divergent national contextual frameworks, the presumption of market failure, the complex systems of care and treatment processes, the variety of stakeholders and heterogeneous systems and the lack of interoperability (e.g., [19]). One of the key applications, and the basis for various add-on services in healthcare, is the Electronic Health Record (EHR), which drives and underpins the digitalization of healthcare. Due to the slow progress of digitalization, the healthcare market still offers great potential for the development of innovative services [16]. The chairman of the board of the Techniker Krankenkasse (TK), one of the leading statutory health insurance companies in Germany, communicated this very clearly in his vision for the TK at a key speech in October 2019:

"TKs vision for 2030 is shaped by the conviction that people live in a few, relatively stable digital ecosystems with high levels of connectivity. Besides Apple and Amazon, a healthcare ecosystem is to be designed by TK with a quality and user experience on a par with Apple & Co. In this context, the regulatory authorities in Germany will hopefully prevent statutory health insurance companies from losing direct contact with the customer during the transition phase as well. The TK ecosystem will include data-based services beyond the mandatory requirements (e.g., electronic patient files) and will persuade and inspire the loyalty of TK-insured persons in the long term. We will clearly use digitization to differentiate ourselves from the competition in order to achieve greater control of the provision of care"[1] (Thomas Ballast 2019; Board member TK, Berlin #eHealthCon October 23, 2019).

In addition to this particular vision for the healthcare sector by this insurance company, the quote also elucidates the threat of new market entrants that it will have to deal with and how it will address these threats in terms of quality, user experience and service offerings. Health record platforms play a central role in this context. In order to develop the full potential of EHR, semantic interoperability, in addition to technical specifications, must be achieved despite its being one of the most challenging tasks in health informatics (e.g., [21]). Especially in the case of providers of national EHRs, such as for Denmark or Norway, a clear consensus about standards is necessary to ensure the proper exchange of information between different healthcare service providers and sectors in order to realize the benefits of platform-based coordination [14, 19, 1]. Germany's

[1] Author´s translation from German into English

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self-administered health system (consisting of associations, institutes and organizations of stakeholders in the health sector e.g., [23]) has not been able to reach a consensus of interoperability issues for decades. In 2019 and 2020, comprehensive changes have taken effect in order to regulate the digitalization of the German healthcare system records and promote innovative health services. This refers in particular to EHRs: by January 1, 2021, all statutory health insurance companies are required by law to provide their policyholders with an EHR. As of June 2020, six potential providers—two insurance companies, Allgemeine Ortskrankenkasse (AOK) and TK, and four service providers (VIVY, IBM, Compugroup Medical and RISE)—have begun developing an EHR in response to governmental specifications. In the German context, health records can be differentiated into one of two types, as shown in Table 1. On the one hand, the EHR represents the governmental required minimal standard of a repository to store and exchange health status information, which is securely stored and shared with other institutions, based on the specifications of the regulatory authorities. The EHR facilitates the longitudinal sharing of medically relevant data, e.g., diagnosis, treatment activities, laboratory data and radiology reports, which can be exchanged among different health service providers across organizations [4, 19] and is primarily administered by physicians. On the other hand are provider-specific Personal Health Records (PHR) which include personal health information and which are primarily administered by the user [4, 19]. PHRs are an additional optional service of the EHR and provide the basis for data generation as well as complementary offers of mostly data-driven services within emerging provider-specific health ecosystems. In this context, and as shown by Ballast's quote above, it is in the interest of providers such as TK and AOK to establish multi-sided health platforms, especially around the PHR, in order to offer a competitive additional benefit to interested insurants, by e.g. exclusive complementors and their digital services. Both records will be managed by the provider/platform owner, but in contrast to the PHR, the EHR will have to follow government specifications and regulations. Regarding PHRs, each of the platform owners address different interests and follow different design approaches over the course of implementation as well as different government structures and rules, e.g., relating to openness [31] of their boundary resources (e.g., [13]). Despite the fact that the EHR will only become mandatory in 2021, competition between platforms has already begun. In terms of interoperability, these government requirements impose various challenges for platform providers and platform owners. This leads to the following two research questions:

RQ 1: How do PHR and their respective ecosystem develop differently over time in a highly regulated market?

RQ 2: Which specific interoperability challenges can be observed prior to the official implementation of EHRs in Germany?

In order to answer these questions, this study follows a research design in digital transformation and platformization (e.g., [11, 26]) in form of a longitudinal, processsensitive, comparative, embedded case study [9, 33]. The case will be analyzed on the basis of primary data (e.g., fieldnotes and interviews) and secondary data (e.g., press releases, professional articles, legal reforms) which will be compiled together in a digital case study database following Yin's approach [33]. In research projects with long-term data, it is particularly important to observe the research phenomenon as a changing process over the development of the research project; however, there are very few precedents of this type of research (e.g., [11]). In the context of multi-sided platforms (MSP), Fürstenau et al. [11] developed a design and management framework, which will be used to analyze and compare the differences between three selected PHR platforms in Germany during the emergence process. The framework was developed by Fürstenau et al. [11] as an extension of the integrative framework for platforms by Gawer & Cusumano [12]. It specifies the four strategic design dimensions (issues) manifested over the course of platform development and contextualizes the design of interoperability as an embedded and interdependent design parameter.

2. Conceptual Background

2.1. Multi-Sided Platforms in Germany

Besides the described differences between PHRs and EHRs, another differentiation exists between government-regulated or open solutions [6], on a regional, national or institutional level. Additionally, the storage location of health records can be either

Table 1: Types of health records in Germany

Type	Regulation	Provider/ Platform owner	Storage Location
EHR	Governmental regulation	Insurance companies	Decentralized by the service provider
PHR	By the platform owner	Insurance companies or free provider	Centralized or decentralized depending on the platform owner

centralized or decentralized (see Table 1). In Germany, the EHR will be a national, decentralized, government-regulated solution, which means that the data will be stored in the "primary information system" of the service provider who generates the EHR data. Other authorized service providers throughout the nation can retrieve requested health data. The data will be shared via the German health information exchange infrastructure, which is a nationwide secure Virtual Private Network (VPN), called Telematic Infrastructure (TI). The technical background processes as well as the user interface are supplied by the EHR provider (see Table 1) via the TI. Gematik as the lead organization is responsible for the technical specifications, standards, testing and operations of the TI. In contrast to the EHR, the PHR is specified by the providers or platform owners. Given that many different independent stakeholder groups – medical service providers, complementors of digital services, and patients – are involved, PHR Platforms can be understood as an MSP [5, 19, 32]. The success of MSPs is significantly influenced by network effects and a highly dynamic ecosystem [8, 26]. Kapoor [18] understands an ecosystem as "a set of actors that contribute to the focal offer's user value proposition" [18 p. 2]. Its actors would include, e.g., participating physicians, complementors of digital health services, insurants, and the insurance company. Concerning platforms and their respective ecosystems, Hein et al. [15] identified three central building blocks of a digital platform ecosystem, consisting of platform owner, value-creation mechanism and complementor. The *value-creation mechanism* facilitates the joint creation of value by the platform owner and complementors and provides a basis for promoting innovation within the platform ecosystem [15]. The *platform owner* basically determines the design, resources and management of the platform ecosystem [15] according to Fürstenau et al.'s [11] design and management framework. Choosing a mode of governance [26] is the responsibility of the platform owner, who also promotes innovation for the platform ecosystem, especially by third-parties who are respectively known as *complementors* [5].

2.2. Interoperability

Our understanding of interoperability is related to the approach of the IEEE [17]. For MSPs, such as PHR platforms, interoperability is an essential precondition for exchanging data [10, 4, 3]. One requirement of Fürstenau et al.'s [11] framework, and also a key competitive parameter, is that the platform must be able to achieve direct network effects through standards and interfaces [8] as well as competitive advantages through the design of the integration and binding of complementors and customers. This requires a certain degree of openness/closeness (e.g., [31]) within the platform's ecosystem, which can be achieved through the definition of governance rules for the boundary resources (e.g., [13]) and the selection of interface standards [27, 11]. In general, interoperability can be achieved through the use of standards, especially open standards. These standards can be assigned to different levels of interoperability according to their respective types. A distinction is made between technical, syntactical, semantical and pragmatic levels (e.g., [3, 25]). In order to implement a PHR/EHR system, the technical level will be represented by the IT architecture as well as its compliance to the TI. Syntactical and semantical interoperability refers to the format, especially regarding the ease of understanding the transmitted message. In order to benefit from the potential of health records (e.g., big data and machine learning algorithms), semantically interoperable data are required [21], i.e., the exchanged information must be able to be uniformly interpreted and understood (e.g., [3, 25]).

3. Method

3.1. Research design

In order to answer the research questions, an essential understanding about the process and events is required, especially regarding the regulatory changes that will occur over the course of the emergence of the EHR and PHR platforms in Germany. These are part of an ongoing parallel and sequential chain of events. We understand events to be actions, reactions or decisions made by the platform owners, conceivable complementors (stakeholders) or government. Episodes are sequences of changes, e.g., by government, and resulting actions, reactions or decisions made by platform owners or complementors, as well as actions that occur during the process of the platform's emergence. The dissemination of health platforms is dynamic, context-sensitive, and time-specific and requires a longitudinal analysis study [32]. For a more nuanced understanding, the events can be considered on different levels as well as in the context of different issues in terms of platformization. Therefore, we have chosen a longitudinal, process-sensitive and comparative perspective with an in-depth view of platformization according to the platform management framework by Fürstenau et al. [11]. The overall study is designed as embedded case study following Eisenhardt [9] and Yin [33] and focusses on contemporary events.

3.2. Case selection and data collection

Germany has one of the oldest healthcare systems in the world. It follows a solidarity principle where every citizen is insured by one of the statutory health insurance providers (numbering 105, as of January 1, 2020), with the exception of certain professional groups (e.g., soldiers, public servants, freelancers, or high earners). Measured in terms of GDP, Germany has the third highest health expenditure [24]. A deeper overview of the German healthcare system is provided by Obermann et al. [23] and Busse et al. [7]. Our study will focus on three emerging PHR platforms with the highest number of potential users and some interesting strategic differences. Two of the platform owners belong to the largest statutory health insurance companies in Germany, the AOK and the TK. In contrast to these incumbent companies, the third platform in our study is the entrant VIVY, a private company that offers a white label solution for statutory health insurance as well as for private insurance companies (see also [2]). Due to the high potential number of users and the significant differences in their PHR solutions, especially in terms of architecture, these three providers are compared in a comparative case study approach [33]. While designing our case study, we reconstructed the process of episodes as well as the relevant events involving the respective actors, including regulatory changes over time, and thus the emergence of the PHR platforms in Germany. We used different sources of data to avoid potential biases within the primary data, and triangulate the results obtained from different sources of secondary data. Table 2 presents an overview of the data used in the case study database [33].

3.3. Data preparation and analysis

The collected data is coded and structured by level of analysis, time stamp and influence directions according to the management framework developed by Fürstenau et al. [11]. Additionally, the temporal bracketing approach by Langley [20] is used to identify relevant events and episodes in the data. This structure enables a differentiation of the data and the selection of decisive events during the emergence of the EHR as well as the PHR platforms. In a further conceptualization, we distinguish between the upcoming events of different, partly interdependent levels of analysis in terms of the impact on the macro, meso or micro level (e.g., [22]). Events with a wide impact on the overall healthcare system can be assigned to the *macro level*, e.g., regulatory changes made by government. In contrast, the *micro level* will include events with a limited scope and impact, such as in a single organization or a small focus group. The *meso level* represents events in between the two, i.e., events orchestrated by the platform owner for their ecosystem or for their insurants. Events on this level have a wider impact on all their insurants and/or the respective ecosystem of the complementors of the emerging PHR platforms.

In terms of the emergence of the case, we identified three overall phases for an initial structuring of the information on the macro level in the data. During the first *Phase, I Experimental PHR phase*, the insurance companies in particular were able to gain initial experience with a PHR. In the second phase, *II Transition phase from PHR to EHR,* it became obvious that an EHR will become mandatory according to specifications. In the third phase, *III EHR becomes mandatory*, the EHR will be introduced in Germany (on January 1, 2021). After this date, every statutory health insurance company must offer an EHR to its insurants. To structure and reconstruct the events and episodes of the platform's emergence, we follow the four "issues" of Fürstenau et al.'s [11] platform design and management framework. The issues follow a platform management point of view on the micro and meso level relating to the platform owner. The first issue, *1) Developing strategy and governance model,* refers to decisions about the vision and governance structures of the platform. Decisions about the architecture and interoperability of the platform can be coded as being part of the second issue, *2) Designing technical architecture and selecting standards.* The third issue, *3) Facilitating participation and community building,* refers to actions and decisions related to developing the community around the platform ecosystem. Decisions to form alliances with

Table 2: Case study database

Document type	Document description	Documents	Pages
Participatory observations	Field notes from various events, including lectures and discussions by responsible stakeholder (from November 2018–May 2020)	31	112
Interviews	Semi-structured and formally recorded and transcribed interviews with health startups (collected in 2019 as a pre-study)	7	72
Press releases	Press releases, position papers, presentation slides, blog articles	59	246
Professional articles	Articles from professional digital health journals	28	212
Legal reforms	Legal reforms to digitize the German healthcare (2004–2020) Statements about the reforms that provide background information	6 20	598 125
Specifications	Specification documents by regulatory authorities	6	422

platforms or authorities can be assigned to the last issue, *4) Engaging with the platform's ecosystem and wider environment.* By structuring the data as described, patterns and causal relationships can be systematically established to reconstruct the case and understand the impact of partially interlinked events i.e. actions, reactions and decisions.

3.4. Case analysis of the emergence of health record platforms in Germany

3.4.1. Introduction to the case analysis. This section shows the dynamics within the emergence of the three focused PHRs/EHRs in Germany over a period of sixteen years. Starting from the regulatory changes on the macro level, the three PHR platforms on the micro and meso levels will be briefly explained. For this purpose, the events are categorized into the three distinct phases as well as the four issues identified by Fürstenau et al. [11]. Figure 1 gives an overview, with more details provided in the following subsections.

3.4.2. The case from the macro level point of view. Initially, the emergence of health records can be described from a macro perspective, i.e., essential events, particularly governmental regulations and legislation as well as the establishment of infrastructure and the definition and selection of standards, which relates especially to issues 1) and 2).

Phase I: Experimental phase of the PHR. The first identified phase starts in 2004 *(01 Jan. 2004)* when statutory health insurance companies were legally allowed to finance PHRs to improve quality and efficiency and to gain initial concrete experience in day-to-day healthcare practice provided by physicians. For twelve years (from 2004 to 2016), this self-administration was not in any way centrally managed or steered to provide a clear vision for the PHRs to interface with that of other service providers and to value-adding services to increase the attractiveness of the Telematic Infrastructure (TI). In December of 2018, gematik published the first version of an EHR, which will require an integrated application of the TI *(19 Dec.2018).* Contrary to expert opinions and European solutions with established standards, e.g., Integrated Healthcare Enterprises (IHE), gematik decided to follow a proprietary non-internationally-standardized approach, which is not interoperable with other existing solutions on a technical or a syntactical level outside of the TI, i.e. with that of other nations. The development of TI was plagued by various problems, delays, inadequate regulations, outdated technologies, etc. (e.g., [30]). These were partly caused by disagreements among the shareholders and stakeholders. Overall, this episode is characterized by the failure of the system of self-administration. The system could not gain sufficient momentum without hierarchical regulatory guidelines, due to direct and indirect network effects, and thus failed to support widespread EHR/PHR solutions. Vastly different particular interests (e.g., [28]) prevent agreement about necessary standards and specifications. After fourteen years, the government lost patience and intervened to demand greater consistency. In order to accelerate the process of digitalization of the healthcare system, the Federal Ministry of Health (FMH) took over the majority of gematik through the Appointment Service and Care Law (ASCL) *(11 May 2019).*

During this first phase, initial solutions from German providers as well as internationally dominated PHR platforms (e.g., Google, Apple, etc.), which are also considered influential and relevant by PHR platform ecosystems, became established, despite the risk of as yet unknown standards and regulations.

Phase: II Transition phase from PHR to EHR. With the ASCL *(11 May 2019),* wide-ranging regulations for EHR were established, including a date for the introduction of technical and infrastructural regulations. Additionally, the responsibilities of interoperability were clearly regulated and assigned according to layers of interoperability. Gematik is in charge of the technical and syntactical specifications of the EHR, especially the infrastructure, and the National Association of Statutory Health Insurance Physicians (ASHIPs) is responsible for establishing the syntactical and semantical specifications for the EHR content. For this purpose, so-called Medical Information Objects (MIO) are defined in order to determine the structure for health documents (i.e., doctor's letter or vaccination certificate etc.) in the EHR. Within this specification, the authorities define the regulatory framework according to issue 2), of Fürstenau et al. [11], regarding the design of the architecture and standards of the EHR. Based on this, the statutory health insurance companies can develop their own EHR/PHR solution, which puts them in direct competition with each other. With the resolution of the Digital Health Service Law (DHSL), Germany is the first country to enable the medical prescription of approved Digital Health Services (DHS) i.e., health apps *(07 Nov. 2019)* that will be financed by statutory health insurance companies, as is clearly regulated by the digital Health Applications Law (DHAL) (*15 Jan. 2020).* This allows potential complements (DHS) for the PHRs/EHRs to be supported. The DHSs are also subject to interoperability requirements in order to transfer data to the EHR, which has been enforced by the Patient Data Protection Law (PDPL) *(11 Apr. 2020).* This law represents a major breakthrough in terms of the semantical interoperability to build an interoperable digital healthcare system based on international standards with the acquisition of the license of the international semantic standard SNOMED CT. However, this only refers to the semantic part of coding and the uniform understanding of health information, but does not render the EHR interoperable internationally.

Phase: III EHR becomes mandatory. According to the ASCL, when the EHR will be introduced (*01 Jan. 2021)*, each statutory health insurance company must offer its insurants an EHR that will take effect on January 1, 2021. One year later, the official financial support for PHRs will end. There will only be a single EHR for each insured person, as provided by his/her health insurance company. Additionally, it must be possible for insurants to transfer their data to another health insurance provider in the EHR, if necessary *(01 Jan. 2022).*

3.4.3. The case of TK and AOK from the meso and micro level point of view. In order to answer the research question, how PHR and their respective ecosystem develop differently over time in a highly-regulated market, we focus in this and the subsequent section on the micro and meso level, i.e., the relevant events during the emergence of the PHR platforms. Initially, the parallels and differences of the incumbent players AOK and TK are described in more detail, whereas the entrant's player VIVY will be described in the next section (3.4.4.).

Phase I: Experimental phase of the PHR. More than twelve years after the PHR was financially supported, the AOK is establishing a PHR solution *(01 June 2016)*. For this purpose, the AOK, as the largest association of health insurance companies with a total of 26 million insurants, is choosing a decentralized approach, i.e., the data will be stored by the healthcare provider who creates the health data for its patient. In terms of data access and exchange, the AOK is following international standards, particularly IHE integration profiles on technical and syntactical levels. The AOK seeks to establish a health network for the service providers, which relates to issue 3) by Fürstenau et al. [11] *(13 Sept. 2016* and *10 Oct. 2017)*.

The second largest health insurance company in Germany with around ten million insurants is also developing a PHR *(21 Feb. 2017)*. In contrast to the AOK, the TK are following a centralized approach to data storage and developing the PHR together with their cooperating company, IBM (IBM Watson, see also [2]), which has many years of experience in data-hosting and artificial intelligence (AI) in healthcare. With regard to the above-cited vision of the TK, its cooperation with IBM illustrates the added value that the TK can offer. This enables TK to operate a preventative care management by offering e.g. AI-based value-added services to its insurants. Despite the different strategies and architectures (centralized/ decentralized) relating to issues 1) and 2 by Fürstenau et al. [11], the two largest insurance companies, AOK and TK decide to cooperate as co-opetition [27] *(11-Dec-2018)* to enable data exchange among hospitals, insurance companies and PHRs via an interface based on the international IHE standard *(11-Apr-2019).*

Phase: II Transition phase from PHR to EHR. Following the publication of the specifications by gematik and ASHIP, both insurance companies (AOK & TK) will be developing an EHR. Given the differences between the existing PHR solutions and the specified EHR in terms of architecture – according to a decentralized approach and interoperability following non-internationally standardized approaches – both platform owners decided to continue to offer their PHRs as an encapsulated solution. With their PHR platform, platform owners can offer complementary services to differentiate their business from the competition, while retaining the flexibility and control according to their own risk aversion (development risks).

Relating to issue *4*) *Engaging with the platform's ecosystem and wider environment* [11], the AOK organized a community event with health startups to expand its PHR ecosystem, and to attract innovative services to their platform, as part of their offering to their insurants (*07 Nov. 2019)*.

Phase: III EHR becomes mandatory. As of January 1, 2021, all statutory health insurance companies are required by law to offer an EHR. One year later, insurants have to be able to transfer their EHR data to another statutory health insurance company, to allow insurants to switch. However, this only refers to interoperability of the specified EHR and not the PHR itself. Thus, some personal data and PHR specific services may not be transferable unless explicitly stipulated by law.

3.4.4. The case of VIVY from the meso and micro level point of view. VIVY and its main shareholder Allianz (70%), offers a PHR solution for other health insurance companies. With the Allianz-Group, VIVY has an economically powerful partner which is one of the world's leading insurance groups. However, Allianz in Germany focuses on private insurance and asset management products. In contrast to AOK's and TK's solutions, VIVY follows a centralized mobile approach with a greater focus on user experience and the autonomy of the data that comes through storing the data encrypted on the insurants' mobile devices (see also [2]).

Phase I: Experimental phase of the PHR. The IT service provider of the statutory health insurance companies (Bitmarck) assigned VIVY the contract to provide a PHR for their customers (statutory health insurance companies); therefore, VIVY became a supplier of PHRs for private and statutory insurance companies *(01 May 2018)*. On September 17, 2018, VIVY released its PHR. Consequently, VIVY became the first platform owner of a PHR to provide a nationwide solution for all insurants of the contractual health insurance companies. This triggered network effects and VIVY quickly acquired additional health insurance companies *(22 July 2019)*. At the time of writing (Oct. 2020), VIVY's ecosystem includes twenty-nine statutory health insurance companies and four private health insurance companies, each with their own instance of PHR. A potential 19,4 million insurants can use their PHR. Additionally, VIVY is cooperating with several hospitals on the expansion of their ecosystems *(12-Aug-2019)*.

Phase: II Transition phase from PHR to EHR. After the announced specification and date of the EHR, VIVY will not offer an official EHR for statutory health insurance companies. Its strategy for this decision remains unclear, but may be based on the large architectural differences between its product and the general EHR specifications and regulatory requirements, or based on the fact that the customer group of the statutory insured do not fit the strategic focus of its shareholders. Therefore, the contract has been awarded to the provider RISE. Nevertheless, VIVY will still be seen by the contract partner as a provider of innovative solutions to connect complementors e.g., digital health applications such as Digital Health Service (DHS), and to offer innovative health services via their mobile PHR solution.

4. Discussion

In order to answer the research questions, the key events in the emergence of the EHRs and PHR platforms were structured into phases and levels to show—on the basis of longitudinal data—how the ecosystems of the PHR platforms emerge. As a result, interoperability challenges at single points of time could be derived from the perspective of the respective stakeholders.

Platform owners' point of view*:* An initial challenge is the appropriate *1) timing of designing technical architecture and selecting standards,* reflecting issue 2) by Fürstenau et al. [11]. During Phase I, the three platform owners have demonstrated a possible PHR design, showing how an EHR could potentially be structured in order to enter the

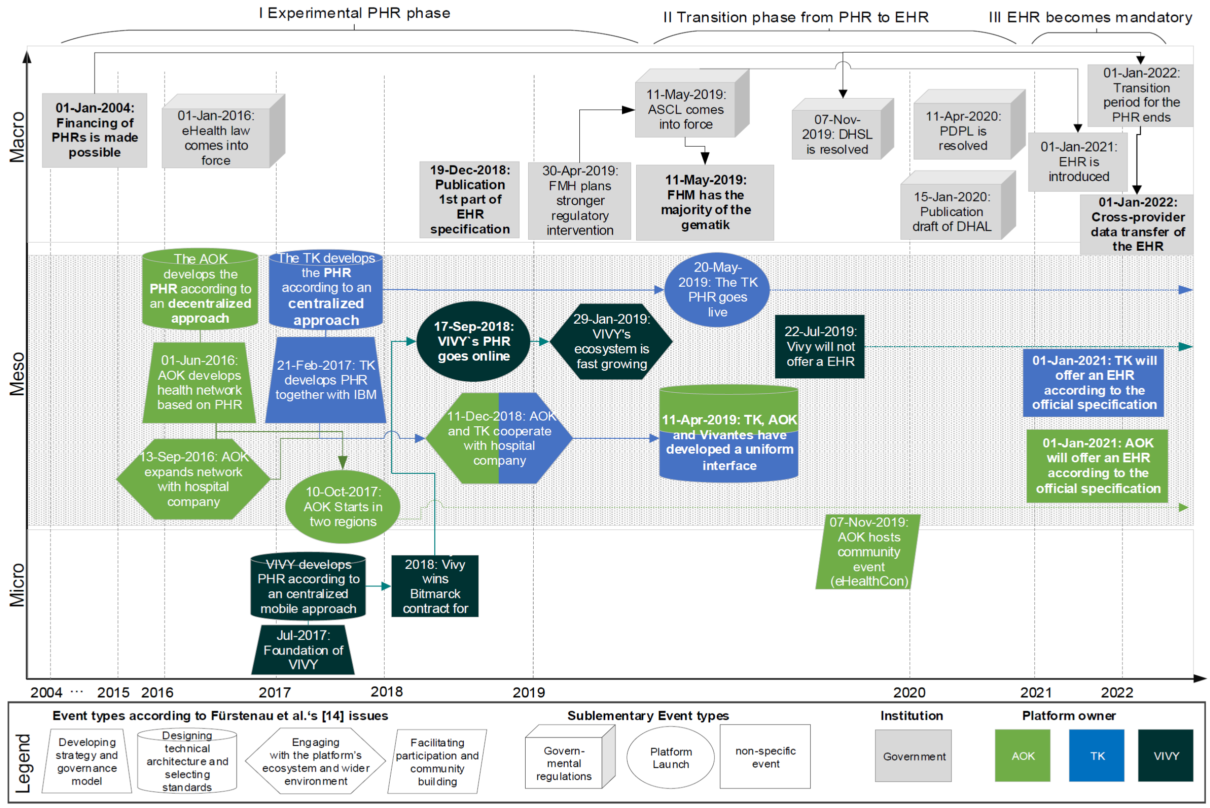

Figure 1. Emergence and dynamics of three PHR platforms in Germany

discussion about technical and syntactical interface specifications on the macro level with gematik and the Association of Statutory Health Insurance Physicians, among others, during the transition to Phase II. This gives providers the opportunity to start diffusion processes at an early stage to promote network effects around their respective solutions and emerging ecosystems. At the same time, there is an investment and *2) the development risk of interfaces*, especially in times of uncertainty regarding the final specifications. The uncertainty that characterized the transition from phase I to phase II is likely to have resulted in costs due to adjustments that had to be made to the interfaces, especially on a technical and a syntactical level. The platform owners AOK and TK have shown how an interface can work according to international standards, as it was to be expected that gematik would follow these standards. However, the published specification of the EHR does not follow IHE, the established international standard. Due to the high level of adaptation of the existing system, AOK and TK decided to develop separate solutions according to the national EHR specification. Therefore, the PHR from AOK and TK will be offered as an additional MSP-offering that fulfill the regulative basic affordances of an EHR but maintain the control and flexibility of the platform while promoting innovation and avoiding further development risks for their ecosystem. In contrast to the EHR, the platform owners of the PHR are free to make decisions about the design of the interfaces. This relates to issues 1) and 3) by Fürstenau et al. [11], and the degree of openness [31] via interfaces [27]. Platform owners have to *3) choose the appropriate Governance Mode* [26] on the meso and micro levels of the platform's ecosystem for co-opetition with competitors, and cooperation with complementors [27] regarding interoperability requirements to promote innovations, e.g., by complementors such as Digital Health Service (DHS). The case of the co-opetition with the two incumbents AOK and TK shows that two competitors with partly different customer groups and a different platform architecture can cooperate in order to avoid being displaced by new entrants and to build solid and partly interoperable PHR platforms.

Complementors' point of view: This case also highlights the challenges for complementors. This includes *4) interoperability as a financing criterion* of digital health services e.g., health startups, to be approved as (DHS) in the context of Germany. Therefore, interoperability has to be an integral part of the strategy to get financial support from statutory health insurance companies. Furthermore, interoperability via standard interfaces is a basic requirement of complementors connecting to PHR/EHR platform ecosystems [3, 4, 10, 11]. In Germany, this concerns at least five health startups during Phase II that have officially approved as DHS (fifteen have applied and will be reviewed, status as of November 2020) in order to be prescribed by physicians and reimbursed by the insurance companies. The different architectures of the platforms and governance modes of the platform owners result in another challenge for the complementors, namely to also *5) choose the appropriate platform in terms of interoperability.* In addition to criteria relating to the size of the ecosystem and to potential users of the platforms, interoperability considerations are crucial, e.g., with regard to the type and nature of the data/information needed from the EHR and/or PHR. The adaptation effort to the PHR platform would be relevant in this context for the complementors. From a technical/syntactical point of view, the complementors has to determine whether the service requires the data/information from the EHR, e.g., doctor's reports, examination results, or from the PHR, such as self-collected vital parameters by the insurants. AI-based services, for instance, as probably intended e.g. by TK with its partner IBM Watson require more stringent interoperability requirements and semantic standards than less extensive services [21]. Based on well-coded health data/information, e.g., SNOMED CT, AI-based services can deliver better results [21]. Another factor arises among the different architectures of the platform (centralized/ decentralized) and respective access via e.g., standardized or less standardized interfaces – the amount of effort necessary for the integration depends on this. The respective adjustments and the threat of switching costs (for additional platforms, etc.) results in *6) binding effects* for the complementors. Platform owners try to avoid multihoming, for users as well as complementors [29]. Detailed solutions within and between the emerging platform ecosystems, especially on a technical level, will be too different, e.g., in the case of VIVY. The health data would be stored directly on the device and could be accessed e.g., by App-based services provided by the complementors, whereas in the case of AOK, the data would be stored in various decentralized IT infrastructures and would have to be retrieved first. This included necessary specifications for the concrete design and linking of business and supply processes, the coding of treatment and billing details, the supplementation of the regulatory EHR mandatory elements, and additional possibly ecosystem-specific value-added services.

Insurants' point of view: The case also shows some challenges for platform users, including the patients/insurants. When an insurant decides to switch their health insurance company, she/he can transfer her/his EHR-specified data to the platform of the new statutory insurance company (from January 1, 2022). However, this does not apply to the additional data held in the PHR. Depending on the insurants' personal data and additional, in some cases PHR-exclusive/specific services, switching costs will result. This can lead to *7) lock-in effects* to the initial platform and thus to the respective statutory health insurance company, effectively preventing multihoming by the platform owners [34]. This aspect would also be interesting regarding whether and what kind of role the emerging tech platforms and ecosystems of Apple, Google or Amazon, etc., will play and whether and how their health services can be tackled, integrated or combined with the respective PHR strategies by the incumbents, as mentioned by Thomas Ballast in his statement (p. 1). Apple, for example, is using the FHIR standard to integrate further health services, and it remains to be seen whether this will also apply to other record solutions.

5. Limitations and outlook

The analysis and discussion of the case-study has certain limitations and carries implications for further research. In this study, the management and design framework by Fürstenau et al. [11] was applied from an external point of view, i.e., in some cases detailed background information would be necessary to elaborate on further instances. For the structuring of the events, three supplementary event types (governmental regulations, platform launch and non-specific event) were used (see Figure 1). Some of the identified aspects are closely linked to this specific German case and are therefore not generally valid, which would have to be examined individually in future studies.

As a brief outlook for this case, three aspects merit being further examined in future research. First, in response to the initial TK quote, it will be interesting to see if and how the relationship between the incumbent ecosystems and international tech giants like Google, Apple and Amazon will develop, considering that they have stated their intention to target health as their next big frontier. A "battle of the platforms" can be expected, which will be shaped by network effects and the decisions of complementors and insurants as well as regulators in response to the chosen strategies of the respective platform owners. Second, platform owners have to compete with each other for domination of the PHR/EHR market segment from 2021 onwards. The effects their chosen strategies will have on the attraction of complementors would represent another avenue for future study, particularly concerning platform architectures. Third, it would help to understand the internal view of complementors, including what challenges they perceive and how they deal with them. The existing demand for technical and economic strategies and principles during the emergence of EHR and PHR platforms in order to handle these challenges should be addressed in further research, e.g., following a design-oriented approach.

6. Conclusion

The study makes the following contributions: First, in contrast to what we know about interoperability and platforms as pre-conditions [3, 4, 10] and design parameters [11, 19], especially in terms of openness [27], this study reveals the central role played by interoperability as a design parameter for emerging MSPs, and contributes to the interoperability discussions of MSPs, especially in healthcare. As part of this we identified seven key challenges for stakeholders, which are: For platform owners: 1) the timing of designing technical architecture and selecting standards, especially in periods of high uncertainty, especially 2) to avoid the development risk of interfaces and resulting adjustments; 3) platform owners have to choose the appropriate governance mode to balance interface openness, e.g., with competitors and complementors. 4) Interoperability can be a criterion for funding or reimbursement and should form part of their strategy, especially for complementors. 5) Complementors also have to choose the appropriate platform to generate interoperability i.e., interfaces and data composition. 6) Proprietary adaptations to an ecosystem can also lead to binding effects. 7) From the perspective of the insurants, there are also challenges resulting from the lack of interoperability between PHR and other platforms, which may result in lock-in effects for the insurants to various, perhaps converging platforms of incumbents and entrants in health as one of the next big "digital transformation battle fields". Second, a discussion and comparison between PHR platforms and the EHR points out the strategic differences between the three providers, which also leads to divergent architectural and interoperability challenges for complementors, insurants, and not least for platform owners themselves. Third, the study provides an overview of the significant changes in the German healthcare system triggered by digitalization and the emergence of MSP platforms and the EHR. Fourth, the discussion about the challenges has implications that can inform researchers as well as insurance companies or technical health service provider e.g. of health platforms, in Germany and also in other countries.

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P3 – Future-Oriented and Patient-Centric? A Qualitative Analysis of Digital Therapeutics and their Interoperability

Author Contribution Statement

The purpose of this statement is to give appropriate credit to each author for their role in the preparation and writing of the paper listed below. I would like to take this opportunity to thank all the co-authors for their contribution. By signing this form, all persons listed as authors acknowledge the contributions made to the specified paper in terms of role and a percentage of the overall amount of work (see below).

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Ideation:	equal	equal	support
Conceptualization:	equal	equal	support
Research design:	equal	lead	support
Data collection:	equal	equal	equal
Data investigation:	equal	equal	support
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Review & editing:	equal	equal	support

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Contributions

Ideation:	support	support	–
Conceptualization:	support	support	–
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Data collection:	equal	equal	equal
Data investigation:	support	support	–
Writing:	support	support	–
Review & editing:	equal	equal	–

Signatures

Place & date: Signature:	____________	____________	____________

The paper was part of the research project DIGIOP. DF acquired the funding for the project, served as the project manager, and worked together with the partners on the project. The associated partners included Charité, represented by RG; the Berlin Institute of Health, represented by AB; the Freie Universität Berlin, represented by MG and LS; and Fraunhofer FOKUS, represented by AH and MW. All authors involved contributed to the data collection. The conceptualization of the paper, data analysis, and writing were primarily carried out by LS and DF. RG and AB contributed to the development of specific subsections. After an initial submission, where constructive feedback was received, the paper underwent intensive revision. LS took the lead in incorporating conceptual additions and elaborating on the implications of the results, working closely with DF. The authors' team provided support during the editing and review process.

P4 – Interoperability Maturity Model: Orchestrator Tool for Platform Ecosystems

Author Contribution Statement

I would like to take this opportunity to thank all supporters of this contribution. By signing this form, the author acknowledge the contributions made to the specified paper in terms of role and a percentage of the overall amount of work (see below).

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Conceptualization:	lead
Research design:	lead
Data collection:	lead
Data investigation:	lead
Writing:	lead
Review & editing:	lead

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Place & date:	
Signature:	

Background on the origins of the paper: My mentor Prof. Gersch supported the idea of condensing the research from the previous work into an artifact in the form of a maturity model and publishing it as a single-author paper. He provided valuable suggestions and support with questions and in establishing empirical contacts.

Part III.

Appendix

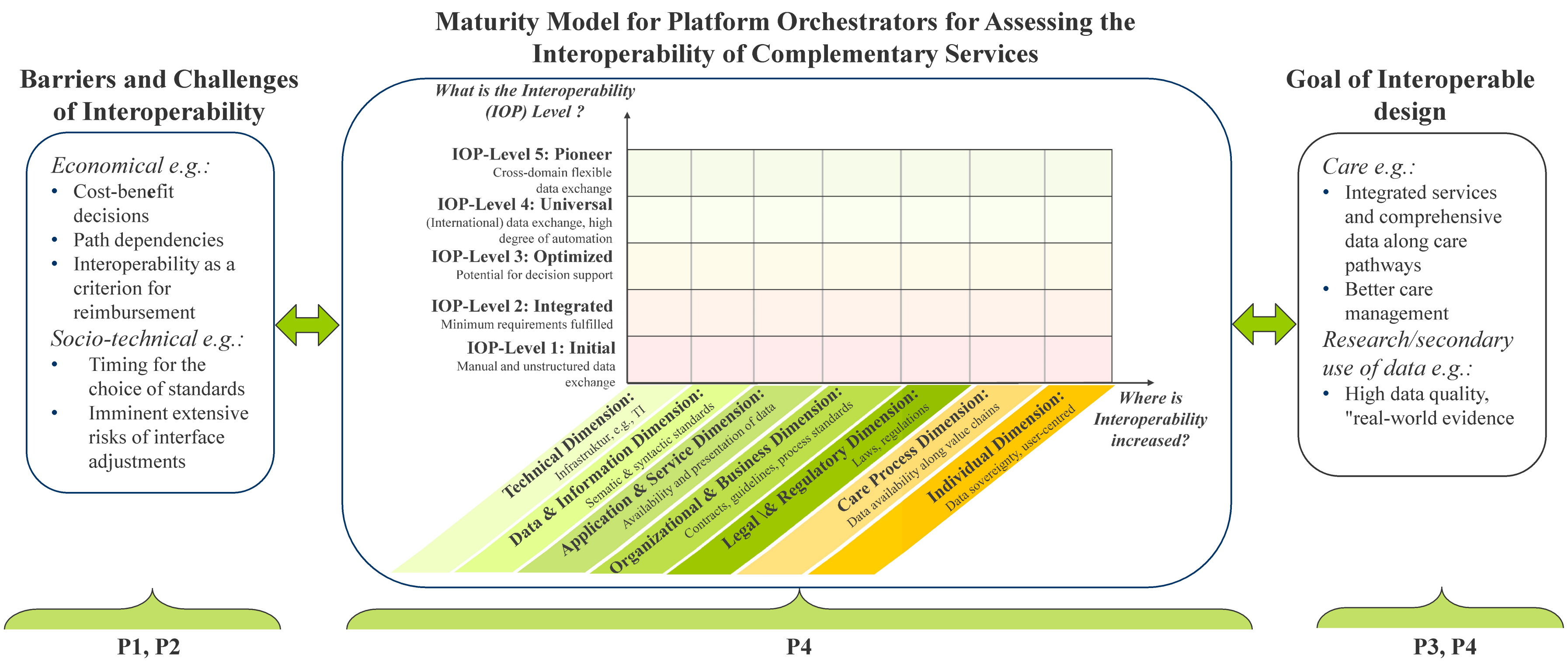
A1 – Interoperability related digitization laws in Germany

Act title[21]	**Act title in German**	**German acronym**	**Status**	**Year**[22]	**Frequency of the term Interoperability**[23]
Statutory Health Insurance Modernization Act	Gesetzliche Krankenversicherungs-Modernisierungsgesetz	GMG	Resolved	2004	0
Act for secure digital communication and applications in the healthcare sector (E-Health Act)	Gesetz für sichere digitale Kommunikation und Anwendungen im Gesundheitswesen (E-Health-Gesetz)	E-Health-Gesetz	Resolved	2015	31
Hospital Structure Act	Krankenhaus-Strukturgesetz	KHSG	Resolved	2015	0
Digital Supply Act	Digitale-Versorgung-Gesetz	DVG	Resolved	2019	2
Appointment Service and Care Act	Terminservice- und Versorgungsgesetz "	TSVG	Resolved	2019	2
Hospital Future Act	Krankenhaus-zukunftsgesetz	KHZG	Resolved	2020	1
Patient Data Protection Act	Patientendaten-Schutzgesetz	PDSG	Resolved	2020	52
Health IT Interoperability Governance Regulation	Gesundheits-IT-Interoperabilitäts-Governance-Verordnung	GIVG	Resolved	2021	6
Digital health applications regulation	Digitale-Gesundheits-anwendungen-Verordnung	DiGAV	Resolved	2021	14
Act on the Further Development of Healthcare care	Gesetzes zur Weiterentwicklung der Gesundheitsversorgung	GVWG	Resolved	2021	0
Draft law on the consolidation of cancer registry data	Entwurf eines Gesetzes zur Zusammenführung von Krebsregisterdaten	Krebsregister	Resolved	2021	18
Digital supply and care - Modernization Act	Digitale Versorgung und Pflege - Modernisierungs-Gesetz	DVPMG	Resolved	2021	24

[21] English translation
[22] Year of publishing
[23] in German

Health IT IOP Regulation	Gesundheits-IT IOP-Verordnung	GIV	Resolved	2021	4
Regulation on the reimbursability of digital care applications	Verordnung zur Erstattungsfähigkeit digitaler Pflegeanwendungen	VDiPA	Ministerial draft	2022	10
Digital Act	Digital-Gesetz	DigiG	Ministerial draft	2023	207
E-prescription specialist service interfaces Prescription	E-Rezept-Fachdienst-Schnittstellen Verordnung	EFSVO	Ministerial draft	2023	1
Health Digital Agency Act	Gesundheits-Digitalagentur-Gesetz	GDAG	Ministerial draft	2024	53
				Total:	**425**

A2 – Summary of the Paper Results



Eidesstattliche Erklärung

Ich versichere hiermit, dass ich die hier eingereichte Dissertation

Managing Interoperability of Digital Health Platform Ecosystems

selbständig und ohne fremde Hilfe angefertigt habe. Von mir wurden keine anderen als die angegebenen Quellen oder Hilfsmittel benutzt.
Ich habe alle von anderen Autoren wörtlich übernommenen Stellen, wie auch die sich an die Gedankengänge anderer Autoren eng anlehnenden Ausführungen, meiner Arbeit besonders gekennzeichnet und verwendete veröffentlichte wie unveröffentlichte Quellen zitiert.
Diese Arbeit hat in gleicher oder ähnlicher Form noch keiner anderen Prüfungsbehörde vorgelegen.

Berlin, den 03. Juni 2024

. . . .

(Datum, Unterschrift)