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The Future of Non-Interventional Studies: Transformation of Data-Producing Arrangements Through EHR2EDC and Health Data Space Services

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Non-Interventional Studies, Value Creation, Real World Evidence, Health Data Space, Business Models

Abstract

Non-interventional studies play a central role in generating real-world evidence. However, the required data production is labor-intensive and difficult to scale. While Electronic Health Record to Electronic Data Capture (EHR2EDC) and health data space services represent possible solutions, in practice, their adoption has remained limited. This raises the question of why technically feasible innovations fail to get adopted. Drawing on an action research approach with organizations participating in non-interventional studies, this work developed existing and prospective value constellations using e3-value network modeling and used them to structure interorganizational negotiations within data-producing arrangements. The findings show that the adoption of service innovations depends on recursive negotiations in which system-level value creation is continuously weighed against actor-level implications. For practice, we offer actionable guidance on how actors can foster the adoption of EHR2EDC and health data space services. For research, we contribute a recursive process model that explains how data-producing arrangements are reconfigured to embed service innovations.

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1. Introduction

In the pharmaceutical industry, *non-interventional studies (NIS)* have become an essential means of generating real-world evidence at the point of care and thereby complement clinical trials. NIS contribute substantially to evaluating the safety and efficacy of medicinal products beyond the controlled settings of clinical trials (Geldof et al., 2019; Mishra & Vora, 2010).

Conducting NIS involves a sequence of coordinated interactions among multiple organizations. Study sponsors come to an agreement with physicians and other trained healthcare professionals to collect personal health data from patients (Wörz & Hundt, 2011). The collected data is subsequently transferred from the study site infrastructure via data standards that are predefined by sponsors to *electronic data capture* (EDC) systems operated by specialized *clinical research organizations (CROs)* (Müller et al., 2023). Despite the growing relevance of NIS in clinical research, their adoption and scalability remain limited, as the underlying data production process is both labor-intensive and highly regulated. At study sites, clinical personnel often face substantial workload pressures from routine patient treatment, leaving limited time and attention for the accurate and consistent documentation required for high-quality data production (Souček et al., 2025; Hesselink et al., 2023). While study sponsors may offer financial reimbursement for the time spent collecting high-quality data, payments are bounded by *fair-market-value (FMV)* regulations that cap hourly rates (Health Research Authority, 2025) and frequently fail to adequately reflect the effort involved as it can only be estimated upfront (Greenberg et al., 2025; Snyder, 2014). Hence, in reality, the feasibility and success of NIS depend on a complex *data-producing arrangement* encompassing socio-technical configurations including multiple organizations, roles, standards, and interfaces that interact to co-create value through the collection, exchange, and interpretation of personal health data (Aaltonen & Stelmaszak, 2024).

Service innovations have the potential to solve challenges in data-producing arrangements and reshape how value is created (Kilgus et al., 2024; Aaltonen & Stelmaszak, 2024; Matzner et al., 2018). In the context of NIS, the organizations are currently confronted with two major service innovations. First, *electronic health record to electronic data capture (EHR2EDC)* services seek to automate substantial parts of the data collection process at the point of care and thereby reduce the manual labor required from physicians and healthcare professionals (Müller et al., 2023). Second, the emergence of *health data space* services provides a data infrastructure that enables data providers to monetize health data by offering it for secondary use (Kari et al., 2024; Möller et al., 2024). While EHR2EDC primarily concerns the transfer of primary health data generated during routine care into study-specific documentation systems, health data spaces predominantly focus on the controlled reuse of health data beyond the original study purpose. While early initiatives such as Health-X dataLOFT or Sphin-X illustrate growing interest in health data infrastructures, the literature has not yet established how such initiatives become routinely embedded in NIS data-producing arrangements (sphin-X e.V., 2025; European Health Data Alliance e.V., 2026).

While both service innovations are technologically feasible and promise to enhance value co-creation in NIS in the healthcare domain, they have not yet been implemented in practice. Indeed, leveraging these innovations extends beyond the mere adoption of new technologies. Often, it requires changes to existing roles, incentive structures, governance mechanisms, and interorganizational interfaces within the broader data-producing arrangement.

Hence, we raise the question: *How can data-producing arrangements in the context of non-interventional clinical studies reconfigure to leverage service innovations for the collection and use of personal health data?*

To investigate this research question, we employed an action research (AR) approach to directly engage with key actors (Susman & Evered, 1978) in the NIS data-producing arrangement and to facilitate a potential digital transformation in industry practice (Matzner et al., 2018). The research team comprised a senior expert from a large pharmaceutical company and three Information Systems (IS) scholars. Together, we iteratively modeled current and prospective value constellations in NIS using the e3-value modeling notation (Gordijn & Akkermans, 2001; Gordijn & Wieringa, 2022; Jussen et al., 2024).

As part of the AR intervention, we convened 12 key actors within a specific NIS data-producing arrangement, including physicians, study site infrastructure operators, CROs, and sponsors. Evaluating and discussing the e3-value models with these actors initiated a structured negotiation process between actors in the arrangement. The AR intervention provided insights into how participating actors evaluated and negotiated the prospective reconfigurations required to leverage EHR2EDC and health data space services within NIS.

This study shows that the adoption of EHR2EDC and health data space services in NIS is less a purely technical challenge than a socio-economic issue, which requires a negotiated, system-level reconfiguration of the underlying data-producing arrangement and a reflection of the economic viability for participating individual organizations. Consequently, we contribute to the literature on data-producing arrangements by proposing a process model that explains how service innovations initiate negotiations over data sharing infrastructures, incentive structures, and the distribution of generated value. For practitioners, we provide practical guidance for fostering the implementation of EHR2EDC and health data space services in NIS.

The paper is structured as follows: Next, we provide an overview of the conceptual background. In the third chapter, we document the AR approach. In the fourth chapter, we present the empirical insights from the AR cycle. In the fifth chapter, we discuss our findings and summarize contributions for researchers and practitioners. In the final chapter, we conclude the paper.

2. Research Background

2.1 Data-Producing Arrangements in Non-Interventional Studies

Digital data are increasingly conceptualized as organizational resources that can be utilized for service innovation and data-driven business models (Hartmann et al., 2016; Engelbrecht et al., 2016; Bellin et al., 2024). From this perspective, digital data is not simply "given," but rather constructed objects that encode selected aspects of reality in bitstrings structured through a priori defined data classes (Alaimo & Kallinikos, 2022). These data classes embody assumptions about which attributes and relationships are considered relevant (Lukyanenko et al., 2019; Faulkner & Runde, 2019). Consequently, data does not exist as a neutral representation of reality. Instead, digital data is the outcome of deliberate data design processes embedded within broader socio-technical contextual settings (Aaltonen et al., 2021; Alaimo & Kallinikos, 2022).

Aaltonen and Stelmaszak (2024) capture such settings through the concept of data-producing arrangements, which they define as "relatively stable sociotechnical configurations" (p. 5) that combine technical, organizational, and cultural elements to enable the production and analysis of digital data. These arrangements encompass not only organizations, human actors, information systems, and interfaces, but also documentation practices, shared data standards, normative values, and overarching regulatory frameworks that jointly shape the production of data (Aaltonen & Stelmaszak, 2024). In interorganizational contexts, data-producing arrangements typically span loosely coupled organizations that assume differentiated roles as data providers, intermediaries facilitating data exchange, and data users (Jussen et al., 2024). As most participating organizations are economically driven entities, their sustained participation

depends on whether they can reasonably expect to recover costs and capture value within an acceptable time frame (Matzner et al., 2021; Schweihoff et al., 2024; Kilgus et al., 2024).

In the healthcare domain, NIS data-producing arrangements represent specific contextual instances of such arrangements. Typically, in the pharmaceutical industry, study sponsors represent data users that design study protocols, electronic case report forms and contract CROs to implement EDC systems, train study sites, and oversee data quality and regulatory compliance (cf. Müller et al., 2023). Sponsors contract investigators that act as data providers. Site contracts commonly combine fixed fees with per-patient reimbursements (Greenberg et al., 2025; Snyder, 2014). However, the current reimbursement structure incentivizes investigators for the time spent on documentation, not the actual value of data. At the point of care, investigators, who are often physicians or other trained healthcare professionals, document treatment in local electronic health record (EHR) systems and subsequently re-enter the required variables manually into the study's EDC system (Müller et al., 2023). To ensure data integrity and regulatory adherence, CROs complement these practices with audit trails, monitoring visits, and verification procedures for the source data (Abbasi et al., 2025). Patients constitute central stakeholders in the data-producing arrangement as the data subjects whose consent, rights, and protection requirements shape the lawful collection, processing, and subsequent secondary use of health data (Hutchings et al., 2021). In addition, in practice, patients retain the right to withdraw their consent for the future use of their data at any time. However, such withdrawal applies only prospectively and does not affect data processing that has already lawfully occurred (Dierks et al., 2021).

Beyond these operational interactions, the NIS data-producing arrangement is embedded within the applicable regulatory and institutional environment. Legal frameworks (e.g., the GDPR in Europe for personal data, which is extended by the European Health Data Space [EHDS] regulation for personal health data), contractual provisions, and ethical requirements jointly determine whether, how, and under which conditions patient data may be collected, processed, shared, and made available for research purposes (Kilgus et al., 2024; Greenberg et al., 2025). These regulatory and institutional elements not only constrain data production processes but also shape incentives and responsibilities across participating actors.

Understanding the sociotechnical configuration in the context of NIS as a data-producing arrangement provides a suitable conceptual basis for analyzing how service innovations might reconfigure the arrangement and influence the data production process.

2.2 EHR2EDC and Health Data Spaces as Service Innovations

Service innovations refer to novel configurations of resources within institutional arrangements that enhance value co-creation among participating actors (Lusch & Nambisan, 2015; Benkenstein et al., 2017; Matzner et al., 2018). Thereby, information systems offer a foundation for the emergence of smart services that adapt to real-world circumstances (Beverungen et al., 2017). Prior research has shown that such service innovations may not only improve existing practices but can also transform the institutional arrangements in which they are embedded (e.g., Wallin & Fuglsang, 2017; Häikiö & Koivumäki, 2016). Accordingly, data-producing arrangements are not static configurations. Rather, they evolve over time through activities that introduce, modify, realign, or question their constitutive elements, including technologies, roles, standards, and incentive structures (Aaltonen & Stelmaszak, 2024). In the context of NIS, two service innovations are emerging that promise to fundamentally alter how personal health data is produced and analyzed.

The first service innovation concerns a novel EHR2EDC service. This service aims to partially automate the transfer of structured

clinical data from local EHR systems into study-specific EDC systems (Müller et al., 2023). Rather than relying on manual data re-entry by human investigators, an EHR2EDC service leverages predefined mappings of data structures and its interfaces to automate and synchronize relevant data elements across heterogeneous EHR and EDC environments.

Figure 1 illustrates the core workflow of an exemplary EHR2EDC service. During a patient visit, the investigator documents care in the local EHR system as part of routine clinical practice. Relevant structured data are then synchronized with the EHR2EDC service, which semi-automatically identifies the study-relevant variables, associates them with the appropriate study and subject identifiers, and transfers them to the EDC system operated by the contracted CRO. In this configuration, data entry activities that were previously performed manually by error-prone human actors across organizational and system boundaries are partially automated, leading to an overall more efficient process.

Initial prospective studies provide first empirical evidence that the implementation of an EHR2EDC service could accurately transfer a substantial share of required data across therapeutic areas and system landscapes. For instance, Ammour et al. (2023) report that 39.6% of EDC entries could be automatically populated and reused in NIS. This implies that an automated data transfer may lead to advantages for the participating actors in the data-producing arrangement.

From a value co-creation perspective, the adoption of an EHR2EDC service has also the potential to considerably reduce the workload associated with manual data documentation at the point of care (cf. Souček et al., 2025). Pilot studies indicate that automation can lead to substantial time savings for investigators compared to the manual re-entry processes. For instance, Sundgren (2023) estimates a time reduction of up to 96.5% when structured health data are transferred automatically rather than relying on a manual entry in EDC systems. These efficiency gains suggest that an EHR2EDC service could alleviate critical bottlenecks in the production of data used in NIS.

Second, health data spaces constitute another salient service innovation for NIS data-producing arrangements. Data spaces are federated open platforms that provide a shared reference architecture and jointly defined semantic models to enable the sovereign sharing of data for secondary use (Otto & Jarke, 2019; Kari et al., 2024; Möller et al., 2024). We build on the established literature that conceptualizes data spaces as the technical and governance infrastructure of broader data

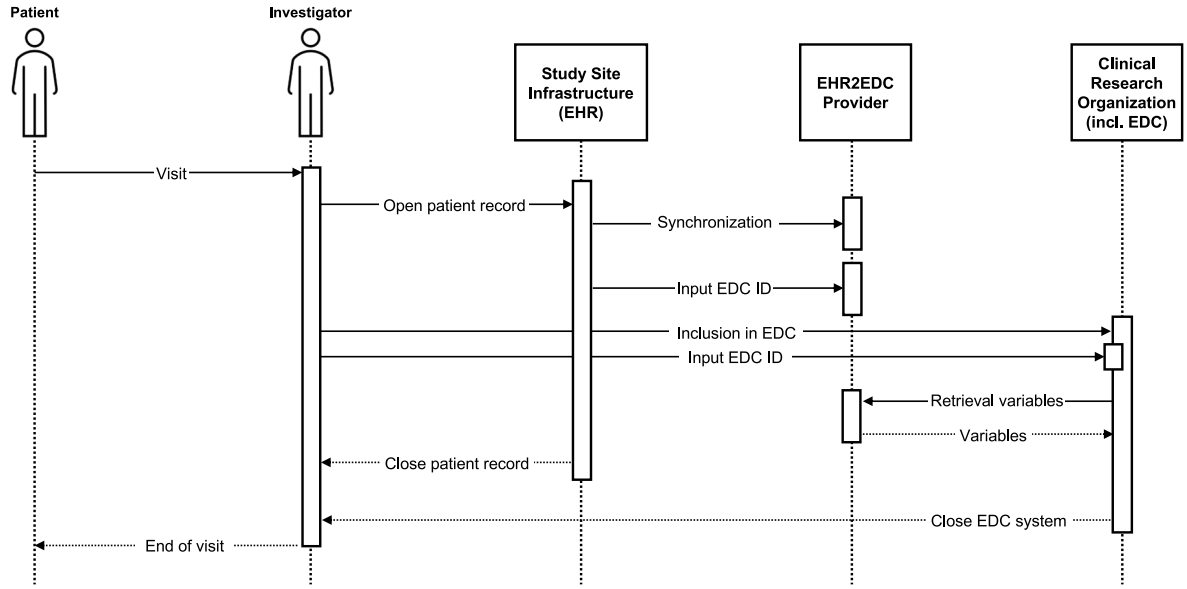


Fig. 1 EHR2EDC service workflow adapted from Müller et al. (2023).

ecosystems and multi-sided networks (Otto & Jarke, 2019; Möller et al., 2024; Konopik, 2025). Unlike conventional data marketplaces that primarily mediate bilateral transactions, data spaces emphasize interoperable standards, decentralized control, shared governance rules, and reusable trust services that enable sustained multi-actor data collaboration (Beverungen et al., 2022). As part of its broader digital strategy, the European Commission has allocated up to two billion euros to support the development of data spaces across multiple industries for the period 2021-2027 in an attempt to foster interoperable and sovereign data sharing among individuals, organizations, and states (European Commission, 2020).

If organizations seek to join and exchange data via a data space, they typically do so through one or more operating companies that act as service providers offering the necessary data space services (cf. Kari et al., 2025; Otto & Jarke, 2019). From the perspective of organizations in NIS, this constitutes a service innovation because new intermediary services reconfigure how actors co-create and capture value from health data (cf. Eustache et al., 2025). Figure 2 illustrates the core components of a health data space. At the infrastructural level, connector services allow organizations to share data under commonly agreed-upon technical, contractual, and usage conditions while retaining control over the data (Möller et al., 2024; Otto & Jarke, 2019). Complementing these connectors, identification, authentication, and certification services enable participating organizations to reliably identify one another and establish trust in the interorganizational sharing of data (Jarke et al., 2019; Möller et al., 2024; Otto et al., 2019). In addition, federated catalogues and shared vocabulary services allow data providers to describe available datasets through standardized metadata, thereby making data assets discoverable across organizational boundaries through metadata catalogs (Guggenberger et

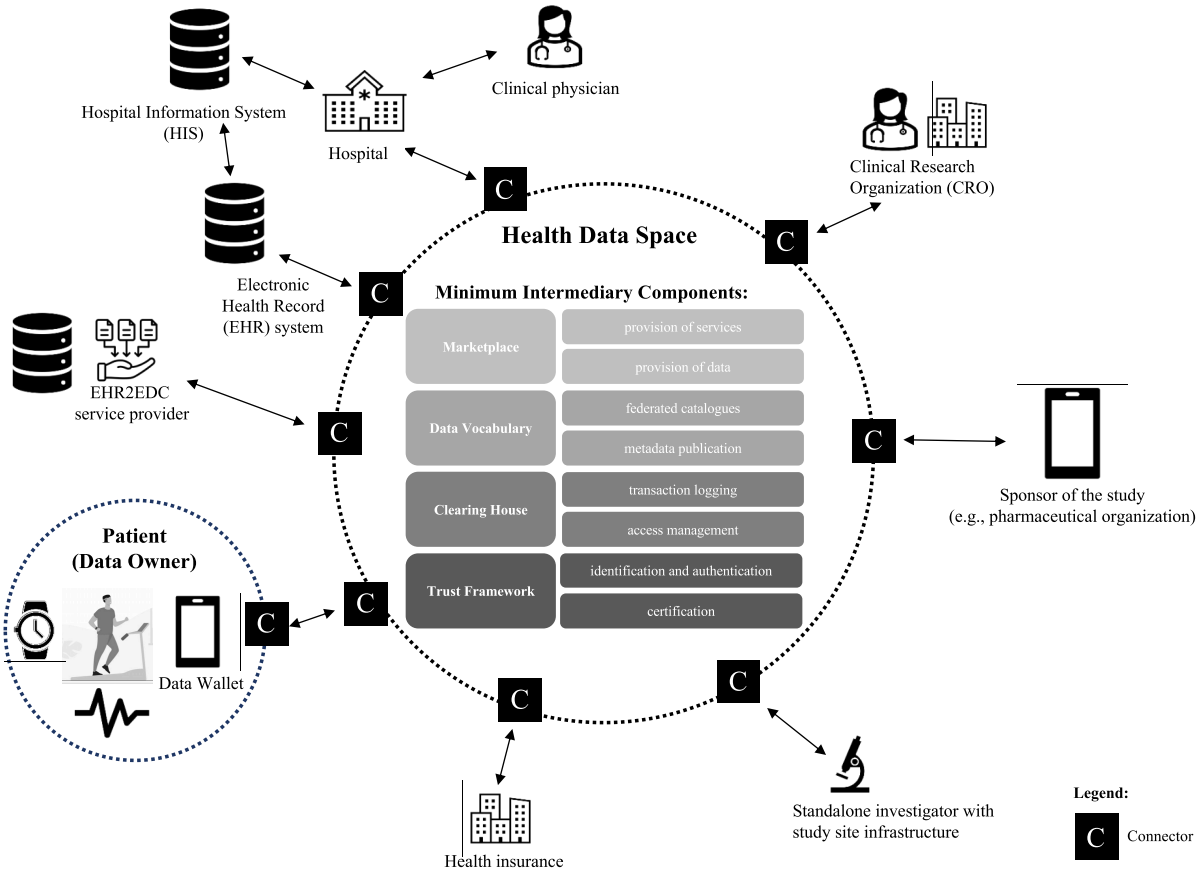


Fig. 2 Core components of a health data space adapted to the context of NIS from Gersch et al. (2024).

al., 2025; Kari et al., 2024). Taken together, these components constitute a federated service infrastructure that enables trusted discovery, access negotiation, and governed exchange between data providers and data users across organizational boundaries (Möller et al., 2024). In the healthcare context, any secondary use of study data remains conditional upon the originally granted patient consent, ethics committee approvals, and applicable legal requirements (Dierks et al., 2021). Specifically, in health data spaces, patients may manage their consent through data wallet applications that enable them to access, manage, and share their own health data (Kari et al., 2024).

While data spaces are already operational in other domains, such as the automotive industry (Kari et al., 2025; Ammann & Hess, 2025), their establishment and adoption in the healthcare industry remain at an early stage (Schurig, 2025). In the context of NIS, health data spaces may represent a considerable opportunity for participating actors within the data-producing arrangement to generate downstream value by making study data available for its secondary use (cf. Kilgus et al., 2024). Thereby, we distinguish between primary health data collected during routine care and study execution and secondary health data reused for subsequent research and data sharing purposes. For example, pharmaceutical companies that act as study sponsors could offer their study data, which was collected during routine care, as secondary health data to other commercial or publicly funded researchers seeking to conduct complementary analyses or independent studies. In consequence, sponsors could extend value creation beyond the original research purpose and reduce the costs incurred during the data collection process (cf. Parsons et al., 2026).

3. Action Research Approach

The research team consisted of a senior NIS expert in a leadership role at a large pharmaceutical company and three IS scholars. The pharmaceutical company is based in the European Union but operates globally. The methodological point of departure emerged from practice. The expert observed EHR2EDC and health data space services as two major service innovations that were technologically feasible and practically widely discussed in the context of NIS. Yet, surprisingly, these service innovations were not progressing toward implementation within the existing data-producing arrangement. This discrepancy between envisioned and realized innovation constituted a concrete practical problem that motivated this research effort. To systematically investigate and address this problem in close collaboration with practitioners, the research team opted for an AR approach (Baum et al., 2006).

AR is widely recognized in IS research as a suitable methodology for engaging with complex, real-world problems while simultaneously generating theoretical contributions (Baskerville & Wood-Harper, 1996; Avison et al., 1999; Checkland & Holwell, 1998). Given the need to both understand and actively shape the evolution of the NIS data-producing arrangement, AR provided an appropriate methodological foundation. In particular, the research team followed the canonical AR framework proposed by Susman and Evered (1978), which structures the inquiry into five iterative phases: diagnosing, action planning, action taking, evaluating, and specifying learnings. Figure 3 illustrates this process model.

In the *diagnosing* phase, the pharmaceutical company had already conducted several empirical assessments to evaluate the current state of value creation in its NIS data-producing arrangement. These efforts included an analysis of the investigators' satisfaction with existing reimbursement models, a quantification of the documentation burden imposed on current study sites, and a customer satisfaction survey among key participating actors. Furthermore, two internal studies were conducted to assess healthcare professionals' willingness to participate in NIS implementing EHR2EDC. A key focus was the extent to which investigators would accept reduced payments resulting from automation.

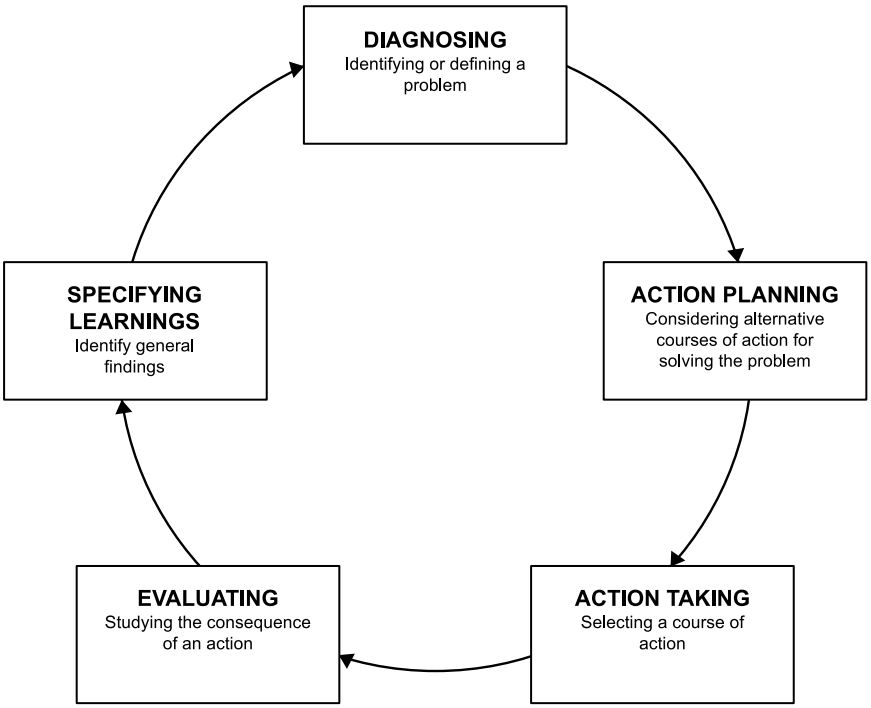


Fig. 3 Action research (AR) methodology adapted from Susman and Evered (1978).

The studies also tested whether nudging instruments could increase participation rates. Collectively, these investigations revealed structural inefficiencies and conflicts within the prevailing data-producing arrangement. Although service innovations such as EHR2EDC and health data spaces appeared well suited to address these challenges and improve the efficiency of the data production process, neither innovation had progressed toward adoption in practice. This persistent implementation gap was identified as the core problem situation motivating the AR cycle (Susman & Evered, 1978).

Early in the research process, it became apparent that the adoption of EHR2EDC and health data space services could not be understood as isolated or selective interventions. Rather, consistent with prior work on data-producing arrangements, their adoption would require systemic transformations in value co-creation constellations across the entire arrangement, affecting roles, responsibilities, and economic evaluations (cf. Aaltonen & Stelmaszak, 2024).

Hence, in the *action planning* phase and in line with Susman and Evered (1978), the research team developed a conceptually informed and practically feasible intervention strategy to address the diagnosed systemic problem. As a planned course of action, the team decided to convene key participating actors of an NIS data-producing arrangement to collaboratively examine the structural reasons underlying the stalled adoption of the two anticipated service innovations. To support this intervention, the team developed shared representations of both existing and prospective value creation structures, reasoning that such artefacts could function as boundary objects to facilitate an interorganizational dialogue.

The e3-value notation is a modeling language for representing value creation and exchange in multi-actor networks (Gordijn & Akkermans, 2001; Gordijn & Wieringa, 2022). Essentially, it distinguishes illustratively between actors (boxes), value activities (text in box), and the value objects (arrows) they exchange, such as data, services, money, or access rights. In this study, we used e3-value models to make the current and prospective value constellations of NIS visually explicit and comparable. Between May and August 2025, the research team iteratively developed e3-value models (cf. Jussen et al., 2024) across six one-hour sessions. During these sessions,

the IS scholars presented successive versions of the models, while the senior expert provided detailed feedback regarding their empirical plausibility and practical relevance. The sessions focused on balancing representational simplicity with analytical rigor, resulting in a baseline model that all team members agreed adequately captured the essential dynamics of value creation in NIS data-producing arrangements. To quantify the potential impact in practice, the senior expert calculated the outcomes in multiple scenarios in which the EHR2EDC implementation would lead to a semi-automation of the data production process. Building on this baseline, the team developed prospective e3-value network models reflecting the anticipated transformations associated with the adoption of EHR2EDC and health data space services. These models formed the analytical foundation for the subsequent intervention.

Following the action plan, in the *action taking* phase, the research team engaged organizations involved in NIS data-producing arrangements and invited them to participate in a collaborative intervention (Susman & Evered, 1978). In AR, action taking does not necessarily involve substantial technical implementation (Checkland & Holwell, 1998). In our specific context, the problem required a soft action, which consisted of facilitated collective sense-making and negotiation using shared value models, with the aim of reframing the problem situation and aligning actor perspectives rather than enacting immediate organizational change (Checkland & Holwell, 1998).

Specifically, a digital workshop was conducted on 15 October 2025 with twelve participants representing key roles within the arrangement, including investigators, study site infrastructure providers, CROs, pharmaceutical sponsors, and independent experts. Table 1 provides an overview of the participants. The workshop lasted a total of 132 minutes. The workshop began with a presentation of the baseline e3-value model illustrating the status quo of value creation in NIS. This was followed by a brief introduction to the conceptual foundations of data-producing arrangements (Aaltonen & Stelmaszak, 2024), EHR2EDC services, and health data spaces to establish a shared understanding among participating actors. Subsequently, the research team presented the prospective value constellations for each service innovation and used these models as boundary objects to stimulate a discussion. Participants were invited to reflect on the systemic barriers to adoption, the structural transformations required within the arrangement, and the business model implications for their respective roles. To actively in-

Tab. 1 List of all participating actors in the workshop.

Nr.	Organization	Position of Participant	Representing Role
#1	University Hospital	Head	Investigator
#2	Association	Former Physician and Leading Expert Role	Independent
#3	Research Institution and IT Company	Former Physician, Researcher and Product Manager	Investigator and Study Site Infrastructure
#4	IT Company	General Manager	Study Site Infrastructure
#5	Research Company	CEO	CRO
#6	Research Company	CEO	CRO
#7	Pharmaceutical company	Head	Sponsor
#8	Pharmaceutical company	Head	Sponsor
#9	Pharmaceutical company	Economist	Sponsor
#10	Research Institution	Professor	Independent
#11	Research Institution	Postdoc	Independent
#12	Research Institution	Doctoral Researcher	Independent

volve participating actors, they were asked to annotate the e3-value models during the negotiation on a shared whiteboard, resulting in 61 written comments capturing their organizational and strategic perspectives. The workshop was recorded to support systematic analysis in the subsequent phases.

In the *evaluation* phase, the IS scholars conducted a qualitative analysis of the intervention outcomes by reviewing the workshop recording and compiling detailed notes during the negotiation process. These notes, together with the written annotations submitted during the workshop, were subsequently clustered into coherent themes (e.g., "efficient integration into clinical workflows", "fair financing and cost allocation", "incentives for physicians and study sites") for each prospective value constellation, enabling a structured evaluation of the intervention (cf. King et al., 2018). In parallel, the senior expert carried out a quantitative assessment by modeling business implications for NIS participating actors based on assumptions articulated during the workshop discussions. This analysis focused on evaluating the economic viability of different implementation pathways for EHR2EDC and related services (Gordijn & Akkermans, 2001; Moschetti et al., 2018).

In the *specifying learning* phase, the full research team convened in October 2025 to jointly interpret and synthesize the insights generated during the first AR cycle (Dervin et al., 2003; Susman & Evered, 1978). The team concluded that additional AR cycles would be required to further support and observe the systemic transformation of the NIS data-producing arrangement over time. Nevertheless, the initial cycle generated substantial conceptual and practical insights, clarified the negotiation dynamics surrounding service innovation adoption, and revealed the need for a broader industry-level dialogue. These outcomes motivated the decision to document and publish the findings from the first AR cycle as a contribution to research on data-producing arrangements and the adoption of service innovations in the context of NIS.

4. Results

4.1 Status Quo of the Value Creation in Non-Interventional Studies

Data-producing arrangements in the field of NIS constitute relatively stable interorganizational configurations in which multiple actors co-create value through the production, sharing, transformation, and interpretation of personal patient data. Ultimately, NIS contribute to the development, regulatory evaluation, and improvement of medicinal products by generating real-world evidence on their safety and effectiveness.

Initially, to analyze the reconfiguration of the NIS data-producing arrangement, we developed a status quo e3-value model. Table 2 summarizes the key organizational actors involved in the arrangement, their core activities related to the data production process, and the pathways in which they co-create and capture value.

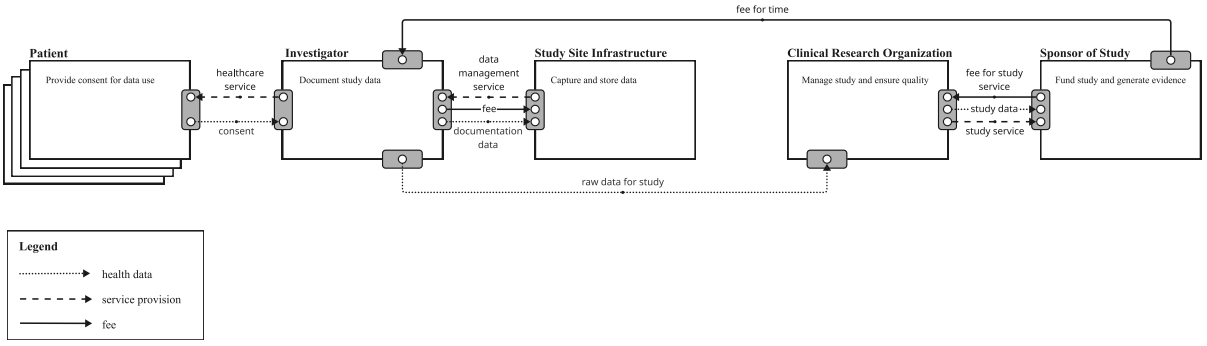


Fig. 4 Status quo of the value co-creation in NIS data-producing arrangements.

Tab. 2 Description of all actors including their data design and value creation activities.

Actor	Description	Data Design Activity	Value Creation in NIS
Sponsor	Pharmaceutical company that holds the market authorization for a drug, funds NIS, and owns the study results.	- Defines research question, study protocol, and case report form - Contracts CROs and study sites - Oversees conduct of the study - Supervises reporting and publication	- Generation of real-world evidence for safety and effectiveness of a drug - Captures value through offering medicinal products
CRO	Specialized service provider for operational study management contracted by the study sponsor.	- Designs, implements, and hosts the EDC system - Trains study sites - Monitors and verifies collected personal health data - Supports study closure	- Reduces operational workload and regulatory risk for sponsors - Ensures data quality - Captures value through service contracts with sponsors
Study Site Infrastructure	IT service provider that offers practice management or hospital IS enabling the documentation of administrative and medical care data.	- Provides IS at the point of care - Supports the documentation of medical appointments, medication, diagnostics - Offers interfaces for routine care systems	- *Currently not creating value for NIS*
Investigator	Health care professional (e.g., physician together with study nurses) responsible for treating patients and performing all activities at the study site.	- Identifies eligible patients - Informs and consents identified patients - Documents treatment in EHR - Manually re-enters relevant variables into EDC	- Collects real-world personal health data - Ensures study execution at the point of care - Captures value by receiving FMV-based compensation from sponsors
Patient	Individual who receives routine medical care and may participate as a data subject in the NIS.	- Receives treatment - Provides informed consent for the use of personal health data for research purposes - May complete complementary questionnaires	- Provides informed consent for the collection and secondary use of personal health data within the scope of the study and applicable legal frameworks - Captures indirect value through safer and more effective therapies

Figure 4 depicts the corresponding e3-value network of the NIS data-producing arrangement. The model shows that value is co-created through a largely sequential and loosely coupled workflow. Health data are generated during routine care at the point of care and subsequently transformed into study-specific, interpretable data through manual and system-mediated processes. This sequential structure makes dependencies between actors explicit and highlights where frictions and inefficiencies arise.

Sponsors play a central role in the data-producing arrangement, as they initiate, design, and finance the production of personal health data in NIS. To operationalize a study, sponsors define the research questions and develop the study protocol, including the data model that specifies which variables investigators must collect and subsequently document.

They conduct site feasibility assessments to identify suitable practices and compensate participating investigators for their study-related activities.

However, sponsor compensation mechanisms are constrained by FMV principles and ethical oversight, which require that payments reflect the estimated time required for documenting the data rather than the actual value generated from the data itself. As a result, sponsors cannot directly pay for higher-quality or more reusable data but must reimburse the expected documentation effort.

CROs act as intermediaries that operationalize the sponsor's protocol into a documentation form, the case report form. They design and operate the EDC system, implement user authentication and audit trails, train study sites, and monitor the quality of the collected data throughout the period of the study. From the sponsor's perspective, CROs contribute to value co-creation by reducing operational complexity and mitigating regulatory risk, while capturing value through service contracts that are tied to the execution of the study.

Providers of the study site infrastructure, e.g., vendors of hospital IS or practice management software, operate the EHR used at the point of care. However, in the status quo, they do not actively participate in value co-creation processes related to NIS. Their systems are optimized for clinical documentation and administrative workflows and typically lack dedicated interfaces or functionalities for data extraction or reuse for research purposes. As a result, study site infrastructures remain largely decoupled from the NIS-specific data production process.

Investigators, typically physicians or trained healthcare professionals, occupy a critical yet constrained role in the data-producing arrangement. In addition to providing routine clinical care, they identify eligible patients, obtain informed consent, and document treatment information. While care is documented in local EHR systems, these systems are not aligned with the study-specific EDC. Consequently, investigators must manually re-enter relevant variables into the EDC, a process that is both time-consuming and prone to errors. FMV-based reimbursement schemes often fail to fully compensate for the time required to produce high-quality data and do not reward additional effort aimed at improving data completeness or accuracy. This misalignment limits investigators' willingness and ability to invest further effort into the data production beyond the minimal contractually specified requirements.

Finally, patients contribute to the arrangement by receiving routine medical care and providing informed consent for the use of their personal health data in NIS. While patients do not directly capture economic value, in the long term, they benefit indirectly through the development of safer and more effective therapies informed by real-world evidence.

4.2 System-Level Impact of an EHR2EDC Service

In the baseline scenario (see Figure 4), manual data work positions investigators as the central locus of the data production within the NIS data-producing arrangement. Value co-creation is therefore directly coupled to individual documentation effort and constrained by investigators' time, attention, and capacity to produce high-quality data alongside routine clinical care. Because investigator compensation is bound to time-based FMV reimbursement schemes, additional effort invested in data quality or completeness cannot be adequately rewarded. As a result, both the scale and quality of data production remain structurally limited, leaving substantial potential for improvement.

Against this backdrop, the adoption of an EHR2EDC service has the potential to alter this dependency by reducing the need for redundant manual data work at the point of care. Figure 5 illustrates an idealized target configuration of value creation in the NIS data-producing arrangement. While the overall sequence of actors remains largely unchanged, in this scenario, the study site infrastructure now can be directly connected to

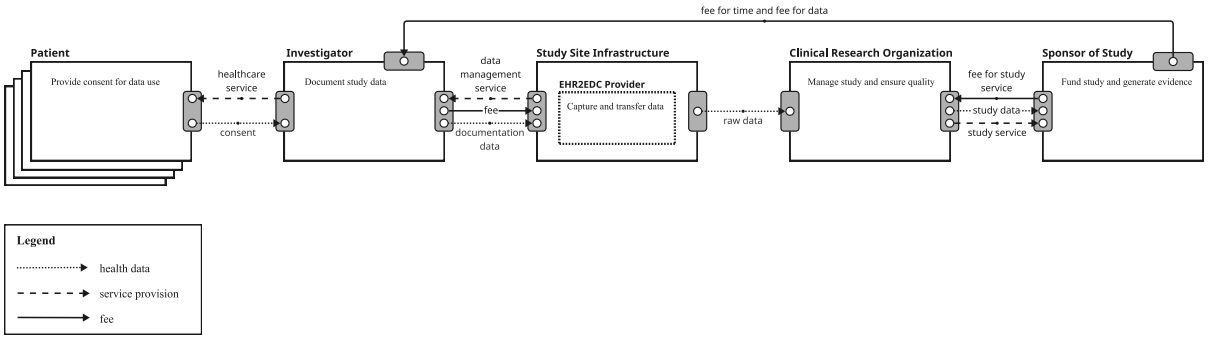


Fig. 5 Impact of the EHR2EDC service innovation on the value co-creation in NIS.

CRO through an EHR2EDC service. By embedding this service within the study site infrastructure, structured clinical data can be extracted from local EHR systems and can be semi-automatically transferred into the EDC system. In reality, it is possible that a large share, but not all, of manual entries can be automated.

From a system-level perspective, this shift relocates data transformation activities from individual investigators to a shared technological service. Investigators remain responsible for high-quality clinical documentation, but their contribution to data production for research purposes is mediated by infrastructure-level services rather than by manual re-entry of collected data. Consequently, value creation in NIS becomes less dependent on individual efforts and more closely tied to the interoperability, performance, and governance of shared digital infrastructures. Efficiency gains are thus collectively produced at the system level. In principle, a higher degree of automated data transfer would lead to less effort for investigators and lower costs for conducting NIS.

While the prospective e3-value model illustrates how EHR2EDC restructures value creation at the system level, it does not by itself make explicit how these changes translate into concrete economic consequences for individual actors. Because negotiations in the data-producing arrangement hinge on whether system-level efficiency gains align with actor-level cost structures, we complement the qualitative model with an exemplary quantitative calculation. This calculation operationalizes the economic effects of partial automation and makes the distributional consequences of EHR2EDC adoption explicit, thereby grounding the subsequent negotiation dynamics in concrete financial terms.

To quantify the systemic potential of EHR2EDC in NIS, we formulated a set of assumptions and calculated the relevant per-patient documentation costs for the key organizational actors involved in the data-producing arrangement. The resulting model

Tab. 3 Exemplary calculation of the impact of EHR2EDC on the data production costs (in Euros) including x = costs for CROs and y = costs for study site infrastructures to adopt EHR2EDC with 50% automation.

Actors	Transaction	Status quo scenario (0% automation)	EHR2EDC scenario (50% automation)
Investigator		1,000	500
CRO	Services	0	x
	SDV	300	180
Study Site Infrastructure		0	y
Sponsor	Services + Investigator fee	-1,000	-(500+x+y)
	SDV fee	-300	-180
	Total sponsor expenditure	**-1,300**	**-(680+x+y)**

is summarized in Table 3. For illustrative modeling purposes, we assume a three-year study horizon to compare the economic implications of the status quo and EHR2EDC scenarios. This assumption does not imply that all NIS follow this duration, as study lengths vary considerably depending on therapeutic area and study design (von Jeinsen & Sudhop, 2013). Furthermore, we assume per-patient investigator fees of €1,000 and exclude single site set-up fees, as these remain constant across scenarios. Investigators are compensated by the sponsor at a rate of €100 per hour for documentation activities. Patients are not compensated for study participation. Payments to CROs for general study management services are likewise excluded, as they represent fixed costs in the model.

Source data verification (SDV) costs are considered separately, as EHR2EDC directly affects this cost component. In the status quo, CROs typically provide SDV as a service to sponsors by visiting each study site once per year and reviewing the source data of recruited and consented patients. Overall SDV costs consist of travel expenses (€300 per visit) and CRO personnel costs (€1,200), reflecting the time spent on site. This results in total SDV costs of €1,500 per year, or €4,500 per study site over three years. Assuming 15 patients per site, SDV costs amount to €300 per patient for the entire study duration.

In the EHR2EDC scenario, we assume a 50% degree of automated data transfer. This reduction in manual documentation effort leads to a corresponding reduction in investigator time and thus halves investigator payments. Moreover, SDV requirements are reduced accordingly. Under this assumption, SDV costs consist of three site visits with €600 personnel costs and €300 travel costs each, resulting in total SDV costs of €180 per patient over the entire study period. At the same time, CROs and study site infrastructure providers incur additional, currently unspecified costs related to the provision and operation of EHR2EDC services, denoted as x and y respectively.

From an economic perspective, a reconfiguration of the data-producing arrangement becomes feasible only if all participating actors can cover their respective costs and perceive the outcome as acceptable. Sponsors must benefit from lower overall expenditures, CROs and infrastructure providers must recover their additional service-related investments, and investigators must be willing to accept lower compensation in exchange for reduced documentation effort. Consequently, the feasibility of EHR2EDC adoption depends on the degree of automation achieved and the associated cost structure of the enabling services.

The exemplary calculation demonstrates that EHR2EDC generates efficiency gains at the system level but simultaneously redistributes costs and revenues across actors. Whether these gains can be realized in practice depends on how additional infrastructure and service costs are allocated and whether reduced investigator payments remain acceptable.

In line with this analysis, the workshop discussions revealed several further aspects that require negotiation and collective coordination of all participating actors in the data-producing arrangement.

First, participating actors emphasized that developing and integrating an EHR2EDC service requires substantial upfront investment that exceeds the financial capacity of any single organization involved in the data-producing arrangement. CROs noted that, although they would benefit from reduced data management costs and a reduced monitoring effort, most CROs do not conduct enough studies to break even on the incurred fixed costs of designing, developing, and maintaining such a data infrastructure. This creates a fundamental conflict. While an EHR2EDC service generates efficiency gains at the system level, these gains cannot be realized within the economics of an individual organization or conducted study. Participants therefore argued that investment costs would need to be shared across multiple CROs and sponsors. Under such a collective approach, CROs could improve operational efficiency and data quality, while sponsors would benefit from lower marginal costs per study and thus the possibility to conduct more studies given a

specific research budget.

Second, participating actors emphasized that EHR2EDC adoption depends on a high degree of interoperability between data formats and standardization efforts. Existing EHR systems differ widely in data formats, documentation practices, and data quality, which limits the overall scalability of a prospective automated data transfer. As a result, harmonized indication-specific data models and shared vocabularies were seen as essential preconditions for an EHR2EDC service. Although some CROs expressed interest in operating EHR2EDC services themselves, they acknowledged that doing so would first require long-term investments in standardized architectures and semantic alignment that cannot be justified on a study-by-study basis.

Third, the discussions revealed concerns about value creation for participating actors who do not directly benefit from efficiency gains in NIS. Study site infrastructure providers and investigators highlighted that they would bear considerable switching, integration, and workflow adaptation costs without receiving higher reimbursement for their activities. Participating actors argued that the adoption of an EHR2EDC service would simultaneously need to offer tangible additional benefits to involved hospitals and clinics. For instance, participating actors mentioned that healthcare providers need to be enabled to leverage high-quality data for their own internal processes. This would incentivize them to produce higher-quality data.

Fourth, sponsors recognized the potential for substantial long-term cost savings through reduced documentation effort, monitoring costs, and requirements for the verification of source data. However, they emphasized the need for scalable and transparent pricing models for EHR2EDC services. Participating actors discussed whether such services should be priced per study, per patient, or through licensing or subscription models, and how break-even points would depend on study volume and reuse of the study infrastructure. Several participating actors further noted that, at a broader level, widespread EHR2EDC service adoption could increase both the volume and quality of NIS conducted in the European Union, strengthening the region's position in real-world evidence generation in the pharmaceutical industry (cf. Benkenstein et al., 2017).

Fifth, the implementation of EHR2EDC implies that investigators would receive lower payments in exchange for reduced documentation effort. While this appears reasonable from an efficiency perspective, established study sites with trained investigators and study nurses must still be willing to accept lower payments and reallocate the time previously spent on documentation to additional studies or patient care. As described, prior to the diagnosing phase of the AR approach, several exploratory studies were conducted under the oversight of the senior expert. Among these, a qualitative study identified a threshold of 20% payment loss acceptance by investigators, which clearly indicates that EHR2EDC constitutes not only a technical challenge but also a socio-economic one.

In general, the findings indicate that the adoption of EHR2EDC constitutes not merely a technological upgrade at the system level. While automation can reduce average data production costs, its realization depends on a negotiation process and collective coordination among participating organizations. The negotiation between organizations encompassed questions regarding the sharing of the investment burden, standardizing data models, aligning incentive structures, and distributing the generated value across participating actors in the entire data arrangement.

4.3 System-Level Impact of Health Data Space Services

Whereas EHR2EDC services primarily restructure how data is produced and transferred to the EDC, the adoption of a health data space enables the secondary use of study data beyond the original sponsor's purpose. With this, the health data space extends the downstream value creation of the NIS data-producing arrangement. Figure 6 illustrates this extension in the e3-value network model.

In this reconfiguration, data generated in NIS can be offered to secondary data users, such as competing sponsors, independent researchers, or other approved organizations. These actors pay fees for data access, thereby creating additional revenue streams for the original data provider. As a result, study data are no longer consumed exclusively within a single sponsor.

While discussing the e3-value model, participating actors revealed several structural issues that require a renegotiation of several aspects in the data-producing arrangement.

First, participating actors highlighted the ambivalent position of study sponsors as both the primary investors in NIS and potential data providers in a health data space. On the one hand, sponsors could generate additional revenues by offering personal health data for its secondary use, allowing them to partially recover their initial study investments through repeated data reuse. On the other hand, sponsors expressed concerns about losing exclusive control over their data, particularly in competitive contexts where unfavorable findings could be exploited by competitors. Accordingly, participating actors argued that sponsors would support secondary data sharing only if governance mechanisms clearly protect their intellectual property and limit negative downstream implications for product-related claims.

Second, participating actors emphasized that personal health data arising from studies is currently produced for a narrowly defined primary purpose. Effectively making this data suitable for secondary use would require changes in how the data is produced at the point of care, including the adoption of standardized data models and documentation practices. However, participating actors repeatedly noted that investigators and study site infrastructure providers are unlikely to adopt additional standards if exclusive secondary use rights and revenues remained with sponsors alone. As a result, several participating actors discussed alternative revenue-sharing models in which investigators and other contributing actors could participate in downstream value creation through health data spaces. Such models would depart from prevailing FMV reimbursement schemes and would require regulatory adjustments, as well as new contractual arrangements.

Third, the workshop surfaced important implications for the business models of intermediary actors, particularly CROs and study site infrastructure providers. In the modeled value constellation, these actors could evolve from purely operational service providers into facilitators of data reuse by supporting standardization, certification, and quality assurance of health data. Several participating actors suggested that CROs, for example, could offer data-related services to hospitals and clinics, such as analytics or benchmarking tools, thereby incentivizing investigators to

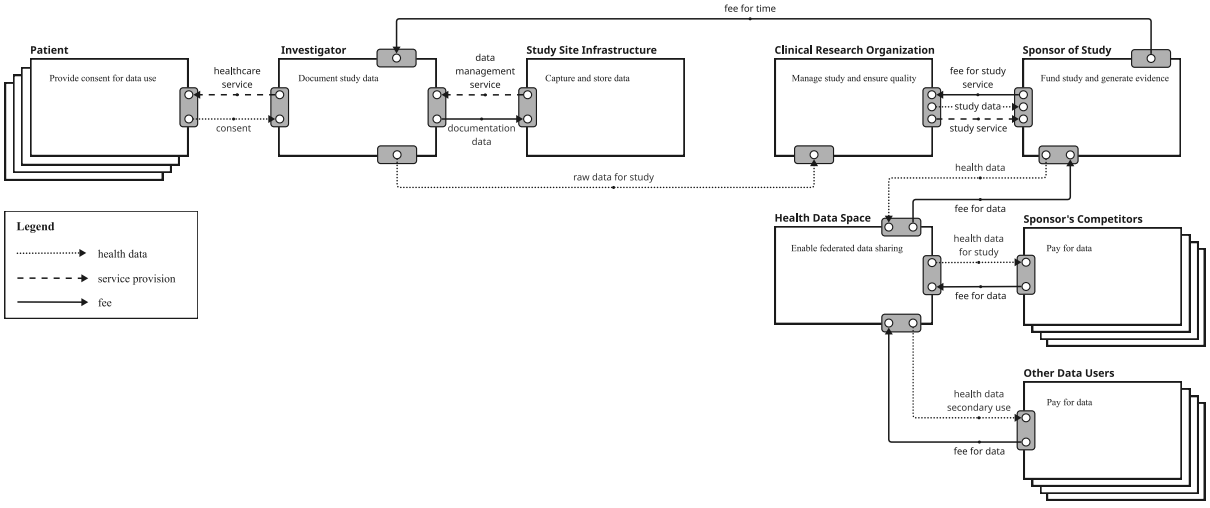


Fig. 6 Impact of the health data space on the data-producing arrangement.

produce high-quality data not only for the original sponsor but also for their own organizational purposes. This could also solve some of the issues presented in the previous section (see 4.2). However, such role changes would require CROs to develop new capabilities and would challenge established business model logics centered on the execution of studies alone.

Generally, these findings indicate that the adoption of health data spaces is not merely a technological extension of the NIS data-producing arrangement. Rather, it constitutes a systemic transformation that hinges on negotiating fundamental questions about data ownership, exclusivity rights, alignment of incentive structures, and the redistribution of value across participating actors with changing or new business models.

4.4 Actor-Level Evaluation Influencing the System-Level Transformation

Even throughout the discussions on the system-level potentials of each service innovation, participating actors constantly pointed out the individual consequences for them in the arrangement. Participating actors that represented investigators and CROs pointed out that the systemic opportunities of EHR2EDC and health data space services will only become realizable if data providers, specifically healthcare professionals, perceive the resulting reconfiguration as favorable for their own value creation.

Fragmented, proprietary implementations were widely viewed as economically inefficient, as they would multiply investment costs and undermine interoperability ambitions, thereby limiting both the automation potential and reuse of health data from studies. Both service innovations were framed as parts of a shared infrastructure rather than competitive assets.

However, the discussions also revealed that system-level benefits do not automatically translate into acceptance at the actor level. No single organization was seen as both willing and able to bear the investment risks associated with developing and maintaining EHR2EDC infrastructure by themselves. Sponsors, CROs, and study site infrastructure providers each face structural constraints that limit their capacity to invest unilaterally. As a result, participants converged on the need for collaborative investment and participatory governance models. However, such collective solutions require explicit negotiation and agreement on how costs, risks, and benefits are redistributed over time.

Within this negotiation process, investigators and sponsors emerged as the pivotal actors. For investigators, adoption depends on whether service innovations improve their position beyond reducing manual workload. Under current FMV reimbursement schemes, a higher quality of data does not translate into higher compensation. Participants therefore questioned whether alternative incentive structures would be necessary to align investigators' efforts with system-level goals, while also acknowledging the importance of non-financial motivations such as an improved quality of care and research relevance.

For sponsors, the evaluation centered on a trade-off between long-term system-level benefits and a potential short-term loss of control. While sponsors recognize the potential for cost reductions and health data reuse, adopting shared data infrastructures challenges project-based budgeting practices and raises concerns about data exclusivity in competitive environments. Participating actors emphasized that sponsors would support these innovations only if governance mechanisms clearly protect intellectual property and align data production with secondary use requirements.

The discussions on the individual actor-level perspective demonstrated that system-level transformation hinges on a negotiation that weighs collective opportunities against actor-level evaluations of how value creation shifts over time. Service innovations can only be implemented if the prospective positions of key participating actors within the data-producing arrangement are explicitly accounted for and perceived as acceptable. In this sense, the adoption of EHR2EDC and

health data spaces is not driven by technical feasibility alone, but by negotiated alignment between systemic value creation and individual value capture.

5. Discussion

5.1 Contributions for Practice

This research shows that the adoption of EHR2EDC and health data space services in the context of NIS cannot be understood as a purely technical form of service innovation. Instead, their adoption requires a systemic reconfiguration of the underlying data-producing arrangement (Aaltonen & Stelmaszak, 2024). By modeling prospective value constellations (Jussen et al., 2024) and jointly discussing them with participating organizations, this study reveals how automation and secondary data use may prospectively transform the data production process (cf. Kilgus et al., 2024; Kari et al., 2024). Our findings demonstrate that the realization of efficiency gains and reuse benefits depends on negotiated changes in data infrastructures, standards, and incentive structures, rather than on the adoption decisions of individual actors in isolation. Similar dynamics have already been observed empirically in other industries, such as the automotive sector, where the adoption of data spaces and related service innovations has likewise depended on participatory governance structures that support the collective negotiation process (Otto & Jarke, 2019; Kari et al., 2025).

For practitioners, this study offers first general guidance on how to organize and govern the implementation of service innovations in data-producing arrangements and second context-specific guidance for implementing EHR2EDC and health data space services in NIS. Furthermore, the findings yield several concrete recommendations for data-producing arrangements in the NIS context.

First, the results point to the practical need for decision-support tools for sponsors and investors that make the economics of automation explicit. Simulation tools that relate reductions and break-even points to parameters such as patient volumes, degrees of automation, and reuse potential can support more informed investment decisions and reduce coordination failures across participating actors.

Second, this research surfaces a critical regulatory and managerial issue concerning investigator compensation schemes. Predominantly time-based reimbursement structures incentivize effort minimization rather than data quality and reuse. A reimbursement scheme that is aligned with data quality, completeness, and prospective reuse potential of data rather than the time spent must be tested and accepted by all actors across the whole data-producing arrangement. The tests must cover a compliance, socio-economic, and risk-benefit evaluation. The findings therefore support ongoing calls for regulatory adjustments that allow investigators to participate in downstream value creation enabled by health data spaces, thereby aligning incentives for high-quality data production with broader system-level objectives.

Third, the study highlights the need to standardize interfaces between study site infrastructures and CRO systems. Interoperability at this boundary determines whether efficiency gains achieved at the point of care can propagate downstream into study management, monitoring activities, and the secondary use of health data (cf. Marx et al., 2024). Fragmented or study-specific interfaces risk merely relocating manual data work rather than eliminating it. Which actors are best positioned to provide EHR2EDC services (CROs or study site infrastructure providers) remains an open question and will depend on market readiness and investment capabilities. Experiences from adjacent domains, such as clinical trials, suggest that a convergence of services across organizational boundaries is likely. From the investigators' perspective, the critical challenge will be to enable seamless access to research workflows at the point of care without introducing additional friction into routine clinical practice (IgniteData, n.d.).

Fourth, the results underscore the necessity

faces at the point of care. Both automation and secondary data use presuppose data that are fit for reuse, yet investigators generate data for a specific purpose and operate under substantial time pressure. Standardized documentation structures, analogous to disease management programs in EHRs but designed for scientific research, combined with intuitive interfaces that align clinical and research needs, are critical to improving data quality without increasing workload.

Fifth, the findings point to the practical relevance of an explicit orchestration role that moderates and balances such multi-actor transformation processes. Depending on the context, this role may range from facilitating communication and alignment among actors to assuming contractually secured entrepreneurial responsibility for specific implementation scenarios (cf. Kari et al., 2025), for example by pre-financing technical, legal, or organizational investments or negotiating adapted reimbursement schemes. Making this orchestration role explicit can help overcome coordination limitations and enable the realization of system-level efficiency gains in practice.

5.2 Contributions for Research

This study primarily contributes to the emerging literature on data-producing arrangements (e.g., Aaltonen & Stelmaszak, 2024) by advancing understanding of how participating organizations drive reconfiguration efforts in practice to enable the adoption of service innovations. Prior research has emphasized that service innovations may act as drivers that transform institutional or organizational arrangements (e.g., Wallin & Fuglsang, 2017). Our findings suggest a complementary and partly inverted perspective in the context of data-producing arrangements. In such complex interorganizational settings, service innovations do not merely function as exogenous triggers of change (Vargo et al., 2015; Jaakkola et al., 2018). Rather, their adoption may presuppose prior or parallel transformations of the affected arrangement itself, which require Benfeldt et al., 2020; Couillault et al., 2017). In this sense, the study does not simply reiterate that service innovation is multi-actor in nature (Lusch & Nambisan, 2015), but specifies more precisely how adoption in data-producing arrangements depends on collective reconfiguration work.

More specifically, our findings suggest that the adoption of service innovations in data-producing arrangements hinges on negotiations over a specific set of arrangement elements, namely data design choices, infrastructural responsibilities, governance mechanisms, incentive structures, and the allocation of downstream value opportunities. The contribution therefore lies in unpacking why system-level improvements in value co-creation do not automatically translate into adoption at the arrangement level. Even when a service innovation promises efficiency gains or additional reuse benefits for the overall arrangement, participating organizations may still resist or delay adoption if they anticipate disproportionate data-production costs, increased regulatory risks, or a loss of control over data and downstream value capture. Thus, the findings contribute to the literature on data-producing arrangements by suggesting that adoption depends on the alignment between system-level value creation and actor-level evaluations of value capture.

Recent work has used e3-value modeling to identify generic value constellations in interorganizational data sharing settings (e.g., Jussen et al., 2024). This study builds on this work by using e3-value models as boundary objects in an action research intervention to examine how prospective value constellations are evaluated and negotiated in a healthcare-specific data-producing arrangement. The findings from our AR approach demonstrate that e3-value network modeling can function as an effective boundary object for moderating complex, multi-actor negotiation processes in data-producing arrangements. By explicitly visualizing value exchanges and interdependencies, e3-value models provide a shared frame that enables heterogeneous actors (e.g., study sites, sponsors, CROs, and infrastructure providers) to articulate interests,

evaluate trade-offs, and surface misalignments early in the process. In situations where service innovations promise system-level efficiency gains but redistribute costs, risks, or control asymmetrically, such representations support structured discussions about acceptable reconfigurations of roles, responsibilities, and governance mechanisms. Practitioners can even use e3-value models as a deliberate intervention tool in an AR approach to reduce ambiguity, align expectations, and prevent adoption deadlocks before technical implementation efforts begin.

Building on these insights, we propose in Figure 7 a process model that conceptualizes the adoption of a service innovation in data-producing arrangements as a negotiation-centered process rather than a linear implementation sequence. The process starts with assessing service innovations that promise improvements in the data production process. These innovations are then assessed in terms of their expected system-level impact on value co-creation across the arrangement. Subsequently, participating organizations evaluate the actor-level implications for value capture, including expected costs, responsibilities, risks, and control over data. Divergences between system-level benefits and actor-specific consequences trigger collective negotiations, in which participating actors renegotiate data design choices, infrastructural responsibilities, governance mechanisms, incentive structures, and value allocation. If these negotiations lead to an acceptable collective reconfiguration of the data-producing arrangement, the service innovation may become adoptable and may subsequently transform the data production process. If not, unresolved tensions feed back into renewed evaluation and negotiation. While we did not observe multiple negotiation cycles empirically, participating organizations anticipated following such a process. In this way, the model offers an ex ante process perspective on how service innovations are assessed and negotiated before implementation. This further points to the potential importance of a trusted neutral orchestrator operating on a strategic level beyond the economics of individual studies that helps balance heterogeneous interests across the arrangement (Mukhopadhyay & Bouwman, 2019). An example for such an orchestrator would be the interorganizational alliance in Catena-X, an automotive data space (Kari et al., 2025).

For scholars studying data ecosystems, interorganizational data sharing, and data

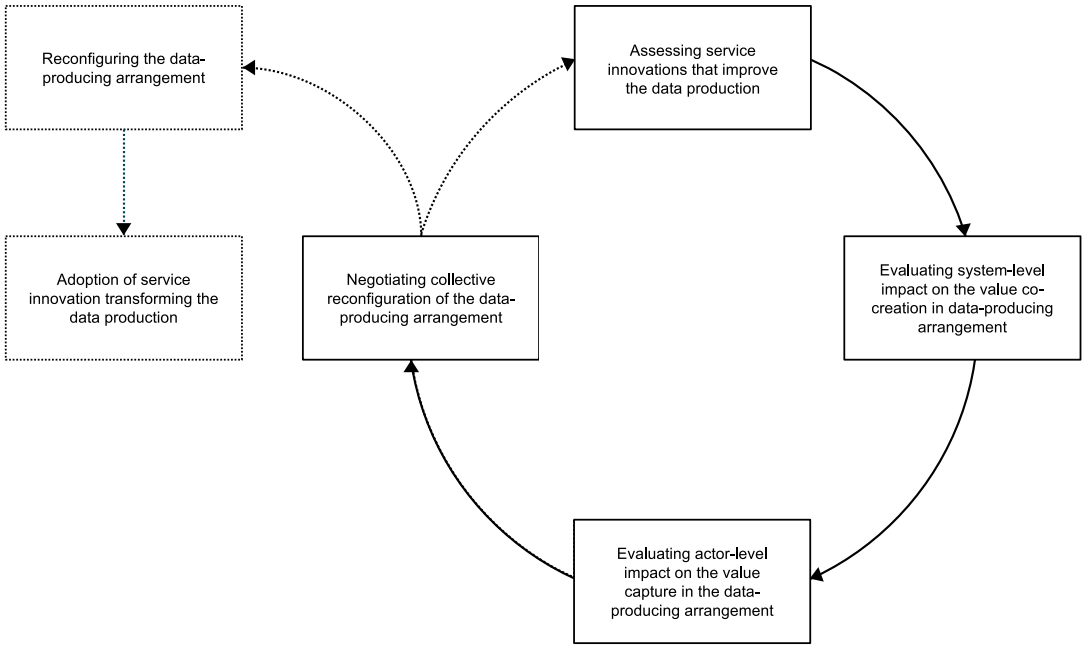


Fig. 7 Model of data-producing arrangements adopting service innovations through a negotiation-centered process.

spaces more broadly (e.g., Jacobides et al., 2018; Jussen et al., 2024; Schweihoff et al., 2024; Kilgus et al., 2024; Möller et al., 2024), our findings may offer an informative empirical case of a comparatively bounded and formalized type of data ecosystem, characterized by a limited number of interdependent actors and relatively stable role constellations. In this respect, the case is interesting because it captures an evolutionary transition in which a data-producing arrangement, originally organized around the coordinated production of data for a specific purpose, faces pressures and opportunities to expand toward downstream sharing and reuse.

5.3 Limitations

This study has several limitations that must be considered when interpreting our findings. As is common in AR approaches, the results are context-specific and closely tied to the empirical setting in which the intervention was conducted (e.g., Susman & Evered, 1978; Baskerville, 1999). In this case, the findings are grounded in a NIS context. While the embedding of the research team in this specific arrangement ensured deep insights into practice, the observations may differ in other domains with distinct regulatory environments, incentive structures, or different degrees of data standardization. The insights may be particularly relevant to adjacent healthcare contexts that similarly rely on coordinated multi-actor data production under strong regulatory requirements, such as clinical trial networks, hospital research collaborations, or patient registries. Beyond healthcare, the findings may also inform other domains in which interorganizational data-producing arrangements are formalized and highly regulated, such as finance or insurance. In such settings, comparable tensions may arise between system-level benefits of service innovations and similar actor-level concerns.

An additional limitation concerns the nature of the applied AR setting. The intervention deliberately created an open, collective exchange aimed at exchanging ideas for the reconfiguration in an NIS context. Such a transparent format rarely exists in practice. As a result, rational argumentation, shared problem framing, and social desirability may have exerted a stronger influence than in more typical, isolated, or dyadic negotiations, where perceived uncertainties, strategic withholding of information, and mistrust toward third parties may play a more dominant role.

Furthermore, the composition of the research team represents a source of bias. As described in the methodology, one member of the author team is a senior expert representing a study sponsor, which may have influenced the framing and interpretation of certain findings. Although the emerging insights were critically discussed and validated in a multi-actor workshop involving representatives from CROs, study site infrastructure providers, investigators, and independent researchers, some interpretations may nonetheless reflect sponsor-related concerns more strongly than those of other actors (Coghlan, 2019).

Additionally, this study focuses on a specific set of service innovations. Deriving directly from practice, we decided to focus on EHR2EDC and health data space services. Other service innovations may be less disruptive and could be adopted without requiring extensive systemic reconfiguration or multi-actor negotiation. Accordingly, the findings should not be generalized to all forms of service innovations in data-producing arrangements without further empirical investigation.

Finally, the study reports findings from a single AR cycle. While this initial cycle generated meaningful insights and informed the conceptual contributions discussed in Section 5.2, additional AR cycles could provide a more longitudinal perspective on how data-producing arrangements evolve over time. Future research could follow subsequent phases of adoption and implementation to examine how negotiated reconfigurations stabilize, adapt, or potentially unravel as service innovations move closer to large-scale deployment. In this regard, further empirical studies on the ongoing adoption of EHR2EDC and health data space services in NIS represent a

promising avenue for extending the present findings.

6. Conclusion

We set out to examine how data-producing arrangements in the context of NIS can reconfigure to leverage EHR2EDC and health data space services for the collection and use of personal health data. To address this question, we modelled e3-value networks representing the status quo and prospective value constellations and used them to structure negotiations among organizations participating in a specific data-producing arrangement. The intervention indicated that realizing efficiency gains from automation and value creation from secondary data use requires participating actors to collectively realign data infrastructures, standards, governance mechanisms, and incentive structures.

Drawing on findings from this AR cycle, we propose an ex ante process model that conceptualizes the prospective adoption of service innovations in data-producing arrangements as a negotiation-centered process in which system-level value creation is weighed against actor-level implications of costs, risks, and control over data. Empirically, the study illustrates how such negotiations surface conflicts between collective benefits and individual feasibility, particularly for investigators, CROs, and sponsors operating under existing regulatory and reimbursement regimes.

For practice, the results highlight that the successful implementation of EHR2EDC and health data spaces requires collaborative investment models, standardized interfaces at the point of care, and revised incentive mechanisms that reward improved data quality and reuse. Looking ahead, further longitudinal design science or action research is needed to contribute to practice with possible reconfigurations and tools that help the NIS data-producing arrangement to transform over time in compliance with emerging regulatory implementations such as the EHDS legislation that will be applicable starting in 2029.

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