XpanDH

Expanding Digital Health through a pan-European EHRxF-based Ecosystem

# D3.4 – (D3.2.2) Readiness Model evaluation process report

## WP3 – Organizational readiness

## 31.07.2024

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| **What did this document aim to achieve?** | This document is designed to guide individual organizations, including healthcare providers and vendors, how to use the Readiness Model (RM) and evaluate their readiness for adopting the European Electronic Health Record exchange Format (EEHRxF). It enables the organizations to systematically evaluate their preparedness for EEHRxF adoption, addressing key legal, organizational, technical, and care delivery aspects. |
| **Present the main methodological approaches in bullet point format** | |
| **What were the main findings or take-away messages? What implications does it have for the XpanDH project?** | |
| **Which project stakeholder group would benefit the most from the document and why?** | |

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# Deliverable Abstract

This document describes the European Electronic Health Record exchange Format (EEHRxF) Readiness assessment process, taking into account artefacts from maturity levels defined by Hospital on FHIR (Fast Healthcare Interoperability Resources), Antilope (Adopting New Technologies in the Lifecycle of Electronic Health Records) and Euro-CAS (European Clinical Application Suite), and considering HIMSS (Healthcare Information and Management Systems Society) maturity models especially the Electronic Medical Record Adoption Model (EMRAM) and Continuity of Care Maturity Model (CCMM). Based on the framework defined in *D3.2-(D3.1.2) - Final version of the X-Bundle Readiness Model* the result of Task 3.1, this assessment process is designed to guide individual organizations, including healthcare providers and vendors, how to use the Readiness Model (RM) and evaluate their readiness for adopting the European Electronic Health Record exchange Format (EEHRxF). It enables them to systematically evaluate their preparedness for EEHRxF adoption, addressing key legal, organizational, technical, and care delivery aspects.

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# List of abbreviations and definitions

| Acronym | Description |
|---|---|
| Antilope | Adopting New Technologies in the Lifecycle of Electronic Health Records |
| CASforEU | Conformity Assessment Scheme for Europe |
| Digital Transformation of Health and Care | A part of Digital Single Market empowering citizens and building a healthier society |
| EEHRxF | European electronic health record exchange format |
| EHDS | European health data space |
| eHDSI | eHealth digital service infrastructure |
| eHDSI Member State Expert Group (eHMSEG) | Composed of Technical, Semantic or Organization Experts according to the configuration, nominated by the participating Member States. It performs the operational impact assessment |
| eHealth | The World Health Organization defines eHealth as the use of information and communication technologies (ICT) for health |
| eHealth Digital Service Infrastructure (eHDSI) | The term used for the generic and core services for the cross-border health data exchange under the Connecting Europe Facility financing |
| Electronic Health Record (EHR) | A collection of longitudinal medical records or similar documentation of an individual in digital form. This set of health information based on the principle one EHR per patient in a country |
| Electronic Health Record Exchange Format (EHRxF) | Seeks to facilitate the cross-border interoperability of EHR, currently being developed by EC, the recommendation released in 2019 |
| ePrescription (eP) | A system allowing to prescribe and dispense medicinal products. It is generally understood as a prescriber's ability to electronically create an accurate, much less error-prone and understandable prescription. The electronic prescription may be either directly sent to a pharmacy or to an ePrescription vault from where every pharmacy can retrieve it. ePrescription may be also used by nurses to administer medicines and by pharmacies to review orders and manage the supply of medicines |
| epSOS | European Patients Smart Open Services |
| Euro-CAS | European Clinical Application Suite |
| FHIR | The HL7 FHIR (Fast Healthcare Interoperability Resources) standard defines how healthcare information can be exchanged between different computer systems regardless of how it is stored in those systems. It allows healthcare information, including clinical and administrative data, to be available securely to those who have a need to access it, and to those who have the right to do so for the benefit of a patient receiving care. The standard is developed by HL7 (Health Level Seven) using a collaborative approach. |
| GDPR | REGULATION (EU) 2016/67 general data protection regulation |
| Health Care Provider (HCP) | An individual healthcare professional or a healthcare institution licensed to provide medical care |

| | |
|---|---|
| Health Level 7 (HL7) | HL7 is a standards development organization, publishing a set of standards for the exchange, integration, sharing, and retrieval of electronic health information. These standards define how information is packaged and communicated from one party to another, setting the language, structure and data types required for seamless integration between systems. |
| HIMSS | Healthcare Information and Management Systems Society |
| HIT | health information technology |
| International Statistical Classification of Diseases and Related Health Problems, Tenth Revision (ICD) | The purpose of the ICD is to permit systematic recording, analysis, interpretation and comparison of mortality and morbidity data collected in different countries or areas and at different times. The ICD is used to translate diagnosis of diseases and other health problems from words into an alphanumeric code, which permits easy storage, retrieval and analysis of the data |
| Interoperability | The ability of different systems, organizations or countries to exchange (health) information and use it meaningfully. That means the participants must be able to understand and interpret the shared information correctly, which basically means using the same standards and processes to provide an eHealth service |
| Logical Observation Identifiers Names and Codes (LOINC) | A terminology for laboratory and clinical observations to send clinical data electronically |
| NIS / NIS2 | Network and information systems / The "NIS 2 Directive," or simply "NIS2," is a European Union directive that specifies cybersecurity requirements that need to be implemented by EU companies that are considered to be critical infrastructure. |
| Patient Summary | A standardized set of basic medical data that includes the most important clinical facts (e.g. allergies/intolerancies, chronic conditions) required to ensure safe provision of healthcare. This summarized version of the patient's medical data gives health professionals the essential information they need to provide care in the case of an unexpected or unscheduled medical situation (e.g. emergency or accident) |
| Refined eHealth European Interoperability Framework (ReEIF) | Provides a common framework of terms and methodologies that serves as a key instrument to address eHealth interoperability issues |
| X-Bundle | The so-called X-bundles, an aggregation of interoperability assets that support the connection of health systems in different ways, based on EEHRxF specifications. |
| Zero Trust | Zero Trust is a security model based on the principle of maintaining strict access controls and not trusting anyone by default, even those already inside the network perimeter. |

# Executive summary

The project XpanDH aims at mobilizing and building capacity in individuals and organizations to create, adapt and explore purposeful use of interoperable digital health solutions based on a shared adoption of the European Electronic Health Records Exchange format (EEHRxF) across Europe

*Task 3.2 Develop the readiness model evaluation process feedback loop* provides a framework to evaluate organizations' readiness for EEHRxF adoption through a readiness model that integrates legal, organizational, and technical requirements for interoperability. It covers Laboratory Result Report and Discharge Report use-cases, emphasizing stakeholder roles and engagement. The readiness model evaluation process framework builds upon *D3.3-(D3.2.1) - Intermediate readiness model evaluation process*, the result of *Task 3.1 Define the X-Bundle Readiness model*. It comprises a Readiness Model for Organizations (RMO) and a Readiness Model for Vendors (RMV).

The recommended process to healthcare providers for using the RMO aims to deepen the understanding of the specific challenges encountered when applying the EEHRxF. This evaluation seeks to identify common obstacles and potential solutions to improve the implementation and effectiveness of EEHRxF.

IT vendors may be interested in assessment according to the EEHRxF Readiness Model to be able to provide EEHRxF-enabled applications - such as electronic health records (EHR), health information exchange (HIE), and other digital health solutions - to healthcare providers.

**Key action points of further improvements:**

- Define scoring schemes for calculating scores from the responses of the Readiness Surveys.
- Further refine the Readiness Model and the Evaluation Process Framework for the Laboratory Report, Hospital Discharge Report, and Diagnostic Imaging Report use cases. Prerequisites include:
  - detailed semantic models of the report for the given medical domain.
  - a supporting tool to check the conformance of software products to the EEHRxF specifications and semantic models.

**Continued work until the end of project:**

Significant feedback on the Readiness Model for Organisations (RMO) and the related processes has been received, particularly during the EC alignment call on July 23rd, 2024. However, due to the limited time elapsed, we were not able to incorporate the requested changes.

*WP3 – Organisational Readiness* will work on further refinements on both Readiness Models, as well as the related processes and guidance, throughout the remaining duration of the project.

# 1 Introduction

The level of maturity level of healthcare organizations in terms of their digital capabilities is particularly critical, when it comes to the successful exchange of medical data. This is because the level and type of guidance required depend significantly on how ready each organization is from both a technical and organizational standpoint. For the scope of this deliverable, we are addressing the digital maturity of healthcare systems across various organizations, regions, and countries within the context of cross-border health data exchange.

When determining the maturity level, it is essential to consider the regulatory and operational characteristics specific to each member country. This includes understanding how healthcare data will be exchanged, the connection to common protocols, and identifying the entry and exit points of data flow. In addition the peculiarities of connecting countries with decentralized or mixed health systems also should be addressed.

Furthermore, it shall be assessed whether healthcare providers are at a technologically adaptable and interoperable level, ensuring they meet the required security standards. The success of sharing medical data among different organizations, regions and countries hinges on convincing stakeholders that the system maintains consistency and guarantees robust data protection.

In summary, evaluating the digital maturity of healthcare systems is essential for ensuring seamless data exchange, compliance with security standards based on Zero Trust, and fostering trust among stakeholders, thereby facilitating efficient and secure cross-border healthcare collaboration.

# 2 Maturity models

The maturity model is an assessment framework used to measure an organization's capacity for continuous improvement in a given discipline. Maturity models assess different aspects relevant to capabilities, such as people, processes and technology.

## 2.1 HIMSS maturity models

HIMSS (Healthcare Information and Management Systems Society) maturity models are frameworks used to assess and guide the maturity level of healthcare organizations in their adoption and implementation of health information technology

(HIT) and electronic health records (EHRs). HIMSS has developed several maturity models tailored to different aspects of healthcare IT.[1]

The HIMSS maturity models typically consist of a series of stages or levels through which healthcare organizations progress as they enhance their IT capabilities and infrastructure. These models provide a structured approach for organizations to evaluate their current state, set goals for improvement, and track their progress over time.

Some of the key HIMSS maturity models include:

- Electronic Medical Record Adoption Model (EMRAM): This model focuses on Electronic Medical Record (EMR) adoption and assesses an organization's capabilities across eight stages, from completely paper-based processes to fully integrated electronic systems. This maturity model is most relevant for the EEHRxF Readiness Model because several stages require (semantic) interoperability.[2]
- Continuity of Care Maturity Model (CCMM): This model focuses on the seamless exchange of patient information across care settings to support coordinated and patient-centred care delivery. CCMM also measures public health capabilities based on the primary data.[3]
- Analytics Maturity Model (AMAM): The AMAM helps healthcare organizations assess their capabilities in utilizing data analytics to improve decision-making, clinical outcomes, and operational efficiency.[4]
- Infrastructure Adoption Model (INFRAM): The INFRAM evaluates an organization's infrastructure capabilities, including its networking, security, and data centre operations, to support the delivery of healthcare services.[5]
- Clinical & Business Intelligence Maturity Model (C&BI MM): This model assesses an organization's maturity in leveraging clinical and business intelligence tools to derive insights from data for strategic decision-making and performance improvement.[6]

[1] https://www.himss.org/what-we-do-solutions/maturity-models
[2] https://www.himss.org/what-we-do-solutions/maturity-models-emram
[3] https://www.himss.org/what-we-do-solutions/digital-health-transformation/maturity-models/continuity-care-maturity-model-ccmm
[4] https://www.himss.org/what-we-do-solutions/digital-health-transformation/maturity-models/adoption-model-analytics-maturity-amam
[5] https://www.himss.org/what-we-do-solutions/maturity-models-infram
[6] https://www.researchgate.net/profile/Jorge-Gomes-4/publication/328317440_Information_System_Maturity_Models_in_Healthcare/links/5bc75560a6fdcc03c789a911/Information-System-Maturity-Models-in-Healthcare.pdf

- Population Health Management (PHM) Maturity Model: This model focuses on assessing an organization's capabilities in managing the health of populations, including risk stratification, care coordination, and patient engagement.[7]

These maturity models serve as valuable tools for healthcare organizations to benchmark their progress, identify areas for improvement, and prioritize investments in IT infrastructure and capabilities to better support patient care delivery and organizational goals.

## 2.2 Artefacts from maturity level of Hospital on FHIR, Antilope and Euro-CAS

When assessing the maturity level of a hospital's integration capabilities using standards like FHIR (Fast Healthcare Interoperability Resources), Antilope (Adopting New Technologies in the Lifecycle of Electronic Health Records), or Euro-CAS (European Clinical Application Suite), there are several artefacts or indicators that can be considered at different levels of maturity. Here's how you might evaluate each:

Maturity levels defined by Hospital on FHIR:

- Basic level: At this level, the hospital might have basic FHIR capabilities implemented, such as being able to retrieve patient demographics or access basic clinical data.
- Intermediate level: The hospital could demonstrate more advanced FHIR capabilities, such as supporting additional FHIR resources like observations, medications, and diagnostic reports.
- Advanced level: At this level, the hospital could demonstrate seamless interoperability with other systems using FHIR, including bidirectional data exchange and support for more complex FHIR resources like care plans, allergies, and immunizations.

Artefacts indicating maturity might include:

- FHIR Server implementation and capability to serve FHIR resources.
- Adoption of FHIR profiles and extensions to represent institution-specific data models.
- Use of SMART on FHIR for integrating third-party applications.
- Implementation of FHIR subscription and event notification mechanisms.

Antilope was a Thematic Network of core European National organizations supporting the adoption and testing of existing eHealth standards and specifications

[7] https://www.himss.org/resources/himss-population-health-management-and-capabilities-model

ad defining an eHealth interoperability framework. Based on the results and recommendations in the Hitch project the network has been set up to promote and drive adoption of testing guidelines as well as testing tools on a European and national level.

It has defined the following maturity levels:

- Basic level: At this stage, the hospital may have started evaluating Antilope concepts and assessing its applicability to their electronic health record (EHR) system.
- Intermediate level: The hospital might have initiated pilot projects or small-scale implementations of Antilope principles within their EHR environment.
- Advanced level: Hospitals at this stage would have fully integrated Antilope standards into their EHR systems, demonstrating comprehensive interoperability and lifecycle management capabilities.

Artefacts might include:

- Documentation of Antilope-compliant data models and data element definitions.
- Implementation of Antilope-conformant workflows for EHR lifecycle management.
- Integration with external systems using Antilope-based messaging and data exchange.

Euro-CAS (European Clinical Application Suite) has been created to develop the sustainable Conformity Assessment Scheme for Europe (CASforEU) and to promote the adoption and take-up of interoperability testing of eHealth solutions against identified eHealth standards and profiles defined in the Refined eHealth European Interoperability Framework (ReEIF).

It has defined the following maturity levels:

- Basic level: Hospitals might have evaluated Euro-CAS and started aligning their clinical applications with Euro-CAS standards.
- Intermediate level: The hospital could have begun implementing Euro-CAS-compliant modules or functionalities within their clinical systems.
- Advanced level: Hospitals fully embracing Euro-CAS would have extensive integration across various clinical applications and demonstrate seamless interoperability following Euro-CAS guidelines.

Artefacts indicating maturity might include:

- Adoption of Euro-CAS data models and terminology standards for clinical documentation.
- Implementation of Euro-CAS interfaces and communication protocols for interoperability.

- Integration of Euro-CAS-compliant decision support systems and clinical decision-making tools.
- Assessing maturity levels using these standards involves evaluating not only the technical capabilities but also the extent of adoption and integration within the hospital's overall IT ecosystem and clinical workflows.
- CCMM and EMRAM are both frameworks developed by HIMSS to assess and guide healthcare organizations in their adoption and implementation of health information technology (HIT) and electronic health records (EHRs). While they serve different purposes, they are both aimed at improving the quality and efficiency of patient care through the use of technology.
- The "circle of trust" paradigm promoted by epSOS (European Patients Smart Open Services), eHDSI (European Health Data Space Initiative) and myHealth@EU refers to a concept in healthcare interoperability and data sharing within the European Union. This paradigm emphasizes the establishment of trusted relationships among various stakeholders involved in exchanging health data across borders and different healthcare systems. It is further explored in Chapter 3 below.

# 3 Aspects of interoperability

## 3.1 Levels of interoperability

Interoperability refers to the capacity of different systems to exchange, interpret and use data in a coherent and meaningful manner. Within the healthcare sector, interoperability means that various healthcare systems can seamlessly exchange and use health information to support patient care, public health purposes and research endeavours.

The European Interoperability Framework identifies four distinct levels of interoperability:

- Technical: facilitates machine-to-machine communication
- Semantic: ensures the exchange of data with unambiguous meaning[8]
- Legal: addresses the ability of organizations operating under different legal frameworks to collaborate effectively.
- Organizational: pertains how organizations cooperate to achieve their mutually agreed-upon objectives.

[8] Stage 6 of HIMSS EMRAM mandates the implementation of semantic interoperability to make the integration of structured data from external sources into the medical record of the patient possible

## 3.2 "Circle of trust" paradigm

The figure below shows the vision of the X-Bundle. If this approach is successful, it is necessary to extend it to all stakeholders in the health data space. If we want to implement this as a general practice, then the method tested in epSOS should be used. This means the circle of trust model instead of the peer-to-peer communication.

Key aspects of the "circle of trust" paradigm:

- Interoperability Framework: The circle of trust operates within a broader interoperability framework, which sets standards and guidelines for the secure exchange of health data among different healthcare organizations, systems, and countries.
- Trusted Relationships: At the core of the circle of trust are trusted relationships established among participating actors, including healthcare providers, patients, healthcare authorities, and other relevant stakeholders.
- Data Governance and Security[9]: The paradigm emphasizes robust data governance and security measures to ensure the confidentiality, integrity, and privacy of health data throughout its lifecycle. This includes adherence to regulations such as the General Data Protection Regulation (GDPR) in the European Union.
- Consent and Authorization: Patients play a central role in the circle of trust by granting consent and authorization for the sharing of their health data across different healthcare settings and jurisdictions. Transparency and patient empowerment are key principles in this regard.
- Technical Standards and Infrastructure: The circle of trust relies on standardized technical protocols and infrastructure to enable seamless interoperability and data exchange. This may include the use of common data models, terminologies, and communication protocols such as HL7 FHIR (Fast Healthcare Interoperability Resources).
- Cross-Border Data Exchange: One of the main objectives of the circle of trust is to facilitate cross-border exchange of health data within the European Union, enabling continuity of care for patients who seek treatment or healthcare services in different Member States.
- Compliance and Accountability: Participating entities are expected to comply with relevant legal and regulatory requirements, as well as adhere to established best practices and guidelines for data sharing and interoperability. Accountability mechanisms ensure that data handling practices are transparent and accountable.

[9] Stage 7 of HIMSS EMRAM obliges hospitals to implement policies and governance guaranteeing data security

- Promoting the acceleration of implementation: This aspect emphasizes the importance of rapidly advancing and adopting the necessary measures and technologies to make the system effective. This ensures that the benefits of interoperability and secure data sharing can be realized as quickly as possible to improve patient care and support public health initiatives.
- Overall, the circle of trust paradigm represents a collaborative approach to healthcare interoperability and data sharing, with a focus on building trust, ensuring data privacy and security, and promoting seamless exchange of health information to support patient care and public health initiatives across borders within the European Union.

## 3.3 Guarantee compliance with the "circle of trust" paradigm

Methods and tools for sharing for data practices in the implementation of construction of national and European health data spaces need to be simple and user-friendly, and they must guarantee the privacy of citizens, as well as data security. This is facilitated by the NIS2 Directive, which provides for measures to ensure a high common level of cybersecurity across the EU and which each Member State is obliged to implement in its own legal order. This NIS2 Directive is the EU-wide legislation on cybersecurity. It provides for legal and security measures to increase the overall level of cyber security in the EU.

The EU cybersecurity rules introduced in 2016 (Directive (EU) 2016/1148 of the European Parliament and of the Council) were updated by the NIS2 Directive (Directive (EU) 2022/2555 of the European Parliament and of the Council) that came into force in 2023. It modernised the existing legal framework to keep up with increased digitisation and an evolving cybersecurity threat landscape. By expanding the scope of the cybersecurity rules to new sectors and entities, it further improves the resilience and incident response capacities of public and private entities, competent authorities and the EU as a whole.

The Directive on measures for a high common level of cybersecurity across the Union (the NIS2 Directive) provides legal measures to boost the overall level of cybersecurity in the EU by ensuring:

- Member States' preparedness, by requiring them to be appropriately prepared against cybersecurity threats, for example, with a Computer Security Incident Response Team (CSIRT) and a competent national network and information systems (NIS) authority.
- cooperation among all the Member States, by setting up a Cooperation Group to support and facilitate strategic cooperation and the exchange of information among Member States.

- a culture of security across sectors that are vital for our economy and society and that rely heavily on ICTs, such as energy, transport, water supply, financial market infrastructures and healthcare.

Businesses identified by the Member States as operators of essential services in the above sectors will have to take appropriate security measures and notify relevant national authorities of serious incidents. Key digital service providers, such as search engines, cloud computing services and online marketplaces, will have to comply with the security and notification requirements under the Directive.

## 3.4 Acceptance levels for X-Bubbles

As defined in the D3.1.1 XpanDH Acceptance Areas document, X-Bubbles are collections of organizations committed to experimenting with the use of EEHRxF within a defined acceptance area and under the conditions defined by the X-Bundle. These use cases can be implemented if the resulting data exchange between partners ensures that each X-Bubble adopts and demonstrates the use of digital solutions within their respective adoption areas while meeting the Network and Information Systems (NIS) audit assurance level of 'high'.

This aspect is particularly critical, as the functional expectation is relatively simple, but highly dependent on each organization's technical and organizational readiness. The experimentation scenarios envisaged in the X-Bubbles of the XpanDH project are illustrated in Figure 1. The XpanDH X-Bubbles encompass six bubbles, each related to six adoption areas deemed relevant for the broad adoption of the EEHRxF, taking into account the available resources and experimentation capacity. Currently, these bubbles involve four countries: Hungary, Portugal, Greece, and Slovakia.

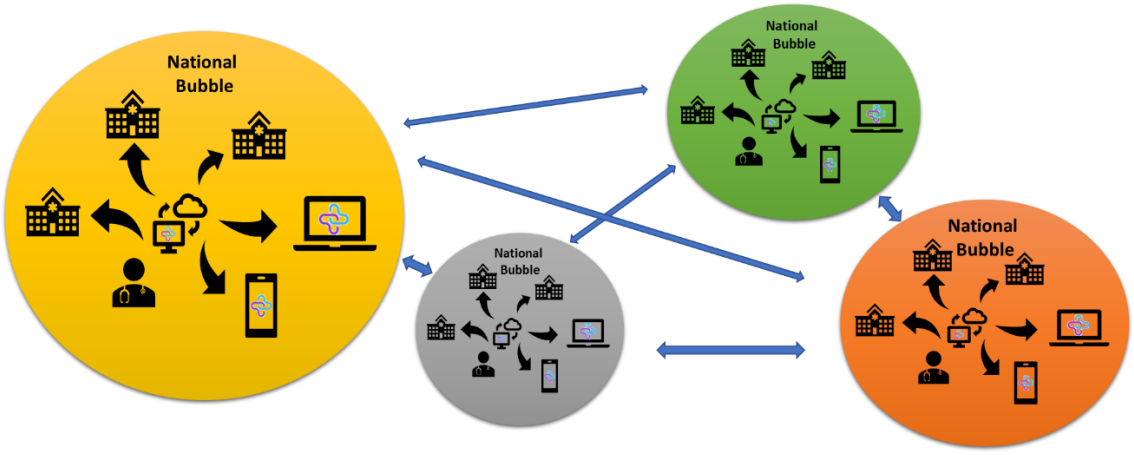


*Figure 1.: XpanDH landscape and project vision*

## 3.5 User-centric approach and multilingualism

Considerations regarding the technical support of standards are complex, as they must address multiple, often conflicting expectations simultaneously. The technological interoperability of the standards analysed relies on the availability of the necessary technical documentation for their implementation and their broad acceptance within specific domains. A significant reference for this is the established practices within countries, with substantial evidence from the semantic and syntactic communication standards interface in this report and their work on communication between HealthData@EU nodes.

A critical decision point involves determining whether the content of the data access application or data request should contain low-level, accurate information. This necessitates a standard for cataloguing the data source at the metadata or data dictionary level. Once a decision is made, the conclusions on communication standards in the report may require some adjustment. It is also important to note that the architecture of HealthData@EU is still under discussion, and it is not known whether the final architecture may influence the conclusions and recommendations of this report.

Sharing structured and highly encoded data is manageable, as it can be relatively easily translated into another language. However, documents containing free-text descriptions require automatic translation using AI tools (e.g., deep learning models, large language models), which may serve only informal purposes and not be suitable as the basis for (emergency) medical care. Such translations can be highly valuable for patients who do not speak the language of the document.

E-health technologies can empower patients by providing access to health information, enabling appointment scheduling, offering telemedicine consultations, facilitating health monitoring through wearable devices, granting access to electronic health records, and supporting participation in online communities. Patients need to play an active role in managing their health and well-being, leveraging technology to enhance their engagement in their healthcare.

For patients, the EEHRxF aims to improve the interoperability and exchange of electronic health records, ultimately benefiting them through better care coordination, increased patient safety, greater empowerment, and streamlined access to healthcare services, both domestically and across European borders.

However, this is contingent on patients having the ability to make choices about sharing their health data. Therefore, it is crucial that cross-border data access is part of the right to self-determination in health data. This should also be made possible through mobile apps or by granting permission via a proxy.

For instance, if data stored in the Hungarian EESZT (National eHealth Infrastructure) is downloaded in PDF format, the integrity of the data can be greatly enhanced by

electronic signing and time-stamping. Additionally, it should be possible to translate the downloaded data into various languages.

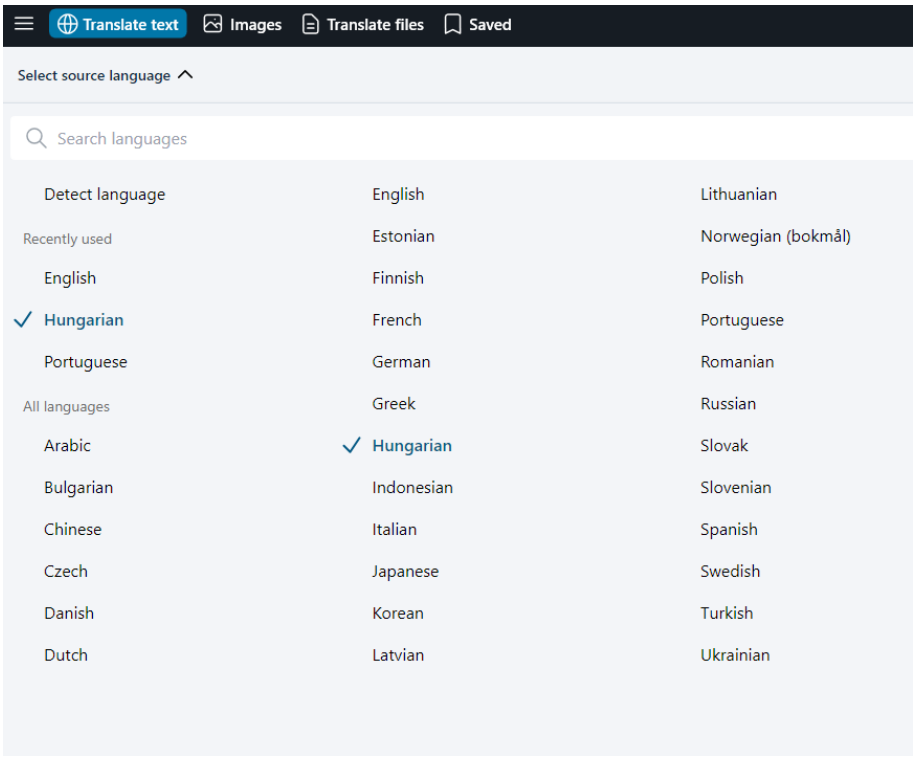


***Figure 2.: Different languages are available in one of the best-known language translators and apps***

# 4 Readiness Model survey

With EHDS Regulation now voted on by the EU Parliament and coming into force, the new EHR interoperability landscape leveraging the EEHRxF is likely to present digital health ecosystem stakeholders with new and complex challenges.

Although the EEHRxF, as defined in Article 6 of Regulation (EU) 2016/679, requires further definition and publication in the form of implementable technical specifications, it is evident that it will include:

- datasets containing electronic health data and defining structures for the content representation of clinical content and other components of the electronic health record;
- coding systems and values to be used in datasets containing electronic health data;
- technical specifications for the exchange of electronic health data, including its content representation, standards and profiles.

While the implementing acts defining such implementable technical specifications are anticipated by 2026, it is imperative to accelerate adoption and preparation based on existing eHealth Network guidelines, MyHealth@EU interoperability assets, and the ISO International Patient Summary standard.

In previous chapters, we examined how selected EC projects leverage the interoperability of core data sets to enhance continuity of care for patients, provide value to health systems, and expand data sets for reuse. Some projects are already using the EEHRxF, others plan to adopt it, while some are working with supplementary data sets for specific use cases.

This Readiness Model survey aims to capture the expected impact of the EEHRxF on current interoperability use cases, in terms of the most pursued benefits from using the EHRxF in the short, medium and long term and identifying the major barriers to using the EEHRxF today.

The survey should be completed by organizations, which are affected by the EEHRxF in daily practice, in particular, organizations that are treating patients and thus are using systems for recording or reading clinical healthcare data.

Disclaimer: The Readiness Model survey is intended to be filled from the perspective of the invited organizations. However, multiple persons may be engaged in answering the questions of the survey. In that case, please name all persons in the respective question in the "Introduction" section. In case a question contains the wording of "you", it's meant the organization's perspective rather than the personal one of the answering person.

# 5 Recommended process for using the Readiness Model for healthcare providers

This chapter introduces the recommended process for using the Readiness Model, aiming to deepen our understanding of the specific challenges encountered when applying the EEHRxF. Through this evaluation, we seek to identify common obstacles and potential solutions to improve the implementation and effectiveness of EEHRxF.

## 5.1 Phase 0: Preparation for decision making

The initial phase in the recommended process for using the Readiness Model is the "Preparation of Decision Making." This crucial phase occurs when an organization is contemplating the adoption of the EEHRxF and deciding to evaluate itself by utilising the Readiness Model. In this phase, the organization must decide whether to conduct a structured evaluation of its readiness and capacity to implement EEHRxF using the Readiness Model.

Key activities in this phase include:

Assessment of organizational needs and goals: the organization begins by identifying its specific needs, objectives, and the potential benefits of adopting EEHRxF. This involves understanding how EEHRxF can enhance interoperability, improve patient care, and align with the organization's strategic goals.

### *Stakeholder engagement*

Engaging key stakeholders, including leadership (hospital directors, strategic and development directors), IT personnel, healthcare providers, and administrative staff, is essential. Their input and support are crucial for a successful adoption process. Stakeholders should be informed about the goals and potential impacts of EEHRxF implementation.

### *Readiness evaluation decision*

The organization decides whether to conduct a thorough evaluation of its current capabilities, resources, and infrastructure using the Readiness Model. This involves considering the technical, organizational, and process-related aspects that will be assessed to determine the level of preparedness for adopting EEHRxF.

### *Risk and benefit analysis*

Analysing the potential risks and benefits associated with EEHRxF adoption helps the organization make an informed decision. This includes understanding the challenges that may arise during implementation and the strategies to mitigate them.

*Final decision making*

Based on the preliminary assessment and readiness evaluation decision, the organization makes an informed choice on whether to proceed with a detailed readiness evaluation and subsequently adopt EEHRxF. This decision should be supported by a clear understanding of the organization's preparedness, potential challenges, and anticipated benefits.

## 5.2 Phase 1: First contact with the Readiness Model

### 5.2.1 Who is getting aware of the survey?

The Readiness Model survey for the EEHRxF is designed to engage and raise awareness among a diverse range of stakeholders within the healthcare and health IT sectors. These stakeholders include:

- Healthcare Providers and Organizations: hospitals, clinics, and healthcare professionals who will be using the EHR systems.
- Health IT Vendors: companies that develop and supply electronic health record systems and related technologies.
- Policy Makers and Government Agencies: officials and bodies involved in healthcare policy and regulation within Europe.
- Research and Academic Institutions: universities and research organizations focusing on health informatics, public health, and related fields.
- Patients and Patient Advocacy Groups: end-users of EHR systems who have a vested interest in the interoperability and exchange of health records.
- Standards Development Organizations: groups involved in developing and promoting standards for health information exchange.
- European Union Institutions: including the European Commission, which supports and funds initiatives related to digital health and interoperability.
- Professional Associations and Networks: organizations representing healthcare professionals and IT specialists, such as the European Society of Radiology or the European Health Telematics Association.
- Key decision makers:
    - Hospital directors
    - Strategic and Development Directors
    - Strategy and strategy managers.
    - For private sector organizations: the owner of the organization.

These stakeholders are crucial for providing input, feedback, and support for the development and implementation of the EEHRxF, ensuring it meets the needs of the healthcare ecosystem in Europe.

### 5.2.2 How can key players of stakeholders be involved in responding to the EEHRxF Readiness Model survey?

To effectively engage key stakeholders in responding to the EEHRxF Readiness Model survey, a strategic and multi-faceted approach should be taken. This approach includes targeted advertisements, specific programs, government outreach, and incentive initiatives. Below are detailed strategies for each involvement method:

*Targeted advertisements:*

- Digital Campaigns: Utilize social media platforms, professional networking sites like LinkedIn, and health-related websites to reach healthcare providers, IT vendors, and professionals.
- Email Newsletters: Send targeted newsletters to stakeholders who are already part of healthcare networks or professional associations.
- Print Media: Advertise in medical journals, magazines, and newspapers that are widely read by healthcare professionals and administrators.

*Specific programs:*

- Webinars and Workshops: Organize online webinars and in-person workshops to explain the EEHRxF readiness model, its benefits, and how to complete the survey. These can be done in collaboration with professional associations.
- Conferences and Symposia: Present the readiness model survey at major healthcare and IT conferences to reach a broad audience.
- Educational Campaigns: Develop and distribute educational materials such as brochures, infographics, and video tutorials explaining the EEHRxF and the importance of the readiness survey.

*Government outreach:*

- Official Communications: Governments can send official communications to healthcare organizations, IT vendors, and professional bodies to encourage participation.
- Public Service Announcements (PSAs): Use PSAs on television, radio, and online platforms to inform and encourage participation from all stakeholders, including patient organizations.

- Collaboration with Professional Bodies: Work with professional healthcare and IT associations to disseminate information and encourage their members to participate.

*Engagement programs and informing for the patient organizations:*

- Town Hall Meetings: Hold virtual and in-person town hall meetings with patient organizations to explain the EEHRxF and the importance of their input.
- Focus Groups: Conduct focus groups with representatives from patient organizations to gather their input and encourage them to spread the word.
- Newsletters and Emails: Send informative newsletters and emails to patient organizations outlining the readiness model and the significance of their participation.

*Incentive programs:*

- Financial Incentives: Provide grants or financial rewards to healthcare organizations and IT vendors that complete the survey and meet certain readiness criteria.
- Certification and Recognition: Offer certifications for organizations that participate in the survey and demonstrate high levels of readiness, which can be used as a mark of quality.
- Technical Support and Training: Provide free or subsidized technical support and training sessions to help organizations prepare for the EEHRxF implementation.
- Access to Resources: Give participating organizations access to exclusive resources, such as advanced tools for EHR implementation and best practice guidelines.
- Pilot Programs: Offer opportunities to participate in pilot programs that provide early access to EEHRxF functionalities and support.

By combining these strategies, key stakeholders can be effectively engaged in the EEHRxF Readiness Model survey. Through targeted advertisements, specific educational programs, government outreach efforts, and various incentive programs, stakeholders will be well-informed and motivated to participate, ensuring comprehensive and valuable feedback for the EEHRxF initiative.

### 5.2.3 Dimensions

The EEHRxF Readiness Model survey aims to engage a wide range of public and private organizations to secure comprehensive and diverse feedback. The survey targets several key categories of stakeholders through both top-down and bottom-up approaches:

- State bodies and European Union institutions,
- Ministries of Health of all EU Member States,
- National Institutes of Public Health and agencies,
- Regional and local health authorities,
- Regional and national health authorities responsible for health care and policy implementation,
- Local health authorities and municipalities,
- European Committee for Standardisation (CEN),
- International Organisation for Standardisation (ISO),
- Private organisations and public Healthcare providers,
- Large hospital networks and health systems,
- Hospitals and primary care practices,
- Specialist centres,
- Health IT vendors,
- EHR system providers,
- Telemedicine and digital health companies,
- Professional associations,
- Patient organizations,
- Academic and research institutions.

By incorporating a diverse array of public bodies and private organizations in the EEHRxF Readiness Model survey ensures that feedback is comprehensive, and representative of the different stakeholders involved in healthcare and digital health innovation. This approach will help identify gaps, understand different perspectives and ensure successful implementation and adoption of EEHRxF across Europe.

## 5.3 Phase 2: Planning, who is filling the different parts of the survey

### 5.3.1 Survey structure and responsibility allocation:

### Survey design and coordination:

- Lead Department: Digital Health Division or Health IT Unit within the Ministry of Health.
    - Responsibilities:
        - Oversee the entire survey process.
        - Ensure alignment with EEHRxF goals.
        - Coordinate with other departments and external stakeholders.

### Survey sections and responsible departments

*Technical Infrastructure and Interoperability:*

- Responsible Department: IT Department / Health Informatics Division
- Responsibilities:
  - Assess current IT infrastructure.
  - Evaluate interoperability capabilities.
  - Identify gaps in technical readiness.

*Data Privacy and Security:*

- Responsible Department: Data Protection Office / Legal Department
- Responsibilities:
  - Ensure compliance with GDPR and other relevant regulations.
  - Review data security measures.
  - Assess readiness for secure data exchange.

*Clinical and Operational Readiness:*

- Responsible Department: Clinical Operations / Quality Assurance
- Responsibilities:
  - Evaluate clinical workflows.
  - Assess integration of EHR into daily operations.
  - Identify training needs for clinical staff.

*Stakeholder Engagement and Training:*

- Responsible Department: Human Resources / Training and Development
- Responsibilities:
  - Plan training programs for staff.
  - Engage with stakeholders (patients, clinicians, IT staff).
  - Collect feedback from end-users.

*Policy and Governance:*

- Responsible Department: Policy and Planning Division
- Responsibilities:
  - Ensure alignment with national and EU health policies.
  - Establish governance frameworks.
  - Define roles and responsibilities for implementation.

*Financial and Resource Planning:*

- Responsible Department: Finance Department
- Responsibilities:
  - Budget for necessary upgrades and training.

- Identify funding sources.
- Monitor financial impact and Return On Investment (ROI).

### 5.3.2 Survey analysis and decision-making:

#### Survey Review Committee:

- Composition:
  - Representatives from each responsible department.
  - External experts (e.g., from academia or industry).
  - Patient organization representatives.
- Responsibilities:
  - Review and validate survey responses.
  - Identify cross-departmental dependencies and overlaps.
  - Make recommendations based on survey findings.

#### Time-schedule planning:

- Preparation Phase (Month 1-2):
  - Define survey objectives and scope.
  - Design survey structure and questions.
  - Assign responsibilities and form the Survey Review Committee.
- Data Collection Phase (Month 3-4):
  - Distribute survey to relevant departments.
  - Provide guidance and support for survey completion.
  - Organize workshops/webinars for clarifying survey details.
- Analysis Phase (Month 5-6):
  - Collect and compile survey responses.
  - Conduct preliminary analysis by individual departments.
  - Review findings in Survey Review Committee meetings.
- Reporting and Recommendations Phase (Month 7-8):
  - Prepare a comprehensive report on readiness.
  - Identify gaps and propose solutions.
  - Submit final report to the Ministry of Health and other relevant bodies.

### 5.3.3 Identifying cross-overs and dependencies:

#### Cross-departmental workshops:

- Frequency: Monthly during data collection and analysis phases.
- Purpose: Identify overlaps and dependencies between departments.
- Outcome: Ensure cohesive and integrated responses.

#### Dependency mapping:

- Tools: Use project management software (e.g., MS Project, Trello) to map dependencies.
- Process:
  - Identify tasks requiring input from multiple departments.
  - Highlight areas where departmental responses intersect.
  - Ensure communication and collaboration across departments.

### Regular status updates:

- Method: Weekly progress meetings and status reports.
- Participants: Department representatives and survey coordinators.
- Objective: Monitor progress, address issues, and ensure timely completion.

By following this structured approach, the survey can be effectively completed, ensuring comprehensive data collection and insightful analysis for the EEHRxF readiness model. This will facilitate the successful implementation of interoperable EHR systems across Europe.

## 5.4 Phase 3: Practical Execution Method for Filling the EEHRxF Readiness Model Survey

To ensure a thorough and collaborative approach, the survey will be filled using a series of multi-disciplinary focus-group meetings. This method promotes input from all relevant departments, ensures comprehensive responses, and identifies cross-departmental dependencies.

### Focus-group meetings:

*Multi-disciplinary focus-groups:*

- Composition:
  - Representatives from each responsible department (IT, Legal, Clinical, HR, Policy, Finance).
  - External experts and patient organization representatives as needed.
- Purpose:
  - Discuss and fill out the survey collaboratively.
  - Ensure all perspectives are considered for each section.
  - Identify and address overlaps and dependencies in real-time.

### Stepwise filling per section:

*Structured sessions:*

- Sections:
  - Technical Infrastructure and Interoperability

- Data Privacy and Security
- Clinical and Operational Readiness
- Stakeholder Engagement and Training
- Policy and Governance
- Financial and Resource Planning

- Approach:
  - Each section is tackled in a dedicated session.
  - Focus-groups review and fill out the relevant parts of the survey together.
  - Use of the "Save-as-draft" function to allow for ongoing review and updates.

*Cross-section review sessions:*

- Analyse the Draft Saving:
- Functionality: Regularly use the "Save-as-draft" feature to save ongoing work.
  - Purpose:
    - Allow for continuous input and revisions.
    - Ensure no information is lost.
    - Enable participants to review and update sections as needed.

### Session scheduling:

*Time-schedule:*

- Preparation Phase (Month 1-2):
  - Define objectives and prepare the survey tool.
  - Schedule focus-group meetings and send invitations.
  - Provide preliminary materials and guidelines to participants.
- Data Collection Phase and All responses (Month 3-4):
  - Duration: 1-2 days / weeks
  - Activities: Discuss and fill survey section collaboratively; save draft.

## 5.5 Phase 4: Quality assurance before approval

### Final review and submission:

- Duration: 2 days
- Activities: Conduct a final review of the entire survey; make any last-minute adjustments.
- Process lead reviews the survey and assures quality
- Eventually circles back sections of the survey to focus-groups for refinement

## 5.6 Phase 5: Approval and submission

### Final submission:

- Duration: 1 days
- Activities: Submit the completed survey; ensure all sections are finalized and consistent.
- CxO level approves the survey
- "Submission" function is used for submitting the survey
- If an "incentive" program stood behind this -> leverage the incentive

### Monitoring and follow-up:

- Monitoring Progress:
  - Status Updates: Weekly progress reports and check-ins.
  - Feedback Loop: Continuous feedback from participants to address any issues promptly.

### Follow-up actions:

- Action Plans: Develop action plans based on survey results.
- Implementation: Start planning for implementing identified changes or improvements.

This collaborative and structured approach ensures that the survey is filled comprehensively and accurately, leveraging the expertise of all relevant stakeholders. The use of multi-disciplinary focus-group meetings, stepwise section filling, and the "Save-as-draft" function facilitates a thorough and iterative process, leading to high-quality survey responses and effective planning for the EEHRxF implementation.

# 6 Recommended process for using the Readiness Model for vendors

First of all, several IT vendors might be particularly interested in assessing the European Electronic Health Record Exchange Format (EEHRxF) Readiness Model due to their involvement in the healthcare sector. The large and the SME EHR System Providers especially those focusing on electronic health records (EHR), health information exchange (HIE), and other digital health solutions. These vendors have a vested interest in ensuring their systems are compatible with the EEHRxF and that they can effectively support interoperability across European healthcare systems.

This is a competitive advantage for the providers to be an early adoption and readiness can position these vendors as leaders in the European market.

On the other side the involvement of IT vendors in the effective roll-out of EEHRxF and their link to the Readiness Model will be a major factor in successful preparation. Several strategies can be followed to engage IT vendors: direct solicitations or creating incentives by presenting opportunities. Direct approaches to suppliers should start by encouraging current key IT suppliers to participate in the survey.

This is also justified by the fact that they are the most likely to be involved in the application development transformation of existing systems. Healthcare IT trade networks, specific industry associations and direct professional contacts can be used to this aim. An important incentive for firms to retain existing market relationships and the possibility of involvement can be an aspect of supportive collaboration.

From a methodological point of view, workshops and webinars to explain the EEHRxF, the Readiness Model and the importance of IT vendor participation may be most effective. This could include interactive question and answer sessions to present the expectations of the client side and provide an opportunity for IT suppliers to ask questions and receive clarification on the survey process. IT suppliers could also be included in the multidisciplinary focus groups, and this would help to ensure that their potential contributions are taken into account in the relevant parts of the survey. Gathering feedback from IT suppliers on the structure and content of the survey could provide an indication of the IT suppliers' capabilities, their preparedness and their responses to the transformation expectations. Moving forward, it is necessary to establish professional forums for ongoing consultation and discussion with IT suppliers during the survey process and subsequent regular monitoring.

The ability to use the IT vendors' readiness model means, first and foremost, the ability to align with standards. It is very important that the standards themselves provide clear guidance on how IT vendors can align their systems and services to the EEHRxF standards. To this end, best practices should be taken into account and examples of successful implementations should be shared to better inform the process.

Evaluation tools and feedback mechanism from IT vendors:

- Self-assessment: develop self-assessment tools based on the readiness model to help IT vendors self-assess their current capabilities and identify areas for improvement.
- Benchmarking: Providing benchmarking data to enable vendors to compare their readiness levels against industry standards and competitors. Providing adequate technical resources, documentation and support is very important to ensure that vendors understand and implement EEHRxF requirements.

- Continuous improvement and iteration: Encourage IT vendors to provide continuous feedback on the readiness model and suggest improvements or modifications based on their experience, which does not prevent interoperability considerations and consideration of feedback from other vendors and evolving standards.

Involving IT vendors in pilot programs can accelerate the development and transformation process:

- Early Adoption: Launch pilot programs that enable IT vendors to implement EEHRxF standards in a controlled and separated environment.
- Case studies: case studies of pilot programs to demonstrate the effectiveness and benefits of EEHRxF compliance.
- Training and certification:
    - Special workshops: organizing practical training workshops to educate IT vendors on the technical aspects of EEHRxF.
    - Certification Programs: Develop certification programs that demonstrate suppliers' compliance with EEHRxF standards, giving them a competitive advantage.
- Collaborative partnerships projects:
    - Encourage collaboration between IT vendors, healthcare providers and government agencies to develop and implement EEHRxF-compliant solutions.
    - Establish innovation labs or centres where suppliers can work on EEHRxF projects and share knowledge.

Involvement of IT vendors in the EEHRxF readiness model assessment will be done through a combination of direct invitations, educational workshops, focus groups and consultation forums. Recommendations for use of the readiness model include alignment with standards, self-assessment tools, technical support and ongoing feedback mechanisms. Publicity and specific programmes to promote the adoption of EEHRxF may include digital campaigns, industry publications, social media outreach, pilot programmes, training and certification initiatives, collaborative projects and financial incentives. These strategies ensure that IT suppliers are well informed, motivated and prepared to contribute to and benefit from the implementation of the EEHRxF.