



Extended EHR@EU Data Space for Primary Use - Xt-EHR

Proposal number: 101128085

[D4.1 Current State of Play on Electronic Health Records and Primary Use of Data]

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ABBREVIATIONS

ACHI	Australian Classification of Health Interventions
ATC code	Anatomical Therapeutic Chemical code
ATNA	Audit Trail and Node Authentication
CDA	Clinical Document Architecture
DICOM	Digital Imaging and Communications in Medicine
ebXML	electronic business using eXtensible Markup Language
EEHRxF	European Electronic Health Record Exchange Format
EHDS	European Health Data Space
eHDSI	eHealth Digital Service Infrastructure
eHMSEG	eHealth Member State Expert Group
EHR	Electronic Health Record
EU	European Union
FHIR	Fast Healthcare Interoperability Resources
GDPR	General Data Protection Regulation
HCP	Health Care Provider
HL7	Health Level 7
ICD	International Classification of Diseases
ICD-10-AM	International Classification of Diseases, 10 th Revision, Australian Modification
IHE	Integrating the Healthcare Enterprise
IHE XDS	IHE cross document sharing
IPS	International Patient Summary
LOINC	Logical Observation Identifiers Names and Codes
MS	Member State(s)
MN-CMS	Maternal & Newborn Clinical Management System
NSCR	National Shared Care Record
NPU	Nomenclature for Properties and Units
OpenEHR	open specifications, clinical models and software that can be used to create standards, and build information and interoperability solutions for healthcare
PS	Patient Summary
RRF	Recovery and Resilience Facility
SNOMED CT	Systematized Nomenclature of Medicine Clinical Terms



EXECUTIVE SUMMARY

This document presents the current state of play on the use of Electronic Health Records (EHRs) and primary use of health data in the European Union (EU). It provides an overview of national systems, including national governance and regulatory frameworks, technical standards employed, adoption rates and the level of interoperability on a national and cross-border scale. The analysis of the existing EHR landscape focuses on the gaps and the level of compliance with the European Health Data Space (EHDS) Regulation, such as the standardisation of priority categories of EHR, and patient's rights about the provision and access to the EHR, as well as recommendations and comments on future EHR systems in Europe.

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1. Introduction

The integration and interoperability of Electronic Health Records (EHRs) in the European Union (EU) are key in advancing healthcare quality, safety, and efficiency within the EU.

The purpose of this deliverable is to explore the current landscape of EHR systems across EU MS, assess the degree of interoperability, and identify best practices and areas for improvement. This work aligns with the broader objectives of enhancing cross-border healthcare collaboration and supporting the future implementation of the EHDS regulation.

This task will produce a report on the state of play in EHR adoption and implementation in EU countries with a strong focus on the possibilities for a standardized cross-border EHR within the scope of the forthcoming EHDS regulation. This deliverable will frame how implementation guides need to be drafted in the light of the current European landscape of EHR systems' implementation, so that its impact and sustainability are assessed and evaluated.

To this end, a mixed-methodology approach was adopted. This included a comprehensive review of the available literature, analysis of legal and policy documents, and data collection through surveys with project partners representing European countries, including healthcare providers, policymakers, and IT experts in the healthcare domain. A qualitative analysis was used to understand the complexities and nuances of national EHR systems. The methodology was designed to provide a robust, multi-dimensional understanding of the EHR landscape, ensuring that the findings are grounded in real-world experiences and evidence from EU MS.

This task will be based on the descriptions of EHR systems, as broadly identified in the currently published proposal for the European Health Data Space (EHDS) Regulation, *Chapter III - EHR systems and wellness applications*, most notably in Section 1 - General provisions for EHR systems¹ (see also Chapter 2.1 of this deliverable).

Building upon the benchmark of X-eHealth deliverables, the proposed work is to highlight, contribute, and support the European eHealth interoperability and the implementation of the European Electronic Health Record Exchange Format (EEHRxF) through the identification of common EU practices in EHR adoption.

The scope of this deliverable encompasses the analysis of status of play concerning the implementation of EHR systems within all 27 EU Member States (MS) and Norway. This document further aims to evaluate the adoption and implementation of EHRs in EU MS, including but not restricted to the technical standards employed, the level of interoperability between national systems, and the alignment with the proposed EHDS regulation. The deliverable will not only

¹ <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52022PC0197>

reflect on the current state, but also offer a perspective on the readiness of the EU healthcare infrastructure for future challenges and integration efforts.

2. Background and Context

The background and context for this deliverable are framed by the increasing digitization of healthcare services and the critical need for interoperable health information systems. In the context of European countries, this is particularly relevant given the mobility of citizens and the cross-border nature of health threats. The European Commission (EC)'s proposal for the establishment of the EHDS underscores the importance of secure access, exchange, and use of health data. The EHDS regulation aims to support healthcare delivery, enable health research and innovation, and empower citizens through access to their health data across Europe.

The backdrop of this deliverable is also characterized by the diverse technological landscape and often complex policy environments across Europe. Therefore, this deliverable will consider the varied stages of digital health maturity, the different legal frameworks in place, and the disparate levels of investment in health IT infrastructure. The convergence of these factors presents both opportunities and challenges for the harmonization of EHR systems and the actualization of the EHDS vision.

By understanding the current state of EHR systems in Europe, this deliverable will contribute to the ongoing discourse on how to effectively navigate the complex interplay of technology, policy, and practice in the realm of digital health.

2.1 Terminological distinction between "EHR" and "EHR systems"

It is important to note that specific types of EHR systems can vary depending on national contexts within the EU due to the diversity of healthcare systems, ICT infrastructures and legislative frameworks across the MS.

In the context of EU-wide initiatives and legislation, and for the purposes of this document, an EHR system can generally be defined as a digital platform or application that systematically collects, stores, and manages patients' health records across different healthcare settings. EHR systems are designed to support the sharing of patient information among healthcare providers to facilitate coordinated care, improve health outcomes, and enhance the efficiency of healthcare services.

The EHDS regulation, while not solely focused on defining EHR systems, aims to establish a common framework for the secure access, exchange, and use of health data across the EU. This includes data from EHR systems, among other sources.

The specific definition of EHR systems used throughout this text aims to be within the context of the EHDS regulation and other EU legislation, emphasizing the importance of interoperability, patient-centricity, data protection, and the facilitation of cross-border health data exchange.

The definitions used throughout this text are as follows:

- **EHR** means a collection of electronic health data related to a natural person and collected in the health system, processed for the purpose of the provision of healthcare.
- **EHR System** means any system where the appliance or software allows to store, intermediate, export, import, convert, edit or view personal electronic health data that belongs to the priority categories of personal electronic health data as referred to in Article 5(1) of the Regulation and is intended by the manufacturer to be used by healthcare providers in providing patient care or by patients to access their health data.

2.2 Other definitions of EHR systems

According to International Organization for Standardization (ISO) (ISO/TR20514 2005), an EHR is a “*repository of information regarding the health status of a subject of care, in computer-processable form*”.

An EHR system, on the other hand, is defined as a “system for recording, retrieving and manipulating information in EHRs”².

Definition of EHR systems from a study on “Quality Requirements for EHR Systems”:³

System for recording, retrieving and manipulating information in EHRs. It comprises different databases and application systems, data repositories, directory services listing human and other resource entities, knowledge services containing terminological systems, care pathways and workflows, end user applications, reporting modules, security and privacy services, and respective hardware and network components.

Definitions of EHR systems by Health Sector Cybersecurity Coordination Center (part of US Department of Health and Human Services⁴):

² https://link.springer.com/referenceworkentry/10.1007/978-3-030-22009-9_442#ref-CR5324

³ Reference: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6291988/>

⁴ reference: <https://www.hhs.gov/sites/default/files/electronic-health-record-systems.pdf>

An electronic record of health-related information on an individual that can be created, gathered, managed, and consulted by authorized clinicians and staff within one health care organization.

We can see from these definitions that, although the general understanding of the purpose of an EHR system is the same, there are differences in the scope of the functions and health data that are included in this term.

The definition of EHR system in the last version (pre-final) of the Regulation on the EHDS, in comparison to other definitions specifically narrows the range of health data categories for the purpose this Regulation.

3. Primary Use of Data in EHR Systems and Barriers to Implementation

EHR systems serve as important tools and enablers in the healthcare domain, transforming the way healthcare data is stored, accessed, and utilized. The primary use of data within EHR systems encompasses several key areas, each contributing to the overarching goal of enhancing the quality of healthcare services and outcomes. The primary use of EHR data is centred on patient care—supporting diagnostics, treatment and clinical decision-making, enhancing patient safety, improving the efficiency and coordination of care, and ultimately leading to better health outcomes. This patient-centric approach leverages the power of digital health records to transform the delivery of healthcare, making it more effective, efficient, and patient-focused.

This deliverable will focus on **primary data use** aspects i.e. the clinical use of EHR data (e.g., patient care, decision support), although the currently out of scope characteristics (secondary data use) of EHR systems, such as the administrative use of EHR data e.g. billing and resource management, as well as the research application of EHR data from e.g. clinical trials and epidemiological studies and its public health implications e.g. disease surveillance and population health tracking, may be dealt with in other projects.

This central focus on patient care encompasses several key aspects:

3.1 Clinical Decision-Making and Patient Care

- **Comprehensive Patient Information:** EHRs consolidate detailed patient histories, including diagnoses, treatment plans, medication lists, allergies, laboratory test results, and imaging studies. This comprehensive data repository is accessible to healthcare providers, ensuring that they have a holistic view of a patient's health status at the point of care and to provide efficient treatment based on recorded health data.

- **Real-Time Access and Continuity of Care:** By providing real-time access to patient data, EHRs facilitate continuity of care across different healthcare settings. Whether patients are visiting their primary care physician, a specialist, or an emergency department, healthcare providers can access up-to-date information, leading to consistent and coordinated care.
- **Clinical Decision Support:** EHR systems often include clinical decision support (CDS) tools that analyse patient data to provide evidence-based recommendations, alerts, and reminders. These tools assist healthcare professionals in making informed decisions, following best practices, and adhering to clinical guidelines, thereby improving patient outcomes.
- **Enhancing Patient Safety and quality of care:** Accessibility of EHR can help to avoid unnecessary repetition of diagnostic procedures and associated health risks (e.g. digital imaging-related exposure to radiation). Inserting health data into EHR in a structured format can also help avoid text errors and their following misjudgement.
- **Medication Management:** EHRs play a crucial role in medication management, including electronic prescribing (e-prescribing) and management of active medications. They help to reduce medication errors through alerts about potential drug interactions, incorrect dosages, and patient allergies. This capability significantly enhances patient safety.
- **Preventive Care and Management of Chronic Conditions:** EHR data supports preventive care by reminding healthcare providers about preventive measures and screenings appropriate for the patient's age, sex, and health status. For patients with chronic conditions, EHRs facilitate the monitoring and management of their health, ensuring that they receive appropriate and timely care.
- **Streamlined Care Workflows:** EHRs streamline clinical workflows by reducing the need for paper records, minimizing redundant tests, and improving the overall efficiency of the healthcare delivery process. This not only saves time but also reduces healthcare costs.
- **Enhanced Communication and Coordination between Healthcare Professionals:** EHRs improve communication and coordination among members of the healthcare team, including doctors, nurses, and other healthcare professionals. They enable the sharing of patient information in a secure manner, ensuring that all team members are informed about the patient's care plan, which is especially important for patients with complex healthcare needs.

3.2 Key Challenges and Barriers to EHR implementation and adoption

The implementation and effective use of EHR systems face numerous challenges and barriers. These issues range from technical difficulties to organizational hurdles and legal constraints, each impacting the potential benefits EHR systems can offer. In 2022, the HORIZON 2020 project “X-eHealth” aimed to develop the basis for a workable, interoperable, secure and implementable EEHRxF, which paved the way for a common framework for the cross-border exchange of laboratory requests and results, medical images and imaging reports, hospital discharge letters and patient information on rare diseases. In the project, a readiness assessment report called ‘Mapping national challenges for EEHRxF adoption’ was delivered, which gave an overview of the national challenges and level of maturity regarding deployment of the new domains of the EEHRxF. The report concluded that most of barriers reported for cross-border healthcare data exchange between EU MS amounted to legal aspects of regulating data exchange both on a national and cross-border level, as well as inadequacies of legacy national healthcare data infrastructures. Moreover, the lack of a common regulation and a lack of common infrastructure were found to be key inhibiting factors for cross-border healthcare data exchanges. This deliverable will briefly touch upon some of the important blockers for implementing EHR systems.

3.2.1 Technical Challenges

Technological standards and interoperability remain the linchpins for the successful functioning of EHR systems. The most prevalent standards facilitating interoperability include IHE cross document sharing - IHE XDS, Health Level 7 (HL7®) Fast Healthcare Interoperability Resources (FHIR®), Clinical Document Architecture (CDA) and OpenEHR. European countries typically exhibit fragmented approaches to EHR implementation, with multiple systems and standards co-existing without full integration. This fragmentation hampers the seamless exchange of information across borders and within some national systems. The following key aspects need to be considered:

- **Interoperability:** Despite advancements, interoperability remains a significant hurdle. The ability of EHR systems to seamlessly exchange and make use of information across different healthcare settings and software platforms is critical. Yet, variations in standards, technologies, and vendor systems often result in siloed data, hindering coordinated care and comprehensive data analysis. This has already been identified as an issue at national levels when there is no uniformity in EHR systems.
- **Data Quality:** The value of EHRs is inherently tied to the quality of data they contain. Issues such as incomplete data entries, errors in data input, and inconsistencies across records can severely impact patient care and research outcomes. Ensuring high data quality demands continuous effort and sophisticated data governance practices.

- **Capacity of national ICT infrastructures:** In addition to capable EHR applications, sound, comprehensive and costly underlying infrastructures are required. These include secured communication network (backbone) with sufficient digital bandwidth capacity, sophisticated systems to ensure redundancy and high availability, and capable data storage systems. This is particularly challenging in the field of digital imaging where immense amount of data needs to be exchanged.

3.2.2 Organizational Challenges

- **Adoption Barriers:** The adoption of EHR systems by healthcare providers can be impeded by several factors, including the high costs of implementation, the complexity of transitioning from paper-based to digital systems, from an existing digital system to a new one and resistance from staff. The perceived disruption to existing workflows and concerns over the time required to enter data into EHRs also contribute to resistance.
- **Change Management:** Successfully integrating EHR systems into healthcare practices requires change management efforts. This includes training staff, redesigning workflows, and managing the cultural shift towards digital record-keeping. Organizations often struggle with these aspects, impacting the effectiveness and efficiency of EHR use.
- **Staff training in interoperability and standards:** A significant barrier to national EHR implementation is the inadequate knowledge and understanding of standards and interoperability issues among hospital IT staff, specifically as an intermediary between the software vendors and healthcare professionals as users of such software, which hinders effective management and procurement decisions necessary for integrating systems between healthcare providers and vendors.

3.2.3 Legal and Ethical Challenges

Data privacy and security are at the forefront of the EHR discussions, with stringent measures required to maintain availability and accessibility as well as patient confidentiality and trust. All EU MS adhere to GDPR, which provides a solid foundation for data protection. However, additional national measures and technologies are employed to safeguard health data. For instance, the use of secured telecommunication networks, encryption, audit trails, access controls, digital identity and patient access models varies, reflecting national priorities and capabilities. Some EU MS have established secure frameworks for digital health services to secure data exchange in healthcare, while other MS are still working to bolster their data security infrastructure to meet and exceed the minimum standards set forth by EU legislation. The following aspects need to be considered:

- **Data Protection and Data Subjects' Rights:** General Data Protection Regulation (GDPR) has provided a general framework for patient data processing and the rights of the individual. However, the needs of the healthcare sector are specific, and the sectorial legal base for EHR sharing is the responsibility of MS. Patients must be informed about how their data is used, stored, and shared within EHR systems. The EHDS regulation provides enhancements of key GDPR rights by introducing mandatory digital services for patients (access to EHR, possibility to amend EHR, accessibility of information on accessing EHR). The EHDS regulation also foresees patient's right to restrict access to healthcare providers. Ensuring that such restriction mechanisms are manageable while respecting patient autonomy and enabling necessary data flows for treatment and care coordination, poses a significant challenge.
- **Data Sharing and Ethical Considerations:** The sharing of health data, essential for patient care and public health initiatives, carries significant legal and ethical considerations. Regulations such as the GDPR in the EU set strict requirements around data privacy and security. Moreover, European ethical principles for digital health⁵ which were set out in 2022 provide a reference to the framework of values and guidelines designed to ensure that the development, implementation, and use of digital health technologies within the EU are conducted in a manner that respects fundamental ethical considerations. While specific documents and policies might evolve, these principles generally draw upon core European values such as respect for human dignity, privacy, equity, and solidarity, particularly in the context of healthcare. Balancing the need for healthcare data sharing with the imperative to protect patient privacy in an ethical way requires careful consideration.

With technical and legislative changes in recent years, following progress in the eHealth Digital Service Infrastructure (eHDSI) / MyHealth@EU and the upcoming EHDS regulation, the European EHR landscape is changing with new opportunities to overcome the obstacles to EHR systems adoption and implementation. Some of the key aspects of these changes are considered in the next chapter.

4. Key aspects of EHR Systems' Implementation in European countries

4.1 Technical Framework Governing EHR systems: European Electronic Health Record Exchange

Format (EEHRxF)

The EEHRxF is part of the EU's broader strategy to enable secure access to and exchange of health data across EU MS, enhancing continuity of care and ensuring that citizens can access their health data securely, irrespective of the EU country they are in. This initiative aligns with the Digital Single

⁵ European ethical principles for digital health,

https://sante.gouv.fr/IMG/pdf/220131_european_ethical_principles_for_digital_health_fr_eng.pdf

Market strategy, aiming to make the EU's single market fit for the digital age, improving the movement of digital data within the EU.

The implementation of EEHRxF across EU MS involves several layers, including legal, technical, and interoperability standards. The degree of implementation varies across countries, depending on their existing digital health infrastructure, legal frameworks, and the extent of their engagement with EU-wide digital health initiatives.

The legal framework for EEHRxF is grounded in the GDPR for data protection and privacy, alongside specific directives and regulations concerning cross-border healthcare and digital health services. The eHealth Network (eHN), a voluntary network set up under Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, provides a platform for national authorities responsible for eHealth to collaborate on the implementation of EEHRxF.

Technical implementation involves the development of interoperable digital health records systems that can communicate across borders. This requires standardizing EHR formats, ensuring secure data exchange protocols, and implementing EU-wide agreed-upon technical specifications.

The extent of implementation varies significantly across the EU due to differences in national healthcare systems, digital infrastructure readiness, and legal frameworks. Some MS face technical and financial barriers to upgrading their health information systems to be fully compatible with EEHRxF standards. Moreover, ensuring the security and privacy of health data during cross-border exchanges remains a critical concern.

The implementation of EEHRxF in EU MS is a work in progress, with varying degrees of adoption and integration into national health systems. While there are significant challenges to overcome, the initiative represents a crucial step towards achieving a Digital Single Market for health services, enhancing healthcare delivery, and ensuring patient data mobility across the EU. The success of EEHRxF implementation will depend on continued collaboration between European countries, investment in digital health infrastructure, and the harmonization of legal and technical standards across Europe.

To streamline the existing disparity of national systems and to address legal, semantic, technical and political aspects of the EHR exchange and health data interoperability, European Commission has proposed a Regulation on the EHDS. The EHDS regulation aims to standardize priority categories of personal electronic health data and facilitate their exchange across the EU. Apart from obligations for manufacture of EHR systems by digital health authorities and healthcare providers, the EHDS regulation will make the participation of MS in the existing cross-border infrastructure (MyHealth@EU) mandatory and will formalise the governance framework. Accordingly, standardisation of priority categories of electronic health data will be stipulated in legal documents (Implementing Acts). Harmonisation initiatives are expected to be intensified

and formalised, and existing initiatives such as EEHRxF are expected to be aligned with forthcoming regulation.

Objectives of the EHDS Regulation

The EHDS regulation aims to:

- **Ensure provision of EHR data for the purpose of treatment:** Ensure mandatory documenting of priority categories within the EHR and providing secure access for health professionals.
- **Enhance Access to EHR data for patients:** Ensure patients have easy and secure digital access to and control of their health data and can share it across borders.
- **Support Health Research and Policymaking:** Facilitate the use of health data for research, policymaking, public health and regulatory purposes, under strict conditions to ensure privacy and security.
- **Foster a Digital Single Market for Health:** Create a standardized framework across the EU for sharing health data, thereby reducing fragmentation and barriers in the digital health market. *Note: The third point is related to the secondary use of data. It is indirectly related to this deliverable because EHRs will be subject to secondary use of data.*

The scope of the EHDS Regulation is very comprehensive and demanding not only in terms of long-term financial and political obligations of the MS and their digital health authorities, but also for the establishment of interoperable EU-wide cross-border digital infrastructures. Such infrastructures will need to be established for both primary EHR use of health data (sharing) for the medical care of individuals (MyHealth@EU) and using existing electronic health data for secondary purposes (HealthData@EU). Moreover, the EHDS Regulation provides obligations for commercial providers of the related EHR systems to follow common standards through mandatory publications of technical specifications, conformity assessments and certifications. Accordingly, the EHDS Regulation aims to enforce the interoperability of digital health (wellness) applications and the sharing of health data the national and EU levels.

Based on the objectives and the discussions surrounding the EHDS, the following presents recommendations to ensure the regulation achieves its goals effectively:

Harmonization of Data Standards and Interoperability

- Establish clear, EU-wide data standards and interoperability requirements for national and cross-organisational EHR systems to facilitate seamless cross-border health data exchange.

- Encourage the adoption of international standards such as FHIR and support the development of open APIs to enable integration with various health IT systems.

Data Privacy and Security

- Uphold and build upon the principles of the GDPR in the processing of health data, ensuring that data sharing and analysis respect the legal basis and the purpose of the processing of data subjects' data and their accuracy.
- Implement robust security measures to protect health data against unauthorized access, breaches, and cybersecurity threats.

Patient Empowerment

- Ensure that patients have more control over their health data, including the right to access, manage, and decide on the sharing of their data across European borders, to the extent of the common regulations and legal frameworks in MS.
- Develop user-friendly digital tools and platforms that enable patients to easily access and share their health data.

Support for Innovation and Research

- Create a conducive environment for using health data in research, innovation, and public health, with clear requirements on data access, usage, and ethical considerations.
- Facilitate the establishment of secure data access points for researchers and innovators while ensuring the protection of personal data.

Infrastructure, Governance and Supervision

- Lay down rules and provisions enhancing cross-border exchange of electronic health data for primary as well as secondary use.
- Establish a strong governance framework for the EHDS, including oversight bodies at the EU and MS levels, to monitor and ensure the implementation, address challenges, and adapt to emerging needs.
- Encourage stakeholder engagement, including healthcare providers, patients, researchers, and industry, in the governance process to ensure the system meets the diverse needs of users.

Funding and Investment

- Allocate adequate funding and resources for the development and maintenance of the EHDS infrastructure, including support for MS in upgrading their health data systems.
- Invest in digital skills training for healthcare professionals and patients to maximize the benefits of the EHDS.

Legal and Regulatory Alignment

- Ensure alignment between the EHDS regulation (as a kind of *Lex Specialis*) and other relevant EU laws and policies, including the GDPR, eIDAS, the European Data Governance Act (DGA), Directive (EU) 2022/2555, the European Cyber Resilience Act (CRA), the European Data Act (DA), the Medical Devices Regulation (MDR), Regulation on in vitro diagnostic medical devices (IVDR) and the EU Artificial Intelligence Act (AIA), to create a coherent legal framework for digital health.

The successful implementation of the EHDS regulation requires a multifaceted approach that balances the need for open access to health data with stringent privacy and security measures. By adopting the above recommendations, the EU can create a resilient, patient-centred health data space that supports high-quality healthcare, promotes research and innovation, and contributes to the digital transformation of health systems across the EU. It is essential for the upcoming regulation to be flexible, future-proof, and inclusive, ensuring that all stakeholders can contribute to and benefit from the EHDS regulation.

Priority categories of personal electronic health data for primary use that are referenced in the regulation on the EHDS:

The proposal for the EHDS regulation explicitly requires MS to implement access to and exchange of personal electronic health data for primary use fully or partially falling under the following categories where data is processed in electronic format (EC proposal, May 2022):

- a. patient summaries;*
- b. electronic prescriptions;*
- c. electronic dispensations;*
- d. medical images and image reports;*
- e. laboratory results;*
- f. discharge reports.*

Note: The names of these categories may also change in the final version of the EHDS regulation.

Focus on these priority categories of health data is important even if current frameworks and standards used in MS may not be in line with EU or other international technical specifications or standards. There may be various scenarios for each of these category, e.g. exclusive exchange of the data upon request, sharing data, different technical concepts for healthcare professionals (and individuals) to access data for different categories, voluntary participation of healthcare providers, participation of only certain levels of healthcare providers (e.g. hospitals, specialists, primary care), types of healthcare services and healthcare providers involved, geographical or regional delimitation, or even partial/extended scopes of the categories, additional categories of health data implemented. Specific implementations of national EHR systems in European countries are considered in the following chapter.

5. State of Play of EHR systems implementation in Europe

The following chapter focuses on showcasing the state of play of EHR systems adoption in European countries. The collected information from European countries (27 EU MS and Norway) is contained in Table 1 (Appendix I) and details: the maturity of implementation, geographical coverage and data standards used in national EHR systems, focusing on the adoption of the 6 primary categories of data in their relation to the EHR systems.

The country profiles below can be seen as summary showing specific aspects of each country's implementation efforts in EHR implementation. It is by no means an extensive list of all activities that European countries are performing, but rather provides a "snapshot" of the current state of affairs regarding EHR implementation, focusing on:

- national regulatory frameworks,
- standards and protocols for achieving interoperability,
- brief overview of the technological infrastructure used in a particular country,
- stakeholder engagement,
- data security and privacy measures in place,
- use cases and best practices,
- economic and social impact analysis,
- future plans and recommendations,
- gap analysis with relevant EU standards and other notable cross-border efforts such as MyHealth@EU.

The countries were asked to provide input on these matters in the period between February and April 2024.

The countries were analysed based on the level of maturity in adopting various EHR solutions. The focus was on the standards used and the general level of interoperability both within the country and on the cross-border level. Due to a complex interplay between different factors that

may enable interoperability between technical solutions, the countries are assessed on a descriptive level, whereas a table with qualitative data is given below, after the country profiles.

The countries were not “rated” or “ranked” in any way, nevertheless their “level of interoperability” is assessed using various data interoperability standards as a proxy.

Note that the countries marked with an asterisk symbol () did not directly provide their information through their representative in Xt-EHR to this deliverable. Their country profiles were based on various sources, including the internet, scientific studies and other data sources such as the internal eHMSEG/MyHealth@EU documentation.*

5.1 Austria

National Regulatory Framework

Austria's EHR system, known as Elektronische Gesundheitsakte (ELGA), operates under the Health Telematics Act 2012 (GTeIG 2012). ELGA, demonstrates a robust legal and regulatory framework that prioritizes the secure and efficient exchange of health data. Governed by specific health data legislation, ELGA's foundation on HL7 CDA and transition efforts towards Fast Healthcare Interoperability Resources (FHIR) indicate a strategic alignment with international data exchange standards and protocols. ELGA is managed by ELGA GmbH, a collaboration between the Austrian government, social insurance institutions, and federal provinces, offering opt-out participation. Compliant with EU directives, including GDPR, ELGA integrates various e-health services like emedication and e-vaccination records.

Standards and Protocols for Interoperability

ELGA is built upon a sophisticated technological infrastructure that supports the HL7 CDA format, facilitating the structured and standardized exchange of healthcare information. The efforts to convert this data into FHIR resources underscore Austria's commitment to adopting cutting-edge technologies for healthcare data management, aiming for enhanced interoperability and accessibility of health records. ELGA adopts HL7, IHE, DICOM standards, and utilizes Terminology for managing Code Systems and Value Sets, including SNOMED-CT and ICD-10. Incorporates IHE Integration profiles for healthcare provider directories and patient indexing (XDS/XCA, XDS-I/XCA-I).

The transition from CDA to FHIR within ELGA is a significant move towards enhancing interoperability, both nationally and internationally. This transition ensures that the mandatory sections of the International Patient Summary (IPS) can be efficiently extracted, laying the groundwork for seamless cross-border health data exchange and improving interoperability with other countries' EHR systems.



Technological Infrastructure

Supports secure data storage and exchange, with a robust infrastructure that accommodates various healthcare sectors. Continuous technological enhancement has led to the integration of additional eHealth applications, such as the eVaccination certificate.

Stakeholder Engagement and Perspectives

Extensive involvement from healthcare providers, patients, IT professionals, and policymakers has contributed to the system's evolution. Increased acceptance and utilization, particularly for services like eMedication, highlight the value seen in interoperability. The development and continuous improvement of ELGA involve multiple stakeholders, including healthcare providers, IT professionals, and patients. By focusing on the transition towards more advanced interoperability standards like FHIR, Austria demonstrates its dedication to meeting the evolving needs of its healthcare ecosystem and enhancing user engagement across the board.

Data Security and Privacy Measures

Implements stringent security protocols, including encryption, access controls, and audit trails to protect patient information. Continual security enhancements respond to regulatory requirements and operational insights. Austria's approach to EHR emphasizes the importance of data security and privacy, adhering to stringent standards that protect patient information. The ongoing enhancements in ELGA's infrastructure are indicative of Austria's proactive stance on cybersecurity, ensuring that health data exchange is secure and complies with international data protection regulations.

Use Cases and Best Practices

Demonstrates success in streamlining care coordination, improving access to medical records, and supporting clinical decision-making. The system's expansion to include telemonitoring reports and living wills, alongside traditional medical eReports, illustrates its comprehensive coverage. The implementation of ELGA, particularly its capability to convert CDA to FHIR, serves as a pivotal use case for other nations aiming to achieve a high degree of EHR interoperability. Austria's approach provides valuable insights into the successful deployment of a national EHR system that is both flexible and scalable, accommodating future advancements in health IT.

Economic and Social Impact Analysis

ELGA's interoperability and system enhancements have led to increased healthcare efficiency, better patient outcomes, and notable economic benefits. The system's modernization efforts contribute significantly to the sustainability of Austria's healthcare landscape.

Future Plans and Recommendations

Austria's ongoing efforts to enhance ELGA, particularly through the adoption of FHIR, reflect a forward-looking approach to EHR system development. Future plans likely include further integration with international health data exchange networks, continuous improvement of data security measures, and increased stakeholder engagement to maximize the benefits of digital health records. Aimed at further expansion and optimization, focusing on interoperability and system functionality enhancement. Advocates for the standardization of data formats, incentivization of stakeholder participation, and collaboration to advance Austria's eHealth initiatives, ensuring long-term viability.

Gap Analysis with EU Standards: Austria's transition from CDA to FHIR within its national EHR system, ELGA, signifies a strategic move towards greater interoperability and alignment with EU standards. This transition not only facilitates cross-border health data exchange but also enhances the system's flexibility and scalability. Addressing the technological and regulatory challenges associated with this transition is paramount to fully realizing the benefits of a highly interoperable EHR system that meets the evolving needs of healthcare providers and patients alike.

Table 1. Overview of EHR Systems' Implementation in Austria

Country:	<u>Austria</u>
National EHR (add number of EHR system in brackets, e.g. <i>Yes (1)</i>)	Yes (1)
EHR Interoperability A) within the country, B) with the other countries (explain in the text above)	A) Yes, B) In progress
Data standards used	HL7 CDA, IHE profiles, SNOMED, national standards
Additional information on data standards	Conversion to FHIR in preparation
IPS compliant	No
Use of priority categories in EHR systems:	
1. Patient summaries	No (HL7 IPS in preparation)
2. Electronic prescriptions	Yes (+eHDSI Go Live Dec 2024)
3. Electronic dispensations	Yes (+eHDSI Go Live Dec 2024)
4. Medical images and images reports	Yes (reports yes; images in 2024)
5. Laboratory results	Yes
6. Discharge reports	Yes
EHR systems coverage	National (nationwide coverage)
Interoperability of national implementation	High coverage, structured data usage

5.2 Belgium

National Regulatory Framework

Belgium's EHR system, operational since 2008 through the eHealth platform, exemplifies the country's commitment to digitalizing healthcare. This platform utilizes a decentralized hub-metahub system, enabling healthcare providers to access EHRs stored across different databases, thereby fostering data sharing and accessibility. Structured information related to the PS is stored in 3 regional vaults.

Standards and Protocols for Interoperability

The hub-metahub architecture supports the retrieval and access of citizens' EHRs, functioning as a reference directory. This unique system addresses the challenges of data fragmentation by pointing to local databases of healthcare providers for required information, thereby facilitating interoperability on a national scale. Belgium has a legacy national standard for data exchange, KMEHR, and has implemented a collaborative, outreaching process for standardization using FHIR.

Technological Infrastructure

Belgium's approach, while innovative, highlights the challenges associated with weak interoperability at both national and international levels due to the non-centralized nature of health data storage. The reliance on individual healthcare providers for data collection and storage poses significant barriers to seamless data exchange.

Stakeholder Engagement and Perspectives

The "masanté" or "mijngezondheid" online portal represents a significant step towards engaging citizens with their health data, allowing access to medical and administrative personal information as well as health-related data. This initiative reflects Belgium's efforts to improve patient access and participation in their healthcare journey.

Data Security and Privacy Measures

While specific details on data security and privacy measures within the eHealth platform are not elaborated, the establishment of such a comprehensive system implies a foundational adherence to stringent security protocols, ensuring that health data exchange is conducted in a secure and privacy-compliant manner.

Significantly a resilient system of double encryption of medical data currently is in place, enabling data exchange, excluding secondary use of data for policy and population health objectives. As a part of the transition towards FHIR, at least one of the regional vaults implements pseudonymization enabling secure exchange for primary use and secondary use of health data.

Use Cases and Best Practices

The eHealth platform itself serves as a pivotal use case for other nations, demonstrating how a decentralized approach to EHR can function effectively with the right infrastructure and standards in place, offering a model for addressing interoperability challenges while maintaining data privacy and security. Cooperation agreements between national and regional governments and clear governance agreements are an important condition to facilitate data exchange on a national level.

Economic and Social Impact Analysis

The deployment of the eHealth platform and the online portal "masanté" (or "mijngezondheid") likely contributes to enhanced healthcare efficiency, patient outcomes, and potential cost savings in Belgium by facilitating access to health records, thereby streamlining healthcare delivery and improving patient care.

The 'quintuple aim' is an important benchmark for all actions regarding health data and data exchange.

Future Plans and Recommendations

Belgium's ongoing efforts to enhance the eHealth platform may include further advancements in interoperability standards, integration with EU-wide health data exchange initiatives, and continuous improvement of the technological infrastructure to overcome existing limitations and foster a more integrated healthcare ecosystem.

Gap Analysis with EU Standards:

Belgium's implementation of the eHealth platform indicates a commitment to leveraging technology for healthcare data management. However, the decentralized nature of data storage and the resulting challenges in national and international interoperability highlight areas for improvement. Addressing these challenges, particularly through enhanced centralization and standardization, will be crucial for Belgium to fully align with EU standards and best practices, thereby optimizing the benefits of digital health records within a unified EHDS.

Table 2. Overview of EHR Systems' Implementation in Belgium

Country:	<u>Belgium</u>
National EHR (add number of EHR system in brackets, e.g. Yes (1))	Yes
EHR Interoperability A) within the country, B) with the other countries (explain in the text above)	A) High, B) -
Data standards used	national standards, transition towards HL7 FHIR
Additional information on data standards	
IPS compliant	-
Use of priority categories in EHR systems:	
1. Patient summaries	Yes
2. Electronic prescriptions	Yes
3. Electronic dispensations	Yes
4. Medical images and images reports	Yes
5. Laboratory results	Yes
6. Discharge reports	Yes
EHR systems coverage	Nationwide coverage
Interoperability of national implementation	Undergoing transition towards HL7 FHIR.

5.3 Bulgaria

National Regulatory Framework

Bulgaria initiated national strategies for eHealth implementation in alignment with the EC eHealth Action Plan starting in 2006. Despite these early efforts, Bulgaria currently lacks a fully integrated and interoperable national EHR system. This gap highlights a significant need for comprehensive legislation and regulatory frameworks to guide the development and implementation of a unified EHR system within the country.

Standards and Protocols for Interoperability

The absence of a national integrated EHR system suggests that Bulgaria is yet to adopt and implement widespread standards and protocols necessary for EHR interoperability. This situation indicates a crucial area for development, with potential focus areas including the adoption of international standards such as HL7 FHIR, IHE profiles, and SNOMED CT to facilitate data exchange and interoperability both nationally and across EU borders.

Technological Infrastructure

Given the lack of a national EHR system, Bulgaria's current technological infrastructure for EHRs remains underdeveloped. Future efforts could focus on establishing a robust technological backbone that supports EHR functionalities, including secure data storage, exchange, and access mechanisms that comply with international interoperability standards.

Stakeholder Engagement and Perspectives

The initial strategies for eHealth implementation suggest an acknowledgment of the importance of digital health. However, without a fully operational national EHR system, stakeholder engagement—including healthcare providers, patients, IT professionals, and policymakers—may be limited. Enhancing engagement through inclusive policy-making processes and public-private partnerships could drive the development of an EHR system that meets the needs of all stakeholders.

Data Security and Privacy Measures

While specific measures for data security and privacy in relation to a national EHR system are not detailed, Bulgaria, like all EU countries, is subject to the GDPR. The development of a national EHR system will need to prioritize data protection and privacy, incorporating robust security measures such as encryption, access controls, and audit trails to safeguard patient information.

Use Cases and Best Practices

Bulgaria's future development of a national EHR system could benefit from examining use cases and best practices from other EU countries that have successfully implemented interoperable EHR systems. Learning from these examples could guide Bulgaria in overcoming current challenges and leveraging digital health technologies to improve healthcare delivery and outcomes.

Economic and Social Impact Analysis

The establishment of a comprehensive national EHR system in Bulgaria is anticipated to have significant economic and social impacts, including improved healthcare efficiency, enhanced patient care, and potential cost savings. By facilitating timely access to patient information, an EHR system can improve clinical decision-making and patient outcomes, contributing to overall health system sustainability.

Future Plans and Recommendations

Bulgaria's path forward involves the development and implementation of a national EHR system that aligns with EU standards and practices. Recommendations for advancing this goal include the adoption of international interoperability standards, investment in technological infrastructure, and engagement with stakeholders to ensure the system addresses the needs of the Bulgarian healthcare ecosystem.

Gap Analysis with EU Standards: Bulgaria's journey towards an integrated and interoperable EHR system is in its early stages. Addressing the current gaps, particularly in legislative and regulatory frameworks, technological infrastructure, and stakeholder engagement, is crucial for aligning with EU standards and best practices. By focusing on these areas, Bulgaria can enhance its healthcare delivery system and fully leverage the benefits of digital health within the EHDS.

Table 3. Overview of EHR Systems' Implementation in Bulgaria

Country:	Bulgaria
National EHR (add number of EHR system in brackets, e.g. Yes (1))	-
EHR Interoperability A) within the country, B) with the other countries (explain in the text above)	A) - B) -
Data standards used	National standards
Additional information on data standards	Transitioning to eHDSI
IPS compliant	-
Use of priority categories in EHR systems:	
1. Patient summaries	-
2. Electronic prescriptions	-
3. Electronic dispensations	-
4. Medical images and images reports	-
5. Laboratory results	-
6. Discharge reports	-
EHR systems coverage	Regional (Limited, major urban areas only)
Interoperability of national implementation	Limited coverage, primarily unstructured data

5.4 Croatia

National Regulatory Framework

Croatia has enacted specific legislation, such as the Law on Data and Information in Healthcare, and Regulation on the Scope and Content of Data and on the Way of Keeping EHR, to manage and

regulate EHRs effectively. Compliance with the GDPR is ensured through the national Law on the Implementation of the General Data Protection Regulation, safeguarding personal health data.

The Health Care Act provides a foundation for organizing digital health services, emphasizing the importance of EHRs in the national healthcare system. Cybersecurity measures are bolstered by the Cybersecurity Act, focusing on securing healthcare information systems against cyber threats. The Patient Rights Act guarantees patients' access to their health information, influencing the development of patient centric EHR systems. The Digital Health Act, currently proposed, aims to further standardize and enhance digital health initiatives, including EHRs.

Croatia's e-Health Strategy outlines the strategic directions for digital health, including the advancement of EHR functionalities. Participation in the EU Cross-Border Healthcare Directive facilitates the exchange of health data across EU MS, enhancing patient care during cross-border mobility.

Standards and Protocols for Interoperability

Adoption of HL7 and SNOMED CT standards ensures interoperable health data exchange and precise clinical documentation within EHRs. IHE profiles are implemented to standardize healthcare data exchange processes, enhancing system interoperability. DICOM standards support the integration of medical imaging data, crucial for comprehensive EHRs. Engagement with European (CEN/TC 251) and international (ISO/TC 215) health informatics standards further supports interoperability efforts.

Technological Infrastructure

The Central Health Information System (CEZIH) acts as the technological backbone for EHR implementation, ensuring secure and efficient data management. A national health information system supports broader healthcare operations, integrating patient management systems with EHR access. Patient access portals and mobile health applications extend EHR functionalities, promoting patient engagement and self-management.

Stakeholder Engagement and Perspectives

Continuous training programs for healthcare providers on EHR functionalities underscore the importance of user competence in digital health. Patient awareness initiatives highlight the benefits and rights related to EHRs, fostering a culture of transparency and participation. Collaboration with EU health projects aligns Croatia with European digital health standards, showcasing a commitment to interoperability and innovation.

Data Security and Privacy Measures



State-of-the-art encryption technologies and access control mechanisms are employed to protect EHR data, aligning with national and EU data protection regulations. Regular security audits and a robust incident response plan underline Croatia's proactive stance on cybersecurity within healthcare.

Use Cases and Best Practices

Successful implementation of cross-border ePrescription and PS services through participation in the eHDSI demonstrates Croatia's leadership in EHR interoperability. The national immunization registry and chronic disease management programs exemplify the effective use of EHRs in public health and patient care. Research and Development Projects: Engages in national and EU-funded projects to explore innovative EHR applications and technologies. Privacy-Enhancing Technologies Adoption: Incorporates technologies such as differential privacy in EHR systems to enhance data privacy without compromising utility. Patient Data Portability Initiatives: Facilitates data portability across EU MS, supporting patient mobility and care continuity.

Economic and Social Impact Analysis

Increased Healthcare Efficiency: Demonstrates significant improvements in administrative efficiency and reduction in medical errors due to EHR adoption.

Enhanced Patient Outcomes: Attributes improvements in patient care outcomes to the effective use of EHRs in treatment planning and monitoring.

Cost Savings: Reports cost savings from reduced paper records management, optimized resource allocation, and decreased duplicate testing.

Public Health Surveillance Enhancement: Utilizes EHR data for real-time public health monitoring and response, notably during the COVID-19 pandemic.

Patient Empowerment: Highlights increased patient engagement and satisfaction through direct access to health information and care management tools.

Digital Health Literacy: Identifies the need for and impact of raising digital health literacy among patients and healthcare providers.

Data-Driven Healthcare Innovation: Fuels healthcare innovation using aggregated EHR data for research and development.

EHR as a Platform for Telemedicine: Expands access to healthcare services, particularly in rural areas, through the integration of telemedicine and EHR systems.

Workforce Transformation: Notes the transformation of healthcare workforce roles and skills due to digital health technology integration.

Privacy and Security Concerns: Addresses public concerns about data privacy and security, emphasizing the measures taken to protect patient information.

Future Plans and Recommendations

Interoperability Expansion: Aims to enhance interoperability standards further, facilitating seamless data exchange beyond current capabilities.

Artificial Intelligence Integration: Plans to integrate AI tools for predictive analytics, diagnosis support, and personalized medicine within EHR systems.

User-Centric Design Focus: Recommends a shift towards more user-friendly EHR interfaces to improve usability for healthcare providers and patients.

Strengthening Data Governance: Emphasizes the importance of robust data governance frameworks to manage and protect health information.

Continuous Education and Training: Advocates for ongoing education and training programs to equip healthcare professionals with necessary digital competencies.

EHR System Scalability: Prioritizes the scalability of EHR systems to accommodate future healthcare demands and technological advancements.

Enhanced Patient Participation: Encourages initiatives to promote patient involvement in their healthcare through EHR functionalities.

Investment in Cybersecurity: Urges increased investment in cybersecurity measures to safeguard health data against evolving threats.

Cross-Sector Collaboration: Recommends fostering cross-sector collaboration to leverage digital health solutions for integrated care delivery.

Evaluation and Continuous Improvement: Suggests regular evaluation of EHR system performance to identify areas for improvement and adaptation to new challenges.

Gap Analysis with EU Standards: Comparing Croatia's EHR implementation with EU standards and best practices reveals a proactive approach toward adopting and integrating digital health technologies. Croatia aligns well with EU directives and interoperability frameworks, showcasing leadership in cross-border healthcare data exchange. However, ongoing efforts to enhance data

structurization, address scalability, and improve user interfaces indicate areas for growth. Further alignment with EU-wide initiatives on AI and blockchain could propel Croatia's EHR system to the forefront of digital health innovation. Continuous stakeholder engagement, investment in cybersecurity, and focus on user-centric design will be crucial in maintaining and advancing Croatia's position in the digital healthcare landscape.

Table 4. Overview of EHR Systems' Implementation in Croatia

Country:	<u>Croatia</u>
National EHR (add number of EHR system in brackets, e.g. <i>Yes (1)</i>)	Yes (1)
EHR Interoperability A) within the country, B) with the other countries (explain in the text above)	A) Partial, B) Yes
Data standards used	Local adaptations of HL7, HRN ENV 13606
Additional information on data standards	Based on FHIR and HL7 ver. 3
IPS compliant	Yes
Use of priority categories in EHR systems:	
1. Patient summaries	Yes (based on HL7 IPS standard, implemented with dataset following Guidelines on PS in cross-border use, via a portal and integrated into EHR)
2. Electronic prescriptions	Yes (partially national standard (WHO code + national part), in cross-border use, via a portal, integrated into EHR)
3. Electronic dispensations	Yes (partially national standard (WHO code + national part), in cross-border use, via a portal, integrated into EHR)
4. Medical images and images reports	No
5. Laboratory results	Yes (based on HL7 IPS, pdf, via a portal, integrated into EHR, not in cross-border use)
6. Discharge reports	Yes (pdf, only national use, not in the portal and not integrated in EHR)
EHR systems coverage	National (Nationwide for certain data categories)
Interoperability of national implementation	Nationwide coverage, mixed structured data usage

5.5 Cyprus

National Regulatory Framework

Cyprus has fortified its national eHealth infrastructure with the enactment of Law No. 59(I)/2019, signalling an important step towards the establishment of a robust eHealth ecosystem. This legislation lays down the cornerstone for a comprehensive EHR system, emphasizing Cyprus's dedication to centralized health data management and accessibility.

Under the purview of this law, the National eHealth Authority (NeHA) assumes significant responsibilities. NeHA sets telemedicine standards, fosters international collaboration on electronic health, monitors eHealth advancements, oversees revenues from anonymous databases, promotes eHealth education, and advises the Ministry, among others.

As the National eHealth Contact Point, the Authority ensures cross-border healthcare continuity and patient safety through electronic services. Its responsibilities include establishing data security systems, safeguarding data confidentiality, integrity, authenticity, and availability, and implementing a health data control mechanism with other MS.

Cyprus boasts a national EHR system, meticulously managed by the Health Insurance Organisation (HIO) to uphold the principles of the General Healthcare System (GHS), a contemporary and patient-centric healthcare model dedicated to delivering top-notch healthcare services to all beneficiaries. Upholding universal coverage, equal treatment, and the freedom to choose providers, the GHS is underpinned by a specialized fund, overseen by the HIO, ensuring financial transactions between beneficiaries and healthcare providers.

While efforts are made to align national health laws with EU directives, Cyprus's unique healthcare system requirements occasionally lead to deviations from EU norms, which are addressed through flexible regulatory practices aimed at gradual harmonization. Engaging in ongoing dialogue and policy-making processes at the EU level, Cyprus remains committed to advocating for and contributing to the development of a harmonized regulatory framework, ensuring its national regulations evolve in tandem with EU standards and technological advancements.

Standards and Protocols for Interoperability

The HIO in Cyprus relies on a comprehensive array of international and proprietary coding systems to effectively manage healthcare data and ensure quality care provision. Central to this endeavour is the utilization of internationally recognized standards such as the International Classification of Diseases - ICD, 10th Edition (ICD-10), Current Procedural Terminology (CPT), Logical Observation Identifier Names and Codes (LOINC), and the International Classification of Primary Care II (ICPC II). Additionally, the HIO employs its own codification system tailored to local healthcare needs, known as the HIO Codification. Complementing these standards are Cyprus specific classifications including the CMP-CY, V1.0 and Diagnosis Related Groups Cyprus (DRG-CY), which facilitate precise diagnosis and resource allocation within the national healthcare system. To streamline medication management, the HIO integrates the Anatomical Therapeutic Chemical (ATC) classification system alongside unique identifiers, ensuring accurate tracking and monitoring of pharmaceutical usage across healthcare facilities. This comprehensive approach to coding and classification underscores the HIO's commitment to leveraging standardized practices while accommodating Cyprus's specific healthcare requirements.

Technological Infrastructure

At the heart of this system lies a robust IT infrastructure, currently under development, with two portals — the Beneficiary Portal and the Provider Portal — accessible online. Beneficiaries can effortlessly manage their healthcare journey, from enrolment to accessing medical history, while providers navigate contracting, referrals, prescriptions, and payment requests. With extensive functionalities, comprehensive training, and technical support provided, the IT system stands poised to facilitate the intricate processes essential for the GHS's optimal functionality, embodying Cyprus's commitment to cutting-edge healthcare provision.

Stakeholder Engagement and Perspectives

The establishment of the National eHealth Authority of Cyprus (NeHA) indicates proactive governance and stakeholder engagement in the eHealth domain. This approach likely involves collaboration with healthcare providers, IT professionals, and patients to ensure that the EHR system meets the diverse needs of Cyprus's healthcare landscape.

Data Security and Privacy Measures

While specific data security and privacy measures for Cyprus's EHR system are not detailed, the implementation of such a system under EU regulations, including GDPR, necessitates rigorous data protection and privacy safeguards. This includes secure data storage, access controls, and encryption to protect patient information against unauthorized access and breaches.

Use Cases and Best Practices

Cyprus has launched a pioneering EHR system called "eHealth4U," built on FHIR standards and fully compliant with the IPS. This innovative system, accessible at <https://dev-ehr.ehealth4u.eu/>, effectively addresses legislative requirements concerning GDPR compliance, consent management, and opt-out services. It encompasses essential functionalities for medical visits, discharge reports, and comprehensive access to laboratory results and imaging reports in PDF format. The guide is available at <https://simplifier.net/ehealth4u/>.

Economic and Social Impact Analysis

The operation of a national EHR system since 2019 in Cyprus likely contributes to enhanced healthcare efficiency, patient outcomes, and potential cost savings. Centralized access to health records facilitates improved care coordination, diagnostic accuracy, and treatment effectiveness, benefiting the overall healthcare system and patient well-being.

Future Plans and Recommendations

As Cyprus continues to develop and refine its EHR system, future plans may include further integration with EU-wide health data exchange initiatives, enhancing interoperability standards, and expanding the scope of health services and functionalities available through the EHR system. This would ensure continued alignment with evolving EU directives and best practices in digital health.

Efforts to fortify the healthcare sector's digital landscape entail a multifaceted approach. Firstly, regular updates and reinforcement of cybersecurity protocols are essential to safeguard sensitive health data from evolving threats, employing cutting-edge encryption technologies and access control systems. Secondly, the integration of international standards like FHIR is paramount to bolster EHR system interoperability within Cyprus and beyond its borders. Thirdly, prioritizing the development of user-friendly interfaces and secure access mechanisms empowers patients to manage their health information, fostering transparency and trust. Moreover, the potential establishment of a centralized EHR system management platform could streamline operations, minimize redundancy, and enhance data coherence across the nation. Additionally, sustainable IT infrastructure development is critical to meet future data demands and accommodate technological advancements. Finally, initiatives aimed at enhancing community health data literacy are imperative, ensuring widespread understanding of secure health information management and the inherent benefits therein. Through these strategic measures, Cyprus can fortify its healthcare ecosystem against emerging challenges while fostering innovation and resilience.



Gap Analysis with EU Standards: Cyprus's EHR implementation showcases a strong foundation in centralized health data management and adherence to modern interoperability standards. Addressing any remaining challenges in system integration, stakeholder engagement, and data security will further align Cyprus's EHR system with EU standards and best practices. The continued development of the EHR system, including the expansion of services and functionalities, will enhance Cyprus's position within the EU's digital health landscape, offering a model for other EU countries to follow.

Table 5. Overview of EHR Systems' Implementation in Cyprus

Country:	Cyprus
National EHR (add number of EHR system in brackets, e.g. Yes (1))	Yes (1)
EHR Interoperability A) within the country, B) with the other countries (explain in the text above)	A) Yes, B) No
Data standards used	HL7 FHIR (pilot), national standards
Additional information on data standards	Proprietary standards transitioning
IPS compliant	Yes (pilot)
Use of priority categories in EHR systems:	
1. Patient summaries	No in production (Yes in pilot)
2. Electronic prescriptions	Yes
3. Electronic dispensations	Yes
4. Medical images and images reports	Partial (reports)
5. Laboratory results	No
6. Discharge reports	No in production (Yes in pilot)
EHR systems coverage	Full
Interoperability of national implementation	No in production (Yes in pilot)

5.6 Czech Republic

National Regulatory Framework

Czech Republic does not operate a centralized national eHealth system or framework for the exchange of medical documentation between healthcare providers. EHRs are existent only very scarcely in information systems of certain healthcare providers. Only recently, the Ministry of Health has adopted the eHealth Act and is beginning to publish standards for some categories of EHR. ePrescription and eDispensation are the only part of EHR, which are operated nationally, stored centrally, and used vary widely between healthcare professionals, pharmacies and patients. Patient summaries are created on-the-fly by only a few healthcare providers (mainly hospitals), who are connected to the National Contact Point for eHealth (NCPeH) and currently are provided mainly for cross-border use of for the patients themselves. Typically, not all sections of the PS can be provided in the required format. In parallel, a number of PSs coexist (if created by Health Care Providers (HCPs), their coordination and consolidation are not established at any level outside of the HCPs, which is a challenge for the development of a usable EHR concept in the Czech Republic.

As mentioned above, it is only recently that CZ has started to publish legislative framework for the future use of EHR. EHR is in general mentioned in the National eHealth Strategy and in the overall healthcare strategic document Health 2030. The main laws that focus on the healthcare provider systems and that can also be used in part to set up the foundations for EHR to are the following:

- Act No. 372/2011 Coll. on healthcare services
- Act No. 325/2021 Coll. on electronization of healthcare
- Decree No. 98/2012 Coll. on medical documentation

The legislation describes the conditions for data protection and privacy, although it is continually being amended and improved. The healthcare service delivery standards are currently under preparation and publication. There is a strong will to make the national regulations to be in alignment with the EU framework, directives and regulations.

Standards and Protocols for Interoperability

As mentioned above, the EHR systems are only beginning to use the standards and protocols for interoperability, which are being prepared and published by the CZ MoH^[1]. In the past, healthcare provider information systems have used only a national proprietary standard (DASTA), incompatible with international standards. For the future, HL7 standards are to be applied for EHR (HL7 CDA/FHIR); IHE IT profiles are also starting to be implemented. DICOM is used for image exchange. Functional and technical specifications of the image exchange systems are mutually different, national.

Technological Infrastructure

Technological infrastructure for EHR systems is not in place in CZ. The healthcare providers are not connected to any national infrastructure or platform. Some regional or commercial networks exist; however, they are limited in their use of standardized exchange formats. Again, the continuously amended eHealth legislation and prepared framework are striving to improve this situation and provide at least the basic rules for interoperability.

Two national image exchange systems (ePACS and ReDiMeD) are operated in the Czech Republic. Although they originally each had their own territorial remit, they currently overlap, so that many HCPs across the country participates in both. The systems allow the exchange of images between HCPs. ePACS has created a HW infrastructure including a central communication unit, while ReDiMeD is a purely SW solution that also enables the exchange of video messages. Each of the two systems uses own identification procedure based on general national identification infrastructure.

Stakeholder Engagement and Perspectives

In the past, the stakeholder engagement has generally been quite low. Recently, this is being changed to ensure progress and acceptance of the newly prepared rules and frameworks by the relevant stakeholder audience. Generally, the barriers to interoperability are the lack of the necessary rules, frameworks and methodical support from the side of the state, and very low level of knowledge and capabilities necessary to implement international interoperability standards on the side of healthcare providers, vendors, and professionals in health IT. On the side of the patients, the main barrier is the lack of existence of access of patients to any of their medical data (not even EHR) online. The only exception is for ePrescription/eDispensation, where the stakeholder engagement is more advanced, as the system is already in use for several years and tools exists for stakeholder engagement.

Data Security and Privacy Measures

Data Security and privacy measures are the responsibility of the individual healthcare providers. CZ MoH ⁶ provides methodical support regarding data security (Metodika kybernetické bezpečnosti | Národní centrum elektronického zdravotnictví). Regarding the cross-border exchanges, all the security measures required by the MyHealth@EU requirements are in place. Currently, the main incidents which happen are cases of personal data leak, when a patient or a healthcare professional receives data from another person. This is because most hospitals do not yet have their patient registries in line with the citizen registry. However, a service is being finalized now, which should ensure that the patient registries in the healthcare providers systems (mainly hospitals) are cleaned and correct.

Use Cases and Best Practices

At the moment, there are not interoperability use cases on national level, which would be widely used and could be presented. The only national system which currently requires the use of international standards is the National Contact Point for eHealth, which verifies whether the connected systems are interoperable, at least to a limited extent. The interoperability testing framework is in place, which is in line with the MyHealth@EU requirements. A good example of practice can be the national ePrescription/eDispensation service, which is ultimately user-friendly for all participants (prescribing doctors, pharmacists, patients). E.g. it is very simple for patients to pick up their medicine at any pharmacy in the country, even if they forget the "code" or have no electronic device; only e.g. ID card can be used to pick up the prescribed medicine. Information

⁶ <https://ncez.mzcr.cz/cs/pozadavky-mz-pro-vyzvy-irop-ehealth-npo-interoperabilita-ii/pozadavky-mz-pro-vyzvyirop-ehealth-npo>

on all dispensed medicines incl. dosage can then be obtained through the eGovernment Citizen portal.

On the other hand, it was found that doctors who need to know a (new) patient's medication often ask the patient directly to say so (the traditional method), rather than logging in and retrieving data in the eDispensation system (estimated to be 50:50 of cases in 2023). The availability of technology and the operation of a service appear to be only one of all the prerequisites for the wide use of a new service in the healthcare sector, especially if there is no EHR providing other important health data; the default method for obtaining such information has always been oral or paper based. In terms of image exchange, the two systems have gradually connected all the major HCPs in the country and are further connecting the smaller ones. ePACS has about 710 users (HCPs) in 3.2024 and ReDiMeD has about half of this number. Currently, the Ministry of Health of the Czech Republic is creating a general national interoperability strategy and testing framework.

Economic and Social Impact Analysis

It is expected that once a national EHR is implemented and a real and efficient of patient data starts flowing within the healthcare system, there should be significant economic and social impacts, as well as savings in healthcare costs. A national concept of EHR shall be designed soon and it will also specify more closely the associated costs. The economic feasibility and sustainability of EHR systems will need to be taken into consideration.

Future Plans and Recommendations

Currently, several projects co-financed from the Recovery and Resilience Facility (RRF) are being realized by the MoH on national level, where the overall objective is to launch the implementation of national EHR and interoperability. These projects are scheduled to end in 2026. On the level of healthcare providers, they have an opportunity to co-finance the update of their systems from EU structural funds, where the implementation of interoperability measures is a condition. These projects are also to be finalized by 2026.

Gap Analysis with EU Standards: While there are ongoing efforts in the Czech Republic towards the development and implementation of EHR systems, gaps remain in regulatory alignment, interoperability standards adoption, infrastructure development, stakeholder engagement, capacities and security measures compared to usual practice in many EU countries. Addressing these gaps is crucial for achieving interoperability and compliance with the EHDS initiative.

Table 6. Overview of EHR Systems' Implementation in Czech Republic

Country:	Czech Republic
National EHR (add number of EHR system in brackets, e.g. Yes (1))	No (EHR under development, individual ISs may exchange certain datasets)
EHR Interoperability A) within the country, B) with the other countries (explain in the text above)	A) Partial, B) Yes
Data standards used	National standards (DASTA in several versions)
Additional information on data standards	New specification of national standards based on int. standards as HL7 CDA, FIR, IHE in preparation
IPS compliant	Yes
Use of priority categories in EHR systems:	
1. Patient summaries	Yes (defined in national legislation as part of patient's health documentation. It has functional technical specification, including semantic. No central/national governance established; creation of PS is left on providers. Standards based on EU PS,
	International Patient Summary – only few healthcare providers implement them -> limited use by patients)
2. Electronic prescriptions	Yes (eHDSI live; national legislation on mandatory ePs; prepared in EHRs and stored in the National Prescription Centre. Also accessible for citizens via government national citizen portal or a mobile app)
3. Electronic dispensations	Yes (access of citizens integrated with eP; access of healthcare professional limited by national legislation)
4. Medical images and images reports	Yes (however functional and technical specification of the two operated systems is proprietary. Systems enable sending/receiving information only in DICOM format. Nationwide (only one system supports also reports))
5. Laboratory results	No (under preparation)
6. Discharge reports	No (under preparation)
EHR systems coverage	Regional (Major cities and regions)
Interoperability of national implementation	Structured data in use, but not fully nationwide

5.7 Denmark

National Regulatory Framework

Denmark's national laws and regulations for EHR systems include stringent data protection, privacy, and healthcare service delivery standards, in alignment with EU directives and regulations. The country focuses on ensuring the security and confidentiality of patient data within the EHR systems, with specific regulations guiding the handling and exchange of health information.

Standards and Protocols for Interoperability

Denmark utilizes the ICD-10-DK system and NOMESCO classifications for procedures, reflecting a commitment to standardized coding within EHRs. Data exchange is facilitated by MedCom, which supports various formats including EDI, CDA, and FHIR, ensuring comprehensive interoperability across healthcare systems. The "sundhedsjournalen" (The E-record) plays a pivotal role in aggregating health records for nationwide access, underpinning the seamless sharing of patient information.

Technological Infrastructure for EHR Systems

The integration of EHR systems across Danish Regions highlights the collaborative effort to enhance healthcare delivery. Notably, different regions employ systems provided by either Epic or Systematic, demonstrating a diverse technological landscape. Challenges include the full integration of new systems like the maternity notes folder ("Graviditetsmappen"), and the need for new rules for merging data sources for a complete PS dataset. The National Service Platform, managed by the Danish Health Data Authority (DHDA), is a crucial component for accessing most of the source data for patient summaries.

Stakeholder Engagement and Perspectives

Denmark's proactive approach to stakeholder engagement, particularly in the context of the eHDSI Project, ensures that healthcare professionals and citizens are considered in the implementation of cross-border ePrescription and PS solutions. The country anticipates increased engagement when transitioning to receiving data as part of the EHDS.

Data Security and Privacy Measures

Denmark is committed to aligning its authentication solutions with the eIDAS regulation and aims to adhere to the National Standard for Assurance Levels (NSIS), particularly regarding the

requirements for Identity Brokers. This alignment underscores Denmark's dedication to maintaining high levels of data security and privacy in cross-border data exchanges.

Use Cases and Best Practices

Denmark leverages an iterative approach, grounded in SAFE methodology and Prince2 project management framework, for the implementation of interoperability use cases. This methodical approach ensures the successful integration of national best practices with MyHealth@EU's business requirements, as demonstrated in solutions like the COVID-19 Pass.

Economic and Social Impact Analysis

An economic impact analysis has been conducted to assess the societal costs associated with the implementation of EHDS in Denmark. While based on initial drafts of the regulation, this analysis provides valuable insights into the economic considerations of adopting EU-wide interoperability standards.

Future Plans and Recommendations

Denmark aspires to enhance European interoperability by making cross-border data for primary and secondary use available within the EU. The DHDA's commitment to these projects signifies Denmark's continued effort to strengthen data exchange mechanisms, contributing to the overall effectiveness of healthcare delivery across Europe.

Gap Analysis with EU Standards: As Denmark advances its EHR systems, continuous updates to national legislation may be required to keep pace with evolving EU directives and the forthcoming EHDS regulations, especially concerning the national PS's detailed requirements. Denmark's use of ICD-10-DK, NOMESCO for procedures, and the adoption of EDI, CDA, and FHIR through MedCom, aligns well with EU recommendations for achieving semantic and structural interoperability. This facilitates the exchange of health data within the country and across EU MS.

Despite significant progress, Denmark faces the challenge of ensuring that all EHR systems across regions can seamlessly exchange data using the most recent standards, such as FHIR. Bridging the gap between older and newer data exchange formats remains critical. The integration efforts and the Health Record (Sundhedsjournalen) system for data sharing across sectors show Denmark's commitment to a unified healthcare data ecosystem, in line with the EU's vision for cross-border health data exchange. The diversity in EHR systems across Danish regions, while beneficial for localized service delivery, may pose challenges in achieving a fully unified national EHR system that aligns with the future requirements of the EHDS, especially for cross-border services like the ePrescription and PS. Denmark's intention to align authentication solutions with the eIDAS regulation and follow the NSIS demonstrates a commitment to the security and privacy standards

expected within the EU. Achieving a harmonized approach to the NSIS, particularly regarding Identity Brokers, presents a challenge due to possible misalignments with other countries. Denmark, like other EU MS, will need to ensure national implementations of NSIS do not hinder cross-border data exchanges due to varying assurance levels and technical specifications.

Table 7. Overview of EHR Systems’ Implementation in Denmark

Country:	<u>Denmark</u>
National EHR (add number of EHR system in brackets, e.g. <i>Yes (1)</i>)	Yes
EHR Interoperability A) within the country, B) with the other countries (explain in the text above)	A) Yes, B) Yes
Data standards used	HL7, National standards
Additional information on data standards	Data exchange support EDI, CDA, FHIR formats
IPS compliant	Yes
Use of priority categories in EHR systems:	
1. Patient summaries	Planned for cross-border country a implementation late 2025
2. Electronic prescriptions	Yes
3. Electronic dispensations	Yes
4. Medical images and images reports	Yes
5. Laboratory results	Yes
6. Discharge reports	Yes
EHR systems coverage	National (Nationwide coverage)
Interoperability of national implementation	Nationwide coverage, structured data

5.8 Estonia

National Regulatory Framework

Estonia launched the Estonian National Health Information System (ENHIS) in 2008, digitalizing more than 99% of health data from hospitals and doctors in private as well as public sector. In 2010 digital prescription was launched and in 2019 the first in EU cross-border digital prescription was launched together with Finland.

ENHIS utilizes HL7 CDA for data exchange, transitioning towards HL7 FHIR standards for enhanced interoperability.



X-Road, an open-source software, is employed for secure data exchange among various organizations, showcasing Estonia's commitment to secure and interoperable data handling.

Cross-border ePrescription and PS services are operational, indicating alignment with EU directives for cross-border healthcare.

Estonia's regulatory framework is aligned with EU directives, including GDPR, emphasizing data protection and privacy in healthcare delivery. Upcoming EHDS directive is very well corresponding to the principles and regulations already established and needs just minor changes to national legislation.

Standards and Protocols for Interoperability

Adoption of HL7 standards and transitioning towards HL7 FHIR demonstrate Estonia's commitment to international interoperability protocols.

The use of X-Road for secure data exchange underscores Estonia's innovative approach to data interoperability.

Estonia's engagement in cross-border health services reflects its compliance with EU standards and its active participation in the EU health data space.

Technological Infrastructure

Estonia has centrally managed distributed Data Exchange Layer X-road that is connecting all the databases to enable the "once-only principle". As all the citizens have unique ID-code, it is easier to connect all the databases and since 2008 eHealth in Estonia has been fully digital with the demand to submit all the priority information to central system managed by Ministry of Social Affairs. Centralized system enables also smooth interoperability cross-border and making data available for secondary use.

ENHIS serves as the technological backbone for EHR in Estonia, integrating healthcare data across the country.

The shift towards HL7 FHIR standards indicates ongoing improvements in the technological infrastructure to support more efficient and versatile data exchange.

Stakeholder Engagement and Perspectives

Estonia's effective use of ENHIS and participation in cross-border health services highlight the positive engagement of stakeholders in the digital health ecosystem.



The successful implementation of cross-border services showcases Estonia's ability to meet both national and EU expectations for healthcare interoperability.

Data Security and Privacy Measures

Utilization of secure frameworks like X-Road for data exchange indicates robust measures for data security and privacy in line with EU standards.

The transition to HL7 FHIR and adherence to GDPR demonstrate Estonia's commitment to ensuring the security and privacy of health data.

Use Cases and Best Practices

Estonia's nationwide digitalization of health records and the operational cross-border ePrescription and PS services serve as exemplary use cases of EHR interoperability. As well, Estonia launched the first ePrescription cross-border together with Finland as early as 2019 and has most probably one of the most complete EHRs where almost all of the patient data is available to patients through the patient portal and patient is in control of its data (log files, access controls, representative control etc).

The integration of health data through ENHIS, coupled with secure data exchange via X-Road, can be considered best practices in achieving EHR interoperability.

Economic and Social Impact Analysis

The digitalization of healthcare data and the implementation of cross-border services enhance healthcare efficiency and patient outcomes, contributing to the social and economic benefits within Estonia.

Future Plans and Recommendations

Continual updates to the ENHIS, including the adoption of newer standards like HL7 FHIR, indicate Estonia's future plans for improving EHR interoperability.

Estonia's active participation in cross-border health initiatives underscores its commitment to enhancing healthcare delivery and interoperability at the EU level. As well, Estonia is planning to implement the EHDS as soon as possible and is working in analysing the best solution for secure processing environments in order to enable the use of environment during next two years.

Gap Analysis with EU Standards: Estonia's EHR implementation exemplifies a proactive and innovative approach to digital health, showcasing significant alignment with EU standards and best practices. The country's early digitalization efforts, secure data exchange infrastructure, and

successful integration into the EU health data space highlight its leadership in EHR interoperability. However, continuous evolution towards newer data exchange standards and further engagement in EU-wide health initiatives will ensure Estonia remains at the forefront of digital health innovation, setting a benchmark for other EU MS.

Table 8. Overview of EHR Systems' Implementation in Estonia

Country:	<u>Estonia</u>
National EHR (add number of EHR system in brackets, e.g. <i>Yes (1)</i>)	Yes
EHR Interoperability A) within the country, B) with the other countries (explain in the text above)	A) Yes, B) Yes
Data standards used	HL7 CDA, X-Road for national exchange
Additional information on data standards	Partially based of FHIR (ongoing transition)
IPS compliant	Partial
Use of priority categories in EHR systems:	
1. Patient summaries	Yes (cross border PS in place)
2. Electronic prescriptions	Yes (cross border eP in place)
3. Electronic dispensations	Yes
4. Medical images and images reports	Yes (not yet available to the patients through the patient portal. Needs further development for cross-border exchange)
5. Laboratory results	Yes (Needs further development for cross-border exchange)
6. Discharge reports	Yes (Needs further development for cross-border exchange)
EHR systems coverage	National (Nationwide coverage)
Interoperability of national implementation	Nationwide coverage, structured data

5.9 Finland

National Regulatory Framework

Finland's EHR infrastructure, known as Kanta Services, is guided by the Finnish Institute for Health and Welfare (THL) and maintained by the Social Insurance Institution of Finland (Kela).

The Act of Client Information Processing in Social and Health Care guides the implementation and use of EHR systems, with additional regulations ensuring compliance with GDPR.



Specific implementing acts cover data access rights of professionals, information security plans, classification systems of systems, and certification of high-risk and Kanta-connected systems.

Standards and Protocols for Interoperability

HL7 standards (Medical Records, HL7 CDA R2, and HL7 FHIR) are applied, alongside many international and national terminology and classification standards, including ICD-10, ATC, and increasing use of SNOMED CT.

International standards for security and functionality of EHR systems are used as a basis for national requirements, such as ISO/HL7 10781 structure for national functional profiles.

Technological Infrastructure

Finland's national Kanta infrastructure platform enables connection for all major healthcare organizations and pharmacies, increasingly including social care organizations.

EHR systems' technology choices vary locally or regionally, but all are connected to the national Kanta infrastructure, with Kanta services implemented and maintained by Kela.

Stakeholder Engagement and Perspectives

Annual customer satisfaction surveys assess satisfaction with Kanta services among EHR system vendors, pharmacies, public healthcare, private healthcare, and citizens.

While stakeholders generally view information security and data protection of Kanta services positively, challenges include clarity of specifications and guidelines, distribution of responsibilities among authorities, and delays in processing matters.

Data Security and Privacy Measures

Mandatory information security plans and risk assessment/classification of all social and health information systems, including EHR systems.

National access control requirements for EHR systems and Kanta services, with patient consent models for cross-organizational EHR information sharing.

Use Cases and Best Practices

Adoption of ePrescription and inclusion of social services in the national infrastructure highlight Finland's progress in EHR interoperability.

The certification process ensures reliability of EHR systems, with a minimum level of essential requirements for interoperability and security.

Economic and Social Impact Analysis

The progress and impacts of social and healthcare digitalization are regularly monitored, focusing on topics in accordance with the Social and Health Care 2020 strategy.

Economic impacts have not been specifically studied; the effects of interoperability of EHR systems are seen over a long-time frame and influenced by many factors.

Future Plans and Recommendations

A new strategy for social and health information management was released by the Finnish Ministry of Social Affairs and Health, focusing on support for individuals managing their health with digital tools and reducing social and health professionals' workload.

Gap Analysis with EU Standards: Finland's comprehensive regulatory framework, advanced technological infrastructure, and commitment to international interoperability standards demonstrate strong alignment with EU best practices. The effective use of Kanta Services and ongoing improvements in EHR interoperability place Finland at the forefront of digital health innovation within the EU. However, the continual evolution of interoperability standards, stakeholder engagement, and data security measures will be essential to maintain this position and address identified challenges, ensuring Finland's EHR system remains adaptable and responsive to future healthcare needs.

Table 9. Overview of EHR Systems' Implementation in Finland

Country:	Finland
National EHR (add number of EHR system in brackets, e.g. Yes (1))	Yes (1 national EHR + >60 certified systems)
EHR Interoperability A) within the country, B) with the other countries (explain in the text above)	A) Yes, B) Yes
Data standards used	HL7 FHIR, HL7 CDA & MR, IHE XDS, SNOMED CT, National standards (Kanta services)
Additional information on data standards	Number of FHIR implementations growing
IPS compliant	Partial
Use of priority categories in EHR systems:	
1. Patient summaries	Yes (national, eHDSI live in 2024-2025, The data needed for PS is collected from encounter-based entries of EHRs. PS is generated on-demand based on this data)
2. Electronic prescriptions	Yes (eHDSI live. All prescriptions digital by law, prepared in EHRs and stored in the National Prescription Centre, NPC)
3. Electronic dispensations	Yes (eHDSI live, prepared in pharmacy systems and stored in the NPC)
4. Medical images and images reports	Yes (Centralized data collection from EHRs to the national EHR infrastructure)
5. Laboratory results	Yes (Centralized data collection from EHRs to the national EHR infrastructure)
6. Discharge reports	Yes (Centralized data collection from EHRs to the national EHR infrastructure. Part of the encounterbased entries of EHRs)
EHR systems coverage	National (Nationwide coverage)
Interoperability of national implementation	High coverage, structured data predominates

5.10 France

National Regulatory Framework

The French EHR (*Mon espace santé*, previously known as *Dossier médical partagé (DMP)*) is developed and managed by ANS (*Agence du numérique en santé*) which is under the Ministry for Solidarity and Health's supervision and is financed primarily by the National Health Insurance Fund (Cnam).

National laws/regulations specific to EHR systems, incl. data protection, privacy, and healthcare service delivery standards:

Opt-out:

- Law n°2019-774 of July 24, 2019, regarding the organization and transformation of the healthcare system (OTSS): provides for the establishment of *Mon espace santé* for each user, granting access to their health data and digital services.
- Article 45 and Article 50 of the OTSS law were supplemented by Article 98 of law n°20201525 of December 7, 2020, accelerating and simplifying public action, which positions the Dossier Médical Partagé - DMP as an integral component of *Mon espace santé*. Furthermore, it allows the automatic creation of the DMP simultaneously with the automatic opening of *Mon espace santé*, in accordance with Article L.1111-13 of the Public Health Code.
- In accordance with the provisions of decree n°2021-1048 of August 4, 2021, in the absence of any opposition expressed by the User (i.e., utilising the “opt-out principle”), a *Mon espace santé profile* is created for all individuals affiliated with a French health insurance scheme.

Data hosting:

- L.1111-8 of the Public Health Code, amended by Law No. 2016-41 of January 26, 2016: *Any natural or legal person who hosts personal health data collected during prevention, diagnosis, care, or medical-social support activities on behalf of individuals or legal entities responsible for the production or collection of such data, or on behalf of the patient themselves, must be approved or certified for this purpose.*
- The hosting of health data of *Mon espace santé* service complies with the requirements applicable to hosting personal health data - the HDS certification. The HDS certification is based on ISO 27001 certification to address data security challenges and is supplemented with additional requirements related to the GDPR and the healthcare domain. The requirements derived from the ISO 27001 standard represent approximately 80% of the applicable requirements for HDS certification.

Security:

- The rules of the PGSSI-S apply as soon as personal health data is used. These rules provide security and ensure the trust of users and professionals in digital healthcare systems. The PGSSI-S is a set of frameworks and legally binding documents establishing requirements related to various aspects of information security in healthcare systems.

Data privacy:

- Since June 1st, 2019, the law of January 6, 1978, known as the "*Loi informatique et libertés*" has been in force. It includes provisions concerning the "national adaptations" permitted by the GDPR that the legislator has chosen to exercise, as well as measures to transpose into French law the "Police-Justice" directive.
- The access rights of various healthcare professionals are established according to an authorization matrix linked to their profession or specialty⁷.
- In the context of implementing MyHealth@EU, France has issued a Decree⁸ regarding specific provisions for the care of patients receiving healthcare services in another MS of the EU. The decree specifies the mechanisms for consent collection, security, and traceability.

Standards and Protocols for Interoperability: ANS is responsible for defining the interoperability standards to facilitate digitalising and harmonising the information exchanged while at the same time respecting the autonomy of the various health Information Systems involved. These standards are dynamic and evolving, jointly developed in conjunction with the relevant stakeholders in the health and social care sectors and based on international standards. The Interoperability Framework for Health Information System (CI-SIS), the health object model (MOS) and associated nomenclatures (NOS), health terminologies and the Interoperability Testing Platform (used for projectathons and in the context of Ségur) are all key contributors to the development of joined-up and mutually compatible eHealth services.

Interoperability Framework for Health Information Systems (CI-SIS)⁹: The Interoperability Framework for Health Information Systems (CI-SIS) encompasses:

- technical interoperability in terms of flows and services, allowing for the exchange of health data while complying with security requirements and protecting the confidentiality of personal health details.
- the interoperability of professional content (content consisting predominantly of CDA R2), allowing health data to be processed and understood by different Information Systems thanks to a common language.

The CI-SIS draws on mature and stable international norms and standards and has been developed in consultation with health and social care professionals as well as information service providers

⁷ <https://www.dmp.fr/documents/d/dmp/matrice-habilitation>

⁸ <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043775966>

⁹ <https://industriels.esante.gouv.fr/en/products-services/ci-sis-interoperability-framework>
<https://industriels.esante.gouv.fr/en/products-services/ci-sis-interoperability-framework-health-information-systems>

specializing in the health sector. Its use facilitates the integration of systems and ensures that the health sector enjoys long-term benefits from its investments.

Additionally, the ANS composed:

- A document outlining the governance of the CI_SIS, detailing the process of its continuous evolution and the various actors involved, along with their respective roles.
- The doctrine of the CI_SIS, describing the methodology for creating a new specification within the CI_SIS.

Health Object Model (MOS) and their associated nomenclatures (NOS)¹⁰: MOS is a collection of concepts described homogeneously and neutrally in terms of technologies. It offers a common and pooled description of the information processed and exchanged in the information systems. The overall consistency of the MOS is founded on the definition and description of its UML concepts. Certain MOS concepts can be coded. They are associated with the nomenclatures of health objects (NOS), i.e. lists of codes/labels.

The MOS and NOS constitute a library of semantic components. This library centralizes definitions, names, structures and coding of the information. This core French vocabulary affords stakeholders the same understanding of the concept being manipulated, regardless of the system from which it originates.

Each MOS concept is equated with other concepts that are part of international initiatives or standards:

- HL7
- Fast Healthcare Interoperability Resources (FHIR), HL7 v2.x and v3
- Semantic Interoperability Community (SEMIC)

Health Terminology Management Centre (CGTS)¹¹: ANS has set up a Health Terminology Management Centre (CGTS) responsible for:

- publishing the various semantic resources (terminologies, coding, alignments) used by health and social care professionals to structure data during treatment in line with the various formats used by industrial companies to incorporate that data into professional eHealth software.
- overseeing collaboration with the production units that produce these semantic resources, retain ownership of them, and are responsible for their maintenance.
- providing support services for users of these semantic resources, in particular industrial companies, in partnership with the production units to optimize their use in healthcare professional software.

¹⁰ <https://ue.esante.gouv.fr/interoperability-cornerstone-expanding-ehealth-services/health-objects-model-and-nomenclatures-mos>

Multi-Terminology Server (MTS)¹²: ANS is rolling out a Multi-Terminology Server (MTS) for posting terminology (nomenclature, dictionaries, classifications, ontologies, alignments, coding, translations, etc.) for the purposes of health sector interoperability.

Data exchange formats in use: HL7 CDA, HL7 FHIR, IHE Profiles.

Coding systems in use: ATC, SMS, EDQM, EDMN, LOINC, SNOMED, NUVA, HL7, IHE, ISO 639/3166, ICD 11, Orpha Code, PathLex, UCUM, TNM...

Interoperability Testing Platform¹³: The interoperability test space for health Information Systems is intended for:

- IT system contractors (for example, healthcare establishments), who can consult the list of IT systems that comply with an interoperability benchmark.
- private organizations (such as software providers) as well as public bodies in the health and social care sectors who are developing IT systems.

This space helps them to speed up the implementation of the interoperability framework with the help of free tools to verify the compliance of their product.

Technological Infrastructure

Patient access: *Mon espace santé* is a national service that has been extended to all French citizens. It can be accessed via the web or through a mobile application, which allows users to view documents stored using a smartphone¹⁴.

¹¹ <https://ue.esante.gouv.fr/interoperability-cornerstone-expanding-ehealth-services/healthterminology-release-centreterminology-release-centre> ¹²
<https://smt.esante.gouv.fr/>

¹³

- <https://ue.esante.gouv.fr/interoperability-cornerstone-expanding-ehealthservices/interoperability-testing-platformservices/interoperability-testing-platform>
- <https://interop.esante.gouv.fr/evs/home.seam>
- <https://ue.esante.gouv.fr/interoperability-cornerstone-expanding-ehealth-services>

¹⁴ <https://www.monespacesante.fr/>

HCP Professionals access: HCP professionals can update or consult a patient's DMP through their software, or through a dedicated website¹¹.

¹¹ <https://www.dmp.fr/>

Only data strictly necessary for patient care can be consulted, within the limits set by the authorization matrix available online, and if the patient has not objected to this consultation when informed¹².

For transparency, all accesses and actions in the patient's DMP are logged and visible to them. Thus, the initial access to view a DMP and the addition of documents are visible to the patient in their Mon espace santé profile. They also receive an automatic email notification to alert them of any activity related to their profile. Any inappropriate access can be penalized.

With the "Séjour du numérique" initiative, most of the HCP's software is updated to make DMP data input simpler and smoother.

Main challenges for the technical infrastructure:

- Ensuring system availability, even during peak connection scenarios, is crucial for Mon Espace Santé, which serves all insured individuals in France.
- Interoperability as it is essential to facilitate the interconnection of software and applications with Mon Espace Santé.

Stakeholder Engagement and Perspectives

To engage and support ecosystem actors, several initiatives are in place:

G_NIUS: The National Portal for eHealth Innovation¹³: As provided for by the Ministerial Roadmap for eHealth, *G_NIUS is the Guichet National de l'Innovation et des Usages en e-Santé, the National Portal for eHealth Innovation (G_NIUS)*. Supported by the Ministerial eHealth Delegation and the ANS, in partnership with the ANSM, Bpifrance, the CNAM, the CNIL and the HAS, G_NIUS is a sectoral web service that directs digital health innovators to the right content and the right experts within the public authorities. The objective of G_NIUS is to simplify life for innovators and to help them save time.

G_NIUS was constructed jointly by all of the stakeholders in the sector at more than 30 online workshops using innovative tools. The services, content and even the interface were thus defined by the players themselves (start-ups, industrial federations, business clusters, support services, agencies and institutions, etc.).

ANS portal for industrials¹⁴: The portal aims to help industrials comply with national standards and regulatory requirements. From advice and events to regulatory texts, industrials can find all the information needed to ensure compliance of their solutions and secure, interoperable services.

¹² <https://www.dmp.fr/documents/d/dmp/matrice-habilitation>.

¹³ <https://gni.us.esante.gouv.fr/en>

¹⁴ <https://industriels.esante.gouv.fr/en>

Concertation platform¹⁹: The digital health roadmap underscores the importance of closely involving all stakeholders (patients, professionals, publishers, and their representatives) in the evolution of digital health. The Concertation platform addresses this challenge. Numerous texts are shared with the ecosystem, such as draft legislative and regulatory texts, the doctrine of digital health, interoperability frameworks (CI-SIS), security (PGSSI-S), and ethics (CENS). Through this platform stakeholders can share their feedback, ideas and questions.

Data Security and Privacy Measures

Since 2012, the General Security Policy for Health Information Systems (PGSSI-S)²⁰ has been setting out the relevant standards and good practices as well as a common framework for Information System security in the health sector. It sets out a framework to which project leaders can refer to when setting the required standards, enabling industrial companies to specify the security levels contained in their products and helping healthcare facilities to define and implement their own Information System security policies. The documents contained in the PGSSI-S are the fruit of working groups consisting of representatives from institutions, healthcare establishments and industrial companies as well as healthcare professionals. A steering committee comprised of representatives from the Ministry of Health (FR MoH), French National Health Insurance Fund (CNAM), French National Solidarity and Autonomy Fund (CNSA), French Data Protection Authority (CNIL) and French National Cybersecurity Agency (ANSSI) have been overseeing and monitoring the discussions. All documents are submitted by the ANS for consultation to industrial companies, healthcare establishments and professionals, and members of the public. Once their comments have been considered, an approved version is posted on ANS official website on a dedicated space¹⁵. It is regularly updated to encompass industrial, technological and regulatory developments as well as adapting to new use cases.

Use Cases and Best Practices

To accelerate the digital transformation of the health system for the benefit of patients and health professionals, the ANS has been officially tasked with implementing national-scale projects:

- **Mon espace santé**: as presented above, *Mon espace santé* is a public service that allows patients to store and share their documents and health data in complete safety to improve care.
- **Structures 3.0**: a program to evaluate and experiment with new use cases of digital technology in health in “real conditions” and share lessons learned.

¹⁹ <https://participez.esante.gouv.fr/>

¹⁵ <https://esante.gouv.fr/securite/pgssi-s/espace-de-publication>

²⁰ <https://ue.esante.gouv.fr/information-systems-security-pre-condition-trust/general-security><https://ue.esante.gouv.fr/information-systems-security-pre-condition-trust/general-security-policy-health-information-systems>

- **Convergence tool:** a practical, educational, self-declarative tool that allows editors to measure the compliance of their solutions, services and devices with the technical doctrine.
- **Emergency medical services:** a portal that enables collaboration among emergency actors, within or between Emergency Medical Service units, facilitating information exchange, document sharing, and event alerts.

Economic and Social Impact Analysis

Since its creation in January 2022, My Health Space has managed to establish itself in the daily lives of French citizens and healthcare professionals and is increasingly used. More than 11 million social insurees have activated their profile to date, and over 300 000 people connect to this digital health record each week.

Mon espace santé consists of several online services:

- A medical profile to enter information related to health monitoring and medical status.
- A shared medical record to store and transmit health data with a healthcare professional.
- A secure health messaging system to communicate with healthcare professionals in complete confidentiality.
- A catalog of referenced digital health services for optimal health monitoring.
- A health calendar to manage medical appointments and receive reminders of key examination dates to be conducted.

Future Plans and Recommendations

The increasing use of health Information Systems not only to coordinate patient treatment but also to assist health and social care professionals with medical decision-making and to evaluate common practices, as well as for the purposes of epidemiology, public health initiatives and clinical research, means that health data is increasingly being communicated and shared virtually to facilitate treatment. This virtual exchange of data requires the definition of common languages for the Information Systems handling this data to avoid having to develop new languages every time two Information Systems want to exchange data.

To address these challenges, the digital health doctrine outlines the following actions for 2024:

- Enrichment of the Interoperability Framework for Health Information Systems (CI-SIS) with new uses cases. Priority will be given to use-cases supported by the *Ségur du numérique*.
- Regular update of health terminologies in the SMT, including ICD-10/ICD-11, SNOMED CT, CCAM...
- Tooling of the CI-SIS:
 - Publishing modules/interoperability specifications using the open-source tools of the HL7 ecosystem.
 - POC of publishing modules/interoperability specifications in the form of an implementation guide.
 - Provision of validators and interoperability testing scenarios.
- Evolution of the multi-terminology server (SMT):
 - Continuing SMT developments along three axes: alignments, SNOMED-CT, and FHIR Terminology Service.
- Convergence of national interoperability specifications:
 - Continuing the gradual convergence towards European specifications, while continuing consultation processes by use case.
 - Publication of a consultation space for European specifications.
- Support and evaluate of the implementation of interoperability reference frameworks through the ANS 2024 projectathon.

Gap Analysis with EU Standards: France's DMP system represents a leading example of EHR interoperability in the EU, leveraging the CDA R2 standard for seamless health data exchange. Addressing any remaining challenges related to system integration, user engagement, and further alignment with upcoming EU health data initiatives (leveraging FHIR standard) will continue to position France at the forefront of digital health innovation within the EU.

Table 10. Overview of EHR Systems' Implementation in France

Country:	France
National EHR (add number of EHR system in brackets, e.g. <i>Yes (1)</i>)	Yes (1)
EHR Interoperability A) within the country, B) with the other countries (explain in the text above)	A) Yes, B) Yes
Data standards used	HL7 CDA, HL7 FHIR (work in progress), IHE Profiles.
Additional information on data standards	
IPS compliant	Yes
Use of priority categories in EHR systems:	
1. Patient summaries	Yes (cross border context: PS-B use case in service since 2021)
2. Electronic prescriptions	Yes (cross border context: eP/eD-B use case planned for 2025, eP/eD-A use case planned for 2026)
3. Electronic dispensations	Yes (cross border context: eP/eD-B use case planned for 2025, eP/eD-A use case planned for 2026)
4. Medical images and images reports	Yes
5. Laboratory results	Yes
6. Discharge reports	Yes
EHR systems coverage	National
Interoperability of national implementation	Structured data (CDA R2: Patient Summary, Laboratory results, ePrescriptions, Discharge reports). Ongoing work to structure the following documents: eDispensations and Medical images and images reports.

5.11 Germany

National Regulatory Framework

e-Health Act (2015): The aim of this law was to exploit the opportunities offered by digitalisation for healthcare and to quickly introduce medical applications to be used by patients. It provided the organisations of self-government with clear guidelines and deadlines, which in some cases lead to sanctions in the event of non-compliance.

Act for Faster Appointments and Better Care (appointment and care law, TSVG), which entered into force on May 11, 2019, obliges all health insurance companies to offer electronic patient records for their insured clients.

Patient Data Protection Act entitles patients to have their doctor fill the electronic patient record with medical data such as findings, diagnoses, medical reports or digital x-rays. Access to the patient file is barrier-free and thus unrestricted for the disabled. It entered into force on October 20, 2020.

Digital Services and Care Modernisation Act, which entered into force on June 9, 2021. Every patient may enter prescription and dispensing information in their electronic patient file.

The most recent law in the field of eHealth is the Digital Act (DigiG) which entered into force on March 26, 2024. A central component of the law is the establishment of an opt out based system for the use of the EHR (electronic Patient Record (ePA) for all). This will promote the exchange and utilization of health data and strategically support healthcare provision. The act also provides for the further development of the interoperability governance in healthcare.

Standards and Protocols for Interoperability:

Standards and Protocols for Interoperability

The variety of different EHR systems and manufacturers used in the ambulatory and inpatient setting as well as proprietary business models make it difficult to implement intersectoral interoperable systems. Technical standards and interfaces for the exchange of data have to be further developed and unified to be appropriately used in all aspects of the Patient Health Record. Especially the ambulatory sector will have to face technical changes to provide the necessary interfaces within their EHR systems as the basis for an interoperable and secure exchange of health data and the intersectoral provision of healthcare. Different measures have been taken to support the adaption of these necessary technical changes for improved interoperability, e.g. the creation of a federal competence centre for interoperability in healthcare (KIG) or the creation of harmonised technical specifications for inpatient and outpatient care.

The existence of a multitude of electronic systems and proprietary business models makes it difficult to implement interoperable systems. Uniform technical standards and interfaces for the exchange of data cannot yet be guaranteed in the way necessary for the use of a Patient Health Record.

Data stored in the ePA in Germany cannot yet be processed completely automatically. Major progress was made through using and implementing technical standards and guidelines, like the

system based on FHIR. For instance, representation of medication data is built on using the FHIR standard.

Technological Infrastructure

Base infrastructure for the exchange of health information of patients relevant for their treatment between healthcare providers is the German “Telematikinfrastuktur” (TI) and the services and applications of the TI. The German EHR (“elektronische Patientenakte”, ePA) and underlying ITSystems (ePA-systems) are implemented according to mandatory specifications (in the same way as for the TI as base infrastructure, services of the TI and other applications of the TI).

Stakeholder Engagement and Perspectives

In March 2023, the Federal Ministry of Health publicly presented the “Digitalisation Strategy for Health and Care”. The strategy was worked out based on a broad stakeholder involvement and gives the digital transformation of healthcare a clear direction.

A need for concrete action in three areas in particular has been identified, i.e., establishment of person-centred and digitally supported cross-sector und cross-professional care processes, use of high-quality data for better care and research, benefit-oriented technologies and applications.

With the Digital Act and the Act on Health Data Use (in force since March 2024), important measures laid down in the strategy have already been initiated/implemented. The establishment of the “ePA for all” is one important example in this context.

Data Security and Privacy Measures

The existing EHR (ePA), as well as the opt-out based system to be introduced in future, are patientcentred systems. Each person can decide whether an ePA should be created and can assign or restrict access rights for healthcare providers. At the same time, the healthcare providers’ need for complete datasets is also considered.

The integrated approach of the TI (see also “Technological Infrastructure”) also includes comprehensive data security and privacy measures. Inter alia data security and privacy requirements and mandatory measures regarding the ePA and ePA-systems are defined in the mandatory specifications for the TI.

Furthermore, different categories of service providers must adhere to varying legal requirements to ensure an adequate level of cyber security concerning the usage of their primary healthcare systems: e.g. section 390 SGB V requires outpatient service providers to comply with a mandatory IT security guideline; section 391 establishes rules concerning service providers in an

inpatient/ambulatory setting. In the near future, the adaptation of Directive (EU) 2022/2555 into national law will impose further cybersecurity requirements for the healthcare sector.

Use Cases and Best Practices

Currently less than 1% of all insured persons (statutory health insurance) have or use an EHR. As a result, the EHRs will be converted into an opt-out application. As a useful application, this is intended to promote the sharing and use of health data in the healthcare system and provide specific support for care.

The ePA must be suitable for supporting treatment across sectors. To this end, the medical use cases and required data are designed in a way that they are structured and interoperable. In the first step data from e-medication should be integrated in the EHR. Further medical use cases, for example data according to patient summaries or data from laboratory results, will be implemented in the next steps.

Economic and Social Impact Analysis

The initial rollout and ongoing development of EHR systems in Germany require significant investment in technology and infrastructure. This includes expenditures on software development, system security, and training for healthcare professionals. While these investments contribute to the economic stimulation of the tech sector, including job creation in IT and cybersecurity, they also represent substantial upfront costs that need to be managed effectively to ensure a positive return on investment. One of the primary social benefits of implementing EHR systems in Germany is the enhancement of patient safety and quality of care. With comprehensive access to patient histories, medication records, and diagnostic information, healthcare providers can make more informed decisions, reducing the risk of medication errors and adverse drug interactions. This holistic view of patient data contributes to personalized and timely care, improving patient outcomes. The EHR system's provision for barrier-free access to patient files, as mandated by the Patient Data Protection Act, promotes accessibility and empowerment. By enabling patients to access their health records easily, Germany's EHR system encourages patient engagement and participation in their healthcare processes. This empowerment can lead to better health literacy and more informed patient choices, contributing to overall societal health and well-being. While the advancement of EHR systems offers numerous benefits, it also raises concerns regarding data privacy and security among German citizens. The potential for data breaches and unauthorized access to sensitive health information can lead to social apprehension towards the use of EHRs. Addressing these concerns effectively through stringent data protection measures and transparent communication is crucial to gaining public trust and ensuring widespread adoption of the system.



Future Plans and Recommendations

The opt-out-based system for the use of the EHR is expected to be implemented in January 2025. To maximize the economic and social benefits of EHR implementation in Germany, continuous evaluation and adaptation of the system are necessary. This includes leveraging technological innovations to enhance system functionalities, addressing interoperability challenges, and fostering a culture of digital health literacy among both healthcare providers and patients. Moreover, prioritizing data security and privacy will be paramount in sustaining public trust and ensuring the successful integration of EHRs into everyday healthcare practices.

Gap analysis with EU standards: Germany's digital healthcare initiatives, including the e-Health Act, Patient Data Protection Act, and recent Digital Acts, demonstrate a commitment to enhancing EHR interoperability and patient data access, aligning with EU principles like GDPR. The adoption of FHIR standards and the establishment of the Telematikinfrastruktur (TI) are significant steps towards interoperability. However, challenges remain in achieving seamless cross-border data exchange and broader adoption of standards across all healthcare sectors. To bridge these gaps, Germany may need to further harmonize national laws with EU directives, encourage wider adoption of interoperability standards, and ensure the TI's full integration with EU-wide health data initiatives.

Table 11. Overview of EHR Systems' Implementation in Germany

Country:	Germany
National EHR (add number of EHR system in brackets, e.g. Yes (1))	Yes
EHR Interoperability A) within the country, B) with the other countries (explain in the text above)	A) Yes, B) Yes
Data standards used	HL7 FHIR, gematik standards
Additional information on data standards	
IPS compliant	Yes
Use of priority categories in EHR systems:	
1. Patient summaries	-
2. Electronic prescriptions	-
3. Electronic dispensations	-
4. Medical images and images reports	-
5. Laboratory results	-
6. Discharge reports	-
EHR systems coverage	Regional (Regional initiatives, moving towards national)
Interoperability of national implementation	Structured data adoption in progress

5.12 Greece

National Regulatory Framework

- Law 4600/2019 provides the legal basis for the operation of the EHR system for Primary Healthcare and establishes the operational and legal framework of National Patient Registries.
- Law 4624/2019 implements GDPR into the national legislation.
- Law 4727/2020 provides the framework for the reformation and modernization of digital governance in Greece.
- Law 4961/2022 sets in force a coherent national legal framework for the utilization of emerging technologies by public bodies and private entities.

The Digital Transformation Bible 2020-2025 (Ministerial Decree 2894/2021) reflects the guiding principles, the strategic axes, the governance and implementation models of all horizontal and vertical interventions for the digital transformation of Greece (with provisions for the health sector and EHR systems).

The national Cybersecurity Strategy defines the objectives, priorities, policy, and regulatory measures needed to secure the public and the private sectors and critical Infrastructures.

Cross-border ePrescription and PS services are operational, demonstrating alignment with EU directives for the provision of cross-border healthcare services.

Standards and Protocols for Interoperability

The Ministry of Health carried out the project Design and Implementation of the National eHealth Interoperability Framework (NeHIF), based on the EU Refined eHealth interoperability Framework (ReEIF). This architecture allows the adoption of IHE integration profiles that will enable both primary and secondary use of data. Those integration profiles are based on the proper orchestration of existing international standards such as DICOM, HL7v2, HL7 CDA, HL7 FHIR, TLS v1.2 and many more. The adoption of this methodology allows thorough testing and even certification of all interconnected systems. However, there are still challenges reported regarding interoperability gaps between different systems. NeHIF served as an important starting point but there is more to be done.

The structural clinical data representation standards that are currently in use in national eHealth services are HL7 CDA and HL7 v2 and the use of IHE profiles and HL7 FHIR data models is properly leveraged in the context of the NCPeH and the EEHRxF implementation, Moreover, commonly agreed international encodings of datasets such as ATC Classification, SNOMED CT, LOINC, FHIR, EDQM, Orphanet are utilized.

Technological Infrastructure

The Ministry of Health is currently implementing its National Recovery and Resilience Plan for the digital transformation of health and care (with major programs for the National EHR system, the national telemedicine network, cancer registries, the digital readiness of hospitals, etc.). However, there are still challenges reported regarding interoperability gaps between different systems.

Stakeholder Engagement and Perspectives

A key factor in the success of digital health initiatives is the involvement of various stakeholders, including healthcare providers, policymakers, IT professionals, and the public. The Greek MoH has made efforts to engage these stakeholders in the design, implementation, and evaluation of digital health solutions.

The establishment of the National Council for eHealth Governance (Ministerial Decision A3(d)/G.P.oik.15332/2019) and its proper activation -that is still lacking- could also play a major

role in stakeholder engagement as it could become the official/political mechanism needed to strengthen stakeholder engagement.

The Digital Transformation Bible has acknowledged the importance of digital literacy and has placed it as a major priority. However, public awareness also plays a major role and Greece plans to intensify its efforts towards that direction.

Data Security and Privacy Measures

Greece has implemented strong data privacy and security measures, adhering to a) the GDPR and other national laws, b) its robust national cybersecurity strategy and c) the eHDSI requirements for secure cross-border data exchanges (Greece is participating in the eHDSI both as Country A and Country B for both the ePrescription service and the PS. IDIKA SA is the NCPeH, responsible for the use of common data standards and formats to ensure interoperability and secure data exchange across different healthcare IT systems used in the EU and had to undergo vigorous testing before receiving the red light for the go-live).

Use Cases and Best Practices

Best practices include the national availability of e-prescriptions and e-dispensations, the EHR for Primary Healthcare (EHR4PH system) that all citizens can access through the governmental portal gov.gr, and the mobile application (MyHealth app) that enables citizens to access and manage many of their medical data and issue medical certificates.

Economic and Social Impact Analysis

The Ministry of Health is aware that EHR interoperability enhances healthcare efficiency, improves healthcare delivery and patient outcomes and may lead to significant savings -both in terms of time spent and use of available resources, i.e. by preventing duplicate testing. EHR interoperability is key for seamless data exchanges, enabling continuous access to citizens' medical records, thus improving treatment plans and ensuring continuity of care, and for reducing administrative burden.

Future Plans and Recommendations

There is no specific Digital Health strategy in Greece as the Digital Transformation Bible 2020/2025 serves as a horizontal strategy. However:

The implementation of the National Recovery and Resilience Plan Greece 2.0 for the digital transformation of health (as mentioned above) is the major driver for digital health in Greece. Most significant projects include the national EHR, the Digital Infrastructure for Cancer, the



National Telemedicine Network, the improvement of the hospitals' digital readiness, the digital transformation of the National Organization for the Provision of Health Services and RIS/PACS.

Moreover, the Ministry of Health is actively engaged in numerous EU health initiatives, projects and joint actions that showcase its commitment to strengthening healthcare delivery and interoperability at national and cross-border level.

Gap Analysis with EU Standards: Greece exhibits a comprehensive approach to the digital health transformation and EHR interoperability, underpinned by a solid legal framework, including GDPR integration and the Digital Transformation Bible guiding digital initiatives in healthcare. The implementation of the National eHealth Interoperability Framework (NeHIF) aligns with EU standards, yet interoperability gaps persist, indicating the need for further system integration efforts. Active stakeholder engagement, robust data security measures, and participation in eHDSI reflect Greece's commitment to secure and interoperable health data exchange. Despite these strengths, challenges in fully seamless system integration and the activation of governance structures like the National Council for eHealth Governance highlight areas for continued development to achieve optimal alignment with EU directives and enhance the efficiency and effectiveness of cross-border and national healthcare services.

Table 12. Overview of EHR Systems' Implementation in Greece

Country:	Greece
National EHR (add number of EHR system in brackets, e.g. Yes (1))	Yes
EHR Interoperability A) within the country, B) with the other countries (explain in the text above)	A) Yes, B)
Data standards used	HL7 CDA, HL7 V2, HL7 FHIR, TLS v1.2, SNOMED CT national standards
Additional information on data standards	Based on FHIR, transitioning to eHDSI
IPS compliant	-
Use of priority categories in EHR systems:	
1. Patient summaries	Yes (cross border PS operational)
2. Electronic prescriptions	Yes (National level as well as cross border eP operational)
3. Electronic dispensations	Yes (national level)
4. Medical images and images reports	-
5. Laboratory results	-
6. Discharge reports	-
EHR systems coverage	Regional (Limited, major urban areas only). The EHR4PH system has national coverage.
Interoperability of national implementation	Limited coverage, unstructured data

5.13 Hungary

National Regulatory Framework

Hungary's EHR systems are regulated comprehensively, emphasizing patient records, reports, and professional registers, with no strict mandates on the data content structure and format.

The regulatory framework ensures data concerning health aligns with EU standards, including GDPR, through several acts such as Act CXII of 2011 and Act XLVII of 1997.

The national legal environment, particularly through Annex 4 of the EMMI Decree 39/2016, outlines mandatory documents for EESZT, indicating a structured approach towards EHR documentation.

Standards and Protocols for Interoperability

Hungary employs various code systems, including ICD-10 for diseases, ICPM with modifications, SNOMED-CT for accurate specialty descriptions, LOINC (planned implementation), and ATC codes (Anatomical Therapeutic Chemical code) for medicine.

Despite the presence of MSZ 22800, a version of EU EN 13606 adapted for Hungary, modern standards like HL7 FHIR are not yet in use, pointing to a gap in adopting contemporary EHR data exchange protocols.

Technological Infrastructure

The National eHealth Infrastructure (EESZT) serves as a central platform, ensuring interoperability among healthcare providers and pharmacies through cloud-based technologies.

Challenges include inhomogeneous network coverage, affecting the necessary bandwidth for large file transfers, such as medical images.

Stakeholder Engagement and Perspectives

Stakeholders appreciate the integration of electronic health services into EESZT, with continuous expansion of its functions.

However, barriers to interoperability include the clarity of specifications and guidelines, distribution of responsibilities, and delays in processing matters.

Data Security and Privacy Measures

EESZT ensures secure access for professional users, with specific content access based on qualifications and institutional roles. Patient consent models allow control over who accesses their EHR data.

Cross-border data exchange is facilitated only through Hungary's National Contact Point for eHealth (NCPeH), part of EESZT.

Use Cases and Best Practices

The EESZT platform's widespread use among healthcare professionals and pharmacy staff, and the inclusion of private service providers since 2020, highlights its critical role in Hungary's EHR system.

Best practices include the use of electronic identification for user authentication, nationwide availability of e-prescriptions, and mobile app access to health documents.

Economic and Social Impact Analysis

E-health services in Hungary aim to provide the most effective treatment with uniform access to patient data across all healthcare levels, emphasizing the role of EESZT in improving healthcare efficiency and reducing administrative burdens.

Future Plans and Recommendations

Hungary's focus on extending and standardizing EHDS functionalities across the EU hints at future plans to ensure maximum security conditions and uniform eIDAS 2.0 implementation.

Gap Analysis with EU Standards: Hungary's EHR system, particularly the EESZT, stands out for its central role in ensuring interoperability, security, and privacy in healthcare data management. However, the adoption of modern data exchange standards like HL7 FHIR is lacking, indicating a gap in utilizing contemporary interoperability protocols. The commitment to data privacy and security aligns with EU regulations, showcasing a solid foundation for future enhancements. Addressing interoperability challenges, especially in adopting newer standards and ensuring uniform network coverage, will be crucial for advancing Hungary's EHR system in line with EU best practices.

Table 13. Overview of EHR Systems' Implementation in Hungary

Country:	Hungary
National EHR (add number of EHR system in brackets, e.g. Yes (1))	Yes (around 60 all together)
EHR Interoperability A) within the country, B) with the other countries (explain in the text above)	A) Yes, B) No (International standards are not required)
Data standards used	HL7 CDA, national EESZT system, various code systems
Additional information on data standards	Also based on ISO 13606-1:2008; HL7 FHIR not in use yet
IPS compliant	No
Use of priority categories in EHR systems:	
1. Patient summaries	No
2. Electronic prescriptions	Yes (eP available at national level)
3. Electronic dispensations	Yes (eD available at national level)
4. Medical images and images reports	No
5. Laboratory results	No (Developed, ready for launch)
6. Discharge reports	No
EHR systems coverage	National (Expanding beyond urban areas)
Interoperability of national implementation	Growing coverage, mixed data structuring

5.14 Ireland

National Regulatory Framework

Ireland is in the process of establishing a national EHR system, with initiatives like the Maternal & Newborn Clinical Management System (MN-CMS) already in place.

The National Shared Care Record System (NSCR) procurement phase was initiated in Q4 of 2023, marking a significant step toward the nationwide EHR implementation. This system aims to facilitate patient care transitions across healthcare settings, supporting the migration of services to community settings and establishing vertically integrated Regional Health Areas.

The legal framework for the NSCR System will be defined by the Health Information Act, aligning with EU Directives, notably following the Irish Government's approval of the Health Information Bill 2023 Scheme on April 18, 2023.



Standards and Protocols for Interoperability

Ireland is focused on drafting standards and protocols for EHR systems as part of the NSCR development, with particular attention to data exchange formats, coding systems, and interoperability frameworks. These standards will serve as prerequisites for the National EHR System's implementation.

Technological Infrastructure

The ongoing tender process is crucial in defining the specifications for the technological infrastructure supporting EHR systems in Ireland. Challenges such as the accessibility and availability of structured, coded data within national systems have been identified, which could hinder the smooth exchange and integration of information across the EHR landscape.

Stakeholder Engagement and Perspectives

Stakeholders from diverse sectors are actively involved in the tender process and procurement initiatives for establishing the NSCR framework. Challenges identified include accessing national digital health data, which encompasses complexities from data standardization and compatibility to privacy and security concerns.

Data Security and Privacy Measures

All cross-border exchanges are to be conducted via the National Contact Point and the secure TESTAnG network, highlighting Ireland's commitment to data security and privacy in the context of EHR.

Use Cases and Best Practices

Ireland's participation in Waves 3 to 7 of "projectathons" demonstrates its commitment to EHDS specifications, emphasizing the importance of adopting these standards and guidelines at a national level for successful practice.

Economic and Social Impact Analysis

The future interoperability enhancements introduced by the EHR project are expected to be particularly significant for individuals opting for medical treatment abroad. This initiative is projected to foster a more interconnected healthcare ecosystem, facilitating efficient communication and collaboration among healthcare professionals across borders, thereby improving patient outcomes and reducing costs associated with medical errors.

Gap Analysis with EU Standards: Ireland's journey towards establishing a national EHR system is characterized by a careful and strategic approach, aligning with EU directives and focusing on interoperability, data security, and stakeholder engagement. The development of the NSCR and the drafting of the Health Information Act indicate a strong foundation for the nationwide EHR implementation. However, the challenge of accessing and integrating structured, coded data, and the ongoing need to finalize standards and protocols for interoperability, highlight areas where Ireland is working to bridge gaps with EU best practices. Continuing to engage stakeholders, ensuring legal alignment with EU regulations, and addressing technological infrastructure challenges will be crucial for Ireland to fully realize the benefits of a national EHR system aligned with EU standards.

Table 14. Overview of EHR Systems' Implementation in Ireland

Country:	<u>Ireland</u>
National EHR (add number of EHR system in brackets, e.g. Yes (1))	In preparation (NSCR system)
EHR Interoperability A) within the country, B) with the other countries (explain in the text above)	A) Partial (MN-CMS), B) Yes (MyHealth@EU)
Data standards used	HL7, IHE profiles, national standards (HIQA)
Additional information on data standards	Future use of FHIR V4 (NSCR) and CDA (MyHealth@EU)
IPS compliant	No
Use of priority categories in EHR systems:	
1. Patient summaries	No (in preparation)
2. Electronic prescriptions	Yes
3. Electronic dispensations	No (in preparation)
4. Medical images and images reports	Yes (NIMIS)
5. Laboratory results	Yes (NIMIS)
6. Discharge reports	Yes (limited)
EHR systems coverage	National (Standalone EPR's (not necessarily national), standalone major hospitals)
Interoperability of national implementation	Limited coverage, primarily unstructured data.

5.15 Italy

National Regulatory Framework

Italy's EHR system is underpinned by foundational Law Decree 179/2012, with the "Electronic Health Record 2.0" detailed in the Ministerial Decree of 7th September 2023. These laws ensure data protection, privacy, and healthcare service delivery, aligning with EU regulations like GDPR.

Agreements in the State-Regions Conference on December 17, 2020, and November 18, 2021, established national guidelines for telemedicine and tele-rehabilitation, emphasizing quality and consistency in healthcare delivery.

Standards and Protocols for Interoperability

The National Health Card System (TS) supports real-time connections between healthcare providers and pharmacies for e-Prescription services. The National Infrastructure for Interoperability (INI) facilitates secure health information exchange between regions, adopting HL7 CDA v2 and PDF formats for medical document exchange, ensuring interoperability across regional EHR systems.

Technological Infrastructure

Italy's technological infrastructure is bolstered by the National Recovery and Resilience Plan (NRRP), enhancing data collection, processing, analysis, and simulation tools. Despite efforts to strengthen infrastructure, challenges persist, including interoperability gaps due to varying systems and standards used across regions and healthcare providers.

Stakeholder Engagement and Perspectives

Stakeholder engagement is vital, with healthcare providers, patients, IT professionals, and policymakers shaping the EHR system's implementation. Challenges include system integration, training for healthcare professionals, and addressing privacy concerns.

Data Security and Privacy Measures

Italy has implemented strong data security and privacy measures, adhering to GDPR. This includes access controls, strong authentication mechanisms, and encryption to secure data within EHRs.

Use Cases and Best Practices

Successful use cases of EHR interoperability in Italy include the national EHR system, facilitating health information exchange among healthcare providers. The National Interoperability

Infrastructure (INI) and the nationwide electronic prescription system are key achievements, with adoption rates of 97.28% for pharmaceutical prescriptions and 95.89% for specialty medical prescriptions.

Economic and Social Impact Analysis

EHR interoperability in Italy leads to enhanced healthcare efficiency, improved patient care, and potential cost savings. Access to comprehensive health records improves diagnosis and treatment outcomes, reducing disparities in care across the country's diverse territories. For a country like Italy, which receives significant tourism and has a migrant worker population, cross-border healthcare facilitated by EHR interoperability likely offers clear economic benefits due to the reduction in administrative burdens, minimisation of duplicative tests and treatments, and enhancement of the continuity of care for transient populations, ultimately leading to a more efficient allocation of healthcare resources and improved health outcomes for both residents and visitors.

Future Plans and Recommendations

Italy aims to further improve EHR interoperability, focusing on standardization, enhanced training for healthcare professionals, collaboration among regional health departments, and regular evaluation of EHR systems' performance. Recommendations include policy alignment with EU directives, continued investment in digital infrastructure, empowerment of patients with access to their health data, and supporting research on EHR interoperability's impact.

Gap Analysis with EU Standards: Italy's EHR system exhibits a robust commitment to enhancing healthcare through digital means, showcasing a comprehensive national framework supported by significant legislative and infrastructural investments. The incorporation of advanced standards for data exchange and the establishment of the National Health Card System for e-Prescriptions are commendable strides towards achieving interoperability and enhancing patient care. However, a gap analysis with EU standards reveals areas needing further development:

Interoperability Across Regions: Despite the National Infrastructure for Interoperability facilitating data exchange, disparities in systems and standards across Italy's regions highlight the need for more unified approaches to ensure seamless nationwide interoperability.

Adoption of Modern Data Standards: The current use of HL7 CDA v2 and PDF formats, while effective, points to an opportunity for Italy to adopt more recent standards like HL7 FHIR, which could offer more flexible and comprehensive data exchange capabilities.



Cross-Border Data Exchange: Challenges remain in facilitating cross-border health data exchanges, an area aligning more closely with EU-wide initiatives, such as the eHDSI, could enhance Italy's integration into the EHDS.

Stakeholder Training and System Integration: Feedback from stakeholders indicates the need for ongoing training for healthcare professionals and addressing integration challenges between diverse EHR systems within the healthcare ecosystem.

Data Security and Privacy: While Italy adheres to GDPR, continuous advancements in data security measures are necessary to address evolving threats and maintain patient trust, especially concerning cross-border data exchanges.

Table 15. Overview of EHR Systems' Implementation in Italy

Country:	<u>Italy</u>
National EHR (add number of EHR system in brackets, e.g. Yes (1))	Yes (At national level, there is an indexing system of regional EHR)
EHR Interoperability A) within the country, B) with the other countries (explain in the text above)	A) Yes B) No (in preparation- eHDSI live in 2025)
Data standards used	HL7 CDA, IHE profiles, ICD9-CM, ATC, LOINC, EMA SPOR under adoption by IT NCA. National standards are mapped to MyHealth@EU MVC
Additional information on data standards	FHIR planned for future adoption
IPS compliant	Compliant with EPS
Use of priority categories in EHR systems:	
1. Patient summaries	Yes (Not yet eHDSI live. National, compiled and signed by the physician, compliant with EPS, eHealth Network (eHN) PS guidelines)
2. Electronic prescriptions	Yes (Not yet eHDSI live, aligned with eHN guidelines)
3. Electronic dispensations	Yes (Not yet eHDSI live, aligned with eHN guidelines)
4. Medical images and images reports	Yes (Included in the national EHR v1.0, not necessarily structured data. HL7 CDA v2 Level 3 specifications defined for the national EHR v2.0, with FHIR adapters. Coherence with eHN guidelines)
5. Laboratory results	Yes (Included in the national EHR v1.0, not necessarily structured data. HL7 CDA V2 Level 3 specifications defined for the national EHR v2.0, with FHIR adapters. General alignment with eHDSI datasets and requirements)
6. Discharge reports	Yes (Included in the national EHR v1.0, not necessarily structured data. HL7 CDA2 specifications defined for the national EHR v2.0, with FHIR adapters. Coherence with eHN guidelines)
EHR systems coverage	Regional (Varied by region, decentralized system)
Interoperability of national implementation	Increasing coverage, structured data in use

5.16 Latvia

National Regulatory Framework

Latvia has enacted legislation to set requirements and guidelines for electronic health. However, the implementation remains in the early stages, the foundational phase has been recently passed and Latvia is moving forward the development phase of digital health infrastructure development.

Standards and Protocols for Interoperability

The details specific to the standards and protocols for interoperability in Latvia's EHR system are not explicitly mentioned. Given the focus on e-prescription, it's likely that standards aligning with EU practices, such as HL7 or SNOMED CT, could be in use for this application.

Technological Infrastructure

According to the regulatory framework, the specification of the technological infrastructure is determined by the system manager. The mandatory use of the e-health system from 2018 does apply to: e-prescriptions, sick leave sheets, laboratory examinations, etc. Amendments to the regulatory acts are currently being planned, which will strengthen the obligation to use the Ehealth system in all medical institutions, regardless of status (private, state) and supervision.

Stakeholder Engagement and Perspectives

Stakeholder engagement in Latvia's EHR system development is multifaceted, involving regular meetings with healthcare providers (every 1-2 months), IT professionals (once per quarter), and patients. This ongoing engagement is crucial for addressing early-stage challenges and expanding the system beyond ePrescriptions.

Data Security and Privacy Measures

As the regulation determines to whom and what access rights are provided, as well as they determine the general requirements for the use of state systems, including security requirements. Latvia complies not only with the requirements set out in the national regulatory acts, but also with the general principles of the GDPR and the robust data protection measures during the evolving of the system are implemented.

Use Cases and Best Practices

The current full functionality of e-prescription in Latvia serves as a primary use case. This highlights the potential for expanding EHR capabilities and integrating more healthcare services digitally.

Economic and Social Impact Analysis

The impact of Latvia's EHR implementation, particularly the economic and social benefits, is not detailed. Generally, successful EHR systems contribute to improved healthcare efficiency, patient outcomes, and potential cost savings.

Future Plans and Recommendations

As Latvia's EHR system is in the early stages of implementation, future plans would likely include expanding the system's capabilities beyond e-prescriptions, enhancing interoperability, and integrating with broader EU digital health initiatives.

Gap Analysis with EU Standards: Given the early stages of EHR implementation in Latvia, there's a significant opportunity for growth and alignment with EU standards and best practices. Expanding the functionality of the EHR system beyond e-prescriptions, improving interoperability, and ensuring robust data protection measures are key areas for development - right now Latvia has already expanded the system functionality towards laboratory results receipt, oncology patients' cards and look forward to the future. Enhancing stakeholder engagement and leveraging EU-wide digital health projects and standards can support Latvia in advancing its EHR system to fully realize the benefits of digital health for patients and healthcare providers.

Table 16. Overview of EHR Systems' Implementation in Latvia

Country:	<u>Latvia</u>
National EHR (add number of EHR system in brackets, e.g. Yes (1))	-
EHR Interoperability A) within the country, B) with the other countries (explain in the text above)	A) Partial B) No
Data standards used	HL7 V3, National standards
Additional information on data standards	Ongoing transition based on HL7 v3
IPS compliant	-
Use of priority categories in EHR systems:	
1. Patient summaries	-
2. Electronic prescriptions	Yes (national level)
3. Electronic dispensations	-
4. Medical images and images reports	-
5. Laboratory results	-
6. Discharge reports	-
EHR systems coverage	Regional (Urban areas predominantly)
Interoperability of national implementation	Limited coverage, primarily unstructured data

5.17 Lithuania

National Regulatory Framework

Lithuania has a national EHR system, defined in the national health system law, effective since 2011. The National Law on Secondary Use of Health Data, effective from 2022, further regulates the related use of health data.

Standards and Protocols for Interoperability

From its inception in 2015, Lithuania's national EHR system, ESPBI, has been based on FHIR for storage and exchange protocols with healthcare institutions. Other standards in use include SNOMED CT, LOINC, ATC, and ICD-10-AM ACHI (Australian Classification of Health Interventions).

Technological Infrastructure

Lithuania's ESPBI is a comprehensive national system facilitating the exchange of health data among patients, healthcare professionals, and institutions. It features a centralized database of



health records, medical images, and integrates data from healthcare institutions' internal systems. For smaller institutions without internal systems, a special eHealth portal is developed.

Stakeholder Engagement and Perspectives

Stakeholders, including healthcare institutions, express a desire for higher digitalization of EHR and better quality of health data. Patients seek easy, understandable, and accessible views of their personal health data, with bidirectional communication with healthcare specialists.

Data Security and Privacy Measures

Lithuania adheres to the Cybersecurity Law in line with the NIS Directive, applicable to all sectors, including healthcare. The Law on State Information Resources Management describes the management requirements for essential information resources.

Use Cases and Best Practices

Notable practices include the implementation of the LOINC standard for laboratory reports and the development of online drug purchase services using ePrescriptions.

Economic and Social Impact Analysis

The introduction of national EHR features has transformed healthcare services, with digital EHRs facilitating telemedicine services and online drug purchases. This digital shift has enhanced the speed and access to healthcare information, reducing the reliance on paper-based documents.

Future Plans and Recommendations

Lithuania's future plans include migrating to the latest FHIR version, adopting OpenEHR, developing telemedicine, mHealth services, and integrated healthcare services for preventive programs and established disease clusters.

Gap Analysis with EU Standards: Lithuania's national EHR system, grounded in advanced interoperability standards such as FHIR and supplemented by comprehensive cybersecurity measures, aligns well with EU directives and best practices. However, the ongoing need to update to the latest FHIR functionalities, alongside efforts to enhance stakeholder engagement, particularly among patients, highlights areas for improvement. Adapting to evolving standards like OpenEHR and expanding services into preventive and telemedicine domains are steps towards closing these gaps. Strengthening patient involvement and ensuring the system's adaptability to future health data exchange protocols will further align Lithuania's EHR system with EU standards, enhancing cross-border healthcare interoperability and data security.

Table 17. Overview of EHR Systems' Implementation in Lithuania

Country:	<u>Lithuania</u>
National EHR (add number of EHR system in brackets, e.g. Yes (1))	Yes
EHR Interoperability A) within the country, B) with the other countries (explain in the text above)	A) Yes, B) Yes
Data standards used	HL7, national health information system
Additional information on data standards	Based on FHIR
IPS compliant	Partial
Use of priority categories in EHR systems:	
1. Patient summaries	Yes
2. Electronic prescriptions	Yes
3. Electronic dispensations	Yes
4. Medical images and images reports	Yes
5. Laboratory results	Yes
6. Discharge reports	Yes
EHR systems coverage	National (Nationwide initiatives)
Interoperability of national implementation	Efforts to increase coverage and data structuring

5.18 Luxembourg

National Regulatory Framework

Luxembourg has established a national eHealth platform under the guidance of Agence eSanté (eHealth agency) following articles 60ter and 60quater of the Social Security Code (2010). One of the main services is a national EHR called DSP (Dossier de Soins Partagé) allowing patients and professionals to share the most important documents for the continuity of care. This initiative was launched in 2014 and started to be operational following the Règlement Grand-Ducal (legal text) from Dec. 6th, 2019.

Standards and Protocols for Interoperability

The DSP uses IHE profiles like XDS.b and formats like CDA or HL7 v.2.5 to ensure interoperability. FHIR and openEHR and currently studied or tested.

The nation's participation in European healthcare interoperability projects like the Connecting Europe Facility (CEF) eHDSI, Trillium Bridge, and EURO-CAS, indicating a strong commitment to cross-border data exchange and collaboration.

Technological Infrastructure

The platform consists of several urbanization components, among them two key registries for health professional and patient identification. The DSP benefits from them. The sharing functionalities works through a single national registry and repository where all authorized actors can search and get documents. A web portal is also available for patients and health professionals, in case their software does not integrate natively. Patients also use a mobile app.

The DSP is the source of the PS that can be shared through the MyHealth@EU NCP, also under the responsibility of Agence eSanté.

Stakeholder Engagement and Perspectives

Luxembourg's engagement in significant European interoperability projects highlights the proactive involvement of stakeholders in enhancing the EHR system's capabilities and ensuring its alignment with European standards for health data exchange.

Data Security and Privacy Measures

The DSP platform's reliance on secure web services and integration with national identification registries underscores Luxembourg's adherence to stringent data security and privacy measures, ensuring the protection of personal health information in line with GDPR and other EU and local regulations.

The national data authority was consulted all along the design of the platform and a Privacy by Design/Privacy Impact Assessment process was conducted.

The DSP itself contains functionalities to help the patient to be in control of the sharing of its data.

Use Cases and Best Practices

Through the DSP, several use cases can be deployed like care pathways, paperless sharing of lab results, discharge letters or imaging reports.

By implementing interoperability standards, the DSP and a national VNA (Vendor Neutral Archive) are working seamlessly to allow the sharing of medical images.

Economic and Social Impact Analysis

While the document does not explicitly detail the economic and social impacts of the EHR system in Luxembourg, the advancements in digital health infrastructure and cross-border interoperability likely contribute to improved healthcare efficiency, patient outcomes, and potential cost savings within the national healthcare setting.

Future Plans and Recommendations

Luxembourg's ongoing participation in European digital health initiatives and its robust national eHealth platform position the country well for future enhancements in EHR interoperability and integration. Continued alignment with EU standards and regulations, like EHDS, alongside investments in digital health innovations, will be key to advancing Luxembourg's EHR system capabilities.

Gap Analysis with EU Standards

Luxembourg's EHR implementation reflects a strong alignment with EU standards and initiatives aimed at enhancing healthcare interoperability and data exchange across borders. The establishment of the DSP and active participation in projects like CEF eHDSI exemplify Luxembourg's commitment to a cohesive European digital health landscape. However, continuous efforts to enhance stakeholder engagement, further integrate with cross-border services, and adopt the latest digital health standards and technologies will ensure Luxembourg remains at the forefront of EHR system development and implementation within the EU.

Table 18. Overview of EHR Systems' Implementation in Luxembourg

Country:	<u>Luxembourg</u>
National EHR (add number of EHR system in brackets, e.g. Yes (1))	Yes
EHR Interoperability A) within the country, B) with the other countries (explain in the text above)	A) Yes, B) Yes
Data standards used	IHE, HL7, DICOM...
Additional information on data standards	International and local terminologies also used
IPS compliant	Yes
Use of priority categories in EHR systems:	
1. Patient summaries	Yes (PDF)
2. Electronic prescriptions	Yes (PDF)
3. Electronic dispensations	Yes (PDF)
4. Medical images and images reports	Yes (PDF for reports)
5. Laboratory results	Yes (PDF)
6. Discharge reports	Yes (PDF)
EHR systems coverage	National (Nationwide for key healthcare services)
Interoperability of national implementation	Good coverage, mixed data usage

5.19 Malta

National Regulatory Framework

Malta's national EHR system is in the process of implementation by the Ministry for Health and Active Ageing. A data platform based on OpenEHR data architecture has been set up, and demographic and clinical data from clinician-facing systems is being migrated to it. A legal framework, aligned with the EHDS Regulation, has been prepared to support the sharing of personal health data between public and private healthcare providers via this National EHR (NEHR) platform. This will therefore be subject to a structured regulatory framework that will govern the implementation and management of shared EHRs in the country. Patients and their linked doctors can already access a large selection of the EHRs stored in Government systems, through the myHealth portal. Access to records via the myHealth portal is based on patient consent, and the portal is also used to manage consent for cross-border transfer of patient summaries in case of need. This popular system, which went live in 2012, exemplifies Malta's commitment to digital health.

Standards and Protocols for Interoperability

The new NEHR platform is based on OpenEHR data standards, and its interfaces will be based on HL7 FHIR standards, which are critical for ensuring interoperability within Malta's healthcare system and with other countries. The adoption of these modern standards facilitates seamless data exchange and integration, aligning with EU legislation and guidelines for cross-border healthcare services.

Technological Infrastructure

Malta's public healthcare IT systems are hosted by Malta IT Agency (MITA), the government's principal IT agency. MITA provides hosting and network infrastructure to all public hospitals and health centres. It also provides information security services to ensure data protection and security for the personal health data hosted on government systems. Since the nineties, corporate health IT systems (such as the Patient Master Index and the Patient Administration System) have been implemented in an integrated manner across all public healthcare facilities. When Mater Dei Hospital, Malta's main hospital, started operating in 2007, a suite of software was introduced that laid the foundation for integrated electronic patient records; these included an order communications system, laboratory information system, radiology information system, picture archiving & communication system, and electronic case summary system. These were interfaced using HL7 interfaces and eventually became data sources for the myHealth portal. In parallel, ePrescribing in the community developed as a result of the development of the Pharmacy of your Choice scheme. In 2020, the government primary healthcare sector transitioned to paperless

Electronic Patient Records, as a result of which Malta has successfully interconnected all the public community health centres in the country, adding to the country's robust digital health infrastructure. The use of OpenEHR and HL7 FHIR within the upcoming National EHRs platform ensures the infrastructure's flexibility and adaptability to evolving healthcare needs.

Stakeholder Engagement and Perspectives

The Information Management Unit within the Ministry for Health and Active Ageing engages on an ongoing basis with a wide range of internal and external stakeholders, including the Ministry Management Board, the Digital Health Steering Committee, senior health service managers, professional associations, academic staff, industry partners, patients, and the general public. The development and continuous enhancement of the myHealth Portal involves collaboration among healthcare providers, IT professionals, policymakers, and patients. Ensuring stakeholder input is critical for addressing system usability, functionality, and integration challenges.

Data Security and Privacy Measures

Operating under the Ministry of Health and Active Ageing and adhering to EU and national data protection legislation, including GDPR, the myHealth Portal and all other public health IT systems have implemented stringent data security and privacy measures. These include encryption, secure access controls with two factor authentication, and compliance with legal requirements to protect patient information.

Use Cases and Best Practices

Malta's implementation of the myHealth Portal¹⁶ serves as a use case for successful engagement of patients and family doctors through digital health services. This bilingual portal uses e-ID (national electronic identification) and two factor authentication to ensure a high level of data protection and security. Access to personal data is entirely in the hands of patients, who give consent through the portal for named doctors to see their data, and/or to make it available for cross-border transfer in case of need. The portal connects to a range of government IT systems, mostly in real time, thus ensuring that the data is up to date. The portal is under constant development and will in future serve as the presentation layer of the National EHRs, leading to best practices in utilizing OpenEHR and HL7 FHIR standards for interoperability and speeding up the transition to paperless health records for improving healthcare delivery and patient care.

¹⁶ www.myhealth.gov.mt



Economic and Social Impact Analysis

The gradual digitalisation of the public healthcare sector in Malta since the nineties has been having an ongoing positive impact on the efficiency and quality of healthcare delivery.

The introduction of a set of new IT systems in 2007, when Mater Dei Hospital started operating, impacted the whole Maltese health ecosystem, first by improving interoperability among all government hospitals and health centres, and then, from 2012 onwards, by increasingly empowering patients and private family doctors by means of improved access to personal health data through the myHealth portal.

The shift to a paperless EHR system and the integration of government health centres across Malta in 2019-2020 contributed to enhanced healthcare efficiency, reduced administrative burdens, and improved patient outcomes. The system's support as a data source for cross-border health services also underscores its potential economic and social benefits.

Future Plans and Recommendations

Once fully implemented, the National EHRs platform will be a crucial enhancement to Malta's EHR environment, as it will greatly facilitate the sharing of personal data between public and private healthcare providers, leading to greater continuity, quality and efficiency of care for patients as they navigate through Malta's healthcare ecosystem. It will also provide more comprehensive data for the existing cross-border PS and facilitate the implementation of the other cross-border use cases envisaged in the EHDS Regulation. The NEHR platform is based on OpenEHR data architecture; whilst this is not an EU level standard, it is fully compatible with other emerging interoperability standards both nationally and internationally and will support the introduction of innovative digital health services, including those related to secondary use of personal health data. Ongoing investments in technological infrastructure, adherence to evolving interoperability standards, and stakeholder engagement will be key to these efforts.

Gap Analysis with EU Standards

Malta's early engagement in EU efforts to establish cross-border eHealth services (epSOS project, 2010 onwards) resulted in early understanding of the importance of the adoption of commonly agreed data storage and messaging standards. Indeed, the earliest use of SNOMED CT, HL7 CDA, and IHE profiles in government health IT systems was a direct result of this involvement. Moreover, Malta has been an active participant in EU-level eHealth governance since the days of the High-Level eHealth Governance Group, which was the forerunner of the eHealth Network, and has therefore been at the forefront of the setting of EU level health informatics standards. In



common with other EU MS, Malta is seeking to align its national standards with those established at EU level. There is wide consensus on the future use of IPS and HL7 FHIR standards; this is an area where Malta still has significant work to do. Malta has been a SNOMED International member since 2011 and was an early adopter of ICD-10 for mortality and morbidity statistics, demonstrating foresight with regard to data standards. Addressing future interoperability challenges will involve continuing updates to the national regulatory framework, technological infrastructure, and stakeholder engagement strategies to further align with EU standards and best practices.

Table 19. Overview of EHR Systems' Implementation in Malta

Country:	Malta
National EHR (add number of EHR system in brackets, e.g. Yes (1))	No (the National EHR system is still in process of implementation)
EHR Interoperability A) within the country, B) with the other countries (explain in the text above)	A) Partial, B) Yes
Data standards used	HL7 v3, DICOM, HL7 CDA R2, IHE profiles, HL7 FHIR (still in development), OpenEHR, SNOMED CT, national terminologies
Additional information on data standards	Transitioning to FHIR for data exchange
IPS compliant	Partial
Use of priority categories in EHR systems:	
1. Patient summaries	Partial (cross-border PS-A is in place)
2. Electronic prescriptions	Partial (so far, ePs are used for tax-funded medicines for chronic illnesses; currently being extended to all prescriptions; cross-border eP-B case being implemented)
3. Electronic dispensations	Partial (so far, ePs are used for tax-funded medicines for chronic illnesses; currently being extended to all prescriptions; cross-border eP-B case being implemented)
4. Medical images and images reports	Yes (in Government records)
5. Laboratory results	Yes (in Government records)
6. Discharge reports	Yes (in Government records)
EHR systems coverage	National (Nationwide efforts underway)
Interoperability of national implementation	Structured data adoption in initial stages

5.20 The Netherlands

National Regulatory Framework

The Netherlands operates under a decentralized system for EHRs, with private companies providing these services. The legal framework includes the WGBO (Medical Treatment Contracts Act) and GDPR, ensuring privacy and protection of personal data.

Standards and Protocols for Interoperability

Standards such as HL7 V2, CDA/FHIR, DICOM, SNOMED, and IHE profiles, based on Nictiz information standards, are used for EPR systems. In 2023, the Netherlands decided to transition almost all exchanges to FHIR STU3/R4, enhancing interoperability and data exchange capabilities.

Technological Infrastructure

The Association of Care Providers for Healthcare Communication (VZVZ) coordinates networks of exchanges through the National Exchange Point (LSP) for electronic data exchange among healthcare providers. Challenges include the alignment of various EPD systems for data exchange and the need for standardization.

Stakeholder Engagement and Perspectives

Stakeholders including the Ministry of Health Welfare and Sport (VWS), Healthcare Insurance Netherlands (Zorgverzekeraars Nederland), professional associations, and patient organizations are involved in promoting interoperability among EPR systems. Solutions include promoting uniform standards and developing coordinated efforts for a consistent direction/vision.

Data Security and Privacy Measures

Measures include adherence to GDPR, robust encryption techniques, stringent access controls, and the Unique Healthcare Provider Identification card (UZI pass) for secure access to digital health records and communication channels.

Use Cases and Best Practices

"Together for Medication Transfer" program fosters interoperability and patient safety through comprehensive medication management. It promotes standardized communication protocols and data formats for efficient information exchange.

Gap Analysis with EU Standards: The Netherlands' EHR implementation showcases an advanced, decentralized approach with a strong emphasis on interoperability, data privacy, and stakeholder engagement. The transition to FHIR and the use of standards such as SNOMED and IHE profiles align with EU standards, promoting seamless data exchange within and across borders. Challenges remain in aligning various EPR systems and ensuring comprehensive data standardization across the healthcare ecosystem. Continued efforts towards national coordination, adoption of the latest interoperability standards, and stakeholder collaboration are essential to address these challenges and further enhance the efficiency and effectiveness of the Dutch EHR system in line with EU directives and best practices.

Table 20. Overview of EHR Systems' Implementation in the Netherlands

Country:	The Netherlands
National EHR (add number of EHR system in brackets, e.g. Yes (1))	No (>30 systems/suppliers)
EHR Interoperability A) within the country, B) with the other countries (explain in the text above)	A) Partial, B) Partial (very few)
Data standards used	HL7 V3/CDA, FHIR, SNOMED, national information standards
Additional information on data standards	In transition from V3/CDA to FHIR. SNOMED to achieve interoperability
IPS compliant	Partial (clinical information models based on IPS)
Use of priority categories in EHR systems:	
1. Patient summaries	Yes (Not an existing document that can be retrieved directly from an information system -> must be compiled from a collection of patient data from one or more sources. Includes: information from primary care (GP) as basis for a fixed set of data following eHN Guidelines for PS (v3.2). Information from e.g. medical specialist care will be added at a later stage. Based on national standards, HL7 CDA)
2. Electronic prescriptions	No (ongoing work on MP9 project aiming at increasing medication safety through better exchange of medication data between healthcare providers. In addition, better insight must be created for the patient. Prescriptions are standardised and do contain structured data. NCPeH is not used for prescriptions yet. existing need to align with EU-developments. eP not yet implemented in MyHealth@EU)
3. Electronic dispensations	No (ongoing work on MP9 project (see above). Dispensations are standardised and do contain structured data. NCPeH is not used for dispensations yet. Existing need to align with EUdevelopments. eD not yet implemented in MyHealth@EU)

4. Medical images and images reports	No (ongoing work on connecting the multiple regional infrastructures to be able to create a 'timeline' to the radiologists: making all imaging studies available of 1 patient in chronological order based on IHE-profiles. Imaging reports are not yet standardised, don't contain structured data. NCPeH is not used for imaging yet. Existing need to align with EU-developments. Imaging not yet implemented in MyHealth@EU)
5. Laboratory results	Yes (The information standard consists of four parts for the exchange of laboratory results: 1) between laboratory, 2) between laboratory and healthcare providers, 3) between laboratory and public health services, 4) between laboratory and patient. Future implementation of part 2 of the information standard on behalf of Dutch Program "Medicatieoverdracht". Part 4 will be further developed in 2024. FHIR or HL7 are used.
	Ongoing preparation for the implementation of "Catalogue Wave 8 Lab" requirements. No data exchange within NCPeH currently
6. Discharge reports	No (National project is being initiated to explore how the HDR-EU can be integrated into the Dutch context including a Dutch fit/gap analysis and a stakeholder analysis to clarify who has interests in the development of an HDR-NL)
EHR systems coverage	National (Nationwide coverage)
Interoperability of national implementation	Nationwide, structured data.

5.21 Norway

National Regulatory Framework

Governed by the Health Records Act, Norway's EHR systems are comprehensive, applying to all health information processes necessary for healthcare delivery. The Regulation of Standards and National e-Health Solutions, under this act, dictates the use of national e-health solutions and standards.

EU directives applicable under the EEA Agreement, such as GDPR implemented via the Personal Data Act 2018, are incorporated, ensuring data protection and privacy adherence in the healthcare sector.

Standards and Protocols for Interoperability

Norway utilizes standardized messages for EHR systems interoperability, supporting the exchange of e-prescriptions, laboratory results, and other clinical documents. These exchanges leverage ebXML (electronic business using eXtensible Markup Language) /ebMS transported via SMTP/POP3 or AMQP.

Document sharing is transitioning towards the IHE XDS standard, with FHIR being progressively adopted for new data sharing services, indicating a move towards more robust and flexible interoperability frameworks.

Technological Infrastructure

The national health network, operated by Norsk helsenett SF, is pivotal for secure digital communication and data exchange among healthcare providers. Mandatory for public health providers, it supports access to shared infrastructure for secure communication and sensitive data exchange.

Stakeholder Engagement and Perspectives

Norway's digital healthcare maturity is evidenced by the broad adoption of EHRs, mandated by the Health Records Act. Advisory councils, involving healthcare authorities, vendors, and other stakeholders, guide eHealth development through a participatory governance model.

Data Security and Privacy Measures

The Norwegian Code of Conduct for information security, "Normen," outlines comprehensive measures for protecting health data beyond statutory requirements. Compliance with Normen is obligatory for entities in the national health network, ensuring high standards of data protection and information security.

Use Cases and Best Practices

The national messaging service exemplifies effective EHR interoperability, facilitating billions of transactions across healthcare levels. Mandatory connectivity to the national health network and the regulated services have significantly accelerated digital adoption in healthcare.

Economic and Social Impact Analysis

EHR interoperability is poised to save costs and improve healthcare efficiency by avoiding duplicate tests and facilitating faster digital solution implementation. Emphasis on early learning



and evaluation of trials before national rollout aims to ensure effective and timely healthcare delivery improvements.

Future Plans and Recommendations

Ongoing projects like the integration of Patients Medications List, Drug Master Data, and Laboratory results into the Summary Care Record highlight Norway's commitment to enhancing EHR interoperability. These initiatives aim to provide comprehensive and coordinated care through seamless information sharing.

Gap Analysis with EU Standards: Norway's EHR system showcases a robust interoperability framework, aligning closely with EU standards through the adoption of GDPR and engagement in the EEA Agreement. The strategic use of standardized messaging and the gradual shift towards FHIR and IHE XDS standards demonstrate a forward-thinking approach to healthcare interoperability. However, challenges such as the need for wider adoption of the IHE XDS standard and further integration of FHIR for seamless data sharing highlight areas for growth. Addressing these gaps, alongside continuing the participatory governance model for stakeholder engagement and upholding stringent data security measures, will ensure Norway's EHR system not only aligns with but also sets benchmarks within the EU's digital health landscape.

Table 21. Overview of EHR Systems' Implementation in Norway

Country:	Norway
National EHR (add number of EHR system in brackets, e.g. Yes (1))	Yes (1) – summary care record
EHR Interoperability A) within the country, B) with the other countries (explain in the text above)	A) Yes, B) In progress (MyHealth@EU with eP + PS to be operational from end of 2025)
Data standards used	HL7 FHIR, ebXML, IHE XDS, national information standards
Additional information on data standards	Partially based on FHIR
IPS compliant	Partial
Use of priority categories in EHR systems:	
1. Patient summaries	Yes (national, centralized, via portal or integrated in EHRs, based on national standards, FHIR and IHE XDS)
2. Electronic prescriptions	Yes (national, centralized, via portal or integrated in EHRs, based on national standards)
3. Electronic dispensations	Yes (national, centralized, via portal or integrated in EHRs, based on national standard)
4. Medical images and images reports	Yes (only image reports - centralized, via portal or integrated in EHRs, based on national standards + FHIR. Several regional solutions for image sharing often based on IHE XDS)
5. Laboratory results	Yes (national pilot, centralized, via portal or integrated in EHRs, based on national standards and FHIR)
6. Discharge reports	Yes (national, centralized, via portal or integrated in EHRs, based on IHE XDS)
EHR systems coverage	National (Nationwide coverage)
Interoperability of national implementation	Nationwide coverage, high use of structured data

5.22 Poland

National Regulatory Framework

In Poland the legal grounds for establishing e-Health Centre (CeZ) system are regulated in the Act of 28 April 2011 on the healthcare information system.

The core of the e-Health system in Poland is Electronic Platform for Collection, Analysis and Sharing of Digital Resources about Medical Events (so called P1) which enables the collection, processing and sharing of digital resources about patients' medical services of electronic medical records (EDM). The system covers all medical entities, regardless of the source of financing for the services they provide. The e-Health system (P1) consists of digital services (e.g. e-prescription, e-referral, EDM), applications (e.g. Internet Patient Account, mojeIKP) and solutions that improve the processes of planning and implementation of health care services. The information system includes databases operating within such as: Medical Information System: Domain-specific ICT systems - an ICT system supporting a specific area of operation of the health care system such as: Register of Medical Services of the National Health Fund, Statistics System in Health Care, Health Care Resources Registration System, Threat Monitoring System, System for Monitoring Accessibility to Health Care Services, Treatment Cost Monitoring System, Integrated System for Monitoring Trade in Medicinal Products, System for Monitoring the Education of Medical Workers, Reimbursement List Handling System, Instrument for the Assessment of Investment Applications in the Health Sector, Register of Medical Assistants, Target Import Handling System, medical registers. Additionally, Poland is implementing the cross-border ePrescription, which is operated by National Contact Point for Cross-Border Healthcare.

In Poland each system has its own specific legal provisions which describes its operation and administration. The P1 system administrator (technical and organisational functions) is an entity subordinate to the minister responsible for health matters, responsible for health care information systems – “e-Health Centre”. The P1 data administrator is the Minister of Health.

Standards and Protocols for Interoperability

The Central System (The P1 Platform) adopts and implements following: HL7 standards: CDA: eprescriptions, e-referrals, results of histopathological tests (cytological tests in the near future); FHIR: medical events: IHE Profiles: XDS and XDS-I (one national domain: central registry of document indexes, many document repositories registering indexes); ATNA - Transition towards FHIR in new services is encouraged (when applicable) Semantic interoperability: ICD-9 for procedures, ICD-10 for diagnosis, ICD-11 (planned to be used in the future instead of ICD-10), LOINC (used in all electronic medical documents for categorization), WHO ATC (e-prescriptions, cross-border e-prescriptions, national registry of medicinal products), SNOMED GPS is widely used in national FHIR value sets. Adoption of SNOMED CT is planned in new services (use cases)

Technological Infrastructure

The P1 Platform supports secure data storage and exchange, with a robust infrastructure that accommodates various healthcare sectors: National wallet mobile application¹⁷, National Patient Portal¹⁸, National e-Health mobile application¹⁹, National Portal for many healthcare professionals.

Stakeholder Engagement and Perspectives

The stakeholders of CeZ solutions are mainly: Service recipients (patients) - this is the largest recipient, this group includes all people using health services in the country; Service providers (entities performing medical activities) - this includes all entities performing medical activities, i.e., among others: hospitals and clinics, medical diagnostic laboratories and individual and group medical, nursing and midwifery practices operating throughout the country; Medical workers - this group includes, among others: doctors, including specialists, nurses, midwives, laboratory diagnosticians, pharmacists, physiotherapists, etc; Public administration bodies - an important stakeholder is the Ministry of Health.

CeZ creates digital services and solutions that support the work of medical professionals and make it easier for citizens to manage health matters. The solutions implemented by CeZ are used by millions of Poles and tens of thousands of medical and pharmaceutical entities. CeZ, implementing the goals and priorities of e-Health in Poland, creates, delivers, develops and maintains secure IT solutions for the health care system that respond to the needs of their users. CeZ is a leader in creating and delivering innovative solutions for the health care system and a supplier of key e-services that are perceived by patients and other participants of the health care system as adequate to their needs, reliable and safe. CeZ intends to continue its activities of creating a digital ecosystem of medical services.

Data Security and Privacy Measures

CeZ ensures security by maintaining a certificate of compliance with ISO 27001. In accordance with the CeZ National Interoperability Framework: applies security measures according to ISO 27002, manages risk according to the ISO 27005 standard, manages business continuity according to the ISO 22301 standard. CeZ uses, among others: Information security policy for contractors, cryptographic security policy, policy for logging security events in applications, information media management procedure, procedure for supervision of documented information, identity and permissions management procedure, information protection regulations, personal data security

¹⁷ reference: [HYPERLINK "https://info.mobywatel.gov.pl/"](https://info.mobywatel.gov.pl/) <https://info.mobywatel.gov.pl/>

¹⁸ reference: <https://pacjent.gov.pl/internetowe-konto-pacjenta/poznaj-mojeikp>

¹⁹ reference: <https://pacjent.gov.pl/internetowe-konto-pacjenta/poznaj-mojeikp>

policy, vulnerability management procedure, the principle of Privacy and Security by design in accordance with the GDPR, anonymization and pseudonymization where necessary, training for employees in the field of GDPR, information security and Security Awareness. Also, to ensure the protection of the health care sector, the Sector CSIRT was established within the CeZ structures.

Use Cases and Best Practices

CeZ's flagship product is the e-Health Centre system (P1). It is the basis of the digital health services ecosystem. It collects data on the course of treatment in one place, such as e-prescriptions, e-referrals and visit history, to which the patient has convenient and easy access on his or her Internet Patient Account (IKP). The system enables the collection, processing and sharing of digital resources about patients' medical events and indexes of electronic medical records (EDM). The system covers all medical entities, regardless of the source of financing for the services they provide. The e-Health Centre system consists of digital services: e-prescription, e-referral, Electronic Medical Documentation (EDM), e-Registration, data on Medical Events (ZM), IKP, [mojeIKP, gabinet.gov.pl](http://mojeIKP.gabinet.gov.pl) and solutions improving planning processes and implementation of health care services. They support the daily work of healthcare entities, medical workers and public administration responsible for the functioning of the health care sector in Poland. They provide patients with digital tools to facilitate health management.

CeZ participates on an ongoing basis in work related to the coordination of support in the health sector, by participating as a member in the work of the Steering Committee for the coordination of ESIF interventions in the health sector (2014-2020 perspective) and in the work of the Steering Committee for coordination of support in the health sector (perspective 2021-2027). Project management at the strategic and organizational level is carried out in accordance with the CeZ P3M standard, adapted to the needs of the organization. The P3M standard is based on improved methodologies and standards adapted to the CeZ environment: PRINCE2, PRINCE2 Agile, PMBOK Guide, SCRUM, AgilePM, SAFe. The goal of Poland's SNOMED International membership is to ensure semantic interoperability, which is crucial for the further development of e-Health in Poland, including: in the implementation of artificial intelligence solutions in health care.

Economic and Social Impact Analysis

For citizens: Eliminating the problem of illegibility, accidental destruction or loss of paper documents (i.e. pregnancy card, child's health booklet, order for laboratory tests); saving time and costs - no need to visit the doctor again to improve the readability of documents or re-issue them in the event of losing the paper version; possibility to obtain a medical consultation in the form of teleconsultation, which ensures convenience, saving time and costs; possibility of quick electronic access of medical staff to the patient's medical data in situations requiring urgent medical intervention, including life-threatening situations, which gives the patient a greater

chance of recovery; possibility of quick access to the patient's historical medical data in the event of continuation of treatment by another specialist or the need to visit another specialist without having to remember to provide a paper document; access for patients to information about possible preventive tests, tailored to the patient's individual characteristics (age, gender, previous diseases and tests already performed, genetic risks, lifestyle, etc.) and about the places of their implementation; increasing the security and control of sensitive medical data by transferring information from the paper version of the pregnancy card or child's health book to a system with an appropriate level of security; reducing the level of abuse in the health care system (tightening the system), resulting in an increase in financial resources for treatment; eliminating the barrier in the use of ICT tools in health care, especially among the group of people belonging to the so-called digitally excluded.

For service providers: Significant reduction in the generally understood cost of issuing documents. Thanks to the launch of e-prescription, doctors manage to save time previously spent on technical activities and use it for activities strictly related to medicine; cost reduction also results from reduced expenses related to the elimination of paper in issuing documents and expenses on rooms and equipment for storing paper documents, which additionally has a positive impact on the environment; full readability and reliability of documents and lower risk of errors (some of the data is loaded into the e-document automatically from the office/hospital system); simplifying the process of ordering laboratory tests - by downloading the central e-order document from the system without the need for the patient to physically deliver the paper document and without the need for manual data entry; increasing the competences of project stakeholders in the use of project products; eliminating the barrier in the use of ICT tools in health care, especially among the group of people belonging to the so-called digitally excluded.

For the healthcare system: Improving the quality and efficiency of the health care system in the area of treatment of patients with cancer and rare diseases; tightening the system for executing orders for laboratory tests (limiting the possibility of falsifying orders, limiting the duplication of the same tests); monitoring the ordering and performance of laboratory tests to obtain statistical data enabling regulatory decisions based on reliable data; increasing the effectiveness and reducing the costs of state activities to carry out preventive examinations; possibility of even better adaptation of preventive programs to real social needs (thanks to expanding knowledge about epidemiological parameters); increasing the scope of available data relevant to making accurate regulatory decisions.

Future Plans and Recommendations

In 2023, CeZ adopted the "Strategy of the e-Health Centre for 2023-2027" - a document setting long-term goals and showing how to achieve them. The implementation of the strategy, one of the key assumptions of which is dialogue with stakeholders, will translate into the creation of



even better e-services in health care that respond to their needs. Strategy goals are: strengthening cooperation based on dialogue with stakeholders, implementation of new eservices in the area of health care, support for decision-making based on e-Health data, e-Health competence centre, increasing the level of process, design and portfolio maturity, digital transformation of internal processes, strengthening the cybersecurity area, building a coherent e-Health architecture, standardization of e-Health services, increasing the level of quality of service provision, and the development and diversification of key competences.

Gap Analysis with EU Standards: Poland is making active approach to enact legislation with accordance to EU legislation, especially in the e-Health Center sector, as well as cybersecurity and data protection. The country's early digitalization efforts, secure data exchange infrastructure, and successful integration into the EU health data space are Poland's strong point. Poland is still observing changes in EU legislation and is making efforts to be in compliance with all new regulations and EU laws.

Table 22. Overview of EHR Systems' Implementation in Poland

Country:	Poland
National EHR (add number of EHR system in brackets, e.g. Yes (1))	Yes (1) - P1 Platform
EHR Interoperability A) within the country, B) with the other countries (explain in the text above)	A) Yes, B) Partial (e-prescription, PS in 2026)
Data standards used	HL7, national e-Health system
Additional information on data standards	Based on CDA, XDS domain and FHIR
IPS compliant	No (in preparation)
Use of priority categories in EHR systems:	
1. Patient summaries	No (in preparation: national, centralized via national portal or integrated in EHRs. Based on national standards, FHIR, eHN Guidelines and MyHealth@EU requirements)
2. Electronic prescriptions	Yes (national, centralized, via national portal or integrated in EHRs, based on national standards, CDA)
3. Electronic dispensations	Yes (national, centralized, via national portal or integrated in EHRs, based on national standards, CDA)
4. Medical images and images reports	No (in preparation: national exchange, One national IHE XDS domain)
5. Laboratory results	Yes (national, distributed in XDS domain, currently based on CDA; national specific: introduced earlier, not based on eHN Guidelines, if shared by a document creator and set as "available/online", docs are available in National Patient Portal)
6. Discharge reports	Yes (national, distributed in XDS domain, currently based on CDA; national specific: introduced earlier, not based on eHN Guidelines, if shared by a document creator and set as "available/online", docs are available in National Patient Portal)
EHR systems coverage	National (Major cities and expanding)
Interoperability of national implementation	Efforts to increase coverage and data structuring

5.23 Portugal

National Regulatory Framework

Portugal's electronic health initiatives began in the late nineties, focusing on telehealth services. The nation's legislation aligns with EU guidelines, particularly the GDPR, ensuring consistency and protection of patient information.

Decree order No. 137-A/2012 establishes the legal regime for prescribing and dispensing medicines and health products, emphasizing electronic processes for prescriptions, dispensing, and billing.

Law No. 25/2012 on advance directives, including living wills and healthcare proxies, and Law no. 53/2017 on mandatory cancer diagnosis reporting, highlight Portugal's comprehensive legal framework supporting EHR systems.

Portugal's eHealth Strategy: Portugal's approach to EHR is anchored in national legislation, notably through laws that establish the framework for electronic prescribing and health data exchange. The strategy for telehealth and the legal regime for ePrescriptions underscores the nation's commitment to integrating digital solutions in healthcare.

Standards and Protocols for Interoperability

Adoption of IHE and HL7: Utilization of global health information exchange standards, such as Integrating the Healthcare Enterprise (IHE) and Health Level Seven (HL7), facilitates interoperability between different healthcare systems within Portugal, ensuring seamless communication and data exchange.

Future Focus on FHIR: Portugal's intent to adopt newer standards like FHIR (Fast Healthcare Interoperability Resources) demonstrates a proactive stance towards enhancing EHR system flexibility and improving data exchange capabilities.

Technological Infrastructure

EHR System Implementations: Portugal has developed a sophisticated EHR infrastructure, with publicly available systems to support data exchange, such as the SClinico system. It also has available comprehensive telehealth services. These implementation supports the healthcare system's digitalization and improves patient care.

Infrastructure Challenges: Despite significant advancements, gaps in the existing infrastructure, particularly regarding total interoperability and system integration, have been identified, indicating areas for future improvement and development.

Stakeholder Engagement and Perspectives

Inclusive Approach to Digital Health: Portugal's strategy involves a wide array of stakeholders, including healthcare professionals, IT experts, and patients, in the ongoing development and refinement of EHR systems, addressing challenges such as system integration and user training.

Overcoming Resistance to Change: Efforts are being made to address resistance to digital transformation within the healthcare sector, emphasizing the importance of stakeholder education and streamlined procedures to enhance adoption rates.

Data Security and Privacy Measures

Robust Security Protocols: Portugal's commitment to data security is evident in its adherence to GDPR and the implementation of advanced security measures for EHR data, including encryption and access control mechanisms, ensuring patient information is protected against unauthorized access.

Challenges in Data Confidentiality: Despite strong security measures, incidents of data breaches highlight the ongoing challenges in ensuring the confidentiality and privacy of health data, necessitating continuous vigilance and updates to security protocols.

Use Cases and Best Practices

Successful Interoperability Initiatives: Portugal's integration of EHR for chronic illness management and the development of standardized data exchange platforms are highlighted as successful use cases, demonstrating best practices in leveraging EHR for improved healthcare delivery.

Standardized Coding Schemes: The adoption of standardized coding and communication protocols for information sharing within the healthcare system exemplifies a structured approach to achieving interoperability and enhancing patient care.

Economic and Social Impact Analysis

Improved Healthcare Efficiency and Outcomes: The implementation of EHR systems in Portugal is anticipated to lead to better healthcare efficiency, reduce unnecessary procedures, and improve



patient outcomes, showcasing the potential economic and social benefits of digital health technologies.

Cross-Border Collaboration Benefits: Emphasis on faster execution and the realization of benefits from EHR interoperability highlights Portugal's commitment to enhancing healthcare efficiency and ensuring timely access to relevant patient information.

Future Plans and Recommendations

Enhancing EHR Interoperability: Portugal's future plans include further improving EHR interoperability through adopting new standards and technologies, focusing on projects that facilitate seamless data sharing across healthcare providers. The RRP fund has several strategic pillars focused on improving national registers, strengthening information sharing between systems and interoperability, reinforcing the dematerialization of additional areas, such as medical devices and complementary means of diagnosis and therapy (CMDT), as well as strengthening information security and cybersecurity, resulting from the possibility of concentrating network and data infrastructures, among other examples.

Policy and Infrastructure Development: Recommendations for ongoing development include continuous policy improvements, infrastructure enhancements, and stakeholder education, with a particular emphasis on cross-national cooperation within the EU to develop common digital health strategies.

Gap Analysis with EU Standards: Portugal's initiatives in EHR implementation and digital health show a commitment to aligning with EU standards through the adoption of global interoperability standards and GDPR compliance. While considerable progress has been made, addressing challenges in system integration, stakeholder engagement, and data security will further enhance Portugal's EHR system's alignment with EU directives and best practices. Future developments focusing on infrastructure improvement and embracing newer data exchange standards like FHIR will be crucial in advancing Portugal's digital health ecosystem within the European framework.

Table 23. Overview of EHR Systems' Implementation in Portugal

Country:	<u>Portugal</u>
National EHR (add number of EHR system in brackets, e.g. Yes (1))	Yes
EHR Interoperability A) within the country, B) with the other countries (explain in the text above)	A) Yes, B) Yes, (MyHealth@EU, PS-A, PS-B, eP-A, ePB since 2020)
Data standards used	IHE, HL7 V2 and CDA, national health data platform
Additional information on data standards	Intending future adoption of FHIR
IPS compliant	Partial
Use of priority categories in EHR systems:	
1. Patient summaries	Yes
2. Electronic prescriptions	Yes
3. Electronic dispensations	Yes
4. Medical images and images reports	Yes (national level)
5. Laboratory results	Yes (national level)
6. Discharge reports	Yes (national level)
EHR systems coverage	National (Nationwide coverage)
Interoperability of national implementation	Nationwide coverage, mixed data usage

5.24 Romania

National Regulatory Framework

Romania has implemented partially at the national EHR system through its health insurance fund. The system primarily focuses on ePrescription, vaccination records, and patient record management. The future development of the system must include legal and regulatory basis for the management and use of other categories (stomatology, imagistic, paraclinics – laboratories data).

Standards and Protocols for Interoperability

The status of Romania's EHR system highlights a significant interoperability challenge. Despite the creation of millions of records, the system's limited interoperability restricts effective data communication among users and healthcare providers (HPs). This limitation underscores the need for adopting more advanced standards and protocols that would enhance system interoperability and data exchange capabilities.

Technological Infrastructure

Given the challenges regarding interoperability, it can be inferred that the existing infrastructure may need enhancements to support more efficient data exchange and integration across different healthcare settings and systems.

Stakeholder Engagement and Perspectives

While specific insights into stakeholder engagement in Romania's EHR system implementation are not provided, the limited use of the system by the population suggests areas for improvement. Enhancing stakeholder engagement, particularly among patients and healthcare providers, could drive higher utilization rates and contribute to the system's overall effectiveness.

Data Security and Privacy Measures

Specific measures implemented within the national EHR system to ensure data security and privacy, critical in fostering trust among users and ensuring compliance with regulatory requirements are implemented. Measures include adherence to GDPR, using health insurance card for access to digital health records by providers.

Use Cases and Best Practices

The initial implementation of Romania's EHR system, focusing on ePrescription and vaccination records, provides a foundation for identifying use cases and best practices. However, expanding the system's functionalities and interoperability could unveil more comprehensive use cases, illustrating the system's potential to improve healthcare delivery and patient outcomes.

Economic and Social Impact Analysis

An analysis of the economic and social impacts of Romania's EHR system is not provided. Nonetheless, enhancing the system's interoperability and utilization could have significant benefits, including improved healthcare efficiency, patient safety, and potentially, cost savings through reduced redundancies and enhanced care coordination.

Future Plans and Recommendations

For Romania, advancing the national EHR system involves addressing interoperability challenges, enhancing stakeholder engagement, and ensuring robust data security and privacy measures. Future plans may include adopting more advanced interoperability standards, improving the technological infrastructure, and fostering broader stakeholder participation in the system's ongoing development and utilization.

Gap Analysis with EU Standards: The primary challenge facing Romania's EHR system is its limited interoperability, which impedes data communication among users and healthcare providers. Aligning with EU standards and best practices necessitates a concerted effort to enhance interoperability through the adoption of widely recognized health informatics standards. Additionally, engaging stakeholders more effectively and ensuring stringent data protection measures will be key in advancing Romania's EHR system towards full compliance with EU directives and achieving the broader objectives of improved healthcare delivery and patient care.

Table 24. Overview of EHR Systems' Implementation in Romania

Country:	<u>Romania</u>
National EHR (add number of EHR system in brackets, e.g. Yes (1))	Yes
EHR Interoperability A) within the country, B) with the other countries (explain in the text above)	A) Yes, B) No
Data standards used	National standards
Additional information on data standards	Starting to adopt HL7 (HL7 adopted for patients record management)
IPS compliant	No (partially)
Use of priority categories in EHR systems:	
1. Patient summaries	Yes (national level)
2. Electronic prescriptions	Yes (national level)
3. Electronic dispensations	Yes (national level)
4. Medical images and images reports	No
5. Laboratory results	No
6. Discharge reports	Yes (national level)
EHR systems coverage	National
Interoperability of national implementation	Starting to adopt structured data

5.25 Slovakia

National Regulatory Framework

The Slovak legislation aligns with EU guidelines, particularly the GDPR, ensuring consistency and protection of patient information.

The most relevant national regulatory framework for EHR is the Act No. 153/2013 on the national health information system and on the amendment and addition of certain laws, as amended, regulates the legal environment, e.g. in the matter of the EHRs.

The national regulatory framework also includes other laws related to the regulation of healthcare services, healthcare providers, health insurers, or social insurance. For example, Act No. 576/2004 includes regulation of management of medical records related to the provision of healthcare services as well as biomedical research and Act No. 578/2004 requires healthcare providers to create electronic records for each treatment encounter.

Standards and Protocols for Interoperability

The standard STN EN 13606, which is used in national health information system, was adopted by the technical commission TC 251 "Health informatics" of the European standardization organization CEN. The aim is to ensure the interoperability of systems and their constituents for exchanging electronic health data. It defines a healthcare record scheme that meets the conditions for record sharing between any systems and services in primary and secondary health care, decision support and quality management.

Technological Infrastructure

The NHIC manages a fully functional solution of national health information system for needs of eHealth in accordance with the applicable national legislation. The national infrastructure is being monitored and upgraded over time by a specialized unit at the NHIC.

If unexpected gaps are detected in the infrastructure, these incidents are immediately solved by a specialized unit at the NHIC.

Stakeholder Engagement and Perspectives

Stakeholder feedback has been an important component for the implementation and continuous development of the national health information system and its services. The NHIC conducts stakeholder surveys and has dedicated employees to promote efficient implementation and operations of the national health information system services across the country. The NHIC has been provided with stakeholder feedback including suggestions from the healthcare providers about reducing complexity and improving operational challenges as well as suggestions from the patients about improving and expanding functionality and accessibility while ensuring confidentiality and safety of their electronic health data. These perspectives highlight the importance of engaging with end-users throughout the system design and implementation process to ensure their needs and concerns are adequately addressed.

Data Security and Privacy Measures

Data security and privacy measures remain an important area for the continuous development and resilient operations of the national health information system due to the rapidly evolving threats and challenges. The continuous work of the NHIC as well as the adoption of best practices has helped to safeguard the electronic patient data from any major data breaches or leaks at the national level. Ensuring the confidentiality, integrity, and availability of health information within the national health information system is paramount to maintaining trust and compliance with data protection regulations.

Use Cases and Best Practices

From the list of priority European use cases, ePrescription and PS are currently available at the national level as parts of national health information system. Slovakia is currently working towards the development of a national contact point for cross-border health information exchange. We are also collecting data at the national level in other use cases, which can in the future support the implementation of the other European use cases.

Economic and Social Impact Analysis

A comprehensive economic and social impact analysis of the implementation of the national EHR has not been conducted at this point. Nonetheless, the data and feedback from stakeholders suggest that the roll out of the national health information system had positive economic and social impacts. It facilitated easier accessibility to health data as well as more efficient data sharing, which are important prerequisites for evidence-based decision making and greater involvement of patients in their care.

Future Plans and Recommendations

Slovakia is actively supporting the continuous improvement of its national digital health services. The NHIC is currently involved in several projects and has a dedicated project management office. Future plans for the improvement of the national health information system include reducing system complexity, improving operational resilience and efficiency, as well as strengthening data and system security to address continually evolving and changing threats. Recommendations for future development include stakeholder engagement, simplification of the user interface, robust data protection measures, and continuous system evaluation and improvement. The NHIC is also currently evaluating the opportunities and challenges associated with the implementation of the EHDS.

Gap Analysis with EU Standards:

The continuous evolution and improvement of the Slovak national health information system includes implementation of new digital health services which are being increasingly developed in alignment with the EU Standards and cross-border interoperability. A comprehensive gap analysis between the EU Standards and the national standard has not been conducted at this point. However, the upcoming regulation on the EHDS will necessitate large changes and more accelerated pace of harmonization of the national standards with the common EU standards.

Table 25. Overview of EHR Systems' Implementation in Slovakia

Country:	Slovakia
National EHR (add number of EHR system in brackets, e.g. Yes (1))	Yes
EHR Interoperability A) within the country, B) with the other countries (explain in the text above)	A) Yes, B) No (in progress)
Data standards used	Mostly national health informatics standards with ISO 13606
Additional information on data standards	Considering adoption of HL7 in the future
IPS compliant	No
Use of priority categories in EHR systems:	
1. Patient summaries	Yes
2. Electronic prescriptions	Yes
3. Electronic dispensations	Yes
4. Medical images and images reports	No (In progress)
5. Laboratory results	Yes
6. Discharge reports	Yes
EHR systems coverage	National (Nationwide initiatives)
Interoperability of national implementation	Structured data usage growing

5.26 Slovenia

National Regulatory Framework

Slovenia's framework for EHRs, guided by the Healthcare Databases Act²⁰, establishes a robust foundation ensuring that all healthcare data processing complies with both national and EU

²⁰ Healthcare databases Act, <http://pisrs.si/Pis.web/pregledPredpisa?id=ZAKO1419>

regulations, including GDPR. This alignment underscores Slovenia's dedication to patient data privacy and the secure handling of health records.

The Digital Health Act, in preparation, signifies Slovenia's forward-thinking approach to enhance legal backing for digital health innovations, ensuring sustained growth and adaptation to emerging health technologies and practices.

Standards and Protocols for Interoperability

The national EHR system's compliance with IHE XDS and OpenEHR standards for interoperability is complemented using SNOMED CT for PS, ensuring that healthcare data is standardized, interoperable, and usable across different health IT systems. However, national coding standards are widely used and many categories of EHR are only available in unstructured (pdf) format.

Integration efforts with eHDSI for cross-border health data exchange further emphasize Slovenia's commitment to EU-wide health interoperability initiatives.

Technological Infrastructure

Slovenia's dedication to building a secure and comprehensive ICT infrastructure for healthcare is evident through ongoing investments in the zNET network and enhancements to the Central Registry of Patient Data (CRPD), facilitating efficient, secure data exchange and management.

The establishment of a high-availability disaster recovery site for the national EHR system demonstrates a strategic approach to ensuring continuity and reliability of healthcare services in any circumstances.

Stakeholder Engagement and Perspectives

Active engagement with healthcare providers and the public through the zVEM patient portal and mobile app²⁷ reflects Slovenia's commitment to transparency, patient empowerment, and inclusivity in healthcare decision-making.

Initiatives to address the administrative and technical challenges faced by healthcare providers are crucial for reducing the burden of data entry and improving the overall efficiency and satisfaction of healthcare professionals.

Data Security and Privacy Measures

Stringent data security protocols, continuous system monitoring through Network operation centre (NOC) and Security operation centre (SOC), and adherence to international cybersecurity standards underline Slovenia's robust measures to protect health data against unauthorized access and cyber threats.

Comprehensive regulation and technical measures are in place to address data privacy in healthcare²⁸. The forthcoming Digital Health Act is expected to reinforce these measures

²⁷ Patient portal zVEM, Available: <https://zvem.ezdrav.si/portal/gost>. Accessed: 8.3.2024

²⁸ Personal data protection Act, <http://www.pisrs.si/Pis.web/pregledPredpisa?id=ZAKO7959>. Accessed: 8.3.2024

Tepej Jočić L. (2021). Impact of Data Protection Regulation on Slovenian eHealth, *J Glbo Health* 2021;11:03063., <https://www.jogh.org/documents/2021/jogh-11-03063.pdf>

Use Cases and Best Practices

Slovenia's integration of a comprehensive eHealth ecosystem, including Prescription, Patient Summaries, and electronic documentation, serves as a model for effective EHR implementation. These systems enhance care coordination, improve medication safety, and facilitate patient access to their health information.

The implementation of the national EHR exchange service as a backbone for secure data exchange among healthcare providers exemplifies a scalable and efficient approach to achieving interoperability within the healthcare sector²¹.

Economic and Social Impact Analysis

The systematic approach to EHR implementation in Slovenia is expected to yield significant long-term benefits, including enhanced healthcare delivery efficiency, reduced duplication of services, and improved patient health outcomes.

²¹ Stanimirovic, D.; Tepej Jovic, L. Accelerated Digitalization of the Epidemiological Measures: Overcoming the Technological and Process Complexities of Establishing the EU Digital COVID Certificate in Slovenia. *Int. J. Environ. Res. Public Health* 2022, 19, 14322. <https://doi.org/10.3390/ijerph192114322>.

Stanimirovic, D.; Tepej Jovic, L. The Slovenian Patient Summary: One Digital Record, Multitude of Applications, *Studies in Health Technology and Informatics*, <https://ebooks.iospress.nl/doi/10.3233/SHTI230487>.

The focus on digital health to facilitate access to care, to the entire population underscores the social impact of EHR interoperability in bridging healthcare disparities.

Future Plans and Recommendations

Slovenia's national eHealth strategy²² and the development of the Digital Health Act signal a comprehensive plan for the continued evolution of the healthcare sector, with a focus on leveraging digital health to enhance patient care, streamline provider workflows, and ensure the sustainability of health services.

The emphasis on increasing resources, capacities, and stronger governance structures for digital health reflects a holistic approach to addressing current challenges and seizing future opportunities in healthcare digitalization.

Gap Analysis with EU Standards: Slovenia's proactive measures in EHR implementation, adherence to international interoperability standards, and the development of a secure ICT infrastructure showcase a strong alignment with EU standards. However, standardisation of laboratory domain and hospital discharge reports remains challenging. Nevertheless, addressing the challenges in system integration, enhancing stakeholder engagement, and refining the regulatory framework through the forthcoming Digital Health Act will further solidify Slovenia's position as a leader in healthcare digitalization within the EU context.

²² Slovenija - e-zdravje za bolj zdravo družbo, <https://www.gov.si/assets/ministrstva/MZ/DOKUMENTI/O-MINISTRSTVU/Slovenija-E-zdravje-za-bolj-zdravo-druzbo-v2.pdf>

Table 26. Overview of EHR Systems' Implementation in Slovenia

Country:	<u>Slovenia</u>
National EHR (add number of EHR system in brackets, e.g. Yes (1))	Yes
EHR Interoperability A) within the country, B) with the other countries (explain in the text above)	A) Yes, B) Production testing started, roll-out for all services planned in 2024
Data standards used	Open EHR, IHE XDS, National eHealth infrastructure (coding standards)
Additional information on data standards	Based on FHIR only for demographic data
IPS compliant	Yes
Use of priority categories in EHR systems:	
1. Patient summaries	Yes (OpenEHR and IHE XDS)
2. Electronic prescriptions	Yes (national standard)
3. Electronic dispensations	Yes (national standard)
4. Medical images and images reports	Partial (Reports only Pdf documents (IHE XDS) Exchange of images with limited capacity)
5. Laboratory results	Partial (only pdf documents (IHE XDS), for the entire population)
6. Discharge reports	Partial (Only pdf document, IHE XDS)
EHR systems coverage	National (Nationwide initiatives)
Interoperability of national implementation	Structured data usage growing

5.27 Spain

National Regulatory Framework

In Spain, the regulation of EHR systems and associated processes is underpinned by a framework that includes specific national laws and decrees, alongside each autonomous region's regulations, all aimed at governing patient autonomy, rights, and obligations concerning clinical information and documentation. Noteworthy legislation includes: Ley 41/2002 for patient autonomy and clinical documentation rights, Real Decreto 572/2023 setting the minimum data set for clinical reports within the National Health System, Real Decreto 81/2014 to ensure cross-border healthcare and regulate medical prescriptions and dispensing orders, Real Decreto 702/2013 amending regulations related to the individual health card, Real Decreto 311/2022 on the National Security Framework, Ley Orgánica 3/2018 concerning Personal Data Protection and Guarantee of Digital Rights, aligning with GDPR for data protection. These regulations provide a robust legal backbone for the privacy, protection, and secure handling of clinical data and foster interoperability and accessibility in healthcare services.

Standards and Protocols for Interoperability

Spain adopts various international standards to facilitate interoperability within EHR systems: HL7 v2.x and HL7 CDA R2 for clinical process integration and report standardization; FHIR is gaining traction for direct use in patient applications and EHR system development; OpenEHR is being increasingly considered for its data archetype approach in EHR systems. Vocabulary and coding systems like SNOMED-CT, ATC, ICD-10-CM, and others are utilized for consistent data representation. The adoption of these standards is widespread across the healthcare ecosystem, ensuring coherent data exchange and system integration.

Technological Infrastructure

Spain's EHR systems are primarily supported by on-premises server infrastructures within private networks managed by hospitals' IT departments or autonomous regions. This setup ensures secure and efficient management of health data across the National Health System (SNS) and various autonomous regions. However, evolving towards FHIR standards and addressing the scalability of software architectures represent significant challenges for enhancing interoperability.

Data Security and Privacy Measures

Access to EHRs by healthcare professionals and citizens is rigorously controlled, leveraging electronic IDs, certification authorities, and 2FA mechanisms. The National Security Framework

mandates comprehensive risk assessments and the implementation of diverse security measures to safeguard clinical data.

Use Cases and Best Practices

The collaborative efforts between the regional health services (17), INGESA, and other stakeholders have been pivotal in creating a unified EHR accessible nationwide, adhering to the standards set by "Real Decreto 572/2023." This cooperation is instrumental in addressing the unique challenges posed by Spain's diverse healthcare ecosystem.

Economic and Social Impact Analysis

The strategic analysis preceding the implementation of PS and ePrescription/eDispensation services highlighted the economic and social benefits of enhanced EHR interoperability. These benefits include improved healthcare quality for both local and EU citizens and potential cost savings.

Future Plans and Recommendations

Spain's experience underscores the importance of national infrastructure for clinical record exchange and adapting to EU standards. The ongoing challenge of accommodating EU requirements, coupled with the need for efficient incident tracking and consistent KPI reporting, are areas identified for future improvement.

Gap Analysis with EU Standards: Regarding its adoption of EU-recommended standards, Spain's use of HL7 v2.x, CDA R2, and emerging adoption of FHIR align with the EU's push towards interoperable healthcare systems. The integration of international coding systems like SNOMEDCT and ICD-10 within Spain's healthcare system indicates strong adherence to EU suggestions for standardized healthcare vocabularies. Although FHIR adoption is underway, it is still in the early stages compared to HL7 v2.x and CDA R2. As FHIR becomes more prevalent in EU initiatives, accelerating its adoption could enhance Spain's alignment with future EU interoperability frameworks. As for its technological Infrastructure and overall alignment with EU Digital Health Objectives, Spain's robust server infrastructure and secure private networks for EHR systems meet the EU's objectives for secure and efficient health data management. However, the transition to FHIR and the need for software architecture evolution present challenges. Adapting to FHIR's requirements for handling JSON files and APIs necessitates significant technological upgrades, highlighting a gap in readiness for the next wave of EU standards for health data exchange. Furthermore, Spain's comprehensive security measures, as mandated by the National Security Framework (ENS), align with the EU's GDPR and eHDSI requirements for health data protection.

The varying degrees of implementation across autonomous regions may lead to uneven security postures, emphasizing the need for a more unified national approach to match EU-wide data security standards consistently. The collaborative framework for EHR unification in Spain reflects the EU's vision for cross-border healthcare interoperability and patient-centred care. Despite significant progress, ongoing efforts to limit changes in CDA documents and enhance incident tracking suggest areas for improvement in maintaining interoperability and ensuring efficient problem resolution within the EU framework.

Table 27. Overview of EHR Systems' Implementation in Spain

Country:	<u>Spain</u>
National EHR (add number of EHR system in brackets, e.g. <i>Yes (1)</i>)	Yes
EHR Interoperability A) within the country, B) with the other countries (explain in the text above)	A) Yes, B) Yes
Data standards used	HL7 V2, HL7 FHIR, HL7 CDA, OpenEHR national interoperability framework
Additional information on data standards	Also based on ISO 13606
IPS compliant	No
Use of priority categories in EHR systems:	
1. Patient summaries	Yes (National and European standard, via Portal and integrated in EHRs, based on national standards)
2. Electronic prescriptions	Yes (National and European standard, via Portal and integrated in EHRs, based on national standards)
3. Electronic dispensations	Yes (National and European standard, via Portal and integrated in EHRs, based on national standards)
4. Medical images and images reports	Yes (only reports (National, via Portal and integrated in EHRs, based on national standards)
5. Laboratory results	Yes (National, via Portal and integrated in EHRs, based on national standards)
6. Discharge reports	Yes (National, via Portal and integrated in EHRs, based on national standards)
EHR systems coverage	National (Nationwide, all autonomous communities)
Interoperability of national implementation	High coverage, structured data widely used

5.28 Sweden

National Regulatory Framework:

In Sweden there are 2-3 different core EHR systems in operation with large scale implementation. Due to the autonomy of the regions (responsible for healthcare, primary and secondary) there is no national governance of EHR system.

The 21 regions and the 290 municipalities, together with their association SALAR (Swedish Association of Local Authorities and Regions), own a company, Inera AB, the mission of which is to provide digital infrastructure and other services.

In addition to the regional and municipal healthcare there is a substantial number of private healthcare providers, these do not have access to the Inera infrastructure. The Swedish Government is working to ensure the availability of an infrastructure available for all healthcare providers, the details for how this will be organized is being pinned out currently.

From a regulatory perspective all processing of health data must comply with the national Patient Data Act (PDL), Health and Medical Services Act (HSL) and the national Public Access to Information and Secrecy Act (OSL).

When it comes to the infrastructure services provided by Inera there are requirements for the authorized users regarding e.g. security in the processing environment, guidelines for encryption levels, and authentication methods. The Swedish eHealth Agency (SEHA) is responsible for the national e-prescription infrastructure which has its own security requirements.

Standards and Protocols for Interoperability:

The infrastructure provided by Inera is mainly built based on HL7 CDA, but this does not apply for all services. In general, there is an increasing use of international standards such as HL7 FHIR, OpenEHR and SNOMED CT as well as a continuation of usage of international and national standards such as ICD, NPU, ATC, ICNP etc. Semantic standards are governed and made available on a national level by either national authorities or appointed organizations. In addition, there is a webservice made available nationally to collect and provide access to information about eHealth specifications in general and also to appointing nationally defined eHealth specifications, following a public consultation ([NGS-tjänsten](#)).

Technological Infrastructure:

The semi-national digital infrastructure administered by Inera AB is based on a health information exchange platform (Nationella Tjänsteplattformen), a SOA-platform using webservice-technology



compliant with WS-I basic profile. The infrastructure for e-prescription is built on FHIR and uses, where relevant, SNOMED CT as coding system.

Stakeholder Engagement and Perspectives:

Sweden has many different stakeholder groups that affect infrastructure, interoperability and standardization. Earlier a broad stakeholder engagement was based on the national agreement mainly between the Swedish Government and SALAR, namely the Vision e-Health 2025. During the last year, partially because of the expected demands of EHDS, there has been a shift in strategic direction and the Swedish Government clearly expresses an ambition as well as the need for taking increased responsibility to ensure an inclusive national digital infrastructure. Key to a successful outcome of this, however, is a nationwide cooperation of all relevant actors within the ecosystem.

Sweden is active in standardization organizations like ISO, HL7, openEHR, WHO, Snomed International.

Data Security and Privacy Measures:

The national Patient Act and the Patient Data Act state requirements concerning privacy and data security when processing health data. Supervision of compliance to integrity and privacy regulation is performed by the Swedish Authority for Privacy Protection (Integritetsskyddsmyndigheten). The Swedish Civil Contingencies Agency (Myndigheten för säkerhet och beredskap) with its National Cyber Security Centre (NCSC) holds a responsibility for analysis, information dissemination and coordination of actions. There is no sector-specific national resource on cyber security.

Use Cases and Best Practices: The implementation of ePrescription, national PS (NPÖ) and the patient access 1177.se serves as best practices, illustrating Sweden's advanced use of digital health solutions to improve healthcare delivery and patient engagement. These initiatives demonstrate the potential of digital health technologies to foster a more integrated and patientcentred healthcare system.

Economic and Social Impact Analysis:

An economic impact analysis is ongoing to assess the societal costs associated with the implementation of EHDS in Sweden. This analysis provides valuable insights into the economic considerations of adopting EU-wide interoperability standards.

Regarding the social impacts connected to health data and interoperability, a national Corona inquiry following the Covid-19 pandemic (SOU 2020:80) pointed at the difficulties of exchanging

patient information, e.g. between regional and municipality healthcare, as a major threat to patient safety.

Future Plans and Recommendations:

Key moving forward in Sweden is collaboration which is undertaken by all large actors nationally. The regions have established a collaborative partnership ensuring joint efforts rather than 21 separate initiatives primarily on the topic of interoperability. This partnership also includes collaboration with governmental authorities. In recent years the Swedish Government has taken a clear position to take increased responsibility for the national digital infrastructure for healthcare. Government efforts are undertaken to contribute to the development of this, just recently a proposal for a roadmap for national digital infrastructure for healthcare was handed over to the ministry as well as a national commission on the future structure of health data. The proposal includes a recommendation that components of the new infrastructure should, as far as possible, be developed and established as modular and universal, sector-agnostic resources as part of the national (non-sector specific) Ena cooperation, for Sweden's digital infrastructure.

Along with the regional partnership described above there is a shift currently undertaken of technical platforms where a substantial part of the 21 regions is in the process of procuring and implementing new core EHR systems.

Gap Analysis with EU Standards:

An analysis has been performed to assess the gap between what is currently available as coded and structured data, and what is required by MyHealth@EU PS and ePrescription/eDispensation specifications. Although mapping and translation is required for certain parts of the specifications, there is an overall good coverage of health data to support participation in MyHealth@EU. The scope of health data may vary across the framework of the European specifications.

Table 28. Overview of EHR Systems' Implementation in Sweden

Country:	Sweden
National EHR (add number of EHR system in brackets, e.g. Yes (1))	No [2-3 core systems]
EHR Interoperability A) within the country, B) with the other countries (explain in the text above)	A) Partly, B) No
Data standards used	HL7, National eHealth services standards, International semantic code systems
Additional information on data standards	eP and eD are based on FHIR
IPS compliant	No
Use of priority categories in EHR systems:	
1. Patient summaries	Yes
2. Electronic prescriptions	Yes
3. Electronic dispensations	Yes
4. Medical images and images reports	Yes
5. Laboratory results	Yes
6. Discharge reports	Yes
EHR systems coverage	National (Nationwide coverage)
Interoperability of national implementation	High interoperability with regards to national services, some usage of structured data – increasing

6. Outcomes

6.1 Key Findings

The gap analysis results underscore a fragmented landscape within the EU. The primary gaps identified—interoperability, adoption and utilization, legislative and regulatory aspects, and innovation in services—show a pattern of highlight systemic issues that impede the realization of a fully integrated European digital health ecosystems.

There are significant differences between European countries in terms of their readiness for electronic sharing of relevant health data between health professionals at all levels and making data available to patients even on the national level. The implementation of systematic EHRs enabling such data sharing is still an open conceptual and/or implementation task in many countries and will require significant efforts in terms of capacity and resources. This should be considered regardless of whether there are experimental or sub-projects that demonstrate the feasibility of participating in MyHealth@EU, but much of the population and its electronic health data (by nature falling into priority categories) remain inaccessible. The relevance, timeliness,

quality and comprehensibility of shared health data for healthcare professionals and patients also deserve significant attention.

The key challenge then remains the interoperability of those systems that are supposed to share data, despite efforts like the eHDSI aimed at facilitating cross-border health data exchange. The variation in EHR system architectures (if available), standards, and compliance underscores the need for a unified approach to ensure seamless health data flow across borders and healthcare providers.

Adoption and utilization gaps reflect not only technological and infrastructural deficiencies but also legal and organizational barriers. These gaps suggest a need for targeted strategies to ensure data subject's rights are preserved, enhance improvement of citizens' digital literacy, fostering a culture of innovation in healthcare, as well as streamlining EHR system interfaces to encourage wider use among healthcare providers.

Legislative and regulatory challenges point to the delicate balance required between advancing digital health initiatives and safeguarding patient data privacy and security. The GDPR provides a robust framework, yet the implementation in the healthcare domain varies, indicating the need for clearer and more specific guidelines and support to ensure compliance across all MS.

Innovation and services gaps reveal an opportunity to leverage EHR systems as platforms for advanced healthcare services, including telemedicine, AI-driven diagnostics, and personalized medicine. However, the uneven distribution of such services indicates a need for investment in digital infrastructure and research to drive innovation.

The following conclusions and figures reflect the maturity of the EHR systems' implementation and adoption based on the data collection exercise contained in Chapter 5 (Country Summaries) and Table 1 (in Appendix I).

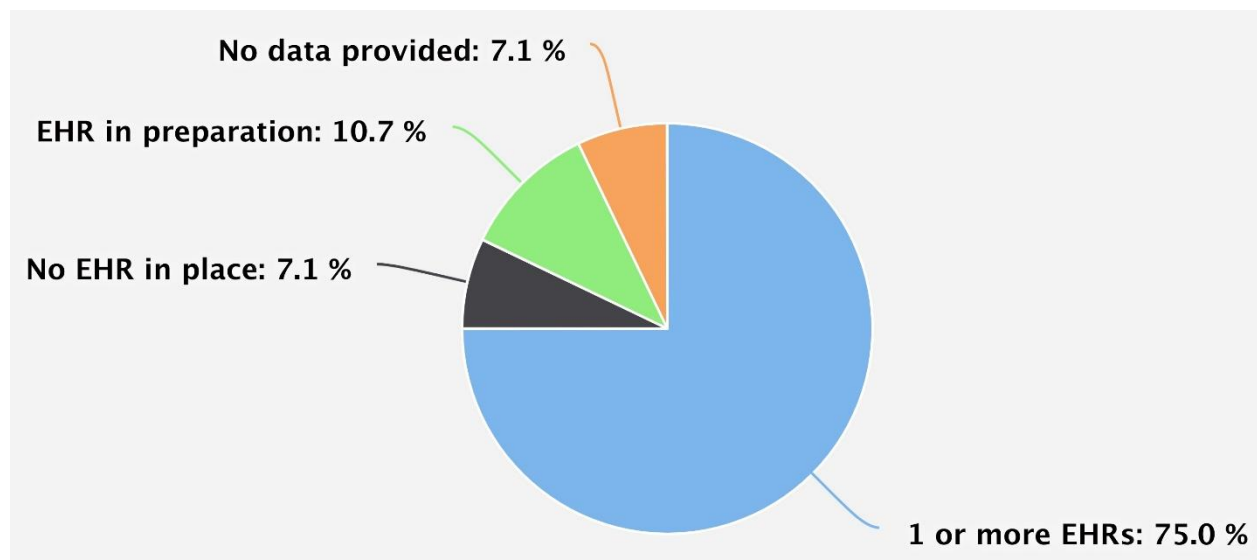


Figure 1. Percentage of countries (EU27 + Norway) implementing national EHR systems

Summary of the key findings:

- **Varied Implementation Landscape:** EHR systems across the EU exhibit significant variability in terms of adoption rates, technological advancement, and interoperability capabilities. While some MS have made considerable progress, others are still navigating the initial stages of EHR implementation or even design.
- **Interoperability Challenges:** A recurring theme across the analysis is the challenge of interoperability, both within individual countries and across borders. The need for standardized data formats and protocols is paramount to overcoming these hurdles.
- **Legislative and Regulatory Frameworks:** The GDPR and the forthcoming EHDS Regulation play a crucial role in shaping the EHR landscape, emphasizing data privacy, security, and cross-border data exchange.
- **Innovation and Patient Empowerment:** Advances in digital health technologies and a shift towards patient-centric care models are driving innovation in EHR systems. There is a growing emphasis on empowering patients with access to and control over their health data.

Common Trends and Challenges:

Interoperability and Data Standards:

- **Challenge:** Achieving interoperability within and across borders remains a significant challenge due to diverse standards and protocols adopted by different countries.
- **Need:** Adoption of universal data exchange standards like HL7 FHIR, SNOMED CT, and IHE profiles to facilitate seamless health data exchange.

Adherence to Legislation and Privacy Regulations:

- **Challenge:** Ensuring EHR systems comply with GDPR, and other relevant healthcare regulations poses difficulties, particularly with evolving cybersecurity threats.
- **Need:** Continuous updates to EHR systems to ensure compliance with data protection laws and safeguard patient privacy.

Differences in National Approaches:

- **Challenge:** Varied approaches to EHR implementation across countries due to differences in healthcare systems, funding, and digital infrastructure readiness.
- **Need:** Greater collaboration and sharing of best practices among EU countries to harmonize EHR implementation strategies.

Stakeholder Engagement:

- **Challenge:** Insufficient engagement of all stakeholders, including healthcare providers, patients, and IT professionals, in the EHR system design and implementation process.
- **Need:** Enhanced mechanisms for stakeholder consultation and feedback to ensure EHR systems meet user needs and encourage wider adoption.

Technological Advancements and AI Integration:

- **Challenge:** Slow integration of advanced technologies such as AI and machine learning in EHR systems for predictive analytics and personalized medicine.
- **Need:** Increased investment in and exploration of emerging technologies to improve healthcare outcomes and system efficiencies.

What is Missing and Can Be Improved?

- **Unified European EHR Framework:** A more cohesive strategy and framework at the EU level could address interoperability issues and standardize data exchange protocols, making cross-border healthcare more seamless.
- **Focus on User-Centric Design:** Future strategies should prioritize the development of EHR systems with strong user-centric designs that accommodate the needs of both healthcare providers and patients, enhancing usability and satisfaction.
- **Enhanced Cybersecurity Measures:** As cybersecurity threats evolve, continuous enhancement of security measures is crucial. Future developments should include state-of-the-art cybersecurity protocols to protect sensitive health data.
- **Public Awareness and Education:** Increasing public awareness about the benefits of EHR systems and educating stakeholders on their use and impact can drive higher adoption rates and foster trust in digital health solutions.
- **Research and Innovation Support:** Encouraging research and innovation in digital health can uncover new ways to overcome existing barriers, integrate cutting-edge technologies, and improve healthcare delivery through EHR systems.

Which standards to implement?

- For European MS aiming to enhance the interoperability, efficiency, and effectiveness of EHR systems, adopting a set of core standards is crucial. These standards facilitate seamless data exchange, ensure system compatibility, and enable comprehensive healthcare delivery across borders. The following standards are widely recognized as essential for MS to adopt; however, their appropriateness of use in the EHR systems – especially concerning cross-border data exchanges, needs to be more closely analysed by MS expert groups such as the eHMSEG Semantic Task Force.
- **HL7 Fast Healthcare Interoperability Resources (FHIR):**
 - A modern standard facilitating the exchange of healthcare information electronically, enabling easier access and integration of healthcare data.
- **Health Level Seven (HL7) v2 and CDA:**
 - HL7 v2 is used for clinical and administrative data exchange, while CDA provides a structure for clinical documents. Both are crucial for legacy system compatibility.
- **Integrating the Healthcare Enterprise (IHE) Profiles:**
 - IHE profiles organize and leverage existing standards like DICOM and HL7 to address specific clinical needs and support interoperable health information exchange.
- **SNOMED CT (Systematized Nomenclature of Medicine -- Clinical Terms):**
 - A comprehensive clinical terminology that provides a standardized way to represent medical conditions and treatments, facilitating clear communication across different EHR systems and healthcare providers.
- **LOINC (Logical Observation Identifiers Names and Codes):**
 - Specifically designed for lab observations and results, LOINC facilitates the exchange and pooling of results for clinical care, research, and management.
- **NPU (Nomenclature for Properties and Units)**
 - The terminology system used in the Scandinavian countries for descriptions of laboratory examinations and units of measurement.

- **DICOM (Digital Imaging and Communications in Medicine):**
 - The standard for handling, storing, printing, and transmitting information in medical imaging, ensuring interoperability of imaging devices and systems.
- **ISO 13606 (Health Informatics - Electronic Health Record Communication):**
 - This standard defines a model for the EHRs to ensure interoperability, supporting secure and interoperable health data exchange.
- **ISO/TC 215 (Health Informatics):**
 - A series of standards covering health information and communications technology (ICT), providing frameworks for data interoperability, security, and exchange.
- **eIDAS Regulation for Electronic Identification and Trust Services:**
 - Although not a health-specific standard, eIDAS is crucial for ensuring secure electronic transactions and access services, including EHR systems, across Europe.

By adopting these standards, MS can ensure that their EHR systems are interoperable, secure, and capable of exchanging health information efficiently, both within and across borders. This adoption also aligns with the European Commission's efforts to create a Digital Single Market, facilitating seamless healthcare service provision and improving patient care throughout the EU.

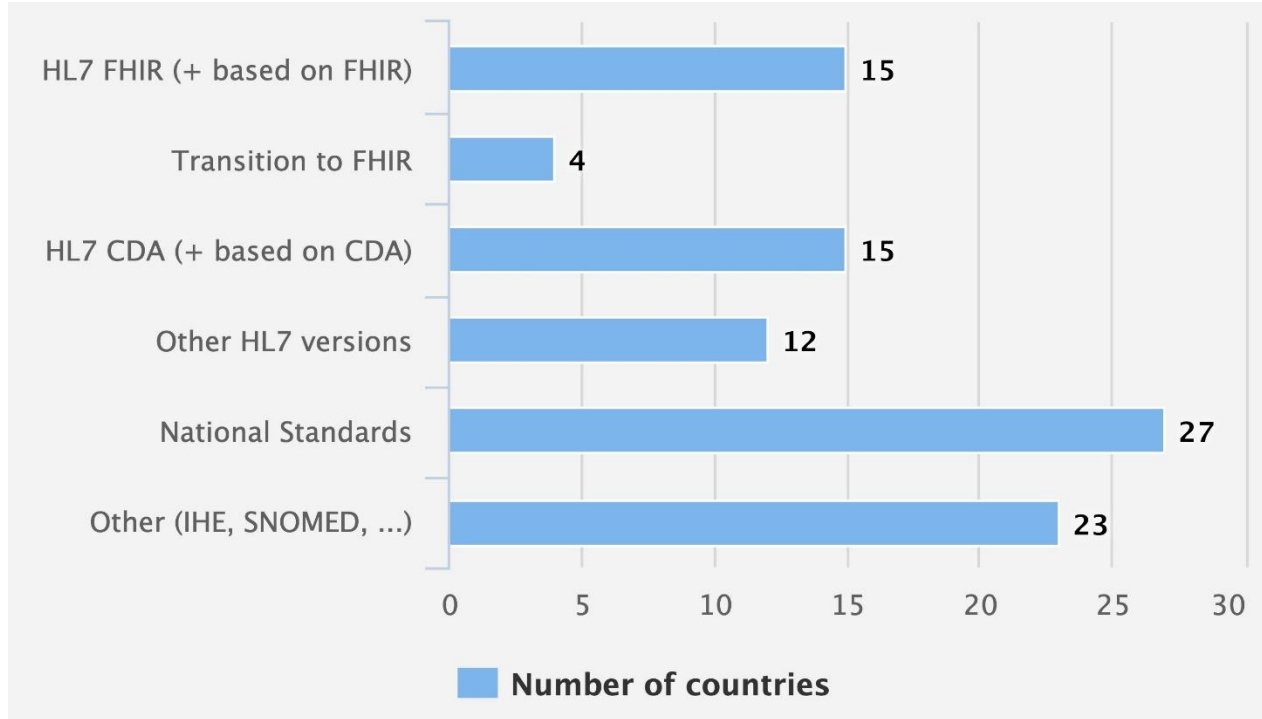


Figure 2. Use of data standards in countries (EU27 + Norway)

Key Insights:

Varied National Implementation Status: Across all service areas, implementation status at the national level varies significantly, with some EU MS demonstrating advanced digital health services and others still enhancing their infrastructure.

EU Cross-border Implementation in Progress: For all mentioned services (PS, ePrescription, Medical Imaging and Report, Laboratory Report and Hospital Discharge Report), cross-border implementation is a work in progress, reflecting ongoing efforts to enhance interoperability and seamless health data exchange across the EU.

Data Exchange Standards: A mix of international and EU-specific standards is employed to facilitate data exchange, including HL7 FHIR, HL7 CDA, DICOM, NPU, and LOINC. The adoption of these standards is crucial for interoperability but varies by service and country.

Maturity and Coverage Level Variances: Maturity levels and the extent of service coverage show considerable variance across the EU. ePrescription and PS services are generally more mature, particularly in countries with well-established EHR systems. Medical Imaging and Reports, Laboratory Reports, and Hospital Discharge Reports are developing, with ongoing efforts to standardize data exchange and integrate these services into cross-border health information networks.

Challenges faced by European countries:

- **Interoperability Challenges:** Many European countries face challenges in achieving interoperability within their decentralized healthcare systems. Despite high levels of digitization in countries like Estonia, Denmark, Finland, and Sweden, data mobility is affected by limited interoperability between regions or autonomous communities, impacting the quality of health services for citizens who may require access to their data across different regions.

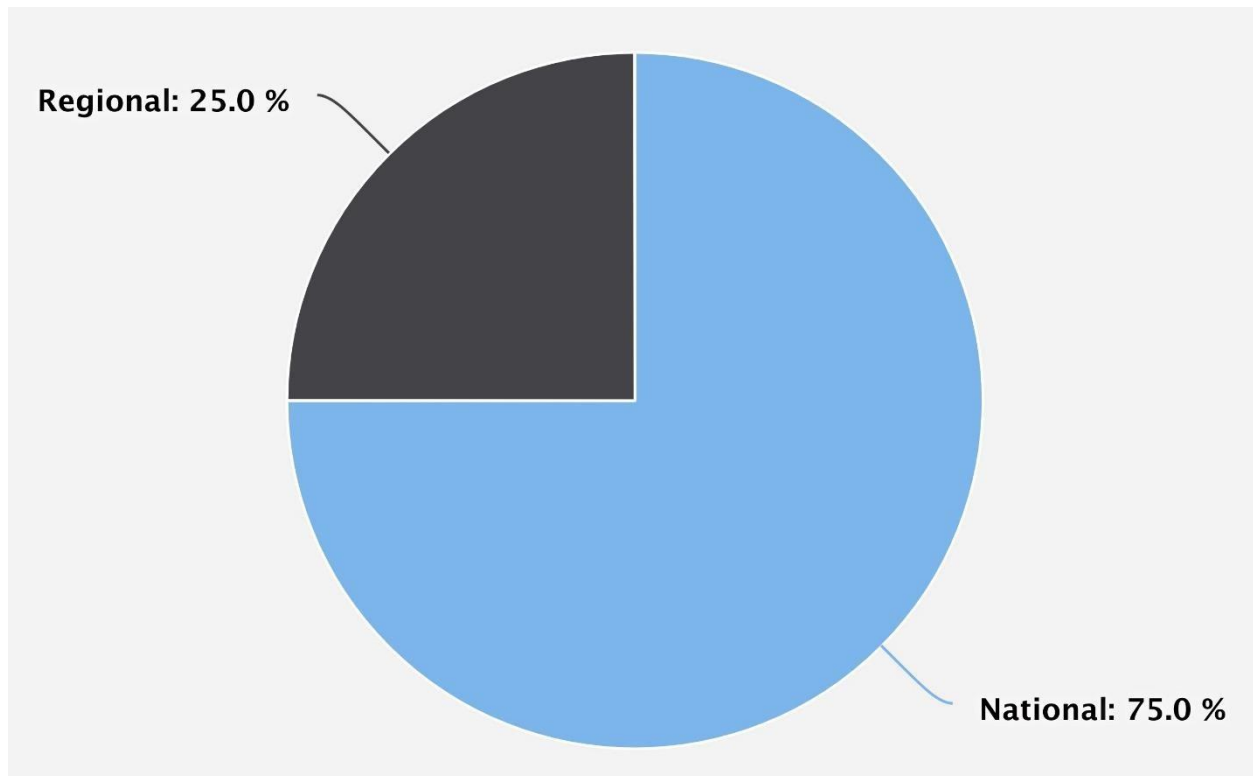


Figure 3. Coverage of EHR systems in countries (EU27 + Norway)

- **Legal Framework Progress:** A significant portion of European countries have made progress in their legal frameworks to support EHR systems. More than 2/3 of the countries studied have enacted national EHR legislation, with a notable number granting legal access to EHR data to their citizens. This legal backing is crucial for fostering trust and ensuring standardized practices across the board.
- **Cross-Border Data Sharing:** Only a few countries, including the Czech Republic, Lithuania, Latvia, Poland, Slovenia and Slovakia, have laws enabling the sharing of EHR

data across national borders. This capability is essential for supporting EU-wide health data exchange initiatives, enhancing patient care, and facilitating mobility across the EU.

- **Usage and Services:** Denmark, Estonia, and Finland lead in the use of EHR systems, with widespread services such as viewing test results, online prescriptions, and appointment scheduling. These services demonstrate the potential benefits of well-implemented EHR systems in improving accessibility and efficiency in healthcare delivery.
- **Impact of eHealth Network:** The eHealth Network, aimed at promoting cross-border health systems and services in the EU, faces challenges in overcoming access barriers to health data due to its non-binding guidelines. This situation underscores the need for more robust, enforceable policies at the EU level to ensure the widespread adoption and implementation of interoperable EHR systems.
- **Technological and Political Challenges:** The implementation and interoperability of EHR systems are not solely technological challenges but also political ones. Viewing EHRs and digital health as opportunities for the health sector and broader R&D-intensive sectors is crucial for Europe's competitiveness in the global market.

MyHealth@EU Perspective: Cross-Border Exchange Mechanisms:

- **MyHealth@EU** relies on the National Contact Points for eHealth (NCPeH) in each participating country. These NCPeHs are responsible for the secure exchange of health data under the eHDSI.
- The infrastructure uses a set of common data standards and formats to ensure interoperability and secure data exchange across different healthcare IT systems used in the EU.
- Implementations may leverage international standards such as HL7 FHIR, HL7 CDA, and IHE profiles, adapting them to the specific requirements of cross-border data exchange.
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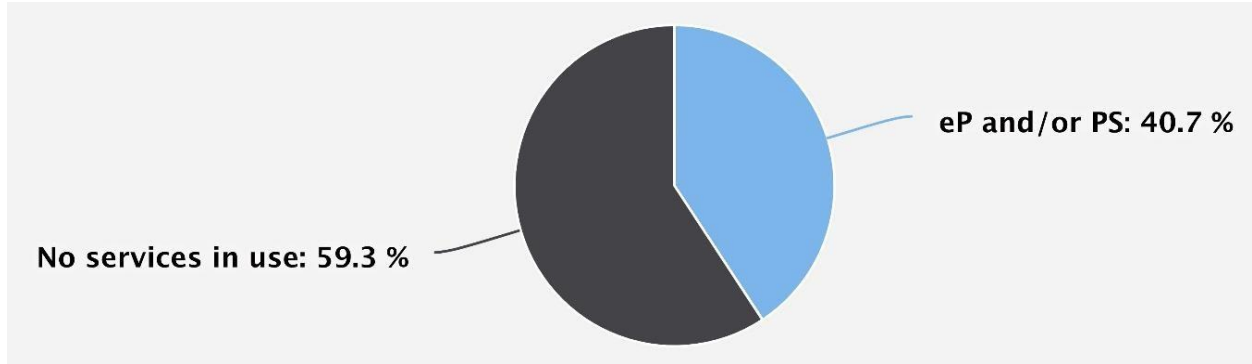


Figure 4. Percentage of EU27 countries in operation with the cross-border services within MyHealth@EU (up to date in April 2024)

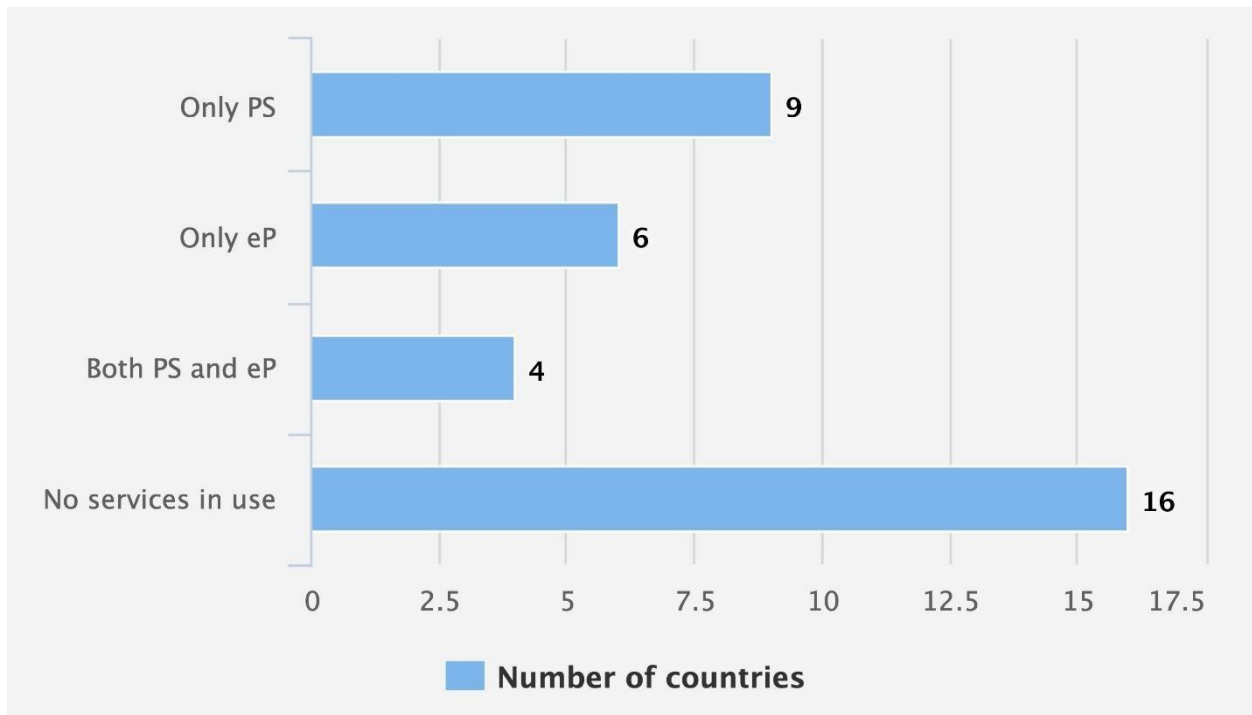


Figure 5. Number of EU27 countries in operation with the cross-border services within MyHealth@EU²³ (up to date in April 2024)

²³ Reference: https://health.ec.europa.eu/ehealth-digital-health-and-care/electronic-cross-border-healthservices_en

Current Challenges and Future Directions:

- **Legal and Regulatory Compliance:** Ensuring data protection and privacy in line with GDPR and other relevant EU regulations.
- **Technical and Semantic Interoperability:** Harmonizing data standards, terminologies, and exchange formats across MS.
- **Adoption and Participation:** Increasing the number of countries participating in each service and ensuring healthcare providers are equipped to access and use cross-border services.
- **Expansion of Services:** Beyond the initial core services, there is an ongoing effort to include more types of health data in cross-border exchanges, such as rare disease registries, cancer screening records, and advanced directives.

The success of MyHealth@EU in facilitating cross-border healthcare interoperability relies on collaborative efforts among MS, continuous technological advancements, and addressing the evolving healthcare needs of EU citizens.

Recommendations for Bridging Gaps:

- **Unified Regulatory Implementation:** Enhance consistency across European countries to ensure uniform application of EU data protection and interoperability standards.
- **Accelerated Adoption of FHIR:** Prioritize the integration of FHIR standards to align with the EU's future direction for health data exchange.
- **Infrastructure Modernization:** Invest in technological upgrades to support JSON, APIs, and modular software architectures, facilitating seamless adaptation to EU interoperability frameworks.
- **National Security Standardization:** Develop nationwide policies for data security that align with EU standards, reducing variability across regions.

Enhanced Interoperability Monitoring: Implement comprehensive KPIs and incident tracking mechanisms to monitor interoperability and security standards compliance effectively.

6.2 Comparative Analysis of EHR Systems in Europe - Insights and Trends

The adoption and implementation of EHR systems within the European countries present a diverse landscape, influenced by individual MS healthcare policies, technological infrastructure, and approaches to data privacy and interoperability. Several key trends have been identified:

- **Interoperability as a Priority:** A key insight from the EU's experience with EHR systems is the critical importance of interoperability—both within countries but also across EU borders. Initiatives like the eHDSI / MyHealth@EU aim to facilitate cross-border health data exchange, supporting the EU's vision of a Digital Single Market. + mention EHDS
- **Data Privacy and Security:** With the GDPR setting a high standard for data protection, EU countries prioritize secure data sharing practices within their EHR systems. This focus on privacy shapes the design and operation of EHR systems, ensuring patient data is protected in line with EU regulations.
- **Digital Health Inequality:** The comparative analysis highlights digital health inequality within the EU, with disparities in EHR system maturity and adoption rates. Addressing these inequalities is essential for realizing the full benefits of digital health across all MS.
- **Adoption of Digital Health Innovations:** EU countries are increasingly integrating digital health innovations into their EHR systems, such as AI for predictive analytics, telemedicine for remote care, and mobile health applications for patient engagement. These innovations are driving improvements in healthcare efficiency, accessibility, and personalized care.

6.3 Steps towards EHR systems' adoption and sustainability

The implementation of EHR systems in accordance with the EHDS regulations represents a critical step towards a unified and efficient digital health ecosystem in the EU. By following these recommendations, European countries can ensure that EHR systems not only comply with EHDS requirements but also contribute to the broader objectives of improving healthcare quality, enhancing patient engagement, and driving medical research and innovation.

Policy Recommendations for Improving EHR Systems and Data Use:

- **Enhance Interoperability:** Adopt and enforce standardized data formats and communication protocols (e.g., FHIR) across the EU via the Commission Implementing Acts and other legislative enablers. Facilitate the development of a standardised EU-wide EHR interoperability framework as an extension of the currently implemented services (ePrescription and PS) that supports seamless data exchange and integration of healthcare services.

- **Support Adoption and Utilization:** Implement comprehensive digital literacy programs for healthcare providers (both as curriculums at the University-level and as part of job training) and patients. Provide financial and technical support to healthcare institutions for EHR system adoption and optimization.
- **Strengthen Legislative and Regulatory Frameworks:** Develop clear, actionable guidelines for EHR implementation that align with GDPR and EHDS requirements, focusing on patient consent and data security. Encourage MS to adopt uniform legislation that facilitates cross-border data sharing while protecting patient privacy in cross-border settings.
- **Drive Innovation:** Invest in digital health research and infrastructure to support the development of advanced EHR functionalities, including AI, telehealth, and personalized medicine. Promote public-private partnerships to accelerate innovation in digital health services.
- **Foster Collaboration:** Encourage collaboration among EU MS, healthcare providers, technology developers, and patients to share best practices, research findings, and innovative solutions. Establish EU-wide initiatives to address the digital health divide and ensure equitable access to advanced healthcare technologies.

Implications for Stakeholders:

- **Healthcare Providers:** Must navigate the complexities of EHR systems while ensuring high-quality patient care. The gaps identified necessitate ongoing training, support for digital transformation initiatives, and active participation in shaping EHR system development to meet clinical needs.
- **Policymakers:** Are tasked with creating conducive environments for EHR system adoption and interoperability. This includes formulating clear policies, investing in digital health infrastructure, and fostering collaborations among EU MS to harmonize EHR standards and practices.
- **Patients:** Stand to benefit significantly from improved EHR systems through enhanced access to their health data, better healthcare outcomes, and the potential for personalized healthcare services. Engaging patients in the development and implementation of EHR systems is crucial for maximizing these benefits.
- **Vendors:** Vendors play a critical role in the successful implementation of EHR systems. They must ensure their products meet regulatory standards and interoperability requirements. This includes ongoing innovation, providing comprehensive support and training for users, and collaborating closely with healthcare providers and policymakers to address evolving needs and challenges in the healthcare landscape.

6.3.1 Recommendations for EHR Systems Implementation regarding the EHDS Regulation

The upcoming EHDS regulation presents a transformative opportunity for the standardization and utilization of EHR systems across the EU. To align with this regulation and maximize its benefits, specific recommendations for the implementation of EHR systems within the context of EHDS are crucial. These recommendations aim to ensure that EHR systems not only comply with EHDS regulations but also leverage them to enhance healthcare delivery, patient empowerment, and innovation. The purpose of these recommendations is to frame how implementation guides should be drafted so that their impact and sustainability can be positively assessed. Below, they are identified as legal, technical and additional recommendations for the EHR system implementors.

LEGAL ASPECTS: Ensuring Compliance with EHDS Regulation

- **Adoption of EHDS-Compliant Data Standards and Protocols:**
 - EHR systems should adhere to data standards and interoperability protocols outlined by the EHDS, facilitating seamless internal and cross-border health data exchange. Adoption of standards such as FHIR and adherence to the Common Data Elements (CDE) will be a key aspect of this effort.
 - Healthcare providers and EHR vendors must update their systems to align with EHDS standards, participating in EU-wide initiatives that promote interoperability and data sharing.
- **Prioritize Data Privacy and Security:**
 - Implement robust data privacy and security measures that exceed the minimum requirements set by the EHDS and GDPR. This includes end-to-end encryption, regular security audits, and transparent data governance policies.
 - Develop and integrate advanced security technologies into EHR systems, ensuring that healthcare professionals have access to EHR within the provision of healthcare and that patients have secure access to their EHR.
- **Facilitate Patient Access and Control:**
 - EHR systems must empower patients with easy access to their health data, allowing them to share it across the EU. This involves creating user-friendly interfaces, ensuring data portability (e.g. via the EU wallet) and informing patients about the processing of their data.
 - Design patient centric EHR platforms that offer intuitive access to health records, including mobile applications and web portals that comply with EHDS accessibility standards.
- **Invest in Infrastructure and Training:**

- Invest in the necessary digital infrastructure to support the integration and operation of EHDS-compliant EHR systems. Additionally, provide training for healthcare providers and administrative staff on the use of these systems and the implications of EHDS regulation.
- Allocate resources for system upgrades and workforce development, ensuring that all stakeholders are equipped to utilize EHR systems effectively within the EHDS framework.
- **Foster Collaboration and Sharing of Best Practices:**
 - Encourage collaboration among EU MS, healthcare providers, EHR vendors, and other stakeholders to share best practices, lessons learned, and innovative solutions related to the implementation of EHDS-compliant EHR systems.
 - Participate in EU-wide forums, workshops, and collaborative projects focused on digital health, aiming to build a cohesive and interoperable health data space across Europe.

To navigate the technological complexities and harness the full potential of EHR systems across the EU, several key points need to be explored. These topics delve into achieving seamless data flow, establishing a stable data core, ensuring interoperable and fair data sharing, standardization, and the sustainability of the digital health market. Addressing these points is crucial for advancing the EU's digital health ecosystem and enhancing healthcare delivery and innovation.

TECHNICAL ASPECTS: Achieving Seamless Data Flow Between EHR Systems using Interoperable Standards

- **Integration of Technologies and Overcoming Barriers to Implementation:**
 - **Use of Technical Standards based on EU needs:** The EU can facilitate seamless data flow by promoting the use of interoperable standards like HL7 FHIR, which enables different EHR systems to communicate effectively. Investing in shared infrastructure and adopting cloud services can also enhance connectivity.
 - **Unified Digital Health Data Strategy for EHRs:** To overcome barriers, the EU should encourage MS to adopt a unified digital health strategy with regards to the EHDS Regulation, provide technical and financial support to healthcare providers for EHR system upgrades, and foster a culture of digital literacy and collaboration across the healthcare sector.
- **Defining a Stable Data Core for EHR Systems**
- **Foundational Data Elements:** A stable data core should include universally accepted patient information (e.g., identification, medical history, medications, allergies, and treatment outcomes) and adhere to interoperability standards like FHIR. This ensures consistency across systems.

- **Leveraging Initiatives:** Initiatives like eHDSI/MyHealth@EU provide frameworks for cross-border health data exchange which can guide the identification of essential data elements and the establishment of a common data model for EHR systems.
- **Interoperable Data Sharing Capabilities**
- ○ **Criteria for Interoperable Data Sharing:** Criteria should include compliance with international standards (e.g., FHIR), data security measures, user-friendly access for patients and healthcare providers, and the ability to support real-time data exchange.
 - **Effective Standards and Terminologies:** Utilizing standards like the ones indicated in the eHN Guideline on the electronic exchange of health data under Cross-Border Directive 2011/24/EU²⁴ as the preferred code systems list (i.e., WHO ICD, ATC, ISO, HL7, EDQM, UCOM, ISO IDMP / EMA RMS, Orphanet nomenclature, EMDN) can enhance interoperability between systems facilitating consistent data representation and sharing across different healthcare systems.
- **Standardization Across Different Systems**
- ○ **Steps for Standardization:** Draft Implementing Acts mandating the use of common standards and protocols for EHR systems. Encourage collaboration between technology providers to ensure their systems are compatible and support data exchange.
 - **Reconciling Digital Maturity Variations:** The EU could establish a phased approach, allowing MS at different levels of digital maturity to adopt EHR standards progressively, e.g. like how other cross-border services are currently being implemented in the scope of eHDSI / MyHealth@EU. Providing targeted support and sharing best practices can help bridge the gap between countries.
- **Commonalities in Data Collection and Sharing**
- ○ **Leveraging Commonalities:** Identifying and standardizing the collection of core health data elements across EU countries can enhance EHR interoperability. Shared data repositories and collaborative platforms can facilitate the exchange of best practices.
 - **Future of Data Sharing:** The distinction between different types of health data (e.g., discharge reports, patient summaries) may become less relevant as systems evolve to support more holistic and patient-centric records. Trends are likely to shift towards ensuring data quality, relevance, and accessibility.

OTHER ASPECTS: Achieving Sustainability in the Digital Health Market

- **Ensuring Sustainability:** Sustainability can be achieved through regulatory support, encouraging innovation within a framework that protects patient data privacy, and ensuring that digital health solutions are accessible and equitable.

²⁴ https://health.ec.europa.eu/system/files/2024-01/ehn_mi_guidelines_en.pdf

- **Encouraging Innovation:** The EU should continue to foster an environment that balances innovation with strict data protection standards. Initiatives that promote research and development, along with funding and incentives for startups, are vital.
- **Public-Private Partnerships:** Optimizing these partnerships involves clear regulatory guidance, mutual benefit sharing, and collaboration in areas like research, technology development, and infrastructure provisioning.
- **Adapting Regulatory Frameworks:** The EU needs to remain flexible and responsive to technological advancements, updating regulations to support sustainable innovation while ensuring patient safety and data protection. The EHDS is one step in that direction but will need to be followed-up with Implementing Acts to ensure common adoption and standardised implementation across European countries.

Exploring these common elements through research, policy development, and stakeholder engagement is essential for advancing the EU's digital health objectives. These aspects not only highlight the challenges and opportunities within the current landscape but also point towards the collaborative efforts required to build a more integrated, efficient, and patient-centred digital health ecosystem across the EU. Continuous dialogue among stakeholders, including policymakers, healthcare providers, technology developers, and patients, will be essential for refining these strategies and implementing effective solutions.

A dynamic definition of EHR systems, centred on the medical data rather than the medical purpose, might focus on these systems as digital collections of patient and population health information in a structured and unstructured format. These records are designed to store data over time, offering a comprehensive view of health histories, treatments, and outcomes. This definition emphasizes the role of EHR systems as repositories of diverse health data types, capable of supporting various healthcare processes through data analytics, sharing, and reporting, irrespective of the specific medical purposes they serve. EHDS regulation indicates EHR as one of the data sources for secondary use. With this in mind, standardization of EHR shall ideally consider not only primary use (for treatment of the individual) but also the potential secondary use cases (however, this is out of scope in this document).

Core Functions of an Interoperable EHR system in a European cross-border setting

The core functions of an Interoperable EHR system in a European cross-border setting, as aligned with the EHDS regulation, eHN guidelines, and other European initiatives, encompass a set of technical specifications and capabilities designed to ensure seamless, secure, and efficient exchange of health data across EU MS. These core functions are crucial for enabling cross-border healthcare services, facilitating patient mobility, and ensuring continuity of care across the EU. Below is a detailed description of these functions:

Interoperable Data Exchange and Structured Data Representation

The EEHRxF facilitates the exchange of structured and unstructured, and coded (fully or partially) and uncoded health data among EU MS, including patient summaries, electronic prescriptions, electronic dispensations, medical images and reports, laboratory results, and discharge reports.

The format supports structured data representation for precise, machine-readable data exchange, enabling the parsing and understanding of exchanged health data by receiving EHR systems or other health applications.

Semantic Interoperability with Controlled Lists and Coding Systems

Semantic interoperability is achieved using standardized data, terminology, and controlled lists (Value Set Catalogues), ensuring that health information retains its meaning across different health systems and languages.

This includes the adoption of coding systems for medications (e.g., ATC, EDQM, UCUM and ISO IDMP / EMA SPOR codes), medical procedures, and health conditions, facilitating accurate and consistent interpretation of health data.

Data Protection and Security Measures

Implementing strict data protection and security measures in line with the GDPR and other relevant EU directives (e.g., eIDAS for electronic identification) to safeguard personal health data during cross-border exchanges.

This includes mechanisms for patient identification, authentication, and authorization, ensuring secure access to health information.

Technical Standards and Interoperability Requirements

Adherence to technical requirements and interoperability standards, including the use of international health informatics standards (e.g., HL7 FHIR, DICOM for medical imaging) to facilitate interoperable health data exchange.

The guidelines also emphasize the importance of testing, audit, and quality standards to ensure reliable and efficient interoperability of EHR systems across EU MS.

Stakeholder Engagement and Education

Engaging healthcare providers, IT professionals, policymakers, and patients in the implementation process to address interoperability barriers and ensure the system meets the needs of all stakeholders.

Providing education, training, and awareness programs to enhance the understanding and effective use of cross-border eHealth services.

Support for Multilingualism

Facilitating the translation of health data to support the provision of healthcare services to patients in a language they understand, thereby improving the quality of care and patient safety during cross-border healthcare interactions.

These core functions highlight the comprehensive approach taken by the EU to achieve interoperability of EHR systems in a cross-border context, ensuring that patients can receive highquality, seamless healthcare services as they move across EU MS.

To achieve a high level of interoperability in the European cross-border setting for EHR systems, several standards and protocols are utilized across different levels of interoperability. These levels include foundational, structural, semantic, and organizational interoperability, each addressing specific aspects of data exchange and integration. Below, we detail the standards and protocols relevant to each level of interoperability within the EU context, specifically aligning with the EHDS regulation, eHN guidelines, and other European directives and regulations.

Foundational Interoperability

- **Protocols and Standards:** HTTPS, SSL/TLS for secure data transmission.
- **Purpose:** Ensure basic connectivity and secure communication channels between EHR systems across borders.

Structural Interoperability

- **Standards:** HL7 FHIR (Fast Healthcare Interoperability Resources), HL7 CDA, IHE XDS (CrossEnterprise Document Sharing).
- **Purpose:** Ensure the structured exchange of health information and documents in a standardized format that both sending and receiving systems can understand.

Semantic Interoperability

- **Terminology Standards:**(ICD-10 and ICD-11 for the classification and coding of diagnoses, symptoms and procedures for claims processing, SNOMED CT for clinical terms, LOINC for laboratory tests and results, ATC for medication codes for disease classifications, and EMDN for medical devices.
- **Controlled Lists and Catalogues:** Value Set Catalogues for specific enumerations and allowable values in data exchange.
- **Purpose:** Ensure that the data exchanged between systems can be accurately interpreted and used meaningfully by the receiving system, preserving the clinical intent and meaning of the data.

Organizational Interoperability

- **Standards and Guidelines:** eHN guidelines, European Interoperability Framework (EIF), Implementing acts under the EHDS regulation.
- **Purpose:** Address policy, legal, and social aspects of interoperability, ensuring that organizational processes and regulations across EU MS support seamless health data exchange.

Technical Considerations and Specific Protocols

- **Data Exchange and APIs:** HL7 FHIR is recommended for API development for healthcare applications, enabling granular access to parts of the health record.
- **Security and Privacy:** eIDAS (Electronic Identification, Authentication, and Trust Services) for secure electronic transactions across EU MS, GDPR for data protection and privacy.
- **Interoperability Testing and Conformance:** IHE profiles and testing tools, Conformance and Interoperability Testing Services (CITS) for ensuring systems meet specified standards.

Adoption Levels and Use Cases

- The adoption of these standards should be tailored to specific use cases such as e, Patient Summaries, Laboratory Results, and Medical Imaging Studies, as highlighted in the EEHRxF and specific eHN guidelines.
- The EHDS proposal outlines the structured and unstructured data exchange formats, emphasizing detailed technical specifications for structured data, including data fields, data types, and coding systems, to support direct interoperability.

Implementing these standards across the various levels of interoperability is critical for achieving a harmonized and efficient cross-border health data exchange in Europe. It supports not only the technical aspects of interoperability but also ensures that the systems are aligned with EU-wide policies and legal frameworks, facilitating a cohesive digital health ecosystem.

6.3.2 Recommendations for Commission Implementing Acts

Considering the challenges identified in the implementation and interoperability of EHR systems within the EU, the following sections detail both the analysis of existing issues and formulate recommendations for Commission Implementing Acts under the EHDS regulation.

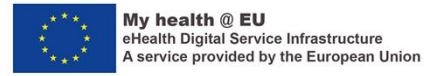
Note that Implementing acts must include a roadmap for adoption that explicitly references implementation stages for achieving maturity and compliance with the preferred standards, related to the readiness level of the majority of the MS. The suggestions below should be taken with caution, as most EU countries might not be able to implement the recommended standards in the short term. Thus, the adoption of standards needs to be leveraged against the cross-border data exchange needs and relative resources of each country. MS-managed bodies such as eHMSEG should be consulted before any practical decisions are taken.

- **Uniform Interoperability Standards:**
 - The current landscape of EHR systems across the EU is characterized by a disparate adoption of interoperability standards, leading to significant barriers in seamless health data exchange across MS.
 - The Implementing Act should mandate the uniform adoption and implementation of interoperability standards and preferred code systems across MS. Such standards need to be vetted against real MS needs and capabilities. It should specify the adoption timeline, transition support mechanisms, and a framework for ongoing updates and compliance monitoring.
- **Cross-Border Data Exchange Mechanisms:**
 - Inconsistent capabilities and mechanisms for cross-border health data exchange hinder the EU's vision for a cohesive health data space, affecting patient care and health service delivery for individuals moving across borders.
 - The Implementing Act should establish detailed protocols and technical requirements for cross-border health data exchange, focusing on key data categories (e.g. ePrescription and PS). The Implementing Act should also outline the roles and responsibilities of national authorities and service providers in supporting these mechanisms.

- **Technical and Security Specifications:**
 - Divergent levels of technical maturity and security measures in EHR systems across MS raise concerns about data security and integrity.
 - The Implementing Act should specify the minimum technical and security requirements for EHR systems, including data encryption, user authentication, and access control. The Implementing Act will provide guidelines for national authorities to certify EHR systems against these standards.
- **EHR System Certification:**
 - The absence of a harmonized EU-wide certification process for EHR systems contributes to variability in system quality, interoperability, and security.
 - The Implementing Act should establish an EU-wide certification scheme for EHR systems to ensure compliance with interoperability, data protection, and technical standards. The Implementing Act should outline the certification process, criteria, and responsible bodies, facilitating mutual recognition of certifications across MS.
- **Governance and Monitoring:**
 - Inadequate governance structures at both EU and national levels impede the effective oversight, monitoring, and enforcement of EHR systems' compliance with established standards.
 - The Implementing Act should create comprehensive governance frameworks for the oversight of EHR systems' deployment and standards compliance, including mechanisms for regular monitoring, reporting, and corrective actions as necessary.
- **Stakeholder Engagement and Training:**
 - Limited engagement and training opportunities for key stakeholders, including healthcare providers and patients, hinder the widespread acceptance and effective use of EHR systems.
 - The Implementing Act should mandate stakeholder engagement strategies and comprehensive training programs for healthcare providers, patients, and IT professionals. The Implementing Act should outline requirements for MS to develop and implement these programs, ensuring broad awareness and competent use of EHR systems.
- **Support for Innovation and Research:**
 - Current limitations on the use of primary health data for research and innovation (i.e. secondary purposes of use) restrict the potential for advancements in healthcare technologies and treatments.
 - The Implementing Act should facilitate the ethical use of anonymized health data for research and innovation, this Act sets forth standards and procedures to protect data



privacy while promoting healthcare innovation. It encourages MS to support research initiatives leveraging EHR data, aligning with EU ethical standards.



7 Conclusion

The landscape of EHR systems in the EU is at a key turning point, with significant potential for transformation and growth across the EU. The advancements in digital health, driven by regulatory changes such as the EHDS Regulation and technological innovations, promise to enhance the efficacy, accessibility, and personalization of healthcare. However, realizing this potential will require concerted efforts to address existing challenges, particularly in interoperability, data privacy, and system adoption. As we move forward, Europe's focus must remain on leveraging EHR systems, not only to improve healthcare delivery, but also to empower patients and foster a data-driven approach to health and wellness. The journey towards a unified and efficient digital health ecosystem in the EU seems complex but achievable, with promising prospects for the future of healthcare. A jointly agreed roadmap adopted at EU and broader level, are the stepping stones for the journey.

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- **9 Appendices**

9.1 Appendix I – Overview of EHR Systems' Implementation in Europe

The data in the Table 29. Below categorizes EHR system coverage into three levels: Low, Moderate, and High. Each level represents the extent to which EHR systems are integrated and cover healthcare providers within each country.

Criteria for Coverage Level and Interoperability Score:

- **Coverage Level:**
 - **High Coverage:** Nationwide or full coverage, indicating extensive integration across healthcare providers.
 - **Moderate Coverage:** National or mixed coverage, showing significant but not complete integration.
 - **Low Coverage:** Regional or limited coverage, suggesting minimal integration.
 - **Unknown:** Insufficient information to categorize.
- **Interoperability Score:**
 - **High:** Advanced interoperability, strong adherence to international standards (e.g., HL7, FHIR).
 - **Moderate:** Partial adherence to standards and mixed levels of data structure.
 - **Low:** Limited interoperability, primarily unstructured data, minimal adherence to international standards.
 - **Unknown:** Insufficient information to categorize.

These rankings are a way to quantify the qualitative data provided in the "Interoperability of national Implementation" column for easier comparison and analysis.

Table 29. EHR Systems Implementation in Europe including information on the adoption of primary categories of data, as proposed by the EHDS Regulation

Country	EHR Coverage	Coverage Level	Interoperability Score	Number of EHR Systems	Data Standards Used	IPS Compliant	Implemented Priority Categories
Austria	National (nationwide coverage)	High	High	1	HL7 CDA, IHE profiles, national standards, SNOMED	NO	Electronic Prescriptions, Electronic Dispensations, Medical Images and Reports, Laboratory Results, Discharge Reports
Belgium	Nationwide coverage	High	High	1	National standards transitioning towards HL7 FHIR	YES	Patient Summaries, Electronic Prescriptions, Electronic Dispensations, Medical Images and Reports, Laboratory Results, Discharge Reports
Bulgaria	Regional (Limited major urban areas only)	Low	Low	Not specified	National standards	NO	None
Croatia	National (nationwide for certain categories)	Moderate	Moderate	1	Based on FHIR and HL7 ver 3, Local adaptations of HL7 HRN ENV 13606	YES	Patient Summaries (partially), Electronic Prescriptions (partially), Electronic dispensations (partially), Laboratory Results, Discharge Reports
Cyprus	National (nationwide for)	High	Unknown	1	HL7 FHIR (pilot), national standards	YES (pilot)	Electronic Prescriptions, Electronic Dispensations,

	certain data categories)						Medical Images and Reports (partially)
Czech Republic	Regional (Major cities and regions)	Low	Low	In development	national standards (DASTA), HL7 CDA, FHIR and IHE in preparation	YES	Patient Summaries (cross border), Electronic Prescriptions, Electronic Dispensations, Medical Images and Reports (partially)
Denmark	National (nationwide coverage)	High	High	1	HL7, national standards	YES	Patient Summaries, Electronic Prescriptions, Electronic Dispensations, Medical Images and Reports, Laboratory Results, Discharge Reports
Estonia	National (nationwide coverage)	High	High	1	HL7 CDA, partially based on FHIR, X-Road for national exchange	Partial	Patient Summaries (cross border), Electronic Prescriptions (cross border), Electronic Dispensations, Medical Images and Reports, Laboratory Results, Discharge Reports
Finland	National (nationwide coverage)	High	High	1 (Kanta Services)	HL7 (CDA, FHIR, MR), IHE, SNOMED, national standards	Partial	Patient Summaries, Electronic Prescriptions, Electronic Dispensations, Medical Images and Reports, Laboratory Results, Discharge Reports

France	National (nationwide coverage)	High	High	1	National standards, HL7 CDA, FHIR, IHE	YES	Patient Summaries, Electronic Prescriptions, Electronic Dispensations, Medical Images and Reports, Laboratory Results, Discharge Reports
Germany	Regional (Regional initiatives, moving towards national)	Low	Low	Multiple, including ePA	National (gematik) standards, HL7 FHIR	YES	Patient Summaries, Electronic Prescriptions, Electronic Dispensations, Medical Images and Reports, Laboratory Results, Discharge Reports
Greece	Regional (Limited major urban areas only)	Low	Low	1	HL7 CDA, HL7 FHIR, HL7 V2, national standards, SNOMED CT, TLS v1.2	YES	Patient Summaries (cross border), Electronic Prescriptions (national and cross border), Electronic Dispensations
Hungary	National (expanding beyond urban areas)	High	Moderate	~60	HL7 CDA, ISO 13606-1:2008, national EESZT system, various code systems	NO	Electronic Prescriptions (national), Electronic Dispensations (national)
Ireland	National (in process of implementation)	High	Low	Multiple, in development	National standards	YES	Electronic Prescriptions, Medical Images and Reports, Laboratory Results, Discharge Reports

Italy	Regional (Varied by region, decentralized system)	High	High	1 (indexing system of regional EHR)	National standards, HL7 CDA, IHE profiles, ICD9-CM, ATC, LOINC	YES	Patient Summaries, Electronic Prescriptions, Electronic Dispensations, Medical Images and Reports, Laboratory Results, Discharge Reports
Latvia	Regional (Urban areas predominantly)	Low/Moderate?	High	Not specified	National standards, HL7 VS	YES	Electronic Prescriptions
Lithuania	National (nationwide coverage)	High	High	1 (ESPBI)	National standards, HL7	Partial	Patient Summaries, Electronic Prescriptions, Electronic Dispensations, Medical Images and Reports, Laboratory Results, Discharge Reports
Luxembourg	National (nationwide for key healthcare services)	Moderate	Moderate	1	DICOM, HL7, IHE	YES	Patient Summaries, Electronic Prescriptions, Electronic Dispensations, Medical Images and Reports, Laboratory Results, Discharge Reports
Malta	National (nationwide efforts underway)	Moderate	Moderate	In process of implementation	DICOM, HL7 CDA R2, HL7 FHIR (in development), HL7 v3, IHE profiles, OpenEHR, SNOMED CT, national terminologies	Partial	Patient Summaries (partially), Electronic Prescriptions (partially), Electronic Dispensations (partially), Medical Images and Reports, Laboratory Results, Discharge Reports

Netherlands	National (nationwide coverage)	High	High	Multiple, decentralized	HL7 CDA/FHIR, DICOM, HL7 V3, IHE profiles, SNOMED	Partial	Patient Summaries, Laboratory Results
Norway	National (nationwide coverage)	High	High	1	National standards, HL7 FHIR, IHE XDS, ebXML	Partial	Patient Summaries, Electronic Prescriptions, Electronic Dispensations, Medical Images and Reports, Laboratory Results, Discharge Reports
Poland	National (Major cities and expanding)	Moderate?	High	1	National standards, HL7 (based on CDA, FHIR)	NO	Electronic Prescriptions, Electronic Dispensations, Laboratory Results, Discharge Reports
Portugal	National (nationwide coverage)	High	High	1	National standards, IHE, HL7 V2, CDA	Partial	Patient Summaries, Electronic Prescriptions, Electronic Dispensations, Medical Images and Reports, Laboratory Results, Discharge Reports
Romania	National (nationwide coverage)	High	Moderate	1	National standards, starting to adopt HL7	Partial	Patient Summaries, Electronic Prescriptions, Electronic Dispensations, Discharge Reports
Slovakia	National (nationwide coverage)	High	High	1	National standards (combined with ISO 13606)	NO	Patient Summaries, Electronic Prescriptions, Electronic Dispensations, Discharge Reports

Slovenia	National (nationwide initiatives)	High	Moderate	1	IHE XDS, Open EHR, national eHealth infrastructure (based on FHIR on demographic data)	YES	Patient Summaries, Electronic Prescriptions, Electronic Dispensations, Medical Images and Reports (partially), Laboratory Results (partially), Discharge Reports (partially)
Spain	National (nationwide coverage)	High	High	Multiple, regional	National standards, HL7 V2, HL7 FHIR, HL7 CDA, OpenEHR	NO	Patient Summaries, Electronic Prescriptions, Electronic Dispensations, Medical Images and Reports, Laboratory Results, Discharge Reports
Sweden	National (nationwide coverage)	High	High	2-3 core systems (no national)	National eHealth services standards, international semantic code systems, HL7 (eP, eD based on FHIR)	NO	Patient Summaries, Electronic Prescriptions, Electronic Dispensations, Medical Images and Reports, Laboratory Results, Discharge Reports

Table 30. Summary of several aspects of EHR Systems Implementation in Europe

Use of Electronic Health Record	Use of Data Standards	Use of cross-border services within MyHealth@EU	Coverage of EHR systems
Countries implementing national EHR systems (1 or more)	Countries implementing HL7 FHIR - based standards / transition to FHIR (ongoing/in prepar.)	Countries implementing Patient Summary	National coverage
Austria	Croatia Austria Belgium	Croatia	Austria
Belgium	Cyprus Czech Republic	Czech Republic	Belgium
Croatia	Denmark Malta	Estonia	Croatia
Cyprus	Estonia	France	Cyprus
Denmark	Finland	Luxembourg	Denmark
Estonia	France	Malta	Estonia
Finland	Germany	Netherlands	Finland
France	Greece	Portugal	Hungary
Germany	Lithuania	Spain	Ireland
Greece	Netherlands		Lithuania
Hungary	Norway		Luxembourg
Italy	Poland		Malta
Lithuania	Slovenia		Netherlands
Luxemburg	Spain		Norway
Norway	Sweden		Poland
Poland	/		Portugal
Portugal			Romania
Romania			Slovakia
Slovakia			Slovenia
Slovenia			Spain
Spain			Sweden

Countries 1) not using national EHR system/s, 2) national EHR system/s in preparation	Countries implementing HL7 CDA or CDA-based standards / other HL7 versions (V2, V3, RIM, ...)	Countries implementing ePrescriptions	Regional coverage
Netherlands Sweden Czech Republic Ireland Malta	Austria Denmark Croatia Estonia Finland Finland Greece France Ireland Greece Italy Hungary Malta Italy Latvia Luxembourg Luxembourg Malta Netherlands Netherlands Portugal Poland Romania Portugal Spain Spain Sweden /	Croatia Estonia Finland Poland Portugal Spain	Bulgaria Czech Republic France Germany Greece Italy Latvia
No information provided	Countries using National Standards / other standards (IHE, SNOMED, OpenEHR, DICOM, ISO 13606, LOINC, EDI, ...)	Countries not yet implementing cross-boarder services within MyHealth@EU	Local coverage
Bulgaria Latvia	Austria Austria Belgium Croatia Bulgaria Cyprus Croatia Czech Republic Cyprus Denmark	Austria Belgium Bulgaria Cyprus Denmark	

Czech Republic	Estonia	Germany
Denmark	Finland	Greece
Finland	Greece	Hungary
France	Hungary	Ireland
Germany	Ireland	Italy
Greece	Italy	Latvia
Hungary	Lithuania	Lithuania
Ireland	Luxembourg	Romania
Italy	Malta	Slovakia
Malta	Netherlands	Slovenia
Latvia	Norway	Sweden
Lithuania	Poland	
Luxembourg	Portugal	
Netherlands	Slovakia	
Norway	Slovenia	
Poland	Spain	
	Sweden	
Portugal		
Romania		
Slovakia		
Slovenia		
Spain		
Sweden		