

# The Emergence of a New European Data Economy: A Systematic Research Agenda for Health Data Spaces

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Data space initiatives, including Gaia-X and the European Health Data Space (EHDS) regulation proposal, aim to establish a decentralized infrastructure for data exchange following European values such as citizen-centricity, transparency, and data sovereignty. European regulators did not only set statutory framework conditions but actively combined technical and regulatory aspects to initiate the co-development of a supranational reference architecture. This frames a novel direction towards a European data economy and is therefore supported with public funding of (research) projects in nine domains, starting with healthcare. Health data spaces represent a transformational endeavor that could fundamentally alter the established platform strategies of dominant organizations. We contribute a systematic research agenda that examines how scholars can harness research opportunities afforded by health data spaces. We propose abduction, action design research, design science research, and behavioral science research as promising approaches to study this phenomenon at different levels of analysis.

## 1. Introduction

In Europe, medical service provision has so far been impaired by nation-specific regulatory barriers and a multitude of mostly paper-based processes, limiting the transformation towards a digitalized and interconnected value chain (Auschra 2018). One example of improving health services through digitalization is provided by precision medicine, whereby healthcare offerings are tailored to patients' individual needs using a data-driven decision-making approach (Kosorok & Laber 2019). It requires service ecosystems to access data from different sources and ensure the growing interconnection between stakeholders (Antman & Loscalzo 2016; Baumgart 2024). The embedding of service systems results in a modular "system of systems", which facilitates the collaboration and data exchange between integrated actors (Holler et al. 2022; Klein & van Vliet 2013). However, interoperable data exchange between most actors in healthcare is still limited, and unharmonized data in clinical information systems is omnipresent. This hinders data flows across organizational boundaries and prevents the provision of integrated, continuous, and data-based patient-centered services (Panch et al. 2019). The lack of coordination between decentralized self-governing health institutions



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results in heterogeneous architectures and standards, which impede innovative services (Busse et al. 2017).

GAFAM (Google, Apple, Facebook, Amazon, Microsoft) have recently underlined their ambitions to capture the digital health industry (Gleiss et al. 2021). This development marks one of the most significant legal, economic, and regulatory challenges for the European Union (EU) (Cabral et al. 2021). One challenge in this fast-changing environment is to compete against the advantages associated with GAFAMs' platform network effects, leading to winner-takes-all dynamics, power imbalances, and information asymmetries (Gawer 2022; Gleiss et al. 2021; Gregory et al. 2021; Rowe & Markus 2022). Dominant organizations control the terms of use to restrict competition (Kölbl et al. 2023), leading to an unequal value distribution among actors (Perscheid et al. 2020). For years, Europeans have focused on various regulatory attempts to limit or correct these problems and drawbacks (Kuebler-Wachendorff et al. 2021). In 2019, the European Commission defined its vision for the future of the European data economy. It allocated a budget of two billion euros to data infrastructures such as Gaia-X and thereby started to design countermeasures actively (European Union 2020). This initiative aims to transform how organizations create value by using decentralized data infrastructures. By actively positioning the principles of citizen-centricity, data sovereignty, and data protection when developing data spaces, the EU tries to underline a strategic competitive advantage made in the EU (Autolitano & Pawlowska 2021).

Data spaces are open platform ecosystems managed by a legitimized orchestrator that institutionalizes an alliance of different organizations (Curry et al. 2019). Hence, they are built on a participatory governance configuration with decentralized infrastructures that distribute power among stakeholders. They facilitate collaboration by enabling actors to transfer and reuse data based on jointly established values, goals, and standards (Beverungen et al. 2022; Otto & Jarke 2019). Data spaces pose implications for the ongoing transformation processes on macro, meso, and micro levels of analysis, as they will fundamentally change institutional, technical, and even organizational framings of value co-creation.

In May 2022, the European Commission published the European Health Data Space (EHDS) regulation proposal, which reflects the first sector-specific data space initiative (European Commission 2022a). As part of the European digital strategy, data spaces in eight other domains will follow (European Commission 2020). The EHDS tries to unleash the potential of a data economy while avoiding the threat of future healthcare market imbalances created by large organizations that lock in valuable data (Ferretti 2022, Genovese et al. 2022). It frames an emerging health

data-sharing economy by establishing the infrastructure, governance model, and interoperability framework to create a single European digital health industry (Hussein et al. 2023). The value creation processes for service developers, providers, and patients are set to shift from single, isolated services to interconnected systems and standardized policy rules to foster the creation of data-based service ecosystems (Hanelt et al. 2021; Riasanow et al. 2019; Vial 2019).

Health data spaces open novel and interesting opportunities to scientifically accompany emerging transformation projects for information systems (IS) and service management researchers. However, the emergence of health data spaces is a complex phenomenon encompassing intertwined technological, regulatory, and managerial perspectives, resulting in a large-scale supranational data infrastructure. While researchers can shift from the role of an ex-post observer to an active contributor in an organizational setting, the rapid development of such initiatives stretches the limits of inductive or deductive research approaches, as they either explain problems retrospectively, ex-post or cross the line into speculation (Sætre & van de Ven 2021). Consequently, this paper raises the following research question: *"How can research on health data spaces be systematically presented, and what methodological considerations can be adopted to understand them comprehensively?"*

To answer this research question, we adopt an iterative research design developing research agenda items, structuring them in a systematic research agenda, discussing a first version in a workshop with 37 participants, and evaluating it iteratively with 10 domain experts. We present the final systematic research agenda that is based on existing research in the service systems research and engineering domain, drawing specifically on three different areas, namely: (1) Abductive, conceptual-theoretical, and empirical transformation research with methodical implications toward Action Design Research (ADR), (2) Design Science Research (DSR), and (3) Behavioral Science Research (BSR) approaches. To provide a nuanced perspective towards researching health data spaces, we distinguish between macro, meso, and micro levels of analysis and separate between their development and operational phases. We argue that health data spaces require advanced methodological approaches to produce research results and artifacts that are timely, relevant, and practical. Abduction can frame an early exploration into health data spaces. As researchers are an active part of consortia co-developing health data spaces, they can also adopt ADR to ensure the artifact's relevance by implementing it into the organizational setting and simultaneously evaluating its real-world implications (Sein et al. 2011). Finally, we argue that further research on health

data spaces should be interdisciplinary, process-orientated, and linked to ongoing real-time developments.

The paper is structured as follows: Next, we summarize current technological and regulatory initiatives to provide an overview of health data spaces and reflect on their current state of research. Then, we describe our research design. Next, we introduce how researchers can explore the phenomenon of health data spaces through the lens of different research paradigms. By providing a research agenda, we systematically outline future research areas. Then, we critically discuss our methodological considerations and reflect on the implications for different stakeholder groups. Finally, we conclude our work by giving recommendations for information systems and service management research.

## 2. The Emergence of European Health Data Spaces

### 2.1. Technological Initiatives to Develop and Operate Health Data Spaces

Currently, existing digital platforms are often controlled by keystone organizations that concentrate power over participating actors and lock data and services into that ecosystem (Gleiss et al. 2021; Rowe & Markus 2022). By contrast, the objective behind the European Gaia-X initiative is to establish a reference architecture for data spaces that establishes sovereign exchange of data by design and distributes platform ownership among actors (Braud et al. 2021). Gaia-X aims at interconnecting the data infrastructures of the participating actors by providing core services that enable decentralized, secure, sovereign, and transparent data exchange that can be the basis for emerging data ecosystems (Otto 2022). Thereby, Gaia-X develops the technical specifications, a “standard of standards” including data models, and a reference implementation for open-source core services that are necessary to enable sovereign data exchange in decentralized data management infrastructures. To ensure compliance with the jointly defined principles, Gaia-X accredits comple-mentors and their services by establishing identification and authentication services, registries, and certification mechanisms (Braud et al. 2021). The German and French ministries fund projects encompassing public and private organizations that started to build data spaces in different domains (Federal Ministry for Economic Affairs and Climate Action 2021a, 2021b).

Data spaces are based on a decentralized data infrastructure that provides services and usage policies according to specified design principles (Otto 2022; Otto & Burmann 2021). Data ecosystems emerge from various interactions and exchanges between data space participants (Braud et al. 2021). The actors can be natural

or legal entities with digitally unique identities that can take up different roles, including that of data holder, data user, and business-to-business (B2B), business-to-costumer (B2C), or business-government (B2G) service provider. Examples include Infrastructure-as-a-Service (IaaS), platform-as-a-service (PaaS), software-as-a-service (SaaS), or, specifically for the health domain, software-as-a-medical-device (SaaMD) (Carroll & Richardson 2016). The relationships between actors are guided by the technical-institutional arrangements of defined infrastructures, services, and usage rules (Gelhaar et al. 2021a; Jacobides et al. 2018). To create a mostly self-governing service ecosystem and prevent lock-in or lock-out effects, Gaia-X builds on the concepts of distributed cloud computing and implements machine-readable rules in its infrastructure layer (Otto & Burmann 2021). Hence, the technological difference to a traditional cloud architecture lies in the absence of a centralized infrastructure that stores and processes data. The data remains in the distributed infrastructures and is only accessible if the data holder and data user agree on a specific interaction scope (Otto 2022).

Figure 1 summarizes the implicit layered reference architecture for the health domain. The *infrastructure layer* encompasses open-source federation services that enable actors to manage identities, authentication, authorization, and sovereignly exchange data. Data holders and users can adopt the Gaia-X connectors to establish a bilateral connection and enable the data holder to consent to data exchange by specifying what kind of data can be accessed, for how long, under which terms of use, and for whom. The connector enforces the agreed-upon machine-readable terms of use and protects the data from unauthorized access (Otto & Burmann 2021). The *data exchange layer* builds on the infrastructure layer to establish a data ecosystem with data holders and data users sovereignly exchanging data. This can also include data intermediary services that support the data discovery (e.g., meta-data catalogs and registries), aggregation, and curation processes of data users. Building on both layers, an *ecosystem layer* can emerge from the interaction and relationships of heterogeneous actors that leverage data to drive innovation by developing and offering data-driven services and business models (Beverungen et al. 2019; 2022). They are guided by the technical-institutional arrangements of the defined infrastructures and the individual terms of use (Jacobides et al. 2018; Marcelo et al. 2019).

The first research stream adopted a *technological perspective* on data spaces and emerged in the 1990s as a design proposal for an architecture adopting distributed data integration concepts (Olesen et al. 1997). The related research stream focuses on intermediary data management services integrating distributed data from heterogeneous sources, identification of identities and relation-

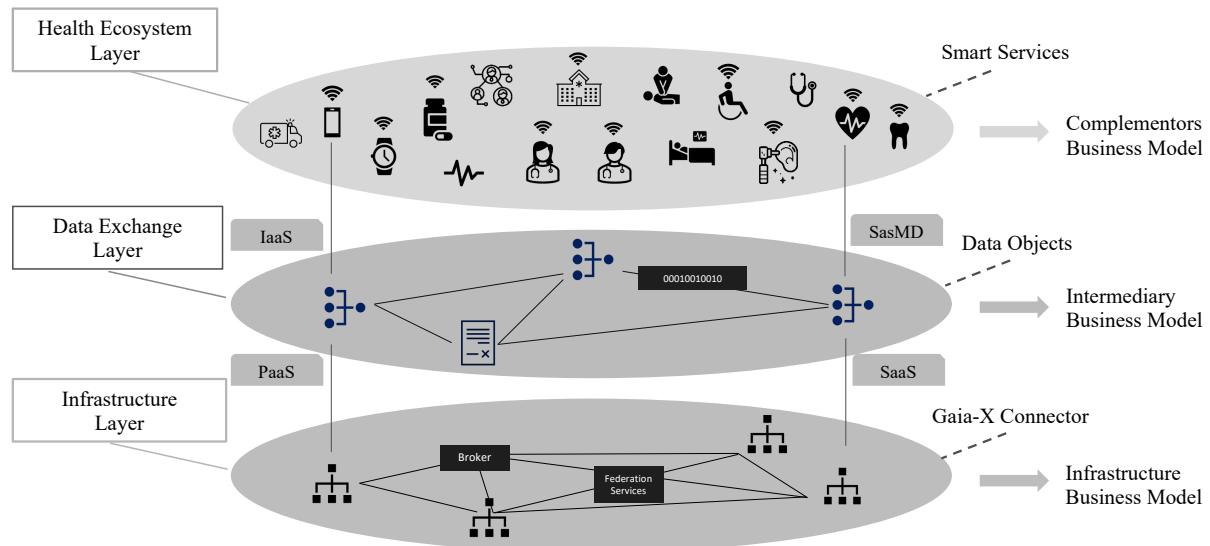


Fig. 1: Gaia-X Reference Architecture for compliant data infrastructures in the healthcare domain inspired by Otto & Burmann (2021, p. 285).

ships between data instances, and interoperability fostering decentralized data ecosystems (Curry et al. 2019; Guo et al. 2021). A second research stream explores data spaces from a sociotechnical perspective. It addresses the design and management of alliance-driven data platforms. Constructing data spaces as platform ecosystems, they describe how multiple actors can develop and collectively manage their decentralized architecture to distribute ownership and foster open, sovereign ecosystems (Otto & Jarke 2019; Beverungen et al. 2022). This enables the emergence of business networks where actors build data-driven services to co-create value (Nativi et al. 2021).

## 2.2. The European Health Data Space Regulation Proposal

In May 2022, the European Commission published the EHDS regulation proposal (European Commission 2022b). It calls for a “cross-border flow of electronic health data and to foster a genuine internal market for electronic health data, digital health products and services” based on European values such as data sovereignty (European Commission 2022b, p. 8). Building on previous regulations, e.g., the General Data Protection Regulation, Data Service Act, and Data Governance Act, all EU member states are obliged to directly implement necessary technological and organizational capabilities for the emergence of health data spaces (Ferretti 2022; Genovese et al. 2022). The Commission accompanied these developments with two billion euros in public funding for technological federated infrastructures such as developing data spaces (European Commission 2018; 2020).

The EHDS specifies roles, primary functions, rights, and duties for a fair data exchange (Shabani 2022). The Commission is responsible for supporting member states in institutionalizing and establishing a cross-border data exchange, enforcing individual data sovereignty, and enabling secondary use of pseudonymized or anonymized health data for services beneficial to the public (Marelli et al. 2023). Secondary health data refers to usage scenarios not primarily intended for when the health data was collected (e.g., research, creating innovations, regulatory interventions, and training artificial intelligence). The EHDS obligates data holders to make the data available for secondary data use scenarios contributing to the public good. Each member state shall comply with the EHDS by appointing at least one Health Data Access Body (HDAB) and Digital Health Authority (DHA). The HDAB receives data use applications from potential data users and reviews their intended contribution to the public benefit. The HDAB must reject data use applications that harm individuals or the collective, such as increasing insurance premiums or marketing initiatives. With those terms and regulations, the EHDS proposal aims to encourage individuals to take control of their health data while also defining conditions in which the data can be used if a citizen does not actively object. Table 1 lists all roles and primary functions in the EHDS, and Figure 2 illustrates the relations between the identified roles. In December 2023, the Parliament voted on its position on the EHDS, leading to current negotiations between the Parliament, EU member states, and the EU Commission in a so-called triilogue. This process is expected to be completed in March 2024, resulting in a

one-year transition period until the regulation is expected to come into force in all EU member states in the first half of 2025.

The novelty of health data spaces is reflected by the current state of scientific literature on health data spaces, which so far does not contain information systems or service management publications in top journals or conferences. Only a few researchers from other disciplines, such as Horgan et al. (2022), Genovese et al. (2022), Marelli et al. (2023), Raab et al. (2023), Nicholson et al. (2023), and Hoeyer et al. (2024) represent some instances of publications on health data spaces. These papers explore EHDS implications. Horgan et al. (2022) and Genovese et al. (2022) highlight benefits that could arise from leveraging health data and fostering stakeholder engage-

ment, including different stakeholder groups, by adopting chronic disease management and patient outcomes. Raab et al. (2023) and Nicholson et al. (2023) contribute high-level architectural propositions on how the EHDS can be implemented and integrated with the existing digital health infrastructure, such as electronic health records (EHRs). Hoeyer et al. (2024) establish a socio-technical perspective on health data spaces highlighting tensions between stakeholders' interests, such as individuals' data sovereignty, versus the collective societal interest in data use for secondary purposes. Marelli et al. (2023) critically reflect on neglecting patient data control, the complication of the work of health professionals and researchers through the proposal, and the potential degradation of generated public value through health data sharing.

Tab. 1: Roles, executing actors, primary functions, and responsibilities in the EHDS proposal. Own representation based on the EHDS proposal (European Commission 2022b).

Role	Actors	Primary Function
Supranational Regulator	European Commission	<ul style="list-style-type: none"> <li>■ Providing the regulatory framework for the EHDS</li> <li>■ Facilitating cross-border data exchange</li> <li>■ Supporting member states in developing security standards</li> </ul>
Supranational Orchestrator	European Health Data Space Board	<ul style="list-style-type: none"> <li>■ Supporting member states in coordinating practices between DHAs</li> <li>■ Linking activities regarding the primary and secondary use of electronic health data</li> </ul>
National Orchestrator	Member States	<ul style="list-style-type: none"> <li>■ Appointing and establishing a national HDAB and DHA</li> <li>■ Establishing data access services at regional and national levels</li> <li>■ Ensuring national EHDS compliance</li> </ul>
National Supervisory Body	Digital Health Authority (DHA)	<ul style="list-style-type: none"> <li>■ Monitoring compliance with personal data rights</li> <li>■ Ensuring the adoption of regional or national rules and mechanisms</li> <li>■ Monitoring data spaces and avoiding conflicts of interest</li> <li>■ Receiving and handling complaints</li> <li>■ Reporting of data space activities</li> </ul>
National Data Space Operator	Health Data Access Body (HDAB)	<ul style="list-style-type: none"> <li>■ Issuing data permits: preparing, combining, and making data available for secondary use</li> <li>■ Granting data access in a secure processing environment</li> <li>■ Establishing data access management: provision of publicly accessible and discoverable health data, implementing data access services, including data pseudonymization or anonymization</li> <li>■ Ensuring health data set quality and their labeling (metadata catalog), as well as fee and charge regulation for data provision</li> <li>■ Monitoring and policing, as well as the possibility of re-contacting (patients or physicians) in the case of relevant medical findings</li> <li>■ Ensuring transparency about access applications, granted authorizations, and findings from data use</li> </ul>
Data Holder	Public, private, non-profit institutions and individual researchers	<ul style="list-style-type: none"> <li>■ Providing health data (data holders may also submit data requests)</li> <li>■ Describing own health data and metadata</li> </ul>
Data User	Public, private, and non-profit institutions and associations, as well as individual researchers	<ul style="list-style-type: none"> <li>■ Describing projects for which data is necessary and providing an adequate explanation</li> <li>■ Submitting applications for data use according to minimum requirements</li> <li>■ Utilizing health data to optimize services, research, and policy</li> </ul>

While these papers comment on the EHDS or propose high-level technical architectures, there is a lack of empirical, conceptual, or theorizing papers. In essence, the legal and public policy research stream discusses the role of regulators in fostering health data spaces and overcoming market imbalances created by large platform organizations that could otherwise be valuable for the public (Ferretti 2022). It addresses that data holders must share anonymized data to maximize the creation of societal value under the premise of balancing the potential risks of limiting individual data sovereignty (Comande & Schneider 2022; Cuno et al. 2019).

Data space research is immature and often encompasses descriptive work (Beverungen et al. 2022; Brost et al. 2018) or characterizes the phenomenon by identifying relevant dimensions and attributing them to morphological boxes to delimit their boundaries (e.g., Gieß et al. 2023). There is no consensus on the definition and boundary conditions obstructing the path to conceptual clar-

ity (Hutterer et al. 2023). Instead, the literature is fragmented into separate research streams exploring either technological, managerial, or regulatory aspects of health data spaces, falling short in relating them to each other. Furthermore, the literature does not sufficiently tie in with established theoretical constructs and the ongoing discourse around data and digital platform ecosystems (e.g., Hein et al. 2020), health infrastructures, and the longitudinal co-development process of alliance-driven platforms (e.g., Flak et al. 2022). The current state of research calls for information systems and service management literature on the emergence, development, and operation of health data spaces. This forms the basis for understanding this large-scale phenomenon and its evolution. After presenting our research design, we propose a research agenda as a starting point for researchers to bring those aspects together and develop a common (theoretical) understanding of health data spaces.

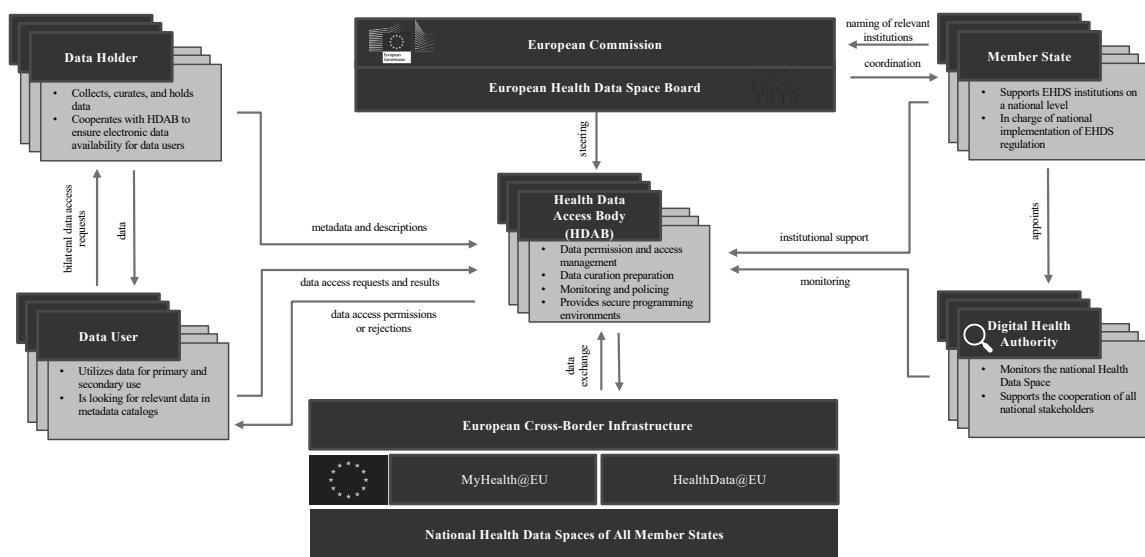


Fig. 2: Roles in the EHDS based on Kari et al. (2023).

### 3. Research Design

Research agendas delineate areas that can guide researchers and practitioners to address relevant working areas. Among others, Tilson et al. (2010), with their highly relevant and often cited research agenda on digital infrastructures, motivated further research on relevant aspects of the phenomenon. With the emergence of health data spaces, we argue that there will be novel research areas on data spaces. This section presents the research design constructing the systematic research agenda.

Data space initiatives constitute a novel phenomenon encompassing the development of large-scale European

data infrastructures with the simultaneous introduction of platform and data regulations shaping resulting data ecosystems. We adopt an iterative process to generate the research agenda representing areas that guide the further exploration and theorization of the emergence and dynamics of health data spaces. We do so based on the researchers' simultaneous commitment to actively contribute to publicly funded projects while generating scientific knowledge on an ongoing, large-scale, and decade-long initiative that intertwines technological (Gaia-X) and regulatory (EHDS) developments. As future developments are still unforeseeable, subject to change, and research is immature, early presumptions and subsequent

adjustments are needed. Hence, we aim to establish a basis for further explanations and theory creation along the lifecycle of data spaces.

The research team encompasses three researchers who are part of a publicly funded Gaia-X project developing an architecture for health data spaces. We have been researching the design, co-development, monetization, governance mechanisms, and stakeholder tensions in (health) data spaces. Furthermore, we attended various health data spaces conferences and workshops covering academic and practitioner topics. Our research projects include a literature review on data spaces, which was conducted in October 2023 and expanded in January 2024.

Our iterative research approach is inspired by Sætre & Van de Ven (2021) arguing for the interplay between a creative process generating hunches on the individual level and an evaluation process at the collective level. Starting at an individual level of the process, we developed hunches by reflecting on the real-world phenomenon and the state of research. Next, in November 2023, we conducted an expert workshop to further develop those hunches. We invited researchers and practitioners who develop, operate, or research platforms for the secondary use of health data. 37 experts participated in the workshop, which lasted 6 hours and included presentations and interactive roundtable discussions. In the first 1.5 hours, the research team and selected experts presented their thoughts on technological, regulatory, and managerial implications. This included a presentation and open discussion on the EHDS proposal. Second, different roundtable discussions, which covered discussions on challenges in developing, operating, and ensuring the economic sustainability of platforms for secondary use of health data, lasted for two hours. Third, the results from the roundtables were presented, followed by an open discussion between all participants. We recorded and transcribed the roundtable discussions, resulting in 84 pages of transcripts. Following the iterative approach, we came together after the workshop to discuss and synthesize our hunches and develop the research agenda items until a consensus was reached. This resulted in 31 initial research agenda items.

We adopted different dimensions to structure the initial research agenda, to which we then assigned the research items. First, we conceptually differentiated between research agenda items that addressed the development of health data spaces and the operation once they are adopted. Currently, the development phase can already be empirically explored compared to the operation phase, which refers to rather prospective research areas that will arise once data can be exchanged through health data spaces. Further, we followed Rousseau (1985) and

Cowen et al. (2022), who propose a multi-level perspective when researching organizational arrangements. Consequently, we assigned each research agenda item to a micro, meso, or macro level of analysis. The micro level sheds light on issues mainly on an individual level, such as patient behavior, their practices, and the organizations they are embedded in. The meso level focuses on larger consortia, sectors, regions, and interorganizational ecosystems. The macro level focuses on national or supranational unions, initiatives, or regulations. To further structure the research agenda along different methodological paradigms, we incorporated DSR and BSR paradigms (Bichler et al. 2016; Hevner et al. 2019; Peffers et al. 2007). BSR represents the traditional scientific discovery process of gaining knowledge through the successive development of theories regarding cause-and-effect assumptions through, e.g., observation and experimentation (Schneider 2011; Winter & Baskerville 2010). This allows researchers to identify and validate causal, explanatory, and predictive relationships between dependent and independent variables (March & Smith 1995). Through continuously developing interrelated scientific studies, this is carried out until a satisfactory degree of maturity is reached (Schneider 2011; Winter & Baskerville 2010). DSR, in contrast, solves practical problems by adopting a design-oriented approach that aims to generate knowledge through the systematic development of useful artifacts (Arnott & Pervan 2012; Hevner et al. 2004; Markus et al. 2002). New artifacts are created through systematical innovation and creation processes (e.g., Hevner et al. 2004).

Subsequently, at a collective level, we iteratively evaluated the emerging research agenda with ten domain experts between January 10th and 23rd of 2024. We sampled researchers who are either planning to submit or already published papers on data spaces or practitioners working on developing (health) data spaces. The final sample consists of five experts who qualify as researchers and practitioners, three who qualify only as researchers, and two who qualify only as practitioners. This ensured that we generated a relevant research agenda for both groups. An overview is given in Table 2.

Before each interview, we sent the current research agenda to the interviewees, which was the starting point and common ground for the discussion and subject to evaluation. We structured the discussion by first addressing the general composition and, subsequently, the content of the research agenda. Following a brief overview of the thematic field of the expert, we (1) discussed the research agenda items in more detail and (2) discussed topics the experts deemed necessary to address. We used an interactive digital whiteboard to collect comments, feedback, and further ideas. Additionally, all conversations were recorded and transcribed, ensuring that we

could go back to the discussions while adapting the systematic research agenda. After each interview, two researchers of the author team met to synthesize the feedback by discussing proposed changes until a consensus was reached. The interviews resulted in us including, and/or modifying items in the research agenda. Each novel version of the research agenda was the subject of the following interview, which ensured that the domain experts could comment on the adopted changes. After reaching saturation in the tenth interview, we finalized the research agenda by analyzing the transcripts of every interview and reflecting on existing literature streams. By doing so, we understood how the research agenda items relate to each other and their potential for an overall knowledge gain. While finalizing the research agenda, we considered how frequently specific topics were addressed and how relevant the interviewees perceived them. This helped to increase its relevance and reliability.

Tab. 2: Description of the Conducted Explorative Expert Interviews.

Role	Number of Interviews	Total Duration	Average Duration	Number of Pages
Researcher	3	2:08 hours	43 min.	34
Practitioner	2	1:23 hours	42 min.	22
Researcher and Practitioner	5	3:58 hours	48 min.	65
<b>Total</b>	<b>10</b>	<b>7:29 hours</b>	<b>44 min.</b>	<b>121</b>

## 4. A Research Agenda for Health Data Spaces

Next, we will systematically present, discuss, and give examples for (1) abductive, conceptual-theoretical, and empirical transformation research, (2) DSR, and (3) BSR. This will reveal numerous novel and promising opportunities to generate scientific evidence. Our final research agenda is visible in Table 3.

### 4.1. Abductive, Conceptual-Theoretical and Empirical Transformation Research

In recent years, digital transformation research has taken center stage in different academic disciplines (Riasanow et al. 2019; Soh et al. 2023; Vial 2019; vom Brocke et al. 2021; Wessel et al. 2021). Service management research has considered not only digital transformation processes of single organizations but also of entire service industries (Matzner et al. 2018).

Traditional research approaches are either inductive, building theory based on patterns derived from data, or deductive, whereby theories are confirmed, further developed, or falsified with the help of hypotheses and

data (Kennedy et al. 2018; Saunders et al. 2019). Both approaches face accusations of either “trailing” or “crystal-gazing” science: Either they provide explanations retrospectively, from a (potentially outdated) ex-post perspective, or they move into the territory of speculation as the events they analyze have not fully materialized and are still ongoing (Sætre & van de Ven 2021). However, analyzing the development and multi-faceted dimensions of real-world phenomena, such as Gaia-X and the emerging EHDS, requires advanced approaches beyond established inductive and deductive research approaches. Researchers in health data spaces actively contribute to developments through their participation and contribution to publicly funded data space research projects. Simultaneously, they provide practical feedback and generate novel knowledge by reflecting on the ongoing process in scientific publications. This allows researchers to become part of and simultaneously observe large-scale, decade-long development initiatives that combine intertwined technological, regulatory, and managerial developments of IT infrastructures, which is a unique possibility (Tilson et al. 2010). However, this also shifts the role of the researcher from being an ex-post observer to an active contributor to real-world developments.

Abduction focuses on rare, at first sight, surprising, real-world phenomena and then moves back and forth between inductive and deductive reasoning approaches. It uses data to explore patterns, locate them in a framework, and subsequently test them (Suddaby 2006). Abduction starts with observing and confirming an anomaly, which helps generate and evaluate hypotheses that might explain this observation, followed by deductive constructing or inductive testing (Sætre & van de Ven 2021). In our case, the anomaly lies in the large-scale real-world development of a European technological initiative and the simultaneous introduction of a regulation that is directly applicable in all member states. As current developments are still ongoing and unfinished, it is just starting to be possible to empirically analyze and observe the operation of health data spaces. This requires presumptions as future developments of this phenomenon are yet unexpected and have not fully materialized. Consequently, abduction provides a suitable iterative methodology for business and service research on health data spaces. Abduction is carried out as a sequence of exploration, followed by iterative steps of induction and deduction, while, at the same time, closely monitoring current developments and legislative changes on a national and international level. As researchers become active actors in consortia developing health data spaces together with industry organizations, ADR can guide this process of integrating scientific insights into developing and evaluating artifacts. The embeddedness of the artifact in the organizational context, in the context of health data

spaces, is provided by, e.g., consortia co-developing the infrastructure, and ensures the relevance of the artifact by interweaving the building process of the artifact with its adoption in the organizational setting and resulting real-world evaluation (Sein et al. 2011). Based on existing preliminary work in related disciplines, it becomes possible to perform conceptually theoretical and empirical transformation research in real time. This complements existing research methods and theories on all levels of analysis.

## 4.2. Design Science Research and Behavioral Science Research Opportunities

For each level of analysis, starting with the macro level, we outline research areas both from a DSR and BSR perspective which occur during the development and operational phase of health data spaces

### 4.2.1 Macro Level of Analysis:

At the **DSR** macro-level of analysis, the *co-development* phase is characterized by the formative role of national and supranational regulatory bodies that develop a vision for health data space initiatives. The active role in shaping the vision is illustrated by a quote from Ursula von der Leyen, the President of the European Commission: "It is not too late to achieve technological sovereignty in some critical technology areas [...]. We will jointly define standards for this new generation of technologies that will become the global norm" (Scott 2019). With this statement, she emphasized the need for governments to support the definition and implementation process of interoperable standards that must comply with European values to operate. As regulators and public institutions have acted primarily as financial facilitators, it is still unclear to what extent they will be involved in developing the infrastructure and whether they will have to establish regulatory frameworks explicitly governing the data exchange in health data spaces. As the overarching vision continues to materialize in the form of specific meta-requirements implementing the EHDS, researchers can adopt DSR methods to support this process by developing and implementing relevant regulatory mechanisms and applicable design principles promoting attributes such as "data sovereignty", and "public good orientation" in technical and organizational artifacts (Hummel et al. 2021). This includes developing hypotheses on how data spaces differentiate from dominant digital platforms to guide the co-development in a direction that can leverage the benefits of platforms without creating undesirable external societal effects (Beverungen et al. 2022).

However, health data spaces are not emerging in a vacuum but aim to foster existing standards and infrastructures. This primarily concerns the federated architecture, the interoperability with existing health data infrastruc-

tures (e.g., EHRs and existing research data centers), and should be accompanied by further developing standards and practical guiding actions for all stakeholders involved (Otto & Jarke 2019). Cross-sectoral standards must be developed to ensure the interoperability of existing and emerging actors acting as data holders and users at different levels (Oliveira et al. 2019). For instance, the Fast Health Interoperability Resource (FHIR) standard provides a step toward interoperability in healthcare. Additionally, several other standards must be developed, such as ontologically appropriated data exchange formats across data spaces. Hoeyer et al. (2024) mention the difficulty that the same interoperability standards have ambiguous meanings in different healthcare systems, as they are shaped by local work practices, making the promise of comparable data likely to fail. Previously, DSR research focused on technical artifacts, including service and interface specifications and superordinate interoperable standards (Hevner & Chatterjee 2010; March & Storey 2008), but (health) data space initiatives such as EHDS and Gaia-X could shift the emphasis on the parallel development of design principles of economic, legal, and political approaches consisting of mainly incentives, precepts, and prohibitions. Therefore, DSR can enable co-development processes between health data space actors, possibly including governmental actors (see Table 1).

Shifting to the *operation* phase, health data spaces are set to enable service innovations that will be gradually introduced into clinical practice. For this, DSR researchers can develop ethical principles and mechanisms to ensure the compliance of data-driven services, e.g., at which point in the digital value chain ownership rights are assigned to which actor. It is not clear in which cases and at what stages the data belongs to society, the generating service provider, the processing company, or the individual (Otto & Burmann 2021). As the healthcare industry is a sensitive sector, the real-world impact of those innovations must be tested. As health data spaces could enable real-time evidence (RTE) on a large scale in the medical field, they can be utilized to evaluate the efficacy and risk profiles of treatments as digital therapeutics (DTx) (Fürstenau et al. 2023). Adopting DSR methods, researchers could develop macro-level mechanisms or B2B and B2G services to incorporate new treatments and prevention methods into overarching medical guidelines based on patient-reported outcome measures (PROMs) and thus transfer regulation to everyday clinical practice (Black 2013; Nelson et al. 2015). This reduces regulatory and medical barriers between the regulated and the unregulated health market. For instance, macro-level mechanisms could be subject to similar dynamics compared to expert committees that accompany and reflect interoperability developments proposing tangible recommendations to the regulator for corresponding

incentives, precepts, and prohibitions (Ludewig et al. 2021; SVR 2021). Furthermore, researchers could develop strategies answering how GAFAM and its dominant platform strategies can be integrated into health data spaces. Given that GAFAM may benefit to individuals through their data-driven health services, they cannot be entirely excluded from their participation, provided they adhere to established regulations, privacy safeguards, and existing rules and standards. The nature of this relationship can further be defined as either cooperation or competitive collaboration (coopetition) that upholds European values while effectively merging both value networks for the advantage of individuals and the collective. Consequently, research should focus on exploring methods and fair conditions under which individual rights can be upheld while also allowing for service provisions by dominant players.

From a **BSR** *co-development* perspective, it remains to be seen how influencing factors, such as regulatory frameworks, technological architectures, and the positions and behavior of involved healthcare market actors (e.g., the decision to participate in health data spaces) are intertwined. For instance, the political agenda including the EHDS and the decision to fund the promotion of Gaia-X and related research projects influences the co-development of health data spaces. This impacts organizational decisions to eventually become an early mover through participating in such development projects. On the other hand, data space regulation is impacted by the actions of involved actors to ex-post readjust regulations so that the actions become aligned with the societally desired directions.

Another mechanism that BSR researchers could explore is path dependency (Sydow et al. 2009). It encompasses self-reinforcing mechanisms that increasingly limit available action spaces over time and jeopardize interdependent decisions so that locked-in situations with less decision freedom occur (Gersch 2022; Sydow et al. 2009). A stable path dependency is assumed for the German healthcare system, especially regarding the established professional boundaries (Gersch & Wessel 2023; Gersch & Sydow 2017). While establishing new care solutions within health data spaces, it is relevant to investigate what kind of path-breaking strategies exist to dismantle the existent dominance of single outpatient or inpatient care providers toward data-based intersectoral care processes (Stache & Sydow 2022; Sydow et al. 2020). It is interesting to see how and whether new actors and institutions arising within the EHDS ecosystem (e.g., the HDAB and HDA) will help to overcome path dependencies.

Moving towards the *operation* phase, it will be imperative to analyze whether implementing the EHDS and associ-

ated health data spaces succeeds in terms of societal perception, acceptance, and actual usage compared to the vision of the EU. It is still unknown which characteristics describe the indicated future European single market and how the European data economy will evolve by utilizing health data spaces. Here, controllability becomes relevant, as health data spaces are complex socio-technical systems without a focal actor that could potentially mandate developments in specific directions. It remains to be seen to what extent the political promises will be fulfilled and if health data spaces can lead to competitive advantages for Europe and the engaged actors. One of the reasons for introducing health data spaces is the desire to build a fairer data economy where not only a few dominant players determine the rules of play, but small and medium organizations can equally benefit from data access (European Union 2020). It can be researched how health data spaces may help overcome platform monopolies.

Additionally, regulators must continuously clarify to what extent health data usage, exchange, and commercialization are legitimized. On the one hand, innovations and medical advancements need to be produced. On the other hand, the privacy and sovereignty of individuals must be protected. Effective data use can protect lives by discovering new medications, detecting diseases early, and personalizing treatment. The regulator must consider ethical fairness and identify which decisions will be advantageous for the majority. The objective is to balance the conflict between the created public value through data usage and the profit maximization interests of private service providers while simultaneously upholding individual data privacy rights. In this context, health data spaces are devices to define and specify individual rights and ethical requirements and implement them technologically, organizationally, and regulatorily.

#### 4.2.2 Meso Level of Analysis:

**DSR** research at the meso level provides insights on time-variant strategy and design options for data platforms and emerging service ecosystems to enable novel architecture designs, business models, and service innovations (Bullinger et al. 2017; Foss & Saebi 2017; Fürstenau et al. 2019; Fürstenau et al. 2021). There is a substantial body of research on how platform owners should design and establish governance structures to orchestrate efficient collaboration and data exchanges (Gawer & Cusumano 2002; Lis & Otto 2020; Schreieck et al. 2016; Tiwana 2014). However, data spaces represent alliance-driven endeavors requiring a collective and participatory governance to orchestrate and manage the co-development. Therefore, collective governance mechanisms are relevant in the context of platform infrastructures (Flak et al. 2022; O'Mahony & Karp 2022; Otto & Jarke 2019). So far, exist-

ing research has focused mostly on intra-organizational governance mechanisms (Lis & Otto 2020; Marheine 2020). Scholars must investigate whether findings from existent platform theories can be generalized to data spaces. Therefore, researchers could explore the influence of the governance design on the value co-creation (Vargo & Lusch 2016, 2017), data governance (Janssen et al. 2020), data generativity, which addresses the capacity of exchange data to be reused beyond its intended purpose (Cennamo & Santaló 2019; Henfridsson & Bygstad 2013; Yoo 2010; Zittrain 2008), and innovation in data spaces. The findings could be used to derive design implications for health data spaces to help foster an ecosystem that produces innovative data-driven services and improves health outcomes.

Specifically for the co-development phase, researchers can develop a governance and institutionalization configuration that enables the joint development of a decentralized architecture in large-scale projects, consortia, and joint ventures (Flak et al. 2022). It also needs to be clarified how the cooperation between private and public organizations can be institutionalized in various forms of private-public partnerships (PPP), as their interests and intentions are conflicting. Therefore, requirements regarding the institutionalization, functions, and tasks of the data space operator need to be specified. This includes mechanisms for how citizens can participate in the early stages of co-development so that their requirements can be implemented. This raises the question of how the interests of individuals generally, and of patients more specifically, can be integrated into their development (cf. Gawer 2022). The co-development phase relies on private organizations contributing to the infrastructure of health data spaces. Therefore, the development process is related to the aspiration of private organizations to develop collaborative business models that amortize initial investments. Health data spaces could afford pay-for-performance business models that link payments to the real-world evidence of healthcare services. It is imperative that they develop sustainable business models that fit the vision of health data spaces and will incentivize them to contribute to their development. Therefore, research can build business planning toolboxes for health data spaces, which consider the new arising business models based on novel tasks (e.g., data trusteeship management, audits, certifications, rollout, scaling, and participation management). Hence, a large proportion of business models depend on the B2B and citizen-to-business exchange of sensible health data; researchers can develop models contributing to a “fair” quantification of the value of health data. In this context, Fiske et al. (2022) mention that the value of data depends on its context and the purpose for which the data is used.

During *operation*, the inter-organizational arrangements continuously shift their focus from jointly developing the prototypes to market-ready services and commercializing them (cf. Flak et al. 2022). Research can build collaborative value creation and realization models supporting a sustainable operation of health data spaces. This can be supplemented by developing governance mechanisms for sovereign health data exchange to create value for organizations. However, this questions how corporations that are inherently known to maximize their profits can simultaneously contribute to the societal good. Researchers could explore governance mechanisms that address the tensions between the societal good and profit orientation of the complementary service providers in health data spaces. While the EHDS and Gaia-X encourage commercialization as they form an essential part of the scaling strategy (Federal Ministry of Economic Affairs and Climate Action 2020), the governance of operating data spaces should ensure that it is compatible with the guiding principle of European values.

From a **BSR** perspective, health data spaces are expected to cause tensions (Mini & Widjaja 2019). This is due to their design characteristics that incorporate divergent stakeholders and their heterogeneous preliminaries, interests, and perspectives (Smith & Lewis, 2011; 2022) in the co-development process. Tensions occur if actors are confronted with apparent social, technical, legal, and organizational dichotomies and obscure the simultaneous presence of conflicting elements or actions (Lewis, 2000; Smith & Lewis, 2011, 2022). Over time, contradictions become salient and reveal explanations for taken actions on different levels (Haring et al., 2022). It will not be a matter of avoiding the emergence of tensions but instead of timely identifying and managing them so that they do not negatively influence their further evolution. If occurring tensions are identified early and managed correctly, they could foster innovations and spur virtuous cycles (Haring et al. 2023; Putnam et al., 2016; Smith & Lewis, 2022). Therefore, research needs to investigate what type of tensions occur during the development of health data spaces. The resolution of tensions influences future actions of data space participants.

Health data spaces need a large and active complementor and user base. Therefore, sufficient incentives need to be in place to motivate their participation. Before implementing incentive systems, it is required to find out what kind of factors and conditions lead to desired behavior. So far, research does not understand what incentives and added value data holder require for sharing their data with others (Gelhaar et al. 2021b). An understanding would inform data space developers how they should design incentive systems in terms of, e.g., financial usage, reciprocity in data sharing, real-time, and performance-based compensations for successful interventions. This

could lead to individuals becoming interested in collecting their health data over longer time periods. Another question is how data from smart wearable trackers can be used to improve preventive methods and how they can be designed in terms of privacy preservation and improving health services without causing user concerns.

Moving toward the *operation* phase, it becomes relevant to investigate if the tensions were resolved by appropriate management strategies or if there is a risk of emerging downward loops as vicious cycles (Haring et al. 2023; Lewis 2000). New problems and conflicts will arise during the operational phase that also need appropriate management strategies. Hoeyer et al. (2024) forecast that the constitution of health data spaces in practice depends on how those conflicts are solved. For instance, they describe the inherent tensions between the empowerment of citizens through data access versus losing control over individual data. It is unknown how tensions interrelate during the operation phase, how they evolve over time, and how suitable management strategies can be implemented (Haring et al. 2023).

Furthermore, health data spaces will challenge actors' behavior, relationships, and positions. For instance, patients will be empowered to access their health data and can easily share it with doctors to receive a second opinion on a diagnosis. Hence, fears of increased transparency in the care process could arise and affect healthcare quality in several ways. Care providers must assume an increased legal risk since liability issues remain open in critical care processes. A possible adverse effect could be that the fear of increased monitoring encourages care providers to make fewer or less precise statements due to the high level of accountability, which may hurt patients' treatment (Aaen et al 2022). Thus, primary service providers may be under increasing pressure to justify how they generate or process their data and make this information available in a transparent, easily accessible, and permanent way. It is possible that incomplete information or limited doctors' or patients' digital literacy could put the ongoing relationship between care providers and patients at risk and increase the digital divide between different population groups. Researchers can investigate how patients' positions and relationships in health data spaces change and what impact these changes have on, for example, the ecosystem's interorganizational coordination mechanisms.

Platform owners of traditional platform ecosystems have a powerful position, where they can determine complementors' actions and decisions by using manipulating and coercion methods (Hurni et al. 2022). Due to the complementors' dependency, they can abuse participating actors and enforce opportunistic behavior for their goals (Kölbl et al., 2023). They capture disproportionately

more value than they create, which leads to less joint value creation for the customer than possible (Clemon et al. 2022; Jacobides et al. 2024). Health data spaces were initiated to overcome this. The concentration of power on a few organizations may manifest itself due to the realization of similar effects observable by digital platforms (e.g., network effects and winner-takes-all dynamics). Research could investigate how power and its dynamics are distributed between orchestrators, health service providers, and patients over time and whether their utilization will lead to more equity and fairness as politically endeavored.

Arrow (1978) researched the effects of information asymmetries between service providers and patients that cause decisions to be made under uncertainty. These issues are addressed by research on shared decision-making (Elwyn et al. 2000; Jaffa & Hwang 2021; Ting et al. 2014) or on signals of trustworthiness (Weiber & Billen 2005). Such research could further differentiate health data spaces from GAFAM's solutions. The multi-layer structure of data spaces (see Figure 1) could be researched concerning actor behavior and go beyond the established technology acceptance models (Lee et al. 2003; Venkatesh et al. 2003; Venkatesh & Davis 2000). One hypothesis is that health data spaces reduce data and information asymmetries between patients and healthcare providers by ensuring data sovereignty. Health data spaces will make patients better informed about their diseases, empower them, and strengthen their relationships with medical providers. Active participation of patients in their decision-making and care processes leads to improvements in physical health, mental health, and quality of life, and fewer regrets about the decisions made (Colley et al., 2017). Hence, it remains to be seen how data space orchestrators can reduce the information asymmetries between different actors.

#### 4.2.3 Micro Level of Analysis:

In the *co-development* phase, **DSR** researchers can develop prototype services for the technological and data exchange layers of the health data space (see Figure 1). This can include data infrastructure and core services that are EHDS compliant, e.g., connectors, federated identities, or metadata catalogs.

In the operation phase, the focus will shift toward the ecosystem layer, as researchers can build artifacts that enable actors to develop innovative data-driven health services (Kohli et al. 2016). For instance, they could develop artifacts (e.g., data utility frameworks, and educational platforms) that support actors to learn about the principles of the EHDS and navigate in the health data space to leverage new opportunities. Especially small and midsize enterprises (SMEs) that do not have a resource abundance to build capabilities necessary to find and

use relevant health data could depend on such artifacts. Furthermore, researchers could develop data-sovereign smart services that combine data sources from the regulated and unregulated healthcare market without copying the data assets (e.g., with compute-to-data approaches). For instance, if the citizen's vital parameters are continuously tracked and analyzed, prescriptive algorithms can prompt users to make a physician's appointment. This can be enriched by PROMs collected via smartphone applications for the continuous monitoring of patients' well-being and be used to decide upon appropriate interventions when the risk of a health-related event increases. When a patient decides to visit the physician after a smart service recommends doing so, the physician could request the collected data, access it, and evaluate it using software-as-service applications. This initial evaluation could provide recommendations for follow-up examinations. This illustrates how service providers, innovators, and research institutions can work together and, by sharing data across the entire patient journey, new services become possible and healthcare improvements can be instantiated (Singhal & Cowie 2020). In this scenario, high requirements in terms of trustworthiness with regard to data sources and algorithms need to be taken into consideration in the context of medical care (Gersch et al. 2021; Wittkowski et al. 2020). Thereby, DSR researchers can develop and test trust-building measures (e.g., data wallets that build on a decentralized data storage). Once health data is accessible to data users, the bottleneck will shift to the collection of high-quality health data. Researchers can investigate mechanisms that nudge citizens to collect health data themselves (e.g., through wearables) and provide access for secondary data use (especially for research). Related to the interconnectedness of actors, there are several questions that arise in the field of, e.g., disease prevention and healthcare provision. Researchers could investigate how the data should be prepared so that physicians can use the offered services without feeling their authority being undermined. They could answer how the data sharing process should be designed so that individuals become willing to share data with their physician. Research topics include design options regarding RTE and telemonitoring. RTE enables fast evidence and feedback obtained from data (Coomarasamy & Khan 2004; Stark et al. 2007), e.g., in assessing the effectiveness of preventive measures.

From a **BSR** perspective, barriers to participating in health data spaces are expected during the *co-development* phase. To overcome these barriers, it can be researched which factors contribute to service complementors' and patients' willingness to use health data spaces and consider this when developing them. Additionally, a deeper understanding of how constructs such as trust, citizen-centricity, data privacy, and data sovereignty (Hummel et

al. 2021) affect the behavior of actors, how they emerge, and possibly change is needed. Similarly, it is relevant to study how constructs such as trust can be operationalized and implemented and how relevant stakeholders perceive them. It is required to investigate whether claims of trust, sovereignty, openness, and inclusiveness will be fulfilled from an infrastructural architecture and actor experience perspective.

During the *operation* phase, research must consider dynamics around health data, including permanent monitoring, reflecting, and learning from data work practices (Hoeyer et al. 2024). Practices represent routines, recurring rewards, or shared logic that are stabilized over time and significantly influence and, if necessary, determine decisions and responses in the context of change processes (Checkland 2004; Wessel et al. 2021). It can be investigated how health data spaces, as novel forms of socio-technical artifacts that represent infrastructures for data sharing, change the behavior of patients and other healthcare actors during treatment (primary use) or when conducting research or product and service development (secondary use). Hoeyer et al. (2024) mention significantly changing practices of daily routines of health service workers and citizens if they can upload and access all health data available to them. For instance, in 2014 the Danish government decided that data records from general practitioners would no longer be accessible to patients as they interpreted them differently from the doctor's intentions (Langhoff et al. 2018; Wadmann & Hoeyer 2018) - a decision the EHDS would overturn.

Furthermore, the collaboration between actors becomes more connected across healthcare service providers, which could reduce the information asymmetry between inpatient and outpatient care. Seamlessly transmitted images of patients through connected care systems promote more efficient cross-sector collaboration, allowing for more coordinated treatment forms (Hamann et al. 2006). This would strengthen patient-centered care and increase the therapeutic success and patients' quality of life (Book 2012). Due to the novel infrastructure, actors will adapt their practices. Research could investigate changing patient, physicians, and actor behavior during therapy due to new artifacts, connected care, and ubiquitous data collection. It will be interesting to see what stakeholder-specific acceptance criteria, perceptions, and users' willingness to use for the created smart services exist. For example, the EHDS requires the availability of all patient data in an easily accessible, immediate, consolidated, and accessible form. For this, the interface of a data wallet can be used. However, what kind of design decisions and functionalities will lead to the best user experience for different user groups (e.g., differencing between digitally-savvy and technically unskilled individuals) is unknown.

It was already mentioned that health data spaces hold many promises for service providers and users. They must be implemented and utilized to know whether these promises can be kept. Consequently, researchers could

investigate whether and, if so, which changes occur, both good and bad for stakeholder groups using health data spaces compared to currently operating electronic health systems and platforms.

Tab. 3: Systematic Research Agenda for Health Data Spaces.

Abductive conceptual-theoretical and empirical research				
	Co-Development of Health Data Spaces		Operation and Use of Health Data Spaces	
	Design Science Research	Behavioral Science Research	Design Science Research	Behavioral Science Research
<i>Macro</i>	<ul style="list-style-type: none"> <li>■ Meta-requirements for regulatory mechanisms implementing the EHDS and rules for participating actors</li> <li>■ Design principles for federated infrastructure for health data spaces with interoperability to existing infrastructures (e.g., EHRs)</li> <li>■ Differences and similarities of design characteristics of health data spaces and dominant digital platforms</li> </ul>	<ul style="list-style-type: none"> <li>■ Intertwining between external factors (e.g., regulatory frameworks), technological architectures, and healthcare market actors</li> <li>■ Analysis of path-breaking strategies in the EHDS in conjunction with existing healthcare market</li> </ul>	<ul style="list-style-type: none"> <li>■ Design principles of monitoring mechanisms and measures supporting an effective operation and use of health data spaces including technical, economic, legal, or regulatory measures (e.g., formatting of interoperability council)</li> <li>■ Definition of mechanisms that integrate dominant digital platforms in compliance with principles of the health data space</li> </ul>	<ul style="list-style-type: none"> <li>■ Evaluation of the EHDS implementation and its effectiveness</li> <li>■ Analysis of whether and how health data spaces help overcoming data monopolies of currently dominant digital platforms</li> <li>■ Balance of organizations profit interests with data sharing for the common good and individual data privacy protection</li> </ul>
<i>Meso</i>	<ul style="list-style-type: none"> <li>■ Technical infrastructure, governance, and institutionalization for the co-development of health data spaces distributing decision rights</li> <li>■ Requirements for collaborative, value propositions and business models and their economic sustainability (e.g., through business planning toolboxes)</li> <li>■ Design principles for defining the fair value for secondary use of health data</li> </ul>	<ul style="list-style-type: none"> <li>■ Identification of tensions in the development phase of health data spaces and finding appropriate management strategies</li> <li>■ Understanding and developing incentive systems for emerging roles in health data spaces</li> </ul>	<ul style="list-style-type: none"> <li>■ Value creation and realization models to support the economic sustainability of digital infrastructures</li> <li>■ Governance mechanisms for interorganizational health data exchange and value co-creation</li> <li>■ Design principles of collaborative health smart service systems for fair distribution of value between health data space actors</li> </ul>	<ul style="list-style-type: none"> <li>■ Identification of tensions' interrelations and their evolution</li> <li>■ Analysis of changing actor and patients' positions in health data spaces</li> <li>■ Distribution of power dynamics between various healthcare actors and patients</li> <li>■ Identification and analysis of information asymmetries (e.g., in healthcare decision-making) between patients and service providers</li> </ul>
<i>Micro</i>	<ul style="list-style-type: none"> <li>■ Development of data infrastructures and core services for an EHDS-compliant architecture</li> <li>■ Development of prototypes showcasing smart services based on secondary use of health data that can be implemented in the EHDS</li> </ul>	<ul style="list-style-type: none"> <li>■ Identification of factors contributing to users' and patients' willingness to use health data spaces and potential barriers</li> <li>■ Identification of factors contributing to promoted values (e.g., trust, citizen centricity, and data sovereignty)</li> </ul>	<ul style="list-style-type: none"> <li>■ Artifacts (including data discovery, utility, and maturity frameworks) supporting health data space users (especially SMEs) to build innovative data-driven services</li> <li>■ Design principles for complementary data sovereign smart services based on the EHDS architecture</li> </ul>	<ul style="list-style-type: none"> <li>■ Changing patient and actor behavior during therapy due to new sociotechnical artifacts, connected care, and practices (e.g., PROMs)</li> <li>■ Analysis of established practices that alter dominant institutional logics</li> <li>■ Stakeholder-specific acceptance analysis and willingness to use offered health smart services (e.g., data wallet) in the EHDS</li> <li>■ Identification if and which changes occur for health data spaces users</li> </ul>

## 5. Discussion

In the discussion, we start by outlining and discussing the methodological implications of the presented research agenda for health data spaces. Then, we present our contributions to academia, society, and practice. Finally, we discuss the generalizability of our findings and relevant limitations.

### 5.1. Methodological Implications

The described developments around health data spaces illustrate the necessity for an aligned research approach. We characterize it as a combination of abduction with iterative sequences including induction and deduction that cover different levels of analysis (micro, meso, and macro) and the relevance of time (development and operational phase), and process-sensitive analysis of transformation processes as interconnected episodes of change. The early stage of abductive research about health data spaces helps to inform and make sense in DSR and BSR research projects and thereby contributes to theory building. In addition, research designs from various disciplines systematically frame and facilitate this type of research. Examples include ADR approaches from the field of service management and IS research (Sein et al. 2011; Sein & Rossi 2019) as well as “Real World Evidence” (RWE) (FDA 2022) and “Real Time Evidence” (RTE) (Buckeridge et al. 2012) from the field of medicine and health services. RWE enables the derivation and testing of hypotheses based on data from medical trials in controlled study designs under realistic conditions, including PROMs (ICHOM 2022, Fürstenau et al. 2021). In individual studies, assumptions about intended behavioral changes can be explored and iteratively adjusted in quasi-real time (Fürstenau et al. 2023). This not only increases the closeness to and intertwinement with reality but also the speed at which new findings can be considered, e.g., in medical guidelines. ADR can benefit when researchers accompany large-scale research projects so that scientific findings can be iteratively implemented in the development of projects. Thereby, the findings (e.g., new artifacts) can be investigated from an interdisciplinary as well as inter-organizational context.

We acknowledge that the dimensions we used to structure the research agenda items cannot be always separated from each other. First, the evolution of health data spaces is a continuous and not linear process. There could be numerous prospective issues regarding the operation of health data spaces that developers must account for, but the architecture will be constantly developed further even once the health data space is initially operational. Therefore, the co-development and operation phases will overlap. At the same time, the co-development phase represents current research areas while the operation phase narrows the field of prospective research areas. Second,

the levels of analysis are closely related to each other as there could be multiple research areas that account for two or all levels of analysis. Third, some research questions could be answered by interchangeably adopting DSR and/or BSR methods. For instance, BSR methods can inform the development of DSR artifacts but also track their impact on stakeholders in the health data space. However, the dimensions improved the structure of the research agenda. Furthermore, while indicating that there are limitations to the definiteness of the dimensions, the experts evaluated the provided structure as useful.

Our research agenda illustrates the interplay and inseparability of DSR and BSR when exploring a novel phenomenon. To face challenging areas of research, the phenomenon needs to be addressed holistically from both perspectives. Results from DSR and BSR research can be further developed by iteratively applying the paradigms in a “research process cycle” (Bichler et al. 2016). Consequently, the two paradigms complement each other, as BSR informs DSR in terms of formulating relevant problems to solve and providing theoretical foundations, in turn, DSR provides utility in form of useful artifacts to its counterpart (Hevner & Chatterjee 2010). In contrast, abduction in the early stage of this phenomenon can support researchers’ sense-making and theory-building process using DSR and BSR approaches.

### 5.2. Contributions

#### 5.2.1 Contributions for Research:

For IS and service management researchers, our results offer a structured research agenda, including novel research areas and opportunities that arise with the emergence of health data spaces. Furthermore, we reflect on the necessity to incorporate a combination of research paradigms and methods to enable the real-time exploration of a phenomenon that is still in its early stages of development. Here, we put forward abduction in combination with ADR and RWE as an effective approach to address this challenge. The proposed methodologies indicate that the potential findings can contribute to numerous research areas.

Based on this, we establish four recommendations for researchers exploring such complex, large-scale phenomena. First, we argue that IS and service management research should be carried out through interdisciplinary approaches. For instance, to comprehensively research health data spaces, at least researchers with backgrounds in computer and information science, business, medical, legal, and social science are needed. Second, to produce holistic results, IS and service management research should capture multiple levels of analysis during different phases over time. For example, the interplay of incor-

porating digitally enabled PROMs into modified medical guidelines at the macro level, the development of such PROMs and their adaptation to the governance mechanisms of an ecosystem at the meso level, and finally the impact of digital practices on individual actors at the micro level could be explored as interlinked sequences of transformation processes, iteratively and sequentially. Third, IS and service management research should iteratively complement the established BSR paradigms with DSR and ADR. Fourth, it should follow a process-sensitive approach to ensure that research on transformation processes is as close as possible to real-world developments and therefore becomes more relevant for practitioners.

### 5.2.2 Contributions for Society:

This paper also demonstrates how researchers can actively accompany projects that are particularly valuable to society across all levels of analysis. The transformation of healthcare will affect everyone, at least in Europe. In today's world, research, industry, and society are intrinsically inseparable. In this work, we focused on research as the instrument with which to investigate and shape a real-world phenomenon. With the establishment of Gaia-X and the EHDS, the EU member states are trying to overcome two path dependencies that have evolved together (Arthur 1994; Pierson 2000; Sydow et al. 2009) with clearly recognizable lock-in effects: The first concerns the dominance of the GAFAM companies and their partially evasive global platform strategies. The second concerns the healthcare systems that have evolved nationally in each member state (Busse et al. 2017; Gersch & Sydow 2017; Wendt et al. 2009) and which the EU tries to align and harmonize, rather than allowing each member state to simply integrate GAFAM into the healthcare system (or not, for the matter). This is an attempt to, e.g., overcome path dependencies and became apparent through the European medical device approval (European Union 2017). Therefore, it presents a historic opportunity for the development of Europe to accompany these attempts as episodes of paramount importance in terms of federated and digitalized health markets, and the chance to build a global competitive advantage promoting patient-centered data sovereignty made in the EU.

### 5.2.3 Contributions for Practitioners:

For practitioners, our results introduce the peculiarities of Gaia-X into the health domain and show what usage scenarios and opportunities arise through data spaces. For service providers aiming to position themselves in these service ecosystems, our examples illustrate what kind of smart health services might become possible and that it might be in their common interest to align

their intra-organizational governance mechanisms and business models according to the reference architecture of data spaces.

Additionally, in view of the involvement of private businesses in initiatives such as Gaia-X and EHDS, it could be figured out how public-private partnerships should be managed so that the interests of society, research institutions, and private enterprises can be aligned. The interest conflict between profit maximization, public value, and safeguarding personal rights is not easy to dissolve, as the involved stakeholders have diverging interests and objectives.

### 5.3. Generalizability and Limitations

We presented and systemically illustrated research options that arise from the current developments around health data spaces and categorized them according to the DSR and BSR research paradigms on a micro, meso, and macro level of analysis separating between the development and operational phase. In this simplified categorization, the interrelationships between the different levels are not fully taken into account. We note that there are numerous research questions that can include different levels or are situated between two levels. However, for illustrative reasons, we chose to provide such a simplification.

Although we constructed the initial research agenda on the basis of a workshop with 37 participants and evaluated it with 10 domain experts, the first iteration of the research agenda was constructed by the research team, which might have been biased because of their own experience in the health data space initiative. Furthermore, we acknowledge that it provides a snapshot of the currently relevant research areas with a prospective outlook on the operation phase. Hence, we propose to view the structured research agenda as non-generalizable current guidance on arising research areas that can inform theory development on health data spaces.

Furthermore, an open question remains if the research agenda can be transferred to other domains such as smart living or smart mobility. This cannot be answered universally for all research areas, as we presented heterogeneous research areas for the DSR and BSR paradigms on different levels of analysis. Therefore, the potential to transfer some of the research areas should be evaluated individually. Particularly the healthcare market is still characterized by numerous national regulatory barriers, some of which do not impact other domains. On the one hand, this makes the healthcare domain particularly intriguing for researchers exploring the influence of regulatory conditions on transformation processes. On the other hand, the corresponding findings are limited in their transferability to other domains. This is espe-

cially valid for national regulations concerning the use of medical data for digital services (Gersch & Wessel 2023; SVR 2021). In addition, the healthcare domain historically evolved around stakeholder arrangements including healthcare providers and health insurance, which also feature national peculiarities. The obtained research results should therefore be aligned with the specifics of national regulations, as varying research options could arise in different legal spheres. Especially at the meso and macro level of analysis, this could restrict the transferability. Nevertheless, there are numerous research options and results that are transferable to other domains. These include, for example, the DSR implications for the development and scaling of data spaces, which can substantially contribute to platform ecosystem research. Furthermore, the design principles of data-sovereign services within service research, for example, could provide fundamental insights that can be leveraged in the research, design, and development of digitally responsible services that foster the co-creation and realization of value.

Generally, the ambition of technical initiatives such as Gaia-X is to create a reference architecture for a decentralized data platform ecosystem. A central question is whether this phenomenon can be scientifically observed as a conventional platform ecosystem and data ecosystem. If this is the case, knowledge gained from this phenomenon can be generalized to platform ecosystem and data ecosystem research. Otherwise, an expansion of existing transformation research would be necessary. We note that this will only become apparent as health data spaces evolve. If, over time, a centralized governance structure is established and enforced by a platform owner organization, we anticipate that it will rather complement existing research, for instance, that of Fürstenau et al. (2019). In particular, the design of governance structures in a highly decentralized platform, based on the Gaia-X reference architecture, could provide generalizable insights into addressing various tensions in platforms and service ecosystems (e.g., Mini & Widjaja 2019). If, however, health data spaces emerge as regulated self-governing instances without a centralized platform ownership, we anticipate that, although similar mechanisms and challenges will be observable (such as network effects and similar technical, regulatory, and organizational frameworks), researchers could explore novel processes.

## 6. Conclusion

This study sheds light on health data spaces as the current European supranational digital strategy to leverage data sharing in accordance with European values. The initiative aims to enable the sovereign exchange of health data, for which it tries to define an overarching techni-

cal, and regulatory framework. However, it is still in the early stages of development, with many aspects not yet defined, such as the prevailing governance mechanisms that will be established for health data spaces. This phenomenon manifested through the Gaia-X initiative and the EHDS demonstrating the emergence of novel, potentially path-breaking artifacts that confront researchers with complex real time developments. This opens numerous research opportunities but also poses challenges for conventional research methodologies.

Therefore, we pursued two central objectives in this study. First, we formulated research areas by systematically categorizing research opportunities regarding (health) data spaces according to the DSR and BSR paradigms on a micro, meso, and macro level of analysis and depending on the stage of their lifecycle (co-development and operation). Researchers can elect to explore some of these research areas in subsequent studies. Second, we outlined implications for IS and service management research that can support researchers exploring such a complex real-world phenomenon in real time. This facilitates appropriate support through research, successive evaluation, and development of practical implications.

Our work underscores the urgent need for a modified set of research questions and adapted research methods to investigate current real-world phenomena such as the emergence of health data spaces. We are eager to see closer collaboration between research and practice now underway in a pivotal episode of this envisaged transformation process towards common European health data spaces.

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