Original Paper

Level of Practice and Alignment With the European Electronic Health Record Exchange Format: Cross-Sectional Survey and Gap Analysis

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Abstract

Background: The European Health Data Space (EHDS) regulation aims to empower citizens and facilitate the seamless exchange of health data across European Union (EU) Member States. A critical enabler of this vision is the European Electronic Health Record Exchange Format (EEHRxF), which establishes a common structure and vocabulary for core health data domains. Despite its strategic importance, the practical implementation of this format faces significant challenges due to the fragmentation of systems, standards, and governance models across Europe.

Objective: This study aims to assess the feasibility of adopting the EEHRxF by evaluating the current level of practice and alignment across selected health care institutions and Member States, focusing on technical, organizational, and semantic readiness.

Methods: Using a multimethod approach, the study analyzed 3 priority categories: patient summaries, laboratory reports, and hospital discharge reports. Data collection included 5 feasibility demonstrators involving organizations from Hungary, Portugal, Greece, and Slovakia, complemented by stakeholder workshops, and 3 online surveys. The assessment used a dual lens: “level of practice” (current availability and structuring of data) and “level of alignment” (perceived importance of data fields).

Results: Analysis of 30 valid survey responses revealed a heterogeneous landscape. Patient summaries showed the highest maturity with 46% (317/682) structured fields, followed by laboratory reports (204/591, 35%), and hospital discharge reports (438/1549, 28%). A significant importance-practice gap was identified: while between 35% (902/2550) and 54% (427/784) of EEHRxF fields were rated as “very important,” a substantial portion of these critical fields remains unstructured (between 136/427, 32% and 445/902, 49%) or completely unavailable (between 47/349, 13% and 113/427, 26%) in current systems. Specific semantic analysis of Logical Observation Identifiers Names and Codes (LOINC) for diabetes management showed limited overlap (only 14 shared codes out of 57 in Hungary and 26 in Portugal), highlighting significant disparities in coding granularity. Technical barriers include reliance on unstructured free-text (up to 237/591, 40% in lab reports) and the continued use of proprietary or national coding systems.

Conclusions: While there is strong conceptual alignment with the EEHRxF vision, practical readiness varies substantially across data domains. Transitioning from proprietary formats to EEHRxF-compliant structures requires targeted investments in digital infrastructure, workforce training, and semantic harmonization. The study recommends that policymakers establish clear timelines and incentivize the adoption of standardized templates to bridge the gap between strategic intent and clinical practice.

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Keywords: European electronic health records exchange format; European health data space; eHealth network guidelines; patient summary; laboratory report; hospital discharge report

Introduction

Context

The European Health Data Space (EHDS) [1] is one of the most ambitious and transformative policy initiatives undertaken by the European Union (EU) in recent decades. Positioned at the intersection of health, digital innovation, and fundamental rights, the EHDS aims to create a trusted framework for the use and sharing of health data across EU Member States and associated countries. Its overarching goal is to empower individuals with secure access to their personal health data, enable its seamless exchange across borders, and facilitate the responsible secondary use of data for research, innovation, policymaking, and public health.

The EHDS is anchored in the broader vision of the EU's digital and health strategies, particularly the European Data Strategy and the Digital Single Market [2]. It is designed to address key fragmentation challenges in Europe's health data landscape, where systems, standards, governance models, and legal interpretations vary widely between countries, by providing both a legal and technical infrastructure that guarantees data interoperability, trust, and value creation. The EHDS seeks to ensure that health data flows across Europe as easily and safely as goods and services, enabling better health care delivery, enhanced medical research, and more resilient public health systems [3].

One of the most critical enablers of this vision is the European Electronic Health Record Exchange Format (EEHRxF). Established to facilitate the interoperability of electronic health records (EHRs) across the EU, the EEHRxF sets out a common structure and vocabulary for core health data domains [4]. Its primary objective is to ensure that any European citizen can access and share their health data in a standardized format, no matter where they receive care in the EU. The EEHRxF plays a strategic role in enabling interoperability across cross-border health services, including the MyHealth@EU infrastructure (European Commission [EC]) [5,6], while also supporting the implementation of the EHDS's primary data use pillar.

The synergies between the EHDS and other European data initiatives, such as the European Open Science Cloud (EOSC) [7], the AI Act [8], and sectoral data spaces (eg, cancer mission and rare diseases) [9], further highlight the strategic role of the EEHRxF. For example, the integration of health data into the EOSC depends on standardized metadata and ontologies; the training of high-risk AI models under the AI Act requires access to high-quality, interoperable datasets; and the development of European Reference Networks for rare diseases hinges on the ability to share structured clinical data across national borders. In all these contexts, the EEHRxF is a key enabler of interoperability, acting as the common reference layer that allows data to flow, be understood, and be reused responsibly.

Objectives of Feasibility Assessment

The EEHRxF currently defines structured formats for several key types of health data: patient summaries; electronic prescriptions; electronic dispensations; medical imaging studies and related imaging reports; medical test results, including laboratory and other diagnostic results and related reports; and discharge reports [1]. These data types were prioritized due to their high impact on continuity of care, especially in cross-border contexts. By harmonizing how this data is represented and exchanged, the EEHRxF supports safer, faster, and more informed clinical decision-making, whether a patient seeks care in another Member State or returns home with medical information that must be integrated into their domestic EHR system.

Technically, the EEHRxF builds on International and European standards such as Health Level Seven International (HL7) Fast Healthcare Interoperability Resources (FHIR) [10,11], Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT) [12,13], Logical Observation Identifiers Names and Codes (LOINC) [14,15], and *International Statistical Classification of Diseases (ICD)* [16,17], while aligning with European profiles and governance through initiatives like Integrating the Health Care Enterprise (IHE) [18] and the European Committee for Standardization/Technical Committee (CEN/TC) 251 [19]. It defines the structure, content, coding, and semantic consistency required to achieve meaningful interoperability. These standards ensure that both syntactic and semantic interoperability are achieved, enabling not just data exchange, but true data understanding across systems and institutions [20].

In addition to technical interoperability, the success of the EEHRxF and the broader EHDS depends on sustained political will, robust governance, cross-border collaboration, and the engagement of a wide range of stakeholders, including health care providers, IT vendors, patients, researchers, and regulators. Capacity building and change management are essential to ensure that standards are adopted and implemented effectively across diverse national systems [21]. Investments in digital infrastructure, workforce training, and semantic harmonization must accompany regulatory and technical developments to ensure that interoperability is not just defined on paper but realized in practice.

The feasibility demonstrators, while focused on technical interoperability, aimed at getting a clear understanding of all these dimensions [22]. The work conducted relied on numerous interactions with the involved entities, promoting open discussions, leveraging their knowledge and expertise on the way current EHR systems are built and used, and what needs to be done at the technical and organizational level for a successful adoption of the EEHRxF.

Research Focus

Among the data domains prioritized for standardization and exchange under EEHRxF are laboratory reports, hospital discharge reports, and patient summaries. These 3 document types play distinct yet complementary roles in ensuring continuity of care, improving patient safety, and enabling efficient clinical decision-making, especially when care is delivered across institutional or national boundaries. While all 3 are central to the EEHRxF, the empirical approach varies according to their current implementation status. Specifically, laboratory reports and hospital discharge reports were selected for hands-on feasibility demonstrators due to the existing gaps in their technical alignment. In contrast, patient summaries were evaluated primarily through expert workshops and stakeholder surveys, reflecting their higher maturity level in existing European digital health implementations.

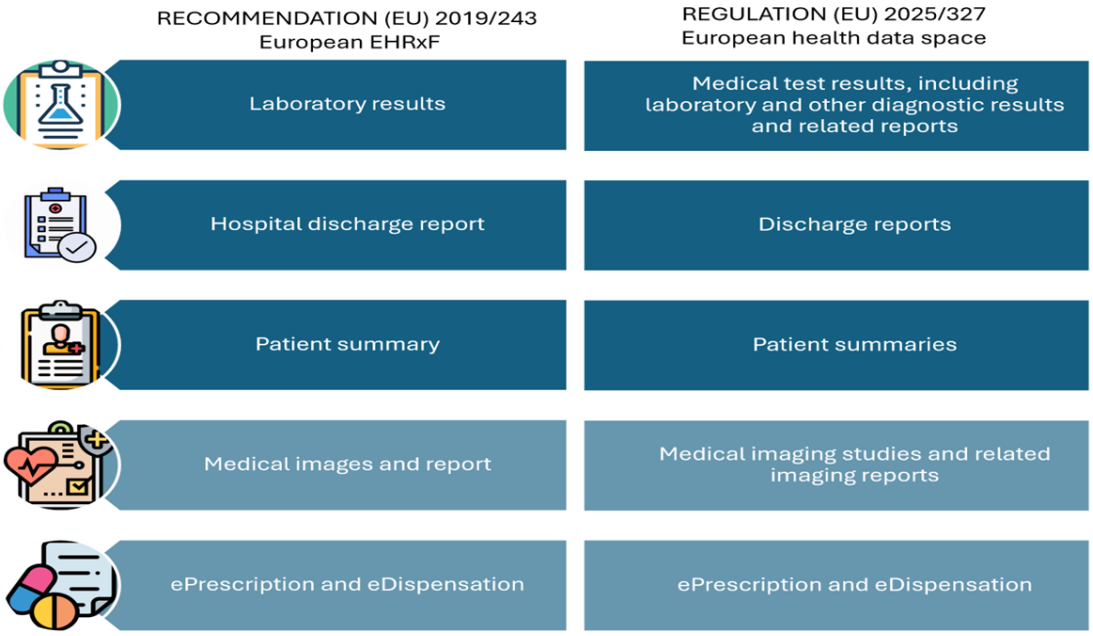
Patient summaries serve as concise overviews of a patient's most essential health information, including current medications, allergies, diagnoses, surgical history, and vaccinations. Designed for use in unplanned care settings, such as emergency rooms or cross-border encounters, they offer clinicians immediate access to critical insights that can inform safe and timely treatment. While the feasibility of this format has already been demonstrated through the MyHealth@EU infrastructure [6], the feasibility demonstration discussed here delved into a more practice-oriented perspective, aiming to understand how particular stakeholders (such as health care providers and professionals, national, regional, and local health infrastructures, and IT vendors) are aligning with it.

Laboratory reports, which include test results such as blood work, microbiology, or pathology findings, are among the most frequently generated and exchanged types of clinical data. The EEHRxF introduces a harmonized structure and coding system (eg, using LOINC for lab test identifiers) to ensure that test results can be interpreted consistently regardless of the country or system where they were produced. This interoperability is particularly important in managing chronic conditions, monitoring infectious disease outbreaks, and coordinating care for mobile populations such as cross-border workers or travelers. In our work, the feasibility demonstration focused on the real-world applicability of the EEHRxF by conducting an in-depth, condition-specific analysis centered on diabetes. The review included a field-by-field mapping of the EEHRxF specification against locally available EHR data, covering field presence, cardinality constraints, semantic encoding, and value set alignment. Special attention was given to the use of standard terminologies (SNOMED CT and LOINC) and their actual implementation within national systems.

Hospital discharge reports are comprehensive clinical documents issued upon a patient's release from hospital care. They provide a detailed record of diagnoses, interventions, procedures, medications administered, and follow-up recommendations. Standardizing discharge reports under the EEHRxF helps address longstanding fragmentation in how clinical data is documented and shared between hospitals and outpatient care providers. Due to the high level of complexity of such documents, the feasibility demonstration involved a comprehensive analysis of the EEHRxF data structure by conducting a systematic review of required data fields, their cardinality constraints, and the semantic coding systems specified for each data element. The exercise aimed to assess the alignment between EEHRxF specifications and the actual data availability and quality in representative national and regional EHR systems. By identifying structural gaps and mismatches in terminology use, the demonstration provided practical insights into the readiness of health data sources to support cross-border interoperability in line with EHDS objectives.

It should be noted that this nomenclature is derived from the priority categories defined in the "Commission Recommendation on a European Electronic Health Record exchange format (C(2019)800) of February 6, 2019" [4], which was the version available at the beginning of this work and is the one used in this paper. However, the EHDS regulation [1] has since changed the names of these priority categories, and the relationship between the 2 versions is presented in Figure 1.

Figure 1. Overview of the priority categories for health data exchange as defined by the European Commission (EC) Recommendation 2019/243 and their transition into the European Health Data Space (EHDS) Regulation. EHRxF: Electronic Health Records Exchange Format; ePrescription: electronic prescription; eDispensation: electronic dispensation; EU: European Union.



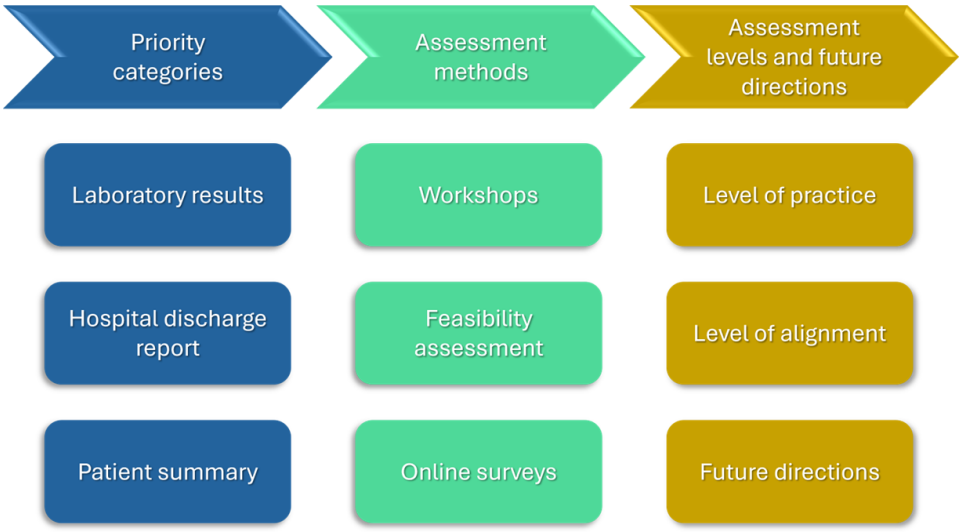
Methods

Study Design

The methodological approach developed to assess levels of practice and alignment with the EEHRxF is depicted in Figure 2. This 3-step strategy aims to guide the discussion with organizations and stakeholders in order to understand the maturity level, identify adoption obstacles, and determine future directions toward the EEHRxF.

The first step involves the selection of specific priority categories where the discussions and feasibility will focus according to the project objectives and involved organizations. The second step is the assessment methods, where the different participants are engaged in structured exercises to evaluate and discuss the adoption of the EEHRxF. Finally, the third step is the determination of assessment levels that translate into concrete metrics for the vision of the organizations involved in relation to the available guidelines. Throughout all steps, challenges, barriers, and adoption opportunities are always considered to determine the future directions on the EEHRxF adoption.

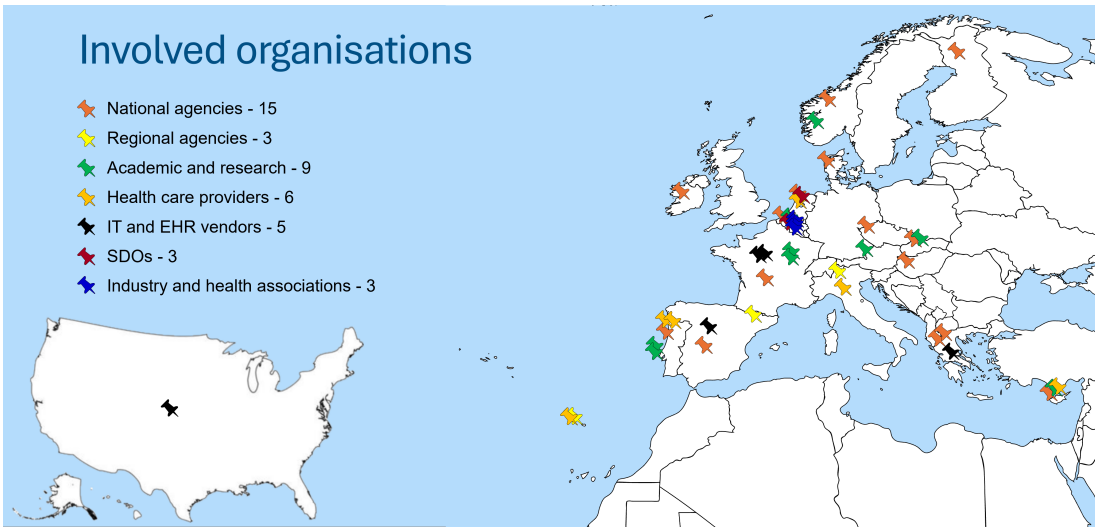
Figure 2. Methodological approach for assessing the European Electronic Health Records Exchange Format (EEHRxF) feasibility, illustrating the sequence from selecting priority categories to applying assessment methods and determining future directions.



Involved Organizations and Priority Categories

The involvement of different types of organizations related to and involved in the production, exchange, and consumption of health data was considered from the beginning of this work. The first group was formed with project partners and increased with the entry of new associated partners. In addition to these, through a series of workshops and online surveys, organizations external to the project were also engaged, and their contributions were collected. The organizations involved in these surveys participated on a voluntary basis; hence they were not preselected. We adopted an open participation approach where questionnaires were disseminated via project networks. As such, the resulting data reflects the insights of self-selected stakeholders who were interested in the topic and chose to contribute their professional expertise to this study. The types of organizations involved, and the respective countries, are shown in Figure 3.

Figure 3. Geographical distribution and types of participating organizations involved in the feasibility assessment. EHR: electronic health record; SDOs: Standards development organizations.



Considering the analysis conducted with organizations and their interest and availability, the selected priority categories were the laboratory report and hospital discharge report, for which a feasibility assessment was conducted. In addition to these categories, and during the project's progress, the patient summary was also considered as a relevant category for analysis. Medical images and reports and electronic prescription (ePrescription) and electronic dispensation (eDispensation) were not considered in this work.

Assessment Methods

The assessment methods used in this work aim to collect as much information as possible about the adoption of EEHRxF. Considering the different levels of maturity of the organizations involved, as well as the available resources, 3 different methods were considered:

1. Workshops: The workshops aim to bring together organizations interested in adopting EEHRxF and others that are working in this direction with the aim of exchanging experiences and extracting insights, barriers, and opportunities. These workshops can be online sessions or in-person events, trying to bring together in the same space those who benefit from using the EEHRxF (national agencies, regional agencies, health care providers, and health care professionals) and those who have a fundamental role in its technical definition (Standards Development Organizations [SDOs], IT and EHR vendors), including also the patient as the final beneficiary.
2. Feasibility assessment: The feasibility assessment aims to assess and validate the appropriateness of the EEHRxF, identifying gaps and planning its adoption via feasibility demonstrators. The feasibility demonstrators are constituted by organizations (partners within expanding digital health through a pan-EEHRxF-based Ecosystem [XpanDH] project consortium) that voluntarily test the use of EEHRxF through the definition of concrete use cases for exchange and adoption scenarios. These demonstrators list and identify needs for better guidelines and draft implementation acts.
3. Online surveys: The online surveys aim to increase the collection of assessment levels across Europe, reaching more organizations (including partners within XpanDH and expanding the European EHRxF to share and effectively use health data within the EHDS [xShare] projects consortia) and facilitating their contribution without being part of the project. Through an online questionnaire, all health information made available by organizations and their alignment with EEHRxF are collected.

Assessment Levels and Future Directions

To assess alignment and practice levels and achieve a common understanding regarding the EEHRxF, the eHealth Network (eHN) guidelines serve as the foundation for specifications in this work. The eHN guidelines on electronic exchange of health data aim to facilitate the cross-border

interoperability of EHRs in the EU. They do so by supporting Member States in their efforts to ensure that citizens can securely access and exchange their health data wherever they are in the EU. The guidelines provide a list of technical requirements and enablers for implementation [23].

Taking into account the developments of the EEHRxF and the work underway on the technical specifications, the eHN guidelines are used as a basis for consensus regarding the data fields that should be part of each priority category. Within the specific scope of this framework, these 2 dimensions are operationalized as follows:

1. Level of Alignment: Defined in this study as the degree to which stakeholders perceive a specific data field as important and relevant for cross-border data exchange. This dimension is not focused solely on semantic or syntactic conformity but instead captures stakeholders' perceived importance of each data field as defined by the EEHRxF. Alignment reflects whether specific data fields are considered very important, important, or not important. This qualitative evaluation is essential for understanding practical prioritization: while EEHRxF defines a harmonized structure, different organizations and national or regional systems assign varying degrees of value to individual fields based on their clinical relevance, legal obligations, technical feasibility, or workflow impact.
2. Level of Practice: Defined in this study as the degree to which a specific data field is currently available within existing health care systems. It assesses whether these data elements are present, if and how they are structured, and whether they are actively populated within routine health care workflows. This dimension reflects the actual practice of local, regional, or national infrastructures to produce and exchange the data elements expected by the EEHRxF.

Furthermore, as future directions, additional fields considered important in each category are collected, as well as the challenges and barriers to the adoption of the EEHRxF in different organizations and possible ways to facilitate this adoption.

Implementation

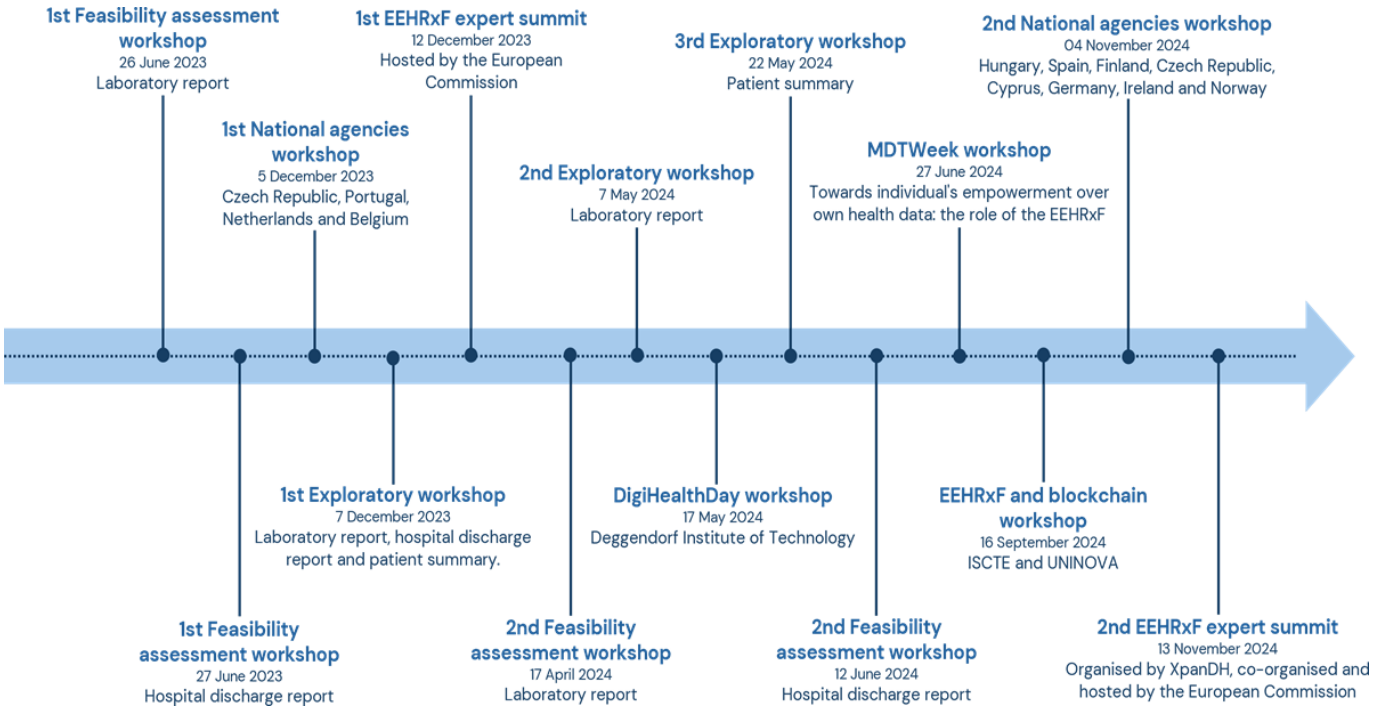
Overview

The implementation of the assessment methods described above was carried out throughout the course of XpanDH as well as used as a starting point for the xShare project (still ongoing). The details on their execution are provided here.

Workshops

Several workshops were held focused on the 3 selected priority categories, with different formats and audiences. Figure 4 shows the series of workshops held during the project.

Figure 4. Timeline of stakeholder engagement and consultation workshops conducted between June 2023 and November 2024 to support the European Electronic Health Record Exchange Format (EEHRxF). ISCTE: Instituto Universitário de Lisboa; MDTWeek: Madeira Digital Transformation Week; UNINOVA: Instituto de Desenvolvimento de Novas Tecnologias.



The feasibility assessment workshops made it possible to align and deepen the work developed in the feasibility demonstrators, as well as disseminate and discuss the results. The exploratory workshops were dedicated to new partners and those external to the projects, where the levels of adoption and implementation prospects of EEHRxF in different contexts were discussed for each priority category. The national agencies workshops aimed to understand the

state of practice in member states, understanding not only the alignment with the EEHRxF at cross-border but also the prospects for adoption at national and regional levels. Finally, the EEHRxF Expert Summits were 2 major events where all results were presented to the community and collaboration with other projects working on EEHRxF was deepened, in partnership with the EC.

Feasibility Assessment

Overview

Regarding feasibility assessment, 5 feasibility demonstrators presented in Table 1 were created focusing on the 2 priority categories, laboratory reports and hospital discharge reports. A set of activities has been developed in the context of each feasibility demonstrator, resulting in structured use cases. These use cases include the definition of motivation, objectives, context of data exchange, current ("AS-IS") and future ("TO-BE") scenarios. Subsequently, each feasibility demonstrator engaged in exercises aimed at understanding existing methods related to data exchange, analyzing internal formats, and identifying requirements for potential implementations, such as the creation, replacement, or modification of systems. Finally, as the main output for the assessment and alignment levels, a gap analysis is carried out between the data structures currently used and those defined by the eHN guidelines for the priority categories considered in the demonstrator.

Table 1. List of feasibility assessment demonstrators.

ID	Partner	Country	Priority category
1	OKFŐ[a]	Hungary	Laboratory report
2	ULS SA[b]	Portugal	Laboratory report
3	ULS SA	Portugal	Hospital discharge report
4	KETEKNY[c]	Greece	Hospital discharge report
5	NCZI[d]	Slovakia	Hospital discharge report

[a]OKFŐ: National Directorate General for Hospitals.
[b]ULS SA: Unidade Local de Saúde de Santo António.
[c]KETEKNY: Greek DRG Institute.
[d]NCZI: Slovakia National Center for Health Information.

The architectural and workflow descriptions provided for the feasibility demonstrators represent "TO-BE" scenarios and future-state visions. These models outline how health care organizations intend to implement the EEHRxF specifications in the mid-to-long term and serve as a continuous work in progress designed to ensure technological readiness for upcoming European regulations. Consequently, the discussed benefits and impacts reflect the outcomes of a rigorous theoretical gap analysis and the anticipated potential of these piloted frameworks.

Feasibility Demonstrator 1

Feasibility demonstrator 1 aims to improve the continuity of care for patients with diabetes by focusing on the exchange of laboratory reports within the context of health data interoperability at a national level. Effective management of diabetes requires regular monitoring of specific laboratory parameters to ensure they remain within safe ranges. Laboratory reports are securely stored in Hungary's National Electronic Health Record System (EESZT; National Directorate General for Hospitals, Hungary), providing access to all health care providers involved in the patient's care. This centralized infrastructure facilitates seamless information exchange, supporting informed clinical decision-making and comprehensive patient management.

In Hungary, all state-funded health care providers and private physicians are legally required to use the EESZT for sharing patient data. Laboratory reports are stored in providers' IT systems according to internally implemented standards and transmitted to the EESZT. Until recently, this data transfer was limited to unstructured PDF documents. However, structured laboratory reports have been introduced, enabling the standardized reporting of more than 400 laboratory measurements using a proprietary XML format. These proprietary codes are mapped to LOINC, allowing for standardized interpretation and broader interoperability. Health care providers can access both legacy PDF reports and the newly introduced structured documents, while patients can retrieve the reports in PDF format via the patient portal.

The demonstrator outlines 2 future scenarios: a short-term and a long-term implementation strategy. In the short term (Figure 5), the existing proprietary XML format [24] will be used for structured data exchange between organizations, leveraging laboratory systems already capable of transmitting such reports and health care systems equipped to process them. At the EESZT level, these structured data will be mapped to the EEHRxF to ensure compatibility with organizations adopting the EEHRxF and to support cross-border data exchange through the eHealth Digital Service Infrastructure (EHDSI).

In the long term (Figure 6), the goal is to transition from the proprietary XML format to the EEHRxF, recognizing that both formats may coexist during the transitional period until full adoption is achieved. While legacy reports will remain in PDF format, newly generated documents will include a PDF representation to maintain compatibility with the patient portal. This phased approach ensures that the structured representation of laboratory data aligns with international standards while maintaining accessibility for health care providers and patients.

Figure 5. Proposed short-term "TO-BE" architectural diagram for feasibility demonstrator 1 (Hungary), illustrating the exchange of structured laboratory reports for diabetes management using a proprietary XML format mapped to the European Electronic Health Record Exchange Format (EEHRxF) via the national eHealth infrastructure. EHDSI: eHealth Digital Service Infrastructure; EESZT: Hungary's National Electronic Health Record System; OKFO: National Directorate General for Hospitals.

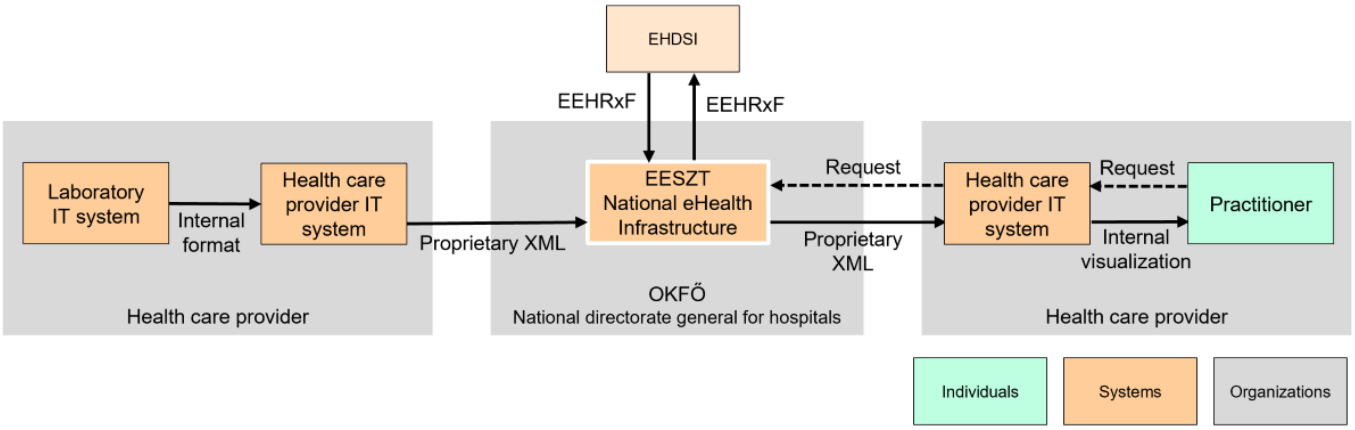
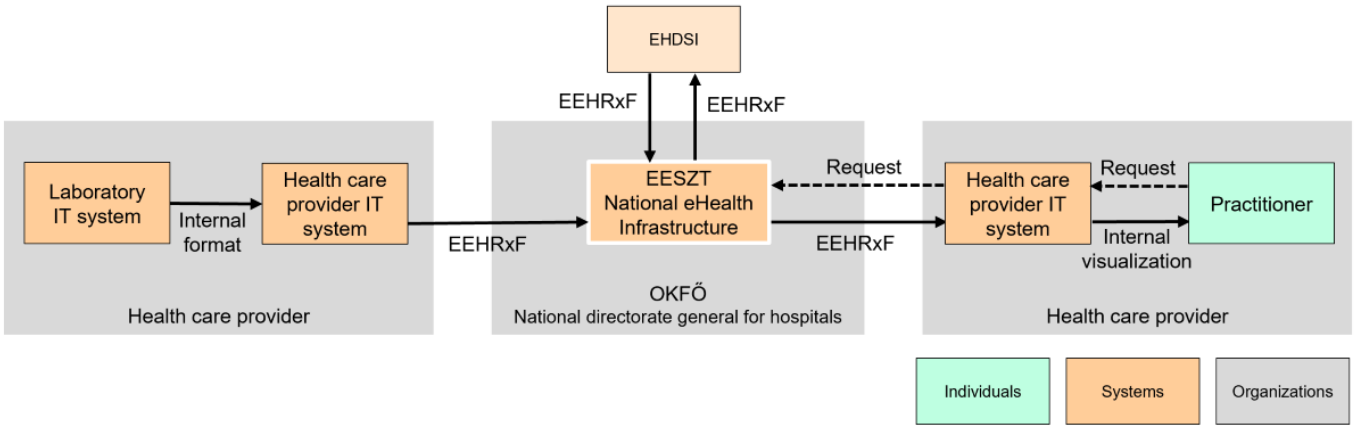


Figure 6. Proposed long-term "TO-BE" architectural diagram for feasibility demonstrator 1 (Hungary), depicting the full transition to the European Electronic Health Record Exchange Format (EEHRxF) standard for exchanging laboratory reports. EHDSI: eHealth Digital Service Infrastructure; EESZT: Hungary's National Electronic Health Record System; OKFO: National Directorate General for Hospitals.

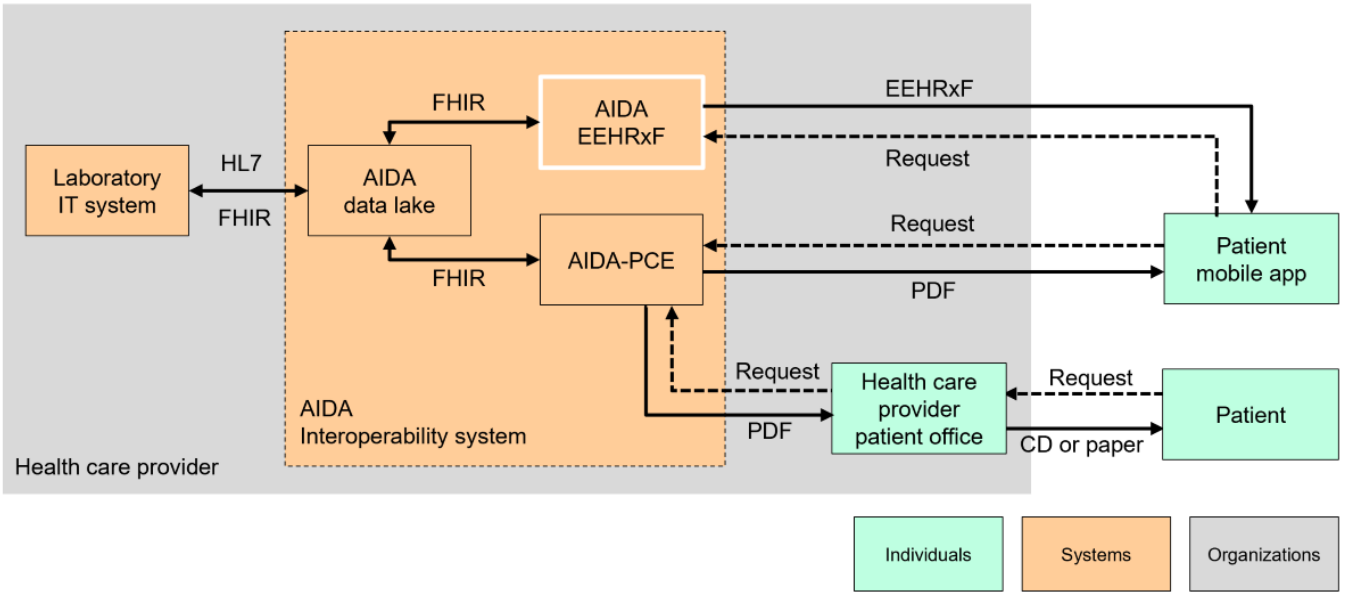


Feasibility Demonstrator 2

Feasibility Demonstrator 2 addresses the continuity of care for patients with diabetes by facilitating the exchange of laboratory reports between hospitals and patients. Effective management of chronic conditions like diabetes requires regular monitoring of specific laboratory parameters to ensure they remain within secure and safe ranges. In this demonstrator, laboratory reports are made accessible to patients who consent to access their structured data through a mobile app. Simultaneously, these laboratory reports are securely stored within the hospital Agency for Integration, Diffusion and Archive of Medical Information (AIDA; Unidade Local de Saúde de Santo António, Portugal) interoperability platform [25], ensuring that all health care professionals involved in the patient's care within the hospital have uninterrupted access to critical health data.

In the baseline infrastructure, Laboratory Information Systems (LIS) push diagnostic reports to the AIDA data lake using standard HL7 or FHIR protocols. Within this ecosystem, internal data transit relies on FHIR repositories, where the AIDA-Clinical Electronic Process (AIDA-PCE) module transforms incoming structured data into static PDF files. While health care professionals retain full native access to the structured data engine within the data lake, patients have legacy access to their laboratory history via the mobile app exclusively in unstructured PDF formats, or alternatively via printed paper copies requested at the patient office. To evolve this setup, the implementation design introduces a dedicated AIDA-EEHRxF module, as conceptualized in Figure 7. This component will dynamically map local laboratory variables directly into standard EEHRxF structures. By incorporating this module, the AIDA architecture will expand its baseline capabilities to output natively structured, compliant health data packages ready for secure cross-border or interinstitutional exchange. This technical shift will allow patients to interact with discretized, structured laboratory values within their mobile apps, supporting granular health tracking, self-management, and clinical transparency.

Figure 7. Proposed "TO-BE" architectural diagram for feasibility demonstrator 2 (Portugal), detailing the integration of a dedicated module to enable structured laboratory data exchange and patient access via mobile apps. AIDA: Agency for Integration, Diffusion and Archive of Medical Information; AIDA-PCE: AIDA-Clinical Electronic Process; CD: compact disc; EEHRxF: European Electronic Health Record Exchange Format; FHIR: Fast Healthcare Interoperability Resources; HL7: Health Level Seven International.



By enabling structured data exchange and ensuring that both health care providers and patients have access to comprehensive laboratory information, Feasibility demonstrator 2 supports proactive diabetes management and fosters a more collaborative approach to patient care. This initiative not only enhances the efficiency of health care delivery within the hospital but also empowers patients to actively participate in monitoring and managing their health conditions.

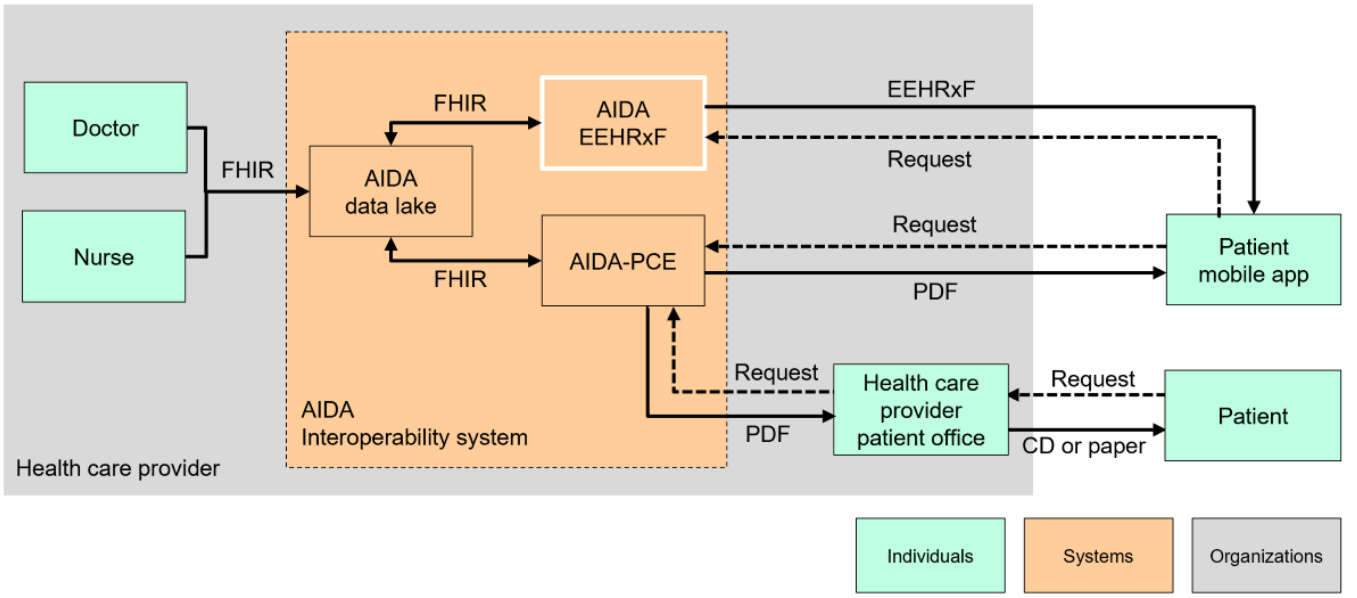
Feasibility Demonstrator 3

Feasibility Demonstrator 3 focuses on ensuring continuity of care, particularly by addressing the information available when a patient is discharged, in the context of hospital-patient health data sharing. Upon discharge, medical and nursing professionals complete a report that summarizes the patient's clinical and administrative status. This hospital discharge report includes details on the patient's condition, future procedures, and prescribed medications. The report is made accessible to patients who have consented to have this information available via a mobile app. It is securely stored within the AIDA platform, ensuring that health care professionals involved in the patient's care within the hospital can access it.

Operationally, the creation of discharge documentation is embedded within the hospital's EHR workflows, which interface directly with the AIDA platform. Physicians and nursing staff input discharge parameters directly into the clinical systems, and data is then aggregated into the AIDA data lake. Internal messaging across the clinical modules is handled through FHIR specifications, with the AIDA-PCE subsystem converting the final validated discharge summaries into PDF documents. Patients traditionally receive these documents at the time of discharge as physical paper printouts or as static digital PDFs uploaded to their personal mobile portal.

The prospective implementation architecture for this domain is illustrated in Figure 8. Sharing the same baseline AIDA technical environment as the previous demonstrator, this deployment will branch out to handle the specific semantic models required for discharge summaries. A specialized iteration of the AIDA-EEHRxF module will be integrated to ingest multidomain inpatient data and export it aligned with the EEHRxF discharge guidelines. This setup will enable the hosting infrastructure to share fully structured discharge records with external networks. Furthermore, the architecture maintains a dual-export strategy, generating a human-readable PDF copy alongside the EEHRxF payload to ensure data readability for receiving regional providers or family doctors who are not yet fully integrated into the EEHRxF standard.

Figure 8. Proposed "TO-BE" architectural diagram for feasibility demonstrator 3 (Portugal), illustrating the generation and export of structured hospital discharge reports compliant with the European Electronic Health Records Exchange Format (EEHRxF) standard. AIDA: Agency for Integration, Diffusion and Archive of Medical Information; AIDA-PCE: AIDA-Clinical Electronic Process; CD: compact disc; FHIR: Fast Healthcare Interoperability Resources.



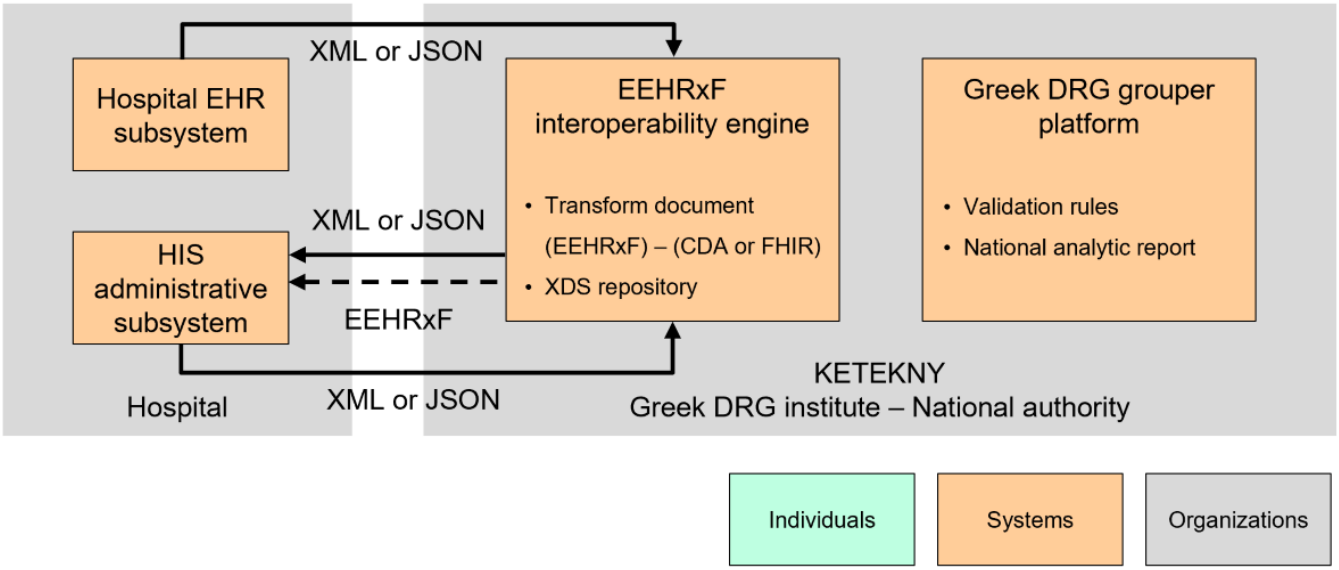
Feasibility Demonstrator 4

Feasibility demonstrator 4 focuses on integrating clinical and administrative information into a unified document that consolidates all patient discharge data. This document serves as a standardized hospital discharge report, transmitted to the national authority and exchanged with health care organizations. It also incorporates additional data generated by the Diagnosis-Related Group (DRG) system [26]. The primary goal of this initiative is to pilot the use of a structured hospital discharge report, including DRG data, to support the systematic collection of administrative and clinical patient information. The initiative aims to enhance data integrity for fair remuneration of hospital services. It also seeks to validate and cross-check coded patient data, ensuring accurate transmission of DRG codes and associated information as computed by the Greek DRG Grouper Platform (KETEKNY) [27].

The current Greek DRG Grouper Platform transmits data to hospitals using proprietary XML or JSON formats. However, these transmissions are not directly linked to official discharge documents. Currently, hospitals issue 2 separate discharge forms: an administrative discharge report and a medical discharge report or letter, which limits workflow efficiency and data standardization.

This demonstrator (Figure 9) aims to establish a standardized process for collecting and transmitting patient hospitalization data in a coded, structured, and interoperable manner. By leveraging the Greek DRG Grouper Platform and the EEHRxF Interoperability Engine, Hospital Information Systems (HIS) can generate unified discharge documents containing all relevant data in compliance with the EEHRxF framework. Hospitals will need to enhance their EHR systems with additional modules to ensure seamless integration with the interoperability framework. This approach augments existing workflows, creating a unified document that aligns with the required information structure without necessitating substantial system overhauls. The Greek DRG Grouper Platform will also function as a national cross-enterprise document sharing (XDS) repository for discharge data, facilitating care transitions such as patient transfers and ensuring continuity of care. Through this standardized and interoperable framework, the initiative aims to improve the availability, reliability, and utility of patient hospitalization information across the health care systems.

Figure 9. Proposed "TO-BE" architectural diagram for feasibility demonstrator 4 (Greece), showing the integration of the national Diagnosis-related group (DRG) Grouper Platform to generate and transmit unified, European Electronic Health Record Exchange Format (EEHRxF)-compliant hospital discharge reports. CDA: Clinical document architecture; DRG: Diagnosis-related group; EHR: electronic health record; FHIR: Fast Healthcare Interoperability Resources; HIS: Hospital information system; KETEKNY: Greek DRG Institute; XDS: Cross-enterprise document sharing.



Feasibility Demonstrator 5

Feasibility Demonstrator 5 focuses on enabling the transmission of hospital discharge report data from Slovakia, stored within the Slovak National Health Information System (NCZI), to health care providers in other countries, with Hungary serving as the destination country in the pilot scenario. The primary objective is to illustrate the benefits of standardized and interoperable cross-border exchange of hospital discharge reports, thereby contributing to improved international health care collaboration.

Currently, no cross-border exchange mechanism exists between Slovakia and Hungary. Within Slovakia, hospital discharge reports are exchanged using the ISO 13606 standard [28], while Hungary relies on an unstructured format (PDF) for similar data. To address these challenges, the NCZI and the Hungarian National Directorate General for Hospitals (OKFŐ) are collaborating on the feasibility of cross-border document exchange via the National Contact Points for eHealth (NCPeH, NCZI). This approach leverages the NCPeH as an intermediary, enabling the exchange of hospital discharge reports while allowing both countries to maintain their existing national standards.

Two phased scenarios have been proposed to achieve this goal. In the short-term scenario (Figure 10), Slovakia will continue to use the ISO 13606 standard, while Hungary will rely on its proprietary XML format for internal data exchange. The NCPeH will facilitate cross-border interoperability by mapping the hospital discharge reports from both national systems to the EEHRxF. This mapping ensures compatibility and enables seamless data sharing without requiring immediate upgrades to the national health information systems.

In the long-term scenario (Figure 11), the goal is to transition from the current use of ISO 13606 in Slovakia and proprietary XML in Hungary to the EEHRxF standard within both countries. During this transition, it is anticipated that legacy and new formats will coexist until full adoption of EEHRxF is achieved across all health care providers. This progressive implementation ensures minimal disruption to existing workflows while promoting the eventual standardization of data exchange both internally and across borders.

Figure 10. Proposed short-term "TO-BE" architectural diagram for feasibility demonstrator 5 (Slovakia and Hungary), demonstrating cross-border exchange of hospital discharge reports by mapping legacy formats to the European Electronic Health Record Exchange Format (EEHRxF) via National Contact Points for eHealth. EU: European Union; ISO: International Organization for Standardization; NCPeH: National Contact Points for eHealth; NCZI: National Center for Health Information; OKFO: National Directorate General for Hospitals.

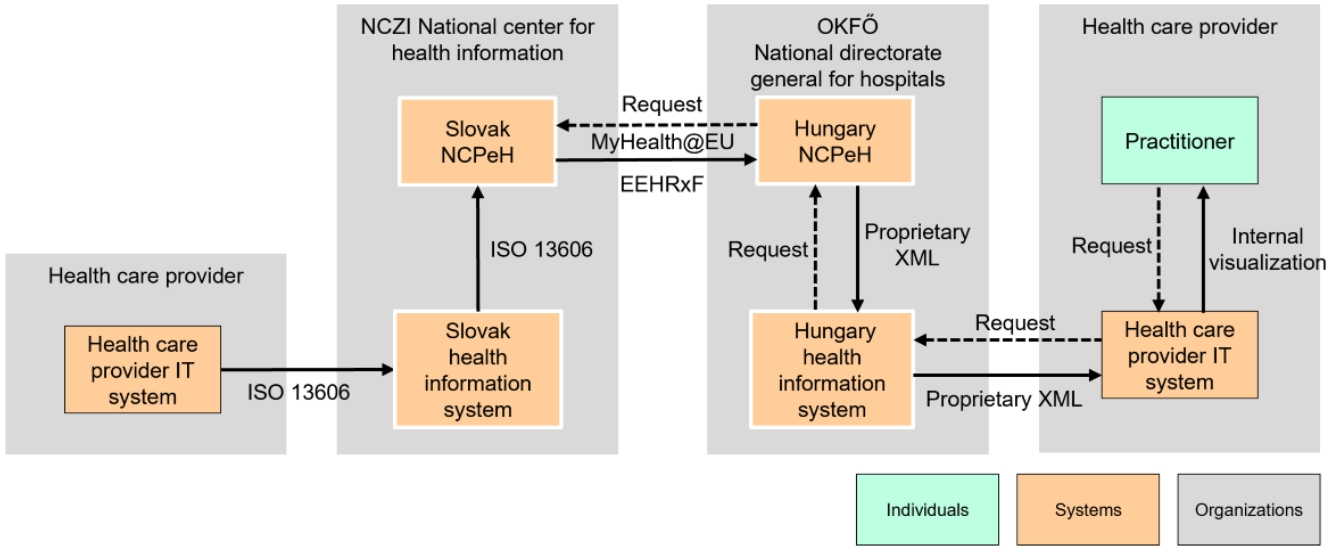
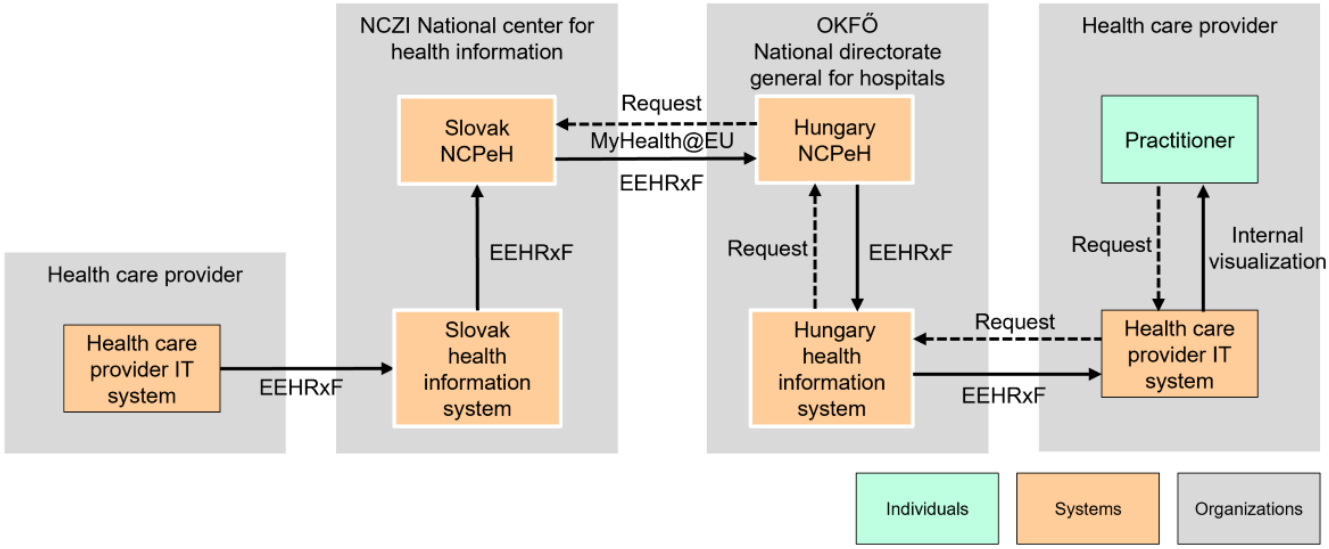


Figure 11. Proposed long-term "TO-BE" architectural diagram for feasibility demonstrator 5 (Slovakia and Hungary), depicting the full adoption of the European Electronic Health Record Exchange Format (EEHRxF) standard for cross-border hospital discharge report exchange. EU: European Union; NCPeH: National Contact Points for eHealth; NCZI: National Center for Health Information; OKFO: National Directorate General for Hospitals.



Online Surveys

To collect more information and have a broader view regarding the possible adoption of the EEHRxF, 3 online surveys related to the assessment of practice for production and exchange of health information in 3 specific priority categories—laboratory report, patient summary, and hospital discharge report—are made available and disseminated through the project's social media and website. While the surveys are available on the EU Survey platform (EC), they were distributed through different channels, including among partners from the XpanDH and xShare project consortia. The aim is to verify the data currently available in the systems compared to that requested in the available guidelines. Furthermore, the coding systems used and the exchange context considered are also asked.

The laboratory report survey has been available online since April 2024 [29]. Until the submission of this paper, 12 responses to this survey were collected, with another 25 having been started but not submitted or finished. Of the 12 responses submitted, 3 refer to health care providers, 2 to IT or EHR vendors, 4 to national authorities, and 3 to regional authorities. Regarding the countries involved, there are responses from the Netherlands (2), France, Cyprus, Italy (2), Portugal (2), Hungary, Ireland, Spain, and Denmark.

The patient summary survey has been available online since May 2024 [30]. Until the submission of this paper,

29 responses to the survey were initiated, 8 of which were completed. Out of the 8 responses completed, 1 refers to health care providers, 2 refer to IT or EHR vendors, 3 refer to national authorities, and 2 refer to regional authorities. Regarding the countries involved, the 8 responses include responses from Spain, Ireland, France, the United States, Cyprus (2 entities responded), Portugal, and Denmark. The inclusion of a US-based organization reflects an international IT vendor that actively develops and deploys solutions within the European market, making its regulatory readiness highly relevant to the EHDS framework.

The hospital discharge report survey has been available online since July 2024 [31]. Until the submission of this paper, 12 responses to the survey were initiated, 10 of which were completed. From the 10 responses completed, 2 refer to health care providers, 1 refers to IT or EHR vendors, 5 refer to national authorities, and 2 to regional authorities. Regarding the countries involved, there are responses from Spain, France, Cyprus, Italy, Portugal (2 entities responded), Greece, Ireland, Slovakia, and Denmark.

Please note that individual respondent identities and their specific institutional affiliations are kept anonymous to ensure participant privacy and compliance with data protection regulations.

Ethical Considerations

This study involved the collection of primary data through online surveys and expert consultations, alongside the analysis of system-level "TO-BE" architectures. Because the research focused exclusively on institutional, technical, and professional opinions regarding the implementation of the EEHRxF, and did not collect private clinical data, patient identifiers, or sensitive medical histories, it was deemed exempt from formal medical ethics committee review in accordance with national regulations and institutional policies of the participating partners.

Before engaging in any evaluation activity, all survey respondents and workshop participants were explicitly informed about the study's scope, objectives, and academic purpose. Participation was entirely voluntary and self-selected. Submission of the online questionnaires constituted formal implied consent for the aggregate use of the provided technical and professional insights.

To safeguard the privacy and confidentiality of all human subjects involved, all survey data were fully anonymized at the point of collection. No Personally Identifiable Information (PII) or IP addresses were recorded. Furthermore, individual institutional affiliations of the survey respondents have been kept confidential and presented strictly in an aggregated, nonattributable format.

Results

Overview

The results presented in this section reflect the levels of practice and levels of alignment obtained through the online surveys. Importantly, the organizations involved in the execution of the feasibility demonstrators also formally completed these surveys, meaning their institutional data are directly integrated into the quantitative metrics. Additionally, a focused evaluation of the use of coding systems for laboratory tests in the follow-up of patients with diabetes is presented within the context of 2 feasibility demonstrators. These results illustrate how existing EHR systems manage interoperability, particularly using standards, and assess their readiness to align with the EEHRxF specification in real-world clinical workflows.

Table 2 summarizes the level of structured data implementation specifically for fields classified by respondents as relevant (ie, "important" or "very important") across the three EEHRxF priority categories analyzed: patient summary, laboratory report, and hospital discharge report.

Table 2. % of structured, unstructured, and unavailable data by EEHRxF[a] category.

Category	Structured fields (%)	Unstructured fields (%)	Unavailable fields (%)	Most common coding system	Sample size (organizations)
Patient summary	46 (317/682)	26 (176/682)	28 (189/682)	SNOMED CT[b] and *ICD-10*[c]	8
Laboratory report	35 (204/591)	40 (237/591)	25 (150/591)	SNOMED CT and LOINC[d]	12
Hospital discharge report	28 (438/1549)	43 (666/1549)	29 (445/1549)	*ICD-10* and SNOMED CT	10

[a]EEHRxF: European Electronic Health Record Exchange Format.
[b]SNOMED CT: Systematized Nomenclature of Medicine Clinical Terms.
[c]*ICD-10: International Statistical Classification of Diseases, Tenth Revision*.
[d]LOINC: Logical Observation Identifiers Names and Codes.

The results reveal a heterogeneous landscape of maturity. Patient summaries show the highest proportion of structured implementation, with 46% (317/682) of relevant fields being structured and coded, reflecting the advanced adoption of standardized formats such as HL7 FHIR and SNOMED CT. Laboratory reports follow, with 35% (204/591) of relevant fields structured, although 40% (237/591) remain unstructured. Hospital discharge reports display the lowest level of structured implementation (438/1549, 28%), with many institutions still relying on free-text documentation. These findings confirm that while conceptual alignment with the EEHRxF is strong, practical readiness varies substantially among data domains, highlighting the need for targeted

investment in structuring core clinical and administrative information.

To further quantify the misalignment between strategic prioritization and actual technical readiness, Table 3 isolates the data fields strictly as "very important" and breaks down their current implementation status.

Table 3. Implementation status of data fields perceived as "very important" (critical gap analysis) across the 3 EEHRxF[a] priority categories.

Category	"very important" fields (%)	"very important" and structured fields (%)	"very important" and unstructured fields (%)	"very important" and unavailable fields (%)	Sample size (Organizations)
Patient summary	54 (427/784)	42 (178/427)	32 (136/427)	26 (113/427)	8
laboratory report	43 (347/804)	39 (135/347)	48 (165/347)	13 (47/347)	12
Hospital discharge report	35 (902/2550)	32 (283/902)	49 (445/902)	19 (174/902)	10

[a]EEHRxF: European Electronic Health Record Exchange Format.

A total of 30 valid responses were analyzed: 8 for the patient summary, 12 for the laboratory report, and 10 for the hospital discharge report. Across the 30 valid responses, "very important" fields represent between 35% (902/2550; hospital discharge report) and 54% (427/784; patient summary) of the total data fields. However, a clear implementation gap is visible, since a substantial portion of these fields remain either unstructured (136/427, 32% to 445/902, 49%) or completely unavailable (47/347, 13% to 113/427, 26%) in current systems, underscoring the practical challenges in achieving full interoperability. Participation spanned 9 Member States and included health care providers, IT or EHR vendors, national authorities, and regional authorities, providing a representative snapshot of differing organizational perspectives on interoperability readiness.

Cross-Sectional Feasibility Assessment

Overview

In the scope of the feasibility demonstrators, and to expand the knowledge collected across the EU, we developed a structured assessment of practice and alignment regarding its focus priority categories. The framework was designed to capture both the operational realities of data collection in health care institutions and the perceived relevance of EEHRxF-defined data fields for clinical and administrative use.

The evaluation was conducted using a standardized methodology across demonstrators and survey participants. Each data field within the 3 selected priority categories, laboratory report, hospital discharge report, and patient summary, was reviewed using structured questionnaires and workshop discussions. Respondents were asked to assess (1) the availability and structured use of the data field (level of practice), and (2) the relevance or perceived necessity of the field (level of alignment). This dual lens allowed for a nuanced understanding of both technical readiness and strategic alignment.

When evaluating the level of practice, we observed that fields related to demographic details, vital signs, and common laboratory test results are often well integrated and maintained in structured formats across participating organizations. In contrast, other data points, such as personal observations or certain contextual metadata, are more likely to be missing, inconsistently recorded, or stored in unstructured form.

Regarding the level of alignment, fields concerning allergies or medication lists were generally rated as very important by stakeholders, whereas certain administrative or patient-generated data elements were considered of lower priority or not yet relevant in some settings.

By assessing both dimensions in parallel, we were able to map not only which data fields are technically and operationally available, but also how they are valued by stakeholders in terms of clinical utility and implementation priority. This distinction is critical: high-practice fields may not always be perceived as essential (eg, some administrative metadata), and high-importance fields may still be lacking in structured implementation. The feasibility demonstrators consistently revealed such divergences, which are valuable for shaping future implementation strategies.

Also, this approach captured mismatches between perceived importance and practical availability, offering insight into both barriers and opportunities. In fact, fields consistently rated as "very important" but with low practice levels point to areas requiring targeted investment, workflow integration, or policy support. Conversely, data elements with high practice but low importance suggest possible redundancy or the need to streamline documentation burdens.

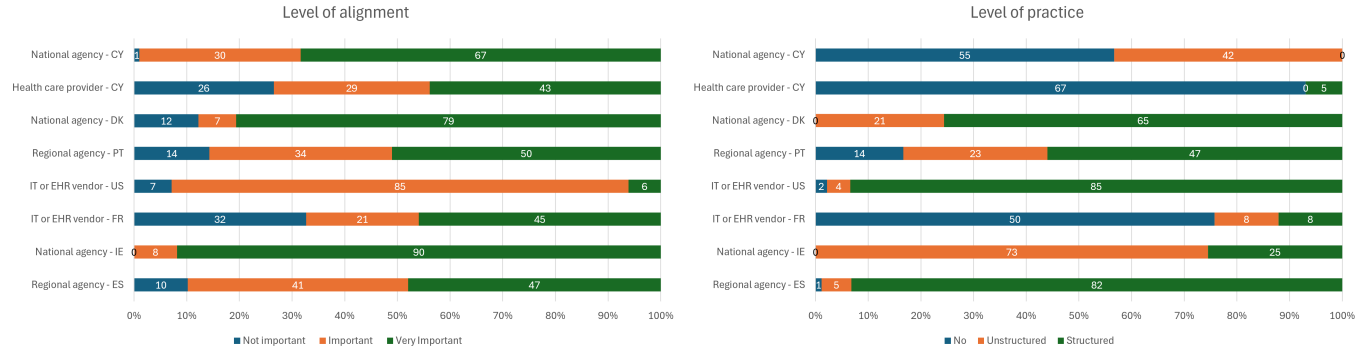
To ensure methodological clarity and consistency, the results are presented using a filtered, 2-tiered approach in Figure 12, Figure 13, and Figure 14. First, the level of alignment charts (left side) account for the entirety of the data fields, ensuring that the total field count evaluated is identical across all respondents for a given category. Second, the level of practice charts (right side) are dynamically filtered to display only the subset of fields that each specific respondent previously classified as either "important" or "very important." This approach ensures that the assessment of practical implementation focuses strictly on the data elements deemed relevant by the stakeholders, which naturally results in different absolute totals between the alignment and practice panels for the same respondent.

Patient Summary

Figure 12 illustrates the relationship between the perceived importance (level of alignment) of patient summary data

fields (left side) and the corresponding level of practice (right side). In the plot on the left, we observe that the majority of responses rate the elements as either "important" or "very important," with relatively few indicating "Not important." This suggests a high level of conceptual or theoretical alignment across the sampled organizations.

Figure 12. Quantitative assessment of the perceived importance (level of alignment) and actual implementation status (level of practice) of European Electronic Health Record Exchange Format (EEHRxF) patient summary data fields across 8 participating organizations. CY: Cyprus; DK: Denmark; EHR: electronic health record; ES: Spain; FR: France; IE: Ireland; PT: Portugal; US: United States.



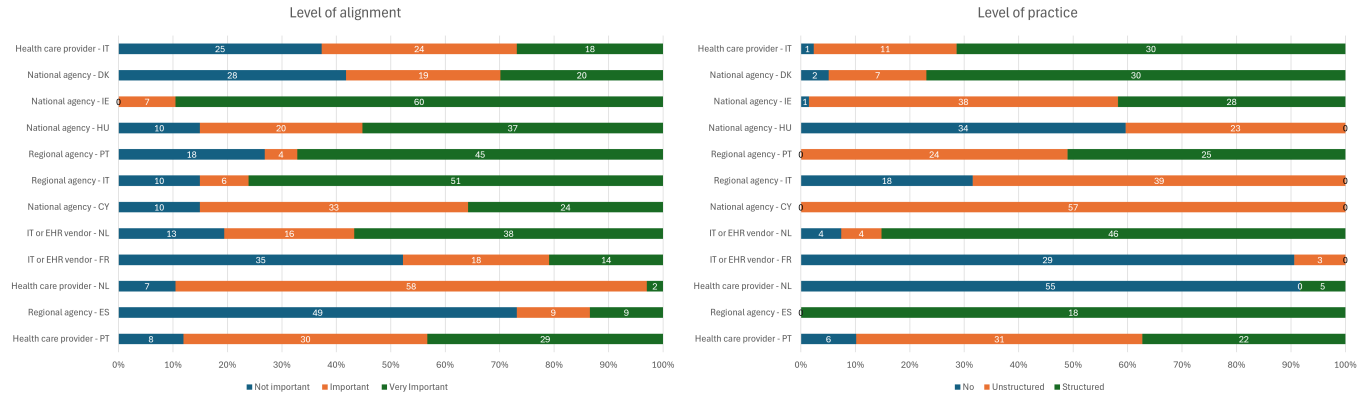
However, when compared to the plot on the right, which depicts the level of practice for those specific fields deemed relevant, a clear divergence becomes evident. Although these data fields are highly valued (as seen in the level of alignment), they are not consistently implemented in a structured manner. Instead, many responses cluster around "unstructured" or even "no" implementation.

For example, in the case of a health care provider in Cyprus, although most data fields are rated as "important" or "very important," they remain largely unavailable in the current system. Similarly, in Ireland, while the national agency recognizes the relevance of various data fields within the patient summary, much of this information is still not accessible in a structured and coded format. This reinforces the notion that awareness and alignment alone are insufficient without parallel investments in infrastructure, interoperability, and data governance frameworks. Addressing these discrepancies is essential for enabling meaningful data exchange and improving the continuity and quality of care.

Laboratory Report

Figure 13 presents a comparative plot analysis of the perceived level of alignment (left side) and the level of practice (right side) concerning the use and management of laboratory reports data fields, as reported by a diverse range of health care stakeholders across multiple European countries.

Figure 13. Quantitative assessment of the perceived importance (level of alignment) and actual implementation status (level of practice) of European Electronic Health Record Exchange Format (EEHRxF) laboratory report data fields across 12 participating organizations. CY: Cyprus; DK: Denmark; EHR: electronic health record; ES: Spain; FR: France; HU: Hungary; IE: Ireland; NL: Netherlands; PT: Portugal.



In the level of alignment, the majority of organizations rate laboratory reports data fields as either "important" or "very important." Notably, health care providers in Portugal and Italy, along with national agencies from Hungary and Cyprus, report a particularly strong alignment, suggesting that these actors recognize the critical role of structured laboratory data for interoperability, clinical decision-making, and data exchange.

In contrast, the level of practice reveals significant variation among the same actors. Despite widespread recognition of importance, many organizations still report that their practices for these valued fields are either "unstructured" or, in some cases, completely absent ("no"). This is especially prominent in the responses from health care providers in the Netherlands and some national agencies, where a disconnect between perceived importance and operational

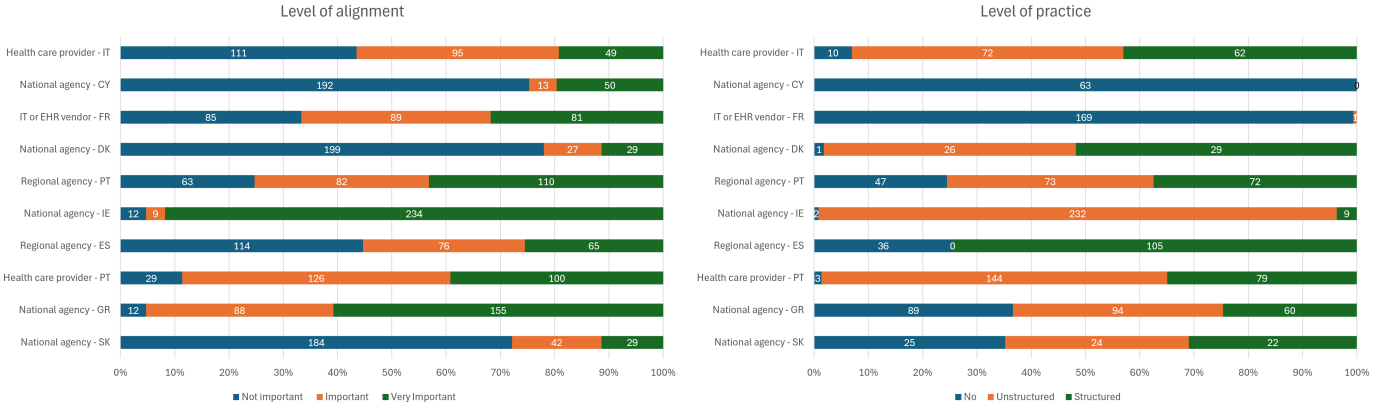
implementation is evident. On the other hand, some IT or EHR vendors and national agencies (eg, the Netherlands and Denmark) show a more structured level of practice, potentially reflecting more advanced digital health infrastructure or more mature data governance policies.

The comparison between these 2 dimensions highlights a misalignment between recognition and practice in several contexts. While laboratory reports are widely acknowledged as important data assets, the transition to structured, standardized, and interoperable formats remains inconsistent. Bridging this gap will likely require coordinated policy efforts, technical infrastructure support, and stronger collaboration among stakeholders, particularly between health care providers and technology vendors.

Hospital Discharge Report

Figure 14 illustrates the level of alignment (left side) and level of practice (right side) regarding the use and management of hospital discharge report data fields, reflecting how the organizations prioritize and operationalize hospital discharge report data, which are critical for continuity of care and information exchange.

Figure 14. Quantitative assessment of the perceived importance (level of alignment) and actual implementation status (level of practice) of European Electronic Health Record Exchange Format (EEHRxF) hospital discharge report data fields across 10 participating organizations. CY: Cyprus; DK: Denmark; EHR: electronic health record; ES: Spain; GR: Greece; FR: France; IE: Ireland; PT: Portugal; SK: Slovakia.



In the level of alignment, while responses from organizations in countries like Ireland, Greece, and Portugal highlight that most data fields are either "important" or "very important," a significant proportion of fields were marked as "not important" by several other respondents (eg, national agencies in Denmark, Cyprus, and Slovakia). This reflects both a shared understanding of the importance of core structured discharge information and the nature of the specifications, where many specific fields may be deemed out of scope or lower priority for certain national contexts.

However, the level of practice for these prioritized fields presents a contrasting scenario. Although the data fields are widely perceived as important, the level of practice shows significant fragmentation. Many stakeholders, particularly health care providers and regional agencies, report that their current practices are "unstructured," and a noticeable number even indicate "no" practice at all. This discrepancy is most evident in cases where national-level alignment is high, yet structured implementation remains limited. For example, some national agencies that assign high alignment to hospital discharge report data fields report predominantly unstructured or absent practices.

The comparison between these 2 dimensions highlights a disconnection between strategic alignment and real-world implementation. While hospital discharge reports are widely valued, especially in policy and planning contexts, their consistent, structured use in clinical workflows and IT systems remains a challenge. This misalignment underscores the need for targeted interventions, such as standardized templates, national guidelines, and EHR integration frameworks, to translate policy-level alignment into concrete, structured practices across the health care ecosystem.

Coding Systems Usage Assessment

In the context of the feasibility demonstrators focused on laboratory reports, an in-depth analysis was carried out on the use of LOINC codes for laboratory report representation in the follow-up of patients with diabetes. To ensure transparency, the methodology for this microanalysis followed a 3-step process:

1. Selection of Organizations: The analysis focused specifically on the 2 partner institutions (based in Hungary and Portugal) that were assigned to lead the laboratory reports feasibility demonstrators within the XpanDH project framework; hence, the participating organizations were not randomly sampled.
2. Selection of Clinical Scope and Test Categories: Diabetes mellitus was consensually selected by the project consortium as the priority clinical use case due to its high prevalence, cross-border relevance, and heavy reliance on standardized routine laboratory monitoring. Subsequently, clinical experts from both participating organizations collaborated to define a core, consensus-based panel of laboratory tests deemed essential for diabetes follow-up.
3. Data Extraction Process: Based on the agreed clinical panel, IT administrators at both institutions performed a targeted data extraction from their respective LIS and integration platforms. They queried their local active

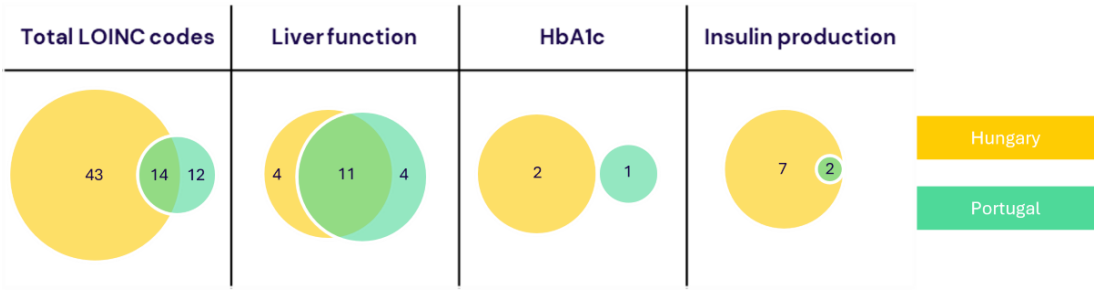
catalogs to identify and export all specific LOINC codes currently mapped to these clinical categories.

The tests considered most important for follow-up of patients with diabetes, as indicated by both demonstrators and for which LOINC codes were extracted, include:

- Liver function tests;
- Hemoglobin measurement;
- Serum lipid and renal panels, including total cholesterol, high-density lipoprotein (HDL), low-density lipoprotein (LDL), triglycerides, creatinine, and estimated glomerular filtration rate (eGFR);
- C-peptide measurement, which is used to assess the body's residual insulin production capacity.

Figure 15 presents the results of the comparative analysis of LOINC code usage between the 2 organizations. The figure displays both the total number of codes used and the degree of overlap between Hungary (yellow) and Portugal (green) for the relevant test categories.

Figure 15. Comparative analysis of LOINC (Logical Observation Identifiers Names and Codes) usage for routine diabetes follow-up laboratory tests between feasibility demonstrator 1 (Hungary) and feasibility demonstrator 2 (Portugal), highlighting semantic interoperability overlaps and disparities. HbA_{1c}: Hemoglobin.



The first set of circles shows the total number of LOINC codes used by each demonstrator for diabetes-related laboratory tests. Hungary reports a total of 57 codes, while Portugal uses 26, with 14 codes shared between the two. This indicates a substantial disparity in coding granularity or implementation coverage, with Hungary adopting a broader coding set.

For liver function tests, both countries show considerable overlap, with 11 codes in common out of 15 used by Hungary and 15 by Portugal, suggesting good alignment in this category.

Regarding hemoglobin, which is a critical test for long-term glucose control in patients with diabetes, Hungary uses 2 codes while Portugal uses only 1, with no overlap. This divergence reflects differences in laboratory workflows, coding practices, or test variants.

In the insulin production (C-peptide) category, Hungary uses 9 LOINC codes, whereas Portugal uses 2, with only 2 codes overlapping. This again illustrates a more extensive use of specific coding in Hungary, offering richer data granularity but also raising questions about semantic alignment.

Overall, the analysis highlights important discrepancies in LOINC code implementation between the 2 countries, even when both recognize the same clinical tests as relevant. While partial overlaps exist, especially in liver function, the divergence in categories like hemoglobin and insulin production underscores the challenges of semantic interoperability. Addressing such differences is crucial to ensure consistent and meaningful data exchange under the EEHRxF, especially for chronic disease monitoring scenarios such as diabetes.

Discussion

Principal Findings

This study demonstrated a strong conceptual alignment with the EEHRxF vision across European health care institutions, alongside a significant gap between strategic importance and practical readiness. Our multimethod assessment highlighted that while a large portion (between 902/2550, 35% and 427/784, 54%) of the defined data fields are perceived as "very important" for clinical care, only a fraction of these (between 283/902, 32% and 178/427, 42%) are currently operationalized in a structured, interoperable format, with a widespread reliance on unstructured free text.

Reflecting these metrics, the alignment of existing health information systems with the EEHRxF reveals a complex and uneven landscape across Member States and health care organizations. While the feasibility demonstrators and supporting surveys conducted confirmed general support for the objectives of the EEHRxF, they also highlighted several critical areas where further harmonization is required to achieve meaningful and sustainable interoperability.

A core dimension of the alignment discussion concerns data structure and availability. Across all 3 priority categories, Patient Summary, Laboratory Report, and Hospital Discharge Report, participants reported varying degrees of adherence to the EEHRxF field requirements. While some data elements are routinely captured and structured, others remain absent or embedded in unstructured free text, making automated exchange and semantic interpretation challenging. For instance, in the case of patient summaries, demographic and medication data are generally well documented, whereas sections such as family medical history or self-reported observations remain underrepresented or inconsistently structured. Similarly, laboratory reports often capture core

test results but lack standardized terminologies, and discharge reports tend to exhibit wide heterogeneity in their composition, depending on local workflows and IT capabilities.

Cardinality and optionality of data fields also emerged as an alignment issue. In several demonstrators, it became clear that while required fields were technically present in the systems, their actual population varied across institutions and use cases. This raises questions about the reliability and completeness of the exchanged records, especially in cross-border contexts where local conventions may differ significantly.

From a semantic interoperability standpoint, the discussion uncovered both progress and limitations. The use of internationally recognized code systems, such as SNOMED CT for clinical terms, LOINC for laboratory observations, and *ICD* for diagnoses, is often patchy. National extensions and proprietary codes are still in use, and in many cases, mappings to the EEHRxF reference terminologies are either incomplete or nonexistent. The feasibility demonstrators also indicated that even when international codes are adopted, the granularity of their application and consistency of use can vary substantially, affecting the interpretability of shared data.

Moreover, participants noted that key contextual metadata, such as data provenance, encryption status, and access permissions, are not always readily integrated into current documentation practices. These attributes are increasingly relevant in the context of secure and compliant data exchange under the EHDS.

Finally, alignment discussions revealed the tension between the standard's evolving nature and real-world readiness. Several stakeholders expressed uncertainty regarding the maturity and stability of EEHRxF specifications, particularly in areas still under development. This uncertainty affects planning and investment decisions and may deter early adopters.

In the next sections, complete details on the findings are provided, in general and per category, including an identification of (possible) new data fields and of the technical barriers and interoperability challenges.

Comparison to Prior Work

While previous studies and historical health IT deployments have extensively documented the technical complexities of cross-border data exchange, our findings corroborate and expand upon prior work by demonstrating that the most significant hurdles are often organizational and human-centric. Consistent with existing literature on large-scale health interoperability, the implementation and scaling of the EEHRxF face several sociotechnical challenges that hinder effective adoption across Member States, extending far beyond specific code or architectural barriers.

Technical Barriers and Interoperability Challenges

The implementation of the EEHRxF brings significant promise but also exposes several technical and semantic challenges that can hinder its successful adoption. These challenges stem from the heterogeneity of national health information systems, the uneven maturity of digital infrastructures, and the complexity of harmonizing data standards across diverse clinical, administrative, and regulatory environments. Table 4 summarizes the main technical barriers and interoperability challenges identified through the feasibility demonstrators, stakeholder workshops, and survey responses.

Table 4. Summary of technical and interoperability challenges in the implementation of the EEHRxF[a] across health care organizations.

Categories and challenges	Description
All categories	
Unavailable and/or unstructured information	• Data unavailable at source or stored in an unstructured way does not allow compliance with EEHRxF.
Security and compliance	• Aspects such as security and compliance are not clearly integrated in the EEHRxF. Need to deal with eg, digital signatures for verifying document authenticity, GDPR[b] compliance, and access permissions.
Patient summary	
Data availability	• Most of the available information is related to IPS[c] and structured in HL7 CDA[d].
Build and update	• The responsibility for creating and maintaining patient summary varies across member states (family doctor and automated systems, etc). • Different strategies for deciding what information should be included in the patient summary in fields such as results, past medicines, and history of problems, etc
Lack of integration in only one patient summary	• Existence of several patient summaries for the same patient in different institutions (eg, public and private).
Laboratory report	
Data availability	• Significant number of unavailable or unstructured data fields in current systems.
Code systems	• Use of LOINC[e] and SNOMED CT[f] relies in many cases on national mapping tables. • Use of proprietary codes mainly in identification and administration fields. • The lists of LOINC and SNOMED CT code systems are very extensive.
Hospital discharge report	

Categories and challenges	Description
Data availability	• Difficult to align between institutions on the importance of data fields, with a significant number of unavailable and unstructured information. • Excessive number of data fields that make it challenging to prioritize and manage information.
Code systems	• Use of national or proprietary code systems is difficult to map for international ones in many organizations. • Use of national implementations of *ICD-10*[g] is quite common, and the transition to *ICD-11*[h] is not expected in the short term.
Plain text	• In many organizations, much of the information is provided in a block in plain text.

[a]EEHRxF: European Electronic Health Record Exchange Format.
[b]GDPR: General Data Protection Regulation.
[c]IPS: International Patient Summary.
[d]HL7 CDA: Health Level Seven International Clinical Document Architecture.
[e]LOINC: Logical Observation Identifiers Names and Codes.
[f]SNOMED CT: Systematized Nomenclature of Medicine Clinical Terms.
[g]*ICD-10: International Statistical Classification of Diseases, Tenth Revision*.
[h]*ICD-11*: *International Statistical Classification of Diseases, Eleventh Revision*.

Feasibility Challenges in EEHRxF Adoption

Overview

The implementation and scaling of the EEHRxF face several challenges that hinder its effective adoption across Member States, in addition to the specific technical barriers described above. These barriers span issues of awareness, stakeholder engagement, digital literacy, and expectations regarding technical maturity.

Limited Awareness and Understanding of EEHRxF

A significant barrier to EEHRxF adoption is the general lack of awareness regarding its goals, structure, and long-term benefits. Many stakeholders, particularly at the national and regional levels, demonstrate limited knowledge of the regulation and its implications. As a result, authorities often attempt to resolve internal interoperability challenges in isolation, without aligning with the broader EU strategy. This lack of strategic alignment undermines the potential for standardized cross-border health data exchange and diminishes the perceived value of transitioning to EEHRxF-compliant standards.

Stakeholder Engagement and Cross-Border Collaboration

The involvement of key stakeholders, such as health care providers, national agencies, vendors, and patient representatives, is critical for the success of EEHRxF. However, fostering meaningful collaboration has proven difficult. Participation in workshops and working groups is frequently constrained by limited time, interest, and available resources. Even when stakeholders are present, they often lack the technical or contextual knowledge required to contribute effectively, impeding the depth and quality of discussions. Moreover, reluctance to commit to decisions during such engagements poses a further challenge, as it hampers consensus-building and delays progress in standardization efforts.

Managing Expectations Regarding Format Maturity

Many early adopters anticipate a fully developed, ready-to-use framework, while in reality, the specification must remain flexible to accommodate the heterogeneous landscapes across Member States. These include differences in national and regional systems, data models, terminologies, and interoperability infrastructures. Successfully managing these expectations requires clear communication, continuous stakeholder engagement, and a phased implementation strategy.

Gaps in Digital and Health Literacy

Digital and health literacy remain foundational barriers to the effective implementation of EEHRxF. For health care professionals, there is a need to raise awareness and provide training on how to use and benefit from EEHRxF in clinical practice. Without such capacity-building, the practical integration of the format into existing workflows may face resistance. Similarly, empowering patients through digital education is crucial to encourage active participation in their own health management. Enhancing patient understanding of health data exchange can significantly increase the impact and adoption of EEHRxF in real-world settings.

Lessons Learned From Feasibility Assessment

Overview

The feasibility demonstrators have delivered meaningful results. They have enabled organizations in 4 countries to identify gaps and issues in their digital health and data infrastructures and, thus, to get a head start in the race to implement the EHDS regulation and specifically the EEHRxF once they become mandatory. All feasibility demonstrators were consulted about their experiences and learnings through written questions, interviews, and a full workshop. The following is a distillation of the success factors and challenges, followed by a few recommendations for future deployments.

Common Success Factors

Leadership

It is critical to involve the right organizations and to develop the appropriate mechanisms in the adoption and deployment of standards. Too long, European governments at every level left it "to the market" to solve the interoperability problem in health care. The EHDS represents a watershed moment and a unique opportunity to change this, but the EHDS cannot do it alone. At Member State and regional levels, the successful adoption of EEHRxF will require the leadership of authorities (or other organizations with soft or hard power over health care providers and industry) to make the uptake of specifications mandatory.

Cocreation

This leadership, however, cannot be delivered through old-style, top-down fiat, but must include rules and regulations as well as collaboration with SDOs and meaningful participation of stakeholders. In this regard, the approach of EU projects, such as XpanDH and xShare, has been a successful instrument to bring many players around the table. The work in the feasibility demonstrators, with the active support from SDOs and the participation of stakeholders, has instilled in the participating organizations the ethos of "cocreation": the spirit of collaboration of public authorities with SDOs, researchers, experts, and industry in developing standards and specifications. However, the approach also revealed challenges such as limited availability of knowledgeable participants, difficulty sustaining engagement, and hesitancy to commit to outcomes, underscoring the need for improved capacity building and facilitation practices.

People

Successful deployment of the EEHRxF will also require human resources. There will be a surging demand for health care professionals, health care managers, and IT specialists, and most importantly for those who can bridge these worlds. They need to be embedded and supported by a web of colleagues, peers, and mentors, and by resources and investment. Looking forward, greater investment is needed in cultivating such hybrid roles, alongside structured networks of mentorship, training, and professional support. This becomes especially important as health and digital literacy gaps were identified both among professionals and the general public.

Common Challenges

A Mature and Stable EEHRxF

Several feasibility demonstrators expressed concern about the lack of robust and stable specifications as a barrier that slowed or impeded the experimentation. In this view, if the EEHRxF is not ready, mature, and stable, then users cannot start. While this friction is inherent in cocreation, clearer communication and alignment around the "living" nature of standards could mitigate misunderstanding.

Cocreation

If specifications were issued as restricted and closed rules without the participation of end users, they would not gain the intended acceptance. Standards are the outcome of successful collaboration. Without the feedback, input, and participation from the user side (including public authorities and clinical domains), there cannot be a mature or stable EEHRxF, and as a result, no successful deployment. On a higher level, this also reinforces the need for structured stakeholder engagement strategies and educational interventions at both national and EU levels.

Time

EEHRxF development, like all standards, will require time and patience, which was limited in the feasibility demonstrators. Tied to timelines and deadlines characteristic of an EU-funded project, and faced with EEHRxF specifications that were not always available at the time and in the quality needed, the feasibility demonstrators had to adapt their timing or ambition.

Technical and Structural Diversity

Implementers struggled with reconciling the EEHRxF structure with existing heterogeneity in national health information systems, data models, and terminologies. The existence of multiple patient summaries for a single individual, differences in data governance models, and reliance on unstructured data made alignment with EEHRxF complex. Moreover, national coding systems (eg, local *International Statistical Classification of Diseases, Tenth Revision [ICD-10]* variants or proprietary lab codes) remain significant barriers to semantic interoperability.

Security, Privacy, and Legal Readiness

Despite the clinical and operational focus, security and compliance elements, such as digital signatures, General Data Protection Regulation (GDPR) alignment, and access controls, remain insufficiently embedded in many implementations. The feasibility demonstrators often lacked structured mechanisms to address these elements. Given the sensitive nature of health data, these aspects should not be deferred to later stages but integrated early in the design process.

Resources

Ultimately, and despite the genuine opportunity of the EU funding, that funding was deemed insufficient for the complexity of the work. All feasibility demonstrators suffered from resource and funding constraints that limited their effectiveness. This also affected the participation and support from health care professionals, which was not always ensured.

Limitations

Our study presents some limitations that reflect the early-stage deployment of the EHDS framework. First, the sample sizes obtained through the online surveys (comprising 8 valid responses for patient summaries, 12 for laboratory reports,

and 10 for hospital discharge reports) are limited. This small sample is directly tied to the novelty of the EEHRxF specifications, which are currently undergoing their initial phase of institutional adoption and awareness building across Member States. Second, a high concentration of responses is tied to the active partners of the XpanDH and xShare project consortia, including the organizations involved in the 5 feasibility demonstrators. This introduces a potential bias, as these organizations represent early adopters with a higher readiness profile than the broader European average. However, this sample is not exclusive to the projects, and capturing the operational realities of these frontrunner institutions is methodologically vital. To mitigate potential single-source biases and enrich the quantitative metrics, we systematically triangulated the survey outcomes with real-world gap analysis data from the 5 detailed feasibility demonstrators and several qualitative multistakeholder workshops, delivering a realistic evaluation of the current transitional phase of European health data interoperability.

Future Directions and Recommendations

Overview

While the EEHRxF establishes a robust foundation for cross-border interoperability of health data, insights gathered from the feasibility demonstrators and stakeholder consultations revealed opportunities to further enrich the format. The proposed data fields, presented in Table 5, emerged directly from the qualitative gap analyses conducted within the feasibility demonstrators. For instance, empirical evaluations of specific clinical scenarios, such as pediatric care workflows in hospital discharge processes, highlighted the operational necessity of fields like "admitting weight." These initial proposals were systematically reviewed, debated, and consensually validated by clinical professionals and IT vendors during our multistakeholder workshops to ensure they addressed genuine real-world documentation gaps. These additions reflect opportunities to enhance the utility, completeness, and semantic depth of EEHRxF-based documents.

Table 5. Summary of possible new data fields for the EEHRxF[a] in all categories.

Categories and data fields	Description
All categories	
Security and compliance–include directly in the report or as metadata	
Digital signature	Digital signature verifying the authenticity of the document.
Compliance status	Status of GDPR[b] compliance.
Access permissions	Roles authorized to access the document.
Patient education and resources	
Patient education materials	Educational resources provided to the patient.
Support services information	Contact details for available support services.
Feedback mechanism	
Patient satisfaction feedback	Mechanism for patients to provide feedback.
Patient summary	
Patient summary header–identification of the patient	
Preferred language	The language the patient prefers for communication
Medical history–previous hospitalizations	
Previous hospitalizations	Record of past hospital stays, including reasons and outcomes. (Date, Reason for Admission, Outcome)
Medical history	
Family medical history	Health conditions that are prevalent in the patient's family.
Patient-provided data–observations and measures	
Personal measures	Measures provided by patient such as average daily steps, average daily heart rate, etc.
Patient-provided data—advance directive	
Proxy information	Contact information for the person authorized to make decisions.
Cultural considerations	Any specific cultural considerations relevant to care.
Plan of care	
Follow-up appointment	Suggested future appointments for ongoing care (Date, Purpose of visit).
Laboratory report	

Categories and data fields	Description
Report header–data protection flag	
Data protection flag	Indicates if the report contains potentially disturbing results.
Access control	Determines who can access the report based on the Data Protection Flag.
Patient notification	Details on how patients are informed about access restrictions.
Patient instructions and follow-up	
Patient instructions	Instructions given to the patient regarding the test.
Follow-up appointment	Details of any necessary follow-up appointment related to the test.
Hospital discharge report	
Patient-related contact information—Preferred HP[c]	
ID organization	Code of HP organization
ID department	Code of department in the HP organization
Encounter-discharge	
Hospitalization outcome	Patient's discharge condition.
Encounter-admission	
Admitting weight	Weight on admission. To be completed for patients aged less than 1 year.

[a]EEHRxF: European Electronic Health Record Exchange Format.
[b]GDPR: General Data Protection Regulation.
[c]HP: health care provider.

Recommendations

Resources and Investment

The EHDS will not be cheap. The EU grants to Member States should be the floor, not the ceiling, of the funding that Member States will use to implement the EHDS, upgrade their IT infrastructures, and develop the services and innovations that make health care better, safer, and more efficient. A clear and detailed cost-benefit analysis will benefit the investment plans of the Member States and organizations.

Training and Awareness

Amid times of demographic change and competition for skilled professionals, the EHDS and associated investments will lead to massive demand for a digital health workforce. And it will call for generalists and specialists who understand other specialists and can build bridges between disciplines. There will be demand for continuing training and retraining. Those demands should be anticipated.

SDO Strengthening

EEHRxF specifications are the sine qua non of the EHDS. Without mature specifications, there is no interoperability. If the EEHRxF specifications are delayed, these delays may affect the timing of the implementing acts, and they, in turn, may affect EHDS implementations in the Member States and regions. SDOs are among the weakest links in this chain of dependencies: they should be equipped with stable and secure funding to be able to host effective cocreation spaces, to deliver robust specifications and services, and to support all implementers.

Time and Realism

IT projects, like all projects, always take longer than anticipated. Prepare for the unexpected, brace for surprises, and assume that things that can go wrong will go wrong. Furthermore, there are technical challenges that require time and effort to be addressed, such as the presence of unstructured data that needs to be mapped and extracted, as well as ensuring consistency in the mapping across the different coding systems used by the organizations.

National Particularities

Both the EHDS and the EEHRxF will face very different conditions for implementation at the national level. Existing and upcoming EEHRxF projects like xShare, Extended EHR@EU Data Space for Primary Use (Xt-EHR), Intelligent Implementations of the European Electronic Health Record Exchange Format (i2X), Xpanding Innovative Alliance (XiA), and the EEHRxF Support Center will deliver important work in this regard. Yet, expectation management is also important in this domain.

Implications for Practice and Future Research

Building on the lessons learned from the feasibility assessment, the recommendations presented in Table 6 distill the key insights into actionable guidance for stakeholders. These recommendations aim to address the systemic challenges identified, such as the instability of EEHRxF specifications, the need for stronger leadership and cocreation mechanisms, and the resource and human capacity constraints faced during implementation.

Table 6. Summary of recommendations for key stakeholders regarding the implementation of the EEHRxF[a].

Target stakeholder	Recommendations
EU[b] policymakers	• Establish clear timelines and milestones for EEHRxF development to avoid hindering Member States and industry readiness. • Create an iterative feedback system for codeveloping EEHRxF with user input, including public authorities and clinicians. • Increase funding for national hubs and collaborative efforts to ensure robust and stable specifications. • Incentivize Member States to align resources and human capacity with EHDS[c] goals.
Member States policymakers	• Strengthen leadership by designating authoritative organizations (eg, health ministries or equivalents) to oversee the mandatory adoption of the EEHRxF and ensure compliance. • Embed cocreation principles in national strategies by fostering collaboration with local SDOs[d], health care providers, and stakeholders. • Expand training programs to include cross-disciplinary roles bridging health care, IT, and policy. • Increase resource allocation for semantic hubs and associated infrastructure to avoid bottlenecks in implementation.
Industry (IT vendors)	• Prioritize partnerships with SDOs and clinical organizations to align IT systems between evolving EEHRxF standards and clinical needs. • Allocate resources for rigorous testing of interoperability tools in real-world environments before release. • Collaborate with health care organizations to cocreate AI-driven solutions for coding translations and semantic interoperability, ensuring user-centric design.
Health care organizations	• Focus on recruiting and training staff with skills to bridge clinical and IT domains, supported by mentorship and investment in professional development. • Collaborate with national semantic hubs to continuously align practices with updated EEHRxF standards. • Actively participate in cocreation forums to contribute real-world insights to standard refinement processes.
Projects	• Prioritize funding adequacy by ensuring project resources match the complexity of the objectives, particularly for cross-border initiatives. • Align project timelines with the maturity of EEHRxF and ensure flexibility to accommodate delays in standards development. • Develop frameworks for cocreation that include consistent stakeholder participation across Member States and sectors. • Pilot solutions that test the robustness and stability of EEHRxF in diverse contexts before scaling.

[a]EEHRxF: European Electronic Health Records Exchange Format.
[b]EU: European Union.
[c]EHDS: European Health Data Space.
[d]SDOs: Standards development organizations.

Conclusions

The feasibility demonstrators have provided concrete, practice-oriented evidence of the potential and challenges in adopting the EEHRxF across real-world health care settings in Europe. Focusing on 3 of the priority domains, laboratory reports, hospital discharge reports, and patient summaries, the demonstrators engaged a diverse set of stakeholders, including health care providers, national authorities, regional authorities, IT vendors, and patients, to assess the technical, organizational, and semantic alignment between existing systems and the EEHRxF specifications.

While based on a limited sample of early adopters, the results indicate a strong conceptual alignment with the EEHRxF vision and a clear recognition of its importance in enabling cross-border health data exchange. However, the demonstrators also revealed a number of barriers that must be addressed to support full-scale adoption. These include the fragmentation of data models, uneven maturity of coding practices (particularly around SNOMED CT, LOINC, and national extensions of *ICD*), frequent reliance on unstructured or proprietary data formats, and varying degrees of awareness and readiness across Member States and health care institutions.

Importantly, the feasibility assessments conducted did more than map gaps; they identified practical paths toward bridging them. Structured use cases, implementation scenarios, and system mapping exercises highlighted opportunities for transition strategies, from proprietary formats to EEHRxF-compliant structures, and underscored the value of phased adoption that accommodates both current capabilities and future goals. These prospective architectures and design scenarios illustrate potential benefits, particularly in chronic disease management and hospital discharge communication, demonstrating how structured, interoperable data could, upon full implementation, positively impact continuity of care, patient safety, and health system efficiency.

Moreover, the project's methodology, combining feasibility demonstrators, collaborative workshops, and wide-reaching surveys, proved effective in building shared understanding, raising awareness, and strengthening cocreation across sectors. The structured assessment of practice and alignment provides a replicable framework that can inform ongoing national implementations and contribute to the broader EHDS agenda.

Ultimately, this exploratory work demonstrates that while the EEHRxF is ambitious in scope, its goals appear achievable with the right mix of leadership, investment, stakeholder engagement, and technical support. To move from feasibility to widespread implementation, future efforts must prioritize structured data, semantic interoperability, robust governance,

and a strong foundation of trust across health care ecosystems. As the EHDS becomes a reality, the insights and tools here presented serve as valuable assets to accelerate adoption and ensure that the exchange of health data across Europe is secure, meaningful, and beneficial to all.

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Generative AI Use

Finally, the authors attest that no generative AI tools were used in the generation of this paper's scientific content.

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Data Availability

The survey questionnaires and aggregated data supporting the findings of this study are available from the corresponding author upon reasonable request. Direct access to individual organizational platforms is restricted due to security regulations.

Authors' Contributions

Conceptualization: FJ, MM, HM, SL, MS
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Validation: FJ, MM, CS
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Conflicts of Interest

None declared.

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Abbreviations

AIDA: Agency for Integration, Diffusion and Archive of Medical Information
AIDA-PCE: AIDA-Clinical electronic process

CEN: European Committee for Standardization
CTS: Centre for Technology and Systems
DRG: Diagnosis-related group
EC: European Commission
EEHRxF: European Electronic Health Records Exchange Format
EESZT: Hungary's National Electronic Health Record System
eGFR: estimated glomerular filtration rate
EHDS: European Health Data Space
EHDSI: eHealth digital service infrastructure
eHN: eHealth Network
EHR: electronic health record
EOSC: European Open Science Cloud
EU: European Union
FCT: Portuguese Foundation for Science and Technology
FHIR: Fast Healthcare Interoperability Resources
GDPR: General Data Protection Regulation
HDL: high-density lipoprotein
HIS: Hospital information system
HL7: Health Level Seven International
i2X: Intelligent implementations of the European electronic health record exchange format
***ICD*:** *International classification of diseases*
***ICD-10*:** *International Statistical Classification of Diseases, Tenth Revision*
IHE: Integrating the health care enterprise
LDL: Low-density lipoprotein
LIS: Laboratory information systems
LOINC: Logical Observation Identifiers Names and Codes
NCPeH: National Contact Points for eHealth
NCZI: National Center for Health Information
OKFŐ: National Directorate General for Hospitals
PII: Personal identifiable information
SDO: Standards development organization
SNOMED CT: Systematized Nomenclature of Medicine Clinical Terms
TC: Technical committee
XDS: Cross-enterprise document sharing
XiA: Xpanding innovative alliance
XpanDH: Expanding digital health through a pan-European EHRxF-based ecosystem
xShare: Expanding the European EHRxF to share and effectively use health data within the EHDS
Xt-EHR: Extended EHR@EU data space for primary use

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