XpanDH

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

D6.3 – D6.2 - Report on EEHRxF new adoption domains

WP6 – Sustainability and Future Action

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What did this document aim to achieve?	This document aimed to identify, evaluate, and structure new EEHRxF adoption domains using a bottom-up, evidence-based methodology, ensuring alignment with governance frameworks (D6.1.1 and D6.1.2) and advancing cross-border healthcare interoperability within the EHDS.
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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List of abbreviations

Acronym	Description
API	Application programming interface
CDA	Clinical Document Architecture
CSS	Common Semantic Strategy
eHAction	eHealth Action
eHN	eHealth Network
EEHRxF	European Electronic Health Records Exchange Format
EHDS	European Health Data Space
eHEIF	eHealth European Interoperability Framework
EHR	Electronic Health Record
FHIR	Fast Healthcare Interoperability Resources
HDR	Hospital Discharge Reports
HL7	Health Level 7
IHE	Integrating Healthcare Enterprise
KPI	Key Performance Indicator
MTB	Multidisciplinary tumour board
SUP	Standardiseret Udtræk af Patientdata
TER	Teleconsultation Encounter Report

Executive summary

Deliverable *D6.3 - Report on EEHRxF new adoption domains* reports on Task 6.2 – *EEHRxF new adoption domains: consumer use case for remote visit, telehealth and telemonitoring* of the XpanDH project, which focuses on identifying and structuring new adoption domains for the European Electronic Health Record Exchange Format (EEHRxF). This work is a pivotal step towards advancing cross-border healthcare interoperability. As emphasised in eHAction *D8.2 - Policy document about technology report*[1], this initiative aims to facilitate the seamless exchange of health information across Member States, enhancing the quality, accessibility, and efficiency of healthcare services in Europe. The recommendations outlined in this deliverable align with the structured governance and asset repository frameworks established in XpanDH deliverables D6.1 - *Governance and operating model for XpanDH asset bundles* and D6.2 - *Published library of documented asset bundles*.

This deliverable explores a methodology to identify new format domains, employing a bottom-up, evidence-based process that translates stakeholder-driven insights into structured recommendations for new domains. The methodology ensures coherence with the governance and asset repository structures defined in previous XpanDH deliverables and includes:

- **Defining Use Cases**: Establishing clear aims, data needs, and standardisation requirements for new adoption domains.
- **Development Planning**: Structuring implementation steps, milestones, and validation strategies.
- **Stakeholder Consultation**: Engaging healthcare professionals, policymakers, industry leaders, and researchers to refine and validate proposed domains.
- **Implementation Considerations**: Ensuring modularity, interoperability, and scalability of new adoption domains within the EEHRxF framework and European Health Data Space (EHDS).

The deliverable identifies **Telehealth**, particularly the **Teleconsultation Encounter Report (TER)**, as a primary new adoption domain. Drawing on the findings of XpanDH's D5.3 - *X-bundle open-source community of the doers* and its Community of Doers (CoD) discussions, this report details how TERs can be structured similarly to **Hospital Discharge Reports (HDRs)** to ensure interoperability and reusability. Denmark's national implementation model is presented as a leading example of structuring and integrating TERs within national and cross-border health data

[1] http://ehaction.eu/wp-content/uploads/2021/06/eHAction-D8.2-Policy-document-about-technology-report-_-for-adoption_19th-eHN.pdf

exchanges. The proposed TER standardisation leverages HL7 FHIR and IHE XDS methodologies to facilitate seamless integration with existing EHR infrastructures.

Additionally, this document outlines other potential EEHRxF expansion domains, drawing from the work of the Community of Doers, including:

- **Multidisciplinary Tumour Boards for Cancer Patients**: Standardising oncology treatment discussions across Member States.
- **ePrescription, eDispensation, and Electronic Product Information**: Enhancing medication safety and cross-border prescription management.

This deliverable contributes to the sustainability of EEHRxF expansion by structuring new domains within the XpanDH **governance and asset repository framework**. Through alignment with XpanDH D6.1 and D6.2, this work ensures that new domains undergo rigorous validation and are seamlessly integrated into the evolving EHDS landscape. The proposed methodology offers a scalable and repeatable approach to digital health transformation, reinforcing the XpanDH project's commitment to fostering cross-border interoperability and sustainable digital health innovation across Europe.

1 Introduction

1.1 Background

The adoption of the European Electronic Health Record Exchange Format (EEHRxF) represents a pivotal step in advancing cross-border healthcare interoperability. This initiative, as emphasised in eHAction D8.2, aims to facilitate the seamless exchange of health information across Member States, enhancing the quality, accessibility and efficiency of healthcare services in Europe. The recommendations outlined by the eHealth Network (eHN) highlight the importance of leveraging iterative approaches and aligning with existing standards, such as IHE Profiles, to address the challenges of interoperability.

Central to this vision is the co-creation approach, which integrates diverse stakeholder perspectives, including policymakers, healthcare providers, patients, and industry leaders. Workshops and teleconferences conducted under the eHAction framework provided critical insights into the barriers and opportunities within adoption domains. These efforts underscored the need for harmonising local initiatives with a universal scope to ensure scalability and sustainability of digital health solutions.

In this context, Task 6.2 of the XpanDH project focused on identifying new adoption domains, with particular emphasis on consumer-oriented use cases such as telehealth, telemonitoring, and remote visits. By building on the foundation established in eHAction D8.2, XpanDH Task 6.2 aimed to provide actionable

methodologies for fostering interoperable solutions that deliver measurable benefits to health systems and citizens alike.

The eHAction D8.2 emphasises the structured process used to engage Member States and stakeholders in developing the EEHRxF. Key activities included a series of workshops and teleconferences, such as the EHRxF workshops, which facilitated consensus on standards like IHE Profiles and proposed iterative approaches for implementation. These consultations highlighted the necessity of building interoperable frameworks that accommodate diverse national systems while aligning with EU-level objectives. For instance, the workshops outlined the inclusion of use cases such as lab results, discharge summaries, and medical imaging, providing a roadmap for enhancing semantic and technical interoperability across Member States.

This deliverable is a critical step in the iterative process leading to the structured approach defined in XpanDH's governance and asset repository framework (XpanDH D6.1 and D6.2). The governance model outlined in D6.1 provides the foundation for the transparent adoption of interoperability assets, ensuring structured development, validation, and sustainable implementation of EEHRxF extensions. Furthermore, XpanDH D6.2 operationalises these principles by cataloguing documented asset bundles into a published library of interoperability resources. Through this document, we align emerging domains of EEHRxF adoption with this overarching governance framework, ensuring that new interoperability use cases can seamlessly integrate into the evolving XpanDH repository. This deliverable serves as a bridge between identifying new domains and formally structuring them into asset bundles for broader adoption under the EHDS framework.

1.2 Scope and objectives

The primary objective of this deliverable is to formalise a methodology for developing new asset bundles that support the next priority adoption domains within the EEHRxF framework. As part of the structured governance model outlined XpanDH in D6.1 and D6.2, this deliverable contributes to identifying, evaluating, and documenting new interoperability domains in alignment with the XpanDH asset repository. This involves:

- Conducting an interoperability needs assessment to identify gaps and opportunities in current frameworks.
- Engaging a diverse group of stakeholders to prioritise adoption domains and use cases based on their relevance and impact.
- Developing a health outcomes benefits case and a health economic assessment to support the creation of robust business cases for adoption domains.
- Proposing an interoperability framework tailored to scaling telehealth and telemonitoring solutions, leveraging insights from the eHAction Common Semantic Strategy (CSS).

This work builds on the X-eHealth specifications and articulates directly with the governance framework introduced in XpanDH D6.1 by ensuring that new domains follow transparent adoption processes and meet asset qualification criteria outlined in D6.2. by applying the eStandards digital compass framework analysis, Task 6.2 ensures that the proposed solutions address the needs of health systems, digital health innovators, and insurance providers. The ultimate goal is to create actionable, interoperable solutions that align with the broader objectives of the EHDS.

Following the asset bundling methodology introduced in XpanDH D6.2, this deliverable contributes to expanding the XpanDH repository by structuring emerging domains into documented, validated asset bundles that can support future EEHRxF extensions. Building on the X-eHealth project—a Horizon 2020 initiative aimed at accelerating the deployment of the EEHRxF through standardisation and harmonisation—this work utilises methodologies and tools developed for laboratory, imaging, discharge report, and patient summary domains. X-eHealth's use-case-driven approach, as detailed in D5.1 - *X-eHealth use cases driven methodology*[2] and D5.6 - *Refine PS functional specifications to account for eHN Guidelines and rare diseases*[3], provides functional specifications and implementable guidelines for HL7 CDA and HL7 FHIR standards. For example, the project's ART-DECOR and FHIR tools have been instrumental in specifying and publishing interoperable templates. These outputs, combined with stakeholder engagement from communities of practice established in WP8, have laid the groundwork for identifying and scaling priority adoption domains such as telehealth and remote monitoring.

The eStandards Digital Health Compass further informs this deliverable by integrating principles of trust, stakeholder alignment, and the reuse of interoperable assets. The compass framework emphasises trust in the dynamic flow of health data, respect for diverse stakeholder perspectives, and iterative co-creation and governance cycles. The eStandards lifecycle—including base standards, use-case-driven sets, and iterative feedback loops—provides a robust foundation for fostering large-scale eHealth adoption. Through this methodology, the XpanDH initiative aligns stakeholder engagement and standards development with the broader objectives of the EHDS, ensuring sustainable digital health transformation.

Through its alignment with the structured governance model of XpanDH D6.1 and the asset documentation strategy of XpanDH D6.2, this deliverable ensures that new EEHRxF adoption domains integrate seamlessly into the XpanDH ecosystem and contribute to a scalable, sustainable digital health infrastructure across Europe.

[2] https://www.x-ehealth.eu/wp-content/uploads/2022/11/D5.1-X-eHealth-use-cases-driven-methodology.pdf
[3] https://www.x-ehealth.eu/wp-content/uploads/2022/11/D5.6-Refine-PS-functional-specifications-to-account-for-eHN-Guidelines-and-rare-diseases.pdf

2 Procedure for development of new asset bundles

2.1 Defining Use Cases

The development of new asset bundles begins with a comprehensive definition of the use case, which serves as the foundational element for all subsequent steps. This process involves:

- **Aims and Rationale**: Clearly articulating the purpose and objectives of the use case, including its anticipated benefits for stakeholders such as patients, healthcare professionals, and policymakers.
- **Data Considerations**: Identifying the types of data required, their sources, and the standards necessary to ensure interoperability. This includes alignment with existing frameworks such as HL7 FHIR, CDA, and IHE Profiles.
- **Standards Considerations**: Ensuring compliance with relevant European and international standards to promote interoperability and scalability.

In alignment with the governance and asset selection principles outlined in XpanDH D6.1, this deliverable follows a structured approach to defining new EEHRxF adoption domains. The governance framework proposed in XpanDH D6.1 ensures that each domain is evaluated against defined quality indicators, including transparency, maturity assessment, and alignment with European interoperability frameworks (EHDS, eHEIF). The approach taken here ensures that all selected use cases meet governance principles that support long-term sustainability and structured adoption.

This initial phase requires close collaboration with stakeholders to ensure that the use case addresses real-world needs and aligns with the broader objectives of the EHDS.

2.2 Development Plan

The development of asset bundles requires a structured and iterative plan, which can be outlined using project management methodologies. Key steps include:

- **Requirement Analysis**: Conducting a detailed assessment of technical, functional, and user requirements.
- **Stakeholder Engagement**: Establishing a mechanism for continuous input and feedback from relevant stakeholders, including patients, healthcare professionals, industry representatives, and policymakers.

- **Milestone Setting**: Defining key milestones and deliverables to ensure progress and alignment with the use case objectives.
- **Resource Allocation**: Identifying and allocating necessary resources, including technical expertise, tools, and financial support.
- **Risk Management**: Anticipating potential risks and developing mitigation strategies to address them proactively.

Regarding Milestone Setting, this deliverable contributes to the structured adoption of EEHRxF domains by ensuring their inclusion into the documented asset bundles described in XpanDH D6.2. As outlined in D6.2, the XpanDH asset repository is designed to systematically categorise and document interoperability assets for structured use within the EHDS ecosystem. To ensure alignment, the development plan outlined in this section adopts the asset selection methodology established in D6.2, ensuring that each domain is evaluated for its relevance, impact, and feasibility of integration into the XpanDH repository.

Furthermore, the approach taken in this deliverable follows the principles of asset cataloguing and structured documentation established in XpanDH D6.2, ensuring that the newly identified EEHRxF domains are not only conceptually validated but also systematically recorded for future deployment. By doing so, this deliverable contributes to the long-term sustainability and integration of these domains into the EHDS framework.

2.3 Tools for Monitoring and Evaluation

To ensure the continuous monitoring and evaluation of development progress, the following tools and methodologies can be employed:

- **Key Performance Indicators (KPIs)**: Establishing metrics to measure progress, quality, and impact.
- **Version Control Systems**: Using tools like GitHub to track changes and updates to specifications.
- **Dashboard Monitoring**: Developing dashboards to provide real-time insights into progress and challenges.
- **Evaluation Frameworks**: Implementing structured frameworks for periodic assessments, including technical reviews, stakeholder feedback sessions, and user acceptance testing.

2.4 Ecosystem Consultation through Co-Creation

Ongoing consultation with the ecosystem is essential to ensure that the development process remains inclusive and responsive. A co-creation approach can be employed, involving:

- **Workshops and Roundtables**: Organising regular events to gather input and foster collaboration among diverse stakeholders.
- **Online Platforms**: Leveraging digital platforms for asynchronous discussions and feedback.
- **Community Engagement**: Establishing dedicated working groups or communities of practice to maintain continuous dialogue and collaboration.

This process not only ensures alignment with stakeholder needs but also promotes a sense of ownership and commitment to the resulting asset bundles.

2.5 Implementation Planning

While the responsibility for detailed implementation planning should remain with individual projects or working groups, this deliverable can outline a high-level process for guiding these efforts:

- **Implementation Strategy**: Defining the key steps for translating asset bundles into actionable solutions, including pilot testing and phased rollouts.
- **Validation Processes**: Establishing mechanisms for technical and functional validation, ensuring compliance with defined standards and requirements.
- **Stakeholder Training**: Providing training and support to ensure smooth adoption and utilisation of the asset bundles.
- **Feedback and Iteration**: Incorporating feedback loops to refine and improve the asset bundles post-implementation.

Within Implementation Strategy, as described in XpanDH D6.2, the X-Bundle registry extends the EHDS specifications beyond regulatory requirements by providing structured repositories for modular and scalable interoperability assets. In this context, the implementation planning outlined in this section integrates reusable components from the EEHRxF domains into structured X-Bundles, ensuring alignment with European interoperability frameworks.

By leveraging the X-Bundle methodology, this document enhances format-building block reusability and ensures the scalability of new adoption domains within the existing EHDS regulatory landscape. This modular approach ensures that EEHRxF components are adaptable across multiple domains, promoting interoperability between Member States while maintaining compliance with evolving EHDS specifications.

By providing this overarching framework, XpanDH can support projects in developing robust implementation plans that align with the goals of the EHDS while allowing flexibility for local adaptation.

3 Proposal for next priority adoption domains

3.1 Telehealth

3.1.1 Introduction to Telehealth Adoption Domain

Telehealth represents a critical domain for advancing the objectives of the EEHRxF within the EHDS. The COVID-19 pandemic underscored the necessity for cross-border telehealth services, including teleconsultations, telemonitoring, and remote healthcare. These services require seamless data exchange to ensure continuity of care, patient safety, and health system efficiency. The XpanDH initiative has leveraged stakeholder engagement, technical frameworks, and policy discussions to formalise a robust methodology for telehealth interoperability, with a specific focus on teleconsultation encounter reports.

3.1.2 The Case for a Teleconsultation Encounter Report (TER)

Building upon insights from the Community of Doers (CoD) working group report (XpanDH D5.3 Annex 5), this deliverable highlights the need for a structured approach to Teleconsultation Encounter Reports (TERs) as part of the EEHRxF framework.

Teleconsultation as an Emerging Data Category

The XpanDH D5.3 Annex 5 identifies TERs as a critical yet underdeveloped component of cross-border interoperability. While hospital discharge letters and clinical notes are commonly shared within national health infrastructures, there is no standardised approach for documenting and exchanging the outcomes of teleconsultations.

Denmark's national model provides a strong use case:

- All discharge letters are uploaded to a national repository using a standard format (SUP), which Denmark is transitioning to EEHRxF.
- Teleconsultation encounters are now considered for integration into the same national infrastructure.
- This model can serve as a blueprint for integrating TERs into EEHRxF and EHDS workflows.
- Interoperability Challenges and Solutions

Currently, TERs lack structured documentation, creating barriers to seamless healthcare coordination.

- XpanDH D5.3 Annex 5 identifies key challenges, including:
    - Limited sharing of TERs across health sectors.
    - Variability in documentation across different healthcare IT systems.
    - Lack of structured templates for teleconsultation documentation.
- Recommended solutions include:
    - Developing a structured template for TERs, based on HL7 FHIR and IHE XDS, ensuring interoperability across healthcare systems.
    - Using EEHRxF to format TERs similarly to hospital discharge reports, enabling their seamless integration into EHDS.
    - Establishing national repositories for TERs, supporting phased adoption of cross-border sharing.
- Implementation Steps for Teleconsultation Encounter Reports

The XpanDH D5.3 Annex 5 outlines a structured implementation plan for TERs, aligning with existing EEHRxF adoption strategies:

1. Pilot Testing: National-level testing of TER templates within secure health data repositories.
2. Integration with EHR Systems: Embedding TER documentation functionality within primary care and hospital IT systems.
3. Expansion to Cross-Border Exchange: Developing TER interoperability profiles for EHDS-based data sharing.
4. Incorporation into EEHRxF: Expanding the scope of EEHRxF to include TERs as a recognised data category.

Key considerations on TERs are outlined below. Comprehensive details should be sought in XpanDH D5.3 Annex 5.

Aim and Rationale

The teleconsultation encounter report aims to standardise clinical documentation of teleconsultations across Member States, ensuring that essential health data flows efficiently and securely between healthcare providers and systems. This will support:

- Continuity of care for patients receiving telehealth services across borders.
- Integration of telehealth data into local/national electronic health record (EHR) systems.

- Enhanced decision-making by healthcare professionals through timely access to comprehensive health information.

Data and Standards Considerations

- **Content:** Key elements of the report include patient identification, teleconsultation details, medical history, diagnostic findings, treatment recommendations, and follow-up plans.
- **Standards:** The teleconsultation encounter report will build on past and existing guidelines such as the epSOS Health Care Encounter Report and HL7 FHIR profiles, ensuring alignment with semantic and technical interoperability frameworks.
- **Exchange:** Secure and interoperable data exchange protocols (e.g., FHIR, HL7, APIs) will be employed to facilitate cross-border data sharing.
- **Development Plan and Project Management**

Steps Taken

1. **Workshops and Stakeholder Engagement**
    - A series of workshops conducted in 2024 facilitated dialogue among stakeholders, including healthcare providers, policymakers, and technical experts, to identify challenges and opportunities in telehealth interoperability.
    - Interactive sessions using tools such as Mentimeter collected insights on enablers, barriers, and potential technical solutions.
2. **Scoping and Methodology Development**
    - A scoping review was conducted that highlighted existing frameworks and gaps in telehealth interoperability, laying the foundation for methodological development. It was submitted for peer-reviewed publication and the manuscript can be found in Annex 1. The scoping review revealed a significant gap in the literature regarding the technical implementation and interoperability challenges of telemonitoring systems, particularly in cross-border healthcare. While some alignment exists around standards such as ISO/IEEE 11073 and HL7 FHIR for local device interoperability, there is a lack of standardised frameworks to facilitate seamless data exchange between different healthcare systems and IT providers at the European level. To bridge this gap, further research, harmonisation efforts, and policy integration—such as embedding telemonitoring

within the EHDS—are essential to ensure scalable, interoperable, and practical telemonitoring solutions across Europe.

- XpanDH Task 6.2 focused on applying the eStandards Digital Compass framework to identify consumer-oriented adoption domains and align with EHDS priorities.

Monitoring Tools

- Regular progress reviews using predefined metrics for data standardisation, technical readiness, and stakeholder engagement.
- Iterative testing phases employing X-Bubbles for feasibility studies, ensuring that frameworks are adaptable and scalable.

Co-Creation and Consultation

- Ongoing consultation with a Community of Doers Working Group on teleconsultation encounter reports, formed as a bottom-up initiative under XpanDH Task 6.2.
- Collaboration with existing EU projects and initiatives, including X-eHealth and xShare, to leverage established methodologies and tools. In total, 79 projects were engaged. The most highly relevant include AIDAVA, eCREAM, Gravitate Health, UNICOM, Procure4Healrth, GenoMed4ALL, CHAIMELEON, POTENTIAL, SMILE, PATHeD, Xt-EHR, xShare. More details can be found in XpanDH D5.2 - *Interoperability Enabler Report*.

Implementation Considerations

While XpanDH defines the process for developing interoperability assets, the responsibility for implementation plans, including validation and deployment, is proposed to rest with Member States or subsequent projects. Key components include:

- Establishing validation frameworks for pilot testing.
- Engaging national health systems to align local EHR integration efforts with EU standards.
- Conducting health economic assessments to support the scalability of telehealth solutions.

3.1.3 Conclusion and Outcomes

The outcome of XpanDH Task 6.2 includes the bottom-up creation of a Community of Doers Working Group on teleconsultation encounter reports, which has provided

a structured approach to integrating telehealth into the EHDS. On this, XpanDH D5.3 Annex 5 offers further details on technical specifications and suggestions to support the adoption of these solutions across Member States.

Format Building Block Reusability

An essential principle in EEHRxF adoption is the reusability of existing format building blocks to accelerate the development of new interoperable data categories. A prime example is the relationship between TERs and Hospital Discharge Reports (HDRs).

D5.3 Annex 5 highlights how TERs share significant structural similarities with HDRs:

- Both document patient encounters and provide key clinical insights to other healthcare professionals.
- Both require structured data fields for diagnosis, treatment decisions, and next steps.
- Both follow the IHE XDS document-sharing model, enabling integration into national repositories.

Modular Adaptation of the Hospital Discharge Report Format

The modularity principle suggests that TERs can be structured using existing components of the HDR format, adapted to include telehealth-specific attributes:

- Encounter Type: Identifying the consultation as a virtual encounter.
- Technical Metadata: Documenting whether the teleconsultation used video, phone, or asynchronous communication.
- Patient Consent & Access Control: Ensuring that patients control who can access TER data, in line with GDPR and EHDS provisions.

Scaling Modularity Across Domains

Applying the format building block reusability principle to TERs ensures rapid implementation while maintaining compatibility with existing EEHRxF components. As new telehealth-related data categories emerge, this modular approach can support scalable interoperability across multiple healthcare domains.

3.2 Other Potential Adoption Domains for EEHRxF Expansion

In addition to telehealth and telemonitoring, XpanDH has identified additional high-priority domains for EEHRxF adoption also through the work of the CoD (XpanDH D5.3). While various possible domains were discussed in different project meetings, understanding their value and the details entailed requires a thorough methodology as already explained. So rather than an extensive list of superficially analysed domains we present two examples of "Other" domains. One is a completely NEW

domain, and the other is an extension of an adoption domain that is actually created out of two data priority categories (ePrescription and eDispensation) but that when expanded with eProduct Information create a value-added service for citizens. These domains address critical interoperability challenges and align with ongoing developments in the EHDS.

3.2.1 Multidisciplinary Tumour Boards for Cancer Patients

We hereby prove the key considerations for the Multidisciplinary Tumour Boards for Cancer Patients focus point. Further details can be found in XpanDH D5.3 Annex 2.

Rationale:

- Multidisciplinary tumour boards (MTBs) are **integral to modern oncology**, facilitating collaborative decision-making among specialists such as oncologists, radiologists, pathologists, and surgeons.
- Despite their importance, MTB workflows **lack standardised digital integration** across hospitals and EU Member States, creating interoperability barriers.
- Existing patient summaries and medical imaging standards **do not fully capture structured MTB discussions and treatment decisions**, leading to fragmented care.

Proposed EEHRxF Integration:

- Development of an **MTB Summary Report** as a new EEHRxF document type.
- Alignment with **oncology-specific HL7 FHIR standards**, ensuring structured recording of treatment plans, diagnostic findings, and clinician recommendations.
- Integration of decision-support tools based on **AI and clinical guidelines**, providing evidence-based recommendations for cancer treatment.

Expected Impact:

- Enhances **cross-border continuity of cancer care**, particularly for patients seeking treatment in different EU countries.
- Facilitates **remote participation in tumour boards**, allowing specialists across Member States to collaborate.
- Reduces **data fragmentation**, ensuring MTB discussions are available within the broader **EHDS framework**.

3.2.2 ePrescription, eDispensation, and Electronic Product Information

We hereby prove the key considerations for the ePrescription, eDispensation and electronic Product Information focus point. Further details can be found in XpanDH D5.3 Annex 3.

Rationale:

- The **ePrescription and eDispensation frameworks** currently in use across Member States **vary significantly**, leading to challenges in cross-border medication reconciliation.
- The **inclusion of structured electronic product information (ePI)** is necessary to provide real-time, interoperable medication data to both **patients and healthcare providers**.
- Existing electronic prescription exchanges **do not systematically integrate pharmacovigilance data**, limiting **real-world evidence collection on medication safety and efficacy**.

Proposed EEHRxF Integration:

- Expansion of **ePrescription and eDispensation** within EEHRxF to support **real-time validation of prescriptions** across EU borders.
- Standardisation of **ePI** using **FHIR-based structured medication records**.
- Inclusion of **pharmacovigilance reporting fields**, enabling automated data collection for medication safety.

Expected Impact:

- Facilitates **seamless prescription and dispensation across Member States**, reducing administrative burdens for cross-border healthcare.
- Enhances **medication adherence and patient safety** by providing structured ePI directly into patients' EHRs.
- Supports **regulatory compliance and monitoring**, integrating pharmacovigilance data with EHDS.

Annexes

Annex 1 – Scoping review

Interoperability of Telemonitoring Data in Digital Health Solutions: A Scoping review[4]

Authors: Diogo Martins, Simon Lewerenz, Anderson Carmo, Henrique Martins

- **ABSTRACT**

Objectives: This scoping review explores the existing literature on the interoperability of telemonitoring systems in cross-border healthcare settings. It focuses on identifying technical standards, enablers, and barriers to effective telemonitoring data exchange across healthcare systems and geographies.

Methods: A systematic search was conducted across databases (MEDLINE, PubMed, ISI Web of Knowledge, DBLP, and Scopus) from January 2000 to May 2023, using keywords such as "telemonitoring", "interoperability", "technical standards", and "cross-border data exchange". Eligibility criteria included peer-reviewed studies examining the interoperability of telemonitoring systems across healthcare providers and cross-border settings. A total of 861 studies were identified, and 25 met the inclusion criteria.

Results: The review identified diverse technical standards, including HL7 FHIR, ISO/IEEE 11073, and IHE profiles, used in telemonitoring systems. However, significant gaps were found in the literature regarding the operational challenges of telemonitoring

[4] Submitted 26 September 2024, Journal: Frontiers in Digital Health, section Health Informatics. Currently under revision.

systems, particularly in cross-border contexts. Many studies focused on technical aspects, with fewer addressing organizational and legal issues. Data transport types, such as Bluetooth and REST APIs, were mentioned, but no common standard for data exchange between devices was identified.

Discussion: The findings highlight the need for further research on the deployment of telemonitoring systems, particularly in cross-border contexts. The lack of harmonization in technical standards poses a barrier to achieving seamless interoperability. The review calls for the development of a robust framework to support telemonitoring integration across healthcare systems.

Conclusions: While telemonitoring shows promise in improving healthcare delivery, significant interoperability challenges remain. Developing common standards at the European level is essential to enhance cross-border telemonitoring services and patient care.

What is already known on this topic: Interoperability challenges significantly hinder the effective integration of telemonitoring systems across healthcare providers and borders. Existing technical standards like HL7 FHIR and ISO/IEEE 11073 are in use but lack harmonisation for cross-border applications. Despite the availability of standards, there is limited understanding of their practical implementation in diverse healthcare settings.

What this study adds: This study identifies specific gaps in the technical, organizational, and legal aspects of telemonitoring interoperability, particularly in cross-border contexts. It highlights the fragmented adoption of interoperability standards and the scarcity of in-depth research on technical implementations.

How this study might affect research, practice or policy: The study calls for the development of a robust and harmonised framework for telemonitoring interoperability, influencing future research, healthcare practices, and policymaking at the European level. It underscores the importance of standardised approaches to accelerate the transition from conceptual studies to practical applications, particularly under the European Health Data Space (EHDS).

- **INTRODUCTION**

Telemonitoring, which involves the remote monitoring of patients' health data via digital devices, has become an integral part of modern healthcare systems, revolutionizing the way patient care is delivered and managed.[1-3] Telemonitoring enables continuous, real-time tracking of patients' physiological parameters, offering numerous benefits. These include cost-effective delivery of healthcare, reduced need for face-to-face consultations and clinic visits, enhanced quality of care, and improved patient self-management and compliance.[4–8] This approach not only alleviates the burden on healthcare systems but also empowers patients to take an active role in managing their health.

Telemonitoring solutions have become particularly important due to several critical factors. The rapid expansion of the aging population necessitates ongoing healthcare support and regular health assessments.[9] Concurrently, the increasing prevalence of chronic diseases requires continuous monitoring and management for affected individuals.[10] Furthermore, the rise in healthcare costs emphasizes the need for cost-effective solutions that can reduce the frequency of in-person consultations and hospital admissions.[9] Telemonitoring addresses these needs by providing real-time health data, and facilitating timely interventions, thus improving overall patient outcomes.

One significant issue with the effective implementation and benefits of telemonitoring is the challenge posed by interoperability and cross-border exchange, especially considering the free movement of individuals within the European Union. Ensuring that telemonitoring systems can seamlessly share and interpret data across different healthcare providers and countries is essential to maintain continuity of care and enhance healthcare delivery across the EU. This is particularly important as all EU citizens and their family members have the right to move and reside freely within the EU, a fundamental right established by Article 21 of the Treaty on the Functioning of the European Union and Article 45 of the EU Charter of Fundamental Rights.[11,12]

According to the Healthcare Information and Management Systems Society (HIMSS), interoperability is defined as the capability of various information systems, devices, and applications to access, exchange, integrate, and collaboratively utilize data efficiently. This has to occur in a coordinated manner both within and across organizational, regional, and national boundaries. The goal is to ensure the timely and seamless transfer of information, ultimately optimizing the health outcomes for individuals and populations worldwide.[13] Interoperability issues can significantly limit or compromise the seamless exchange of health data between different telemonitoring systems, healthcare providers, and countries. Although achieving interoperability is technically feasible for most providers, various technological, organizational, and environmental factors can impede its implementation.[14] This is due to interoperability being a matter affecting a wide range of stakeholders including the public, health professionals, and the private sector [15]. Addressing these challenges is crucial to ensure the effective integration of telemonitoring solutions across diverse healthcare settings, thereby optimizing patient care and enhancing healthcare delivery on a broader scale. Indeed, in a recent review, a key regulatory consideration and policy implication

highlighted was the development of standardized telemedicine practices on a global scale to facilitate cross-broader telehealth[16].

Importantly, the use of technical standards is essential to ensure that diverse devices and applications used for telemonitoring can communicate seamlessly[17] across different health systems in the EU, as previously highlighted by the European Commission in a call for the harmonization of medical device standards[18]. Without standardized protocols, health data captured by telemonitoring devices may not be consistently readable or usable when shared across borders, impeding the continuity of care. Standards for device-to-device interoperability are essential here[17], as they ensure that data generated by various telemonitoring devices can be effectively communicated and processed.

The eHealth ecosystem at European level aims to facilitate safe and efficient cross-border exchange of data for healthcare and research purposes, proposing the European Electronic Health Record Exchange format (EEHRxF) as an EU-wide standard.[19] The HL7 FHIR standard is one of the standards recommended by the eHealth Network for this purpose.[20]The European Health Data Space (EHDS) and the European Electronic Health Record Exchange Format (EEHRxF) aim to address these needs by establishing frameworks that facilitate both the direct communication between devices and the standardized structuring of this information within EHRs[19,20]. These initiatives are crucial in overcoming the technical and semantic challenges that currently limit cross-border telemedicine, paving the way for a more cohesive and reliable healthcare experience for patients and providers across the EU. By elaborating on these points, we emphasize that standards are not merely a technical requirement but a foundational need for secure, efficient, and continuous healthcare across the EU.

The principal aim of this scoping review is to map the existing literature on the interoperability of cross-border telemonitoring services with a focus on technical standards and interoperability issues. Taking such action had previously been called for.[21] By identifying and analysing the enablers and barriers to effective data exchange and integration across different healthcare systems and geographical boundaries, this review seeks to provide a comprehensive understanding of the current landscape. This knowledge will support the development of strategies to overcome interoperability challenges, ensuring seamless, efficient, and patient-centred telemonitoring solutions. Ultimately, the insights gained from this review will inform future research and policy efforts aimed at optimizing telemonitoring services to enhance healthcare delivery and patient outcomes globally.

The main research questions were: (1) What evidence of using interoperable telemonitoring solutions exist and what is its impact on patient care? (2) Which standards or communication protocols between different telemonitoring solutions? (3) Which interoperability frameworks current exists that supports the deploy or understanding on a multi-dimensional level, the implementation of telemonitoring solutions? Thus, our specific objective was to summarize the results of previous studies that focused on technical artifacts or specifications, architecture, standards or guidelines for telemonitoring solutions.

- **METHODS**

This scoping review was performed according to Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) statement.[22]

- **Search strategy**

A literature search was conducted from January 2000 to May 2023 in the following databases: MEDLINE, PubMed, ISI Web of Knowledge, DBLP and Scopus. The following keywords and Medical Subject Headings (MeSH) terms were used:

- Technical standards OR Architecture AND telemonitoring;
- Telemonitoring AND Technical standards OR Telemonitoring AND Architecture;
- Telemonitoring AND standards AND Interoperability;
- Telemonitoring AND FHIR AND Interoperability;
- Telemonitoring AND FHIR AND Interoperability OR telemonitoring data sharing architecture;
- Telemonitoring AND cross country.
- **Eligibility criteria**

Inclusion criteria were full-text research articles written in all languages, with English and Portuguese articles read by the author, and articles in other languages translated as needed. The articles had to be published in peer-reviewed journals and assess telemonitoring solutions, specifically in cross-border settings and cross-organizations. They needed to focus on the benefits, use, and impact of interoperable telemonitoring solutions with different providers or systems, examine technical artifacts or specifications, IT architectures, technical standards or guidelines for telemonitoring solutions, and evaluate the impact and benefits of using telemonitoring solutions based on a common technical framework or international standards. The studies also had to address the enablers and barriers of using telemonitoring solutions in continuous monitoring, non-continuous monitoring, and home care monitoring.

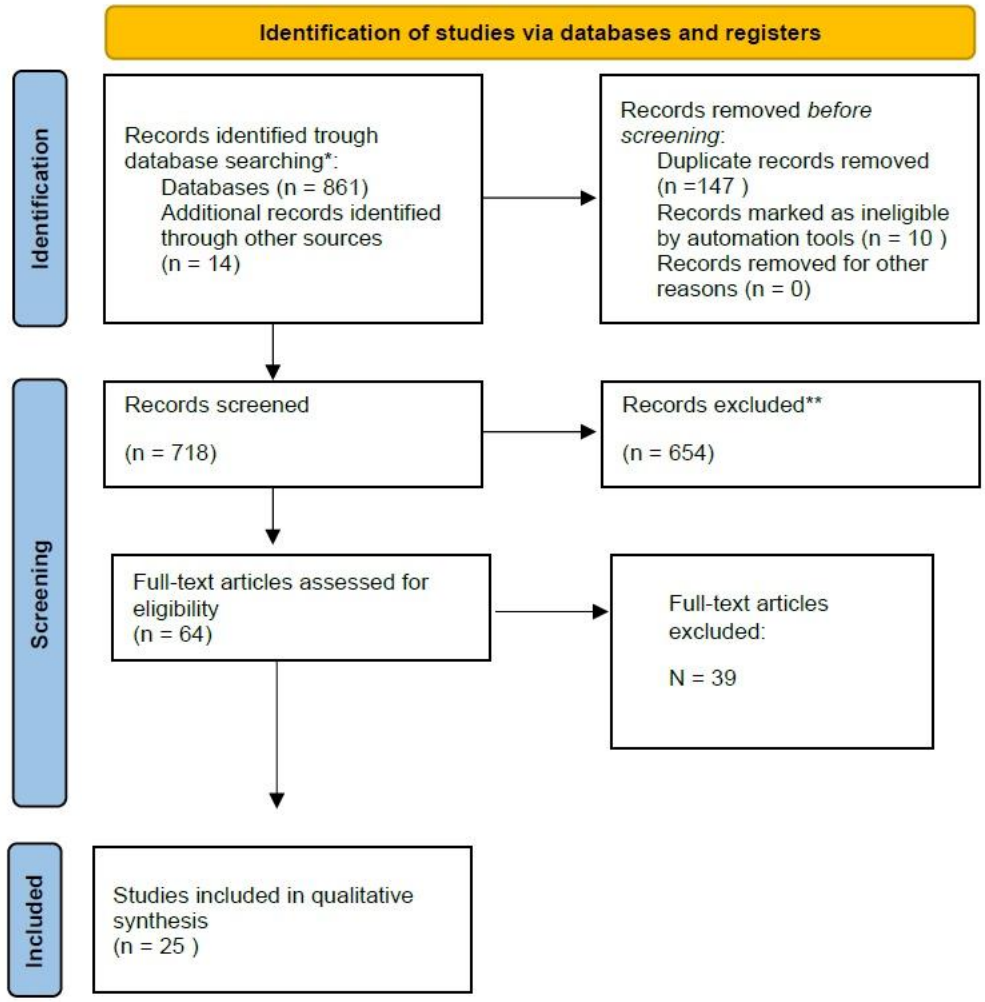
Studies were excluded if they (1) assessed only the benefits of EHRs in general (i.e., did not focus on mobile health records), or (2) assessed the use of telemonitoring solutions in areas not related to healthcare.

- **Study Selection**

Articles were identified through database searches. To identify additional publications, reference lists of identified studies and relevant reviews were manually checked. After duplicates were removed, titles and abstracts resulting from application of the first author search strategy were reviewed for eligibility by a single reviewer according to the eligibility criteria. Uncertainty and doubts were discussed with a third researcher, and a consensus was reached. Potentially relevant studies were identified, and the full texts were obtained. These studies were reviewed and selected for final inclusion according to inclusion and exclusion criteria for full-text review by the first author.

A total of 861 studies were identified from all databases and search methods. After full text-review a total of 25 studies met all criteria and were considered for this review (see Figure 1 and Table 1).

Figure 1 – Flowchart of study selection.



In Table 1, we present the main reasons for the exclusion of the 39 articles. It is important to note that some articles were excluded based on multiple criteria.

Table 1 – Reasons of the exclusion criteria

Reasons of Exclusion	**Number of articles that did not meet each criterion**
Use of telemonitoring solutions, devices or remote monitoring technologies (Intervention/Exposure)	19

Telemonitoring and Interoperability or telemonitoring data sharing architecture (Comparator)	24
Assessing telemonitoring solutions, specifically the use on cross border settings and cross organisations (Comparator)	32
Examining the technical artifacts or specifications, IT architectures, technical standards or guidelines for telemonitoring solutions (Comparator)	27
Assessing the benefits, use and impact of telemonitoring solutions that are interoperable with different providers or systems in different contexts (Outcome)	25
Examining the technical artifacts or specifications, IT architectures, technical standards or guidelines for telemonitoring solutions (Outcome)	25
Examining the impact and benefits of using telemonitoring solutions, based on a common technical framework or the use of international standards (Outcome)	25
Policy Makers, Healthcare professionals, Patients, Citizens and SDOs (Population)	18
Full text not available	2
Full text not accessible	4
Full text duplicate	1

Note. Articles were excluded based on multiple criteria.

- **Data extraction and synthesis**

Relevant data was extracted from each included article on the following parameters: country of origin, year, and type of study. A narrative synthesis was conducted, organized according to technical domain the following main issues:

Area of intervention 1: data and communication standards used (e.g., RESTful web-services, SOAP);

Area of intervention 2: ICT framework and architectures (e.g., Continua, ICT Architecture - IHE XDS-profile);

Area of intervention 3: interoperability standards used (ISO/IEEE 11073 Personal Health Device (PHD);

Area of intervention 4: transports types used (e.g., HL7, XML, Json).

- **RESULTS**
- **Study characteristics**

The studies included were published between 2005 and 2022, with an increasing number of publications since 2014. Most studies were conducted in Italy (n = 5; 20%) and Spain (n = 5; 20%), but there was a wide variety of other locations (Austria, Belgium, China, France, Germany, Romania, Panama, and the United Kingdom).

In terms of study methodologies, the majority were observational (n = 23, 92%), with 13 focusing on conceptual development (52%), 6 on design and implementation (24%), 4 on evaluation and assessment (16%), and 2 on reviews and analyses (8%). Most of the articles did not specify the sample (64%), whilst 9 studies were conducted with specific patient groups (e.g., focusing on chronic diseases, cardiac diseases, COPD, and Parkinson's, mostly in elderly populations).

The main focus was on technical aspects of interoperability for telemonitoring solutions according to the Refined eHealth European Interoperability Framework (ReEIF).[23] With 25 of the studies reporting on technical aspects, the included papers also recounted information related to Legal aspects (2 studies), organizational aspects (16

studies), semantic aspects (9 studies). Detailed article characteristics can be found as supplementary material.

- **Technical areas of intervention**

To analyse the results, we organised them into four technical areas: Data and communication standards, ICT framework and architectures, Interoperability standards, Transport types. This categorisation was inspired by the "Defining an Open Platform" documentation from Apperta Foundation[5] and the OSI Model[6]. While these technical areas are mapped to their primary OSI layers in Table 2. We acknowledge that many standards span multiple layers rather than being confined strictly to a single OSI level. Our categorisation reflects the primary impact areas of each technical area, while allowing for flexibility across multiple layers depending on the specific role and application of each standard.

Table 2 - Technical areas relation to OSI model

Area	Definition	OSI Layers
Data and Communication Standards	These standards dictate the formats, rules, and protocols for data exchange and communication between systems	Primarily operate at the Application, Presentation, and Session layers
ICT Framework and Architectures	These are comprehensive guidelines and structures for designing and managing IT infrastructure, including policies, practices, and tools.	multiple layers but often emphasize the higher layers (Application, Presentation, Session) for ensuring overall system design integrity and interoperability
Interoperability Standards	Standards that ensure different systems, devices, and	Cross several layers but focus heavily on the Application, Presentation, and Session layers

[5] Accessed at: https://apperta.org/assets/Apperta_Defining_an_Open_Platform.pdf
[6] "Open Systems Interconnection" is a reference model standardizing the functions of a telecommunication or computing system into seven abstraction layers: Application, Presentation, Session, Transport, Network, Data Link, Physical. Accessed at: https://www.iso.org/standard/20269.html

	applications can work together seamlessly	to enable smooth data exchange and functional integration.
Transport Types:	Methods and protocols used to transfer data between systems over a network.	Operate at the Transport layer, ensuring reliable data transmission and error handling

An overview of the analysis is provided with further details as supplementary material.

- Data and communication standards

Various standards used in telemonitoring solutions were identified. HL7 standards, including HL7 FHIR [7]and CDA[8], were referenced in 8 studies. ISO/IEEE 11073 [9]standards for device communication appeared in 9 studies. REST API or REST APIs FHIR based were noted in 4 studies, while XML[10] was referenced in 5 studies. IT infrastructure from IHE[11] was mentioned in 1 study. Additionally, 3 studies referred to other standards without a specific standard.

- ICT framework and architectures

The analysis identified diverse standards and frameworks used in telemonitoring solutions. HL7 standards, including FHIR and CDA, were referenced in 8 studies, while ISO/IEEE 11073 standards appeared in 9 studies. REST APIs, particularly FHIR-based, were mentioned in 4 studies, with XML referenced in 5 studies. IT infrastructure from IHE was noted in 1 study, with the IHE Profile Framework specifically referred to in 6 studies. The Continua Alliance framework was mentioned in 1 study, conceptual frameworks with RESTful services in 4 studies, and SOA or XML frameworks in 4

[7] Health Level Seven International Fast Healthcare Interoperability Resources
[8] Clinical Document Architecture
[9] ISO/IEEE 11073: Health Informatics – Medical/health device communication standards
[10] Extensible Markup Language
[11] IHE: Integrating the healthcare Enterprise

studies. Additionally, 3 studies referred to other standards without a specific partner, and 11 studies mentioned other frameworks without specific standardization.

- Interoperability standards

The analysis identified several studies focusing on various IT infrastructure and interoperability standards used in telemonitoring solutions. Studies referring to IT infrastructure from IHE, including HL7 standards, totalled 10. ISO/IEEE 11073/IEEE 1073 standards were referenced in 11 studies. RestAPI or REST APIs FHIR-based methods were mentioned in 2 studies, while the Continua Framework was noted in 1 study. Additionally, 6 studies utilized other interoperability methods that were non-standard.

- Transport types

In terms transport types used, the analysis identified various transport types used in telemonitoring solutions. Bluetooth, RFID, and ZigBee were referenced in 10 studies. RestAPI or REST APIs FHIR-based methods, along with JSON in FHIR resources, were mentioned in 3 studies. SOP, XML, and similar standards appeared in 4 studies, while 8 studies did not specify the transport types used.

- **DISCUSSION**

The results of this review revealed a scarcity of technical articles, indicating a significant gap in the literature regarding the detailed technical implementation and operational challenges of telemonitoring systems. This rejoins previous findings.[24] Specifically, there is a notable lack of in-depth studies on the deployment and integration of telemonitoring solutions, device-to-device communication protocols, and the practical aspects of achieving seamless interoperability. This gap underscores the need for more comprehensive research focused on the technical aspects, including the configuration of device communication standards like ISO/IEEE 11073 and the integration of these

devices with healthcare IT infrastructures using standards such as HL7 FHIR or defined technical workflow based on IHE profiles. Enhanced technical documentation and research can facilitate better understanding, replication, and improvement of telemonitoring solutions, particularly in a cross-border context.

The review indicated some alignment in the use of ISO/IEEE 11073 standards, highlighting their importance in promoting interoperability between devices in telemonitoring systems. These standards are crucial as they ensure that devices from various manufacturers can communicate effectively with each other and with healthcare providers' EHR systems, enabling value-based care.[25] The ISO/IEEE 11073 standards include protocols for real-time data exchange, device plug-and-play interoperability, and standardized data formats, which are essential for seamless integration.[26] However, while these standards enable effective local data transmission, their scope is primarily to near-field device communication and does not directly address the broader requirements of cross-border interoperability.

This interoperability is vital for cross-border healthcare, where devices and systems from different regions need to work together without compatibility issues. By adopting ISO/IEEE 11073 standards, healthcare providers can ensure reliable and efficient telemonitoring, ultimately enhancing patient care across different countries. The use of such standard as a common standard for devices interoperability or communication seems and early adopter to be tested and upscaled as generic standards, but as well on cross-border context. While there is some indication of the use of IT infrastructure from the Integrating the Healthcare Enterprise (IHE), including HL7 standards, for telemonitoring purposes, the evidence remains limited and suggests that adoption is still in its early stages. Several studies have shown that these infrastructures are adapted for specific telemonitoring needs.[27-31] For instance, HL7 FHIR is used for exchanging

healthcare information electronically, providing a robust framework for integrating telemonitoring data with EHR systems. However, the adaptation of these standards often involves customizing profiles to fit specific telemonitoring requirements, such as remote patient monitoring and chronic disease management.[26] This adaptability highlights the flexibility of these standards but also emphasizes the need for standardized profiles that cater to telemonitoring in cross-border scenarios.

Despite some popularity for certain franchises, the review identified a lack of common standards for data exchange between devices and EHR systems. Bridging this gap is essential to ensure that data is accessible to patients, researchers, and healthcare providers using a common standard or method. Enhancing interoperability at this level will improve data accessibility and utility, facilitating better patient care and more effective research. The implementation rules and guidelines to be used as baseline for any implementation at European Level, both for cross-border exchange and for country-level report sharing could be based on HL7 FHIR standard, as ongoing harmonization efforts already adopt it for this purpose.[20] As the EEHRxF is proposed as an EU standard for healthcare, further exploration by research appears essential to validate or invalidate this.

The review revealed a lack of evidence regarding the use of standards in a cross-border context, with only three studies reflecting on data exchange between different entities. Although these standards theoretically apply to cross-border scenarios, additional aspects defined by the ReEIF need to be addressed.[23] Furthermore, 15 studies identified the need to exchange data between different applications and IT providers, highlighting the necessity for further research and development in cross-border interoperability.

Both findings of a variety of different approaches to interoperability and of scarce evidence of interoperability point to the same suggestion: there is the need for a more

robust framework around telemonitoring.[32] In Europe, the European Health Data Space regulation was adopted in April 2024 and serves as a flagship effort for empowering eHealth.[33] In forward-looking countries, telemonitoring is already being included in efforts to implement EHDS requirements.[34] Telemedicine is mentioned in different provisions (Recitals 21/22, Article 13), and appears to be one of the next domains to be included in the EHDS.[35] Including telemonitoring as one facet of telemedicine in the EHDS through additional implementation acts can help bridge the gaps identified in this research, namely the lack of harmonization and evidence of telemonitoring interoperability services.

- **CONCLUSIONS**

This scoping review highlighted the diverse range of standards and frameworks utilized in telemonitoring solutions, ranging from ISO/IEEE 11073 to HL7 FHIR standards and IHE profiles, emphasizing the varying approaches to achieving interoperability and effective data communication in healthcare.

Additionally, this review uncovered the lack of evidence of use of standards, thus the need for further research to understand how telemonitoring solutions can leverage new healthcare standards to enhance interoperability and accelerate the transition from conceptual studies to practical applications.

With this, it appears that working towards a robust framework is needed to support practice and research. Internationally funded efforts such as X-eHealth, XpanDH, xShare, or Xt-EHR projects are crucial to foster harmonization. Furthermore, including telemonitoring into legislative frameworks could be pivotal for interoperability developments. In this line of work, it is crucial to establish common standards at the European level to enhance the interoperability of telemonitoring solutions. These

standards will enable the healthcare domain to effectively leverage telemedicine technologies, accelerating the transition from conceptual studies to practical applications across Europe.

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- **Author Contributions**

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- **Data availability**

Data available upon request.

- **Competing interest**

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

- **Consent to participate**

Not applicable to this scoping review of literature.

- **Ethical considerations**

Not applicable to this scoping review of literature.

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